

## **16.2.8 Listings of Individual Laboratory Measurements by Subject and Other Safety Observations**

Appendix 16.2.8.1.1.1	Clinical Laboratory Report - Serum Chemistry (I of V)
Appendix 16.2.8.1.1.2	Clinical Laboratory Report - Serum Chemistry (II of V)
Appendix 16.2.8.1.1.3	Clinical Laboratory Report - Serum Chemistry (III of V)
Appendix 16.2.8.1.1.4	Clinical Laboratory Report - Serum Chemistry (IV of V)
Appendix 16.2.8.1.1.5	Clinical Laboratory Report - Serum Chemistry (V of V)
Appendix 16.2.8.1.2.1	Clinical Laboratory Report - Hematology (I of V)
Appendix 16.2.8.1.2.2	Clinical Laboratory Report - Hematology (II of V)
Appendix 16.2.8.1.2.3	Clinical Laboratory Report - Hematology (III of V)
Appendix 16.2.8.1.2.4	Clinical Laboratory Report - Hematology (IV of V)
Appendix 16.2.8.1.2.5	Clinical Laboratory Report - Hematology (V of V)
Appendix 16.2.8.1.3.1	Clinical Laboratory Report - Urinalysis (I of VI)
Appendix 16.2.8.1.3.2	Clinical Laboratory Report - Urinalysis (II of VI)
Appendix 16.2.8.1.3.3	Clinical Laboratory Report - Urinalysis (III of VI)
Appendix 16.2.8.1.3.4	Clinical Laboratory Report - Urinalysis (IV of VI)
Appendix 16.2.8.1.3.5	Clinical Laboratory Report - Urinalysis (V of VI)
Appendix 16.2.8.1.3.6	Clinical Laboratory Report - Urinalysis (VI of VI)
Appendix 16.2.8.1.4	Clinical Laboratory Report – Comments (Safety Population)
Appendix 16.2.8.1.5	Urine Drug Screens (Safety Population)
Appendix 16.2.8.1.6	Pregnancy Tests (Safety Population)
Appendix 16.2.8.1.7	Serum FSH (Safety Population)
Appendix 16.2.8.1.8	Urine Cotinine Screens (Safety Population)
Appendix 16.2.8.1.9	Serology Sample Collection (Safety Population)
Appendix 16.2.8.1.10	Exhaled CO Measurement (Safety Population)
Appendix 16.2.8.2	Vital Signs (Safety Population)
Appendix 16.2.8.3	12-Lead Electrocardiogram (Safety Population)
Appendix 16.2.8.4	Phone Call (Safety Population)

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1001	59/F	Screen	02JUL2018	VLN non-mentholated	5.1	47	61.892
		End Of Study	07SEP2018	VLN non-mentholated	4.8	43	51.282
1002	30/M	Screen	02JUL2018	VLN non-mentholated	4.8	42	85.765
		End Of Study	07SEP2018	VLN non-mentholated	4.6	48	79.576
1003	38/M	Screen	03JUL2018	VLN mentholated	4.6	44	100.796
		End Of Study	07SEP2018	VLN mentholated	4.9	44	94.607
1007	37/M	Screen	12JUL2018	VLN non-mentholated	4.8	44	69.85
		End Of Study	07SEP2018	VLN non-mentholated	4.4	46	68.081
1008	48/M	Screen	12JUL2018	VLN mentholated	4.3	46	76.923
		End Of Study	07SEP2018	VLN mentholated	4.5	44	77.807
1010	32/M	Screen	13JUL2018	UB mentholated	4.3	49	91.07
		End Of Study	06SEP2018	UB mentholated	4.6	52 HN	87.533
1011	36/M	Screen	13JUL2018	UB non-mentholated	4.5	49	80.46
		End Of Study	06SEP2018	UB non-mentholated	4	52 HN	87.533
1013	36/F	Screen	16JUL2018	VLN non-mentholated	4.4	43	74.271
		End Of Study	14SEP2018	VLN non-mentholated	4.9	42	54.819

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1014	36/F	Screen	16JUL2018	VLN mentholated	4.6	46	61.892
		End Of Study	14SEP2018	VLN mentholated	4.1	43	53.05
1015	49/F	Screen	16JUL2018	VLN mentholated	4.6	49	70.734
		End Of Study	14SEP2018	VLN mentholated	4.6	49	60.124
1016	54/M	Screen	16JUL2018	UB non-mentholated	5	42	64.545
		End Of Study	13SEP2018	UB non-mentholated	3.9	44	56.587 LN
1017	41/F	Screen	17JUL2018	UB mentholated	5	47	61.008
		End Of Study	13SEP2018	UB mentholated	4.6	43	57.471
1018	41/F	Screen	17JUL2018	VLN mentholated	4.7	48	85.765 HN
		End Of Study	15AUG2018	VLN mentholated	4.5	50	87.533 HN
1019	30/M	Screen	17JUL2018	VLN non-mentholated	4.6	48	80.46
		End Of Study	14SEP2018	VLN non-mentholated	4.5	45	69.85
1020	36/F	Screen	17JUL2018	VLN non-mentholated	4.6	45	72.502
		End Of Study	14SEP2018	VLN non-mentholated	4.2	40	59.24
1021	49/F	Screen	17JUL2018	UB non-mentholated	4.6	45	78.691
		End Of Study	13SEP2018	UB non-mentholated	4.6	42	78.691

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1023	50/F	Screen	17JUL2018	VLN non-mentholated	4.9	46	52.166
		End Of Study	14SEP2018	VLN non-mentholated	4.6	42	44.209
1029	35/F	Screen	26JUL2018	VLN mentholated	4.7	44	60.124
		End Of Study	11OCT2018	VLN mentholated	4.6	45	53.05
1032	53/F	Screen	13AUG2018	VLN mentholated	4.6	46	51.282
		End Of Study	11OCT2018	VLN mentholated	4.4	44	43.324 LN
1034	45/M	Screen	13AUG2018	VLN non-mentholated	4.6	43	55.703 LN
		End Of Study	10OCT2018	VLN non-mentholated	4.5	46	57.471 LN
1035	44/M	Screen	13AUG2018	VLN non-mentholated	4.4	48	110.522 HN
		End Of Study	11OCT2018	VLN non-mentholated	4.7	42	105.217
1036	38/F	Screen	13AUG2018	UB mentholated	4.4	39	68.081
		End Of Study	10OCT2018	UB mentholated	4.3	42	64.545
1037	29/M	Screen	13AUG2018	UB mentholated	5	47	66.313
		End Of Study	10OCT2018	UB mentholated	5.2	47	71.618
1038	39/F	Screen	13AUG2018	VLN non-mentholated	4.5	44	63.66
		End Of Study	11OCT2018	VLN non-mentholated	4.4	43	55.703

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		-----	-----		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1042	47/M	Screen	13AUG2018	VLN non-mentholated	4.2	43	76.039
		End Of Study	11OCT2018	VLN non-mentholated	4	45	66.313
1045	58/M	Screen	14AUG2018	UB non-mentholated	5.7 HN	49	81.344
		End Of Study	10OCT2018	UB non-mentholated	4.7	46	69.85
1046	45/M	Screen	14AUG2018	UB mentholated	4.5	47	65.429
		End Of Study	10OCT2018	UB mentholated	4.5	46	65.429
1050	33/F	Screen	14AUG2018	VLN non-mentholated	4.4	44	68.081
		End Of Study	10OCT2018	VLN non-mentholated	4.3	39	59.24
1051	36/F	Screen	14AUG2018	UB mentholated	4.2	41	61.892
		End Of Study	10OCT2018	UB mentholated	4.5	43	56.587
1052	31/M	Screen	14AUG2018	VLN mentholated	4.5	47	74.271
		End Of Study	11OCT2018	VLN mentholated	4.1	45	66.313
1053	42/M	Screen	14AUG2018	VLN mentholated	4.5	45	91.954
		End Of Study	11OCT2018	VLN mentholated	4.5	48	86.649
1054	56/M	Screen	14AUG2018	UB non-mentholated	4.4	41	83.112
		End Of Study	10OCT2018	UB non-mentholated	4.1	44	76.923

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1055	39/F	Screen	14AUG2018	VLN mentholated	4.1	46	53.935
		End Of Study	11OCT2018	VLN mentholated	4	44	42.44 LN
1056	48/M	Screen	14AUG2018	VLN non-mentholated	4.7	45	76.923
		End Of Study	11OCT2018	VLN non-mentholated	4.2	46	70.734
1058	30/M	Screen	15AUG2018	VLN non-mentholated	4.6	46	83.112
		End Of Study	11OCT2018	VLN non-mentholated	4.5	45	75.155
1059	38/M	Screen	27AUG2018	UB non-mentholated	4.6	48	99.912
		End Of Study	24OCT2018	UB non-mentholated	4.3	45	91.954
1060	55/M	Screen	27AUG2018	VLN mentholated	4.5	45	76.923
		End Of Study	24OCT2018	VLN mentholated	4.6	44	76.039
1063	31/M	Screen	27AUG2018	VLN mentholated	4.4	50	83.996
		End Of Study	25OCT2018	VLN mentholated	4.8	49	90.186
1064	34/M	Screen	27AUG2018	UB non-mentholated	4.1	45	100.796
1066	62/M	Screen	27AUG2018	VLN non-mentholated	4.4	45	84.881
		End Of Study	24OCT2018	VLN non-mentholated	4.5	43	84.881

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1069	40/F	Screen	28AUG2018	UB non-mentholated	4.4	45	58.355
		End Of Study	24OCT2018	UB non-mentholated	4.2	42	62.776
1070	53/M	Screen	28AUG2018	VLN non-mentholated	4.4	47	85.765
		End Of Study	24OCT2018	VLN non-mentholated	4	43	85.765
1071	42/M	Screen	28AUG2018	VLN non-mentholated	4.5	43	81.344
1072	59/M	Screen	28AUG2018	VLN mentholated	5.1	48	74.271
		End Of Study	22OCT2018	VLN mentholated	4.2	47	77.807
1074	42/M	Screen	28AUG2018	VLN non-mentholated	4.3	47	73.386
		End Of Study	24OCT2018	VLN non-mentholated	4.5	46	80.46
1075	26/F	Screen	29AUG2018	UB non-mentholated	4.2	47	61.892
		End Of Study	24OCT2018	UB non-mentholated	4.1	45	61.008
1077	49/F	Screen	28AUG2018	VLN non-mentholated	5.3 HN	46	53.935
		End Of Study	24OCT2018	VLN non-mentholated	4.4	41	64.545
1078	51/F	Screen	28AUG2018	VLN non-mentholated	4.7	47	54.819
		End Of Study	24OCT2018	VLN non-mentholated	3.9	46	54.819

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1079	33/M	Screen	29AUG2018	VLN mentholated	4.6	44	83.996
		End Of Study	24OCT2018	VLN mentholated	4.1	38 LN	81.344
1082	37/M	Screen	30AUG2018	VLN non-mentholated	4.3	50	75.155
		End Of Study	24OCT2018	VLN non-mentholated	4.3	49	73.386
1083	54/F	Screen	04SEP2018	VLN non-mentholated	5.3 HN	46	76.923
		End Of Study	31OCT2018	VLN non-mentholated	4.3	41	66.313
1084	42/M	Screen	04SEP2018	VLN non-mentholated	4.7	44	73.386
1086	54/M	Screen	04SEP2018	VLN non-mentholated	4.5	46	79.576
		End Of Study	31OCT2018	VLN non-mentholated	4.6	44	94.607
1088	26/M	Screen	04SEP2018	VLN mentholated	4.5	47	76.039
		End Of Study	31OCT2018	VLN mentholated	4.4	43	82.228
1089	60/F	Screen	04SEP2018	UB non-mentholated	4.4	45	68.965
		End Of Study	31OCT2018	UB non-mentholated	4.6	45	80.46 HN
1092	43/F	Screen	05SEP2018	VLN mentholated	4.2	43	56.587
		End Of Study	31OCT2018	VLN mentholated	4	43	74.271

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		Name	Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1094	46/M	Screen	05SEP2018	VLN mentholated	4.7	47	98.143
		End Of Study	31OCT2018	VLN mentholated	4.3	43	61.892
1095	55/F	Screen	07SEP2018	VLN mentholated	4.2	44	60.124
		End Of Study	31OCT2018	VLN mentholated	4.5	44	86.649 HN
1096	42/F	Screen	07SEP2018	VLN non-mentholated	4.2	42	67.197
		End Of Study	31OCT2018	VLN non-mentholated	3.9	43	53.935
1097	30/M	Screen	07SEP2018	VLN mentholated	5	48	91.954
		End Of Study	31OCT2018	VLN mentholated	4.5	41	53.935 LN
1098	63/M	Screen	18SEP2018	VLN non-mentholated	4.9	48	83.112
		End Of Study	16NOV2018	VLN non-mentholated	5.5 HN	44	80.46
1099	46/F	Screen	18SEP2018	VLN non-mentholated	4.7	42	57.471
		End Of Study	16NOV2018	VLN non-mentholated	4.4	38 LN	57.471
1100	59/M	Screen	18SEP2018	VLN non-mentholated	4.3	49	78.691
		End Of Study	16NOV2018	VLN non-mentholated	4.7	47	91.07
1101	41/M	Screen	18SEP2018	VLN non-mentholated	4.2	48	67.197
		End Of Study	16NOV2018	VLN non-mentholated	4.6	46	68.965

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		-----	-----		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
Screen	Name	Date					
1103	43/M	Screen	18SEP2018	VLN non-mentholated	4.8	46	92.838
		End Of Study	16NOV2018	VLN non-mentholated	4.1	44	103.448
1105	47/F	Screen	19SEP2018	VLN non-mentholated	4.5	48	61.892
		End Of Study	16NOV2018	VLN non-mentholated	4	41	58.355
1106	42/M	Screen	19SEP2018	UB non-mentholated	5	47	74.271
		End Of Study	16NOV2018	UB non-mentholated	5	46	84.881
1107	45/M	Screen	21SEP2018	VLN non-mentholated	4.8	47	84.881
		End Of Study	16NOV2018	VLN non-mentholated	4.3	41	88.417
1108	54/M	Screen	21SEP2018	UB non-mentholated	4.2	45	89.301
		End Of Study	16NOV2018	UB non-mentholated	4.4	45	88.417
1109	58/M	Screen	21SEP2018	UB non-mentholated	4.2	47	82.228
		End Of Study	16NOV2018	UB non-mentholated	4.5	43	86.649
1112	59/F	Screen	21SEP2018	VLN non-mentholated	4.8	46	57.471
		End Of Study	16NOV2018	VLN non-mentholated	4.5	40	69.85
1114	26/F	Screen	24SEP2018	UB non-mentholated	3.8	49	63.66
		End Of Study	16NOV2018	UB non-mentholated	4.7	48	65.429

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
1115	29/M	Screen	24SEP2018	VLN non-mentholated	4.8	50	81.344
2002	49/M	Screen	29JUN2018	UB mentholated	5.4 HN	46	78.691
		End Of Study	05SEP2018	UB mentholated	5.3 HN	47	85.765
2003	41/F	Screen	29JUN2018	VLN mentholated	4.9	45	59.24
		End Of Study	29AUG2018	VLN mentholated	4.6	39	60.124
2007	57/F	Screen	29JUN2018	VLN non-mentholated	5.5 HN	48	86.649
		End Of Study	29AUG2018	VLN non-mentholated	4.4	40	83.996
2008	42/M	Screen	06JUL2018	VLN mentholated	4.2	41	80.46
		End Of Study	29AUG2018	VLN mentholated	4.3	38	82.228
2009	55/M	Screen	29JUN2018	VLN non-mentholated	4.5	43	112.29
2010	27/M	Screen	29JUN2018	UB mentholated	4.5	45	91.07
		End Of Study	29AUG2018	UB mentholated	5	43	97.259
2011	32/F	Screen	29JUN2018	VLN mentholated	4.4	47	76.923
		End Of Study	29AUG2018	VLN mentholated	4.1	39	82.228
2014	37/M	Screen	02JUL2018	VLN mentholated	4.6	45	88.417

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2014	37/M	End Of Study	29AUG2018	VLN mentholated	4.4	42	94.607
2015	57/F	Screen	02JUL2018	UB mentholated	4.7	46	64.545
		End Of Study	29AUG2018	UB mentholated	4.8	39	65.429
2016	45/F	Screen	02JUL2018	VLN mentholated	4.2	48	62.776
		End Of Study	03AUG2018	VLN mentholated	4.2	42	65.429
2017	30/M	Screen	02JUL2018	VLN mentholated	4.2	44	79.576
		End Of Study	29AUG2018	VLN mentholated	4.2	43	82.228
2018	26/F	Screen	02JUL2018	UB mentholated	4.4	48	61.008
		End Of Study	29AUG2018	UB mentholated	4.1	41	60.124
2020	60/F	Screen	02JUL2018	VLN mentholated	4.1	43	51.282
		End Of Study	29AUG2018	VLN mentholated	4.3	40	58.355
2021	31/M	Screen	02JUL2018	VLN mentholated	4.4	49	85.765
		End Of Study	29AUG2018	VLN mentholated	4.5	44	91.07
2023	35/M	Screen	02JUL2018	VLN mentholated	4.1	46	84.881
		End Of Study	29AUG2018	VLN mentholated	4.1	39	88.417

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2024	26/M	Screen	03JUL2018	UB non-mentholated	4.4	51	68.081
2025	59/M	Screen	03JUL2018	UB non-mentholated	4.9	43	60.124 LN
		End Of Study	29AUG2018	UB non-mentholated	4.8	39	79.576
2028	36/M	Screen	06JUL2018	VLN non-mentholated	4.4	46	68.081
		End Of Study	29AUG2018	VLN non-mentholated	5.5 HN	43	68.965
2029	56/M	Screen	09JUL2018	UB mentholated	4.1	47	88.417
		End Of Study	05SEP2018	UB mentholated	4.5	42	85.765
2039	49/F	Screen	13JUL2018	VLN mentholated	4.1	47	63.66
		End Of Study	05SEP2018	VLN mentholated	3.9	40	57.471
2050	57/M	Screen	20JUL2018	UB mentholated	4.9	42	83.112
		End Of Study	20SEP2018	UB mentholated	4.3	40	72.502
2052	54/M	Screen	20JUL2018	VLN mentholated	4.8	46	76.923
		End Of Study	20SEP2018	VLN mentholated	5.3 HN	45	77.807
2057	52/M	Screen	23JUL2018	VLN mentholated	4.6	44	68.081
		End Of Study	20SEP2018	VLN mentholated	3.7	43	71.618

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2058	37/F	Screen	23JUL2018	VLN mentholated	3.9	40	66.313
		End Of Study	20SEP2018	VLN mentholated	4.9	42	68.965
2059	56/F	Screen	23JUL2018	UB mentholated	4.3	41	66.313
		End Of Study	20SEP2018	UB mentholated	4.3	36	55.703
2060	37/F	Screen	23JUL2018	VLN mentholated	4.4	46	58.355
		End Of Study	20SEP2018	VLN mentholated	4.2	41	60.124
2064	52/M	Screen	23JUL2018	VLN mentholated	5.2	48	79.576
		End Of Study	20SEP2018	VLN mentholated	4.8	47	76.923
2066	30/F	Screen	23JUL2018	VLN mentholated	5.2	41	78.691
		End Of Study	20SEP2018	VLN mentholated	4.4	40	73.386
2067	52/M	Screen	23JUL2018	VLN non-mentholated	6 HN	43	81.344
		End Of Study	20SEP2018	VLN non-mentholated	4.9	41	82.228
2075	34/M	Screen	30JUL2018	VLN mentholated	4.5	47	79.576
		End Of Study	22AUG2018	VLN mentholated	4.1	42	76.039
2076	42/M	Screen	30JUL2018	VLN mentholated	4.4	46	108.753
		End Of Study	14OCT2018	VLN mentholated	4.5	42	116.711 HN

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		-----	-----		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2086	36/M	Screen	03AUG2018	VLN non-mentholated	4.7	46	86.649
		End Of Study	01OCT2018	VLN non-mentholated	4.4	49	99.027
2088	39/F	Screen	03AUG2018	VLN mentholated	4.5	43	69.85
		End Of Study	14OCT2018	VLN mentholated	4.1	42	72.502
2092	50/F	Screen	06AUG2018	VLN mentholated	5.5 HN	47	68.081
		End Of Study	14OCT2018	VLN mentholated	4.4	40	63.66
2099	52/M	Screen	09AUG2018	VLN non-mentholated	4.3	44	69.85
		End Of Study	14OCT2018	VLN non-mentholated	3.9	41	66.313 LN
2100	48/F	Screen	09AUG2018	UB mentholated	4	45	59.24
		End Of Study	14OCT2018	UB mentholated	3.9	42	60.124
2108	60/F	Screen	13AUG2018	VLN non-mentholated	4.4	48	48.63 LN
		End Of Study	14OCT2018	VLN non-mentholated	4.1	46	53.935
2110	41/F	Screen	13AUG2018	UB mentholated	5	43	58.355
		End Of Study	20OCT2018	UB mentholated	4.3	39	58.355
2113	51/F	Screen	15AUG2018	VLN mentholated	4.9	45	67.197

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		-----	-----		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
		Name	Date				
2115	46/F	Screen	15AUG2018	VLN mentholated	4.4	43	61.892
2119	48/M	Screen	20AUG2018	VLN mentholated	5.3 HN	43	82.228
		End Of Study	20OCT2018	VLN mentholated	5.2	44	81.344
2120	62/F	Screen	20AUG2018	VLN non-mentholated	4.5	44	79.576
		End Of Study	20OCT2018	VLN non-mentholated	4.3	44	79.576
2122	60/M	Screen	20AUG2018	UB non-mentholated	5	46	91.07
		End Of Study	20OCT2018	UB non-mentholated	4.8	40	81.344
2125	35/M	Screen	21AUG2018	UB mentholated	4.7	52	96.375
		End Of Study	20OCT2018	UB mentholated	4.2	44	99.027
2126	37/M	Screen	21AUG2018	VLN mentholated	4.9	46	78.691
		End Of Study	20OCT2018	VLN mentholated	4.5	41	90.186
2136	64/M	Screen	27AUG2018	VLN non-mentholated	5	46	90.186
		End Of Study	19OCT2018	VLN non-mentholated	4.8	44	87.533
2140	56/F	Screen	30AUG2018	UB non-mentholated	4.8	40	66.313
		End Of Study	06NOV2018	UB non-mentholated	3.8	39	70.734

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2142	30/F	Screen	31AUG2018	VLN non-mentholated	4.9	47	58.355
		End Of Study	08OCT2018	VLN non-mentholated	4.9	43	56.587
2143	63/M	Screen	04SEP2018	VLN non-mentholated	5	48	97.259
		End Of Study	06NOV2018	VLN non-mentholated	4.8	41	98.143
2158	43/F	Screen	18SEP2018	UB non-mentholated	4.6	43	64.545
2159	37/M	Screen	19SEP2018	VLN non-mentholated	4.8	43	69.85
		End Of Study	02DEC2018	VLN non-mentholated	4.8	34 LN	76.039
2164	65/F	Screen	27SEP2018	VLN non-mentholated	4.7	43	68.081
		End Of Study	02DEC2018	VLN non-mentholated	4.6	38	66.313
2168	32/F	Screen	28SEP2018	VLN non-mentholated	4.4	43	61.892
		End Of Study	02DEC2018	VLN non-mentholated	4.2	37	61.892
2170	51/F	Screen	28SEP2018	UB non-mentholated	5.8 HN	44	92.838 HN
		End Of Study	02DEC2018	UB non-mentholated	4.8	39	73.386
2175	40/F	Screen	01OCT2018	UB mentholated	5.3 HN	46	55.703
		End Of Study	02DEC2018	UB mentholated	4.5	41	56.587

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		Name	Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2189	28/M	Screen	04OCT2018	VLN mentholated	4.5	42	71.618
		End Of Study	06NOV2018	VLN mentholated	4.4	42	82.228
2211	29/F	Screen	10OCT2018	VLN mentholated	4.1	40	55.703
		End Of Study	02DEC2018	VLN mentholated	4.6	34 LN	57.471
2212	32/M	Screen	10OCT2018	UB mentholated	4.4	46	81.344
		End Of Study	02DEC2018	UB mentholated	4.4	41	95.491
2213	29/M	Screen	10OCT2018	VLN mentholated	3.9	44	74.271
		End Of Study	02DEC2018	VLN mentholated	4.3	41	78.691
2215	59/F	Screen	10OCT2018	UB mentholated	4.7	48	75.155
		End Of Study	02DEC2018	UB mentholated	4.5	43	73.386
2220	37/M	Screen	11OCT2018	VLN non-mentholated	4.5	46	85.765
		End Of Study	02DEC2018	VLN non-mentholated	4.5	40	93.722
2235	26/F	Screen	19OCT2018	VLN mentholated	4.4	49	56.587
		End Of Study	16DEC2018	VLN mentholated	4.6	37	62.776
2244	31/M	Screen	25OCT2018	VLN non-mentholated	4.3	44	67.197
		End Of Study	16DEC2018	VLN non-mentholated	4.8	41	72.502

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.1 Clinical Laboratory Report - Serum Chemistry (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Potassium	Albumin	Creatinine
		----- Name	----- Date		001: 3.7-5.2 002: 3.5-5.2 (mmol/L)	001: 39-50 002: <60: 35-55 002: >=60: 36-48 (g/L)	001: F: 44.209-79.576 002: F: 50.398-88.417 001: M: 61.008-106.101 002: M: 67.197-112.29 (umol/L)
2247	28/M	Screen	06NOV2018	VLN mentholated	3.6	46	84.881
		End Of Study	28DEC2018	VLN mentholated	4.3	47	87.533
2251	27/M	Screen	09NOV2018	UB non-mentholated	4.3	48	85.765
		End Of Study	19JAN2019	UB non-mentholated	4.4	48	96.375
2257	55/F	Screen	14NOV2018	UB non-mentholated	4.8	49	53.05
		End Of Study	19JAN2019	UB non-mentholated	4.6	46	55.703
2259	49/M	Screen	14NOV2018	UB mentholated	4.3	41	112.29
		End Of Study	19JAN2019	UB mentholated	4.1	35	106.101
2269	48/M	Screen	26NOV2018	VLN mentholated	5	44	98.143
		End Of Study	19JAN2019	VLN mentholated	4.7	41	94.607
2272	37/M	Screen	28NOV2018	VLN mentholated	4.1	48	85.765
		End Of Study	19JAN2019	VLN mentholated	4.3	42	91.07

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1001	59/F	Screen	02JUL2018	VLN non-mentholated	5.3	141 HN	22
		End Of Study	07SEP2018	VLN non-mentholated	5.8	130 HN	22
1002	30/M	Screen	02JUL2018	VLN non-mentholated	4.2	65	14
		End Of Study	07SEP2018	VLN non-mentholated	5.2	79	13
1003	38/M	Screen	03JUL2018	VLN mentholated	5.4	60	40
		End Of Study	07SEP2018	VLN mentholated	5	65	36
1007	37/M	Screen	12JUL2018	VLN non-mentholated	5.4	66	33
		End Of Study	07SEP2018	VLN non-mentholated	5.2	60	36
1008	48/M	Screen	12JUL2018	VLN mentholated	6.4 HN	76	24
		End Of Study	07SEP2018	VLN mentholated	6 HN	74	21
1010	32/M	Screen	13JUL2018	UB mentholated	5.1	74	18
		End Of Study	06SEP2018	UB mentholated	5.2	74	16
1011	36/M	Screen	13JUL2018	UB non-mentholated	5.5	83	14
		End Of Study	06SEP2018	UB non-mentholated	5.8	92	24
1013	36/F	Screen	16JUL2018	VLN non-mentholated	4.6	56	14

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1013	36/F	End Of Study	14SEP2018	VLN non-mentholated	5.3	60	8 LN
1014	36/F	Screen	16JUL2018	VLN mentholated	4.7	126 HN	13
		End Of Study	14SEP2018	VLN mentholated	5.6	112	18
1015	49/F	Screen	16JUL2018	VLN mentholated	5.1	73	14
		End Of Study	14SEP2018	VLN mentholated	5.2	70	11
1016	54/M	Screen	16JUL2018	UB non-mentholated	5.4	95	15
		End Of Study	13SEP2018	UB non-mentholated	5.8	108	31
1017	41/F	Screen	17JUL2018	UB mentholated	4.9	90	17
		End Of Study	13SEP2018	UB mentholated	5	82	17
1018	41/F	Screen	17JUL2018	VLN mentholated	4.8	63	23
		End Of Study	15AUG2018	VLN mentholated	5.6	68	23
1019	30/M	Screen	17JUL2018	VLN non-mentholated	4.8	69	22
		End Of Study	14SEP2018	VLN non-mentholated	5.3	59	19
1020	36/F	Screen	17JUL2018	VLN non-mentholated	5.2	53	13
		End Of Study	14SEP2018	VLN non-mentholated	5.2	55	13

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1021	49/F	Screen	17JUL2018	UB non-mentholated	5.3	80	16
		End Of Study	13SEP2018	UB non-mentholated	5.2	71	10
1023	50/F	Screen	17JUL2018	VLN non-mentholated	4.9	91	27
		End Of Study	14SEP2018	VLN non-mentholated	6 HN	88	25
1029	35/F	Screen	26JUL2018	VLN mentholated	4.6	63	27
		End Of Study	11OCT2018	VLN mentholated	5.2	50	12
1032	53/F	Screen	13AUG2018	VLN mentholated	4.9	61	14
		End Of Study	11OCT2018	VLN mentholated	5	53	14
1034	45/M	Screen	13AUG2018	VLN non-mentholated	6.5 HN	79	16
		End Of Study	10OCT2018	VLN non-mentholated	5.5	94	17
1035	44/M	Screen	13AUG2018	VLN non-mentholated	5.7	73	32
		End Of Study	11OCT2018	VLN non-mentholated	5.2	62	29
1036	38/F	Screen	13AUG2018	UB mentholated	5.1	80	15
		End Of Study	10OCT2018	UB mentholated	4.7	95	12
1037	29/M	Screen	13AUG2018	UB mentholated	5.2	79	27

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1037	29/M	End Of Study	10OCT2018	UB mentholated	4.8	77	25
1038	39/F	Screen	13AUG2018	VLN non-mentholated	5.2	73	18
		End Of Study	11OCT2018	VLN non-mentholated	4.6	65	19
1042	47/M	Screen	13AUG2018	VLN non-mentholated	5.4	106	19
		End Of Study	11OCT2018	VLN non-mentholated	4.8	87	18
1045	58/M	Screen	14AUG2018	UB non-mentholated	5.8	145 HN	15
		End Of Study	10OCT2018	UB non-mentholated	4.1	121 HN	15
1046	45/M	Screen	14AUG2018	UB mentholated	5.9 HN	84	36
		End Of Study	10OCT2018	UB mentholated	5.2	71	33
1050	33/F	Screen	14AUG2018	VLN non-mentholated	4.8	104	23
		End Of Study	10OCT2018	VLN non-mentholated	5.4	85	18
1051	36/F	Screen	14AUG2018	UB mentholated	4.9	86	23
		End Of Study	10OCT2018	UB mentholated	4.8	83	20
1052	31/M	Screen	14AUG2018	VLN mentholated	5.1	77	7 LN
		End Of Study	11OCT2018	VLN mentholated	4.6	76	8 LN

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1053	42/M	Screen	14AUG2018	VLN mentholated	5.8	55	17
		End Of Study	11OCT2018	VLN mentholated	5.3	64	13
1054	56/M	Screen	14AUG2018	UB non-mentholated	5.3	91	33
		End Of Study	10OCT2018	UB non-mentholated	5.1	94	35
1055	39/F	Screen	14AUG2018	VLN mentholated	5.1	83	11
		End Of Study	11OCT2018	VLN mentholated	5.4	80	10
1056	48/M	Screen	14AUG2018	VLN non-mentholated	5.4	56	29
		End Of Study	11OCT2018	VLN non-mentholated	5.6	75	19
1058	30/M	Screen	15AUG2018	VLN non-mentholated	5.3	96	21
		End Of Study	11OCT2018	VLN non-mentholated	5.1	106	14
1059	38/M	Screen	27AUG2018	UB non-mentholated	5.1	77	35
		End Of Study	24OCT2018	UB non-mentholated	4.7	69	31
1060	55/M	Screen	27AUG2018	VLN mentholated	5	64	10
		End Of Study	24OCT2018	VLN mentholated	5.6	61	12
1063	31/M	Screen	27AUG2018	VLN mentholated	5.4	66	19

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1063	31/M	End Of Study	25OCT2018	VLN mentholated	5.1	79	25
1064	34/M	Screen	27AUG2018	UB non-mentholated	5.3	48	29
1066	62/M	Screen	27AUG2018	VLN non-mentholated	4.7	93	12
		End Of Study	24OCT2018	VLN non-mentholated	4.1	90	14
1069	40/F	Screen	28AUG2018	UB non-mentholated	4.9	98	16
		End Of Study	24OCT2018	UB non-mentholated	5.2	94	13
1070	53/M	Screen	28AUG2018	VLN non-mentholated	6 HN	57	20
		End Of Study	24OCT2018	VLN non-mentholated	6.1 HN	56	20
1071	42/M	Screen	28AUG2018	VLN non-mentholated	6 HN	109	65
1072	59/M	Screen	28AUG2018	VLN mentholated	5.7	59	17
		End Of Study	22OCT2018	VLN mentholated	5.7	54	18
1074	42/M	Screen	28AUG2018	VLN non-mentholated	5.3	89	53
		End Of Study	24OCT2018	VLN non-mentholated	4.7	83	22
1075	26/F	Screen	29AUG2018	UB non-mentholated	4.9	57	11

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1075	26/F	End Of Study	24OCT2018	UB non-mentholated	5.2	66	10
1077	49/F	Screen	28AUG2018	VLN non-mentholated	5.3	79	27
		End Of Study	24OCT2018	VLN non-mentholated	5.4	77	19
1078	51/F	Screen	28AUG2018	VLN non-mentholated	5.5	82	11
		End Of Study	24OCT2018	VLN non-mentholated	5.4	90	12
1079	33/M	Screen	29AUG2018	VLN mentholated	5.8	94	56
		End Of Study	24OCT2018	VLN mentholated	5.1	63	33
1082	37/M	Screen	30AUG2018	VLN non-mentholated	5.8	89	18
		End Of Study	24OCT2018	VLN non-mentholated	5.3	80	31
1083	54/F	Screen	04SEP2018	VLN non-mentholated	4.9	80	25
		End Of Study	31OCT2018	VLN non-mentholated	4.9	71	10
1084	42/M	Screen	04SEP2018	VLN non-mentholated	5.2	52	26
1086	54/M	Screen	04SEP2018	VLN non-mentholated	5.8	65	24
		End Of Study	31OCT2018	VLN non-mentholated	4.9	65	10

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1088	26/M	Screen	04SEP2018	VLN mentholated	5.3	69	19
		End Of Study	31OCT2018	VLN mentholated	5.4	76	20
1089	60/F	Screen	04SEP2018	UB non-mentholated	5.6	68	9 LN
		End Of Study	31OCT2018	UB non-mentholated	5.1	67	31
1092	43/F	Screen	05SEP2018	VLN mentholated	5.2	67	12
		End Of Study	31OCT2018	VLN mentholated	5.6	59	21
1094	46/M	Screen	05SEP2018	VLN mentholated	5.1	63	8 LN
		End Of Study	31OCT2018	VLN mentholated	5.6	70	8 LN
1095	55/F	Screen	07SEP2018	VLN mentholated	6.2 HN	96	28
		End Of Study	31OCT2018	VLN mentholated	5.8	66	9 LN
1096	42/F	Screen	07SEP2018	VLN non-mentholated	5.6	63	28
		End Of Study	31OCT2018	VLN non-mentholated	5.5	90	25
1097	30/M	Screen	07SEP2018	VLN mentholated	5.5	67	14
		End Of Study	31OCT2018	VLN mentholated	5.8	71	21
1098	63/M	Screen	18SEP2018	VLN non-mentholated	5.2	83	11

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1098	63/M	End Of Study	16NOV2018	VLN non-mentholated	4.8	90	11
1099	46/F	Screen	18SEP2018	VLN non-mentholated	5.9 HN	91	25
		End Of Study	16NOV2018	VLN non-mentholated	6.2 HN	86	16
1100	59/M	Screen	18SEP2018	VLN non-mentholated	5.1	89	45
		End Of Study	16NOV2018	VLN non-mentholated	4.8	86	50
1101	41/M	Screen	18SEP2018	VLN non-mentholated	5.4	63	78 HN
		End Of Study	16NOV2018	VLN non-mentholated	5.6	76	90 HN
1103	43/M	Screen	18SEP2018	VLN non-mentholated	5.2	79	32
		End Of Study	16NOV2018	VLN non-mentholated	4.9	68	21
1105	47/F	Screen	19SEP2018	VLN non-mentholated	4.8	78	0 LN
		End Of Study	16NOV2018	VLN non-mentholated	4.7	79	23
1106	42/M	Screen	19SEP2018	UB non-mentholated	5.2	87	29
		End Of Study	16NOV2018	UB non-mentholated	5.8	84	35
1107	45/M	Screen	21SEP2018	VLN non-mentholated	4.9	80	38
		End Of Study	16NOV2018	VLN non-mentholated	5.2	65	31

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
1108	54/M	Screen	21SEP2018	UB non-mentholated	5.1	99	15
		End Of Study	16NOV2018	UB non-mentholated	5.6	93	16
1109	58/M	Screen	21SEP2018	UB non-mentholated	5.1	80	22
		End Of Study	16NOV2018	UB non-mentholated	4.7	75	17
1112	59/F	Screen	21SEP2018	VLN non-mentholated	5.7	130 HN	14
		End Of Study	16NOV2018	VLN non-mentholated	5.8	128 HN	17
1114	26/F	Screen	24SEP2018	UB non-mentholated	4.4	132 HN	12
		End Of Study	16NOV2018	UB non-mentholated	5.3	120 HN	10
1115	29/M	Screen	24SEP2018	VLN non-mentholated	5.3	102	27
2002	49/M	Screen	29JUN2018	UB mentholated	5.8 HN	81	29
		End Of Study	05SEP2018	UB mentholated	5.4	66	18
2003	41/F	Screen	29JUN2018	VLN mentholated	5	54	10
		End Of Study	29AUG2018	VLN mentholated	4.9	50	7
2007	57/F	Screen	29JUN2018	VLN non-mentholated	5.1	63	12
		End Of Study	29AUG2018	VLN non-mentholated	5.5	50	10

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2008	42/M	Screen	06JUL2018	VLN mentholated	4.6	60	38
		End Of Study	29AUG2018	VLN mentholated	3.5 LN	59	15
2009	55/M	Screen	29JUN2018	VLN non-mentholated	4.6	64	23
2010	27/M	Screen	29JUN2018	UB mentholated	5.2	66	25
		End Of Study	29AUG2018	UB mentholated	5.2	63	28
2011	32/F	Screen	29JUN2018	VLN mentholated	4.9	54	21
		End Of Study	29AUG2018	VLN mentholated	5.3	46	19
2014	37/M	Screen	02JUL2018	VLN mentholated	5.6 HN	70	30
		End Of Study	29AUG2018	VLN mentholated	5.2	62	25
2015	57/F	Screen	02JUL2018	UB mentholated	4.4	99	23
		End Of Study	29AUG2018	UB mentholated	4.3	92	25
2016	45/F	Screen	02JUL2018	VLN mentholated	5.1	96	22
		End Of Study	03AUG2018	VLN mentholated	4.7	83	7
2017	30/M	Screen	02JUL2018	VLN mentholated	4.7	107	39
		End Of Study	29AUG2018	VLN mentholated	4.2	85	31

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2018	26/F	Screen	02JUL2018	UB mentholated	4.6	59	21
		End Of Study	29AUG2018	UB mentholated	5.2	53	12
2020	60/F	Screen	02JUL2018	VLN mentholated	4.9	92	15
		End Of Study	29AUG2018	VLN mentholated	4.7	84	12
2021	31/M	Screen	02JUL2018	VLN mentholated	5.2	82	32
		End Of Study	29AUG2018	VLN mentholated	5.1	62	22
2023	35/M	Screen	02JUL2018	VLN mentholated	4.8	54	50 HN
		End Of Study	29AUG2018	VLN mentholated	4.4	46	25
2024	26/M	Screen	03JUL2018	UB non-mentholated	4.8	68	51 HN
		End Of Study	03JUL2018	UB non-mentholated	5.4	86	17
2025	59/M	Screen	03JUL2018	UB non-mentholated	5.7 HN	79	16
		End Of Study	29AUG2018	UB non-mentholated	5.7 HN	79	16
2028	36/M	Screen	06JUL2018	VLN non-mentholated	4.9	64	15
		End Of Study	29AUG2018	VLN non-mentholated	5.6 HN	64	19
2029	56/M	Screen	09JUL2018	UB mentholated	5.2	75	25
		End Of Study	05SEP2018	UB mentholated	5.8 HN	57	15

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2039	49/F	Screen	13JUL2018	VLN mentholated	4.6	57	17
		End Of Study	05SEP2018	VLN mentholated	5.1	49	10
2050	57/M	Screen	20JUL2018	UB mentholated	6.2 HN	113	21
		End Of Study	20SEP2018	UB mentholated	7.7 HN	102	19
2052	54/M	Screen	20JUL2018	VLN mentholated	5.8 HN	71	41
		End Of Study	20SEP2018	VLN mentholated	6 HN	50	33
2057	52/M	Screen	23JUL2018	VLN mentholated	5.9 HN	58	26
		End Of Study	20SEP2018	VLN mentholated	5.7 HN	46	20
2058	37/F	Screen	23JUL2018	VLN mentholated	5.2	46	11
		End Of Study	20SEP2018	VLN mentholated	5.1	52	14
2059	56/F	Screen	23JUL2018	UB mentholated	4.4	80	13
		End Of Study	20SEP2018	UB mentholated	4.4	70	15
2060	37/F	Screen	23JUL2018	VLN mentholated	4.5	46	5
		End Of Study	20SEP2018	VLN mentholated	4.6	43	5
2064	52/M	Screen	23JUL2018	VLN mentholated	4.5	82	28

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2064	52/M	End Of Study	20SEP2018	VLN mentholated	5.1	72	17
2066	30/F	Screen	23JUL2018	VLN mentholated	4.8	51	11
		End Of Study	20SEP2018	VLN mentholated	4.9	46	18
2067	52/M	Screen	23JUL2018	VLN non-mentholated	4.7	72	37
		End Of Study	20SEP2018	VLN non-mentholated	5.1	68	19
2075	34/M	Screen	30JUL2018	VLN mentholated	4.8	65	91 HN
		End Of Study	22AUG2018	VLN mentholated	5.5	70	80 HN
2076	42/M	Screen	30JUL2018	VLN mentholated	5.6 HN	85	9
		End Of Study	14OCT2018	VLN mentholated	5.3	84	13
2086	36/M	Screen	03AUG2018	VLN non-mentholated	4.9	71	24
		End Of Study	01OCT2018	VLN non-mentholated	4.1	67	7
2088	39/F	Screen	03AUG2018	VLN mentholated	4.9	66	13
		End Of Study	14OCT2018	VLN mentholated	4.9	69	19
2092	50/F	Screen	06AUG2018	VLN mentholated	5.5	100	14
		End Of Study	14OCT2018	VLN mentholated	4.8	86	15

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2099	52/M	Screen	09AUG2018	VLN non-mentholated	4.7	86	39
		End Of Study	14OCT2018	VLN non-mentholated	5	85	34
2100	48/F	Screen	09AUG2018	UB mentholated	4.3	64	9
		End Of Study	14OCT2018	UB mentholated	4.3	61	9
2108	60/F	Screen	13AUG2018	VLN non-mentholated	5.8 HN	76	12
		End Of Study	14OCT2018	VLN non-mentholated	5.6 HN	72	16
2110	41/F	Screen	13AUG2018	UB mentholated	4.5	65	12
		End Of Study	20OCT2018	UB mentholated	5.5	56	23
2113	51/F	Screen	15AUG2018	VLN mentholated	5.4	61	19
2115	46/F	Screen	15AUG2018	VLN mentholated	4.5	81	25
2119	48/M	Screen	20AUG2018	VLN mentholated	5	53	21
		End Of Study	20OCT2018	VLN mentholated	4.8	63	24
2120	62/F	Screen	20AUG2018	VLN non-mentholated	6 HN	103	15
		End Of Study	20OCT2018	VLN non-mentholated	7.4 HN	94	13

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2122	60/M	Screen	20AUG2018	UB non-mentholated	4.8	90	12
		End Of Study	20OCT2018	UB non-mentholated	4.8	80	14
2125	35/M	Screen	21AUG2018	UB mentholated	4.7	42	13
		End Of Study	20OCT2018	UB mentholated	4.6	37 LN	14
2126	37/M	Screen	21AUG2018	VLN mentholated	4.9	95	44
		End Of Study	20OCT2018	VLN mentholated	4.9	74	32
2136	64/M	Screen	27AUG2018	VLN non-mentholated	5.7 HN	80	24
		End Of Study	19OCT2018	VLN non-mentholated	5	85	20
2140	56/F	Screen	30AUG2018	UB non-mentholated	4.9	56	11
		End Of Study	06NOV2018	UB non-mentholated	4.8	58	13
2142	30/F	Screen	31AUG2018	VLN non-mentholated	4.6	104	37 HN
		End Of Study	08OCT2018	VLN non-mentholated	4.1	92	23
2143	63/M	Screen	04SEP2018	VLN non-mentholated	5.5	90	15
		End Of Study	06NOV2018	VLN non-mentholated	4.8	82	14
2158	43/F	Screen	18SEP2018	UB non-mentholated	4.7	84	13

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2159	37/M	Screen	19SEP2018	VLN non-mentholated	5	86	23
		End Of Study	02DEC2018	VLN non-mentholated	4.9	68	16
2164	65/F	Screen	27SEP2018	VLN non-mentholated	4.4	67	11
		End Of Study	02DEC2018	VLN non-mentholated	5.4	65	21
2168	32/F	Screen	28SEP2018	VLN non-mentholated	4.9	79	17
		End Of Study	02DEC2018	VLN non-mentholated	5.2	70	12
2170	51/F	Screen	28SEP2018	UB non-mentholated	5.1	83	11
		End Of Study	02DEC2018	UB non-mentholated	5	76	11
2175	40/F	Screen	01OCT2018	UB mentholated	5.1	58	12
		End Of Study	02DEC2018	UB mentholated	5.3	56	15
2189	28/M	Screen	04OCT2018	VLN mentholated	4.6	87	22
		End Of Study	06NOV2018	VLN mentholated	5.4	75	26
2211	29/F	Screen	10OCT2018	VLN mentholated	4.4	73	11
		End Of Study	02DEC2018	VLN mentholated	4.7	49	13
2212	32/M	Screen	10OCT2018	UB mentholated	4.8	47	14

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2212	32/M	End Of Study	02DEC2018	UB mentholated	4.9	43	20
2213	29/M	Screen	10OCT2018	VLN mentholated	4.6	74	22
		End Of Study	02DEC2018	VLN mentholated	5.4	73	21
2215	59/F	Screen	10OCT2018	UB mentholated	4.7	115	9
		End Of Study	02DEC2018	UB mentholated	5.5	96	14
2220	37/M	Screen	11OCT2018	VLN non-mentholated	4.9	61	28
		End Of Study	02DEC2018	VLN non-mentholated	5.3	54	27
2235	26/F	Screen	19OCT2018	VLN mentholated	4.4	70	23
		End Of Study	16DEC2018	VLN mentholated	5.2	70	19
2244	31/M	Screen	25OCT2018	VLN non-mentholated	4.8	100	26
		End Of Study	16DEC2018	VLN non-mentholated	5.7 HN	97	21
2247	28/M	Screen	06NOV2018	VLN mentholated	4.9	59	28
		End Of Study	28DEC2018	VLN mentholated	4.6	61	31
2251	27/M	Screen	09NOV2018	UB non-mentholated	5.1	94	11
		End Of Study	19JAN2019	UB non-mentholated	4.9	95	11

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.2 Clinical Laboratory Report - Serum Chemistry (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Glucose 001: 4.1-5.8 002: 3.6-5.5 (mmol/L)	Alkaline Phosphatase 001: F: 37-1 001: M: 45-1 002: 39-117 (IU/L)	Alanine Amino- transferase 001: 10-67 002: F: 0-32 002: M: 0-44 (IU/L)
		Name	Date				
2257	55/F	Screen	14NOV2018	UB non-mentholated	5.1	89	14
		End Of Study	19JAN2019	UB non-mentholated	4.8	89	12
2259	49/M	Screen	14NOV2018	UB mentholated	4.7	65	24
		End Of Study	19JAN2019	UB mentholated	4.8	51	22
2269	48/M	Screen	26NOV2018	VLN mentholated	5.3	82	35
		End Of Study	19JAN2019	VLN mentholated	5.1	77	22
2272	37/M	Screen	28NOV2018	VLN mentholated	4.9	49	17
		End Of Study	19JAN2019	VLN mentholated	4.8	45	15

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1001	59/F	Screen	02JUL2018	VLN non-mentholated		23			7.6
		Start Of Week -1	19JUL2018	VLN non-mentholated			NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated		16	NEGATIVE		6.9
1002	30/M	Screen	02JUL2018	VLN non-mentholated		18			6.4
		End Of Study	07SEP2018	VLN non-mentholated		18			7.3
1003	38/M	Screen	03JUL2018	VLN mentholated		24			7.2
		End Of Study	07SEP2018	VLN mentholated		21			6.9
1007	37/M	Screen	12JUL2018	VLN non-mentholated		20			6.9
		End Of Study	07SEP2018	VLN non-mentholated		25			7
1008	48/M	Screen	12JUL2018	VLN mentholated		25			7.1
		End Of Study	07SEP2018	VLN mentholated		16			6.6
1010	32/M	Screen	13JUL2018	UB mentholated		19			7.5
		End Of Study	06SEP2018	UB mentholated		20			7.8
1011	36/M	Screen	13JUL2018	UB non-mentholated		16			7.5
		End Of Study	06SEP2018	UB non-mentholated		18			7.6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1013	36/F	Screen	16JUL2018	VLN non-mentholated		20			
		Start Of Week -1	26JUL2018	VLN non-mentholated					
		End Of Study	14SEP2018	VLN non-mentholated		13 LN			
1014	36/F	Screen	16JUL2018	VLN mentholated		20			
		Start Of Week -1	26JUL2018	VLN mentholated					
		End Of Study	14SEP2018	VLN mentholated		26			
1015	49/F	Screen	16JUL2018	VLN mentholated		18			
		Start Of Week -1	26JUL2018	VLN mentholated					
		End Of Study	14SEP2018	VLN mentholated		16			
1016	54/M	Screen	16JUL2018	UB non-mentholated		17			
		End Of Study	13SEP2018	UB non-mentholated		28			
1017	41/F	Screen	17JUL2018	UB mentholated		21			
		Start Of Week -1	26JUL2018	UB mentholated					
		End Of Study	13SEP2018	UB mentholated		17			
1018	41/F	Screen	17JUL2018	VLN mentholated		17			
		Start Of Week -1	26JUL2018	VLN mentholated					
		End Of Study	15AUG2018	VLN mentholated		20			

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1019	30/M	Screen	17JUL2018	VLN non-mentholated		19			7.4
		End Of Study	14SEP2018	VLN non-mentholated		15			6.9
1020	36/F	Screen	17JUL2018	VLN non-mentholated		13	LN	NEGATIVE	7.5
		Start Of Week -1	26JUL2018	VLN non-mentholated				NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated		15			6.9
1021	49/F	Screen	17JUL2018	UB non-mentholated		15		NEGATIVE	7.1
		Start Of Week -1	26JUL2018	UB non-mentholated				NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated		10	LN		6.4
1023	50/F	Screen	17JUL2018	VLN non-mentholated		24		NEGATIVE	7
		Start Of Week -1	26JUL2018	VLN non-mentholated				NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated		19			6.4
1029	35/F	Screen	26JUL2018	VLN mentholated		29		NEGATIVE	7.5
		Start Of Week -1	22AUG2018	VLN mentholated				NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated		16			7.2
1032	53/F	Screen	13AUG2018	VLN mentholated		16		NEGATIVE	6.8
		Start Of Week -1	22AUG2018	VLN mentholated				NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated		14			6.6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1034	45/M	Screen	13AUG2018	VLN non-mentholated		17			6.5
		End Of Study	10OCT2018	VLN non-mentholated		19			7.1
1035	44/M	Screen	13AUG2018	VLN non-mentholated		29			7.1
		End Of Study	11OCT2018	VLN non-mentholated		23			6.4
1036	38/F	Screen	13AUG2018	UB mentholated		18			6.3
		Start Of Week -1	22AUG2018	UB mentholated			NEGATIVE		
		End Of Study	10OCT2018	UB mentholated		14	NEGATIVE		7
1037	29/M	Screen	13AUG2018	UB mentholated		17			7.3
		End Of Study	10OCT2018	UB mentholated		16			7
1038	39/F	Screen	13AUG2018	VLN non-mentholated		13	LN		7.1
		Start Of Week -1	22AUG2018	VLN non-mentholated				NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated		15	NEGATIVE		6.9
1042	47/M	Screen	13AUG2018	VLN non-mentholated		18			6.4
		End Of Study	11OCT2018	VLN non-mentholated		15			6.5
1045	58/M	Screen	14AUG2018	UB non-mentholated		15			7.5
		End Of Study	10OCT2018	UB non-mentholated		15			6.6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1046	45/M	Screen	14AUG2018	UB mentholated		21			7.7
		End Of Study	10OCT2018	UB mentholated		19			7.2
1050	33/F	Screen	14AUG2018	VLN non-mentholated		16		NEGATIVE	6.9
		Start Of Week -1	22AUG2018	VLN non-mentholated				NEGATIVE	
		End Of Study	10OCT2018	VLN non-mentholated		15			6.2 LN
1051	36/F	Screen	14AUG2018	UB mentholated		16		NEGATIVE	6.9
		Start Of Week -1	22AUG2018	UB mentholated				NEGATIVE	
		End Of Study	10OCT2018	UB mentholated		14			6.8
1052	31/M	Screen	14AUG2018	VLN mentholated		10 LN			7.1
		End Of Study	11OCT2018	VLN mentholated		11 LN			6.9
1053	42/M	Screen	14AUG2018	VLN mentholated		15			7.4
		End Of Study	11OCT2018	VLN mentholated		14			7.7
1054	56/M	Screen	14AUG2018	UB non-mentholated		19			6.7
		End Of Study	10OCT2018	UB non-mentholated		19			6.8
1055	39/F	Screen	14AUG2018	VLN mentholated		12 LN		NEGATIVE	6.9
		Start Of Week -1	22AUG2018	VLN mentholated				NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
1055	39/F	End Of Study	11OCT2018	VLN mentholated	11 LN		6.5
1056	48/M	Screen	14AUG2018	VLN non-mentholated	20		7.2
		End Of Study	11OCT2018	VLN non-mentholated	19		7.4
1058	30/M	Screen	15AUG2018	VLN non-mentholated	17		7.3
		End Of Study	11OCT2018	VLN non-mentholated	14		7.4
1059	38/M	Screen	27AUG2018	UB non-mentholated	28		7.5
		End Of Study	24OCT2018	UB non-mentholated	22		6.9
1060	55/M	Screen	27AUG2018	VLN mentholated	13 LN		7.9
		End Of Study	24OCT2018	VLN mentholated	13 LN		7.3
1063	31/M	Screen	27AUG2018	VLN mentholated	19		7.2
		End Of Study	25OCT2018	VLN mentholated	19		7.3
1064	34/M	Screen	27AUG2018	UB non-mentholated	29		6.9
1066	62/M	Screen	27AUG2018	VLN non-mentholated	19		7.5
		End Of Study	24OCT2018	VLN non-mentholated	18		7.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1069	40/F	Screen	28AUG2018	UB non-mentholated		17			7.7
		Start Of Week -1	05SEP2018	UB non-mentholated					
		End Of Study	24OCT2018	UB non-mentholated		13 LN	NEGATIVE		7.2
1070	53/M	Screen	28AUG2018	VLN non-mentholated		16			7.7
		End Of Study	24OCT2018	VLN non-mentholated		14			7.1
1071	42/M	Screen	28AUG2018	VLN non-mentholated		43			7.4
1072	59/M	Screen	28AUG2018	VLN mentholated		18			7.4
		End Of Study	22OCT2018	VLN mentholated		16			7
1074	42/M	Screen	28AUG2018	VLN non-mentholated		39			7.6
		End Of Study	24OCT2018	VLN non-mentholated		19			7.2
1075	26/F	Screen	28AUG2018	UB non-mentholated		15	NEGATIVE		7.2
		Start Of Week -1	05SEP2018	UB non-mentholated					
		End Of Study	24OCT2018	UB non-mentholated		13 LN	NEGATIVE		7.1
1077	49/F	Screen	28AUG2018	VLN non-mentholated		20	NEGATIVE		7.1
		Start Of Week -1	05SEP2018	VLN non-mentholated			NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
1077	49/F	End Of Study	24OCT2018	VLN non-mentholated	14		6.3
1078	51/F	Screen	28AUG2018	VLN non-mentholated	18	NEGATIVE NEGATIVE	7.1
		Start Of Week -1	05SEP2018	VLN non-mentholated			
		End Of Study	24OCT2018	VLN non-mentholated	17		6.9
1079	33/M	Screen	29AUG2018	VLN mentholated	27		6.7
		End Of Study	24OCT2018	VLN mentholated	18		5.7 LN
1082	37/M	Screen	30AUG2018	VLN non-mentholated	22		7.5
		End Of Study	24OCT2018	VLN non-mentholated	23		7.5
1083	54/F	Screen	04SEP2018	VLN non-mentholated	18	NEGATIVE NEGATIVE	7
		Start Of Week -1	12SEP2018	VLN non-mentholated			
		End Of Study	31OCT2018	VLN non-mentholated	13 LN		6.5
1084	42/M	Screen	04SEP2018	VLN non-mentholated	25		7.1
1086	54/M	Screen	04SEP2018	VLN non-mentholated	25		7.6
		End Of Study	31OCT2018	VLN non-mentholated	15		7.1
1088	26/M	Screen	04SEP2018	VLN mentholated	18		7.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
1088	26/M	End Of Study	31OCT2018	VLN mentholated	15		6.5
1089	60/F	Screen	04SEP2018	UB non-mentholated	15	NEGATIVE NEGATIVE	7.4
		Start Of Week -1	12SEP2018	UB non-mentholated			
		End Of Study	31OCT2018	UB non-mentholated	20		6.9
1092	43/F	Screen	05SEP2018	VLN mentholated	17	NEGATIVE NEGATIVE	6.7
		Start Of Week -1	12SEP2018	VLN mentholated			
		End Of Study	31OCT2018	VLN mentholated	19		7.2
1094	46/M	Screen	05SEP2018	VLN mentholated	12 LN		7.1
		End Of Study	31OCT2018	VLN mentholated	15		6.6
1095	55/F	Screen	07SEP2018	VLN mentholated	19	NEGATIVE NEGATIVE	6.6
		Start Of Week -1	12SEP2018	VLN mentholated			
		End Of Study	31OCT2018	VLN mentholated	11 LN		6.8
1096	42/F	Screen	07SEP2018	VLN non-mentholated	22	NEGATIVE NEGATIVE	6.6
		Start Of Week -1	12SEP2018	VLN non-mentholated			
		End Of Study	31OCT2018	VLN non-mentholated	17		6.5
1097	30/M	Screen	07SEP2018	VLN mentholated	19		7.6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1097	30/M	End Of Study	31OCT2018	VLN mentholated		15			6.5
1098	63/M	Screen	18SEP2018	VLN non-mentholated		16			7.5
		End Of Study	16NOV2018	VLN non-mentholated		13 LN			7.4
1099	46/F	Screen	18SEP2018	VLN non-mentholated		21			6.9
		Start Of Week -1	28SEP2018	VLN non-mentholated			NEGATIVE		
		End Of Study	16NOV2018	VLN non-mentholated		13 LN	NEGATIVE		6.4
1100	59/M	Screen	18SEP2018	VLN non-mentholated		26			7.1
		End Of Study	16NOV2018	VLN non-mentholated		32			7
1101	41/M	Screen	18SEP2018	VLN non-mentholated		64 HN			7.6
		End Of Study	16NOV2018	VLN non-mentholated		75 HN			7.6
1103	43/M	Screen	18SEP2018	VLN non-mentholated		24			6.7
		End Of Study	16NOV2018	VLN non-mentholated		18			6.4
1105	47/F	Screen	19SEP2018	VLN non-mentholated		13 LN			7.1
		Start Of Week -1	28SEP2018	VLN non-mentholated			NEGATIVE		
		End Of Study	16NOV2018	VLN non-mentholated		22	NEGATIVE		6.4

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase		Choriogonadotropin Beta	Protein	
		Name	Date		001: 14-48	002: 0-40 (IU/L)		001: 6.3-8.1	002: 6-8.5 (g/dL)
1106	42/M	Screen	19SEP2018	UB non-mentholated	25			7.1	
		End Of Study	16NOV2018	UB non-mentholated	26			7	
1107	45/M	Screen	21SEP2018	VLN non-mentholated	24			7.1	
		End Of Study	16NOV2018	VLN non-mentholated	18			6.4	
1108	54/M	Screen	21SEP2018	UB non-mentholated	18			7.1	
		End Of Study	16NOV2018	UB non-mentholated	16			7	
1109	58/M	Screen	21SEP2018	UB non-mentholated	23			7.4	
		End Of Study	16NOV2018	UB non-mentholated	16			6.8	
1112	59/F	Screen	21SEP2018	VLN non-mentholated	19		NEGATIVE	7.1	
		Start Of Week -1	28SEP2018	VLN non-mentholated			NEGATIVE		
		End Of Study	16NOV2018	VLN non-mentholated	20			6.4	
1114	26/F	Screen	24SEP2018	UB non-mentholated	20		NEGATIVE	7.3	
		Start Of Week -1	28SEP2018	UB non-mentholated			NEGATIVE		
		End Of Study	16NOV2018	UB non-mentholated	16			7.3	
1115	29/M	Screen	24SEP2018	VLN non-mentholated	26			8.2	HN

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2002	49/M	Screen	29JUN2018	UB mentholated	35		7.1
		End Of Study	05SEP2018	UB mentholated	25		6.9
2003	41/F	Screen	29JUN2018	VLN mentholated	16		7.1
		End Of Study	29AUG2018	VLN mentholated	15		6.2
2007	57/F	Screen	29JUN2018	VLN non-mentholated	15		6.9
		End Of Study	29AUG2018	VLN non-mentholated	16		6
2008	42/M	Screen	06JUL2018	VLN mentholated	30		6.7
		End Of Study	29AUG2018	VLN mentholated	18		6.4
2009	55/M	Screen	29JUN2018	VLN non-mentholated	21		6.7
2010	27/M	Screen	29JUN2018	UB mentholated	13		7.2
		End Of Study	29AUG2018	UB mentholated	22		6.9
2011	32/F	Screen	29JUN2018	VLN mentholated	17		7.3
		End Of Study	29AUG2018	VLN mentholated	22		5.9 LN
2014	37/M	Screen	02JUL2018	VLN mentholated	27		7.3
		End Of Study	29AUG2018	VLN mentholated	25		6.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2015	57/F	Screen	02JUL2018	UB mentholated	21		6.8
		End Of Study	29AUG2018	UB mentholated	20		5.9 LN
2016	45/F	Screen	02JUL2018	VLN mentholated	23		7.1
		End Of Study	03AUG2018	VLN mentholated	11		6.1
2017	30/M	Screen	02JUL2018	VLN mentholated	28		6.9
		End Of Study	29AUG2018	VLN mentholated	25		6.5
2018	26/F	Screen	02JUL2018	UB mentholated	22		7.2
		End Of Study	29AUG2018	UB mentholated	15		6.6
2020	60/F	Screen	02JUL2018	VLN mentholated	18		7.1
		End Of Study	29AUG2018	VLN mentholated	17		6.6
2021	31/M	Screen	02JUL2018	VLN mentholated	53 HN		7.4
		End Of Study	29AUG2018	VLN mentholated	42 HN		6.5
2023	35/M	Screen	02JUL2018	VLN mentholated	33		7.6
		End Of Study	29AUG2018	VLN mentholated	22		6.9
2024	26/M	Screen	03JUL2018	UB non-mentholated	169 HN		7.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2025	59/M	Screen	03JUL2018	UB non-mentholated	20		6.6
		End Of Study	29AUG2018	UB non-mentholated	23		6.4
2028	36/M	Screen	06JUL2018	VLN non-mentholated	16		7.4
		End Of Study	29AUG2018	VLN non-mentholated	22		6.8
2029	56/M	Screen	09JUL2018	UB mentholated	18		7.3
		End Of Study	05SEP2018	UB mentholated	12		6.2
2039	49/F	Screen	13JUL2018	VLN mentholated	22		7.4
		End Of Study	05SEP2018	VLN mentholated	14		6.5
2050	57/M	Screen	20JUL2018	UB mentholated	35		7.2
		End Of Study	20SEP2018	UB mentholated	16		6.7
2052	54/M	Screen	20JUL2018	VLN mentholated	38		6.8
		End Of Study	20SEP2018	VLN mentholated	31		6.5
2057	52/M	Screen	23JUL2018	VLN mentholated	26		6.8
		End Of Study	20SEP2018	VLN mentholated	22		6.4
2058	37/F	Screen	23JUL2018	VLN mentholated	15		6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
2058	37/F	End Of Study	20SEP2018	VLN mentholated	14		6.7
2059	56/F	Screen	23JUL2018	UB mentholated	17		7
		End Of Study	20SEP2018	UB mentholated	11		6.1
2060	37/F	Screen	23JUL2018	VLN mentholated	14		7.1
		End Of Study	20SEP2018	VLN mentholated	9		6.3
2064	52/M	Screen	23JUL2018	VLN mentholated	32		7.1
		End Of Study	20SEP2018	VLN mentholated	18		6.7
2066	30/F	Screen	23JUL2018	VLN mentholated	20		6.8
		End Of Study	20SEP2018	VLN mentholated	26		6.5
2067	52/M	Screen	23JUL2018	VLN non-mentholated	35		6.2
		End Of Study	20SEP2018	VLN non-mentholated	19		6.1
2075	34/M	Screen	30JUL2018	VLN mentholated	71 HN		7.6
		End Of Study	22AUG2018	VLN mentholated	63 HN		6.6
2076	42/M	Screen	30JUL2018	VLN mentholated	18		7
		End Of Study	14OCT2018	VLN mentholated	21		6.3

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2086	36/M	Screen	03AUG2018	VLN non-mentholated	25		6.8
		End Of Study	01OCT2018	VLN non-mentholated	13		6.9
2088	39/F	Screen	03AUG2018	VLN mentholated	15		6.9
		End Of Study	14OCT2018	VLN mentholated	17		6.5
2092	50/F	Screen	06AUG2018	VLN mentholated	18		7.5
		End Of Study	14OCT2018	VLN mentholated	15		6.1
2099	52/M	Screen	09AUG2018	VLN non-mentholated	30		7
		End Of Study	14OCT2018	VLN non-mentholated	26		6.3
2100	48/F	Screen	09AUG2018	UB mentholated	14		7.2
		End Of Study	14OCT2018	UB mentholated	11		6.6
2108	60/F	Screen	13AUG2018	VLN non-mentholated	18		7
		End Of Study	14OCT2018	VLN non-mentholated	20		6.5
2110	41/F	Screen	13AUG2018	UB mentholated	24		7.4
		End Of Study	20OCT2018	UB mentholated	30		6.6
2113	51/F	Screen	15AUG2018	VLN mentholated	19		7.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
2115	46/F	Screen	15AUG2018	VLN mentholated	24		7.1
2119	48/M	Screen	20AUG2018	VLN mentholated	19		6.3
		End Of Study	20OCT2018	VLN mentholated	20		6.6
2120	62/F	Screen	20AUG2018	VLN non-mentholated	19		6.8
		End Of Study	20OCT2018	VLN non-mentholated	18		6.8
2122	60/M	Screen	20AUG2018	UB non-mentholated	14		7.1
		End Of Study	20OCT2018	UB non-mentholated	16		6.4
2125	35/M	Screen	21AUG2018	UB mentholated	22		7.7
		End Of Study	20OCT2018	UB mentholated	20		6.7
2126	37/M	Screen	21AUG2018	VLN mentholated	25		7.1
		End Of Study	20OCT2018	VLN mentholated	23		6.3
2136	64/M	Screen	27AUG2018	VLN non-mentholated	23		6.9
		End Of Study	19OCT2018	VLN non-mentholated	25		6.6
2140	56/F	Screen	30AUG2018	UB non-mentholated	10		6.9
		End Of Study	06NOV2018	UB non-mentholated	16		6.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2142	30/F	Screen	31AUG2018	VLN non-mentholated	30		7.4
		End Of Study	08OCT2018	VLN non-mentholated	25		6.9
2143	63/M	Screen	04SEP2018	VLN non-mentholated	17		7
		End Of Study	06NOV2018	VLN non-mentholated	15		6.1
2158	43/F	Screen	18SEP2018	UB non-mentholated	19		6.3
2159	37/M	Screen	19SEP2018	VLN non-mentholated	20		6.6
		End Of Study	02DEC2018	VLN non-mentholated	14		5.1 LN
2164	65/F	Screen	27SEP2018	VLN non-mentholated	15		7.4
		End Of Study	02DEC2018	VLN non-mentholated	14		6.6
2168	32/F	Screen	28SEP2018	VLN non-mentholated	23		6.8
		End Of Study	02DEC2018	VLN non-mentholated	15		5.8 LN
2170	51/F	Screen	28SEP2018	UB non-mentholated	17		7
		End Of Study	02DEC2018	UB non-mentholated	16		6.1
2175	40/F	Screen	01OCT2018	UB mentholated	13		6.6
		End Of Study	02DEC2018	UB mentholated	13		5.9 LN

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase 001: 14-48 002: 0-40 (IU/L)	Choriogonadotropin Beta	Protein 001: 6.3-8.1 002: 6-8.5 (g/dL)
		Name	Date				
2189	28/M	Screen	04OCT2018	VLN mentholated	15		7.3
		End Of Study	06NOV2018	VLN mentholated	16		6.9
2211	29/F	Screen	10OCT2018	VLN mentholated	14		6.8
		End Of Study	02DEC2018	VLN mentholated	14		5.6 LN
2212	32/M	Screen	10OCT2018	UB mentholated	13		7.6
		End Of Study	02DEC2018	UB mentholated	18		6.7
2213	29/M	Screen	10OCT2018	VLN mentholated	14		6.4
		End Of Study	02DEC2018	VLN mentholated	17		6.1
2215	59/F	Screen	10OCT2018	UB mentholated	13		7.7
		End Of Study	02DEC2018	UB mentholated	17		6.9
2220	37/M	Screen	11OCT2018	VLN non-mentholated	24		7.2
		End Of Study	02DEC2018	VLN non-mentholated	20		6.4
2235	26/F	Screen	19OCT2018	VLN mentholated	14		6.9
		End Of Study	16DEC2018	VLN mentholated	14		6.1
2244	31/M	Screen	25OCT2018	VLN non-mentholated	14		6.8

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.3 Clinical Laboratory Report - Serum Chemistry (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Aspartate Amino- transferase	Choriogonadotropin Beta	Protein
		Name	Date		001: 14-48 002: 0-40 (IU/L)		001: 6.3-8.1 002: 6-8.5 (g/dL)
2244	31/M	End Of Study	16DEC2018	VLN non-mentholated	14		6.3
2247	28/M	Screen	06NOV2018	VLN mentholated	27		6.7
		End Of Study	28DEC2018	VLN mentholated	25		7.1
2251	27/M	Screen	09NOV2018	UB non-mentholated	17		7.4
		End Of Study	19JAN2019	UB non-mentholated	18		7.2
2257	55/F	Screen	14NOV2018	UB non-mentholated	15		7
		End Of Study	19JAN2019	UB non-mentholated	13		6.6
2259	49/M	Screen	14NOV2018	UB mentholated	14		6.6
		End Of Study	19JAN2019	UB mentholated	19		5.6 LN
2269	48/M	Screen	26NOV2018	VLN mentholated	26		7
		End Of Study	19JAN2019	VLN mentholated	17		6.5
2272	37/M	Screen	28NOV2018	VLN mentholated	18		7.7
		End Of Study	19JAN2019	VLN mentholated	16		6.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium		Bilirubin		Urate	
		Name	Date		001: 135-143 002: 134-144 (mmol/L)		001: 0.2-1.6 002: 0-1.2 (mg/dL)		001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)	
1001	59/F	Screen	02JUL2018	VLN non-mentholated	144	HN	0.2		4.4	
		End Of Study	07SEP2018	VLN non-mentholated	140		0	LN	3.6	
1002	30/M	Screen	02JUL2018	VLN non-mentholated	144	HN	0.5		6.6	
		End Of Study	07SEP2018	VLN non-mentholated	140		0.4		5.7	
1003	38/M	Screen	03JUL2018	VLN mentholated	142		0.3		5.5	
		End Of Study	07SEP2018	VLN mentholated	139		0	LN	4.3	
1007	37/M	Screen	12JUL2018	VLN non-mentholated	140		0.3		7.2	
		End Of Study	07SEP2018	VLN non-mentholated	142		0	LN	7.3	
1008	48/M	Screen	12JUL2018	VLN mentholated	143		0.3		6.5	
		End Of Study	07SEP2018	VLN mentholated	142		0.2		4.3	
1010	32/M	Screen	13JUL2018	UB mentholated	142		0.4		4.9	
		End Of Study	06SEP2018	UB mentholated	139		0.3		4.6	
1011	36/M	Screen	13JUL2018	UB non-mentholated	141		0.4		8.3	HN
		End Of Study	06SEP2018	UB non-mentholated	140		0.2		6.3	
1013	36/F	Screen	16JUL2018	VLN non-mentholated	142		0.3		3.6	
		End Of Study	14SEP2018	VLN non-mentholated	137		0	LN	2.5	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1014	36/F	Screen	16JUL2018	VLN mentholated	139	0.4	3.8
		End Of Study	14SEP2018	VLN mentholated	138	0.2	2.7
1015	49/F	Screen	16JUL2018	VLN mentholated	143	0.5	3.9
		End Of Study	14SEP2018	VLN mentholated	141	0 LN	3.6
1016	54/M	Screen	16JUL2018	UB non-mentholated	143	0.5	5.9
		End Of Study	13SEP2018	UB non-mentholated	138	0.5	5.3
1017	41/F	Screen	17JUL2018	UB mentholated	142	0.5	4.6
		End Of Study	13SEP2018	UB mentholated	138	0.2	4.1
1018	41/F	Screen	17JUL2018	VLN mentholated	141	0.3	5.2
		End Of Study	15AUG2018	VLN mentholated	143	0.3	5.1
1019	30/M	Screen	17JUL2018	VLN non-mentholated	141	0.6	5.1
		End Of Study	14SEP2018	VLN non-mentholated	139	0.2	3.7
1020	36/F	Screen	17JUL2018	VLN non-mentholated	142	0.3	7.9 HN
		End Of Study	14SEP2018	VLN non-mentholated	140	0 LN	6.6 HN
1021	49/F	Screen	17JUL2018	UB non-mentholated	141	0.3	5.6
		End Of Study	13SEP2018	UB non-mentholated	136	0.2	4.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1023	50/F	Screen	17JUL2018	VLN non-mentholated	143	0.8	4.2
		End Of Study	14SEP2018	VLN non-mentholated	140	0.4	3.3
1029	35/F	Screen	26JUL2018	VLN mentholated	138	0.2	3.8
		End Of Study	11OCT2018	VLN mentholated	134 LN	0 LN	3.1
1032	53/F	Screen	13AUG2018	VLN mentholated	139	0.5	3.9
		End Of Study	11OCT2018	VLN mentholated	141	0 LN	3.2
1034	45/M	Screen	13AUG2018	VLN non-mentholated	142	0.3	5.9
		End Of Study	10OCT2018	VLN non-mentholated	140	0.2	6.2
1035	44/M	Screen	13AUG2018	VLN non-mentholated	139	0.6	6.8
		End Of Study	11OCT2018	VLN non-mentholated	137	0.2	5.4
1036	38/F	Screen	13AUG2018	UB mentholated	139	0.2	4
		End Of Study	10OCT2018	UB mentholated	137	0 LN	3.8
1037	29/M	Screen	13AUG2018	UB mentholated	141	0.4	5.7
		End Of Study	10OCT2018	UB mentholated	142	0.2	5.3
1038	39/F	Screen	13AUG2018	VLN non-mentholated	140	0.3	4.9
		End Of Study	11OCT2018	VLN non-mentholated	137	0.2	4.3

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1042	47/M	Screen	13AUG2018	VLN non-mentholated	140	0.6	7.1
		End Of Study	11OCT2018	VLN non-mentholated	139	1	6.9
1045	58/M	Screen	14AUG2018	UB non-mentholated	140	0.4	4.7
		End Of Study	10OCT2018	UB non-mentholated	140	0.2	4.3
1046	45/M	Screen	14AUG2018	UB mentholated	142	0.4	6.7
		End Of Study	10OCT2018	UB mentholated	138	0.2	5.3
1050	33/F	Screen	14AUG2018	VLN non-mentholated	142	0.2	5.2
		End Of Study	10OCT2018	VLN non-mentholated	141	0 LN	4.2
1051	36/F	Screen	14AUG2018	UB mentholated	141	0.5	4
		End Of Study	10OCT2018	UB mentholated	140	0.3	3.1
1052	31/M	Screen	14AUG2018	VLN mentholated	142	0.4	6.4
		End Of Study	11OCT2018	VLN mentholated	138	0.4	6
1053	42/M	Screen	14AUG2018	VLN mentholated	140	0.4	5.5
		End Of Study	11OCT2018	VLN mentholated	136	0.3	5.1
1054	56/M	Screen	14AUG2018	UB non-mentholated	142	0.5	5.6
		End Of Study	10OCT2018	UB non-mentholated	143	0.3	5.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1055	39/F	Screen	14AUG2018	VLN mentholated	143	0.2	3.6
		End Of Study	11OCT2018	VLN mentholated	139	0 LN	2.7
1056	48/M	Screen	14AUG2018	VLN non-mentholated	139	0.4	5.8
		End Of Study	11OCT2018	VLN non-mentholated	136	0.4	5.5
1058	30/M	Screen	15AUG2018	VLN non-mentholated	138	0.3	5
		End Of Study	11OCT2018	VLN non-mentholated	137	0.2	3.9
1059	38/M	Screen	27AUG2018	UB non-mentholated	141	0.4	5.5
		End Of Study	24OCT2018	UB non-mentholated	140	0.2	5.2
1060	55/M	Screen	27AUG2018	VLN mentholated	140	0.3	6.8
		End Of Study	24OCT2018	VLN mentholated	139	0.2	6
1063	31/M	Screen	27AUG2018	VLN mentholated	140	0.6	6.2
		End Of Study	25OCT2018	VLN mentholated	139	0.3	5.3
1064	34/M	Screen	27AUG2018	UB non-mentholated	141	0.4	7.6
1066	62/M	Screen	27AUG2018	VLN non-mentholated	142	0.4	4.8
		End Of Study	24OCT2018	VLN non-mentholated	142	0.2	4.8

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1069	40/F	Screen	28AUG2018	UB non-mentholated	138	0.3	4.9
		End Of Study	24OCT2018	UB non-mentholated	137	0 LN	4.7
1070	53/M	Screen	28AUG2018	VLN non-mentholated	140	0.3	6.9
		End Of Study	24OCT2018	VLN non-mentholated	142	0.3	7
1071	42/M	Screen	28AUG2018	VLN non-mentholated	139	0.4	6
1072	59/M	Screen	28AUG2018	VLN mentholated	142	0.3	6.3
		End Of Study	22OCT2018	VLN mentholated	142	0.4	5.9
1074	42/M	Screen	28AUG2018	VLN non-mentholated	142	0.5	7
		End Of Study	24OCT2018	VLN non-mentholated	141	0.2	5.8
1075	26/F	Screen	29AUG2018	UB non-mentholated	140	0.5	3.2
		End Of Study	24OCT2018	UB non-mentholated	141	0.3	2.7
1077	49/F	Screen	28AUG2018	VLN non-mentholated	143	0.2	3.9
		End Of Study	24OCT2018	VLN non-mentholated	140	0 LN	3.7
1078	51/F	Screen	28AUG2018	VLN non-mentholated	141	0.8	4.6
		End Of Study	24OCT2018	VLN non-mentholated	139	0.2	3.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1079	33/M	Screen	29AUG2018	VLN mentholated	142	0.3	4.9
		End Of Study	24OCT2018	VLN mentholated	140	0.3	4.1
1082	37/M	Screen	30AUG2018	VLN non-mentholated	141	0.3	5.4
		End Of Study	24OCT2018	VLN non-mentholated	140	0.3	5
1083	54/F	Screen	04SEP2018	VLN non-mentholated	144 HN	0.5	4.5
		End Of Study	31OCT2018	VLN non-mentholated	140	0 LN	5.1
1084	42/M	Screen	04SEP2018	VLN non-mentholated	142	0.3	5.5
1086	54/M	Screen	04SEP2018	VLN non-mentholated	141	0.5	6.1
		End Of Study	31OCT2018	VLN non-mentholated	138	0.2	4.1
1088	26/M	Screen	04SEP2018	VLN mentholated	141	0.7	5
		End Of Study	31OCT2018	VLN mentholated	141	0.2	4.3
1089	60/F	Screen	04SEP2018	UB non-mentholated	144 HN	0.5	5.3
		End Of Study	31OCT2018	UB non-mentholated	138	0.6	4.2
1092	43/F	Screen	05SEP2018	VLN mentholated	139	0.3	5
		End Of Study	31OCT2018	VLN mentholated	138	0.2	5.6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1094	46/M	Screen	05SEP2018	VLN mentholated	145 HN	0.2	5.8
		End Of Study	31OCT2018	VLN mentholated	142	0.2	4.2
1095	55/F	Screen	07SEP2018	VLN mentholated	141	0.2	7 HN
		End Of Study	31OCT2018	VLN mentholated	142	0.2	4.6
1096	42/F	Screen	07SEP2018	VLN non-mentholated	139	0.2	3.9
		End Of Study	31OCT2018	VLN non-mentholated	141	0 LN	5.5
1097	30/M	Screen	07SEP2018	VLN mentholated	140	0.4	5.1
		End Of Study	31OCT2018	VLN mentholated	137	0 LN	2.6 LN
1098	63/M	Screen	18SEP2018	VLN non-mentholated	138	0.5	5.4
		End Of Study	16NOV2018	VLN non-mentholated	142	0.2	5.3
1099	46/F	Screen	18SEP2018	VLN non-mentholated	141	0.2	6.2 HN
		End Of Study	16NOV2018	VLN non-mentholated	141	0 LN	5.6
1100	59/M	Screen	18SEP2018	VLN non-mentholated	141	0.4	5
		End Of Study	16NOV2018	VLN non-mentholated	141	0.3	5
1101	41/M	Screen	18SEP2018	VLN non-mentholated	136	1	5.3
		End Of Study	16NOV2018	VLN non-mentholated	141	0.5	4.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1103	43/M	Screen	18SEP2018	VLN non-mentholated	135	0.4	4.2
		End Of Study	16NOV2018	VLN non-mentholated	140	0.3	4.5
1105	47/F	Screen	19SEP2018	VLN non-mentholated	141	0.4	3.3
		End Of Study	16NOV2018	VLN non-mentholated	141	0.2	3.6
1106	42/M	Screen	19SEP2018	UB non-mentholated	141	0.3	7.7
		End Of Study	16NOV2018	UB non-mentholated	139	0.3	6.6
1107	45/M	Screen	21SEP2018	VLN non-mentholated	142	1.1	7.4
		End Of Study	16NOV2018	VLN non-mentholated	140	0.5	6
1108	54/M	Screen	21SEP2018	UB non-mentholated	141	0.3	5.6
		End Of Study	16NOV2018	UB non-mentholated	141	0.2	5.8
1109	58/M	Screen	21SEP2018	UB non-mentholated	140	0.3	5.2
		End Of Study	16NOV2018	UB non-mentholated	144 HN	0.2	5.2
1112	59/F	Screen	21SEP2018	VLN non-mentholated	141	0.3	4.1
		End Of Study	16NOV2018	VLN non-mentholated	141	0 LN	4.2
1114	26/F	Screen	24SEP2018	UB non-mentholated	143	0.4	5.1
		End Of Study	16NOV2018	UB non-mentholated	140	0.3	3.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
1115	29/M	Screen	24SEP2018	VLN non-mentholated	141	0.5	7.5
2002	49/M	Screen	29JUN2018	UB mentholated	141	0.4	5
		End Of Study	05SEP2018	UB mentholated	143	0.2	5.9
2003	41/F	Screen	29JUN2018	VLN mentholated	141	0.5	4.6
		End Of Study	29AUG2018	VLN mentholated	142	0.6	5.6
2007	57/F	Screen	29JUN2018	VLN non-mentholated	143	1	4.3
		End Of Study	29AUG2018	VLN non-mentholated	143	0.7	4.7
2008	42/M	Screen	06JUL2018	VLN mentholated	142	1.2	5
		End Of Study	29AUG2018	VLN mentholated	142	1.1	4.9
2009	55/M	Screen	29JUN2018	VLN non-mentholated	139	0.4	5.9
2010	27/M	Screen	29JUN2018	UB mentholated	143	0.2	7
		End Of Study	29AUG2018	UB mentholated	141	0.3	8.2
2011	32/F	Screen	29JUN2018	VLN mentholated	142	0.3	3.8
		End Of Study	29AUG2018	VLN mentholated	140	0.4	4.9
2014	37/M	Screen	02JUL2018	VLN mentholated	141	<0.2	5.6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2014	37/M	End Of Study	29AUG2018	VLN mentholated	140	0.7	6.4
2015	57/F	Screen	02JUL2018	UB mentholated	143	0.5	6.2
		End Of Study	29AUG2018	UB mentholated	144	0.3	5.3
2016	45/F	Screen	02JUL2018	VLN mentholated	141	0.4	4.1
		End Of Study	03AUG2018	VLN mentholated	141	0.2	4
2017	30/M	Screen	02JUL2018	VLN mentholated	143	<0.2	4.5
		End Of Study	29AUG2018	VLN mentholated	140	0.4	5.5
2018	26/F	Screen	02JUL2018	UB mentholated	141	0.3	4.9
		End Of Study	29AUG2018	UB mentholated	140	0.3	4.8
2020	60/F	Screen	02JUL2018	VLN mentholated	149 HN	0.5	3.2
		End Of Study	29AUG2018	VLN mentholated	143	0.5	3.8
2021	31/M	Screen	02JUL2018	VLN mentholated	136	0.7	4.6
		End Of Study	29AUG2018	VLN mentholated	138	0.9	4.1
2023	35/M	Screen	02JUL2018	VLN mentholated	143	0.2	6.5
		End Of Study	29AUG2018	VLN mentholated	141	0.4	6.9

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2024	26/M	Screen	03JUL2018	UB non-mentholated	141	0.8	5.7
2025	59/M	Screen	03JUL2018	UB non-mentholated	143	0.2	4.1
		End Of Study	29AUG2018	UB non-mentholated	141	0.4	4.5
2028	36/M	Screen	06JUL2018	VLN non-mentholated	137	0.6	5.1
		End Of Study	29AUG2018	VLN non-mentholated	140	0.6	5.9
2029	56/M	Screen	09JUL2018	UB mentholated	139	0.4	5.4
		End Of Study	05SEP2018	UB mentholated	140	0.4	6.6
2039	49/F	Screen	13JUL2018	VLN mentholated	141	0.3	3.1
		End Of Study	05SEP2018	VLN mentholated	141	0.2	3.3
2050	57/M	Screen	20JUL2018	UB mentholated	139	0.6	5.4
		End Of Study	20SEP2018	UB mentholated	139	0.5	6.3
2052	54/M	Screen	20JUL2018	VLN mentholated	141	0.4	4.9
		End Of Study	20SEP2018	VLN mentholated	143	0.5	5.4
2057	52/M	Screen	23JUL2018	VLN mentholated	142	0.5	5.1
		End Of Study	20SEP2018	VLN mentholated	142	0.7	6.4

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2058	37/F	Screen	23JUL2018	VLN mentholated	143	0.3	4.9
		End Of Study	20SEP2018	VLN mentholated	143	0.2	5.7
2059	56/F	Screen	23JUL2018	UB mentholated	144	0.2	4.4
		End Of Study	20SEP2018	UB mentholated	142	0.3	5.6
2060	37/F	Screen	23JUL2018	VLN mentholated	142	0.4	3.5
		End Of Study	20SEP2018	VLN mentholated	141	0.2	4.1
2064	52/M	Screen	23JUL2018	VLN mentholated	144	0.4	6.4
		End Of Study	20SEP2018	VLN mentholated	142	0.3	7.3
2066	30/F	Screen	23JUL2018	VLN mentholated	140	0.4	5.3
		End Of Study	20SEP2018	VLN mentholated	139	0.4	6.3
2067	52/M	Screen	23JUL2018	VLN non-mentholated	143	0.4	6.6
		End Of Study	20SEP2018	VLN non-mentholated	143	0.6	7
2075	34/M	Screen	30JUL2018	VLN mentholated	140	0.5	6.8
		End Of Study	22AUG2018	VLN mentholated	139	<0.2	5.8
2076	42/M	Screen	30JUL2018	VLN mentholated	146 HN	0.8	5.2
		End Of Study	14OCT2018	VLN mentholated	139	0.7	4.6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2086	36/M	Screen	03AUG2018	VLN non-mentholated	142	0.6	4.9
		End Of Study	01OCT2018	VLN non-mentholated	139	0.5	5.8
2088	39/F	Screen	03AUG2018	VLN mentholated	139	0.3	5.4
		End Of Study	14OCT2018	VLN mentholated	140	<0.2	5.8
2092	50/F	Screen	06AUG2018	VLN mentholated	147 HN	0.6	5.2
		End Of Study	14OCT2018	VLN mentholated	139	0.3	4.9
2099	52/M	Screen	09AUG2018	VLN non-mentholated	140	1	6.7
		End Of Study	14OCT2018	VLN non-mentholated	139	0.5	6.7
2100	48/F	Screen	09AUG2018	UB mentholated	141	0.3	3.7
		End Of Study	14OCT2018	UB mentholated	143	0.3	3.7
2108	60/F	Screen	13AUG2018	VLN non-mentholated	138	0.8	5
		End Of Study	14OCT2018	VLN non-mentholated	134	0.7	5.9
2110	41/F	Screen	13AUG2018	UB mentholated	136	0.5	8.3 HN
		End Of Study	20OCT2018	UB mentholated	139	0.2	8 HN
2113	51/F	Screen	15AUG2018	VLN mentholated	142	0.2	6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2115	46/F	Screen	15AUG2018	VLN mentholated	142	0.3	6.8
2119	48/M	Screen	20AUG2018	VLN mentholated	138	0.4	4.8
		End Of Study	20OCT2018	VLN mentholated	141	0.3	6.2
2120	62/F	Screen	20AUG2018	VLN non-mentholated	141	0.5	6.3
		End Of Study	20OCT2018	VLN non-mentholated	144	0.5	6.9
2122	60/M	Screen	20AUG2018	UB non-mentholated	143	0.3	3.6 LN
		End Of Study	20OCT2018	UB non-mentholated	143	0.3	4.5
2125	35/M	Screen	21AUG2018	UB mentholated	137	1.1	5.3
		End Of Study	20OCT2018	UB mentholated	142	0.9	6.3
2126	37/M	Screen	21AUG2018	VLN mentholated	140	0.2	5.9
		End Of Study	20OCT2018	VLN mentholated	142	0.5	7.2
2136	64/M	Screen	27AUG2018	VLN non-mentholated	141	0.4	4.9
		End Of Study	19OCT2018	VLN non-mentholated	138	0.4	5.7
2140	56/F	Screen	30AUG2018	UB non-mentholated	146 HN	0.5	3
		End Of Study	06NOV2018	UB non-mentholated	143	0.6	4.6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2142	30/F	Screen	31AUG2018	VLN non-mentholated	135	0.5	3.1
		End Of Study	08OCT2018	VLN non-mentholated	128 LN	0.5	2.9
2143	63/M	Screen	04SEP2018	VLN non-mentholated	142	0.6	4.9
		End Of Study	06NOV2018	VLN non-mentholated	143	0.5	5
2158	43/F	Screen	18SEP2018	UB non-mentholated	144	0.3	3.4
2159	37/M	Screen	19SEP2018	VLN non-mentholated	142	0.2	4.5
		End Of Study	02DEC2018	VLN non-mentholated	143	0.2	5.2
2164	65/F	Screen	27SEP2018	VLN non-mentholated	142	0.3	4.7
		End Of Study	02DEC2018	VLN non-mentholated	141	0.3	4.7
2168	32/F	Screen	28SEP2018	VLN non-mentholated	143	<0.2	5.1
		End Of Study	02DEC2018	VLN non-mentholated	143	<0.2	5
2170	51/F	Screen	28SEP2018	UB non-mentholated	141	<0.2	4.8
		End Of Study	02DEC2018	UB non-mentholated	143	0.4	4.4
2175	40/F	Screen	01OCT2018	UB mentholated	138	<0.2	3.8
		End Of Study	02DEC2018	UB mentholated	141	0.3	4.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2189	28/M	Screen	04OCT2018	VLN mentholated	142	0.3	4.9
		End Of Study	06NOV2018	VLN mentholated	141	0.2	4.7
2211	29/F	Screen	10OCT2018	VLN mentholated	136	0.5	4.9
		End Of Study	02DEC2018	VLN mentholated	141	<0.2	3.5
2212	32/M	Screen	10OCT2018	UB mentholated	143	0.6	6.2
		End Of Study	02DEC2018	UB mentholated	143	0.5	7.1
2213	29/M	Screen	10OCT2018	VLN mentholated	140	0.6	4.6
		End Of Study	02DEC2018	VLN mentholated	143	0.6	5.6
2215	59/F	Screen	10OCT2018	UB mentholated	142	0.5	5.5
		End Of Study	02DEC2018	UB mentholated	143	0.3	6.5
2220	37/M	Screen	11OCT2018	VLN non-mentholated	138	0.3	5
		End Of Study	02DEC2018	VLN non-mentholated	142	0.3	5.5
2235	26/F	Screen	19OCT2018	VLN mentholated	138	0.5	4.7
		End Of Study	16DEC2018	VLN mentholated	141	<0.2	5.3
2244	31/M	Screen	25OCT2018	VLN non-mentholated	139	0.6	5.6
		End Of Study	16DEC2018	VLN non-mentholated	141	0.3	6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.4 Clinical Laboratory Report - Serum Chemistry (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Sodium 001: 135-143 002: 134-144 (mmol/L)	Bilirubin 001: 0.2-1.6 002: 0-1.2 (mg/dL)	Urate 001: F: 2.3-5.9 002: F: 2.5-7.1 001: M: 3.5-7.8 002: M: 3.7-8.6 (mg/dL)
		Name	Date				
2247	28/M	Screen	06NOV2018	VLN mentholated	140	0.7	4.4
		End Of Study	28DEC2018	VLN mentholated	141	0.3	4
2251	27/M	Screen	09NOV2018	UB non-mentholated	141	0.4	4.5
		End Of Study	19JAN2019	UB non-mentholated	141	0.4	5.5
2257	55/F	Screen	14NOV2018	UB non-mentholated	141	0.6	4.2
		End Of Study	19JAN2019	UB non-mentholated	142	0.5	4.9
2259	49/M	Screen	14NOV2018	UB mentholated	142	0.6	4.7
		End Of Study	19JAN2019	UB mentholated	141	0.5	5.9
2269	48/M	Screen	26NOV2018	VLN mentholated	139	<0.2	5.3
		End Of Study	19JAN2019	VLN mentholated	138	0.3	5.6
2272	37/M	Screen	28NOV2018	VLN mentholated	143	0.4	5.2
		End Of Study	19JAN2019	VLN mentholated	139	0.4	5.4

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1001	59/F	Screen	02JUL2018	VLN non-mentholated	54.8	12	26.5
		End Of Study	07SEP2018	VLN non-mentholated		16	25.3
1002	30/M	Screen	02JUL2018	VLN non-mentholated		4 LN	29.5
		End Of Study	07SEP2018	VLN non-mentholated		7	27.9
1003	38/M	Screen	03JUL2018	VLN mentholated		18	30.9
		End Of Study	07SEP2018	VLN mentholated		17	29
1007	37/M	Screen	12JUL2018	VLN non-mentholated		11	29.8
		End Of Study	07SEP2018	VLN non-mentholated		15	26.1
1008	48/M	Screen	12JUL2018	VLN mentholated		14	29
		End Of Study	07SEP2018	VLN mentholated		11	27.9
1010	32/M	Screen	13JUL2018	UB mentholated		16	30.6
		End Of Study	06SEP2018	UB mentholated		17	28.8
1011	36/M	Screen	13JUL2018	UB non-mentholated		16	28.3
		End Of Study	06SEP2018	UB non-mentholated		16	29.5
1013	36/F	Screen	16JUL2018	VLN non-mentholated		14	26.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1013	36/F	End Of Study	14SEP2018	VLN non-mentholated		14	25
1014	36/F	Screen	16JUL2018	VLN mentholated		10	24
		End Of Study	14SEP2018	VLN mentholated		9	23.5 LN
1015	49/F	Screen	16JUL2018	VLN mentholated		13	29.7
		End Of Study	14SEP2018	VLN mentholated		16	27.6
1016	54/M	Screen	16JUL2018	UB non-mentholated		9	29.7
		End Of Study	13SEP2018	UB non-mentholated		8	25.7
1017	41/F	Screen	17JUL2018	UB mentholated		11	30.1
		End Of Study	13SEP2018	UB mentholated		13	25.4
1018	41/F	Screen	17JUL2018	VLN mentholated		14	28.8
		End Of Study	15AUG2018	VLN mentholated		17	26.6
1019	30/M	Screen	17JUL2018	VLN non-mentholated		12	28.8
		End Of Study	14SEP2018	VLN non-mentholated		12	25.1
1020	36/F	Screen	17JUL2018	VLN non-mentholated		9	26.6
		End Of Study	14SEP2018	VLN non-mentholated		15	24.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1021	49/F	Screen	17JUL2018	UB non-mentholated		9	26.9
		End Of Study	13SEP2018	UB non-mentholated		12	23 LN
1023	50/F	Screen	17JUL2018	VLN non-mentholated		7	30.5
		End Of Study	14SEP2018	VLN non-mentholated		12	27.1
1029	35/F	Screen	26JUL2018	VLN mentholated		11	24.8
		End Of Study	11OCT2018	VLN mentholated		11	23.3 LN
1032	53/F	Screen	13AUG2018	VLN mentholated	67.5	11	26.6
		End Of Study	11OCT2018	VLN mentholated		13	25.8
1034	45/M	Screen	13AUG2018	VLN non-mentholated		6 LN	29
		End Of Study	10OCT2018	VLN non-mentholated		11	25.6
1035	44/M	Screen	13AUG2018	VLN non-mentholated		9	26.8
		End Of Study	11OCT2018	VLN non-mentholated		13	24.8
1036	38/F	Screen	13AUG2018	UB mentholated		10	25.7
		End Of Study	10OCT2018	UB mentholated		16	25.9
1037	29/M	Screen	13AUG2018	UB mentholated		13	27

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1037	29/M	End Of Study	10OCT2018	UB mentholated		16	29.6
1038	39/F	Screen	13AUG2018	VLN non-mentholated		10	26.1
		End Of Study	11OCT2018	VLN non-mentholated		13	24.4
1042	47/M	Screen	13AUG2018	VLN non-mentholated		21 HN	24.8
		End Of Study	11OCT2018	VLN non-mentholated		12	28.1
1045	58/M	Screen	14AUG2018	UB non-mentholated		15	26.6
		End Of Study	10OCT2018	UB non-mentholated		16	26
1046	45/M	Screen	14AUG2018	UB mentholated		11	27.2
		End Of Study	10OCT2018	UB mentholated		13	27.8
1050	33/F	Screen	14AUG2018	VLN non-mentholated		14	25.3
		End Of Study	10OCT2018	VLN non-mentholated		17	25.2
1051	36/F	Screen	14AUG2018	UB mentholated		6	23.2 LN
		End Of Study	10OCT2018	UB mentholated		10	23.2 LN
1052	31/M	Screen	14AUG2018	VLN mentholated		8	28.3
		End Of Study	11OCT2018	VLN mentholated		9	28.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1053	42/M	Screen	14AUG2018	VLN mentholated		9	25.9
		End Of Study	11OCT2018	VLN mentholated		13	24.9
1054	56/M	Screen	14AUG2018	UB non-mentholated		15	27.8
		End Of Study	10OCT2018	UB non-mentholated		17	27.7
1055	39/F	Screen	14AUG2018	VLN mentholated		5 LN	25.3
		End Of Study	11OCT2018	VLN mentholated		13	26.2
1056	48/M	Screen	14AUG2018	VLN non-mentholated		11	27.3
		End Of Study	11OCT2018	VLN non-mentholated		14	28.3
1058	30/M	Screen	15AUG2018	VLN non-mentholated		10	25.8
		End Of Study	11OCT2018	VLN non-mentholated		14	25.7
1059	38/M	Screen	27AUG2018	UB non-mentholated		15	24.7
		End Of Study	24OCT2018	UB non-mentholated		17	24.2
1060	55/M	Screen	27AUG2018	VLN mentholated		13	26.3
		End Of Study	24OCT2018	VLN mentholated		13	24.6
1063	31/M	Screen	27AUG2018	VLN mentholated		12	26.8

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1063	31/M	End Of Study	25OCT2018	VLN mentholated		14	28.2
1064	34/M	Screen	27AUG2018	UB non-mentholated		13	27.3
1066	62/M	Screen	27AUG2018	VLN non-mentholated		11	29.4
		End Of Study	24OCT2018	VLN non-mentholated		13	29
1069	40/F	Screen	28AUG2018	UB non-mentholated		10	24
		End Of Study	24OCT2018	UB non-mentholated		12	24.6
1070	53/M	Screen	28AUG2018	VLN non-mentholated		15	28.8
		End Of Study	24OCT2018	VLN non-mentholated		16	28.4
1071	42/M	Screen	28AUG2018	VLN non-mentholated		16	27.4
1072	59/M	Screen	28AUG2018	VLN mentholated		12	28
		End Of Study	22OCT2018	VLN mentholated		12	26.8
1074	42/M	Screen	28AUG2018	VLN non-mentholated		9	25.3
		End Of Study	24OCT2018	VLN non-mentholated		12	25.7
1075	26/F	Screen	29AUG2018	UB non-mentholated		15	24.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1075	26/F	End Of Study	24OCT2018	UB non-mentholated		15	24.5
1077	49/F	Screen	28AUG2018	VLN non-mentholated	57.6	14	27.8
		End Of Study	24OCT2018	VLN non-mentholated		15	26.1
1078	51/F	Screen	28AUG2018	VLN non-mentholated	67.9	14	28.3
		End Of Study	24OCT2018	VLN non-mentholated		17	25.4
1079	33/M	Screen	29AUG2018	VLN mentholated		13	27.4
		End Of Study	24OCT2018	VLN mentholated		13	25
1082	37/M	Screen	30AUG2018	VLN non-mentholated		12	29.3
		End Of Study	24OCT2018	VLN non-mentholated		15	27.7
1083	54/F	Screen	04SEP2018	VLN non-mentholated	72.4	14	26.8
		End Of Study	31OCT2018	VLN non-mentholated		14	25.8
1084	42/M	Screen	04SEP2018	VLN non-mentholated		12	27.7
1086	54/M	Screen	04SEP2018	VLN non-mentholated		8	26.9
		End Of Study	31OCT2018	VLN non-mentholated		13	28.1

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1088	26/M	Screen	04SEP2018	VLN mentholated		15	25.8
		End Of Study	31OCT2018	VLN mentholated		17	25.3
1089	60/F	Screen	04SEP2018	UB non-mentholated		10	25.6
		End Of Study	31OCT2018	UB non-mentholated		15	27
1092	43/F	Screen	05SEP2018	VLN mentholated		11	25.4
		End Of Study	31OCT2018	VLN mentholated		15	23 LN
1094	46/M	Screen	05SEP2018	VLN mentholated		14	29.6
		End Of Study	31OCT2018	VLN mentholated		16	24.5
1095	55/F	Screen	07SEP2018	VLN mentholated	79.5	16	24.9
		End Of Study	31OCT2018	VLN mentholated		15	28.1
1096	42/F	Screen	07SEP2018	VLN non-mentholated		12	25.9
		End Of Study	31OCT2018	VLN non-mentholated		14	24
1097	30/M	Screen	07SEP2018	VLN mentholated		12	29.6
		End Of Study	31OCT2018	VLN mentholated		10	24.7
1098	63/M	Screen	18SEP2018	VLN non-mentholated		16	24.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1098	63/M	End Of Study	16NOV2018	VLN non-mentholated		20	28.8
1099	46/F	Screen	18SEP2018	VLN non-mentholated		11	26.3
		End Of Study	16NOV2018	VLN non-mentholated		16	25.9
1100	59/M	Screen	18SEP2018	VLN non-mentholated		16	25.5
		End Of Study	16NOV2018	VLN non-mentholated		22 HN	26.3
1101	41/M	Screen	18SEP2018	VLN non-mentholated		8	28
		End Of Study	16NOV2018	VLN non-mentholated		15	27.3
1103	43/M	Screen	18SEP2018	VLN non-mentholated		10	28.4
		End Of Study	16NOV2018	VLN non-mentholated		18	29
1105	47/F	Screen	19SEP2018	VLN non-mentholated		13	27.1
		End Of Study	16NOV2018	VLN non-mentholated		18 HN	24.9
1106	42/M	Screen	19SEP2018	UB non-mentholated		11	26.6
		End Of Study	16NOV2018	UB non-mentholated		18	27.4
1107	45/M	Screen	21SEP2018	VLN non-mentholated		11	25.5
		End Of Study	16NOV2018	VLN non-mentholated		16	24.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
1108	54/M	Screen	21SEP2018	UB non-mentholated		14	25.6
		End Of Study	16NOV2018	UB non-mentholated		16	28.2
1109	58/M	Screen	21SEP2018	UB non-mentholated		14	21.2 LN
		End Of Study	16NOV2018	UB non-mentholated		21 HN	23.5 LN
1112	59/F	Screen	21SEP2018	VLN non-mentholated	51.5	11	26.6
		End Of Study	16NOV2018	VLN non-mentholated		16	25.1
1114	26/F	Screen	24SEP2018	UB non-mentholated		9	27.2
		End Of Study	16NOV2018	UB non-mentholated		14	27.1
1115	29/M	Screen	24SEP2018	VLN non-mentholated		14	26
2002	49/M	Screen	29JUN2018	UB mentholated		15	25
		End Of Study	05SEP2018	UB mentholated		20	26
2003	41/F	Screen	29JUN2018	VLN mentholated		7	24
		End Of Study	29AUG2018	VLN mentholated		7	24
2007	57/F	Screen	29JUN2018	VLN non-mentholated	175.6	17	25
		End Of Study	29AUG2018	VLN non-mentholated		17	25

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2008	42/M	Screen	06JUL2018	VLN mentholated		9	24
		End Of Study	29AUG2018	VLN mentholated		8	25
2009	55/M	Screen	29JUN2018	VLN non-mentholated		17	22
2010	27/M	Screen	29JUN2018	UB mentholated		8	20
		End Of Study	29AUG2018	UB mentholated		12	27
2011	32/F	Screen	29JUN2018	VLN mentholated		6	22
		End Of Study	29AUG2018	VLN mentholated		8	23
2014	37/M	Screen	02JUL2018	VLN mentholated		7	24
		End Of Study	29AUG2018	VLN mentholated		8	25
2015	57/F	Screen	02JUL2018	UB mentholated	55.3	12	25
		End Of Study	29AUG2018	UB mentholated		9	24
2016	45/F	Screen	02JUL2018	VLN mentholated		10	24
		End Of Study	03AUG2018	VLN mentholated		12	24
2017	30/M	Screen	02JUL2018	VLN mentholated		6	23
		End Of Study	29AUG2018	VLN mentholated		9	23

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2018	26/F	Screen	02JUL2018	UB mentholated		9	22
		End Of Study	29AUG2018	UB mentholated		8	24
2020	60/F	Screen	02JUL2018	VLN mentholated		8	25
		End Of Study	29AUG2018	VLN mentholated		11	28
2021	31/M	Screen	02JUL2018	VLN mentholated		11	22
		End Of Study	29AUG2018	VLN mentholated		9	24
2023	35/M	Screen	02JUL2018	VLN mentholated		11	26
		End Of Study	29AUG2018	VLN mentholated		12	27
2024	26/M	Screen	03JUL2018	UB non-mentholated		8	26
2025	59/M	Screen	03JUL2018	UB non-mentholated		12	25
		End Of Study	29AUG2018	UB non-mentholated		10	26
2028	36/M	Screen	06JUL2018	VLN non-mentholated		12	24
		End Of Study	29AUG2018	VLN non-mentholated		14	26
2029	56/M	Screen	09JUL2018	UB mentholated		11	26
		End Of Study	05SEP2018	UB mentholated		11	26

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2039	49/F	Screen	13JUL2018	VLN mentholated	72.6	9	25
		End Of Study	05SEP2018	VLN mentholated		10	24
2050	57/M	Screen	20JUL2018	UB mentholated		10	23
		End Of Study	20SEP2018	UB mentholated		14	22
2052	54/M	Screen	20JUL2018	VLN mentholated		11	21
		End Of Study	20SEP2018	VLN mentholated		14	25
2057	52/M	Screen	23JUL2018	VLN mentholated		15	32 HN
		End Of Study	20SEP2018	VLN mentholated		13	27
2058	37/F	Screen	23JUL2018	VLN mentholated		9	24
		End Of Study	20SEP2018	VLN mentholated		11	22
2059	56/F	Screen	23JUL2018	UB mentholated		10	23
		End Of Study	20SEP2018	UB mentholated		15	23
2060	37/F	Screen	23JUL2018	VLN mentholated		11	24
		End Of Study	20SEP2018	VLN mentholated		11	24
2064	52/M	Screen	23JUL2018	VLN mentholated		6	28

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2064	52/M	End Of Study	20SEP2018	VLN mentholated		13	24
2066	30/F	Screen	23JUL2018	VLN mentholated		11	25
		End Of Study	20SEP2018	VLN mentholated		10	25
2067	52/M	Screen	23JUL2018	VLN non-mentholated		5 LN	30 HN
		End Of Study	20SEP2018	VLN non-mentholated		14	31 HN
2075	34/M	Screen	30JUL2018	VLN mentholated		10	24
		End Of Study	22AUG2018	VLN mentholated		11	27
2076	42/M	Screen	30JUL2018	VLN mentholated		13	26
		End Of Study	14OCT2018	VLN mentholated		13	22
2086	36/M	Screen	03AUG2018	VLN non-mentholated		14	24
		End Of Study	01OCT2018	VLN non-mentholated		14	26
2088	39/F	Screen	03AUG2018	VLN mentholated		11	22
		End Of Study	14OCT2018	VLN mentholated		15	22
2092	50/F	Screen	06AUG2018	VLN mentholated		9	24
		End Of Study	14OCT2018	VLN mentholated		8	23

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2099	52/M	Screen	09AUG2018	VLN non-mentholated		8	25
		End Of Study	14OCT2018	VLN non-mentholated		10	24
2100	48/F	Screen	09AUG2018	UB mentholated		10	25
		End Of Study	14OCT2018	UB mentholated		11	26
2108	60/F	Screen	13AUG2018	VLN non-mentholated	56.8	7 LN	28
		End Of Study	14OCT2018	VLN non-mentholated		11	26
2110	41/F	Screen	13AUG2018	UB mentholated		9	23
		End Of Study	20OCT2018	UB mentholated		16	21
2113	51/F	Screen	15AUG2018	VLN mentholated	58.2	8	26
2115	46/F	Screen	15AUG2018	VLN mentholated		15	22
2119	48/M	Screen	20AUG2018	VLN mentholated		12	26
		End Of Study	20OCT2018	VLN mentholated		16	24
2120	62/F	Screen	20AUG2018	VLN non-mentholated		13	22
		End Of Study	20OCT2018	VLN non-mentholated		15	21

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2122	60/M	Screen	20AUG2018	UB non-mentholated		17	26
		End Of Study	20OCT2018	UB non-mentholated		18	25
2125	35/M	Screen	21AUG2018	UB mentholated		12	23
		End Of Study	20OCT2018	UB mentholated		12	24
2126	37/M	Screen	21AUG2018	VLN mentholated		10	25
		End Of Study	20OCT2018	VLN mentholated		13	25
2136	64/M	Screen	27AUG2018	VLN non-mentholated		13	27
		End Of Study	19OCT2018	VLN non-mentholated		13	25
2140	56/F	Screen	30AUG2018	UB non-mentholated		12	27
		End Of Study	06NOV2018	UB non-mentholated		17	30 HN
2142	30/F	Screen	31AUG2018	VLN non-mentholated		4 LN	20
		End Of Study	08OCT2018	VLN non-mentholated		4 LN	19 LN
2143	63/M	Screen	04SEP2018	VLN non-mentholated		11	27
		End Of Study	06NOV2018	VLN non-mentholated		13	28
2158	43/F	Screen	18SEP2018	UB non-mentholated		15	25

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2159	37/M	Screen	19SEP2018	VLN non-mentholated		5 LN	22
		End Of Study	02DEC2018	VLN non-mentholated		7	26
2164	65/F	Screen	27SEP2018	VLN non-mentholated	30.9	8	27
		End Of Study	02DEC2018	VLN non-mentholated		11	26
2168	32/F	Screen	28SEP2018	VLN non-mentholated		4 LN	24
		End Of Study	02DEC2018	VLN non-mentholated		5 LN	23
2170	51/F	Screen	28SEP2018	UB non-mentholated		22	25
		End Of Study	02DEC2018	UB non-mentholated		13	23
2175	40/F	Screen	01OCT2018	UB mentholated		8	24
		End Of Study	02DEC2018	UB mentholated		12	21
2189	28/M	Screen	04OCT2018	VLN mentholated		11	26
		End Of Study	06NOV2018	VLN mentholated		9	25
2211	29/F	Screen	10OCT2018	VLN mentholated		8	22
		End Of Study	02DEC2018	VLN mentholated		11	24
2212	32/M	Screen	10OCT2018	UB mentholated		13	24

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2212	32/M	End Of Study	02DEC2018	UB mentholated		16	24
2213	29/M	Screen	10OCT2018	VLN mentholated		11	24
		End Of Study	02DEC2018	VLN mentholated		15	24
2215	59/F	Screen	10OCT2018	UB mentholated	77	10	28
		End Of Study	02DEC2018	UB mentholated		14	23
2220	37/M	Screen	11OCT2018	VLN non-mentholated		15	23
		End Of Study	02DEC2018	VLN non-mentholated		16	23
2235	26/F	Screen	19OCT2018	VLN mentholated		9	20
		End Of Study	16DEC2018	VLN mentholated		9	19 LN
2244	31/M	Screen	25OCT2018	VLN non-mentholated		6	22
		End Of Study	16DEC2018	VLN non-mentholated		9	24
2247	28/M	Screen	06NOV2018	VLN mentholated		8	27
		End Of Study	28DEC2018	VLN mentholated		10	23
2251	27/M	Screen	09NOV2018	UB non-mentholated		9	27
		End Of Study	19JAN2019	UB non-mentholated		12	28

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.1.5 Clinical Laboratory Report - Serum Chemistry (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	FSH 001: F: 40-153 002: F: FSHROF (IU/L)	Urea Nitrogen 001: F: 6-17 001: M: 7-20 002: 6-20 002: 6-24 002: 8-27 (mg/dL)	Carbon Dioxide 001: 24-33.2 002: 20-29 (mmol/L)
		Name	Date				
2257	55/F	Screen	14NOV2018	UB non-mentholated	72.4	10	26
		End Of Study	19JAN2019	UB non-mentholated		15	25
2259	49/M	Screen	14NOV2018	UB mentholated		7	28
		End Of Study	19JAN2019	UB mentholated		9	27
2269	48/M	Screen	26NOV2018	VLN mentholated		11	23
		End Of Study	19JAN2019	VLN mentholated		12	23
2272	37/M	Screen	28NOV2018	VLN mentholated		10	25
		End Of Study	19JAN2019	VLN mentholated		10	27

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
1001	59/F	Screen	02JUL2018	VLN non-mentholated	138		4.31		490	HN
		End Of Study	07SEP2018	VLN non-mentholated	133		4.12		507	HN
1002	30/M	Screen	02JUL2018	VLN non-mentholated	167		5.11		211	
		End Of Study	07SEP2018	VLN non-mentholated	161		4.81		188	
1003	38/M	Screen	03JUL2018	VLN mentholated	154		4.73		352	
		End Of Study	07SEP2018	VLN mentholated	149		4.64		319	
1007	37/M	Screen	12JUL2018	VLN non-mentholated	162		4.97		251	
		End Of Study	07SEP2018	VLN non-mentholated	155		4.66		219	
1008	48/M	Screen	12JUL2018	VLN mentholated	149		4.53		190	
		End Of Study	07SEP2018	VLN mentholated	142		4.28		214	
1010	32/M	Screen	13JUL2018	UB mentholated	157		4.57		160	
		End Of Study	06SEP2018	UB mentholated	162		4.74		170	
1011	36/M	Screen	13JUL2018	UB non-mentholated	159		4.5		176	
		End Of Study	06SEP2018	UB non-mentholated	155		4.4		177	
1013	36/F	Screen	16JUL2018	VLN non-mentholated	121		3.75		349	
		End Of Study	14SEP2018	VLN non-mentholated	114	LN	3.57		319	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1014	36/F	Screen	16JUL2018	VLN mentholated	138		4.19		314
		End Of Study	14SEP2018	VLN mentholated	118 LN		3.59		234
1015	49/F	Screen	16JUL2018	VLN mentholated	149		4.49		257
		End Of Study	14SEP2018	VLN mentholated	155		4.65		246
1016	54/M	Screen	16JUL2018	UB non-mentholated	167		5.11		234
		End Of Study	13SEP2018	UB non-mentholated	156		4.68		190
1017	41/F	Screen	17JUL2018	UB mentholated	145		4.42		280
		End Of Study	13SEP2018	UB mentholated	135		4.12		294
1018	41/F	Screen	17JUL2018	VLN mentholated	147		4.41		266
		End Of Study	15AUG2018	VLN mentholated	154		4.81 HN		293
1019	30/M	Screen	17JUL2018	VLN non-mentholated	158		4.57		279
		End Of Study	14SEP2018	VLN non-mentholated	151		4.36		290
1020	36/F	Screen	17JUL2018	VLN non-mentholated	130		4.09		250
		End Of Study	14SEP2018	VLN non-mentholated	118 LN		3.77		274
1021	49/F	Screen	17JUL2018	UB non-mentholated	131		4.08		361
		End Of Study	13SEP2018	UB non-mentholated	124		3.88		325

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1023	50/F	Screen	17JUL2018	VLN non-mentholated	141		4.35		299
		End Of Study	14SEP2018	VLN non-mentholated	130		4.04		289
1029	35/F	Screen	26JUL2018	VLN mentholated	138		4.19		356
		End Of Study	11OCT2018	VLN mentholated	136		4.17		324
1032	53/F	Screen	13AUG2018	VLN mentholated	148		4.68		105 LN
		End Of Study	11OCT2018	VLN mentholated	138		4.29		127 LN
1034	45/M	Screen	13AUG2018	VLN non-mentholated	155		4.65		296
		End Of Study	10OCT2018	VLN non-mentholated	144		4.3		305
1035	44/M	Screen	13AUG2018	VLN non-mentholated	188 HN		5.39 HN		245
		End Of Study	11OCT2018	VLN non-mentholated	174		5.01		246
1036	38/F	Screen	13AUG2018	UB mentholated	141		4.15		317
		End Of Study	10OCT2018	UB mentholated	138		4.02		277
1037	29/M	Screen	13AUG2018	UB mentholated	150		4.62		226
		End Of Study	10OCT2018	UB mentholated	152		4.74		245
1038	39/F	Screen	13AUG2018	VLN non-mentholated	142		4.35		276
		End Of Study	11OCT2018	VLN non-mentholated	138		4.17		260

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		Name	Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1042	47/M	Screen	13AUG2018	VLN non-mentholated	153		4.59		236
		End Of Study	11OCT2018	VLN non-mentholated	155		4.6		216
1045	58/M	Screen	14AUG2018	UB non-mentholated	166		4.87		193
		End Of Study	10OCT2018	UB non-mentholated	153		4.55		173
1046	45/M	Screen	14AUG2018	UB mentholated	146		4.44		272
		End Of Study	10OCT2018	UB mentholated	141		4.32		261
1050	33/F	Screen	14AUG2018	VLN non-mentholated	137		4.18		194
		End Of Study	10OCT2018	VLN non-mentholated	124		3.83		164
1051	36/F	Screen	14AUG2018	UB mentholated	130		3.99		259
		End Of Study	10OCT2018	UB mentholated	127		3.97		246
1052	31/M	Screen	14AUG2018	VLN mentholated	139		4.35		201
		End Of Study	11OCT2018	VLN mentholated	135 LN		4.19		217
1053	42/M	Screen	14AUG2018	VLN mentholated	135 LN		3.96 LN		271
		End Of Study	11OCT2018	VLN mentholated	140		4.02 LN		284
1054	56/M	Screen	14AUG2018	UB non-mentholated	161		4.76		214
		End Of Study	10OCT2018	UB non-mentholated	157		4.82		212

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
1055	39/F	Screen	14AUG2018	VLN mentholated	136		4.12		230	
		End Of Study	11OCT2018	VLN mentholated	131		3.97		217	
1056	48/M	Screen	14AUG2018	VLN non-mentholated	165		4.93		264	
		End Of Study	11OCT2018	VLN non-mentholated	156		4.71		256	
1058	30/M	Screen	15AUG2018	VLN non-mentholated	150		4.38		213	
		End Of Study	11OCT2018	VLN non-mentholated	143		4.24		258	
1059	38/M	Screen	27AUG2018	UB non-mentholated	161		4.85		247	
		End Of Study	24OCT2018	UB non-mentholated	157		4.83		240	
1060	55/M	Screen	27AUG2018	VLN mentholated	132 LN		4.2		287	
		End Of Study	24OCT2018	VLN mentholated	124 LN		4.02 LN		310	
1063	31/M	Screen	27AUG2018	VLN mentholated	162		4.85		236	
		End Of Study	25OCT2018	VLN mentholated	165		4.93		266	
1064	34/M	Screen	27AUG2018	UB non-mentholated	168		4.9		315	
1066	62/M	Screen	27AUG2018	VLN non-mentholated	136		4.19		221	
		End Of Study	24OCT2018	VLN non-mentholated	132 LN		4.24		286	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1069	40/F	Screen	28AUG2018	UB non-mentholated	136		4.22		300
		End Of Study	24OCT2018	UB non-mentholated	126		4.05		320
1070	53/M	Screen	28AUG2018	VLN non-mentholated	154		4.76		263
		End Of Study	24OCT2018	VLN non-mentholated	144		4.66		247
1071	42/M	Screen	28AUG2018	VLN non-mentholated	153		4.7		213
1072	59/M	Screen	28AUG2018	VLN mentholated	150		4.5		332
		End Of Study	22OCT2018	VLN mentholated	148		4.46		310
1074	42/M	Screen	28AUG2018	VLN non-mentholated	164		4.94		237
		End Of Study	24OCT2018	VLN non-mentholated	154		4.89		295
1075	26/F	Screen	29AUG2018	UB non-mentholated	133		3.92		138 LN
		End Of Study	24OCT2018	UB non-mentholated	130		4		139 LN
1077	49/F	Screen	28AUG2018	VLN non-mentholated	136		4.13		329
		End Of Study	24OCT2018	VLN non-mentholated	128		4.09		345
1078	51/F	Screen	28AUG2018	VLN non-mentholated	140		4.3		235
		End Of Study	24OCT2018	VLN non-mentholated	138		4.31		240

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
1079	33/M	Screen	29AUG2018	VLN mentholated	162		4.73		317	
		End Of Study	24OCT2018	VLN mentholated	152		4.67		343	
1082	37/M	Screen	30AUG2018	VLN non-mentholated	154		4.58		269	
		End Of Study	24OCT2018	VLN non-mentholated	152		4.77		275	
1083	54/F	Screen	04SEP2018	VLN non-mentholated	155		4.77 HN		303	
		End Of Study	31OCT2018	VLN non-mentholated	144		4.46		301	
1084	42/M	Screen	04SEP2018	VLN non-mentholated	148		4.44		341	
1086	54/M	Screen	04SEP2018	VLN non-mentholated	165		4.95		267	
		End Of Study	31OCT2018	VLN non-mentholated	146		4.38		204	
1088	26/M	Screen	04SEP2018	VLN mentholated	161		4.69		230	
		End Of Study	31OCT2018	VLN mentholated	154		4.59		209	
1089	60/F	Screen	04SEP2018	UB non-mentholated	137		4.34		291	
		End Of Study	31OCT2018	UB non-mentholated	124		3.96		203	
1092	43/F	Screen	05SEP2018	VLN mentholated	132		4.11		248	
		End Of Study	31OCT2018	VLN mentholated	122		3.92		260	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		Name	Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1094	46/M	Screen	05SEP2018	VLN mentholated	151		4.47		237
		End Of Study	31OCT2018	VLN mentholated	149		4.49		207
1095	55/F	Screen	07SEP2018	VLN mentholated	138		4.23		164
		End Of Study	31OCT2018	VLN mentholated	138		4.16		173
1096	42/F	Screen	07SEP2018	VLN non-mentholated	138		4.11		303
		End Of Study	31OCT2018	VLN non-mentholated	127		3.93		268
1097	30/M	Screen	07SEP2018	VLN mentholated	159		4.79		347
		End Of Study	31OCT2018	VLN mentholated	153		4.66		308
1098	63/M	Screen	18SEP2018	VLN non-mentholated	148		4.47		278
		End Of Study	16NOV2018	VLN non-mentholated	152		4.69		287
1099	46/F	Screen	18SEP2018	VLN non-mentholated	132		4.2		275
		End Of Study	16NOV2018	VLN non-mentholated	120		3.81		287
1100	59/M	Screen	18SEP2018	VLN non-mentholated	157		4.72		308
		End Of Study	16NOV2018	VLN non-mentholated	155		4.69		282
1101	41/M	Screen	18SEP2018	VLN non-mentholated	168		4.93		148 LN
		End Of Study	16NOV2018	VLN non-mentholated	162		4.76		184

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count 001: 155-361 002: 150-379 (thou/uL)
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1103	43/M	Screen	18SEP2018	VLN non-mentholated	156		4.63		300
		End Of Study	16NOV2018	VLN non-mentholated	151		4.5		248
1105	47/F	Screen	19SEP2018	VLN non-mentholated	145		4.43		215
		End Of Study	16NOV2018	VLN non-mentholated	137		4.23		200
1106	42/M	Screen	19SEP2018	UB non-mentholated	155		4.47		216
		End Of Study	16NOV2018	UB non-mentholated	160		4.71		234
1107	45/M	Screen	21SEP2018	VLN non-mentholated	173		4.9		243
		End Of Study	16NOV2018	VLN non-mentholated	159		4.52		235
1108	54/M	Screen	21SEP2018	UB non-mentholated	142		4.37		243
		End Of Study	16NOV2018	UB non-mentholated	137		4.25		237
1109	58/M	Screen	21SEP2018	UB non-mentholated	159		4.72		230
		End Of Study	16NOV2018	UB non-mentholated	149		4.47		221
1112	59/F	Screen	21SEP2018	VLN non-mentholated	140		4.33		228
		End Of Study	16NOV2018	VLN non-mentholated	140		4.31		215
1114	26/F	Screen	24SEP2018	UB non-mentholated	136		3.96		302
		End Of Study	16NOV2018	UB non-mentholated	140		4.1		351

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
1115	29/M	Screen	24SEP2018	VLN non-mentholated	157		4.54		308
2002	49/M	Screen	29JUN2018	UB mentholated	139		4.18		241
		End Of Study	05SEP2018	UB mentholated	143		4.46		220
2003	41/F	Screen	29JUN2018	VLN mentholated	144		4.26		231
		End Of Study	29AUG2018	VLN mentholated	138		4.11		185
2007	57/F	Screen	29JUN2018	VLN non-mentholated	139		4.02		293
		End Of Study	29AUG2018	VLN non-mentholated	123		3.56		238
2008	42/M	Screen	06JUL2018	VLN mentholated	132		3.98		230
		End Of Study	29AUG2018	VLN mentholated	130		4.08		240
2009	55/M	Screen	29JUN2018	VLN non-mentholated	149		4.34		247
2010	27/M	Screen	29JUN2018	UB mentholated	136		4.18		342
		End Of Study	29AUG2018	UB mentholated	143		4.39		327
2011	32/F	Screen	29JUN2018	VLN mentholated	139		4.12		225
		End Of Study	29AUG2018	VLN mentholated	130		3.84		191
2014	37/M	Screen	02JUL2018	VLN mentholated	155		4.52		198

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
2014	37/M	End Of Study	29AUG2018	VLN mentholated	154		4.54		179	
2015	57/F	Screen	02JUL2018	UB mentholated	157		4.61		230	
		End Of Study	29AUG2018	UB mentholated	147		4.42		210	
2016	45/F	Screen	02JUL2018	VLN mentholated	143		4.17		225	
		End Of Study	03AUG2018	VLN mentholated	132		3.93		230	
2017	30/M	Screen	02JUL2018	VLN mentholated	148		4.34		216	
		End Of Study	29AUG2018	VLN mentholated	141		4.06		196	
2018	26/F	Screen	02JUL2018	UB mentholated	129		3.9		270	
		End Of Study	29AUG2018	UB mentholated	123		3.68		262	
2020	60/F	Screen	02JUL2018	VLN mentholated	128		3.98		281	
		End Of Study	29AUG2018	VLN mentholated	124		3.89		265	
2021	31/M	Screen	02JUL2018	VLN mentholated	154		4.5		290	
		End Of Study	29AUG2018	VLN mentholated	137		4.15		265	
2023	35/M	Screen	02JUL2018	VLN mentholated	150		4.37		320	
		End Of Study	29AUG2018	VLN mentholated	141		4.2		298	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		-----	-----		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
2024	26/M	Screen	03JUL2018	UB non-mentholated	167		4.75		302	
2025	59/M	Screen	03JUL2018	UB non-mentholated	140		4.2		182	
		End Of Study	29AUG2018	UB non-mentholated	143		4.28		184	
2028	36/M	Screen	06JUL2018	VLN non-mentholated	148		4.2		264	
		End Of Study	29AUG2018	VLN non-mentholated	140		4.2		232	
2029	56/M	Screen	09JUL2018	UB mentholated	163		4.71		261	
		End Of Study	05SEP2018	UB mentholated	151		4.49		252	
2039	49/F	Screen	13JUL2018	VLN mentholated	128		3.8		235	
		End Of Study	05SEP2018	VLN mentholated	116		3.53		226	
2050	57/M	Screen	20JUL2018	UB mentholated	161		4.57		221	
		End Of Study	20SEP2018	UB mentholated	149		4.25		205	
2052	54/M	Screen	20JUL2018	VLN mentholated	157		4.59		188	
		End Of Study	20SEP2018	VLN mentholated	150		4.45		197	
2057	52/M	Screen	23JUL2018	VLN mentholated	150		4.59		287	
		End Of Study	20SEP2018	VLN mentholated	145		4.41		229	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		Name	Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
2058	37/F	Screen	23JUL2018	VLN mentholated	121		3.84		183
		End Of Study	20SEP2018	VLN mentholated	118		3.79		228
2059	56/F	Screen	23JUL2018	UB mentholated	125		3.85		184
		End Of Study	20SEP2018	UB mentholated	115		3.7		198
2060	37/F	Screen	23JUL2018	VLN mentholated	128		3.85		253
		End Of Study	20SEP2018	VLN mentholated	123		3.7		218
2064	52/M	Screen	23JUL2018	VLN mentholated	151		4.38		231
		End Of Study	20SEP2018	VLN mentholated	150		4.51		207
2066	30/F	Screen	23JUL2018	VLN mentholated	135		3.95		238
		End Of Study	20SEP2018	VLN mentholated	133		3.94		232
2067	52/M	Screen	23JUL2018	VLN non-mentholated	147		4.39		267
		End Of Study	20SEP2018	VLN non-mentholated	165		4.96		189
2075	34/M	Screen	30JUL2018	VLN mentholated	138		4.05		242
		End Of Study	22AUG2018	VLN mentholated	118 LN		3.61 LN		254
2076	42/M	Screen	30JUL2018	VLN mentholated	160		4.68		227
		End Of Study	14OCT2018	VLN mentholated	154		4.39		228

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		-----	-----		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
Number	Gender	Name	Date	Group					(thou/uL)
2086	36/M	Screen	03AUG2018	VLN non-mentholated	160		4.61		207
		End Of Study	01OCT2018	VLN non-mentholated	163		4.76		219
2088	39/F	Screen	03AUG2018	VLN mentholated	137		4.03		203
		End Of Study	14OCT2018	VLN mentholated	132		3.89		218
2092	50/F	Screen	06AUG2018	VLN mentholated	156		4.56		391 HN
		End Of Study	14OCT2018	VLN mentholated	138		4.14		331
2099	52/M	Screen	09AUG2018	VLN non-mentholated	168		4.86		188
		End Of Study	14OCT2018	VLN non-mentholated	162		4.73		178
2100	48/F	Screen	09AUG2018	UB mentholated	133		4		311
		End Of Study	14OCT2018	UB mentholated	126		3.71		275
2108	60/F	Screen	13AUG2018	VLN non-mentholated	159		4.64		297
		End Of Study	14OCT2018	VLN non-mentholated	155		4.61		314
2110	41/F	Screen	13AUG2018	UB mentholated	131		3.83		253
		End Of Study	20OCT2018	UB mentholated	132		3.92		226
2113	51/F	Screen	15AUG2018	VLN mentholated	131		3.92		255

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
2115	46/F	Screen	15AUG2018	VLN mentholated	139		4.13		207	
2119	48/M	Screen	20AUG2018	VLN mentholated	154		4.51		275	
		End Of Study	20OCT2018	VLN mentholated	165		4.91		266	
2120	62/F	Screen	20AUG2018	VLN non-mentholated	152		4.51		202	
		End Of Study	20OCT2018	VLN non-mentholated	149		4.6		196	
2122	60/M	Screen	20AUG2018	UB non-mentholated	150		4.49		193	
		End Of Study	20OCT2018	UB non-mentholated	148		4.43		185	
2125	35/M	Screen	21AUG2018	UB mentholated	170		4.83		121	LN
		End Of Study	20OCT2018	UB mentholated	157		4.54		131	LN
2126	37/M	Screen	21AUG2018	VLN mentholated	172		4.91		360	
		End Of Study	20OCT2018	VLN mentholated	154		4.64		406	HN
2136	64/M	Screen	27AUG2018	VLN non-mentholated	140		4.08		268	
		End Of Study	19OCT2018	VLN non-mentholated	133		4.17		246	
2140	56/F	Screen	30AUG2018	UB non-mentholated	145		4.26		242	
		End Of Study	06NOV2018	UB non-mentholated	135		4.02		257	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
2142	30/F	Screen	31AUG2018	VLN non-mentholated	167	HN	4.72	HN	328
		End Of Study	08OCT2018	VLN non-mentholated	142		4.25		265
2143	63/M	Screen	04SEP2018	VLN non-mentholated	169		4.79		159
		End Of Study	06NOV2018	VLN non-mentholated	158		4.55		133 LN
2158	43/F	Screen	18SEP2018	UB non-mentholated	131		3.9		267
2159	37/M	Screen	19SEP2018	VLN non-mentholated	163		4.7		289
		Unscheduled	04OCT2018	VLN non-mentholated	147		4.3		283
		End Of Study	02DEC2018	VLN non-mentholated	150		4.63		239
2164	65/F	Screen	27SEP2018	VLN non-mentholated	152		4.5		283
		End Of Study	02DEC2018	VLN non-mentholated	142		4.44		315
2168	32/F	Screen	28SEP2018	VLN non-mentholated	142		4.11		243
		End Of Study	02DEC2018	VLN non-mentholated	127		3.9		234
2170	51/F	Screen	28SEP2018	UB non-mentholated	138		4.23		251
		End Of Study	02DEC2018	UB non-mentholated	133		4.08		223
2175	40/F	Screen	01OCT2018	UB mentholated	135		4.06		313
		End Of Study	02DEC2018	UB mentholated	131		4.05		309

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		
2189	28/M	Screen	04OCT2018	VLN mentholated	149		4.35		243
		End Of Study	06NOV2018	VLN mentholated	145		4.2		248
2211	29/F	Screen	10OCT2018	VLN mentholated	143		4.22		249
		End Of Study	02DEC2018	VLN mentholated	131		4.09		238
2212	32/M	Screen	10OCT2018	UB mentholated	151		4.37		246
		End Of Study	02DEC2018	UB mentholated	153		4.62		261
2213	29/M	Screen	10OCT2018	VLN mentholated	159		4.57		290
		End Of Study	02DEC2018	VLN mentholated	165		4.88		266
2215	59/F	Screen	10OCT2018	UB mentholated	141		4.09		264
		End Of Study	02DEC2018	UB mentholated	139		4.17		282
2220	37/M	Screen	11OCT2018	VLN non-mentholated	147		4.26		194
		End Of Study	02DEC2018	VLN non-mentholated	147		4.48		205
2235	26/F	Screen	19OCT2018	VLN mentholated	115		3.71		279
		End Of Study	16DEC2018	VLN mentholated	114		3.71		269
2244	31/M	Screen	25OCT2018	VLN non-mentholated	170		4.83		261
		End Of Study	16DEC2018	VLN non-mentholated	165		4.83		247

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.1 Clinical Laboratory Report - Hematology (I of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Hemoglobin		Hematocrit		Platelet Count	
		----- Name	----- Date		001: F: 120-159 002: F: 111-159 001: M: 136-174 002: M: 130-177 (g/L)		001: F: 3.53-4.7 002: F: 3.4-4.66 001: M: 4.06-5.23 002: M: 3.75-5.1 (v/v)		001: 155-361 002: 150-379 (thou/uL)	
2247	28/M	Screen	06NOV2018	VLN mentholated	145		4.26		188	
		End Of Study	28DEC2018	VLN mentholated	141		4.27		206	
2251	27/M	Screen	09NOV2018	UB non-mentholated	139		4		257	
		End Of Study	19JAN2019	UB non-mentholated	147		4.27		258	
2257	55/F	Screen	14NOV2018	UB non-mentholated	150		4.4		337	
		End Of Study	19JAN2019	UB non-mentholated	146		4.32		307	
2259	49/M	Screen	14NOV2018	UB mentholated	162		4.55		241	
		End Of Study	19JAN2019	UB mentholated	161		4.58		186	
2269	48/M	Screen	26NOV2018	VLN mentholated	156		4.51		364	
		End Of Study	19JAN2019	VLN mentholated	149		4.39		335	
2272	37/M	Screen	28NOV2018	VLN mentholated	151		4.51		248	
		End Of Study	19JAN2019	VLN mentholated	142		4.21		222	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		Basophils	
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)		001: 3.7-11.5 002: 3.4-10.8 (thou/uL)		001: 0-2 002: Not Estab. (%)	
1001	59/F	Screen	02JUL2018	VLN non-mentholated	4.45		9.3		0.5	
		End Of Study	07SEP2018	VLN non-mentholated	4.4		12.2 HN		0.7	
1002	30/M	Screen	02JUL2018	VLN non-mentholated	5.44		5.9		1	
		End Of Study	07SEP2018	VLN non-mentholated	5.23		5.9		0.5	
1003	38/M	Screen	03JUL2018	VLN mentholated	5.6		6.6		0.3	
		End Of Study	07SEP2018	VLN mentholated	5.43		8.8		0.2	
1007	37/M	Screen	12JUL2018	VLN non-mentholated	5.54		7.4		0.4	
		End Of Study	07SEP2018	VLN non-mentholated	5.22		6.1		0.3	
1008	48/M	Screen	12JUL2018	VLN mentholated	4.66		6.9		0.1	
		Unscheduled	16JUL2018	VLN mentholated			7		0.3	
		End Of Study	07SEP2018	VLN mentholated	4.34 LN		10.3		0.2	
1010	32/M	Screen	13JUL2018	UB mentholated	5.2		8.6		0.3	
		End Of Study	06SEP2018	UB mentholated	5.26		8.2		0.6	
1011	36/M	Screen	13JUL2018	UB non-mentholated	5.02		6.3		0.2	
		End Of Study	06SEP2018	UB non-mentholated	4.84		6.7		0.3	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1013	36/F	Screen	16JUL2018	VLN non-mentholated	4.18	7.5	0
		End Of Study	14SEP2018	VLN non-mentholated	3.95	7.7	0.1
1014	36/F	Screen	16JUL2018	VLN mentholated	4.11	11.7 HR	0.4
		Unscheduled	23JUL2018	VLN mentholated		9.6	
		End Of Study	14SEP2018	VLN mentholated	3.53 LN	9.1	0.3
1015	49/F	Screen	16JUL2018	VLN mentholated	4.56	6.3	0.5
		End Of Study	14SEP2018	VLN mentholated	4.72	6.9	0.6
1016	54/M	Screen	16JUL2018	UB non-mentholated	5	6.3	0.5
		End Of Study	13SEP2018	UB non-mentholated	4.72	5.8	0.7
1017	41/F	Screen	17JUL2018	UB mentholated	4.94	7.5	0.4
		End Of Study	13SEP2018	UB mentholated	4.59	8.5	0.5
1018	41/F	Screen	17JUL2018	VLN mentholated	4.64	8.2	0.2
		End Of Study	15AUG2018	VLN mentholated	4.83	8.5	0.5
1019	30/M	Screen	17JUL2018	VLN non-mentholated	4.97	11.3	0.1
		End Of Study	14SEP2018	VLN non-mentholated	4.8	9	0.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1020	36/F	Screen	17JUL2018	VLN non-mentholated	4.64	8	0.2
		End Of Study	14SEP2018	VLN non-mentholated	4.3	8.3	0.5
1021	49/F	Screen	17JUL2018	UB non-mentholated	4.61	8.3	0.2
		End Of Study	13SEP2018	UB non-mentholated	4.37	9.5	0.2
1023	50/F	Screen	17JUL2018	VLN non-mentholated	4.86	9	0.2
		End Of Study	14SEP2018	VLN non-mentholated	4.52	9.8	0.3
1029	35/F	Screen	26JUL2018	VLN mentholated	4.33	8.5	0.2
		End Of Study	11OCT2018	VLN mentholated	4.31	9.8	0.1
1032	53/F	Screen	13AUG2018	VLN mentholated	4.94	5.1	0.2
		End Of Study	11OCT2018	VLN mentholated	4.46	4.1	0.2
1034	45/M	Screen	13AUG2018	VLN non-mentholated	4.27 LN	10.2	0.2
		End Of Study	10OCT2018	VLN non-mentholated	4.06 LN	9	0.4
1035	44/M	Screen	13AUG2018	VLN non-mentholated	5.62	6.8	0.3
		End Of Study	11OCT2018	VLN non-mentholated	5.26	6.1	0.3
1036	38/F	Screen	13AUG2018	UB mentholated	4.31	4.6	0.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1036	38/F	End Of Study	10OCT2018	UB mentholated	4.21	5.6	0.2
1037	29/M	Screen	13AUG2018	UB mentholated	5.42	5.9	0.2
		End Of Study	10OCT2018	UB mentholated	5.46	7.5	0.1
1038	39/F	Screen	13AUG2018	VLN non-mentholated	4.61	6.4	0.2
		End Of Study	11OCT2018	VLN non-mentholated	4.46	8.6	0.2
1042	47/M	Screen	13AUG2018	VLN non-mentholated	4.53	8.8	0.1
		End Of Study	11OCT2018	VLN non-mentholated	4.66	10.1	0
1045	58/M	Screen	14AUG2018	UB non-mentholated	5.11	8	0.5
		End Of Study	10OCT2018	UB non-mentholated	4.69	9.8	0.3
1046	45/M	Screen	14AUG2018	UB mentholated	4.9	8.8	0.1
		End Of Study	10OCT2018	UB mentholated	4.72	9.6	0.3
1050	33/F	Screen	14AUG2018	VLN non-mentholated	4.51	6.9	0.3
		End Of Study	10OCT2018	VLN non-mentholated	4.09	5.9	0.3
1051	36/F	Screen	14AUG2018	UB mentholated	4.25	12.8 HN	0.2
		End Of Study	10OCT2018	UB mentholated	4.22	12.5 HN	0.2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1052	31/M	Screen	14AUG2018	VLN mentholated	4.7	5	0.8
		End Of Study	11OCT2018	VLN mentholated	4.57	4.2	0.5
1053	42/M	Screen	14AUG2018	VLN mentholated	4.28 LN	9.6	0.2
		End Of Study	11OCT2018	VLN mentholated	4.35 LN	10.6	0.2
1054	56/M	Screen	14AUG2018	UB non-mentholated	4.9	9.6	0.2
		End Of Study	10OCT2018	UB non-mentholated	4.84	10.9	0.4
1055	39/F	Screen	14AUG2018	VLN mentholated	4.55	8.7	0.1
		End Of Study	11OCT2018	VLN mentholated	4.34	9.1	0.1
1056	48/M	Screen	14AUG2018	VLN non-mentholated	5.07	8.9	0.1
		End Of Study	11OCT2018	VLN non-mentholated	4.83	8.6	0.2
1058	30/M	Screen	15AUG2018	VLN non-mentholated	5.09	6.9	0.3
		End Of Study	11OCT2018	VLN non-mentholated	4.87	6.6	0.5
1059	38/M	Screen	27AUG2018	UB non-mentholated	5.23	8.8	0.3
		End Of Study	24OCT2018	UB non-mentholated	5.01	7.2	0.4
1060	55/M	Screen	27AUG2018	VLN mentholated	5.07	5.6	0.4

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1060	55/M	End Of Study	24OCT2018	VLN mentholated	4.73	7.1	0.4
1063	31/M	Screen	27AUG2018	VLN mentholated	5.14	6.6	0.5
		End Of Study	25OCT2018	VLN mentholated	5.22	8.2	0.5
1064	34/M	Screen	27AUG2018	UB non-mentholated	5.09	8.1	0.2
1066	62/M	Screen	27AUG2018	VLN non-mentholated	5.03	3.8	0.5
		End Of Study	24OCT2018	VLN non-mentholated	4.98	3.6 LN	0.6
1069	40/F	Screen	28AUG2018	UB non-mentholated	4.35	11.9 HN	0.2
		End Of Study	24OCT2018	UB non-mentholated	4.05	13 HR	0.2
		Unscheduled	06NOV2018	UB non-mentholated		9.6	
1070	53/M	Screen	28AUG2018	VLN non-mentholated	5.17	7.6	0.4
		End Of Study	24OCT2018	VLN non-mentholated	4.96	7.3	0.6
1071	42/M	Screen	28AUG2018	VLN non-mentholated	5	8.8	0.3
1072	59/M	Screen	28AUG2018	VLN mentholated	5.06	10.1	0.4
		End Of Study	22OCT2018	VLN mentholated	4.9	11.3	0.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1074	42/M	Screen	28AUG2018	VLN non-mentholated	5.02	9.7	0.2
		End Of Study	24OCT2018	VLN non-mentholated	4.93	9.1	0.2
1075	26/F	Screen	29AUG2018	UB non-mentholated	4.24	5.1	0.2
		End Of Study	24OCT2018	UB non-mentholated	4.16	6.7	0.1
1077	49/F	Screen	28AUG2018	VLN non-mentholated	4.46	8.8	0.5
		End Of Study	24OCT2018	VLN non-mentholated	4.28	7.7	0.8
		Unscheduled	24NOV2018	VLN non-mentholated		8.1	
1078	51/F	Screen	28AUG2018	VLN non-mentholated	4.16	9.1	0
		End Of Study	24OCT2018	VLN non-mentholated	4.11	8.5	0.1
1079	33/M	Screen	29AUG2018	VLN mentholated	5.23	9.2	0.2
		End Of Study	24OCT2018	VLN mentholated	4.92	10.2	0.4
1082	37/M	Screen	30AUG2018	VLN non-mentholated	4.7	8.7	0.2
		End Of Study	24OCT2018	VLN non-mentholated	4.67	7.3	0.3
1083	54/F	Screen	04SEP2018	VLN non-mentholated	4.97	9.7	0.4
		End Of Study	31OCT2018	VLN non-mentholated	4.65	8.2	0.5
		Unscheduled	06NOV2018	VLN non-mentholated		7.9	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1084	42/M	Screen	04SEP2018	VLN non-mentholated	4.75	8.9	0.3
1086	54/M	Screen	04SEP2018	VLN non-mentholated	5.07	9.9	0.2
		End Of Study	31OCT2018	VLN non-mentholated	4.52	8.5	0.2
1088	26/M	Screen	04SEP2018	VLN mentholated	4.93	7.2	0.3
		End Of Study	31OCT2018	VLN mentholated	4.76	7.8	0.3
1089	60/F	Screen	04SEP2018	UB non-mentholated	5.31 HN	6.8	0.1
		End Of Study	31OCT2018	UB non-mentholated	4.93	8.6	0.1
		Unscheduled	09NOV2018	UB non-mentholated		8.4	
1092	43/F	Screen	05SEP2018	VLN mentholated	4.61	6.3	0.5
		End Of Study	31OCT2018	VLN mentholated	4.35	6.6	0.5
1094	46/M	Screen	05SEP2018	VLN mentholated	4.75	6.2	0.3
		End Of Study	31OCT2018	VLN mentholated	4.69	5.7	0.2
1095	55/F	Screen	07SEP2018	VLN mentholated	4.69	9.4	0.2
		End Of Study	31OCT2018	VLN mentholated	4.63	6.9	0.3
		Unscheduled	09NOV2018	VLN mentholated		7.5	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1096	42/F	Screen	07SEP2018	VLN non-mentholated	4.38	8.2	0.1
		End Of Study	31OCT2018	VLN non-mentholated	4.09	8.2	0.2
1097	30/M	Screen	07SEP2018	VLN mentholated	5.02	8.5	0.1
		End Of Study	31OCT2018	VLN mentholated	4.87	8.5	0.2
1098	63/M	Screen	18SEP2018	VLN non-mentholated	4.73	7.2	0.7
		End Of Study	16NOV2018	VLN non-mentholated	4.93	7.2	0.6
1099	46/F	Screen	18SEP2018	VLN non-mentholated	4.47	8.6	0.7
		End Of Study	16NOV2018	VLN non-mentholated	3.96	8.5	0.5
1100	59/M	Screen	18SEP2018	VLN non-mentholated	5.09	9.3	0.4
		End Of Study	16NOV2018	VLN non-mentholated	5	8.6	0.2
1101	41/M	Screen	18SEP2018	VLN non-mentholated	5.08	7.8	0.6
		End Of Study	16NOV2018	VLN non-mentholated	4.86	6.7	0.3
1103	43/M	Screen	18SEP2018	VLN non-mentholated	5.14	8.4	0.6
		End Of Study	16NOV2018	VLN non-mentholated	4.9	7.9	0.6
1105	47/F	Screen	19SEP2018	VLN non-mentholated	4.49	13.1 HN	0.1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1105	47/F	End Of Study	16NOV2018	VLN non-mentholated	4.29	7	0.1
1106	42/M	Screen	19SEP2018	UB non-mentholated	4.81	10.2	0.2
		End Of Study	16NOV2018	UB non-mentholated	5.01	9.9	0.2
1107	45/M	Screen	21SEP2018	VLN non-mentholated	5.15	12.2 HR	0.3
		Unscheduled	25SEP2018	VLN non-mentholated		10.9	0.4
		End Of Study	16NOV2018	VLN non-mentholated	4.8	12.1 HN	0.3
1108	54/M	Screen	21SEP2018	UB non-mentholated	4.73	6	0.5
		End Of Study	16NOV2018	UB non-mentholated	4.58	6.6	0.5
1109	58/M	Screen	21SEP2018	UB non-mentholated	5.03	11.1	0.4
		Unscheduled	25SEP2018	UB non-mentholated		7.9	0.4
		End Of Study	16NOV2018	UB non-mentholated	4.74	9.8	0.7
1112	59/F	Screen	21SEP2018	VLN non-mentholated	4.81	7.4	0.5
		End Of Study	16NOV2018	VLN non-mentholated	4.81	5.4	0.7
1114	26/F	Screen	24SEP2018	UB non-mentholated	4.35	7.4	0.5
		End Of Study	16NOV2018	UB non-mentholated	4.48	9.6	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
1115	29/M	Screen	24SEP2018	VLN non-mentholated	5.14	7.5	0.3
2002	49/M	Screen	29JUN2018	UB mentholated	4.8	6	0
		End Of Study	05SEP2018	UB mentholated	5.05	5.8	0
2003	41/F	Screen	29JUN2018	VLN mentholated	4.42	8.4	0
		End Of Study	29AUG2018	VLN mentholated	4.2	6.9	0
2007	57/F	Screen	29JUN2018	VLN non-mentholated	4.51	6.9	0
		End Of Study	29AUG2018	VLN non-mentholated	3.96	5	1
2008	42/M	Screen	06JUL2018	VLN mentholated	5.25	6.4	1
		End Of Study	29AUG2018	VLN mentholated	5.31	4.4	1
2009	55/M	Screen	29JUN2018	VLN non-mentholated	5.02	8.6	1
2010	27/M	Screen	29JUN2018	UB mentholated	4.86	7.8	0
		End Of Study	29AUG2018	UB mentholated	5.08	7.7	0
2011	32/F	Screen	29JUN2018	VLN mentholated	4.64	6.9	0
		End Of Study	29AUG2018	VLN mentholated	4.27	5.3	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		Basophils	
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)		001: 3.7-11.5 002: 3.4-10.8 (thou/uL)		001: 0-2 002: Not Estab. (%)	
2014	37/M	Screen	02JUL2018	VLN mentholated	4.69		7.7		0	
		End Of Study	29AUG2018	VLN mentholated	4.74		6.4		0	
2015	57/F	Screen	02JUL2018	UB mentholated	4.88		10.3		0	
		End Of Study	29AUG2018	UB mentholated	4.66		9		0	
2016	45/F	Screen	02JUL2018	VLN mentholated	5.18		5.8		0	
		End Of Study	03AUG2018	VLN mentholated	4.82		6.3		0	
2017	30/M	Screen	02JUL2018	VLN mentholated	5.03		7.8		0	
		End Of Study	29AUG2018	VLN mentholated	4.75		9.2		0	
2018	26/F	Screen	02JUL2018	UB mentholated	4.49		6.3		0	
		End Of Study	29AUG2018	UB mentholated	4.25		5.4		0	
2020	60/F	Screen	02JUL2018	VLN mentholated	4.47		6.3		1	
		End Of Study	29AUG2018	VLN mentholated	4.43		5.3		1	
2021	31/M	Screen	02JUL2018	VLN mentholated	5.15		4.4		1	
		End Of Study	29AUG2018	VLN mentholated	4.64		5.3		1	
2023	35/M	Screen	02JUL2018	VLN mentholated	4.95		6.4		1	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2023	35/M	End Of Study	29AUG2018	VLN mentholated	4.73	7.1	0
2024	26/M	Screen	03JUL2018	UB non-mentholated	5.2	7	1
2025	59/M	Screen	03JUL2018	UB non-mentholated	4.89	6.3	1
		End Of Study	29AUG2018	UB non-mentholated	4.92	5.8	0
2028	36/M	Screen	06JUL2018	VLN non-mentholated	4.96	10.8	0
		End Of Study	29AUG2018	VLN non-mentholated	4.78	6.9	0
2029	56/M	Screen	09JUL2018	UB mentholated	5.52	9.8	1
		End Of Study	05SEP2018	UB mentholated	5.18	9.4	0
2039	49/F	Screen	13JUL2018	VLN mentholated	4.96	7.2	0
		End Of Study	05SEP2018	VLN mentholated	4.55	6.3	0
2050	57/M	Screen	20JUL2018	UB mentholated	5.23	6.8	0
		End Of Study	20SEP2018	UB mentholated	4.87	5.4	1
2052	54/M	Screen	20JUL2018	VLN mentholated	4.75	6.4	0
		End Of Study	20SEP2018	VLN mentholated	4.64	4.9	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2057	52/M	Screen	23JUL2018	VLN mentholated	5.1	7.2	0
		End Of Study	20SEP2018	VLN mentholated	4.93	7.2	0
2058	37/F	Screen	23JUL2018	VLN mentholated	4.82	4.3	0
		End Of Study	20SEP2018	VLN mentholated	4.78	3.9	1
2059	56/F	Screen	23JUL2018	UB mentholated	5.1	7	1
		End Of Study	20SEP2018	UB mentholated	4.86	5.3	1
2060	37/F	Screen	23JUL2018	VLN mentholated	4.81	10.2	0
		End Of Study	20SEP2018	VLN mentholated	4.65	4.7	0
2064	52/M	Screen	23JUL2018	VLN mentholated	4.82	11.3 HN	0
		End Of Study	20SEP2018	VLN mentholated	4.93	9	0
2066	30/F	Screen	23JUL2018	VLN mentholated	4.39	7.4	0
		End Of Study	20SEP2018	VLN mentholated	4.33	6.7	0
2067	52/M	Screen	23JUL2018	VLN non-mentholated	4.76	7.2	0
		End Of Study	20SEP2018	VLN non-mentholated	5.36	10.4	0
2075	34/M	Screen	30JUL2018	VLN mentholated	4.08 LN	6.1	1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2075	34/M	End Of Study	22AUG2018	VLN mentholated	3.58 LN	6.8	1
2076	42/M	Screen	30JUL2018	VLN mentholated	5.11	7.7	0
		End Of Study	14OCT2018	VLN mentholated	4.88	6.7	0
2086	36/M	Screen	03AUG2018	VLN non-mentholated	5.18	9	0
		End Of Study	01OCT2018	VLN non-mentholated	5.23	7	0
2088	39/F	Screen	03AUG2018	VLN mentholated	4.28	7.7	0
		End Of Study	14OCT2018	VLN mentholated	4.09	6.4	0
2092	50/F	Screen	06AUG2018	VLN mentholated	4.64	6.4	1
		End Of Study	14OCT2018	VLN mentholated	4.15	5.6	1
2099	52/M	Screen	09AUG2018	VLN non-mentholated	5.76	7.1	0
		End Of Study	14OCT2018	VLN non-mentholated	5.39	6.5	1
2100	48/F	Screen	09AUG2018	UB mentholated	4.32	6	0
		End Of Study	14OCT2018	UB mentholated	3.94	5.5	0
2108	60/F	Screen	13AUG2018	VLN non-mentholated	4.87	9.1	0
		End Of Study	14OCT2018	VLN non-mentholated	4.8	8.2	1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2110	41/F	Screen	13AUG2018	UB mentholated	4.1	8.4	0
		End Of Study	20OCT2018	UB mentholated	4	6.4	0
2113	51/F	Screen	15AUG2018	VLN mentholated	4.72	7.7	0
2115	46/F	Screen	15AUG2018	VLN mentholated	4.31	7.4	0
2119	48/M	Screen	20AUG2018	VLN mentholated	5.27	10	0
		End Of Study	20OCT2018	VLN mentholated	5.53	7.6	0
2120	62/F	Screen	20AUG2018	VLN non-mentholated	5	8.6	0
		End Of Study	20OCT2018	VLN non-mentholated	4.87	7.7	0
2122	60/M	Screen	20AUG2018	UB non-mentholated	5.35	3.1 LN	1
		End Of Study	20OCT2018	UB non-mentholated	5.16	3.4	1
2125	35/M	Screen	21AUG2018	UB mentholated	5.37	4.1	0
		End Of Study	20OCT2018	UB mentholated	4.96	4	0
2126	37/M	Screen	21AUG2018	VLN mentholated	5.51	7.9	0
		End Of Study	20OCT2018	VLN mentholated	4.95	7.2	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2136	64/M	Screen	27AUG2018	VLN non-mentholated	4.35	7.1	1
		End Of Study	19OCT2018	VLN non-mentholated	4.13 LN	7.2	1
2140	56/F	Screen	30AUG2018	UB non-mentholated	4.66	6.4	0
		End Of Study	06NOV2018	UB non-mentholated	4.4	5.9	1
2142	30/F	Screen	31AUG2018	VLN non-mentholated	4.98	9.6	1
		End Of Study	08OCT2018	VLN non-mentholated	4.4	8.6	0
2143	63/M	Screen	04SEP2018	VLN non-mentholated	5.25	9.6	0
		End Of Study	06NOV2018	VLN non-mentholated	4.92	10.2	0
2158	43/F	Screen	18SEP2018	UB non-mentholated	4.34	6.9	0
2159	37/M	Screen	19SEP2018	VLN non-mentholated	5.15	13 HN	0
		Unscheduled	04OCT2018	VLN non-mentholated	4.68	6.7	0
		End Of Study	02DEC2018	VLN non-mentholated	4.79	7.3	0
2164	65/F	Screen	27SEP2018	VLN non-mentholated	5.27	8.1	0
		End Of Study	02DEC2018	VLN non-mentholated	4.96	7.2	0
2168	32/F	Screen	28SEP2018	VLN non-mentholated	4.73	10	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2168	32/F	End Of Study	02DEC2018	VLN non-mentholated	4.28	9	0
2170	51/F	Screen	28SEP2018	UB non-mentholated	4.72	7.7	0
		End Of Study	02DEC2018	UB non-mentholated	4.39	9.8	0
2175	40/F	Screen	01OCT2018	UB mentholated	4.46	8.6	0
		End Of Study	02DEC2018	UB mentholated	4.3	9.2	0
2189	28/M	Screen	04OCT2018	VLN mentholated	4.77	5.2	0
		End Of Study	06NOV2018	VLN mentholated	4.59	3.6	1
2211	29/F	Screen	10OCT2018	VLN mentholated	5.1	5	0
		End Of Study	02DEC2018	VLN mentholated	4.69	5.6	0
2212	32/M	Screen	10OCT2018	UB mentholated	5.13	7.9	0
		End Of Study	02DEC2018	UB mentholated	5.16	6.6	0
2213	29/M	Screen	10OCT2018	VLN mentholated	5.16	7.6	0
		End Of Study	02DEC2018	VLN mentholated	5.27	5.3	0
2215	59/F	Screen	10OCT2018	UB mentholated	4.66	8.1	0
		End Of Study	02DEC2018	UB mentholated	4.52	6.2	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2220	37/M	Screen	11OCT2018	VLN non-mentholated	4.44	5.4	0
		End Of Study	02DEC2018	VLN non-mentholated	4.47	5.5	1
2235	26/F	Screen	19OCT2018	VLN mentholated	5.18	11.5 HN	0
		End Of Study	16DEC2018	VLN mentholated	5.06	9.2	0
2244	31/M	Screen	25OCT2018	VLN non-mentholated	5.62	9.2	0
		End Of Study	16DEC2018	VLN non-mentholated	5.49	9.9	0
2247	28/M	Screen	06NOV2018	VLN mentholated	4.72	7.1	0
		End Of Study	28DEC2018	VLN mentholated	4.66	7.4	0
2251	27/M	Screen	09NOV2018	UB non-mentholated	4.49	7.1	0
		End Of Study	19JAN2019	UB non-mentholated	4.82	6	0
2257	55/F	Screen	14NOV2018	UB non-mentholated	5.02	8.5	1
		End Of Study	19JAN2019	UB non-mentholated	4.95	6.5	2
2259	49/M	Screen	14NOV2018	UB mentholated	4.69	5.1	0
		End Of Study	19JAN2019	UB mentholated	4.74	4.5	0
2269	48/M	Screen	26NOV2018	VLN mentholated	4.97	7.1	1

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.2 Clinical Laboratory Report - Hematology (II of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	Basophils
		Name	Date		001: F: 3.95-5.21 002: F: 3.77-5.28 001: M: 4.43-5.81 002: M: 4.14-5.8 (mil/uL)	001: 3.7-11.5 002: 3.4-10.8 (thou/uL)	001: 0-2 002: Not Estab. (%)
2269	48/M	End Of Study	19JAN2019	VLN mentholated	4.81	5.9	1
2272	37/M	Screen	28NOV2018	VLN mentholated	4.86	3.9	0
		End Of Study	19JAN2019	VLN mentholated	4.56	4.9	0

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	----- Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1001	59/F	Screen	02JUL2018	VLN non-mentholated	0.1	0.1	1.4
		End Of Study	07SEP2018	VLN non-mentholated	0.1	0.1	1.1
1002	30/M	Screen	02JUL2018	VLN non-mentholated	0.1	0.2	2.9
		End Of Study	07SEP2018	VLN non-mentholated	0	0.2	2.9
1003	38/M	Screen	03JUL2018	VLN mentholated	0	0.4	5.5
		End Of Study	07SEP2018	VLN mentholated	0	0.8 HN	9.2 HN
1007	37/M	Screen	12JUL2018	VLN non-mentholated	0	0.2	2.6
		End Of Study	07SEP2018	VLN non-mentholated	0	0.2	3.8
1008	48/M	Screen	12JUL2018	VLN mentholated	0	0.1	2
		Unscheduled	16JUL2018	VLN mentholated	0	0.1	1.3
		End Of Study	07SEP2018	VLN mentholated	0	0.1	1.4
1010	32/M	Screen	13JUL2018	UB mentholated	0	0.3	3.6
		End Of Study	06SEP2018	UB mentholated	0.1	0.3	3.8
1011	36/M	Screen	13JUL2018	UB non-mentholated	0	0.3	4.1
		End Of Study	06SEP2018	UB non-mentholated	0	0.3	3.7
1013	36/F	Screen	16JUL2018	VLN non-mentholated	0	0.3	3.3

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1013	36/F	End Of Study	14SEP2018	VLN non-mentholated	0	0.4	5.2
1014	36/F	Screen	16JUL2018	VLN mentholated	0.1	0.3	2.5
		End Of Study	14SEP2018	VLN mentholated	0	0.2	2.3
1015	49/F	Screen	16JUL2018	VLN mentholated	0	0.1	1.1
		End Of Study	14SEP2018	VLN mentholated	0	0.1	1.9
1016	54/M	Screen	16JUL2018	UB non-mentholated	0	0.3	5
		End Of Study	13SEP2018	UB non-mentholated	0	0.3	5
1017	41/F	Screen	17JUL2018	UB mentholated	0	0.2	2
		End Of Study	13SEP2018	UB mentholated	0	0.1	1.7
1018	41/F	Screen	17JUL2018	VLN mentholated	0	0.1	1.3
		End Of Study	15AUG2018	VLN mentholated	0	0.2	2.2
1019	30/M	Screen	17JUL2018	VLN non-mentholated	0	0.2	1.3
		End Of Study	14SEP2018	VLN non-mentholated	0	0.3	2.9
1020	36/F	Screen	17JUL2018	VLN non-mentholated	0	0.2	2
		End Of Study	14SEP2018	VLN non-mentholated	0	0.2	2.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	----- Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1021	49/F	Screen	17JUL2018	UB non-mentholated	0	0.2	2.2
		End Of Study	13SEP2018	UB non-mentholated	0	0.3	3.1
1023	50/F	Screen	17JUL2018	VLN non-mentholated	0	0.1	1.3
		End Of Study	14SEP2018	VLN non-mentholated	0	0.2	2.1
1029	35/F	Screen	26JUL2018	VLN mentholated	0	0.2	2.2
		End Of Study	11OCT2018	VLN mentholated	0	0.2	2
1032	53/F	Screen	13AUG2018	VLN mentholated	0	0.1	2
		End Of Study	11OCT2018	VLN mentholated	0	0.1	2
1034	45/M	Screen	13AUG2018	VLN non-mentholated	0	0.7 HN	6.4
		End Of Study	10OCT2018	VLN non-mentholated	0	0.8 HN	9 HN
1035	44/M	Screen	13AUG2018	VLN non-mentholated	0	0.2	3
		End Of Study	11OCT2018	VLN non-mentholated	0	0.2	2.5
1036	38/F	Screen	13AUG2018	UB mentholated	0	0.1	2.2
		End Of Study	10OCT2018	UB mentholated	0	0.1	2.3
1037	29/M	Screen	13AUG2018	UB mentholated	0	0.1	1.5
		End Of Study	10OCT2018	UB mentholated	0	0.1	1.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		-----	-----		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1038	39/F	Screen	13AUG2018	VLN non-mentholated	0	0.2	3.5
		End Of Study	11OCT2018	VLN non-mentholated	0	0.3	3
1042	47/M	Screen	13AUG2018	VLN non-mentholated	0	0.2	2
		End Of Study	11OCT2018	VLN non-mentholated	0	0.1	1.1
1045	58/M	Screen	14AUG2018	UB non-mentholated	0	0.2	2.3
		End Of Study	10OCT2018	UB non-mentholated	0	0.1	1.1
1046	45/M	Screen	14AUG2018	UB mentholated	0	0.2	1.8
		End Of Study	10OCT2018	UB mentholated	0	0.1	1.4
1050	33/F	Screen	14AUG2018	VLN non-mentholated	0	0.2	3.3
		End Of Study	10OCT2018	VLN non-mentholated	0	0.2	3.9
1051	36/F	Screen	14AUG2018	UB mentholated	0	0.4	3
		End Of Study	10OCT2018	UB mentholated	0	0.5	4.2
1052	31/M	Screen	14AUG2018	VLN mentholated	0	0.2	4
		End Of Study	11OCT2018	VLN mentholated	0	0.2	4.1
1053	42/M	Screen	14AUG2018	VLN mentholated	0	0.1	0.5
		End Of Study	11OCT2018	VLN mentholated	0	0.1	1.3

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1054	56/M	Screen	14AUG2018	UB non-mentholated	0	0.3	3.1
		End Of Study	10OCT2018	UB non-mentholated	0	0.3	3
1055	39/F	Screen	14AUG2018	VLN mentholated	0	0.1	1.5
		End Of Study	11OCT2018	VLN mentholated	0	0.1	1.4
1056	48/M	Screen	14AUG2018	VLN non-mentholated	0	0.1	1.6
		End Of Study	11OCT2018	VLN non-mentholated	0	0.4	4.1
1058	30/M	Screen	15AUG2018	VLN non-mentholated	0	0.2	3.1
		End Of Study	11OCT2018	VLN non-mentholated	0	0.2	2.9
1059	38/M	Screen	27AUG2018	UB non-mentholated	0	0.1	1.1
		End Of Study	24OCT2018	UB non-mentholated	0	0.1	1.3
1060	55/M	Screen	27AUG2018	VLN mentholated	0	0.1	2.1
		End Of Study	24OCT2018	VLN mentholated	0	0.1	1.8
1063	31/M	Screen	27AUG2018	VLN mentholated	0	0.4	5.3
		End Of Study	25OCT2018	VLN mentholated	0	0.3	3.8
1064	34/M	Screen	27AUG2018	UB non-mentholated	0	0.2	2.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1066	62/M	Screen	27AUG2018	VLN non-mentholated	0	0.2	6.4
		End Of Study	24OCT2018	VLN non-mentholated	0	0.3	7
1069	40/F	Screen	28AUG2018	UB non-mentholated	0	0.2	1.4
		End Of Study	24OCT2018	UB non-mentholated	0	0.2	1.6
1070	53/M	Screen	28AUG2018	VLN non-mentholated	0	0.4	5.1
		End Of Study	24OCT2018	VLN non-mentholated	0	0.5	7.3
1071	42/M	Screen	28AUG2018	VLN non-mentholated	0	0.1	1.6
1072	59/M	Screen	28AUG2018	VLN mentholated	0	0	0.4 LN
		End Of Study	22OCT2018	VLN mentholated	0.1	0.1	0.5
1074	42/M	Screen	28AUG2018	VLN non-mentholated	0	0.4	3.6
		End Of Study	24OCT2018	VLN non-mentholated	0	0.4	4.5
1075	26/F	Screen	29AUG2018	UB non-mentholated	0	0.1	2.8
		End Of Study	24OCT2018	UB non-mentholated	0	0.1	1.9
1077	49/F	Screen	28AUG2018	VLN non-mentholated	0	0.3	3.5
		End Of Study	24OCT2018	VLN non-mentholated	0.1	0.4	5.7

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1078	51/F	Screen	28AUG2018	VLN non-mentholated	0	0.2	2.4
		End Of Study	24OCT2018	VLN non-mentholated	0	0.1	1.5
1079	33/M	Screen	29AUG2018	VLN mentholated	0	0.5	4.9
		End Of Study	24OCT2018	VLN mentholated	0	1.1 HN	10.7 HN
1082	37/M	Screen	30AUG2018	VLN non-mentholated	0	0.2	1.7
		End Of Study	24OCT2018	VLN non-mentholated	0	0.1	1.9
1083	54/F	Screen	04SEP2018	VLN non-mentholated	0	0.5	5.3
		End Of Study	31OCT2018	VLN non-mentholated	0	0.4	5.1
1084	42/M	Screen	04SEP2018	VLN non-mentholated	0	0.2	2.6
1086	54/M	Screen	04SEP2018	VLN non-mentholated	0	0.1	1.2
		End Of Study	31OCT2018	VLN non-mentholated	0	0.2	2
1088	26/M	Screen	04SEP2018	VLN mentholated	0	0.1	1.3
		End Of Study	31OCT2018	VLN mentholated	0	0.1	1.3
1089	60/F	Screen	04SEP2018	UB non-mentholated	0	0.1	1.2
		End Of Study	31OCT2018	UB non-mentholated	0	0.2	2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1092	43/F	Screen	05SEP2018	VLN mentholated	0	0.1	1.3
		End Of Study	31OCT2018	VLN mentholated	0	0.2	2.4
1094	46/M	Screen	05SEP2018	VLN mentholated	0	0.1	1.5
		End Of Study	31OCT2018	VLN mentholated	0	0.1	2.4
1095	55/F	Screen	07SEP2018	VLN mentholated	0	0.1	1.5
		End Of Study	31OCT2018	VLN mentholated	0	0.2	2.3
1096	42/F	Screen	07SEP2018	VLN non-mentholated	0	0.1	0.9
		End Of Study	31OCT2018	VLN non-mentholated	0	0.1	0.9
1097	30/M	Screen	07SEP2018	VLN mentholated	0	0.2	1.9
		End Of Study	31OCT2018	VLN mentholated	0	0.2	2
1098	63/M	Screen	18SEP2018	VLN non-mentholated	0.1	0.2	2.6
		End Of Study	16NOV2018	VLN non-mentholated	0	0.2	3.2
1099	46/F	Screen	18SEP2018	VLN non-mentholated	0.1	0.7 HN	8 HN
		End Of Study	16NOV2018	VLN non-mentholated	0	0.2	2.8
1100	59/M	Screen	18SEP2018	VLN non-mentholated	0	0.2	2.6
		End Of Study	16NOV2018	VLN non-mentholated	0	0.3	3.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1101	41/M	Screen	18SEP2018	VLN non-mentholated	0.1	0.2	2
		End Of Study	16NOV2018	VLN non-mentholated	0	0.1	1.3
1103	43/M	Screen	18SEP2018	VLN non-mentholated	0.1	0.1	1.3
		End Of Study	16NOV2018	VLN non-mentholated	0.1	0.2	2.4
1105	47/F	Screen	19SEP2018	VLN non-mentholated	0	0.1	0.4 LN
		End Of Study	16NOV2018	VLN non-mentholated	0	0	0.6
1106	42/M	Screen	19SEP2018	UB non-mentholated	0	0.2	1.5
		End Of Study	16NOV2018	UB non-mentholated	0	0.1	1.2
1107	45/M	Screen	21SEP2018	VLN non-mentholated	0	0.3	2.1
		Unscheduled	25SEP2018	VLN non-mentholated	0	0.4	3.5
		End Of Study	16NOV2018	VLN non-mentholated	0	0.3	2.7
1108	54/M	Screen	21SEP2018	UB non-mentholated	0	0.1	1
		End Of Study	16NOV2018	UB non-mentholated	0	0.1	1.2
1109	58/M	Screen	21SEP2018	UB non-mentholated	0	0.1	0.8
		Unscheduled	25SEP2018	UB non-mentholated	0	0.1	0.8
		End Of Study	16NOV2018	UB non-mentholated	0.1	0.2	2.3

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
1112	59/F	Screen	21SEP2018	VLN non-mentholated	0	0.4	5.3
		End Of Study	16NOV2018	VLN non-mentholated	0	0.2	3.2
1114	26/F	Screen	24SEP2018	UB non-mentholated	0	0.4	5.4
		End Of Study	16NOV2018	UB non-mentholated	0	0.3	2.6
1115	29/M	Screen	24SEP2018	VLN non-mentholated	0	0.1	1.5
2002	49/M	Screen	29JUN2018	UB mentholated	0	0	0
		End Of Study	05SEP2018	UB mentholated	0	0.2	3
2003	41/F	Screen	29JUN2018	VLN mentholated	0	0	0
		End Of Study	29AUG2018	VLN mentholated	0	0.1	1
2007	57/F	Screen	29JUN2018	VLN non-mentholated	0	0.3	4
		End Of Study	29AUG2018	VLN non-mentholated	0.1	0.2	4
2008	42/M	Screen	06JUL2018	VLN mentholated	0	0.1	2
		End Of Study	29AUG2018	VLN mentholated	0	0.1	3
2009	55/M	Screen	29JUN2018	VLN non-mentholated	0.1	0.3	4
2010	27/M	Screen	29JUN2018	UB mentholated	0	0.4	5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2010	27/M	End Of Study	29AUG2018	UB mentholated	0	0.3	4
2011	32/F	Screen	29JUN2018	VLN mentholated	0	0.1	1
		End Of Study	29AUG2018	VLN mentholated	0	0.1	3
2014	37/M	Screen	02JUL2018	VLN mentholated	0	0.1	1
		End Of Study	29AUG2018	VLN mentholated	0	0.1	2
2015	57/F	Screen	02JUL2018	UB mentholated	0	0.2	2
		End Of Study	29AUG2018	UB mentholated	0	0.2	2
2016	45/F	Screen	02JUL2018	VLN mentholated	0	0.1	2
		End Of Study	03AUG2018	VLN mentholated	0	0.1	2
2017	30/M	Screen	02JUL2018	VLN mentholated	0	0	0
		End Of Study	29AUG2018	VLN mentholated	0	0.1	1
2018	26/F	Screen	02JUL2018	UB mentholated	0	0.1	2
		End Of Study	29AUG2018	UB mentholated	0	0.2	3
2020	60/F	Screen	02JUL2018	VLN mentholated	0	0.1	1
		End Of Study	29AUG2018	VLN mentholated	0	0.1	2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2021	31/M	Screen	02JUL2018	VLN mentholated	0.1	0.1	3
		End Of Study	29AUG2018	VLN mentholated	0.1	0.3	5
2023	35/M	Screen	02JUL2018	VLN mentholated	0	0.2	3
		End Of Study	29AUG2018	VLN mentholated	0	0.3	5
2024	26/M	Screen	03JUL2018	UB non-mentholated	0	0.2	2
2025	59/M	Screen	03JUL2018	UB non-mentholated	0	0.2	3
		End Of Study	29AUG2018	UB non-mentholated	0	0.3	5
2028	36/M	Screen	06JUL2018	VLN non-mentholated	0	0.7 HN	6
		End Of Study	29AUG2018	VLN non-mentholated	0	0.5 HN	7
2029	56/M	Screen	09JUL2018	UB mentholated	0.1	0.1	1
		End Of Study	05SEP2018	UB mentholated	0	0.2	2
2039	49/F	Screen	13JUL2018	VLN mentholated	0	0.1	1
		End Of Study	05SEP2018	VLN mentholated	0	0.1	2
2050	57/M	Screen	20JUL2018	UB mentholated	0	0.1	2
		End Of Study	20SEP2018	UB mentholated	0.1	0.2	3

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	----- Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2052	54/M	Screen	20JUL2018	VLN mentholated	0	0.1	1
		End Of Study	20SEP2018	VLN mentholated	0	0.2	3
2057	52/M	Screen	23JUL2018	VLN mentholated	0	0.1	1
		End Of Study	20SEP2018	VLN mentholated	0	0.2	2
2058	37/F	Screen	23JUL2018	VLN mentholated	0	0.1	1
		End Of Study	20SEP2018	VLN mentholated	0	0	1
2059	56/F	Screen	23JUL2018	UB mentholated	0	0.3	4
		End Of Study	20SEP2018	UB mentholated	0	0.3	6
2060	37/F	Screen	23JUL2018	VLN mentholated	0	0.3	3
		End Of Study	20SEP2018	VLN mentholated	0	0.2	4
2064	52/M	Screen	23JUL2018	VLN mentholated	0	0.4	3
		End Of Study	20SEP2018	VLN mentholated	0	0.3	4
2066	30/F	Screen	23JUL2018	VLN mentholated	0	0.4	6
		End Of Study	20SEP2018	VLN mentholated	0	0.5 HN	8
2067	52/M	Screen	23JUL2018	VLN non-mentholated	0	0.2	2
		End Of Study	20SEP2018	VLN non-mentholated	0	0.2	2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2075	34/M	Screen	30JUL2018	VLN mentholated	0.1	0.1	1
		End Of Study	22AUG2018	VLN mentholated	0	0.1	2
2076	42/M	Screen	30JUL2018	VLN mentholated	0	0.1	1
		End Of Study	14OCT2018	VLN mentholated	0	0.1	1
2086	36/M	Screen	03AUG2018	VLN non-mentholated	0	0.1	1
		End Of Study	01OCT2018	VLN non-mentholated	0	0	0
2088	39/F	Screen	03AUG2018	VLN mentholated	0	0.1	1
		End Of Study	14OCT2018	VLN mentholated	0	0.2	3
2092	50/F	Screen	06AUG2018	VLN mentholated	0.1	0.1	1
		End Of Study	14OCT2018	VLN mentholated	0	0.1	2
2099	52/M	Screen	09AUG2018	VLN non-mentholated	0	0.2	2
		End Of Study	14OCT2018	VLN non-mentholated	0	0.2	3
2100	48/F	Screen	09AUG2018	UB mentholated	0	0.3	4
		End Of Study	14OCT2018	UB mentholated	0	0.3	6
2108	60/F	Screen	13AUG2018	VLN non-mentholated	0	0.1	1
		End Of Study	14OCT2018	VLN non-mentholated	0	0.2	3

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2110	41/F	Screen	13AUG2018	UB mentholated	0	0.1	2
		End Of Study	20OCT2018	UB mentholated	0	0.2	3
2113	51/F	Screen	15AUG2018	VLN mentholated	0	0.1	1
2115	46/F	Screen	15AUG2018	VLN mentholated	0	0.1	2
2119	48/M	Screen	20AUG2018	VLN mentholated	0	0.3	3
		End Of Study	20OCT2018	VLN mentholated	0	0.3	3
2120	62/F	Screen	20AUG2018	VLN non-mentholated	0	0.3	3
		End Of Study	20OCT2018	VLN non-mentholated	0	0.2	3
2122	60/M	Screen	20AUG2018	UB non-mentholated	0	0.1	3
		End Of Study	20OCT2018	UB non-mentholated	0	0.1	2
2125	35/M	Screen	21AUG2018	UB mentholated	0	0.1	3
		End Of Study	20OCT2018	UB mentholated	0	0.1	2
2126	37/M	Screen	21AUG2018	VLN mentholated	0	0.3	3
		End Of Study	20OCT2018	VLN mentholated	0	0.2	3
2136	64/M	Screen	27AUG2018	VLN non-mentholated	0.1	0.3	4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2136	64/M	End Of Study	19OCT2018	VLN non-mentholated	0.1	0.2	2
2140	56/F	Screen	30AUG2018	UB non-mentholated	0	0.1	2
		End Of Study	06NOV2018	UB non-mentholated	0	0.1	2
2142	30/F	Screen	31AUG2018	VLN non-mentholated	0.1	0.3	3
		End Of Study	08OCT2018	VLN non-mentholated	0	0.1	1
2143	63/M	Screen	04SEP2018	VLN non-mentholated	0	0.4	4
		End Of Study	06NOV2018	VLN non-mentholated	0	0.4	4
2158	43/F	Screen	18SEP2018	UB non-mentholated	0	0.1	1
2159	37/M	Screen	19SEP2018	VLN non-mentholated	0	0.1	1
		Unscheduled	04OCT2018	VLN non-mentholated	0	0.1	2
		End Of Study	02DEC2018	VLN non-mentholated	0	0.1	1
2164	65/F	Screen	27SEP2018	VLN non-mentholated	0	0.2	2
		End Of Study	02DEC2018	VLN non-mentholated	0	0.2	2
2168	32/F	Screen	28SEP2018	VLN non-mentholated	0	0.2	2
		End Of Study	02DEC2018	VLN non-mentholated	0	0.2	2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2170	51/F	Screen	28SEP2018	UB non-mentholated	0	0.1	1
		End Of Study	02DEC2018	UB non-mentholated	0	0.1	1
2175	40/F	Screen	01OCT2018	UB mentholated	0	0.1	1
		End Of Study	02DEC2018	UB mentholated	0	0.2	2
2189	28/M	Screen	04OCT2018	VLN mentholated	0	0.1	2
		End Of Study	06NOV2018	VLN mentholated	0	0.1	3
2211	29/F	Screen	10OCT2018	VLN mentholated	0	0.1	1
		End Of Study	02DEC2018	VLN mentholated	0	0.1	2
2212	32/M	Screen	10OCT2018	UB mentholated	0	0	0
		End Of Study	02DEC2018	UB mentholated	0	0.1	1
2213	29/M	Screen	10OCT2018	VLN mentholated	0	0.3	4
		End Of Study	02DEC2018	VLN mentholated	0	0.3	6
2215	59/F	Screen	10OCT2018	UB mentholated	0	0.1	1
		End Of Study	02DEC2018	UB mentholated	0	0.1	2
2220	37/M	Screen	11OCT2018	VLN non-mentholated	0	0.1	2
		End Of Study	02DEC2018	VLN non-mentholated	0	0.1	2

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.3 Clinical Laboratory Report - Hematology (III of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Basophils	Absolute Eosinophils	Eosinophils
		----- Name	Date		001: 0-0.1 002: 0-0.2 (thou/uL)	001: 0-0.5 002: 0-0.4 (thou/uL)	001: 0.5-7.4 002: Not Estab. (%)
2235	26/F	Screen	19OCT2018	VLN mentholated	0	0.4	3
		End Of Study	16DEC2018	VLN mentholated	0	0.2	3
2244	31/M	Screen	25OCT2018	VLN non-mentholated	0	0.1	1
		End Of Study	16DEC2018	VLN non-mentholated	0	0.1	1
2247	28/M	Screen	06NOV2018	VLN mentholated	0	0.1	2
		End Of Study	28DEC2018	VLN mentholated	0	0.1	1
2251	27/M	Screen	09NOV2018	UB non-mentholated	0	1.1 HN	15
		End Of Study	19JAN2019	UB non-mentholated	0	0.9 HN	15
2257	55/F	Screen	14NOV2018	UB non-mentholated	0.1	0.1	1
		End Of Study	19JAN2019	UB non-mentholated	0.1	0.1	2
2259	49/M	Screen	14NOV2018	UB mentholated	0	0	1
		End Of Study	19JAN2019	UB mentholated	0	0.1	2
2269	48/M	Screen	26NOV2018	VLN mentholated	0	0.2	3
		End Of Study	19JAN2019	VLN mentholated	0	0.3	4
2272	37/M	Screen	28NOV2018	VLN mentholated	0	0	1
		End Of Study	19JAN2019	VLN mentholated	0	0.1	1

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes 001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)	Absolute Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
		Name	Date				
1001	59/F	Screen	02JUL2018	VLN non-mentholated	2.8	30.1	0.4
		End Of Study	07SEP2018	VLN non-mentholated	3.5 HN	28.4	0.5
1002	30/M	Screen	02JUL2018	VLN non-mentholated	1.7	29.1	0.2 LN
		End Of Study	07SEP2018	VLN non-mentholated	1.9	32	0.3
1003	38/M	Screen	03JUL2018	VLN mentholated	1.7	25.6	0.5
		End Of Study	07SEP2018	VLN mentholated	2.2	24.5	0.7
1007	37/M	Screen	12JUL2018	VLN non-mentholated	1.8	23.6	0.7
		End Of Study	07SEP2018	VLN non-mentholated	1.8	30.1	0.5
1008	48/M	Screen	12JUL2018	VLN mentholated	4.3 HR	62.2 HR	0.5
		Unscheduled	16JUL2018	VLN mentholated	4.9 HN	69.3 HN	0.3
		End Of Study	07SEP2018	VLN mentholated	5 HN	48.8 HN	0.5
1010	32/M	Screen	13JUL2018	UB mentholated	2.1	24.6	0.8
		End Of Study	06SEP2018	UB mentholated	2.6	32.3	0.4
1011	36/M	Screen	13JUL2018	UB non-mentholated	2.1	33.8	0.3
		End Of Study	06SEP2018	UB non-mentholated	2.4	36.2	0.4
1013	36/F	Screen	16JUL2018	VLN non-mentholated	2	26.2	0.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes 001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)	Absolute Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
		----- Name	Date					
1013	36/F	End Of	Study	14SEP2018	VLN non-mentholated	2.3	29.3	0.7
1014	36/F	Screen		16JUL2018	VLN mentholated	3	25.6	0.9
		End Of	Study	14SEP2018	VLN mentholated	2.7	29.4	0.7
1015	49/F	Screen		16JUL2018	VLN mentholated	2.4	37.5	0.4
		End Of	Study	14SEP2018	VLN mentholated	2.7	38.8	0.4
1016	54/M	Screen		16JUL2018	UB non-mentholated	1.4	21.9	0.8
		End Of	Study	13SEP2018	UB non-mentholated	1.4	23.9	0.9
1017	41/F	Screen		17JUL2018	UB mentholated	2.9	38.7	0.5
		End Of	Study	13SEP2018	UB mentholated	3.5 HN	40.9	0.4
1018	41/F	Screen		17JUL2018	VLN mentholated	2.3	27.8	0.4
		End Of	Study	15AUG2018	VLN mentholated	2.5	29.3	0.6
1019	30/M	Screen		17JUL2018	VLN non-mentholated	3.5 HN	31.5	0.8
		End Of	Study	14SEP2018	VLN non-mentholated	3.8 HN	41.8	0.7
1020	36/F	Screen		17JUL2018	VLN non-mentholated	1.8	23	0.4
		End Of	Study	14SEP2018	VLN non-mentholated	2.3	27	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
1021	49/F	Screen	17JUL2018	UB non-mentholated	3.1		36.8		0.5	
		End Of Study	13SEP2018	UB non-mentholated	3.6	HN	37.8		0.5	
1023	50/F	Screen	17JUL2018	VLN non-mentholated	2.6		28.3		0.4	
		End Of Study	14SEP2018	VLN non-mentholated	3		30.3		0.4	
1029	35/F	Screen	26JUL2018	VLN mentholated	2.5		29.3		0.5	
		End Of Study	11OCT2018	VLN mentholated	3.7	HN	37.8		0.3	
1032	53/F	Screen	13AUG2018	VLN mentholated	1.4		28.4		0.4	
		End Of Study	11OCT2018	VLN mentholated	1.6		38.4		0.3	
1034	45/M	Screen	13AUG2018	VLN non-mentholated	2.3		22.4		0.7	
		End Of Study	10OCT2018	VLN non-mentholated	3.2		35.1		0.7	
1035	44/M	Screen	13AUG2018	VLN non-mentholated	2.2		32.8		0.6	
		End Of Study	11OCT2018	VLN non-mentholated	2.6		42		0.3	
1036	38/F	Screen	13AUG2018	UB mentholated	1.1		24.2		0.3	
		End Of Study	10OCT2018	UB mentholated	1.8		32.7		0.3	
1037	29/M	Screen	13AUG2018	UB mentholated	2.4		39.6		0.4	
		End Of Study	10OCT2018	UB mentholated	2.9		39.2		0.6	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes	Lymphocytes	Absolute Monocytes
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	001: 15.8-45.8 002: Not Estab. (%)	001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
1038	39/F	Screen	13AUG2018	VLN non-mentholated	2	31.2	0.3
		End Of Study	11OCT2018	VLN non-mentholated	2.6	30.4	0.5
1042	47/M	Screen	13AUG2018	VLN non-mentholated	1.9	21.8	0.6
		End Of Study	11OCT2018	VLN non-mentholated	1.5	14.4 LN	0.7
1045	58/M	Screen	14AUG2018	UB non-mentholated	2.8	35.5	0.4
		End Of Study	10OCT2018	UB non-mentholated	2.4	24.5	0.9
1046	45/M	Screen	14AUG2018	UB mentholated	2.8	31.9	0.7
		End Of Study	10OCT2018	UB mentholated	3.4 HN	35	0.6
1050	33/F	Screen	14AUG2018	VLN non-mentholated	2	28.2	0.4
		End Of Study	10OCT2018	VLN non-mentholated	2	33.9	0.3
1051	36/F	Screen	14AUG2018	UB mentholated	3.3 HN	26	0.7
		End Of Study	10OCT2018	UB mentholated	4.3 HN	33.9	0.8
1052	31/M	Screen	14AUG2018	VLN mentholated	1.5	29.4	0.3
		End Of Study	11OCT2018	VLN mentholated	1.4	34.4	0.2 LN
1053	42/M	Screen	14AUG2018	VLN mentholated	2.7	27.5	0.6
		End Of Study	11OCT2018	VLN mentholated	2.7	25.3	0.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
1054	56/M	Screen	14AUG2018	UB non-mentholated	3		31.4		1	HN
		End Of Study	10OCT2018	UB non-mentholated	3.5	HN	31.7		0.8	
1055	39/F	Screen	14AUG2018	VLN mentholated	2.5		28.7		0.5	
		End Of Study	11OCT2018	VLN mentholated	2.9		31.5		0.5	
1056	48/M	Screen	14AUG2018	VLN non-mentholated	2.3		26.2		0.6	
		End Of Study	11OCT2018	VLN non-mentholated	2		23		0.8	
1058	30/M	Screen	15AUG2018	VLN non-mentholated	1.9		27.8		0.5	
		End Of Study	11OCT2018	VLN non-mentholated	2.2		33.2		0.4	
1059	38/M	Screen	27AUG2018	UB non-mentholated	2.6		29.1		0.4	
		End Of Study	24OCT2018	UB non-mentholated	3.4	HN	46.6	HN	0.5	
1060	55/M	Screen	27AUG2018	VLN mentholated	2.1		37.2		0.4	
		End Of Study	24OCT2018	VLN mentholated	3.1		43.2		0.7	
1063	31/M	Screen	27AUG2018	VLN mentholated	1.4		22		0.6	
		End Of Study	25OCT2018	VLN mentholated	2		24.2		0.7	
1064	34/M	Screen	27AUG2018	UB non-mentholated	3.2		39.8		0.5	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Absolute Monocytes
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)	
1066	62/M	Screen	27AUG2018	VLN non-mentholated	0.9 LN	22.5	0.5
		End Of Study	24OCT2018	VLN non-mentholated	1.4	39.6	0.3
1069	40/F	Screen	28AUG2018	UB non-mentholated	2.7	22.6	0.8
		End Of Study	24OCT2018	UB non-mentholated	3.2	24.3	0.9
1070	53/M	Screen	28AUG2018	VLN non-mentholated	1.8	23.6	0.5
		End Of Study	24OCT2018	VLN non-mentholated	2.2	30.7	0.5
1071	42/M	Screen	28AUG2018	VLN non-mentholated	3.2	36.4	0.5
1072	59/M	Screen	28AUG2018	VLN mentholated	3.8 HN	37.9	0.7
		End Of Study	22OCT2018	VLN mentholated	4.1 HN	36.5	0.7
1074	42/M	Screen	28AUG2018	VLN non-mentholated	2.8	29.2	0.4
		End Of Study	24OCT2018	VLN non-mentholated	3.3 HN	36.3	0.5
1075	26/F	Screen	29AUG2018	UB non-mentholated	1.4	27.9	0.4
		End Of Study	24OCT2018	UB non-mentholated	2.1	31	0.4
1077	49/F	Screen	28AUG2018	VLN non-mentholated	3.1	34.5	0.5
		End Of Study	24OCT2018	VLN non-mentholated	4.3 HR	55.9 HN	0.4
		Unscheduled	24NOV2018	VLN non-mentholated	3.7 HN		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes	Lymphocytes	Absolute Monocytes
		----- Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uLi)	001: 15.8-45.8 002: Not Estab. (%)	001: 0.3-0.9 002: 0.1-0.9 (thou/uLi)
1078	51/F	Screen	28AUG2018	VLN non-mentholated	2.4	26.3	0.6
		End Of Study	24OCT2018	VLN non-mentholated	2.6	30.8	0.5
1079	33/M	Screen	29AUG2018	VLN mentholated	2.3	25.1	0.7
		End Of Study	24OCT2018	VLN mentholated	2.8	27.1	1 HN
1082	37/M	Screen	30AUG2018	VLN non-mentholated	2.8	32.1	0.8
		End Of Study	24OCT2018	VLN non-mentholated	3	41	0.6
1083	54/F	Screen	04SEP2018	VLN non-mentholated	3.2	33	0.5
		End Of Study	31OCT2018	VLN non-mentholated	4.4 HR	52.8 HN	0.5
		Unscheduled	06NOV2018	VLN non-mentholated	3.6 HN		
1084	42/M	Screen	04SEP2018	VLN non-mentholated	2	22.7	0.9
1086	54/M	Screen	04SEP2018	VLN non-mentholated	2.9	29.1	0.5
		End Of Study	31OCT2018	VLN non-mentholated	2.9	34.5	0.6
1088	26/M	Screen	04SEP2018	VLN mentholated	2	27.6	0.5
		End Of Study	31OCT2018	VLN mentholated	2.9	37.4	0.5
1089	60/F	Screen	04SEP2018	UB non-mentholated	3	44.3	0.4
		End Of Study	31OCT2018	UB non-mentholated	4.3 HR	49.8 HN	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		----- Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
1089	60/F	Unscheduled	09NOV2018	UB non-mentholated	3.4	HN				
1092	43/F	Screen	05SEP2018	VLN mentholated	2.5		40.3		0.3	
		End Of Study	31OCT2018	VLN mentholated	3.3	HN	49.5	HN	0.3	
1094	46/M	Screen	05SEP2018	VLN mentholated	2.1		33.4		0.4	
		End Of Study	31OCT2018	VLN mentholated	2		35.3		0.3	
1095	55/F	Screen	07SEP2018	VLN mentholated	3.5	HN	37.6		0.5	
		End Of Study	31OCT2018	VLN mentholated	4.1	HR	58.6	HR	0.4	
		Unscheduled	09NOV2018	VLN mentholated	3.9	HN	52.1	HN		
1096	42/F	Screen	07SEP2018	VLN non-mentholated	1.9		23.1		0.6	
		End Of Study	31OCT2018	VLN non-mentholated	2.6		31.8		0.7	
1097	30/M	Screen	07SEP2018	VLN mentholated	2.1		25		0.9	
		End Of Study	31OCT2018	VLN mentholated	2.7		31.5		1.4	HN
1098	63/M	Screen	18SEP2018	VLN non-mentholated	2		27.1		0.6	
		End Of Study	16NOV2018	VLN non-mentholated	2.2		30.4		0.9	
1099	46/F	Screen	18SEP2018	VLN non-mentholated	2.5		28.8		0.7	
		End Of Study	16NOV2018	VLN non-mentholated	3.3	HN	38.7		0.8	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
1100	59/M	Screen	18SEP2018	VLN non-mentholated	3.2		34.6		0.7	
		End Of Study	16NOV2018	VLN non-mentholated	3.7	HN	42.8		0.6	
1101	41/M	Screen	18SEP2018	VLN non-mentholated	1.9		24		0.8	
		End Of Study	16NOV2018	VLN non-mentholated	2.3		33.8		0.8	
1103	43/M	Screen	18SEP2018	VLN non-mentholated	2.3		27.4		0.7	
		End Of Study	16NOV2018	VLN non-mentholated	3		38		0.6	
1105	47/F	Screen	19SEP2018	VLN non-mentholated	2.9		22.4		0.7	
		End Of Study	16NOV2018	VLN non-mentholated	3.2		45.6		0.6	
1106	42/M	Screen	19SEP2018	UB non-mentholated	1.7		16.6		0.9	
		End Of Study	16NOV2018	UB non-mentholated	3.1		31.4		0.6	
1107	45/M	Screen	21SEP2018	VLN non-mentholated	2.3		18.6		0.7	
		Unscheduled	25SEP2018	VLN non-mentholated	2.5		22.7		1	HN
		End Of Study	16NOV2018	VLN non-mentholated	3.9	HN	32.2		0.9	
1108	54/M	Screen	21SEP2018	UB non-mentholated	1.8		29.8		0.5	
		End Of Study	16NOV2018	UB non-mentholated	2.3		34.9		0.6	
1109	58/M	Screen	21SEP2018	UB non-mentholated	1.9		16.7		0.5	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes	Lymphocytes	Absolute Monocytes
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	001: 15.8-45.8 002: Not Estab. (%)	001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
1109	58/M	Unscheduled	25SEP2018	UB non-mentholated	1.3	16.2	0.4
		End Of Study	16NOV2018	UB non-mentholated	3.3 HN	33.5	0.5
1112	59/F	Screen	21SEP2018	VLN non-mentholated	1.9	25.7	0.4
		End Of Study	16NOV2018	VLN non-mentholated	2.4	45.1	0.5
1114	26/F	Screen	24SEP2018	UB non-mentholated	2.7	37.1	0.6
		End Of Study	16NOV2018	UB non-mentholated	2	21	0.7
1115	29/M	Screen	24SEP2018	VLN non-mentholated	2.1	27.4	0.7
2002	49/M	Screen	29JUN2018	UB mentholated	1.6	27	0.5
		End Of Study	05SEP2018	UB mentholated	1.7	29	0.6
2003	41/F	Screen	29JUN2018	VLN mentholated	2.3	27	0.5
		End Of Study	29AUG2018	VLN mentholated	2.5	36	0.6
2007	57/F	Screen	29JUN2018	VLN non-mentholated	2	29	0.4
		End Of Study	29AUG2018	VLN non-mentholated	1.5	30	0.4
2008	42/M	Screen	06JUL2018	VLN mentholated	1.4	22	0.6
		End Of Study	29AUG2018	VLN mentholated	1.8	41	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
2009	55/M	Screen	29JUN2018	VLN non-mentholated	3.1		36		0.7	
2010	27/M	Screen	29JUN2018	UB mentholated	2.9		37		0.6	
		End Of Study	29AUG2018	UB mentholated	2.5		33		0.6	
2011	32/F	Screen	29JUN2018	VLN mentholated	2.7		39		0.4	
		End Of Study	29AUG2018	VLN mentholated	1.8		35		0.4	
2014	37/M	Screen	02JUL2018	VLN mentholated	2.4		31		0.4	
		End Of Study	29AUG2018	VLN mentholated	2.2		34		0.5	
2015	57/F	Screen	02JUL2018	UB mentholated	4.8 HN		47		0.5	
		End Of Study	29AUG2018	UB mentholated	4.2 HN		47		0.3	
2016	45/F	Screen	02JUL2018	VLN mentholated	2.8		48		0.2	
		End Of Study	03AUG2018	VLN mentholated	2.8		44		0.3	
2017	30/M	Screen	02JUL2018	VLN mentholated	2.4		30		0.4	
		End Of Study	29AUG2018	VLN mentholated	4.5 HN		48		0.5	
2018	26/F	Screen	02JUL2018	UB mentholated	2.2		34		0.3	
		End Of Study	29AUG2018	UB mentholated	1.9		36		0.3	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes 001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)	Absolute Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
		Name	Date				
2020	60/F	Screen	02JUL2018	VLN mentholated	2.3	37	0.3
		End Of Study	29AUG2018	VLN mentholated	2.5	46	0.4
2021	31/M	Screen	02JUL2018	VLN mentholated	1.7	39	0.3
		End Of Study	29AUG2018	VLN mentholated	2.7	51	0.4
2023	35/M	Screen	02JUL2018	VLN mentholated	2.1	33	0.6
		End Of Study	29AUG2018	VLN mentholated	2.6	37	0.7
2024	26/M	Screen	03JUL2018	UB non-mentholated	1.7	25	0.5
2025	59/M	Screen	03JUL2018	UB non-mentholated	1.4	21	0.5
		End Of Study	29AUG2018	UB non-mentholated	1.6	27	0.4
2028	36/M	Screen	06JUL2018	VLN non-mentholated	2.1	19	0.7
		End Of Study	29AUG2018	VLN non-mentholated	1.7	24	0.6
2029	56/M	Screen	09JUL2018	UB mentholated	3.1	31	0.8
		End Of Study	05SEP2018	UB mentholated	3.1	33	0.8
2039	49/F	Screen	13JUL2018	VLN mentholated	3	42	0.3
		End Of Study	05SEP2018	VLN mentholated	2.6	41	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
2050	57/M	Screen	20JUL2018	UB mentholated	2.2		32		0.4	
		End Of Study	20SEP2018	UB mentholated	1.8		34		0.4	
2052	54/M	Screen	20JUL2018	VLN mentholated	1		16		0.7	
		End Of Study	20SEP2018	VLN mentholated	1.2		24		0.5	
2057	52/M	Screen	23JUL2018	VLN mentholated	1.7		23		0.7	
		End Of Study	20SEP2018	VLN mentholated	1.5		21		0.8	
2058	37/F	Screen	23JUL2018	VLN mentholated	2.5		57		0.3	
		End Of Study	20SEP2018	VLN mentholated	2.5		64		0.3	
2059	56/F	Screen	23JUL2018	UB mentholated	3.7 HN		53		0.4	
		End Of Study	20SEP2018	UB mentholated	3		56		0.4	
2060	37/F	Screen	23JUL2018	VLN mentholated	1.4		14		0.8	
		End Of Study	20SEP2018	VLN mentholated	1.1		24		0.4	
2064	52/M	Screen	23JUL2018	VLN mentholated	2.7		24		0.8	
		End Of Study	20SEP2018	VLN mentholated	2.3		25		0.8	
2066	30/F	Screen	23JUL2018	VLN mentholated	3		41		0.6	
		End Of Study	20SEP2018	VLN mentholated	2.8		41		0.6	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes 001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)	Absolute Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
		Name	Date				
2067	52/M	Screen	23JUL2018	VLN non-mentholated	2.4	34	0.6
		End Of Study	20SEP2018	VLN non-mentholated	2.8	27	0.7
2075	34/M	Screen	30JUL2018	VLN mentholated	1.7	28	0.6
		End Of Study	22AUG2018	VLN mentholated	2.2	32	0.8
2076	42/M	Screen	30JUL2018	VLN mentholated	2	26	0.6
		End Of Study	14OCT2018	VLN mentholated	1.8	27	0.6
2086	36/M	Screen	03AUG2018	VLN non-mentholated	2.1	23	0.6
		End Of Study	01OCT2018	VLN non-mentholated	2.2	31	0.6
2088	39/F	Screen	03AUG2018	VLN mentholated	3	39	0.3
		End Of Study	14OCT2018	VLN mentholated	2.4	37	0.3
2092	50/F	Screen	06AUG2018	VLN mentholated	1.7	27	0.5
		End Of Study	14OCT2018	VLN mentholated	1.5	26	0.4
2099	52/M	Screen	09AUG2018	VLN non-mentholated	1.1	15	0.6
		End Of Study	14OCT2018	VLN non-mentholated	1	15	0.5
2100	48/F	Screen	09AUG2018	UB mentholated	2	34	0.3
		End Of Study	14OCT2018	UB mentholated	1.7	30	0.4

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	001: 15.8-45.8 002: Not Estab. (%)	001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
2108	60/F	Screen	13AUG2018	VLN non-mentholated	2.6	28	0.8	
		End Of Study	14OCT2018	VLN non-mentholated	1.8	22	0.6	
2110	41/F	Screen	13AUG2018	UB mentholated	3.2 HN	38	0.5	
		End Of Study	20OCT2018	UB mentholated	2.9	45	0.5	
2113	51/F	Screen	15AUG2018	VLN mentholated	3.4 HN	44	0.4	
2115	46/F	Screen	15AUG2018	VLN mentholated	3.5 HN	48	0.4	
2119	48/M	Screen	20AUG2018	VLN mentholated	2.3	23	0.8	
		End Of Study	20OCT2018	VLN mentholated	1.8	24	0.4	
2120	62/F	Screen	20AUG2018	VLN non-mentholated	2.8	33	0.6	
		End Of Study	20OCT2018	VLN non-mentholated	2.6	33	0.5	
2122	60/M	Screen	20AUG2018	UB non-mentholated	1	33	0.3	
		End Of Study	20OCT2018	UB non-mentholated	1.4	40	0.2	
2125	35/M	Screen	21AUG2018	UB mentholated	1.6	39	0.4	
		End Of Study	20OCT2018	UB mentholated	1.5	37	0.5	
2126	37/M	Screen	21AUG2018	VLN mentholated	3.5 HN	45	0.5	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes	Lymphocytes	Absolute
		----- Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	001: 15.8-45.8 002: Not Estab. (%)	Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
2126	37/M	End Of Study	20OCT2018	VLN mentholated	3.8 HN	53	0.5
2136	64/M	Screen	27AUG2018	VLN non-mentholated	1.8	25	0.5
		End Of Study	19OCT2018	VLN non-mentholated	2.2	30	0.3
2140	56/F	Screen	30AUG2018	UB non-mentholated	2.9	45	0.5
		End Of Study	06NOV2018	UB non-mentholated	2.7	45	0.5
2142	30/F	Screen	31AUG2018	VLN non-mentholated	2.6	27	0.4
		End Of Study	08OCT2018	VLN non-mentholated	1.8	21	0.4
2143	63/M	Screen	04SEP2018	VLN non-mentholated	2.3	24	0.6
		End Of Study	06NOV2018	VLN non-mentholated	2	20	0.6
2158	43/F	Screen	18SEP2018	UB non-mentholated	2	29	0.6
2159	37/M	Screen	19SEP2018	VLN non-mentholated	2.1	16	0.6
		Unscheduled	04OCT2018	VLN non-mentholated	1.8	27	0.5
		End Of Study	02DEC2018	VLN non-mentholated	1.9	26	0.4
2164	65/F	Screen	27SEP2018	VLN non-mentholated	4.4 HN	55	0.6
		End Of Study	02DEC2018	VLN non-mentholated	3.4 HN	47	0.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit -----		Product Group	Absolute Lymphocytes 001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		Lymphocytes 001: 15.8-45.8 002: Not Estab. (%)		Absolute Monocytes 001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
		Name	Date							
2168	32/F	Screen	28SEP2018	VLN non-mentholated	3.2	HN	32		0.5	
		End Of Study	02DEC2018	VLN non-mentholated	3.5	HN	39		0.3	
2170	51/F	Screen	28SEP2018	UB non-mentholated	1.9		25		0.5	
		End Of Study	02DEC2018	UB non-mentholated	1.5		15		0.7	
2175	40/F	Screen	01OCT2018	UB mentholated	3.4	HN	39		0.5	
		End Of Study	02DEC2018	UB mentholated	3.2	HN	35		0.6	
2189	28/M	Screen	04OCT2018	VLN mentholated	1.2		22		0.6	
		End Of Study	06NOV2018	VLN mentholated	1.1		31		0.4	
2211	29/F	Screen	10OCT2018	VLN mentholated	2		40		0.4	
		End Of Study	02DEC2018	VLN mentholated	2.8		50		0.2	
2212	32/M	Screen	10OCT2018	UB mentholated	2.8		36		0.5	
		End Of Study	02DEC2018	UB mentholated	2.1		31		0.4	
2213	29/M	Screen	10OCT2018	VLN mentholated	2		26		0.5	
		End Of Study	02DEC2018	VLN mentholated	1.5		28		0.4	
2215	59/F	Screen	10OCT2018	UB mentholated	3.6	HN	44		0.6	
		End Of Study	02DEC2018	UB mentholated	2.8		45		0.3	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes		Lymphocytes		Absolute Monocytes	
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)		001: 15.8-45.8 002: Not Estab. (%)		001: 0.3-0.9 002: 0.1-0.9 (thou/uL)	
2220	37/M	Screen	11OCT2018	VLN non-mentholated	2.5		47		0.5	
		End Of Study	02DEC2018	VLN non-mentholated	2		36		0.5	
2235	26/F	Screen	19OCT2018	VLN mentholated	4.3 HN		37		0.7	
		End Of Study	16DEC2018	VLN mentholated	3.4 HN		37		0.5	
2244	31/M	Screen	25OCT2018	VLN non-mentholated	3.3 HN		36		0.7	
		End Of Study	16DEC2018	VLN non-mentholated	3.6 HN		37		0.7	
2247	28/M	Screen	06NOV2018	VLN mentholated	2.7		37		0.5	
		End Of Study	28DEC2018	VLN mentholated	2.6		35		0.4	
2251	27/M	Screen	09NOV2018	UB non-mentholated	3		42		0.5	
		End Of Study	19JAN2019	UB non-mentholated	2.2		36		0.6	
2257	55/F	Screen	14NOV2018	UB non-mentholated	3.1		36		0.6	
		End Of Study	19JAN2019	UB non-mentholated	2.5		38		0.7	
2259	49/M	Screen	14NOV2018	UB mentholated	2		39		0.6	
		End Of Study	19JAN2019	UB mentholated	2.1		46		0.5	
2269	48/M	Screen	26NOV2018	VLN mentholated	3.1		44		0.5	
		End Of Study	19JAN2019	VLN mentholated	2.8		47		0.5	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.4 Clinical Laboratory Report - Hematology (IV of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Absolute Lymphocytes	Lymphocytes	Absolute Monocytes
		Name	Date		001: 1.1-3.2 002: 0.7-3.1 (thou/uL)	001: 15.8-45.8 002: Not Estab. (%)	001: 0.3-0.9 002: 0.1-0.9 (thou/uL)
2272	37/M	Screen	28NOV2018	VLN mentholated	1.8	45	0.3
		End Of Study	19JAN2019	VLN mentholated	2.5	50	0.6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes		Absolute Neutrophils		Neutrophils	
		Name	Date		001: 4.9-12.8 002: Not Estab. (%)		001: 1.6-7.7 002: 1.4-7 (thou/uL)		001: 38.4-74.2 002: Not Estab. (%)	
1001	59/F	Screen	02JUL2018	VLN non-mentholated	4.2	LN	5.9		63.6	
		End Of Study	07SEP2018	VLN non-mentholated	4.4	LN	7.9	HN	65.2	
1002	30/M	Screen	02JUL2018	VLN non-mentholated	4.1	LN	3.7		62.6	
		End Of Study	07SEP2018	VLN non-mentholated	5.3		3.5		59.1	
1003	38/M	Screen	03JUL2018	VLN mentholated	6.9		4		61.5	
		End Of Study	07SEP2018	VLN mentholated	8.3		5.1		57.6	
1007	37/M	Screen	12JUL2018	VLN non-mentholated	9.2		4.7		63.4	
		End Of Study	07SEP2018	VLN non-mentholated	8.2		3.5		56.9	
1008	48/M	Screen	12JUL2018	VLN mentholated	6.5		2		29.1	LR
		Unscheduled	16JUL2018	VLN mentholated	4.9		1.7		24.1	LN
		End Of Study	07SEP2018	VLN mentholated	4.6	LN	4.6		44.9	
1010	32/M	Screen	13JUL2018	UB mentholated	8.9		5.4		62.3	
		End Of Study	06SEP2018	UB mentholated	4.9		4.8		58	
1011	36/M	Screen	13JUL2018	UB non-mentholated	5.2		3.6		56.5	
		End Of Study	06SEP2018	UB non-mentholated	6.1		3.6		53.7	
1013	36/F	Screen	16JUL2018	VLN non-mentholated	6		4.8		64.2	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1013	36/F	End Of Study	14SEP2018	VLN non-mentholated	8.7	4.3	56.3
1014	36/F	Screen	16JUL2018	VLN mentholated	7.2	7.5	64
		End Of Study	14SEP2018	VLN mentholated	7.8	5.5	60
1015	49/F	Screen	16JUL2018	VLN mentholated	5.8	3.5	54.9
		End Of Study	14SEP2018	VLN mentholated	5.9	3.6	52.7
1016	54/M	Screen	16JUL2018	UB non-mentholated	12.3	3.8	60.1
		End Of Study	13SEP2018	UB non-mentholated	15.2 HN	3.2	55.2
1017	41/F	Screen	17JUL2018	UB mentholated	6.4	3.9	52.4
		End Of Study	13SEP2018	UB mentholated	5.2	4.4	51.5
1018	41/F	Screen	17JUL2018	VLN mentholated	4.6 LN	5.4	65.9
		End Of Study	15AUG2018	VLN mentholated	6.8	5.2	61
1019	30/M	Screen	17JUL2018	VLN non-mentholated	6.9	6.7	59.9
		End Of Study	14SEP2018	VLN non-mentholated	7.8	4.2	47.1
1020	36/F	Screen	17JUL2018	VLN non-mentholated	4.4 LN	5.6	70.3
		End Of Study	14SEP2018	VLN non-mentholated	4.4 LN	5.4	65

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1021	49/F	Screen	17JUL2018	UB non-mentholated	6.3	4.5	54.4
		End Of Study	13SEP2018	UB non-mentholated	5.4	5.1	53.4
1023	50/F	Screen	17JUL2018	VLN non-mentholated	4.5 LN	5.9	65.6
		End Of Study	14SEP2018	VLN non-mentholated	4.3 LN	6.1	62.8
1029	35/F	Screen	26JUL2018	VLN mentholated	5.3	5.3	62.6
		End Of Study	11OCT2018	VLN mentholated	3.2 LN	5.5	56.8
1032	53/F	Screen	13AUG2018	VLN mentholated	8.1	3.1	61.1
		End Of Study	11OCT2018	VLN mentholated	7.3	2.1	51.9
1034	45/M	Screen	13AUG2018	VLN non-mentholated	6.4	6.6	64.4
		End Of Study	10OCT2018	VLN non-mentholated	8	4.2	47.2
1035	44/M	Screen	13AUG2018	VLN non-mentholated	8.1	3.7	55.4
		End Of Study	11OCT2018	VLN non-mentholated	5.2	3	49.5
1036	38/F	Screen	13AUG2018	UB mentholated	7.4	3.1	66
		End Of Study	10OCT2018	UB mentholated	6.1	3.3	58.7
1037	29/M	Screen	13AUG2018	UB mentholated	7.1	3.1	51.4
		End Of Study	10OCT2018	UB mentholated	8.2	3.8	50.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1038	39/F	Screen	13AUG2018	VLN non-mentholated	5.2	3.8	59.7
		End Of Study	11OCT2018	VLN non-mentholated	5.8	5.2	60.4
1042	47/M	Screen	13AUG2018	VLN non-mentholated	6.3	6.1	69.2
		End Of Study	11OCT2018	VLN non-mentholated	7.1	7.8 HN	77.1 HN
1045	58/M	Screen	14AUG2018	UB non-mentholated	5	4.5	56.3
		End Of Study	10OCT2018	UB non-mentholated	9.4	6.3	64.4
1046	45/M	Screen	14AUG2018	UB mentholated	7.9	5.1	58
		End Of Study	10OCT2018	UB mentholated	6.4	5.4	56.5
1050	33/F	Screen	14AUG2018	VLN non-mentholated	5.6	4.3	62.5
		End Of Study	10OCT2018	VLN non-mentholated	5.4	3.3	56.3
1051	36/F	Screen	14AUG2018	UB mentholated	5.7	8.3 HN	64.9
		End Of Study	10OCT2018	UB mentholated	6.2	6.9	55.3
1052	31/M	Screen	14AUG2018	VLN mentholated	6.4	3	59.4
		End Of Study	11OCT2018	VLN mentholated	4.3 LN	2.4	56.5
1053	42/M	Screen	14AUG2018	VLN mentholated	6	6.3	65.6
		End Of Study	11OCT2018	VLN mentholated	4.4 LN	7.3	68.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1054	56/M	Screen	14AUG2018	UB non-mentholated	10.5	5.2	54.5
		End Of Study	10OCT2018	UB non-mentholated	7.6	6.2	56.7
1055	39/F	Screen	14AUG2018	VLN mentholated	5.8	5.5	63.7
		End Of Study	11OCT2018	VLN mentholated	6	5.5	60.7
1056	48/M	Screen	14AUG2018	VLN non-mentholated	6.8	5.8	65.2
		End Of Study	11OCT2018	VLN non-mentholated	9.7	5.4	62.9
1058	30/M	Screen	15AUG2018	VLN non-mentholated	7.6	4.2	61.1
		End Of Study	11OCT2018	VLN non-mentholated	6.4	3.8	56.8
1059	38/M	Screen	27AUG2018	UB non-mentholated	4.4 LN	5.7	64.9
		End Of Study	24OCT2018	UB non-mentholated	6.5	3.2	45.1
1060	55/M	Screen	27AUG2018	VLN mentholated	7.7	2.9	52.4
		End Of Study	24OCT2018	VLN mentholated	9.3	3.2	45.2
1063	31/M	Screen	27AUG2018	VLN mentholated	9.3	4.1	62.7
		End Of Study	25OCT2018	VLN mentholated	8.7	5.1	62.4
1064	34/M	Screen	27AUG2018	UB non-mentholated	5.8	4.2	51.6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1066	62/M	Screen	27AUG2018	VLN non-mentholated	13 HN	2.2	57.6
		End Of Study	24OCT2018	VLN non-mentholated	9.3	1.6	43.5
1069	40/F	Screen	28AUG2018	UB non-mentholated	6.7	8.2 HN	68.7
		End Of Study	24OCT2018	UB non-mentholated	7	8.6 HR	66.4
		Unscheduled	06NOV2018	UB non-mentholated		6.8	
1070	53/M	Screen	28AUG2018	VLN non-mentholated	7.1	4.8	63.5
		End Of Study	24OCT2018	VLN non-mentholated	6.6	4	54.5
1071	42/M	Screen	28AUG2018	VLN non-mentholated	5.8	4.9	55.7
1072	59/M	Screen	28AUG2018	VLN mentholated	7	5.5	54.2
		End Of Study	22OCT2018	VLN mentholated	6.1	6.4	56.3
1074	42/M	Screen	28AUG2018	VLN non-mentholated	4.3 LN	6	62.5
		End Of Study	24OCT2018	VLN non-mentholated	5.6	4.8	53.2
1075	26/F	Screen	29AUG2018	UB non-mentholated	7.3	3.1	61.6
		End Of Study	24OCT2018	UB non-mentholated	5.8	4.1	61.1
1077	49/F	Screen	28AUG2018	VLN non-mentholated	5.4	4.9	55.9
		End Of Study	24OCT2018	VLN non-mentholated	5.7	2.5	31.8 LR

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes		Absolute Neutrophils		Neutrophils	
		Name	Date		001: 4.9-12.8	002: Not Estab. (%)	001: 1.6-7.7	002: 1.4-7 (thou/uL)	001: 38.4-74.2	002: Not Estab. (%)
1077	49/F	Unscheduled	24NOV2018	VLN non-mentholated						44.4
1078	51/F	Screen	28AUG2018	VLN non-mentholated		7		5.8		64.1
		End Of Study	24OCT2018	VLN non-mentholated		6		5.2		61.4
1079	33/M	Screen	29AUG2018	VLN mentholated		7.7		5.7		61.8
		End Of Study	24OCT2018	VLN mentholated		9.5		5.3		51.8
1082	37/M	Screen	30AUG2018	VLN non-mentholated		8.7		5		57.1
		End Of Study	24OCT2018	VLN non-mentholated		8.1		3.6		48.6
1083	54/F	Screen	04SEP2018	VLN non-mentholated		5.2		5.4		55.9
		End Of Study	31OCT2018	VLN non-mentholated		5.9		2.9		35.5 LN
1084	42/M	Screen	04SEP2018	VLN non-mentholated		10.2		5.7		63.7
1086	54/M	Screen	04SEP2018	VLN non-mentholated		4.5 LN		6.4		64.8
		End Of Study	31OCT2018	VLN non-mentholated		6.9		4.8		56.3
1088	26/M	Screen	04SEP2018	VLN mentholated		6.9		4.6		63.6
		End Of Study	31OCT2018	VLN mentholated		6.5		4.2		54.4
1089	60/F	Screen	04SEP2018	UB non-mentholated		5.4		3.3		48.7

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		----- Name	----- Date				
1089	60/F	End Of Study	31OCT2018	UB non-mentholated	4.4 LN	3.8	43.6
1092	43/F	Screen	05SEP2018	VLN mentholated	4.6 LN	3.3	53.1
		End Of Study	31OCT2018	VLN mentholated	3.9 LN	2.9	43.5
1094	46/M	Screen	05SEP2018	VLN mentholated	5.8	3.6	58.8
		End Of Study	31OCT2018	VLN mentholated	4.5 LN	3.3	57.4
1095	55/F	Screen	07SEP2018	VLN mentholated	5.2	5.2	55.3
		End Of Study	31OCT2018	VLN mentholated	6.2	2.2	32.3 LR
		Unscheduled	09NOV2018	VLN mentholated			40.9
1096	42/F	Screen	07SEP2018	VLN non-mentholated	7.8	5.6	67.9
		End Of Study	31OCT2018	VLN non-mentholated	8.5	4.8	58.4
1097	30/M	Screen	07SEP2018	VLN mentholated	10.1	5.3	62.7
		End Of Study	31OCT2018	VLN mentholated	16.2 HN	4.2	49.9
1098	63/M	Screen	18SEP2018	VLN non-mentholated	8.3	4.4	61
		End Of Study	16NOV2018	VLN non-mentholated	11.9	3.9	53.5
1099	46/F	Screen	18SEP2018	VLN non-mentholated	8.4	4.6	53.9
		End Of Study	16NOV2018	VLN non-mentholated	9.9	4.1	47.9

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
1100	59/M	Screen	18SEP2018	VLN non-mentholated	7.8	5.1	54.4
		End Of Study	16NOV2018	VLN non-mentholated	7.2	3.9	46
1101	41/M	Screen	18SEP2018	VLN non-mentholated	9.7	4.9	63.2
		End Of Study	16NOV2018	VLN non-mentholated	11.5	3.5	52.8
1103	43/M	Screen	18SEP2018	VLN non-mentholated	8.6	5.2	62
		End Of Study	16NOV2018	VLN non-mentholated	7.4	4.1	51.3
1105	47/F	Screen	19SEP2018	VLN non-mentholated	5.3	9.4 HN	71.6
		End Of Study	16NOV2018	VLN non-mentholated	7.8	3.2	45.8
1106	42/M	Screen	19SEP2018	UB non-mentholated	9.1	7.4	72.3
		End Of Study	16NOV2018	UB non-mentholated	6.1	6	60.8
1107	45/M	Screen	21SEP2018	VLN non-mentholated	6	8.8 HR	72.6
		Unscheduled	25SEP2018	VLN non-mentholated	9	7	64
		End Of Study	16NOV2018	VLN non-mentholated	7.1	6.9	57.3
1108	54/M	Screen	21SEP2018	UB non-mentholated	8	3.6	60.4
		End Of Study	16NOV2018	UB non-mentholated	8.7	3.6	54.4
1109	58/M	Screen	21SEP2018	UB non-mentholated	4.8 LN	8.6 HR	77 HN

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes	Absolute Neutrophils	Neutrophils
		Name	Date		001: 4.9-12.8 002: Not Estab. (%)	001: 1.6-7.7 002: 1.4-7 (thou/uL)	001: 38.4-74.2 002: Not Estab. (%)
1109	58/M	Unscheduled	25SEP2018	UB non-mentholated	5.3	6.1	77 HN
		End Of Study	16NOV2018	UB non-mentholated	5.1	5.7	58.3
1112	59/F	Screen	21SEP2018	VLN non-mentholated	5.8	4.6	62.4
		End Of Study	16NOV2018	VLN non-mentholated	9.1	2.2	41.5
1114	26/F	Screen	24SEP2018	UB non-mentholated	8	3.6	48.7
		End Of Study	16NOV2018	UB non-mentholated	6.9	6.6	68.9
1115	29/M	Screen	24SEP2018	VLN non-mentholated	9.6	4.5	60.7
2002	49/M	Screen	29JUN2018	UB mentholated	8	3.8	64
		End Of Study	05SEP2018	UB mentholated	10	3.4	58
2003	41/F	Screen	29JUN2018	VLN mentholated	6	5.6	66
		End Of Study	29AUG2018	VLN mentholated	9	3.7	54
2007	57/F	Screen	29JUN2018	VLN non-mentholated	6	4.1	60
		End Of Study	29AUG2018	VLN non-mentholated	7	2.9	58
2008	42/M	Screen	06JUL2018	VLN mentholated	9	4.2	66
		End Of Study	29AUG2018	VLN mentholated	9	2	47

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2009	55/M	Screen	29JUN2018	VLN non-mentholated	8	4.4	51
2010	27/M	Screen	29JUN2018	UB mentholated	8	3.9	50
		End Of Study	29AUG2018	UB mentholated	8	4.3	55
2011	32/F	Screen	29JUN2018	VLN mentholated	6	3.7	53
		End Of Study	29AUG2018	VLN mentholated	8	2.9	55
2014	37/M	Screen	02JUL2018	VLN mentholated	5	4.8	63
		End Of Study	29AUG2018	VLN mentholated	8	3.6	55
2015	57/F	Screen	02JUL2018	UB mentholated	5	4.8	47
		End Of Study	29AUG2018	UB mentholated	3	4.2	47
2016	45/F	Screen	02JUL2018	VLN mentholated	4	2.6	45
		End Of Study	03AUG2018	VLN mentholated	5	3.1	49
2017	30/M	Screen	02JUL2018	VLN mentholated	6	4.9	63
		End Of Study	29AUG2018	VLN mentholated	6	4.1	44
2018	26/F	Screen	02JUL2018	UB mentholated	5	3.7	58
		End Of Study	29AUG2018	UB mentholated	6	2.9	55

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2020	60/F	Screen	02JUL2018	VLN mentholated	5	3.5	56
		End Of Study	29AUG2018	VLN mentholated	7	2.4	44
2021	31/M	Screen	02JUL2018	VLN mentholated	8	2.2	50
		End Of Study	29AUG2018	VLN mentholated	8	1.9	35
2023	35/M	Screen	02JUL2018	VLN mentholated	9	3.5	55
		End Of Study	29AUG2018	VLN mentholated	9	3.5	49
2024	26/M	Screen	03JUL2018	UB non-mentholated	7	4.6	65
2025	59/M	Screen	03JUL2018	UB non-mentholated	9	4.2	66
		End Of Study	29AUG2018	UB non-mentholated	8	3.4	59
2028	36/M	Screen	06JUL2018	VLN non-mentholated	6	7.4 HN	68
		End Of Study	29AUG2018	VLN non-mentholated	8	4.1	60
2029	56/M	Screen	09JUL2018	UB mentholated	8	5.7	59
		End Of Study	05SEP2018	UB mentholated	9	5.3	56
2039	49/F	Screen	13JUL2018	VLN mentholated	5	3.7	52
		End Of Study	05SEP2018	VLN mentholated	6	3.2	50

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2050	57/M	Screen	20JUL2018	UB mentholated	5	4.1	61
		End Of Study	20SEP2018	UB mentholated	7	3	55
2052	54/M	Screen	20JUL2018	VLN mentholated	11	4.5	71
		End Of Study	20SEP2018	VLN mentholated	11	3	62
2057	52/M	Screen	23JUL2018	VLN mentholated	10	4.7	65
		End Of Study	20SEP2018	VLN mentholated	11	4.7	65
2058	37/F	Screen	23JUL2018	VLN mentholated	7	1.5	34
		End Of Study	20SEP2018	VLN mentholated	9	1 LN	26
2059	56/F	Screen	23JUL2018	UB mentholated	5	2.6	38
		End Of Study	20SEP2018	UB mentholated	7	1.6	30
2060	37/F	Screen	23JUL2018	VLN mentholated	7	7.6 HN	75
		End Of Study	20SEP2018	VLN mentholated	9	2.9	63
2064	52/M	Screen	23JUL2018	VLN mentholated	7	7.3 HN	65
		End Of Study	20SEP2018	VLN mentholated	9	5.6	62
2066	30/F	Screen	23JUL2018	VLN mentholated	8	3.3	45
		End Of Study	20SEP2018	VLN mentholated	8	2.8	42

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2067	52/M	Screen	23JUL2018	VLN non-mentholated	9	3.9	55
		End Of Study	20SEP2018	VLN non-mentholated	7	6.6	63
2075	34/M	Screen	30JUL2018	VLN mentholated	9	3.7	60
		End Of Study	22AUG2018	VLN mentholated	12	3.7	54
2076	42/M	Screen	30JUL2018	VLN mentholated	7	5.1	66
		End Of Study	14OCT2018	VLN mentholated	9	4.1	62
2086	36/M	Screen	03AUG2018	VLN non-mentholated	7	6.2	69
		End Of Study	01OCT2018	VLN non-mentholated	8	4.2	60
2088	39/F	Screen	03AUG2018	VLN mentholated	4	4.3	55
		End Of Study	14OCT2018	VLN mentholated	5	3.5	55
2092	50/F	Screen	06AUG2018	VLN mentholated	8	4.1	63
		End Of Study	14OCT2018	VLN mentholated	8	3.6	64
2099	52/M	Screen	09AUG2018	VLN non-mentholated	8	5.2	74
		End Of Study	14OCT2018	VLN non-mentholated	8	4.8	73
2100	48/F	Screen	09AUG2018	UB mentholated	5	3.4	57
		End Of Study	14OCT2018	UB mentholated	7	3.2	58

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes	Absolute Neutrophils	Neutrophils
		----- Name	----- Date		001: 4.9-12.8 002: Not Estab. (%)	001: 1.6-7.7 002: 1.4-7 (thou/uL)	001: 38.4-74.2 002: Not Estab. (%)
2108	60/F	Screen	13AUG2018	VLN non-mentholated	8	5.5	61
		End Of Study	14OCT2018	VLN non-mentholated	7	5.5	68
2110	41/F	Screen	13AUG2018	UB mentholated	6	4.5	53
		End Of Study	20OCT2018	UB mentholated	7	2.9	45
2113	51/F	Screen	15AUG2018	VLN mentholated	5	3.8	49
2115	46/F	Screen	15AUG2018	VLN mentholated	5	3.4	45
2119	48/M	Screen	20AUG2018	VLN mentholated	8	6.6	66
		End Of Study	20OCT2018	VLN mentholated	5	5.1	67
2120	62/F	Screen	20AUG2018	VLN non-mentholated	7	4.9	57
		End Of Study	20OCT2018	VLN non-mentholated	7	4.4	57
2122	60/M	Screen	20AUG2018	UB non-mentholated	9	1.7	54
		End Of Study	20OCT2018	UB non-mentholated	6	1.7	51
2125	35/M	Screen	21AUG2018	UB mentholated	11	1.9	47
		End Of Study	20OCT2018	UB mentholated	13	2	49
2126	37/M	Screen	21AUG2018	VLN mentholated	6	3.6	46

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes	Absolute Neutrophils	Neutrophils
		----- Name	Date		001: 4.9-12.8 002: Not Estab. (%)	001: 1.6-7.7 002: 1.4-7 (thou/uL)	001: 38.4-74.2 002: Not Estab. (%)
2126	37/M	End Of Study	20OCT2018	VLN mentholated	7	2.7	37
2136	64/M	Screen	27AUG2018	VLN non-mentholated	7	4.5	62
		End Of Study	19OCT2018	VLN non-mentholated	5	4.4	62
2140	56/F	Screen	30AUG2018	UB non-mentholated	7	2.9	46
		End Of Study	06NOV2018	UB non-mentholated	9	2.6	44
2142	30/F	Screen	31AUG2018	VLN non-mentholated	4	6.3	65
		End Of Study	08OCT2018	VLN non-mentholated	4	6.2	73
2143	63/M	Screen	04SEP2018	VLN non-mentholated	6	6.3	66
		End Of Study	06NOV2018	VLN non-mentholated	6	7.1 HN	70
2158	43/F	Screen	18SEP2018	UB non-mentholated	8	4.2	61
2159	37/M	Screen	19SEP2018	VLN non-mentholated	4	10.2 HN	78
		Unscheduled	04OCT2018	VLN non-mentholated	8	4.3	64
		End Of Study	02DEC2018	VLN non-mentholated	5	4.9	67
2164	65/F	Screen	27SEP2018	VLN non-mentholated	7	2.9	36
		End Of Study	02DEC2018	VLN non-mentholated	7	3.1	43

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2168	32/F	Screen	28SEP2018	VLN non-mentholated	5	6	60
		End Of Study	02DEC2018	VLN non-mentholated	3	5	56
2170	51/F	Screen	28SEP2018	UB non-mentholated	6	5.2	68
		End Of Study	02DEC2018	UB non-mentholated	7	7.6 HN	77
2175	40/F	Screen	01OCT2018	UB mentholated	6	4.5	53
		End Of Study	02DEC2018	UB mentholated	6	5.1	56
2189	28/M	Screen	04OCT2018	VLN mentholated	12	3.2	63
		End Of Study	06NOV2018	VLN mentholated	10	2	55
2211	29/F	Screen	10OCT2018	VLN mentholated	9	2.5	50
		End Of Study	02DEC2018	VLN mentholated	4	2.5	44
2212	32/M	Screen	10OCT2018	UB mentholated	7	4.5	57
		End Of Study	02DEC2018	UB mentholated	7	4.1	61
2213	29/M	Screen	10OCT2018	VLN mentholated	7	4.7	62
		End Of Study	02DEC2018	VLN mentholated	8	3	58
2215	59/F	Screen	10OCT2018	UB mentholated	8	3.8	46
		End Of Study	02DEC2018	UB mentholated	4	3.1	49

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes 001: 4.9-12.8 002: Not Estab. (%)	Absolute Neutrophils 001: 1.6-7.7 002: 1.4-7 (thou/uL)	Neutrophils 001: 38.4-74.2 002: Not Estab. (%)
		Name	Date				
2220	37/M	Screen	11OCT2018	VLN non-mentholated	9	2.3	43
		End Of Study	02DEC2018	VLN non-mentholated	9	2.9	52
2235	26/F	Screen	19OCT2018	VLN mentholated	6	6.1	53
		End Of Study	16DEC2018	VLN mentholated	5	5.1	55
2244	31/M	Screen	25OCT2018	VLN non-mentholated	8	5	55
		End Of Study	16DEC2018	VLN non-mentholated	7	5.4	55
2247	28/M	Screen	06NOV2018	VLN mentholated	8	3.8	53
		End Of Study	28DEC2018	VLN mentholated	6	4.3	58
2251	27/M	Screen	09NOV2018	UB non-mentholated	7	2.5	36
		End Of Study	19JAN2019	UB non-mentholated	10	2.3	39
2257	55/F	Screen	14NOV2018	UB non-mentholated	6	4.7	56
		End Of Study	19JAN2019	UB non-mentholated	11	3	47
2259	49/M	Screen	14NOV2018	UB mentholated	11	2.5	49
		End Of Study	19JAN2019	UB mentholated	12	1.8	40
2269	48/M	Screen	26NOV2018	VLN mentholated	7	3.3	46
		End Of Study	19JAN2019	VLN mentholated	9	2.3	39

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.2.5 Clinical Laboratory Report - Hematology (V of V)

Subject Number	Age\$/ Gender	Visit		Product Group	Monocytes	Absolute Neutrophils	Neutrophils
		Name	Date		001: 4.9-12.8 002: Not Estab. (%)	001: 1.6-7.7 002: 1.4-7 (thou/uL)	001: 38.4-74.2 002: Not Estab. (%)
2272	37/M	Screen	28NOV2018	VLN mentholated	8	1.8	47
		End Of Study	19JAN2019	VLN mentholated	11	1.8	37

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1001	59/F	Screen	02JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	24JUL2018	VLN non-mentholated			NEGATIVE
		End Of Week 2	08AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 4	22AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 6	05SEP2018	VLN non-mentholated			NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1002	30/M	Screen	02JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1003	38/M	Screen	03JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
1007	37/M	Screen	12JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1008	48/M	Screen	12JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
1010	32/M	Screen	13JUL2018	UB mentholated	NEGATIVE	NEGATIVE	
		End Of Study	06SEP2018	UB mentholated	NEGATIVE	NEGATIVE	
1011	36/M	Screen	13JUL2018	UB non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1011	36/M	End Of Study	06SEP2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1013	36/F	Screen	16JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	31JUL2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	15AUG2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	29AUG2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	12SEP2018	VLN non-mentholated				NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1014	36/F	Screen	16JUL2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	31JUL2018	VLN mentholated				NEGATIVE
		End Of Week 2	15AUG2018	VLN mentholated				NEGATIVE
		End Of Week 4	29AUG2018	VLN mentholated				NEGATIVE
		End Of Week 6	12SEP2018	VLN mentholated				NEGATIVE
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE		NEGATIVE	
1015	49/F	Screen	16JUL2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	31JUL2018	VLN mentholated				NEGATIVE
		End Of Week 2	15AUG2018	VLN mentholated				NEGATIVE
		End Of Week 4	29AUG2018	VLN mentholated				NEGATIVE
		End Of Week 6	12SEP2018	VLN mentholated				NEGATIVE
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1016	54/M	Screen	16JUL2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1017	41/F	Screen	17JUL2018	UB mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	31JUL2018	UB mentholated			NEGATIVE
		End Of Week 2	15AUG2018	UB mentholated			NEGATIVE
		End Of Week 4	29AUG2018	UB mentholated			NEGATIVE
		End Of Week 6	12SEP2018	UB mentholated			NEGATIVE
		End Of Study	13SEP2018	UB mentholated	NEGATIVE	NEGATIVE	
1018	41/F	Screen	17JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	31JUL2018	VLN mentholated			NEGATIVE
		End Of Study	15AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
1019	30/M	Screen	17JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1020	36/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	31JUL2018	VLN non-mentholated			NEGATIVE
		End Of Week 2	15AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 4	29AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 6	12SEP2018	VLN non-mentholated			NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1021	49/F	Screen	17JUL2018	UB non-mentholated	TRACE	NEGATIVE	
		End Of Week -1	31JUL2018	UB non-mentholated			NEGATIVE
		End Of Week 2	15AUG2018	UB non-mentholated			NEGATIVE
		End Of Week 4	29AUG2018	UB non-mentholated			NEGATIVE
		End Of Week 6	12SEP2018	UB non-mentholated			NEGATIVE
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1023	50/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	31JUL2018	VLN non-mentholated			NEGATIVE
		End Of Week 2	15AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 4	29AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 6	12SEP2018	VLN non-mentholated			NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1029	35/F	Screen	26JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	27AUG2018	VLN mentholated			NEGATIVE
		End Of Week 2	11SEP2018	VLN mentholated			NEGATIVE
		End Of Week 4	25SEP2018	VLN mentholated			NEGATIVE
		End Of Week 6	09OCT2018	VLN mentholated			NEGATIVE
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1032	53/F	Screen	13AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	27AUG2018	VLN mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1032	53/F	End Of Week 2	11SEP2018	VLN mentholated				NEGATIVE
		End Of Week 4	25SEP2018	VLN mentholated				NEGATIVE
		End Of Week 6	09OCT2018	VLN mentholated				NEGATIVE
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	
1034	45/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1035	44/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1036	38/F	Screen	13AUG2018	UB mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	27AUG2018	UB mentholated				NEGATIVE
		End Of Week 2	11SEP2018	UB mentholated				NEGATIVE
		End Of Week 4	25SEP2018	UB mentholated				NEGATIVE
		End Of Week 6	09OCT2018	UB mentholated				NEGATIVE
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		NEGATIVE	
1037	29/M	Screen	13AUG2018	UB mentholated	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		NEGATIVE	
1038	39/F	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	27AUG2018	VLN non-mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1038	39/F	End Of Week 2	11SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	25SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	09OCT2018	VLN non-mentholated				NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1042	47/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1045	58/M	Screen	14AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1046	45/M	Screen	14AUG2018	UB mentholated	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		NEGATIVE	
1050	33/F	Screen	14AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	27AUG2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	11SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	25SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	09OCT2018	VLN non-mentholated				NEGATIVE
		End Of Study	10OCT2018	VLN non-mentholated	TRACE		NEGATIVE	
1051	36/F	Screen	14AUG2018	UB mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	27AUG2018	UB mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1051	36/F	End Of Week 2	11SEP2018	UB mentholated				NEGATIVE
		End Of Week 4	25SEP2018	UB mentholated				NEGATIVE
		End Of Week 6	09OCT2018	UB mentholated				NEGATIVE
		End Of Study	10OCT2018	UB mentholated	TRACE		NEGATIVE	
		Unscheduled	12NOV2018	UB mentholated	NEGATIVE		NEGATIVE	
1052	31/M	Screen	14AUG2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	
1053	42/M	Screen	14AUG2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	
1054	56/M	Screen	14AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		Unscheduled	22OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1055	39/F	Screen	14AUG2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	27AUG2018	VLN mentholated				NEGATIVE
		End Of Week 2	11SEP2018	VLN mentholated				NEGATIVE
		End Of Week 4	25SEP2018	VLN mentholated				NEGATIVE
		End Of Week 6	09OCT2018	VLN mentholated				NEGATIVE
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1056	48/M	Screen	14AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1058	30/M	Screen	15AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1059	38/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1060	55/M	Screen	27AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1063	31/M	Screen	27AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	25OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1064	34/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1066	62/M	Screen	27AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1069	40/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	10SEP2018	UB non-mentholated			NEGATIVE
		End Of Week 2	25SEP2018	UB non-mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1069	40/F	End Of Week 6	23OCT2018	UB non-mentholated			NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated	1+ *R	NEGATIVE	
		Unscheduled	06NOV2018	UB non-mentholated	TRACE	NEGATIVE	
1070	53/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1071	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1072	59/M	Screen	28AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	22OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1074	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1075	26/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE	NEGATIVE	NEGATIVE NEGATIVE NEGATIVE
		End Of Week -1	10SEP2018	UB non-mentholated			
		End Of Week 2	25SEP2018	UB non-mentholated			
		End Of Week 6	23OCT2018	UB non-mentholated			
		End Of Study	24OCT2018	UB non-mentholated	TRACE	NEGATIVE	
		Unscheduled	31OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1077	49/F	Screen	28AUG2018	VLN non-mentholated	TRACE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1077	49/F	End Of Week -1	10SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	25SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	23OCT2018	VLN non-mentholated				NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated	TRACE		NEGATIVE	
		Unscheduled	24NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1078	51/F	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	10SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	25SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	23OCT2018	VLN non-mentholated				NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1079	33/M	Screen	28AUG2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	
1082	37/M	Screen	30AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1083	54/F	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	17SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	02OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	16OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	30OCT2018	VLN non-mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1083	54/F	End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1084	42/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1086	54/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1088	26/M	Screen	04SEP2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE		NEGATIVE	
1089	60/F	Screen	04SEP2018	UB non-mentholated	TRACE		NEGATIVE	
		End Of Week -1	17SEP2018	UB non-mentholated				NEGATIVE
		End Of Week 2	02OCT2018	UB non-mentholated				NEGATIVE
		End Of Week 4	16OCT2018	UB non-mentholated				NEGATIVE
		End Of Week 6	30OCT2018	UB non-mentholated				NEGATIVE
		End Of Study	31OCT2018	UB non-mentholated	1+ *R		NEGATIVE	
		Unscheduled	09NOV2018	UB non-mentholated	TRACE		NEGATIVE	
1092	43/F	Screen	05SEP2018	VLN mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	17SEP2018	VLN mentholated				NEGATIVE
		End Of Week 2	02OCT2018	VLN mentholated				NEGATIVE
		End Of Week 4	16OCT2018	VLN mentholated				NEGATIVE
		End Of Week 6	30OCT2018	VLN mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1092	43/F	End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1094	46/M	Screen	05SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1095	55/F	Screen	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	17SEP2018	VLN mentholated			NEGATIVE
		End Of Week 2	02OCT2018	VLN mentholated			NEGATIVE
		End Of Week 4	16OCT2018	VLN mentholated			NEGATIVE
		End Of Week 6	30OCT2018	VLN mentholated			NEGATIVE
		End Of Study	31OCT2018	VLN mentholated	TRACE	NEGATIVE	
1096	42/F	Screen	07SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	17SEP2018	VLN non-mentholated			NEGATIVE
		End Of Week 2	02OCT2018	VLN non-mentholated			NEGATIVE
		End Of Week 4	16OCT2018	VLN non-mentholated			NEGATIVE
		End Of Week 6	30OCT2018	VLN non-mentholated			NEGATIVE
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	06NOV2018	VLN non-mentholated	TRACE	NEGATIVE	
1097	30/M	Screen	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	10SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1098	63/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	TRACE *N		NEGATIVE	
1099	46/F	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	03OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	18OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	01NOV2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	15NOV2018	VLN non-mentholated				NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	3+ *R		NEGATIVE	
		Unscheduled	27NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1100	59/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1101	41/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1103	43/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1105	47/F	Screen	19SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	03OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	18OCT2018	VLN non-mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
1105	47/F	End Of Week 4	01NOV2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	15NOV2018	VLN non-mentholated				NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1106	42/M	Screen	19SEP2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1107	45/M	Screen	21SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
1108	54/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1109	58/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE		NEGATIVE	
1112	59/F	Screen	21SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE	
		End Of Week -1	03OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	18OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	01NOV2018	VLN non-mentholated				NEGATIVE
		End Of Week 6	15NOV2018	VLN non-mentholated				NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
1114	26/F	Screen	24SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Week -1	03OCT2018	UB non-mentholated			NEGATIVE
		End Of Week 2	18OCT2018	UB non-mentholated			NEGATIVE
		End Of Week 4	01NOV2018	UB non-mentholated			NEGATIVE
		End Of Week 6	15NOV2018	UB non-mentholated			NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1115	29/M	Screen	24SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
2002	49/M	Screen	29JUN2018	UB mentholated	Negative	Negative	
		End Of Study	05SEP2018	UB mentholated	Negative	Negative	
2003	41/F	Screen	29JUN2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	11JUL2018	VLN mentholated			NEGATIVE
		End Of Week -1	16JUL2018	VLN mentholated			NEGATIVE
		End Of Week 2	31JUL2018	VLN mentholated			NEGATIVE
		End Of Week 4	14AUG2018	VLN mentholated			NEGATIVE
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
		End Of Week 6	28AUG2018	VLN mentholated			NEGATIVE
2007	57/F	Screen	29JUN2018	VLN non-mentholated	Trace *N	Negative	NEGATIVE
		Start Of Week -1	11JUL2018	VLN non-mentholated			NEGATIVE
		End Of Week -1	16JUL2018	VLN non-mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2007	57/F	End Of Week 2	31JUL2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	14AUG2018	VLN non-mentholated				NEGATIVE
		End Of Study	28AUG2018	VLN non-mentholated	Negative		Negative	
		End Of Week 6	28AUG2018	VLN non-mentholated				NEGATIVE
2008	42/M	Screen	06JUL2018	VLN mentholated	Negative		Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	
2009	55/M	Screen	29JUN2018	VLN non-mentholated	Negative		Negative	
2010	27/M	Screen	29JUN2018	UB mentholated	Negative		Negative	
		End Of Study	28AUG2018	UB mentholated	Negative		Negative	
2011	32/F	Screen	29JUN2018	VLN mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	11JUL2018	VLN mentholated				NEGATIVE
		End Of Week -1	16JUL2018	VLN mentholated				NEGATIVE
		End Of Week 2	31JUL2018	VLN mentholated				NEGATIVE
		End Of Week 4	14AUG2018	VLN mentholated				NEGATIVE
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	
		End Of Week 6	28AUG2018	VLN mentholated				NEGATIVE
2014	37/M	Screen	02JUL2018	VLN mentholated	Negative		Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		-----	-----		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2015	57/F	Screen	02JUL2018	UB mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	11JUL2018	UB mentholated			NEGATIVE
		End Of Week -1	16JUL2018	UB mentholated			NEGATIVE
		End Of Week 2	31JUL2018	UB mentholated			NEGATIVE
		End Of Week 4	14AUG2018	UB mentholated			NEGATIVE
		End Of Study	28AUG2018	UB mentholated	Negative	Negative	
		End Of Week 6	28AUG2018	UB mentholated			NEGATIVE
2016	45/F	Screen	02JUL2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	11JUL2018	VLN mentholated			NEGATIVE
		End Of Week -1	16JUL2018	VLN mentholated			NEGATIVE
		End Of Week 2	31JUL2018	VLN mentholated			NEGATIVE
		End Of Study	03AUG2018	VLN mentholated	Negative	Negative	
2017	30/M	Screen	02JUL2018	VLN mentholated	Negative	Trace *N	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2018	26/F	Screen	02JUL2018	UB mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	11JUL2018	UB mentholated			NEGATIVE
		End Of Week -1	16JUL2018	UB mentholated			NEGATIVE
		End Of Week 2	31JUL2018	UB mentholated			NEGATIVE
		End Of Week 4	14AUG2018	UB mentholated			NEGATIVE
		End Of Study	28AUG2018	UB mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2018	26/F	End Of Week 6	28AUG2018	UB mentholated				NEGATIVE
2020	60/F	Screen	02JUL2018	VLN mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	11JUL2018	VLN mentholated				NEGATIVE
		End Of Week -1	16JUL2018	VLN mentholated				NEGATIVE
		End Of Week 2	31JUL2018	VLN mentholated				NEGATIVE
		End Of Week 4	14AUG2018	VLN mentholated				NEGATIVE
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	
		End Of Week 6	28AUG2018	VLN mentholated				NEGATIVE
2021	31/M	Screen	02JUL2018	VLN mentholated	Negative		Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	
2023	35/M	Screen	02JUL2018	VLN mentholated	Negative		Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative		Negative	
2024	26/M	Screen	03JUL2018	UB non-mentholated	Negative		Negative	
2025	59/M	Screen	03JUL2018	UB non-mentholated	Negative		Negative	
		End Of Study	28AUG2018	UB non-mentholated	Negative		Negative	
2028	36/M	Screen	06JUL2018	VLN non-mentholated	Negative		Negative	
		End Of Study	28AUG2018	VLN non-mentholated	Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2029	56/M	Screen	09JUL2018	UB mentholated	Negative	Negative	
		End Of Study	05SEP2018	UB mentholated	Negative	Negative	
2039	49/F	Screen	13JUL2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	18JUL2018	VLN mentholated			NEGATIVE
		End Of Week -1	23JUL2018	VLN mentholated			NEGATIVE
		End Of Week 2	07AUG2018	VLN mentholated			NEGATIVE
		End Of Week 4	21AUG2018	VLN mentholated			NEGATIVE
		End Of Week 6	04SEP2018	VLN mentholated			NEGATIVE
		End Of Study	05SEP2018	VLN mentholated	Negative	Negative	
2050	57/M	Screen	20JUL2018	UB mentholated	Negative	Negative	
		End Of Study	20SEP2018	UB mentholated	Negative	Trace *N	
2052	54/M	Screen	20JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2057	52/M	Screen	23JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2058	37/F	Screen	23JUL2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	02AUG2018	VLN mentholated			NEGATIVE
		End Of Week -1	07AUG2018	VLN mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2058	37/F	End Of Week 2	22AUG2018	VLN mentholated				NEGATIVE
		End Of Week 4	05SEP2018	VLN mentholated				NEGATIVE
		End Of Week 6	19SEP2018	VLN mentholated				NEGATIVE
		End Of Study	20SEP2018	VLN mentholated	Negative		Negative	
2059	56/F	Screen	23JUL2018	UB mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	02AUG2018	UB mentholated				NEGATIVE
		End Of Week -1	07AUG2018	UB mentholated				NEGATIVE
		End Of Week 2	22AUG2018	UB mentholated				NEGATIVE
		End Of Week 4	05SEP2018	UB mentholated				NEGATIVE
		End Of Week 6	19SEP2018	UB mentholated				NEGATIVE
		End Of Study	20SEP2018	UB mentholated	Negative		Negative	
2060	37/F	Screen	23JUL2018	VLN mentholated	3+ *N		Negative	NEGATIVE
		Start Of Week -1	02AUG2018	VLN mentholated				NEGATIVE
		End Of Week -1	07AUG2018	VLN mentholated				NEGATIVE
		End Of Week 2	22AUG2018	VLN mentholated				NEGATIVE
		End Of Week 4	05SEP2018	VLN mentholated				NEGATIVE
		End Of Week 6	19SEP2018	VLN mentholated				NEGATIVE
		End Of Study	20SEP2018	VLN mentholated	Negative		Negative	
2064	52/M	Screen	23JUL2018	VLN mentholated	Negative		Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2066	30/F	Screen	23JUL2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	02AUG2018	VLN mentholated			NEGATIVE
		End Of Week -1	07AUG2018	VLN mentholated			NEGATIVE
		End Of Week 2	22AUG2018	VLN mentholated			NEGATIVE
		End Of Week 4	05SEP2018	VLN mentholated			NEGATIVE
		End Of Week 6	19SEP2018	VLN mentholated			NEGATIVE
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2067	52/M	Screen	23JUL2018	VLN non-mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN non-mentholated	Negative	Negative	
2075	34/M	Screen	30JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	22AUG2018	VLN mentholated	Negative	Negative	
2076	42/M	Screen	30JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	13OCT2018	VLN mentholated	Negative	Negative	
2086	36/M	Screen	03AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01OCT2018	VLN non-mentholated	Negative	Negative	
2088	39/F	Screen	03AUG2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	26AUG2018	VLN mentholated			NEGATIVE
		End Of Week -1	31AUG2018	VLN mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2088	39/F	End Of Week 2	15SEP2018	VLN mentholated				NEGATIVE
		End Of Week 4	29SEP2018	VLN mentholated				NEGATIVE
		End Of Study	13OCT2018	VLN mentholated	Negative		Negative	
		End Of Week 6	13OCT2018	VLN mentholated				NEGATIVE
2092	50/F	Screen	06AUG2018	VLN mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	26AUG2018	VLN mentholated				NEGATIVE
		End Of Week -1	31AUG2018	VLN mentholated				NEGATIVE
		End Of Week 2	15SEP2018	VLN mentholated				NEGATIVE
		End Of Week 4	29SEP2018	VLN mentholated				NEGATIVE
		End Of Study	13OCT2018	VLN mentholated	Negative		Negative	
		End Of Week 6	13OCT2018	VLN mentholated				NEGATIVE
2099	52/M	Screen	09AUG2018	VLN non-mentholated	Negative		Negative	
		End Of Study	13OCT2018	VLN non-mentholated	Negative		Negative	
2100	48/F	Screen	09AUG2018	UB mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	26AUG2018	UB mentholated				NEGATIVE
		End Of Week -1	31AUG2018	UB mentholated				NEGATIVE
		End Of Week 2	15SEP2018	UB mentholated				NEGATIVE
		End Of Week 4	29SEP2018	UB mentholated				NEGATIVE
		End Of Study	13OCT2018	UB mentholated	Negative		Negative	
		End Of Week 6	13OCT2018	UB mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2108	60/F	Screen	13AUG2018	VLN non-mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	26AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week -1	31AUG2018	VLN non-mentholated			NEGATIVE
		End Of Week 2	15SEP2018	VLN non-mentholated			NEGATIVE
		End Of Week 4	29SEP2018	VLN non-mentholated			NEGATIVE
		End Of Study	13OCT2018	VLN non-mentholated	Negative	Negative	
		End Of Week 6	13OCT2018	VLN non-mentholated			NEGATIVE
2110	41/F	Screen	13AUG2018	UB mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	01SEP2018	UB mentholated			NEGATIVE
		End Of Week -1	06SEP2018	UB mentholated			NEGATIVE
		End Of Week 2	21SEP2018	UB mentholated			NEGATIVE
		End Of Week 4	05OCT2018	UB mentholated			NEGATIVE
		End Of Study	19OCT2018	UB mentholated	Negative	Negative	
		End Of Week 6	19OCT2018	UB mentholated			NEGATIVE
2113	51/F	Screen	15AUG2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	01SEP2018	VLN mentholated			NEGATIVE
		End Of Week -1	06SEP2018	VLN mentholated			NEGATIVE
		End Of Week 2	21SEP2018	VLN mentholated			NEGATIVE
2115	46/F	Screen	15AUG2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	01SEP2018	VLN mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2115	46/F	End Of Week -1	06SEP2018	VLN mentholated				NEGATIVE
		End Of Week 2	21SEP2018	VLN mentholated				NEGATIVE
2119	48/M	Screen	20AUG2018	VLN mentholated	Negative		Negative	
		End Of Study	19OCT2018	VLN mentholated	Negative		Negative	
2120	62/F	Screen	20AUG2018	VLN non-mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	01SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week -1	06SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	21SEP2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	05OCT2018	VLN non-mentholated				NEGATIVE
		End Of Study	19OCT2018	VLN non-mentholated	Negative		Negative	
		End Of Week 6	19OCT2018	VLN non-mentholated				NEGATIVE
2122	60/M	Screen	20AUG2018	UB non-mentholated	Trace *N		Negative	
		End Of Study	19OCT2018	UB non-mentholated	Negative		Negative	
2125	35/M	Screen	21AUG2018	UB mentholated	Negative		Negative	
		End Of Study	19OCT2018	UB mentholated	Negative		Negative	
2126	37/M	Screen	21AUG2018	VLN mentholated	Negative		Negative	
		End Of Study	19OCT2018	VLN mentholated	Negative		Trace *N	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2136	64/M	Screen	27AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	19OCT2018	VLN non-mentholated	Negative	Negative	
2140	56/F	Screen	30AUG2018	UB non-mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	18SEP2018	UB non-mentholated			NEGATIVE
		End Of Week -1	23SEP2018	UB non-mentholated			NEGATIVE
		End Of Week 2	08OCT2018	UB non-mentholated			NEGATIVE
		End Of Week 4	22OCT2018	UB non-mentholated			NEGATIVE
		End Of Study	05NOV2018	UB non-mentholated	Negative	Negative	
		End Of Week 6	05NOV2018	UB non-mentholated			NEGATIVE
2142	30/F	Screen	31AUG2018	VLN non-mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	18SEP2018	VLN non-mentholated			NEGATIVE
		End Of Week -1	23SEP2018	VLN non-mentholated			NEGATIVE
		End Of Study	08OCT2018	VLN non-mentholated	Negative	Negative	
		End Of Week 2	08OCT2018	VLN non-mentholated			NEGATIVE
2143	63/M	Screen	04SEP2018	VLN non-mentholated	Negative	Negative	
		End Of Study	05NOV2018	VLN non-mentholated	Negative	Negative	
2158	43/F	Screen	18SEP2018	UB non-mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	14OCT2018	UB non-mentholated			NEGATIVE
		End Of Week -1	19OCT2018	UB non-mentholated			NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2158	43/F	End Of Week 2	03NOV2018	UB non-mentholated				NEGATIVE
		End Of Week 4	17NOV2018	UB non-mentholated				NEGATIVE
2159	37/M	Screen	19SEP2018	VLN non-mentholated	Negative		Negative	
		End Of Study	01DEC2018	VLN non-mentholated	Negative		Negative	
2164	65/F	Screen	27SEP2018	VLN non-mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	14OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week -1	19OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	03NOV2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	17NOV2018	VLN non-mentholated				NEGATIVE
		End Of Study	01DEC2018	VLN non-mentholated	Negative		Negative	
		End Of Week 6	01DEC2018	VLN non-mentholated				NEGATIVE
2168	32/F	Screen	28SEP2018	VLN non-mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	14OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week -1	19OCT2018	VLN non-mentholated				NEGATIVE
		End Of Week 2	03NOV2018	VLN non-mentholated				NEGATIVE
		End Of Week 4	17NOV2018	VLN non-mentholated				NEGATIVE
		End Of Study	01DEC2018	VLN non-mentholated	Trace *N		Negative	
		End Of Week 6	01DEC2018	VLN non-mentholated				NEGATIVE
2170	51/F	Screen	28SEP2018	UB non-mentholated	2+ *N		Negative	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		Name	Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2170	51/F	Start Of Week -1	14OCT2018	UB non-mentholated				NEGATIVE
		End Of Week -1	19OCT2018	UB non-mentholated				NEGATIVE
		End Of Week 2	03NOV2018	UB non-mentholated				NEGATIVE
		End Of Week 4	17NOV2018	UB non-mentholated				NEGATIVE
		End Of Study	01DEC2018	UB non-mentholated	Trace *N	Negative		
		End Of Week 6	01DEC2018	UB non-mentholated				NEGATIVE
2175	40/F	Screen	01OCT2018	UB mentholated	Negative	Negative		NEGATIVE
		Start Of Week -1	14OCT2018	UB mentholated				NEGATIVE
		End Of Week -1	19OCT2018	UB mentholated				NEGATIVE
		End Of Study	01DEC2018	UB mentholated	Negative	Negative		
2189	28/M	Screen	04OCT2018	VLN mentholated	Negative	Negative		
		End Of Study	06NOV2018	VLN mentholated	Negative	Negative		
2211	29/F	Screen	10OCT2018	VLN mentholated	1+ *N	Negative		NEGATIVE
		Start Of Week -1	14OCT2018	VLN mentholated				NEGATIVE
		End Of Week -1	19OCT2018	VLN mentholated				NEGATIVE
		End Of Week 2	03NOV2018	VLN mentholated				NEGATIVE
		End Of Week 4	17NOV2018	VLN mentholated				NEGATIVE
		End Of Study	01DEC2018	VLN mentholated	2+ *Y	Negative		
		End Of Week 6	01DEC2018	VLN mentholated				NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2212	32/M	Screen	10OCT2018	UB mentholated	Negative	Negative	
		End Of Study	01DEC2018	UB mentholated	Negative	Negative	
2213	29/M	Screen	10OCT2018	VLN mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN mentholated	Negative	Trace *N	
2215	59/F	Screen	10OCT2018	UB mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	14OCT2018	UB mentholated			NEGATIVE
		End Of Week -1	19OCT2018	UB mentholated			NEGATIVE
		End Of Week 2	03NOV2018	UB mentholated			NEGATIVE
		End Of Week 4	17NOV2018	UB mentholated			NEGATIVE
		End Of Study	01DEC2018	UB mentholated	Negative	Negative	
		End Of Week 6	01DEC2018	UB mentholated			NEGATIVE
2220	37/M	Screen	11OCT2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN non-mentholated	Negative	Negative	
2235	26/F	Screen	19OCT2018	VLN mentholated	Negative	Negative	NEGATIVE
		Start Of Week -1	28OCT2018	VLN mentholated			NEGATIVE
		End Of Week -1	02NOV2018	VLN mentholated			NEGATIVE
		End Of Week 2	17NOV2018	VLN mentholated			NEGATIVE
		End Of Week 4	01DEC2018	VLN mentholated			NEGATIVE
		End Of Study	15DEC2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood		Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative		001: NEGATIVE 002: Negative	
2235	26/F	End Of Week 6	15DEC2018	VLN mentholated				NEGATIVE
2244	31/M	Screen	25OCT2018	VLN non-mentholated	Negative		Negative	
		End Of Study	16DEC2018	VLN non-mentholated	Negative		Negative	
2247	28/M	Screen	06NOV2018	VLN mentholated	Negative		Negative	
		End Of Study	28DEC2018	VLN mentholated	Negative		Negative	
2251	27/M	Screen	09NOV2018	UB non-mentholated	Negative		Negative	
		End Of Study	19JAN2019	UB non-mentholated	Negative		Negative	
2257	55/F	Screen	14NOV2018	UB non-mentholated	Negative		Negative	NEGATIVE
		Start Of Week -1	01DEC2018	UB non-mentholated				NEGATIVE
		End Of Week -1	06DEC2018	UB non-mentholated				NEGATIVE
		End Of Week 2	21DEC2018	UB non-mentholated				NEGATIVE
		End Of Week 4	04JAN2019	UB non-mentholated				NEGATIVE
		End Of Week 6	18JAN2019	UB non-mentholated				NEGATIVE
		End Of Study	19JAN2019	UB non-mentholated	Negative		Negative	
2259	49/M	Screen	14NOV2018	UB mentholated	Negative		Negative	
		End Of Study	19JAN2019	UB mentholated	Negative		Negative	
2269	48/M	Screen	26NOV2018	VLN mentholated	Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.1 Clinical Laboratory Report - Urinalysis (I of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Occult Blood	Glucose	Choriogonadotropin Beta
		----- Name	----- Date		001: F: NEG, T 001: M: NEGATI 002: Negative	001: NEGATIVE 002: Negative	
2269	48/M	End Of Study	19JAN2019	VLN mentholated	Negative	Negative	
2272	37/M	Screen	28NOV2018	VLN mentholated	Negative	Negative	
		End Of Study	19JAN2019	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked, Y = Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)	001: 0-7 002: 0 - 5 (/HPF)	001: 5-8 002: 5-7.5
1001	59/F	Screen	02JUL2018	VLN non-mentholated			5
		End Of Study	07SEP2018	VLN non-mentholated			6
1002	30/M	Screen	02JUL2018	VLN non-mentholated			7
		End Of Study	07SEP2018	VLN non-mentholated			6.5
1003	38/M	Screen	03JUL2018	VLN mentholated			5.5
		End Of Study	07SEP2018	VLN mentholated			5.5
1007	37/M	Screen	12JUL2018	VLN non-mentholated			5.5
		End Of Study	07SEP2018	VLN non-mentholated			6
1008	48/M	Screen	12JUL2018	VLN mentholated			5.5
		End Of Study	07SEP2018	VLN mentholated			7.5
1010	32/M	Screen	13JUL2018	UB mentholated			7
		End Of Study	06SEP2018	UB mentholated			6.5
1011	36/M	Screen	13JUL2018	UB non-mentholated			6.5
		End Of Study	06SEP2018	UB non-mentholated			6.5
1013	36/F	Screen	16JUL2018	VLN non-mentholated			7.5
		End Of Study	14SEP2018	VLN non-mentholated			7

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1014	36/F	Screen	16JUL2018	VLN mentholated					6.5
		End Of Study	14SEP2018	VLN mentholated					7.5
1015	49/F	Screen	16JUL2018	VLN mentholated					6.5
		End Of Study	14SEP2018	VLN mentholated					7.5
1016	54/M	Screen	16JUL2018	UB non-mentholated					7
		End Of Study	13SEP2018	UB non-mentholated	2		10 HN		8
1017	41/F	Screen	17JUL2018	UB mentholated					8
		End Of Study	13SEP2018	UB mentholated					6.5
1018	41/F	Screen	17JUL2018	VLN mentholated					6.5
		End Of Study	15AUG2018	VLN mentholated					5
1019	30/M	Screen	17JUL2018	VLN non-mentholated					6.5
		End Of Study	14SEP2018	VLN non-mentholated					6.5
1020	36/F	Screen	17JUL2018	VLN non-mentholated					5
		End Of Study	14SEP2018	VLN non-mentholated					7
1021	49/F	Screen	17JUL2018	UB non-mentholated					6.5
		End Of Study	13SEP2018	UB non-mentholated					7.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Page 3 of 19

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)	001: 0-7 002: 0 - 5 (/HPF)	001: 5-8 002: 5-7.5
1023	50/F	Screen	17JUL2018	VLN non-mentholated			7.5
		End Of Study	14SEP2018	VLN non-mentholated			8
1029	35/F	Screen	26JUL2018	VLN mentholated			6
		End Of Study	11OCT2018	VLN mentholated			6
1032	53/F	Screen	13AUG2018	VLN mentholated			7
		End Of Study	11OCT2018	VLN mentholated			7.5
1034	45/M	Screen	13AUG2018	VLN non-mentholated			5
		End Of Study	10OCT2018	VLN non-mentholated			5
1035	44/M	Screen	13AUG2018	VLN non-mentholated			6.5
		End Of Study	11OCT2018	VLN non-mentholated			5.5
1036	38/F	Screen	13AUG2018	UB mentholated			7
		End Of Study	10OCT2018	UB mentholated			5
1037	29/M	Screen	13AUG2018	UB mentholated			7
		End Of Study	10OCT2018	UB mentholated			6
1038	39/F	Screen	13AUG2018	VLN non-mentholated			6.5
		End Of Study	11OCT2018	VLN non-mentholated			6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1042	47/M	Screen	13AUG2018	VLN non-mentholated					5.5
		End Of Study	11OCT2018	VLN non-mentholated					7
1045	58/M	Screen	14AUG2018	UB non-mentholated					5.5
		End Of Study	10OCT2018	UB non-mentholated					6
1046	45/M	Screen	14AUG2018	UB mentholated					5.5
		End Of Study	10OCT2018	UB mentholated					5
1050	33/F	Screen	14AUG2018	VLN non-mentholated					6
		End Of Study	10OCT2018	VLN non-mentholated					6.5
1051	36/F	Screen	14AUG2018	UB mentholated					6
		End Of Study	10OCT2018	UB mentholated		4 HR	4		6.5
		Unscheduled	12NOV2018	UB mentholated					7.5
1052	31/M	Screen	14AUG2018	VLN mentholated					8
		End Of Study	11OCT2018	VLN mentholated		1	11 HN		7.5
1053	42/M	Screen	14AUG2018	VLN mentholated					6.5
		End Of Study	11OCT2018	VLN mentholated					6.5
1054	56/M	Screen	14AUG2018	UB non-mentholated					5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Page 5 of 19

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1054	56/M	End Of Study	10OCT2018	UB non-mentholated	1		10 HR		5.5
		Unscheduled	22OCT2018	UB non-mentholated					5.5
1055	39/F	Screen	14AUG2018	VLN mentholated					7
		End Of Study	11OCT2018	VLN mentholated					6.5
1056	48/M	Screen	14AUG2018	VLN non-mentholated					7.5
		End Of Study	11OCT2018	VLN non-mentholated					6.5
1058	30/M	Screen	15AUG2018	VLN non-mentholated					5.5
		End Of Study	11OCT2018	VLN non-mentholated					6.5
1059	38/M	Screen	27AUG2018	UB non-mentholated					8.5 HN
		End Of Study	24OCT2018	UB non-mentholated					5.5
1060	55/M	Screen	27AUG2018	VLN mentholated					6
		End Of Study	24OCT2018	VLN mentholated					6
1063	31/M	Screen	27AUG2018	VLN mentholated					7.5
		End Of Study	25OCT2018	VLN mentholated					7
1064	34/M	Screen	27AUG2018	UB non-mentholated					6.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		-----	-----		001: 0-3	002: 0 - 2	001: 0-7	002: 0 - 5	
		Name	Date		(/HPF)		(/HPF)		001: 5-8 002: 5-7.5
1066	62/M	Screen	27AUG2018	VLN non-mentholated					6
		End Of Study	24OCT2018	VLN non-mentholated					6
1069	40/F	Screen	28AUG2018	UB non-mentholated					6
		End Of Study	24OCT2018	UB non-mentholated	1		3		5
		Unscheduled	06NOV2018	UB non-mentholated					6
1070	53/M	Screen	28AUG2018	VLN non-mentholated					6
		End Of Study	24OCT2018	VLN non-mentholated					6
1071	42/M	Screen	28AUG2018	VLN non-mentholated					5
1072	59/M	Screen	28AUG2018	VLN mentholated					6.5
		End Of Study	22OCT2018	VLN mentholated					6.5
1074	42/M	Screen	28AUG2018	VLN non-mentholated					5.5
		End Of Study	24OCT2018	VLN non-mentholated					5.5
1075	26/F	Screen	28AUG2018	UB non-mentholated					7.5
		End Of Study	24OCT2018	UB non-mentholated	6 HR		54 HR		6.5
		Unscheduled	31OCT2018	UB non-mentholated					6
1077	49/F	Screen	28AUG2018	VLN non-mentholated					5.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1077	49/F	End Of Study	24OCT2018	VLN non-mentholated	6 HR		6		6.5
		Unscheduled	24NOV2018	VLN non-mentholated					6
1078	51/F	Screen	28AUG2018	VLN non-mentholated					5.5
		End Of Study	24OCT2018	VLN non-mentholated					6
1079	33/M	Screen	28AUG2018	VLN mentholated					6
		End Of Study	24OCT2018	VLN mentholated					6
1082	37/M	Screen	30AUG2018	VLN non-mentholated					6.5
		End Of Study	24OCT2018	VLN non-mentholated					6.5
1083	54/F	Screen	04SEP2018	VLN non-mentholated					6
		End Of Study	31OCT2018	VLN non-mentholated					5.5
1084	42/M	Screen	04SEP2018	VLN non-mentholated					6.5
1086	54/M	Screen	04SEP2018	VLN non-mentholated					7
		End Of Study	31OCT2018	VLN non-mentholated					6.5
1088	26/M	Screen	04SEP2018	VLN mentholated					5.5
		End Of Study	31OCT2018	VLN mentholated					6.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1089	60/F	Screen	04SEP2018	UB non-mentholated					7.5
		End Of Study	31OCT2018	UB non-mentholated	3		7		5.5
		Unscheduled	09NOV2018	UB non-mentholated					6
1092	43/F	Screen	05SEP2018	VLN mentholated					6
		End Of Study	31OCT2018	VLN mentholated					5.5
1094	46/M	Screen	05SEP2018	VLN mentholated					7.5
		End Of Study	31OCT2018	VLN mentholated					6.5
1095	55/F	Screen	07SEP2018	VLN mentholated					6.5
		End Of Study	31OCT2018	VLN mentholated					6.5
1096	42/F	Screen	07SEP2018	VLN non-mentholated					6
		End Of Study	31OCT2018	VLN non-mentholated	3		6		6
		Unscheduled	06NOV2018	VLN non-mentholated					6.5
1097	30/M	Screen	07SEP2018	VLN mentholated	0		16 HR		7
		Unscheduled	10SEP2018	VLN mentholated					6
		End Of Study	31OCT2018	VLN mentholated					6
1098	63/M	Screen	18SEP2018	VLN non-mentholated					5.5
		End Of Study	16NOV2018	VLN non-mentholated	1		1		5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1099	46/F	Screen	18SEP2018	VLN non-mentholated					5.5
		End Of Study	16NOV2018	VLN non-mentholated	53 HR		6		5.5
		Unscheduled	27NOV2018	VLN non-mentholated					5
1100	59/M	Screen	18SEP2018	VLN non-mentholated					5.5
		End Of Study	16NOV2018	VLN non-mentholated					5
1101	41/M	Screen	18SEP2018	VLN non-mentholated					7
		End Of Study	16NOV2018	VLN non-mentholated					6.5
1103	43/M	Screen	18SEP2018	VLN non-mentholated					8
		End Of Study	16NOV2018	VLN non-mentholated					5
1105	47/F	Screen	19SEP2018	VLN non-mentholated					5
		End Of Study	16NOV2018	VLN non-mentholated					5
1106	42/M	Screen	19SEP2018	UB non-mentholated					6.5
		End Of Study	16NOV2018	UB non-mentholated					5
1107	45/M	Screen	21SEP2018	VLN non-mentholated					5.5
		End Of Study	16NOV2018	VLN non-mentholated					6
1108	54/M	Screen	21SEP2018	UB non-mentholated					6.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
1108	54/M	End Of Study	16NOV2018	UB non-mentholated					7
1109	58/M	Screen	21SEP2018	UB non-mentholated					7.5
		End Of Study	16NOV2018	UB non-mentholated					6
1112	59/F	Screen	21SEP2018	VLN non-mentholated					6.5
		End Of Study	16NOV2018	VLN non-mentholated					5
1114	26/F	Screen	24SEP2018	UB non-mentholated					6
		End Of Study	16NOV2018	UB non-mentholated					5.5
1115	29/M	Screen	24SEP2018	VLN non-mentholated					5.5
2002	49/M	Screen	29JUN2018	UB mentholated					5.5
		End Of Study	05SEP2018	UB mentholated					6
2003	41/F	Screen	29JUN2018	VLN mentholated					6.5
		End Of Study	28AUG2018	VLN mentholated		0-2		6-10 *N	6.5
2007	57/F	Screen	29JUN2018	VLN non-mentholated		0-2		0-5	6
		End Of Study	28AUG2018	VLN non-mentholated					5.5
2008	42/M	Screen	06JUL2018	VLN mentholated					7.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)	001: 0-7 002: 0 - 5 (/HPF)	001: 5-8 002: 5-7.5
2008	42/M	End Of Study	28AUG2018	VLN mentholated			5.5
2009	55/M	Screen	29JUN2018	VLN non-mentholated			5.5
2010	27/M	Screen	29JUN2018	UB mentholated			5
		End Of Study	28AUG2018	UB mentholated			5.5
2011	32/F	Screen	29JUN2018	VLN mentholated			5.5
		End Of Study	28AUG2018	VLN mentholated			6.5
2014	37/M	Screen	02JUL2018	VLN mentholated			5.5
		End Of Study	28AUG2018	VLN mentholated			6
2015	57/F	Screen	02JUL2018	UB mentholated			6
		End Of Study	28AUG2018	UB mentholated			5
2016	45/F	Screen	02JUL2018	VLN mentholated			7
		End Of Study	03AUG2018	VLN mentholated			5
2017	30/M	Screen	02JUL2018	VLN mentholated			5
		End Of Study	28AUG2018	VLN mentholated			5
2018	26/F	Screen	02JUL2018	UB mentholated			7

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)	001: 0-7 002: 0 - 5 (/HPF)	001: 5-8 002: 5-7.5
2018	26/F	End Of Study	28AUG2018	UB mentholated			7
2020	60/F	Screen	02JUL2018	VLN mentholated			6.5
		End Of Study	28AUG2018	VLN mentholated			6.5
2021	31/M	Screen	02JUL2018	VLN mentholated			6
		End Of Study	28AUG2018	VLN mentholated			6.5
2023	35/M	Screen	02JUL2018	VLN mentholated			5.5
		End Of Study	28AUG2018	VLN mentholated			5.5
2024	26/M	Screen	03JUL2018	UB non-mentholated			8.5 HN
2025	59/M	Screen	03JUL2018	UB non-mentholated			5.5
		End Of Study	28AUG2018	UB non-mentholated			6.5
2028	36/M	Screen	06JUL2018	VLN non-mentholated			6.5
		End Of Study	28AUG2018	VLN non-mentholated			6.5
2029	56/M	Screen	09JUL2018	UB mentholated			7
		End Of Study	05SEP2018	UB mentholated			6.5
2039	49/F	Screen	13JUL2018	VLN mentholated			6.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
2039	49/F	End Of Study	05SEP2018	VLN mentholated					6
2050	57/M	Screen	20JUL2018	UB mentholated	0-2		0-5		5.5
		End Of Study	20SEP2018	UB mentholated					5
2052	54/M	Screen	20JUL2018	VLN mentholated					6
		End Of Study	20SEP2018	VLN mentholated					6.5
2057	52/M	Screen	23JUL2018	VLN mentholated					7.5
		End Of Study	20SEP2018	VLN mentholated					7.5
2058	37/F	Screen	23JUL2018	VLN mentholated	0-2		0-5		5
		End Of Study	20SEP2018	VLN mentholated					6.5
2059	56/F	Screen	23JUL2018	UB mentholated					6
		End Of Study	20SEP2018	UB mentholated					6
2060	37/F	Screen	23JUL2018	VLN mentholated	11-30 *N		None seen		5.5
		End Of Study	20SEP2018	VLN mentholated					7
2064	52/M	Screen	23JUL2018	VLN mentholated					7
		End Of Study	20SEP2018	VLN mentholated					6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		-----	-----		001: 0-3	002: 0 - 2	001: 0-7	002: 0 - 5	
		Name	Date		(/HPF)		(/HPF)		001: 5-8 002: 5-7.5
2066	30/F	Screen	23JUL2018	VLN mentholated					6
		End Of Study	20SEP2018	VLN mentholated					7
2067	52/M	Screen	23JUL2018	VLN non-mentholated					6.5
		End Of Study	20SEP2018	VLN non-mentholated					7
2075	34/M	Screen	30JUL2018	VLN mentholated	0-2		0-5		5.5
		End Of Study	22AUG2018	VLN mentholated					6.5
2076	42/M	Screen	30JUL2018	VLN mentholated					5.5
		End Of Study	13OCT2018	VLN mentholated					6.5
2086	36/M	Screen	03AUG2018	VLN non-mentholated					5
		End Of Study	01OCT2018	VLN non-mentholated					7
2088	39/F	Screen	03AUG2018	VLN mentholated					6
		End Of Study	13OCT2018	VLN mentholated					5.5
2092	50/F	Screen	06AUG2018	VLN mentholated					6
		End Of Study	13OCT2018	VLN mentholated					6
2099	52/M	Screen	09AUG2018	VLN non-mentholated					6.5
		End Of Study	13OCT2018	VLN non-mentholated					6.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
2100	48/F	Screen	09AUG2018	UB mentholated					6
		End Of Study	13OCT2018	UB mentholated					5.5
2108	60/F	Screen	13AUG2018	VLN non-mentholated					7.5
		End Of Study	13OCT2018	VLN non-mentholated					6.5
2110	41/F	Screen	13AUG2018	UB mentholated	None seen 0-2		6-10 *N 0-5		5.5
		End Of Study	19OCT2018	UB mentholated					6
2113	51/F	Screen	15AUG2018	VLN mentholated					6.5
2115	46/F	Screen	15AUG2018	VLN mentholated					6.5
2119	48/M	Screen	20AUG2018	VLN mentholated	0-2		0-5		6.5
		End Of Study	19OCT2018	VLN mentholated					6.5
2120	62/F	Screen	20AUG2018	VLN non-mentholated					5.5
		End Of Study	19OCT2018	VLN non-mentholated					6
2122	60/M	Screen	20AUG2018	UB non-mentholated	0-2		0-5		6.5
		End Of Study	19OCT2018	UB non-mentholated					8 HN
2125	35/M	Screen	21AUG2018	UB mentholated					6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit ----- Name	Date	Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
					001: 0-3	002: 0 - 2	001: 0-7	002: 0 - 5	
					(/HPF)		(/HPF)		001: 5-8 002: 5-7.5
2125	35/M	End Of Study	19OCT2018	UB mentholated					7.5
2126	37/M	Screen	21AUG2018	VLN mentholated					5
		End Of Study	19OCT2018	VLN mentholated					5.5
2136	64/M	Screen	27AUG2018	VLN non-mentholated					5.5
		End Of Study	19OCT2018	VLN non-mentholated	3-10 *N		6-10 *N		5.5
2140	56/F	Screen	30AUG2018	UB non-mentholated	0-2		6-10 *N		7.5
		End Of Study	05NOV2018	UB non-mentholated					6.5
2142	30/F	Screen	31AUG2018	VLN non-mentholated	0-2		0-5		5.5
		End Of Study	08OCT2018	VLN non-mentholated					6
2143	63/M	Screen	04SEP2018	VLN non-mentholated					6
		End Of Study	05NOV2018	VLN non-mentholated					7
2158	43/F	Screen	18SEP2018	UB non-mentholated					6.5
2159	37/M	Screen	19SEP2018	VLN non-mentholated					7
		End Of Study	01DEC2018	VLN non-mentholated					7
2164	65/F	Screen	27SEP2018	VLN non-mentholated	0-2		0-5		6.5

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
2164	65/F	End Of Study	01DEC2018	VLN non-mentholated	0-2		0-5		6
2168	32/F	Screen	28SEP2018	VLN non-mentholated					6.5
		End Of Study	01DEC2018	VLN non-mentholated	None seen		None seen		6
2170	51/F	Screen	28SEP2018	UB non-mentholated	11-30 *N		0-5		6
		End Of Study	01DEC2018	UB non-mentholated	11-30 *N		0-5		5.5
2175	40/F	Screen	01OCT2018	UB mentholated					5.5
		End Of Study	01DEC2018	UB mentholated					5
2189	28/M	Screen	04OCT2018	VLN mentholated					6
		End Of Study	06NOV2018	VLN mentholated					6
2211	29/F	Screen	10OCT2018	VLN mentholated	3-10 *N		0-5		6.5
		End Of Study	01DEC2018	VLN mentholated	0-2		0-5		5.5
2212	32/M	Screen	10OCT2018	UB mentholated					7
		End Of Study	01DEC2018	UB mentholated					7
2213	29/M	Screen	10OCT2018	VLN mentholated					7.5
		End Of Study	01DEC2018	VLN mentholated					6

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.2 Clinical Laboratory Report - Urinalysis (II of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count		White Blood Cell Count		pH, Urine
		----- Name	----- Date		001: 0-3 002: 0 - 2 (/HPF)		001: 0-7 002: 0 - 5 (/HPF)		
2215	59/F	Screen	10OCT2018	UB mentholated					7.5
		End Of Study	01DEC2018	UB mentholated	0-2		0-5		5
2220	37/M	Screen	11OCT2018	VLN non-mentholated					6
		End Of Study	01DEC2018	VLN non-mentholated					7
2235	26/F	Screen	19OCT2018	VLN mentholated					5.5
		End Of Study	15DEC2018	VLN mentholated					5
2244	31/M	Screen	25OCT2018	VLN non-mentholated					5
		End Of Study	16DEC2018	VLN non-mentholated					5.5
2247	28/M	Screen	06NOV2018	VLN mentholated					6
		End Of Study	28DEC2018	VLN mentholated	0-2		0-5		6.5
2251	27/M	Screen	09NOV2018	UB non-mentholated					7
		End Of Study	19JAN2019	UB non-mentholated					7.5
2257	55/F	Screen	14NOV2018	UB non-mentholated					7
		End Of Study	19JAN2019	UB non-mentholated					7
2259	49/M	Screen	14NOV2018	UB mentholated					6.5
		End Of Study	19JAN2019	UB mentholated	0-2		0-5		5.5

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Red Blood Cell Count	White Blood Cell Count	pH, Urine
		-----	-----		001: 0-3 002: 0 - 2 (/HPF)	001: 0-7 002: 0 - 5 (/HPF)	
Number	Gender	Name	Date	Group			001: 5-8 002: 5-7.5
<hr/>							
2269	48/M	Screen	26NOV2018	VLN mentholated			5.5
		End Of Study	19JAN2019	VLN mentholated			6
2272	37/M	Screen	28NOV2018	VLN mentholated			5.5
		End Of Study	19JAN2019	VLN mentholated			6

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
1001	59/F	Screen	02JUL2018	VLN non-mentholated	1.014	NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated	1.022	TRACE	NEGATIVE
1002	30/M	Screen	02JUL2018	VLN non-mentholated	1.006	NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated	1.003 LN	NEGATIVE	NEGATIVE
1003	38/M	Screen	03JUL2018	VLN mentholated	1.035 HN	NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN mentholated	1.035 HN	NEGATIVE	NEGATIVE
1007	37/M	Screen	12JUL2018	VLN non-mentholated	1.012	NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated	1.026	NEGATIVE	NEGATIVE
1008	48/M	Screen	12JUL2018	VLN mentholated	1.028	NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN mentholated	1.021	NEGATIVE	NEGATIVE
1010	32/M	Screen	13JUL2018	UB mentholated	1.005	NEGATIVE	NEGATIVE
		End Of Study	06SEP2018	UB mentholated	1.007	NEGATIVE	NEGATIVE
1011	36/M	Screen	13JUL2018	UB non-mentholated	1.017	NEGATIVE	NEGATIVE
		End Of Study	06SEP2018	UB non-mentholated	1.022	NEGATIVE	NEGATIVE
1013	36/F	Screen	16JUL2018	VLN non-mentholated	1.024	TRACE	NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated	1.003 LN	TRACE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
1014	36/F	Screen	16JUL2018	VLN mentholated	1.003	LN	NEGATIVE		NEGATIVE	
		End Of Study	14SEP2018	VLN mentholated	1.015		NEGATIVE		NEGATIVE	
1015	49/F	Screen	16JUL2018	VLN mentholated	1.002	LN	NEGATIVE		NEGATIVE	
		End Of Study	14SEP2018	VLN mentholated	1.004	LN	NEGATIVE		NEGATIVE	
1016	54/M	Screen	16JUL2018	UB non-mentholated	1.004	LN	NEGATIVE		NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated	1.008		1+ *N		NEGATIVE	
1017	41/F	Screen	17JUL2018	UB mentholated	1.002	LN	NEGATIVE		NEGATIVE	
		End Of Study	13SEP2018	UB mentholated	1.016		NEGATIVE		NEGATIVE	
1018	41/F	Screen	17JUL2018	VLN mentholated	1.002	LN	NEGATIVE		NEGATIVE	
		End Of Study	15AUG2018	VLN mentholated	1.023		NEGATIVE		NEGATIVE	
1019	30/M	Screen	17JUL2018	VLN non-mentholated	1.031	HN	TRACE		NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	1.025		NEGATIVE		NEGATIVE	
1020	36/F	Screen	17JUL2018	VLN non-mentholated	1.03		NEGATIVE		NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	1.019		NEGATIVE		NEGATIVE	
1021	49/F	Screen	17JUL2018	UB non-mentholated	1.005		TRACE		NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated	1.01		NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
1023	50/F	Screen	17JUL2018	VLN non-mentholated	1.004	LN	NEGATIVE		NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	1.005		NEGATIVE		NEGATIVE	
1029	35/F	Screen	26JUL2018	VLN mentholated	1.004	LN	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	1.003	LN	NEGATIVE		NEGATIVE	
1032	53/F	Screen	13AUG2018	VLN mentholated	1.005		NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	1.007		NEGATIVE		NEGATIVE	
1034	45/M	Screen	13AUG2018	VLN non-mentholated	1.007		NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	VLN non-mentholated	1.025		NEGATIVE		NEGATIVE	
1035	44/M	Screen	13AUG2018	VLN non-mentholated	1.005		NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	1.017		NEGATIVE		NEGATIVE	
1036	38/F	Screen	13AUG2018	UB mentholated	1.004	LN	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	1.027		NEGATIVE		NEGATIVE	
1037	29/M	Screen	13AUG2018	UB mentholated	1.003	LN	NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	1.023		NEGATIVE		NEGATIVE	
1038	39/F	Screen	13AUG2018	VLN non-mentholated	1.002	LN	NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	1.005		NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
1042	47/M	Screen	13AUG2018	VLN non-mentholated	1.011		NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	1.012		TRACE		NEGATIVE	
1045	58/M	Screen	14AUG2018	UB non-mentholated	1.017		NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB non-mentholated	1.007		NEGATIVE		NEGATIVE	
1046	45/M	Screen	14AUG2018	UB mentholated	1.019		NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	1.021		NEGATIVE		NEGATIVE	
1050	33/F	Screen	14AUG2018	VLN non-mentholated	1.013		NEGATIVE		NEGATIVE	
		End Of Study	10OCT2018	VLN non-mentholated	1.017		NEGATIVE		NEGATIVE	
1051	36/F	Screen	14AUG2018	UB mentholated	1.014		TRACE		NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	1.022		1+ *R		NEGATIVE	
		Unscheduled	12NOV2018	UB mentholated	1.014		NEGATIVE		NEGATIVE	
1052	31/M	Screen	14AUG2018	VLN mentholated	1.012		NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	1.025		1+ *N		NEGATIVE	
1053	42/M	Screen	14AUG2018	VLN mentholated	1.009		NEGATIVE		NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	1.012		NEGATIVE		NEGATIVE	
1054	56/M	Screen	14AUG2018	UB non-mentholated	1.028		TRACE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
1054	56/M	End Of Study	10OCT2018	UB non-mentholated	1.025	1+ *R	NEGATIVE
		Unscheduled	22OCT2018	UB non-mentholated	1.026	TRACE	NEGATIVE
1055	39/F	Screen	14AUG2018	VLN mentholated	1.004 LN	NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated	1.005	NEGATIVE	NEGATIVE
1056	48/M	Screen	14AUG2018	VLN non-mentholated	1.003 LN	NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated	1.012	NEGATIVE	NEGATIVE
1058	30/M	Screen	15AUG2018	VLN non-mentholated	1.01	NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated	1.006	NEGATIVE	NEGATIVE
1059	38/M	Screen	27AUG2018	UB non-mentholated	1.025	TRACE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated	1.027	NEGATIVE	NEGATIVE
1060	55/M	Screen	27AUG2018	VLN mentholated	1.011	NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN mentholated	1.018	NEGATIVE	NEGATIVE
1063	31/M	Screen	27AUG2018	VLN mentholated	1.007	TRACE	NEGATIVE
		End Of Study	25OCT2018	VLN mentholated	1.007	NEGATIVE	NEGATIVE
1064	34/M	Screen	27AUG2018	UB non-mentholated	1.02	NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
1066	62/M	Screen	27AUG2018	VLN non-mentholated	1.016	NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated	1.015	TRACE	NEGATIVE
1069	40/F	Screen	28AUG2018	UB non-mentholated	1.01	NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated	1.022	TRACE	NEGATIVE
		Unscheduled	06NOV2018	UB non-mentholated	1.015	NEGATIVE	NEGATIVE
1070	53/M	Screen	28AUG2018	VLN non-mentholated	1.003 LN	NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated	1.025	NEGATIVE	NEGATIVE
1071	42/M	Screen	28AUG2018	VLN non-mentholated	1.018	NEGATIVE	NEGATIVE
1072	59/M	Screen	28AUG2018	VLN mentholated	1.004 LN	NEGATIVE	NEGATIVE
		End Of Study	22OCT2018	VLN mentholated	1.016	NEGATIVE	NEGATIVE
1074	42/M	Screen	28AUG2018	VLN non-mentholated	1.025	TRACE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated	1.021	TRACE	NEGATIVE
1075	26/F	Screen	28AUG2018	UB non-mentholated	1.009	TRACE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated	1.02	3+ *R	NEGATIVE
		Unscheduled	31OCT2018	UB non-mentholated	1.01	NEGATIVE	NEGATIVE
1077	49/F	Screen	28AUG2018	VLN non-mentholated	1.006	NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
1077	49/F	End Of Study	24OCT2018	VLN non-mentholated	1.02		2+ *R		NEGATIVE	
		Unscheduled	24NOV2018	VLN non-mentholated	1.012		TRACE		NEGATIVE	
1078	51/F	Screen	28AUG2018	VLN non-mentholated	1.022		NEGATIVE		NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	1.022		NEGATIVE		NEGATIVE	
1079	33/M	Screen	28AUG2018	VLN mentholated	1.008		NEGATIVE		NEGATIVE	
		End Of Study	24OCT2018	VLN mentholated	1.015		NEGATIVE		NEGATIVE	
1082	37/M	Screen	30AUG2018	VLN non-mentholated	1.007		NEGATIVE		NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	1.013		NEGATIVE		NEGATIVE	
1083	54/F	Screen	04SEP2018	VLN non-mentholated	1.005		NEGATIVE		NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	1.019		NEGATIVE		NEGATIVE	
1084	42/M	Screen	04SEP2018	VLN non-mentholated	1.003	LN	NEGATIVE		NEGATIVE	
1086	54/M	Screen	04SEP2018	VLN non-mentholated	1.009		TRACE		NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	1.012		NEGATIVE		NEGATIVE	
1088	26/M	Screen	04SEP2018	VLN mentholated	1.008		NEGATIVE		NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	1.021		NEGATIVE		NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
1089	60/F	Screen	04SEP2018	UB non-mentholated	1.013	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	UB non-mentholated	1.024	TRACE	NEGATIVE
		Unscheduled	09NOV2018	UB non-mentholated	1.003 LN	NEGATIVE	NEGATIVE
1092	43/F	Screen	05SEP2018	VLN mentholated	1.018	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated	1.022	NEGATIVE	NEGATIVE
1094	46/M	Screen	05SEP2018	VLN mentholated	1.017	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated	1.021	NEGATIVE	NEGATIVE
1095	55/F	Screen	07SEP2018	VLN mentholated	1.01	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated	1.008	NEGATIVE	NEGATIVE
1096	42/F	Screen	07SEP2018	VLN non-mentholated	1.01	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN non-mentholated	1.015	1+ *R	NEGATIVE
		Unscheduled	06NOV2018	VLN non-mentholated	1.006	NEGATIVE	NEGATIVE
1097	30/M	Screen	07SEP2018	VLN mentholated	1.023	1+ *R	NEGATIVE
		Unscheduled	10SEP2018	VLN mentholated	1.018	NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated	1.024	NEGATIVE	NEGATIVE
1098	63/M	Screen	18SEP2018	VLN non-mentholated	1.017	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.02	NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
001 = Lincoln, 002 = High Point, F = Female, M = Male  
\* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
PI interpretation: N = Not Clinically Significant, R = To be rechecked  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity 001: 1.005-1.03 002: 1.005-1.03	Leukocyte Esterase 001: NEG, TRACE 002: Negative	Nitrite 001: NEGATIVE 002: Negative
		----- Name	----- Date				
1099	46/F	Screen	18SEP2018	VLN non-mentholated	1.011	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.026	1+ *R	NEGATIVE
		Unscheduled	27NOV2018	VLN non-mentholated	1.021	NEGATIVE	NEGATIVE
1100	59/M	Screen	18SEP2018	VLN non-mentholated	1.025	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.023	NEGATIVE	NEGATIVE
1101	41/M	Screen	18SEP2018	VLN non-mentholated	1.003 LN	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.023	TRACE	NEGATIVE
1103	43/M	Screen	18SEP2018	VLN non-mentholated	1.005	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.018	NEGATIVE	NEGATIVE
1105	47/F	Screen	19SEP2018	VLN non-mentholated	1.007	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.024	NEGATIVE	NEGATIVE
1106	42/M	Screen	19SEP2018	UB non-mentholated	1.016	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated	1.029	NEGATIVE	NEGATIVE
1107	45/M	Screen	21SEP2018	VLN non-mentholated	1.007	NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated	1.019	NEGATIVE	NEGATIVE
1108	54/M	Screen	21SEP2018	UB non-mentholated	1.018	NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
1108	54/M	End Of Study	16NOV2018	UB non-mentholated	1.021		NEGATIVE		NEGATIVE	
1109	58/M	Screen	21SEP2018	UB non-mentholated	1.007		NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	1.019		NEGATIVE		NEGATIVE	
1112	59/F	Screen	21SEP2018	VLN non-mentholated	1.008		NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	1.01		NEGATIVE		NEGATIVE	
1114	26/F	Screen	24SEP2018	UB non-mentholated	1.006		NEGATIVE		NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	1.01		TRACE		NEGATIVE	
1115	29/M	Screen	24SEP2018	VLN non-mentholated	1.025		NEGATIVE		NEGATIVE	
2002	49/M	Screen	29JUN2018	UB mentholated	1.015		Negative		Negative	
		End Of Study	05SEP2018	UB mentholated	1.011		Negative		Negative	
2003	41/F	Screen	29JUN2018	VLN mentholated	1.005		Negative		Negative	
		End Of Study	28AUG2018	VLN mentholated	1.006		1+ *N		Negative	
2007	57/F	Screen	29JUN2018	VLN non-mentholated	1.01		Negative		Negative	
		End Of Study	28AUG2018	VLN non-mentholated	1.01		Negative		Negative	
2008	42/M	Screen	06JUL2018	VLN mentholated	1.01		Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity 001: 1.005-1.03 002: 1.005-1.03	Leukocyte Esterase 001: NEG, TRACE 002: Negative	Nitrite 001: NEGATIVE 002: Negative
		----- Name	----- Date				
2008	42/M	End Of Study	28AUG2018	VLN mentholated	1.028	Negative	Negative
2009	55/M	Screen	29JUN2018	VLN non-mentholated	1.027	Negative	Negative
2010	27/M	Screen	29JUN2018	UB mentholated	1.024	Negative	Negative
		End Of Study	28AUG2018	UB mentholated	1.023	Negative	Negative
2011	32/F	Screen	29JUN2018	VLN mentholated	1.016	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	1.018	Negative	Negative
2014	37/M	Screen	02JUL2018	VLN mentholated	1.025	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	1.028	Negative	Negative
2015	57/F	Screen	02JUL2018	UB mentholated	1.028	Negative	Negative
		End Of Study	28AUG2018	UB mentholated	>=1.030 *N	Negative	Negative
2016	45/F	Screen	02JUL2018	VLN mentholated	1.022	Negative	Negative
		End Of Study	03AUG2018	VLN mentholated	1.016	Negative	Negative
2017	30/M	Screen	02JUL2018	VLN mentholated	1.028	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	1.018	Negative	Negative
2018	26/F	Screen	02JUL2018	UB mentholated	1.018	Negative	Negative

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
2018	26/F	End Of Study	28AUG2018	UB mentholated	1.009	Negative	Negative
2020	60/F	Screen	02JUL2018	VLN mentholated	1.027	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	1.023	Negative	Negative
2021	31/M	Screen	02JUL2018	VLN mentholated	1.011	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	1.025	Negative	Negative
2023	35/M	Screen	02JUL2018	VLN mentholated	1.029	Negative	Negative
		End Of Study	28AUG2018	VLN mentholated	>=1.030 *N	Negative	Negative
2024	26/M	Screen	03JUL2018	UB non-mentholated	1.017	Negative	Negative
2025	59/M	Screen	03JUL2018	UB non-mentholated	1.023	Negative	Negative
		End Of Study	28AUG2018	UB non-mentholated	1.023	Negative	Negative
2028	36/M	Screen	06JUL2018	VLN non-mentholated	1.018	Negative	Negative
		End Of Study	28AUG2018	VLN non-mentholated	1.024	Negative	Negative
2029	56/M	Screen	09JUL2018	UB mentholated	1.009	Negative	Negative
		End Of Study	05SEP2018	UB mentholated	1.02	Negative	Negative
2039	49/F	Screen	13JUL2018	VLN mentholated	1.012	Negative	Negative

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
2039	49/F	End Of Study	05SEP2018	VLN mentholated	1.019		Negative		Negative	
2050	57/M	Screen	20JUL2018	UB mentholated	1.022		Trace *N		Negative	
		End Of Study	20SEP2018	UB mentholated	1.029		Negative		Negative	
2052	54/M	Screen	20JUL2018	VLN mentholated	1.012		Negative		Negative	
		End Of Study	20SEP2018	VLN mentholated	1.024		Negative		Negative	
2057	52/M	Screen	23JUL2018	VLN mentholated	1.008		Negative		Negative	
		End Of Study	20SEP2018	VLN mentholated	1.019		Negative		Negative	
2058	37/F	Screen	23JUL2018	VLN mentholated	1.021		Trace *N		Negative	
		End Of Study	20SEP2018	VLN mentholated	1.016		Negative		Negative	
2059	56/F	Screen	23JUL2018	UB mentholated	1.023		Negative		Negative	
		End Of Study	20SEP2018	UB mentholated	1.019		Negative		Negative	
2060	37/F	Screen	23JUL2018	VLN mentholated	1.021		Negative		Negative	
		End Of Study	20SEP2018	VLN mentholated	1.02		Negative		Negative	
2064	52/M	Screen	23JUL2018	VLN mentholated	<=1.005	*N	Negative		Negative	
		End Of Study	20SEP2018	VLN mentholated	1.006		Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		----- Name	Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
2066	30/F	Screen	23JUL2018	VLN mentholated	1.026	Negative	Negative
		End Of Study	20SEP2018	VLN mentholated	1.022	Negative	Negative
2067	52/M	Screen	23JUL2018	VLN non-mentholated	1.005	Negative	Negative
		End Of Study	20SEP2018	VLN non-mentholated	1.021	Negative	Negative
2075	34/M	Screen	30JUL2018	VLN mentholated	1.021	Trace *N	Negative
		End Of Study	22AUG2018	VLN mentholated	<=1.005 *N	Negative	Negative
2076	42/M	Screen	30JUL2018	VLN mentholated	1.015	Negative	Negative
		End Of Study	13OCT2018	VLN mentholated	1.014	Negative	Negative
2086	36/M	Screen	03AUG2018	VLN non-mentholated	1.028	Negative	Negative
		End Of Study	01OCT2018	VLN non-mentholated	1.018	Negative	Negative
2088	39/F	Screen	03AUG2018	VLN mentholated	1.013	Negative	Negative
		End Of Study	13OCT2018	VLN mentholated	1.021	Negative	Negative
2092	50/F	Screen	06AUG2018	VLN mentholated	<=1.005 *N	Negative	Negative
		End Of Study	13OCT2018	VLN mentholated	1.008	Negative	Negative
2099	52/M	Screen	09AUG2018	VLN non-mentholated	1.02	Negative	Negative
		End Of Study	13OCT2018	VLN non-mentholated	1.026	Negative	Negative

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
2100	48/F	Screen	09AUG2018	UB mentholated	1.028		Negative		Negative	
		End Of Study	13OCT2018	UB mentholated	>=1.030	*N	Negative		Negative	
2108	60/F	Screen	13AUG2018	VLN non-mentholated	1.007		Negative		Negative	
		End Of Study	13OCT2018	VLN non-mentholated	1.015		Negative		Negative	
2110	41/F	Screen	13AUG2018	UB mentholated	1.007		2+ *N		Negative	
		End Of Study	19OCT2018	UB mentholated	1.017		2+ *N		Negative	
2113	51/F	Screen	15AUG2018	VLN mentholated	1.011		Negative		Negative	
2115	46/F	Screen	15AUG2018	VLN mentholated	1.019		Negative		Negative	
2119	48/M	Screen	20AUG2018	VLN mentholated	>=1.030	*N	Negative		Negative	
		End Of Study	19OCT2018	VLN mentholated	1.021		Negative		Positive *N	
2120	62/F	Screen	20AUG2018	VLN non-mentholated	1.011		Negative		Negative	
		End Of Study	19OCT2018	VLN non-mentholated	1.016		Negative		Negative	
2122	60/M	Screen	20AUG2018	UB non-mentholated	1.022		Negative		Negative	
		End Of Study	19OCT2018	UB non-mentholated	1.02		Negative		Negative	
2125	35/M	Screen	21AUG2018	UB mentholated	1.019		Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		----- Name	----- Date		001: 1.005-1.03 002: 1.005-1.03		001: NEG, TRACE 002: Negative		001: NEGATIVE 002: Negative	
2125	35/M	End Of Study	19OCT2018	UB mentholated	1.011		Negative		Negative	
2126	37/M	Screen	21AUG2018	VLN mentholated	1.022		Negative		Negative	
		End Of Study	19OCT2018	VLN mentholated	>=1.030 *N		Negative		Negative	
2136	64/M	Screen	27AUG2018	VLN non-mentholated	1.026		Negative		Negative	
		End Of Study	19OCT2018	VLN non-mentholated	1.027		1+ *N		Positive *N	
2140	56/F	Screen	30AUG2018	UB non-mentholated	1.015		1+ *N		Negative	
		End Of Study	05NOV2018	UB non-mentholated	1.01		Negative		Negative	
2142	30/F	Screen	31AUG2018	VLN non-mentholated	1.014		Trace *N		Negative	
		End Of Study	08OCT2018	VLN non-mentholated	<=1.005 *N		Negative		Negative	
2143	63/M	Screen	04SEP2018	VLN non-mentholated	1.015		Negative		Negative	
		End Of Study	05NOV2018	VLN non-mentholated	1.023		Negative		Negative	
2158	43/F	Screen	18SEP2018	UB non-mentholated	1.024		Negative		Negative	
2159	37/M	Screen	19SEP2018	VLN non-mentholated	1.006		Negative		Negative	
		End Of Study	01DEC2018	VLN non-mentholated	1.005		Negative		Negative	
2164	65/F	Screen	27SEP2018	VLN non-mentholated	1.016		2+ *N		Negative	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
2164	65/F	End Of Study	01DEC2018	VLN non-mentholated	1.009		Trace *N		Negative	
2168	32/F	Screen	28SEP2018	VLN non-mentholated	1.005		Negative		Negative	
		End Of Study	01DEC2018	VLN non-mentholated	1.007		Negative		Negative	
2170	51/F	Screen	28SEP2018	UB non-mentholated	1.025		Negative		Negative	
		End Of Study	01DEC2018	UB non-mentholated	1.021		Negative		Negative	
2175	40/F	Screen	01OCT2018	UB mentholated	1.014		Negative		Negative	
		End Of Study	01DEC2018	UB mentholated	1.013		Negative		Negative	
2189	28/M	Screen	04OCT2018	VLN mentholated	1.019		Negative		Negative	
		End Of Study	06NOV2018	VLN mentholated	1.019		Negative		Negative	
2211	29/F	Screen	10OCT2018	VLN mentholated	1.006		Negative		Negative	
		End Of Study	01DEC2018	VLN mentholated	1.019		Negative		Negative	
2212	32/M	Screen	10OCT2018	UB mentholated	1.019		Negative		Negative	
		End Of Study	01DEC2018	UB mentholated	1.022		Negative		Negative	
2213	29/M	Screen	10OCT2018	VLN mentholated	1.022		Negative		Negative	
		End Of Study	01DEC2018	VLN mentholated	1.024		Negative		Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.3 Clinical Laboratory Report - Urinalysis (III of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity		Leukocyte Esterase		Nitrite	
		Name	Date		001: 1.005-1.03	002: 1.005-1.03	001: NEG, TRACE	002: Negative	001: NEGATIVE	002: Negative
2215	59/F	Screen	10OCT2018	UB mentholated	1.011		Negative		Negative	
		End Of Study	01DEC2018	UB mentholated	1.022		Trace *N		Negative	
2220	37/M	Screen	11OCT2018	VLN non-mentholated	>=1.030	*N	Negative		Negative	
		End Of Study	01DEC2018	VLN non-mentholated	1.024		Negative		Negative	
2235	26/F	Screen	19OCT2018	VLN mentholated	1.028		Negative		Negative	
		End Of Study	15DEC2018	VLN mentholated	1.024		Negative		Negative	
2244	31/M	Screen	25OCT2018	VLN non-mentholated	1.027		Negative		Negative	
		End Of Study	16DEC2018	VLN non-mentholated	1.028		Negative		Negative	
2247	28/M	Screen	06NOV2018	VLN mentholated	1.018		Negative		Negative	
		End Of Study	28DEC2018	VLN mentholated	1.015		Trace *N		Negative	
2251	27/M	Screen	09NOV2018	UB non-mentholated	1.008		Negative		Negative	
		End Of Study	19JAN2019	UB non-mentholated	1.019		Negative		Negative	
2257	55/F	Screen	14NOV2018	UB non-mentholated	1.006		Negative		Negative	
		End Of Study	19JAN2019	UB non-mentholated	1.023		Negative		Negative	
2259	49/M	Screen	14NOV2018	UB mentholated	1.026		Negative		Negative	
		End Of Study	19JAN2019	UB mentholated	1.021		Trace *N		Negative	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



Subject Number	Age\$/ Gender	Visit		Product Group	Specific Gravity	Leukocyte Esterase	Nitrite
		Name	Date		001: 1.005-1.03 002: 1.005-1.03	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: Negative
2269	48/M	Screen	26NOV2018	VLN mentholated	1.017	Negative	Negative
		End Of Study	19JAN2019	VLN mentholated	1.024	Negative	Negative
2272	37/M	Screen	28NOV2018	VLN mentholated	1.029	Negative	Negative
		End Of Study	19JAN2019	VLN mentholated	1.026	Negative	Negative

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range, L = Below Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1001	59/F	Screen	02JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1002	30/M	Screen	02JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1003	38/M	Screen	03JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN mentholated		TRACE	NEGATIVE
1007	37/M	Screen	12JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1008	48/M	Screen	12JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	07SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
1010	32/M	Screen	13JUL2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	06SEP2018	UB mentholated		NEGATIVE	NEGATIVE
1011	36/M	Screen	13JUL2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	06SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
1013	36/F	Screen	16JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	----- Date				
1014	36/F	Screen	16JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
1015	49/F	Screen	16JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
1016	54/M	Screen	16JUL2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	13SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
1017	41/F	Screen	17JUL2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	13SEP2018	UB mentholated		NEGATIVE	NEGATIVE
1018	41/F	Screen	17JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	15AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
1019	30/M	Screen	17JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1020	36/F	Screen	17JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1021	49/F	Screen	17JUL2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	13SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range  
 PI interpretation: N = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1023	50/F	Screen	17JUL2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	14SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1029	35/F	Screen	26JUL2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1032	53/F	Screen	13AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1034	45/M	Screen	13AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1035	44/M	Screen	13AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1036	38/F	Screen	13AUG2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB mentholated		NEGATIVE	NEGATIVE
1037	29/M	Screen	13AUG2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB mentholated		TRACE	NEGATIVE
1038	39/F	Screen	13AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1042	47/M	Screen	13AUG2018	VLN non-mentholated		TRACE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1045	58/M	Screen	14AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB non-mentholated		NEGATIVE	NEGATIVE
1046	45/M	Screen	14AUG2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB mentholated		NEGATIVE	NEGATIVE
1050	33/F	Screen	14AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1051	36/F	Screen	14AUG2018	UB mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB mentholated		NEGATIVE	NEGATIVE
		Unscheduled	12NOV2018	UB mentholated		NEGATIVE	NEGATIVE
1052	31/M	Screen	14AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1053	42/M	Screen	14AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1054	56/M	Screen	14AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	10OCT2018	UB non-mentholated		TRACE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1054	56/M	Unscheduled	22OCT2018	UB non-mentholated		TRACE	NEGATIVE
1055	39/F	Screen	14AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1056	48/M	Screen	14AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1058	30/M	Screen	15AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	11OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1059	38/M	Screen	27AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated		TRACE	NEGATIVE
1060	55/M	Screen	27AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1063	31/M	Screen	27AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	25OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1064	34/M	Screen	27AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
1066	62/M	Screen	27AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1069	40/F	Screen	28AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	06NOV2018	UB non-mentholated		NEGATIVE	NEGATIVE
1070	53/M	Screen	28AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated		TRACE	NEGATIVE
1071	42/M	Screen	28AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1072	59/M	Screen	28AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	22OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1074	42/M	Screen	28AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated		TRACE	NEGATIVE
1075	26/F	Screen	28AUG2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	UB non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	31OCT2018	UB non-mentholated		NEGATIVE	NEGATIVE
1077	49/F	Screen	28AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	24NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1078	51/F	Screen	28AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1078	51/F	End Of Study	24OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1079	33/M	Screen	28AUG2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1082	37/M	Screen	30AUG2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	24OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1083	54/F	Screen	04SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1084	42/M	Screen	04SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1086	54/M	Screen	04SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1088	26/M	Screen	04SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1089	60/F	Screen	04SEP2018	UB non-mentholated		TRACE	NEGATIVE
		End Of Study	31OCT2018	UB non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	09NOV2018	UB non-mentholated		NEGATIVE	NEGATIVE
1092	43/F	Screen	05SEP2018	VLN mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
1092	43/F	End Of Study	31OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1094	46/M	Screen	05SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1095	55/F	Screen	07SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1096	42/F	Screen	07SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	06NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1097	30/M	Screen	07SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
		Unscheduled	10SEP2018	VLN mentholated		NEGATIVE	NEGATIVE
		End Of Study	31OCT2018	VLN mentholated		NEGATIVE	NEGATIVE
1098	63/M	Screen	18SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1099	46/F	Screen	18SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		Unscheduled	27NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1100	59/M	Screen	18SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	Date				
1100	59/M	End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1101	41/M	Screen	18SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1103	43/M	Screen	18SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1105	47/F	Screen	19SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1106	42/M	Screen	19SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated		TRACE	NEGATIVE
1107	45/M	Screen	21SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1108	54/M	Screen	21SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated		NEGATIVE	NEGATIVE
1109	58/M	Screen	21SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated		NEGATIVE	NEGATIVE
1112	59/F	Screen	21SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	Date				
1112	59/F	End Of Study	16NOV2018	VLN non-mentholated		NEGATIVE	NEGATIVE
1114	26/F	Screen	24SEP2018	UB non-mentholated		NEGATIVE	NEGATIVE
		End Of Study	16NOV2018	UB non-mentholated		NEGATIVE	NEGATIVE
1115	29/M	Screen	24SEP2018	VLN non-mentholated		NEGATIVE	NEGATIVE
2002	49/M	Screen	29JUN2018	UB mentholated		Negative	0.2
		End Of Study	05SEP2018	UB mentholated		Negative	0.2
2003	41/F	Screen	29JUN2018	VLN mentholated		Negative	0.2
		End Of Study	28AUG2018	VLN mentholated	0-10	Negative	0.2
2007	57/F	Screen	29JUN2018	VLN non-mentholated	0-10	Negative	0.2
		End Of Study	28AUG2018	VLN non-mentholated		Negative	0.2
2008	42/M	Screen	06JUL2018	VLN mentholated		Negative	0.2
		End Of Study	28AUG2018	VLN mentholated		Trace *N	1
2009	55/M	Screen	29JUN2018	VLN non-mentholated		Negative	0.2
2010	27/M	Screen	29JUN2018	UB mentholated		Negative	0.2
		End Of Study	28AUG2018	UB mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	Date				
2011	32/F	Screen	29JUN2018	VLN mentholated		Negative	1
		End Of Study	28AUG2018	VLN mentholated		Negative	1
2014	37/M	Screen	02JUL2018	VLN mentholated		Trace *N	0.2
		End Of Study	28AUG2018	VLN mentholated		Trace *N	0.2
2015	57/F	Screen	02JUL2018	UB mentholated		Negative	1
		End Of Study	28AUG2018	UB mentholated		Negative	0.2
2016	45/F	Screen	02JUL2018	VLN mentholated		Negative	0.2
		End Of Study	03AUG2018	VLN mentholated		Negative	0.2
2017	30/M	Screen	02JUL2018	VLN mentholated		Trace *N	0.2
		End Of Study	28AUG2018	VLN mentholated		Negative	0.2
2018	26/F	Screen	02JUL2018	UB mentholated		Negative	0.2
		End Of Study	28AUG2018	UB mentholated		Negative	0.2
2020	60/F	Screen	02JUL2018	VLN mentholated		Negative	1
		End Of Study	28AUG2018	VLN mentholated		Negative	0.2
2021	31/M	Screen	02JUL2018	VLN mentholated		Negative	0.2
		End Of Study	28AUG2018	VLN mentholated		Negative	1

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	----- Date				
2023	35/M	Screen	02JUL2018	VLN mentholated		Negative	0.2
		End Of Study	28AUG2018	VLN mentholated		Negative	1
2024	26/M	Screen	03JUL2018	UB non-mentholated		Negative	0.2
2025	59/M	Screen	03JUL2018	UB non-mentholated		Negative	0.2
		End Of Study	28AUG2018	UB non-mentholated		Negative	0.2
2028	36/M	Screen	06JUL2018	VLN non-mentholated		Negative	0.2
		End Of Study	28AUG2018	VLN non-mentholated		Negative	1
2029	56/M	Screen	09JUL2018	UB mentholated		Negative	0.2
		End Of Study	05SEP2018	UB mentholated		Negative	0.2
2039	49/F	Screen	13JUL2018	VLN mentholated		Negative	0.2
		End Of Study	05SEP2018	VLN mentholated		Negative	1
2050	57/M	Screen	20JUL2018	UB mentholated	None seen	Negative	1
		End Of Study	20SEP2018	UB mentholated		Negative	0.2
2052	54/M	Screen	20JUL2018	VLN mentholated		Negative	0.2
		End Of Study	20SEP2018	VLN mentholated		Negative	0.2
2057	52/M	Screen	23JUL2018	VLN mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	Date				
2057	52/M	End Of Study	20SEP2018	VLN mentholated		Negative	1
2058	37/F	Screen	23JUL2018	VLN mentholated	0-10	Negative	0.2
		End Of Study	20SEP2018	VLN mentholated		Negative	0.2
2059	56/F	Screen	23JUL2018	UB mentholated		Negative	1
		End Of Study	20SEP2018	UB mentholated		Negative	0.2
2060	37/F	Screen	23JUL2018	VLN mentholated	0-10	Negative	0.2
		End Of Study	20SEP2018	VLN mentholated		Negative	1
2064	52/M	Screen	23JUL2018	VLN mentholated		Negative	0.2
		End Of Study	20SEP2018	VLN mentholated		Negative	0.2
2066	30/F	Screen	23JUL2018	VLN mentholated		Negative	0.2
		End Of Study	20SEP2018	VLN mentholated		Negative	1
2067	52/M	Screen	23JUL2018	VLN non-mentholated		Negative	0.2
		End Of Study	20SEP2018	VLN non-mentholated		Negative	0.2
2075	34/M	Screen	30JUL2018	VLN mentholated	0-10	Negative	0.2
		End Of Study	22AUG2018	VLN mentholated		Negative	0.2
2076	42/M	Screen	30JUL2018	VLN mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	Date				
2076	42/M	End Of Study	13OCT2018	VLN mentholated		Negative	0.2
2086	36/M	Screen	03AUG2018	VLN non-mentholated		Negative	0.2
		End Of Study	01OCT2018	VLN non-mentholated		Negative	0.2
2088	39/F	Screen	03AUG2018	VLN mentholated		Negative	0.2
		End Of Study	13OCT2018	VLN mentholated		Negative	0.2
2092	50/F	Screen	06AUG2018	VLN mentholated		Negative	0.2
		End Of Study	13OCT2018	VLN mentholated		Negative	0.2
2099	52/M	Screen	09AUG2018	VLN non-mentholated		Negative	1
		End Of Study	13OCT2018	VLN non-mentholated		Negative	0.2
2100	48/F	Screen	09AUG2018	UB mentholated		Negative	1
		End Of Study	13OCT2018	UB mentholated		Trace *N	0.2
2108	60/F	Screen	13AUG2018	VLN non-mentholated		Negative	0.2
		End Of Study	13OCT2018	VLN non-mentholated		Negative	0.2
2110	41/F	Screen	13AUG2018	UB mentholated	0-10	Negative	0.2
		End Of Study	19OCT2018	UB mentholated	>10 *N	Negative	0.2
2113	51/F	Screen	15AUG2018	VLN mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	----- Date				
2115	46/F	Screen	15AUG2018	VLN mentholated		Negative	1
2119	48/M	Screen	20AUG2018	VLN mentholated		Trace *N	0.2
		End Of Study	19OCT2018	VLN mentholated	0-10	Negative	0.2
2120	62/F	Screen	20AUG2018	VLN non-mentholated		Negative	0.2
		End Of Study	19OCT2018	VLN non-mentholated		Negative	0.2
2122	60/M	Screen	20AUG2018	UB non-mentholated	0-10	Negative	0.2
		End Of Study	19OCT2018	UB non-mentholated		Negative	0.2
2125	35/M	Screen	21AUG2018	UB mentholated		Negative	1
		End Of Study	19OCT2018	UB mentholated		Negative	0.2
2126	37/M	Screen	21AUG2018	VLN mentholated		Negative	0.2
		End Of Study	19OCT2018	VLN mentholated		Negative	0.2
2136	64/M	Screen	27AUG2018	VLN non-mentholated		Negative	0.2
		End Of Study	19OCT2018	VLN non-mentholated	0-10	Trace *N	1
2140	56/F	Screen	30AUG2018	UB non-mentholated	0-10	Negative	0.2
		End Of Study	05NOV2018	UB non-mentholated		Negative	0.2
2142	30/F	Screen	31AUG2018	VLN non-mentholated	>10 *N	Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	----- Date				
2142	30/F	End Of Study	08OCT2018	VLN non-mentholated		Negative	0.2
2143	63/M	Screen	04SEP2018	VLN non-mentholated		Negative	0.2
		End Of Study	05NOV2018	VLN non-mentholated		Trace *N	1
2158	43/F	Screen	18SEP2018	UB non-mentholated		Negative	0.2
2159	37/M	Screen	19SEP2018	VLN non-mentholated		Negative	0.2
		End Of Study	01DEC2018	VLN non-mentholated		Negative	0.2
2164	65/F	Screen	27SEP2018	VLN non-mentholated	0-10	Negative	1
		End Of Study	01DEC2018	VLN non-mentholated	0-10	Negative	0.2
2168	32/F	Screen	28SEP2018	VLN non-mentholated		Negative	0.2
		End Of Study	01DEC2018	VLN non-mentholated	0-10	Negative	0.2
2170	51/F	Screen	28SEP2018	UB non-mentholated	0-10	Negative	1
		End Of Study	01DEC2018	UB non-mentholated	0-10	Negative	0.2
2175	40/F	Screen	01OCT2018	UB mentholated		Negative	0.2
		End Of Study	01DEC2018	UB mentholated		Negative	0.2
2189	28/M	Screen	04OCT2018	VLN mentholated		Trace *N	1
		End Of Study	06NOV2018	VLN mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.4 Clinical Laboratory Report - Urinalysis (IV of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells	Ketones	Urobilinogen
		----- Name	Date		002: 0 - 10 (/HPF)	001: NEG, TRACE 002: Negative	001: NEGATIVE 002: 0.2-1
2211	29/F	Screen	10OCT2018	VLN mentholated	0-10	1+ *N	0.2
		End Of Study	01DEC2018	VLN mentholated	0-10	Negative	0.2
2212	32/M	Screen	10OCT2018	UB mentholated		Negative	0.2
		End Of Study	01DEC2018	UB mentholated		Negative	0.2
2213	29/M	Screen	10OCT2018	VLN mentholated		Negative	0.2
		End Of Study	01DEC2018	VLN mentholated		Negative	0.2
2215	59/F	Screen	10OCT2018	UB mentholated		Negative	0.2
		End Of Study	01DEC2018	UB mentholated	0-10	Negative	0.2
2220	37/M	Screen	11OCT2018	VLN non-mentholated		Negative	0.2
		End Of Study	01DEC2018	VLN non-mentholated		Negative	0.2
2235	26/F	Screen	19OCT2018	VLN mentholated		Negative	0.2
		End Of Study	15DEC2018	VLN mentholated		Negative	0.2
2244	31/M	Screen	25OCT2018	VLN non-mentholated		Negative	0.2
		End Of Study	16DEC2018	VLN non-mentholated		Negative	0.2
2247	28/M	Screen	06NOV2018	VLN mentholated		Negative	0.2
		End Of Study	28DEC2018	VLN mentholated	None seen	Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Epithelial Cells 002: 0 - 10 (/HPF)	Ketones 001: NEG, TRACE 002: Negative	Urobilinogen 001: NEGATIVE 002: 0.2-1
		----- Name	----- Date				
2251	27/M	Screen	09NOV2018	UB non-mentholated	0-10	Negative	0.2
		End Of Study	19JAN2019	UB non-mentholated		Negative	0.2
2257	55/F	Screen	14NOV2018	UB non-mentholated	0-10	Negative	0.2
		End Of Study	19JAN2019	UB non-mentholated		Negative	0.2
2259	49/M	Screen	14NOV2018	UB mentholated	0-10	Negative	1
		End Of Study	19JAN2019	UB mentholated		Negative	0.2
2269	48/M	Screen	26NOV2018	VLN mentholated	0-10	Negative	0.2
		End Of Study	19JAN2019	VLN mentholated		Negative	0.2
2272	37/M	Screen	28NOV2018	VLN mentholated	0-10	Negative	0.2
		End Of Study	19JAN2019	VLN mentholated		Negative	0.2

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen	Bacteria	Casts
		Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)	001: NEGATIVE 002: None seen/Few	001: 0-1 (/LPF)
1001	59/F	Screen	02JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		
1002	30/M	Screen	02JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		
1003	38/M	Screen	03JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE		
1007	37/M	Screen	12JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		
1008	48/M	Screen	12JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE		
1010	32/M	Screen	13JUL2018	UB mentholated	NEGATIVE		
		End Of Study	06SEP2018	UB mentholated	NEGATIVE		
1011	36/M	Screen	13JUL2018	UB non-mentholated	NEGATIVE		
		End Of Study	06SEP2018	UB non-mentholated	NEGATIVE		
1013	36/F	Screen	16JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
1014	36/F	Screen	16JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE		
1015	49/F	Screen	16JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE		
1016	54/M	Screen	16JUL2018	UB non-mentholated	NEGATIVE		
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	0
1017	41/F	Screen	17JUL2018	UB mentholated	NEGATIVE		
		End Of Study	13SEP2018	UB mentholated	NEGATIVE		
1018	41/F	Screen	17JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	15AUG2018	VLN mentholated	NEGATIVE		
1019	30/M	Screen	17JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		
1020	36/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		
1021	49/F	Screen	17JUL2018	UB non-mentholated	NEGATIVE		
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen	Bacteria	Casts
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)	001: NEGATIVE 002: None seen/Few	001: 0-1 (/LPF)
1023	50/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		
1029	35/F	Screen	26JUL2018	VLN mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		
1032	53/F	Screen	13AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		
1034	45/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	10OCT2018	VLN non-mentholated	NEGATIVE		
1035	44/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		
1036	38/F	Screen	13AUG2018	UB mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		
1037	29/M	Screen	13AUG2018	UB mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		
1038	39/F	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		Name	Date				
1042	47/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		
1045	58/M	Screen	14AUG2018	UB non-mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE		
1046	45/M	Screen	14AUG2018	UB mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		
1050	33/F	Screen	14AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	10OCT2018	VLN non-mentholated	NEGATIVE		
1051	36/F	Screen	14AUG2018	UB mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		
		Unscheduled	12NOV2018	UB mentholated	NEGATIVE	NEGATIVE	2 HR
1052	31/M	Screen	14AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	3 HN
1053	42/M	Screen	14AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		
1054	56/M	Screen	14AUG2018	UB non-mentholated	NEGATIVE		
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	3 HR

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen	Bacteria	Casts
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)	001: NEGATIVE 002: None seen/Few	001: 0-1 (/LPF)
1054	56/M	Unscheduled	22OCT2018	UB non-mentholated	NEGATIVE		
1055	39/F	Screen	14AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		
1056	48/M	Screen	14AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		
1058	30/M	Screen	15AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		
1059	38/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE		
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		
1060	55/M	Screen	27AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE		
1063	31/M	Screen	27AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	25OCT2018	VLN mentholated	NEGATIVE		
1064	34/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE		
1066	62/M	Screen	27AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen		Bacteria		Casts 001: 0-1 (/LPF)
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)		001: NEGATIVE 002: None seen/Few		
1069	40/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE				
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		2 HR
		Unscheduled	06NOV2018	UB non-mentholated	NEGATIVE				
1070	53/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE				
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE				
1071	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE				
1072	59/M	Screen	28AUG2018	VLN mentholated	NEGATIVE				
		End Of Study	22OCT2018	VLN mentholated	NEGATIVE				
1074	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE				
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE				
1075	26/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE				
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		1+ *N		4 HR
		Unscheduled	31OCT2018	UB non-mentholated	NEGATIVE				
1077	49/F	Screen	28AUG2018	VLN non-mentholated	NEGATIVE				
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		1
		Unscheduled	24NOV2018	VLN non-mentholated	NEGATIVE				
1078	51/F	Screen	28AUG2018	VLN non-mentholated	NEGATIVE				

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
1078	51/F	End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		
1079	33/M	Screen	28AUG2018	VLN mentholated	NEGATIVE		
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE		
1082	37/M	Screen	30AUG2018	VLN non-mentholated	NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		
1083	54/F	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE		
1084	42/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		
1086	54/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE		
1088	26/M	Screen	04SEP2018	VLN mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE		
1089	60/F	Screen	04SEP2018	UB non-mentholated	NEGATIVE		
		End Of Study	31OCT2018	UB non-mentholated	NEGATIVE	1+ *N	2 HR
		Unscheduled	09NOV2018	UB non-mentholated	NEGATIVE		
1092	43/F	Screen	05SEP2018	VLN mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
1092	43/F	End Of Study	31OCT2018	VLN mentholated	NEGATIVE		
1094	46/M	Screen	05SEP2018	VLN mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE		
1095	55/F	Screen	07SEP2018	VLN mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE		
1096	42/F	Screen	07SEP2018	VLN non-mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	0
		Unscheduled	06NOV2018	VLN non-mentholated	NEGATIVE		
1097	30/M	Screen	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	5 HR
		Unscheduled	10SEP2018	VLN mentholated	NEGATIVE		
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE		
1098	63/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	1
1099	46/F	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	4 HR
		Unscheduled	27NOV2018	VLN non-mentholated	NEGATIVE		
1100	59/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen		Bacteria		Casts 001: 0-1 (/LPF)
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)		001: NEGATIVE 002: None seen/Few		
1100	59/M	End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1101	41/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1103	43/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1105	47/F	Screen	19SEP2018	VLN non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1106	42/M	Screen	19SEP2018	UB non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE				
1107	45/M	Screen	21SEP2018	VLN non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1108	54/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE				
1109	58/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE				
1112	59/F	Screen	21SEP2018	VLN non-mentholated	NEGATIVE				

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen		Bacteria		Casts 001: 0-1 (/LPF)
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)		001: NEGATIVE 002: None seen/Few		
1112	59/F	End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE				
1114	26/F	Screen	24SEP2018	UB non-mentholated	NEGATIVE				
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE				
1115	29/M	Screen	24SEP2018	VLN non-mentholated	NEGATIVE				
2002	49/M	Screen	29JUN2018	UB mentholated	0.2				
		End Of Study	05SEP2018	UB mentholated	0.2				
2003	41/F	Screen	29JUN2018	VLN mentholated	0.2				
		End Of Study	28AUG2018	VLN mentholated	0.2		Few		
2007	57/F	Screen	29JUN2018	VLN non-mentholated	0.2		None seen		
		End Of Study	28AUG2018	VLN non-mentholated	0.2				
2008	42/M	Screen	06JUL2018	VLN mentholated	0.2				
		End Of Study	28AUG2018	VLN mentholated	1				
2009	55/M	Screen	29JUN2018	VLN non-mentholated	0.2				
2010	27/M	Screen	29JUN2018	UB mentholated	0.2				
		End Of Study	28AUG2018	UB mentholated	0.2				

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
2011	32/F	Screen	29JUN2018	VLN mentholated	1		
		End Of Study	28AUG2018	VLN mentholated	1		
2014	37/M	Screen	02JUL2018	VLN mentholated	0.2		
		End Of Study	28AUG2018	VLN mentholated	0.2		
2015	57/F	Screen	02JUL2018	UB mentholated	1		
		End Of Study	28AUG2018	UB mentholated	0.2		
2016	45/F	Screen	02JUL2018	VLN mentholated	0.2		
		End Of Study	03AUG2018	VLN mentholated	0.2		
2017	30/M	Screen	02JUL2018	VLN mentholated	0.2		
		End Of Study	28AUG2018	VLN mentholated	0.2		
2018	26/F	Screen	02JUL2018	UB mentholated	0.2		
		End Of Study	28AUG2018	UB mentholated	0.2		
2020	60/F	Screen	02JUL2018	VLN mentholated	1		
		End Of Study	28AUG2018	VLN mentholated	0.2		
2021	31/M	Screen	02JUL2018	VLN mentholated	0.2		
		End Of Study	28AUG2018	VLN mentholated	1		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
2023	35/M	Screen	02JUL2018	VLN mentholated	0.2		
		End Of Study	28AUG2018	VLN mentholated	1		
2024	26/M	Screen	03JUL2018	UB non-mentholated	0.2		
2025	59/M	Screen	03JUL2018	UB non-mentholated	0.2		
		End Of Study	28AUG2018	UB non-mentholated	0.2		
2028	36/M	Screen	06JUL2018	VLN non-mentholated	0.2		
		End Of Study	28AUG2018	VLN non-mentholated	1		
2029	56/M	Screen	09JUL2018	UB mentholated	0.2		
		End Of Study	05SEP2018	UB mentholated	0.2		
2039	49/F	Screen	13JUL2018	VLN mentholated	0.2		
		End Of Study	05SEP2018	VLN mentholated	1		
2050	57/M	Screen	20JUL2018	UB mentholated	1	Few	
		End Of Study	20SEP2018	UB mentholated	0.2		
2052	54/M	Screen	20JUL2018	VLN mentholated	0.2		
		End Of Study	20SEP2018	VLN mentholated	0.2		
2057	52/M	Screen	23JUL2018	VLN mentholated	0.2		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range, H = Above Normal Range

PI interpretation: N = Not Clinically Significant, R = To be rechecked

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen		Bacteria		Casts 001: 0-1 (/LPF)
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)		001: NEGATIVE 002: None seen/Few		
2057	52/M	End Of Study	20SEP2018	VLN mentholated	1				
2058	37/F	Screen	23JUL2018	VLN mentholated	0.2			Few	
		End Of Study	20SEP2018	VLN mentholated	0.2				
2059	56/F	Screen	23JUL2018	UB mentholated	1				
		End Of Study	20SEP2018	UB mentholated	0.2				
2060	37/F	Screen	23JUL2018	VLN mentholated	0.2			Few	
		End Of Study	20SEP2018	VLN mentholated	1				
2064	52/M	Screen	23JUL2018	VLN mentholated	0.2				
		End Of Study	20SEP2018	VLN mentholated	0.2				
2066	30/F	Screen	23JUL2018	VLN mentholated	0.2				
		End Of Study	20SEP2018	VLN mentholated	1				
2067	52/M	Screen	23JUL2018	VLN non-mentholated	0.2				
		End Of Study	20SEP2018	VLN non-mentholated	0.2				
2075	34/M	Screen	30JUL2018	VLN mentholated	0.2			None seen	
		End Of Study	22AUG2018	VLN mentholated	0.2				
2076	42/M	Screen	30JUL2018	VLN mentholated	0.2				

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
2076	42/M	End Of Study	13OCT2018	VLN mentholated	0.2		
2086	36/M	Screen	03AUG2018	VLN non-mentholated	0.2		
		End Of Study	01OCT2018	VLN non-mentholated	0.2		
2088	39/F	Screen	03AUG2018	VLN mentholated	0.2		
		End Of Study	13OCT2018	VLN mentholated	0.2		
2092	50/F	Screen	06AUG2018	VLN mentholated	0.2		
		End Of Study	13OCT2018	VLN mentholated	0.2		
2099	52/M	Screen	09AUG2018	VLN non-mentholated	1		
		End Of Study	13OCT2018	VLN non-mentholated	0.2		
2100	48/F	Screen	09AUG2018	UB mentholated	1		
		End Of Study	13OCT2018	UB mentholated	0.2		
2108	60/F	Screen	13AUG2018	VLN non-mentholated	0.2		
		End Of Study	13OCT2018	VLN non-mentholated	0.2		
2110	41/F	Screen	13AUG2018	UB mentholated	0.2		Few
		End Of Study	19OCT2018	UB mentholated	0.2		Few
2113	51/F	Screen	15AUG2018	VLN mentholated	0.2		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen		Bacteria		Casts 001: 0-1 (/LPF)
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)		001: NEGATIVE 002: None seen/Few		
2115	46/F	Screen	15AUG2018	VLN mentholated	1				
2119	48/M	Screen	20AUG2018	VLN mentholated	0.2				
		End Of Study	19OCT2018	VLN mentholated	0.2		Few		
2120	62/F	Screen	20AUG2018	VLN non-mentholated	0.2				
		End Of Study	19OCT2018	VLN non-mentholated	0.2				
2122	60/M	Screen	20AUG2018	UB non-mentholated	0.2		Few		
		End Of Study	19OCT2018	UB non-mentholated	0.2				
2125	35/M	Screen	21AUG2018	UB mentholated	1				
		End Of Study	19OCT2018	UB mentholated	0.2				
2126	37/M	Screen	21AUG2018	VLN mentholated	0.2				
		End Of Study	19OCT2018	VLN mentholated	0.2				
2136	64/M	Screen	27AUG2018	VLN non-mentholated	0.2				
		End Of Study	19OCT2018	VLN non-mentholated	1		Few		
2140	56/F	Screen	30AUG2018	UB non-mentholated	0.2		Few		
		End Of Study	05NOV2018	UB non-mentholated	0.2				
2142	30/F	Screen	31AUG2018	VLN non-mentholated	0.2		Few		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		Name	Date				
2142	30/F	End Of Study	08OCT2018	VLN non-mentholated	0.2		
2143	63/M	Screen	04SEP2018	VLN non-mentholated	0.2		
		End Of Study	05NOV2018	VLN non-mentholated	1		
2158	43/F	Screen	18SEP2018	UB non-mentholated	0.2		
2159	37/M	Screen	19SEP2018	VLN non-mentholated	0.2		
		End Of Study	01DEC2018	VLN non-mentholated	0.2		
2164	65/F	Screen	27SEP2018	VLN non-mentholated	1		Few
		End Of Study	01DEC2018	VLN non-mentholated	0.2		Few
2168	32/F	Screen	28SEP2018	VLN non-mentholated	0.2		
		End Of Study	01DEC2018	VLN non-mentholated	0.2		Few
2170	51/F	Screen	28SEP2018	UB non-mentholated	1		Few
		End Of Study	01DEC2018	UB non-mentholated	0.2		Few
2175	40/F	Screen	01OCT2018	UB mentholated	0.2		
		End Of Study	01DEC2018	UB mentholated	0.2		
2189	28/M	Screen	04OCT2018	VLN mentholated	1		
		End Of Study	06NOV2018	VLN mentholated	0.2		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.5 Clinical Laboratory Report - Urinalysis (V of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen 001: NEGATIVE 002: 0.2-1 (mg/dL)	Bacteria 001: NEGATIVE 002: None seen/Few	Casts 001: 0-1 (/LPF)
		----- Name	Date				
2211	29/F	Screen	10OCT2018	VLN mentholated	0.2		
		End Of Study	01DEC2018	VLN mentholated	0.2	Few	
2212	32/M	Screen	10OCT2018	UB mentholated	0.2		
		End Of Study	01DEC2018	UB mentholated	0.2		
2213	29/M	Screen	10OCT2018	VLN mentholated	0.2		
		End Of Study	01DEC2018	VLN mentholated	0.2		
2215	59/F	Screen	10OCT2018	UB mentholated	0.2		
		End Of Study	01DEC2018	UB mentholated	0.2	Few	
2220	37/M	Screen	11OCT2018	VLN non-mentholated	0.2		
		End Of Study	01DEC2018	VLN non-mentholated	0.2		
2235	26/F	Screen	19OCT2018	VLN mentholated	0.2		
		End Of Study	15DEC2018	VLN mentholated	0.2		
2244	31/M	Screen	25OCT2018	VLN non-mentholated	0.2		
		End Of Study	16DEC2018	VLN non-mentholated	0.2		
2247	28/M	Screen	06NOV2018	VLN mentholated	0.2		
		End Of Study	28DEC2018	VLN mentholated	0.2	None seen	

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Urobilinogen	Bacteria	Casts
		----- Name	Date		001: NEGATIVE 002: 0.2-1 (mg/dL)	001: NEGATIVE 002: None seen/Few	001: 0-1 (/LPF)
-----							
2251	27/M	Screen	09NOV2018	UB non-mentholated	0.2		
		End Of Study	19JAN2019	UB non-mentholated	0.2		
2257	55/F	Screen	14NOV2018	UB non-mentholated	0.2		
		End Of Study	19JAN2019	UB non-mentholated	0.2		
2259	49/M	Screen	14NOV2018	UB mentholated	1		
		End Of Study	19JAN2019	UB mentholated	0.2	Few	
2269	48/M	Screen	26NOV2018	VLN mentholated	0.2		
		End Of Study	19JAN2019	VLN mentholated	0.2		
2272	37/M	Screen	28NOV2018	VLN mentholated	0.2		
		End Of Study	19JAN2019	VLN mentholated	0.2		

Note: \$Age is derived from birth date to date of informed consent  
 001 = Lincoln, 002 = High Point, F = Female, M = Male  
 \* = No Match to Normal Range, H = Above Normal Range  
 PI interpretation: N = Not Clinically Significant, R = To be rechecked  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein		Bilirubin		Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date		001: NEG, TRACE 002: Negative/Trace		001: NEGATIVE 002: Negative		
1001	59/F	Screen	02JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1002	30/M	Screen	02JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1003	38/M	Screen	03JUL2018	VLN mentholated	TRACE		NEGATIVE		
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE		NEGATIVE		
1007	37/M	Screen	12JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	07SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1008	48/M	Screen	12JUL2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	07SEP2018	VLN mentholated	NEGATIVE		NEGATIVE		
1010	32/M	Screen	13JUL2018	UB mentholated	NEGATIVE		NEGATIVE		
		End Of Study	06SEP2018	UB mentholated	NEGATIVE		NEGATIVE		
1011	36/M	Screen	13JUL2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	06SEP2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1013	36/F	Screen	16JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1014	36/F	Screen	16JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
1015	49/F	Screen	16JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	14SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
1016	54/M	Screen	16JUL2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1017	41/F	Screen	17JUL2018	UB mentholated	NEGATIVE	NEGATIVE	
		End Of Study	13SEP2018	UB mentholated	NEGATIVE	NEGATIVE	
1018	41/F	Screen	17JUL2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	15AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
1019	30/M	Screen	17JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1020	36/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1021	49/F	Screen	17JUL2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	13SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Protein		Bilirubin		Hyaline Casts 002: None seen (/LPF)
		----- Name	Date		001: NEG, TRACE 002: Negative/Trace		001: NEGATIVE 002: Negative		
1023	50/F	Screen	17JUL2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	14SEP2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1029	35/F	Screen	26JUL2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1032	53/F	Screen	13AUG2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1034	45/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	10OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1035	44/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1036	38/F	Screen	13AUG2018	UB mentholated	NEGATIVE		NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		NEGATIVE		
1037	29/M	Screen	13AUG2018	UB mentholated	NEGATIVE		NEGATIVE		
		End Of Study	10OCT2018	UB mentholated	NEGATIVE		NEGATIVE		
1038	39/F	Screen	13AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1042	47/M	Screen	13AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1045	58/M	Screen	14AUG2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1046	45/M	Screen	14AUG2018	UB mentholated	NEGATIVE	NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	NEGATIVE	NEGATIVE	
1050	33/F	Screen	14AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	10OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1051	36/F	Screen	14AUG2018	UB mentholated	NEGATIVE	NEGATIVE	
		End Of Study	10OCT2018	UB mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	12NOV2018	UB mentholated	NEGATIVE	NEGATIVE	
1052	31/M	Screen	14AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1053	42/M	Screen	14AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1054	56/M	Screen	14AUG2018	UB non-mentholated	TRACE	NEGATIVE	
		End Of Study	10OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein		Bilirubin		Hyaline Casts 002: None seen (/LPF)
		----- Name	Date		001: NEG, TRACE 002: Negative/Trace		001: NEGATIVE 002: Negative		
1054	56/M	Unscheduled	22OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1055	39/F	Screen	14AUG2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1056	48/M	Screen	14AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1058	30/M	Screen	15AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	11OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1059	38/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1060	55/M	Screen	27AUG2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1063	31/M	Screen	27AUG2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	25OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1064	34/M	Screen	27AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1066	62/M	Screen	27AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein		Bilirubin		Hyaline Casts 002: None seen (/LPF)
		----- Name	Date		001: NEG, TRACE 002: Negative/Trace		001: NEGATIVE 002: Negative		
1069	40/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		Unscheduled	06NOV2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1070	53/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1071	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1072	59/M	Screen	28AUG2018	VLN mentholated	NEGATIVE		NEGATIVE		
		End Of Study	22OCT2018	VLN mentholated	NEGATIVE		NEGATIVE		
1074	42/M	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1075	26/F	Screen	28AUG2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		
		Unscheduled	31OCT2018	UB non-mentholated	NEGATIVE		NEGATIVE		
1077	49/F	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
		Unscheduled	24NOV2018	VLN non-mentholated	NEGATIVE		NEGATIVE		
1078	51/F	Screen	28AUG2018	VLN non-mentholated	NEGATIVE		NEGATIVE		

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1078	51/F	End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1079	33/M	Screen	28AUG2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1082	37/M	Screen	30AUG2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	24OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1083	54/F	Screen	04SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1084	42/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1086	54/M	Screen	04SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1088	26/M	Screen	04SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1089	60/F	Screen	04SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	09NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1092	43/F	Screen	05SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1092	43/F	End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1094	46/M	Screen	05SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1095	55/F	Screen	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1096	42/F	Screen	07SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	06NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1097	30/M	Screen	07SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		Unscheduled	10SEP2018	VLN mentholated	NEGATIVE	NEGATIVE	
		End Of Study	31OCT2018	VLN mentholated	NEGATIVE	NEGATIVE	
1098	63/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1099	46/F	Screen	18SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	TRACE	NEGATIVE	
		Unscheduled	27NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1100	59/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1100	59/M	End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1101	41/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1103	43/M	Screen	18SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1105	47/F	Screen	19SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1106	42/M	Screen	19SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1107	45/M	Screen	21SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1108	54/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1109	58/M	Screen	21SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1112	59/F	Screen	21SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
1112	59/F	End Of Study	16NOV2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
1114	26/F	Screen	24SEP2018	UB non-mentholated	NEGATIVE	NEGATIVE	
		End Of Study	16NOV2018	UB non-mentholated	NEGATIVE	NEGATIVE	
1115	29/M	Screen	24SEP2018	VLN non-mentholated	NEGATIVE	NEGATIVE	
2002	49/M	Screen	29JUN2018	UB mentholated	Negative	Negative	
		End Of Study	05SEP2018	UB mentholated	Negative	Negative	
2003	41/F	Screen	29JUN2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	None seen
2007	57/F	Screen	29JUN2018	VLN non-mentholated	Negative	Negative	None seen
		End Of Study	28AUG2018	VLN non-mentholated	Negative	Negative	
2008	42/M	Screen	06JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2009	55/M	Screen	29JUN2018	VLN non-mentholated	Negative	Negative	
2010	27/M	Screen	29JUN2018	UB mentholated	Negative	Negative	
		End Of Study	28AUG2018	UB mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2011	32/F	Screen	29JUN2018	VLN mentholated	Trace	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2014	37/M	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2015	57/F	Screen	02JUL2018	UB mentholated	Negative	Negative	
		End Of Study	28AUG2018	UB mentholated	Negative	Negative	
2016	45/F	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	03AUG2018	VLN mentholated	Negative	Negative	
2017	30/M	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2018	26/F	Screen	02JUL2018	UB mentholated	Negative	Negative	
		End Of Study	28AUG2018	UB mentholated	Negative	Negative	
2020	60/F	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2021	31/M	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10



## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2023	35/M	Screen	02JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN mentholated	Negative	Negative	
2024	26/M	Screen	03JUL2018	UB non-mentholated	Negative	Negative	
2025	59/M	Screen	03JUL2018	UB non-mentholated	Negative	Negative	
		End Of Study	28AUG2018	UB non-mentholated	Negative	Negative	
2028	36/M	Screen	06JUL2018	VLN non-mentholated	Negative	Negative	
		End Of Study	28AUG2018	VLN non-mentholated	Negative	Negative	
2029	56/M	Screen	09JUL2018	UB mentholated	Negative	Negative	
		End Of Study	05SEP2018	UB mentholated	Negative	Negative	
2039	49/F	Screen	13JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	05SEP2018	VLN mentholated	Negative	Negative	
2050	57/M	Screen	20JUL2018	UB mentholated	Negative	Negative	None seen
		End Of Study	20SEP2018	UB mentholated	Negative	Negative	
2052	54/M	Screen	20JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2057	52/M	Screen	23JUL2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2057	52/M	End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2058	37/F	Screen	23JUL2018	VLN mentholated	Negative	Negative	None seen
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2059	56/F	Screen	23JUL2018	UB mentholated	Negative	Negative	
		End Of Study	20SEP2018	UB mentholated	Negative	Negative	
2060	37/F	Screen	23JUL2018	VLN mentholated	Negative	Negative	None seen
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2064	52/M	Screen	23JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2066	30/F	Screen	23JUL2018	VLN mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN mentholated	Negative	Negative	
2067	52/M	Screen	23JUL2018	VLN non-mentholated	Negative	Negative	
		End Of Study	20SEP2018	VLN non-mentholated	Negative	Negative	
2075	34/M	Screen	30JUL2018	VLN mentholated	Negative	Negative	None seen
		End Of Study	22AUG2018	VLN mentholated	Negative	Negative	
2076	42/M	Screen	30JUL2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2076	42/M	End Of Study	13OCT2018	VLN mentholated	Negative	Negative	
2086	36/M	Screen	03AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01OCT2018	VLN non-mentholated	Negative	Negative	
2088	39/F	Screen	03AUG2018	VLN mentholated	Negative	Negative	
		End Of Study	13OCT2018	VLN mentholated	Negative	Negative	
2092	50/F	Screen	06AUG2018	VLN mentholated	Negative	Negative	
		End Of Study	13OCT2018	VLN mentholated	Negative	Negative	
2099	52/M	Screen	09AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	13OCT2018	VLN non-mentholated	Negative	Negative	
2100	48/F	Screen	09AUG2018	UB mentholated	Negative	Negative	
		End Of Study	13OCT2018	UB mentholated	Trace	Negative	
2108	60/F	Screen	13AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	13OCT2018	VLN non-mentholated	Negative	Negative	
2110	41/F	Screen	13AUG2018	UB mentholated	Negative	Negative	None seen
		End Of Study	19OCT2018	UB mentholated	Negative	Negative	None seen
2113	51/F	Screen	15AUG2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2115	46/F	Screen	15AUG2018	VLN mentholated	Negative	Negative	
2119	48/M	Screen	20AUG2018	VLN mentholated	Negative	Negative	Present *N
		End Of Study	19OCT2018	VLN mentholated	Negative	Negative	
2120	62/F	Screen	20AUG2018	VLN non-mentholated	Negative	Negative	
		End Of Study	19OCT2018	VLN non-mentholated	Negative	Negative	
2122	60/M	Screen	20AUG2018	UB non-mentholated	Negative	Negative	None seen
		End Of Study	19OCT2018	UB non-mentholated	Negative	Negative	
2125	35/M	Screen	21AUG2018	UB mentholated	Negative	Negative	
		End Of Study	19OCT2018	UB mentholated	Negative	Negative	
2126	37/M	Screen	21AUG2018	VLN mentholated	Negative	Negative	
		End Of Study	19OCT2018	VLN mentholated	Negative	Negative	
2136	64/M	Screen	27AUG2018	VLN non-mentholated	Negative	Negative	None seen
		End Of Study	19OCT2018	VLN non-mentholated	Trace	Negative	
2140	56/F	Screen	30AUG2018	UB non-mentholated	Negative	Negative	None seen
		End Of Study	05NOV2018	UB non-mentholated	Negative	Negative	
2142	30/F	Screen	31AUG2018	VLN non-mentholated	Negative	Negative	None seen

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2142	30/F	End Of Study	08OCT2018	VLN non-mentholated	Negative	Negative	
2143	63/M	Screen	04SEP2018	VLN non-mentholated	Negative	Negative	
		End Of Study	05NOV2018	VLN non-mentholated	Negative	Negative	
2158	43/F	Screen	18SEP2018	UB non-mentholated	Negative	Negative	
2159	37/M	Screen	19SEP2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN non-mentholated	Negative	Negative	
2164	65/F	Screen	27SEP2018	VLN non-mentholated	Negative	Negative	None seen
		End Of Study	01DEC2018	VLN non-mentholated	Negative	Negative	None seen
2168	32/F	Screen	28SEP2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN non-mentholated	Negative	Negative	None seen
2170	51/F	Screen	28SEP2018	UB non-mentholated	Negative	Negative	None seen
		End Of Study	01DEC2018	UB non-mentholated	Negative	Negative	None seen
2175	40/F	Screen	01OCT2018	UB mentholated	Negative	Negative	
		End Of Study	01DEC2018	UB mentholated	Negative	Negative	
2189	28/M	Screen	04OCT2018	VLN mentholated	Negative	Negative	
		End Of Study	06NOV2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2211	29/F	Screen	10OCT2018	VLN mentholated	Negative	Negative	None seen
		End Of Study	01DEC2018	VLN mentholated	Negative	Negative	None seen
2212	32/M	Screen	10OCT2018	UB mentholated	Negative	Negative	
		End Of Study	01DEC2018	UB mentholated	Negative	Negative	
2213	29/M	Screen	10OCT2018	VLN mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN mentholated	Negative	Negative	
2215	59/F	Screen	10OCT2018	UB mentholated	Negative	Negative	None seen
		End Of Study	01DEC2018	UB mentholated	Negative	Negative	
2220	37/M	Screen	11OCT2018	VLN non-mentholated	Negative	Negative	
		End Of Study	01DEC2018	VLN non-mentholated	Negative	Negative	
2235	26/F	Screen	19OCT2018	VLN mentholated	Negative	Negative	
		End Of Study	15DEC2018	VLN mentholated	Negative	Negative	
2244	31/M	Screen	25OCT2018	VLN non-mentholated	Negative	Negative	
		End Of Study	16DEC2018	VLN non-mentholated	Trace	Negative	
2247	28/M	Screen	06NOV2018	VLN mentholated	Negative	Negative	None seen
		End Of Study	28DEC2018	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

## Appendix 16.2.8.1.3.6 Clinical Laboratory Report - Urinalysis (VI of VI)

Subject Number	Age\$/ Gender	Visit		Product Group	Protein 001: NEG, TRACE 002: Negative/Trace	Bilirubin 001: NEGATIVE 002: Negative	Hyaline Casts 002: None seen (/LPF)
		----- Name	----- Date				
2251	27/M	Screen	09NOV2018	UB non-mentholated	Negative	Negative	
		End Of Study	19JAN2019	UB non-mentholated	Negative	Negative	
2257	55/F	Screen	14NOV2018	UB non-mentholated	Negative	Negative	
		End Of Study	19JAN2019	UB non-mentholated	Negative	Negative	
2259	49/M	Screen	14NOV2018	UB mentholated	Negative	Negative	None seen
		End Of Study	19JAN2019	UB mentholated	Negative	Negative	
2269	48/M	Screen	26NOV2018	VLN mentholated	Negative	Negative	
		End Of Study	19JAN2019	VLN mentholated	Negative	Negative	
2272	37/M	Screen	28NOV2018	VLN mentholated	Negative	Negative	
		End Of Study	19JAN2019	VLN mentholated	Negative	Negative	

Note: \$Age is derived from birth date to date of informed consent

001 = Lincoln, 002 = High Point, F = Female, M = Male

\* = No Match to Normal Range

PI interpretation: N = Not Clinically Significant

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LAB.SAS 18JUN2019 11:10

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1001	Screening	02JUL2018	VLN non-mentholated	Hematology	Platelet Count	490	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	07SEP2018	VLN non-mentholated	Serum Chemistry	Alanine Aminotransferase	22	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Albumin	43	g/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Alkaline Phosphatase	130	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Aspartate Aminotransferase	16	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Bilirubin	0	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC; LESS THAN 0.2 MG/DL
					Carbon Dioxide	25.3	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Creatinine	51.282	umol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Glucose	5.8	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Potassium	4.8	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Protein	6.9	g/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Sodium	140	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urate	3.6	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urea Nitrogen	16	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11



Subject		Visit							
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment	
1001	End Of Study	07SEP2018	VLN non-mentholated	Hematology	Platelet Count	507	thou/uL	VERIFIED BY REPEAT ANALYSIS; LOST TO FOLLOW UP AND WAS ELEVATED AT SCREENING VERIFIED BY REPEAT ANALYSIS; NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.	
					White Blood Cell Count	12.2	thou/uL		
1002	Screening	02JUL2018	VLN non-mentholated	Serum Chemistry	Urea Nitrogen	4	mg/dL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.	
1003	End Of Study	07SEP2018	VLN mentholated	Serum Chemistry	Alanine Aminotransferase	36	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Albumin	44	g/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Alkaline Phosphatase	65	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Aspartate Aminotransferase	21	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Bilirubin	0	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC; LESS THAN 0.2 MG/DL	
					Carbon Dioxide	29	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Creatinine	94.607	umol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	
					Glucose	5	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC	

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1003	End Of Study	07SEP2018	VLN mentholated	Serum Chemistry	Potassium	4.9	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Protein	6.9	g/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Sodium	139	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urate	4.3	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urea Nitrogen	17	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
1007	End Of Study	07SEP2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
1008	Screening	12JUL2018	VLN mentholated	Hematology	Lymphocytes	62.2	%	VERIFIED BY MANUAL DIFFERENTIAL
					Neutrophils	29.1	%	VERIFIED BY MANUAL DIFFERENTIAL
	Unscheduled	16JUL2018	VLN mentholated	Hematology	Absolute Lymphocytes	4.9	thou/uL	TOTAL WBC NORMAL
					Lymphocytes	69.3	%	TOTAL WBC NORMAL
					Neutrophils	24.1	%	VERIFIED BY MANUAL DIFFERENTIAL; TOTAL WBC NORMAL
	End Of Study	07SEP2018	VLN mentholated	Serum Chemistry	Alanine Aminotransferase	21	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Albumin	44	g/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Alkaline Phosphatase	74	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1008	End Of Study	07SEP2018	VLN mentholated	Serum Chemistry	Aspartate Aminotransferase	16	IU/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Bilirubin	0.2	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Carbon Dioxide	27.9	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Creatinine	77.807	umol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Glucose	6	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Potassium	4.5	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Protein	6.6	g/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Sodium	142	mmol/L	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urate	4.3	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
					Urea Nitrogen	11	mg/dL	SERUM SAMPLE IS SLIGHTLY LIPEMIC
				Hematology	Absolute Lymphocytes	5	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1013	End Of Study	14SEP2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
				Hematology	Hemoglobin	114	g/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1014	Screening	16JUL2018	VLN mentholated	Hematology	White Blood Cell Count	11.7	thou/uL	VERIFIED BY REPEAT ANALYSIS NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	14SEP2018	VLN mentholated	Hematology	Hemoglobin	118	g/L	
1015	End Of Study	14SEP2018	VLN mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
1016	End Of Study	13SEP2018	UB non-mentholated	Serum Chemistry	Creatinine	56.587	umol/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY. ASYMPTOMATIC ASYMPTOMATIC
				Urinalysis	Leukocyte Esterase 1+ White Blood Cell Count	10	/HPF	
1019	End Of Study	14SEP2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	3.8	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1020	Screening	17JUL2018	VLN non-mentholated	Serum Chemistry	Urate	7.9	mg/dL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY. LESS THAN 0.2 MG/DL
	End Of Study	14SEP2018	VLN non-mentholated	Serum Chemistry Hematology	Bilirubin Hemoglobin	0 118	mg/dL g/L	

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1021	End Of Study	13SEP2018	UB non-mentholated	Hematology	Absolute Lymphocytes	3.6	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1029	End Of Study	11OCT2018	VLN mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
				Hematology	Absolute Lymphocytes	3.7	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1032	Screening	13AUG2018	VLN mentholated	Hematology	Platelet Count	105	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	11OCT2018	VLN mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
					Creatinine	43.324	umol/L	A LOW VALUE FOR THIS PARAMETER IS NOT CONSISTENT WITH ANY COMMON DISEASE STATE.
1034	Screening	13AUG2018	VLN non-mentholated	Serum Chemistry	Creatinine	55.703	umol/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	10OCT2018	VLN non-mentholated	Serum Chemistry	Creatinine	57.471	umol/L	A LOW VALUE FOR THIS PARAMETER IS NOT CONSISTENT WITH ANY COMMON DISEASE STATE.
1036	End Of Study	10OCT2018	UB mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1045	Screening	14AUG2018	UB non-mentholated	Serum Chemistry	Alkaline Phosphatase	145	IU/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1050	End Of Study	10OCT2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
1051	Screening	14AUG2018	UB mentholated	Hematology	White Blood Cell Count	12.8	thou/uL	VERIFIED BY REPEAT ANALYSIS; NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	10OCT2018	UB mentholated	Hematology	Absolute Lymphocytes	4.3	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
					White Blood Cell Count	12.5	thou/uL	VERIFIED BY REPEAT ANALYSIS; NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
				Urinalysis	Casts	2	/LPF	HYALINE; HYDRATE WELL AND RECHECK IN ABOUT 1 WEEK
					Leukocyte Esterase 1+			HYDRATE WELL AND RECHECK IN ABOUT 1 WEEK
					Red Blood Cell Count	4	/HPF	HYDRATE WELL AND RECHECK IN ABOUT ONE WEEK
1052	End Of Study	11OCT2018	VLN mentholated	Urinalysis	Casts	3	/LPF	HYALINE; HYALINE CASTS

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit							
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment	
1052	End Of Study	11OCT2018	VLN mentholated	Urinalysis	Leukocyte Esterase	1+		NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY. ASYMPTOMATIC, FOLLOW UP WITH PCP	
					White Blood Cell Count	11	/HPF	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY. ASYMPTOMATIC, FOLLOW UP WITH PCP	
1054	End Of Study	10OCT2018	UB non-mentholated	Urinalysis	Casts	3	/LPF	HYALINE; HYDRATE WELL AND RECHECK IN ABOUT ONE WEEK	
					Leukocyte Esterase	1+		HYDRATE WELL AND RECHECK IN ABOUT ONE WEEK	
					White Blood Cell Count	10	/HPF	HYDRATE WELL AND RECHECK IN ABOUT ONE WEEK	
1055	End Of Study	11OCT2018	VLN mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL	
					Creatinine	42.44	umol/L	A LOW VALUE FOR THIS PARAMETER IS NOT CONSISTENT WITH ANY COMMON DISEASE STATE.	
1060	End Of Study	24OCT2018	VLN mentholated	Hematology	Hemoglobin	124	g/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.	

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1066	Screening	27AUG2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	0.9	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1069	Screening	28AUG2018	UB non-mentholated	Hematology	White Blood Cell Count	11.9	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	24OCT2018	UB non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
				Urinalysis	Casts	2	/LPF	HYALINE
					Occult Blood	1+		RECHECK IF NOT ON MENSES
1072	Screening	28AUG2018	VLN mentholated	Hematology	Absolute Lymphocytes	3.8	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1075	End Of Study	24OCT2018	UB non-mentholated	Urinalysis	Casts	4	/LPF	HYALINE
1077	End Of Study	24OCT2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
				Hematology	Neutrophils	31.8	%	VERIFIED BY MANUAL DIFFERENTIAL
				Urinalysis	Casts	1	/LPF	HYALINE
	Unscheduled	24NOV2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	3.7	thou/uL	IMPROVING, WBC WNL.
1079	End Of Study	24OCT2018	VLN mentholated	Hematology	Absolute Eosinophils	1.1	thou/uL	LOST TO FOLLOW UP, ASYMPTOMATIC

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1083	End Of Study	31OCT2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
	Unscheduled	06NOV2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	3.6	thou/uL	IMPROVING
1089	End Of Study	31OCT2018	UB non-mentholated	Urinalysis	Casts Occult Blood	2 1+	/LPF	HYALINE QUERY MENSES
1095	End Of Study	31OCT2018	VLN mentholated	Hematology	Neutrophils	32.3	%	VERIFIED BY MANUAL DIFFERENTIAL
	Unscheduled	09NOV2018	VLN mentholated	Hematology	Absolute Lymphocytes	3.9	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1096	End Of Study	31OCT2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
1097	Screening	07SEP2018	VLN mentholated	Urinalysis	Casts White Blood Cell Count	5 16	/LPF /HPF	HYALINE CAST HYDRATE AND RECHECK IN 2-3 DAYS
	End Of Study	31OCT2018	VLN mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
					Creatinine	53.935	umol/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1098	End Of Study	16NOV2018	VLN non-mentholated	Urinalysis	Casts Occult Blood	1 TRACE	/LPF	HYALINE MICRO NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1099	End Of Study	16NOV2018	VLN non-mentholated	Serum Chemistry Urinalysis	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
					Casts	4	/LPF	HYALINE; RECHECK
					Leukocyte Esterase	1+		UA WITH MICRO IF POSITIVE
					Occult Blood	3+		UA WITH MICRO IF POSITIVE
					Red Blood Cell Count	53	/HPF	RECHECK
1100	End Of Study	16NOV2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	3.7	thou/uL	TOTAL WBC WNL
1101	Screening	18SEP2018	VLN non-mentholated	Serum Chemistry	Alanine Aminotransferase	78	IU/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
					Aspartate Aminotransferase	64	IU/L	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
	End Of Study	16NOV2018	VLN non-mentholated	Serum Chemistry	Alanine Aminotransferase	90	IU/L	LOST TO FOLLOW UP, ELEVATED PREDOSE
					Aspartate Aminotransferase	75	IU/L	LOST TO FOLLOW UP, ELEVATED PREDOSE
1105	Screening	19SEP2018	VLN non-mentholated	Serum Chemistry	Alanine Aminotransferase	0	IU/L	LESS THAN 5 U/L; NOT CLINICALLY SIGNIFICANT FOR THIS STUDY

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
1105	Screening	19SEP2018	VLN non-mentholated	Hematology	Absolute Neutrophils	9.4	thou/uL	NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
					White Blood Cell Count	13.1	thou/uL	VERIFIED BY REPEAT ANALYSIS; NOT SIGNIFICANT IN THE CONTEXT OF THIS STUDY.
1107	Screening	21SEP2018	VLN non-mentholated	Hematology	White Blood Cell Count	12.2	thou/uL	VERIFIED BY REPEAT ANALYSIS
	End Of Study	16NOV2018	VLN non-mentholated	Hematology	Absolute Lymphocytes	3.9	thou/uL	CONSISTENT WITH SCREENING
					White Blood Cell Count	12.1	thou/uL	VERIFIED BY REPEAT ANALYSIS; CONSISTENT WITH SCREENING
1112	End Of Study	16NOV2018	VLN non-mentholated	Serum Chemistry	Bilirubin	0	mg/dL	LESS THAN 0.2 MG/DL
2007	Screening	29JUN2018	VLN non-mentholated	Serum Chemistry	FSH	175.6	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
2015	Screening	02JUL2018	UB mentholated	Serum Chemistry	FSH	55.3	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .
2039	Screening	13JUL2018	VLN mentholated	Serum Chemistry	FSH	72.6	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .
2108	Screening	13AUG2018	VLN non-mentholated	Serum Chemistry	FSH	56.8	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
2113	Screening	15AUG2018	VLN mentholated	Serum Chemistry	FSH	58.2	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .
2122	End Of Study	20OCT2018	UB non-mentholated	Hematology	Platelet Count	185	thou/uL	PLATELETS APPEAR CLUMPED. . . . . .
					White Blood Cell Count	3.4	thou/uL	WBC DETERIORATION NOTED ON THE BLOOD SMEAR. . . . . .
2164	Screening	27SEP2018	VLN non-mentholated	Serum Chemistry	FSH	30.9	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.4 Clinical Laboratory Report - Comments (Safety Population)

Subject		Visit						
Number	Name	Date	Product Group	Lab Panel	Test	Result	Unit	Comment
2215	Screening	10OCT2018	UB mentholated	Serum Chemistry	FSH	77	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .
2257	Screening	14NOV2018	UB non-mentholated	Serum Chemistry	FSH	72.4	IU/L	ADULT FEMALE: FOLLICULAR PHASE 3.5 - 12.5 OVULATION PHASE 4.7 - 21.5 LUTEAL PHASE 1.7 - 7.7 POSTMENOPAUSAL 25.8 - 134.8 . . . . .

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 WNL = Within Normal Limits

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-LCO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1001	Screening	02JUL2018	VLN non-mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	19JUL2018	VLN non-mentholated		19JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	24JUL2018	VLN non-mentholated		24JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08AUG2018	VLN non-mentholated		08AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	22AUG2018	VLN non-mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	05SEP2018	VLN non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 2 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1001	End Of Study	07SEP2018	VLN non-mentholated		07SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1002	Screening	02JUL2018	VLN non-mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	19JUL2018	VLN non-mentholated		19JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	24JUL2018	VLN non-mentholated		24JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	08AUG2018	VLN non-mentholated		08AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	22AUG2018	VLN non-mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 3 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1002	End Of Week 4	22AUG2018	VLN non-mentholated		22AUG2018	Opiate	NEGATIVE
	End Of Week 6	05SEP2018	VLN non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	07SEP2018	VLN non-mentholated		07SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1003	Screening	03JUL2018	VLN mentholated		03JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	19JUL2018	VLN mentholated		19JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	24JUL2018	VLN mentholated		24JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08AUG2018	VLN mentholated		08AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 4 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1003	End Of Week 2	08AUG2018	VLN mentholated		08AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	05SEP2018	VLN mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	07SEP2018	VLN mentholated		07SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
1007	Screening	12JUL2018	VLN non-mentholated		12JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	19JUL2018	VLN non-mentholated		19JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	24JUL2018	VLN non-mentholated		24JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 5 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1007	End Of Week -1	24JUL2018	VLN non-mentholated		24JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	08AUG2018	VLN non-mentholated		08AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	22AUG2018	VLN non-mentholated		22AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	05SEP2018	VLN non-mentholated		05SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	07SEP2018	VLN non-mentholated		07SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
1008	Screening	12JUL2018	VLN mentholated		12JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	19JUL2018	VLN mentholated		19JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 6 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1008	Start Of Week -1	19JUL2018	VLN mentholated		19JUL2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week -1	24JUL2018	VLN mentholated		24JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08AUG2018	VLN mentholated		08AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	05SEP2018	VLN mentholated		05SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	07SEP2018	VLN mentholated		07SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
1010	Screening	13JUL2018	UB mentholated		13JUL2018	Cocaine	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 7 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1010	Screening	13JUL2018	UB mentholated		13JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	19JUL2018	UB mentholated		19JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	24JUL2018	UB mentholated		24JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08AUG2018	UB mentholated		08AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	22AUG2018	UB mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	05SEP2018	UB mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	06SEP2018	UB mentholated		06SEP2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 8 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1010	End Of Study	06SEP2018	UB mentholated		06SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1011	Screening	13JUL2018	UB non-mentholated		13JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	19JUL2018	UB non-mentholated		19JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	24JUL2018	UB non-mentholated		24JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	08AUG2018	UB non-mentholated		08AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	22AUG2018	UB non-mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 9 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1011	End Of Week 6	05SEP2018	UB non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	06SEP2018	UB non-mentholated		06SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1013	Screening	16JUL2018	VLN non-mentholated		16JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	26JUL2018	VLN non-mentholated		26JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	31JUL2018	VLN non-mentholated		31JUL2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 2	15AUG2018	VLN non-mentholated		15AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 10 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1013	End Of Week 2	15AUG2018	VLN non-mentholated		15AUG2018	Opiate	NEGATIVE
	End Of Week 4	29AUG2018	VLN non-mentholated		29AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	12SEP2018	VLN non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	14SEP2018	VLN non-mentholated		14SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1014	Screening	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	26JUL2018	VLN mentholated		26JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 11 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1014	End Of Week -1	31JUL2018	VLN mentholated		31JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	15AUG2018	VLN mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	29AUG2018	VLN mentholated		29AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	12SEP2018	VLN mentholated		12SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	14SEP2018	VLN mentholated		14SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
1015	Screening	16JUL2018	VLN mentholated		16JUL2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	26JUL2018	VLN mentholated		26JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 12 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1015	Start Of Week -1	26JUL2018	VLN mentholated		26JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	15AUG2018	VLN mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	29AUG2018	VLN mentholated		29AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	12SEP2018	VLN mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	14SEP2018	VLN mentholated		14SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1016	Screening	16JUL2018	UB non-mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 13 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1016	Screening	16JUL2018	UB non-mentholated		16JUL2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	26JUL2018	UB non-mentholated		26JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31JUL2018	UB non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	15AUG2018	UB non-mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	29AUG2018	UB non-mentholated		29AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	12SEP2018	UB non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	13SEP2018	UB non-mentholated		13SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 14 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1016	End Of Study	13SEP2018	UB non-mentholated		13SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1017	Screening	17JUL2018	UB mentholated		17JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	Start Of Week -1	26JUL2018	UB mentholated		26JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	31JUL2018	UB mentholated		31JUL2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	15AUG2018	UB mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	29AUG2018	UB mentholated		29AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	12SEP2018	UB mentholated		12SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 15 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1017	End Of Week 6	12SEP2018	UB mentholated		12SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	13SEP2018	UB mentholated		13SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1018	Screening	17JUL2018	VLN mentholated		17JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	26JUL2018	VLN mentholated		26JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	31JUL2018	VLN mentholated		31JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	15AUG2018	VLN mentholated		15AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 16 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1019	Screening	17JUL2018	VLN non-mentholated		17JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
			VLN non-mentholated		26JUL2018	Opiate	NEGATIVE
	Start Of Week -1	26JUL2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
			VLN non-mentholated		31JUL2018	Opiate	NEGATIVE
	End Of Week -1	31JUL2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
			VLN non-mentholated		15AUG2018	Opiate	NEGATIVE
	End Of Week 2	15AUG2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
			VLN non-mentholated		29AUG2018	Opiate	NEGATIVE
	End Of Week 4	29AUG2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
			VLN non-mentholated		12SEP2018	Opiate	NEGATIVE
	End Of Week 6	12SEP2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 17 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1019	End Of Study	14SEP2018	VLN non-mentholated		14SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1020	Screening	17JUL2018	VLN non-mentholated		17JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	Start Of Week -1	26JUL2018	VLN non-mentholated		26JUL2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	31JUL2018	VLN non-mentholated		31JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15AUG2018	VLN non-mentholated		15AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	29AUG2018	VLN non-mentholated		29AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 18 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1020	End Of Week 4	29AUG2018	VLN non-mentholated		29AUG2018	Opiate	NEGATIVE
	End Of Week 6	12SEP2018	VLN non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	14SEP2018	VLN non-mentholated		14SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1021	Screening	17JUL2018	UB non-mentholated		17JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	26JUL2018	UB non-mentholated		26JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31JUL2018	UB non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	15AUG2018	UB non-mentholated		15AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 19 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1021	End Of Week 2	15AUG2018	UB non-mentholated		15AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	29AUG2018	UB non-mentholated		29AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	12SEP2018	UB non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	13SEP2018	UB non-mentholated		13SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1023	Screening	17JUL2018	VLN non-mentholated		17JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	26JUL2018	VLN non-mentholated		26JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31JUL2018	VLN non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 20 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1023	End Of Week -1	31JUL2018	VLN non-mentholated		31JUL2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	15AUG2018	VLN non-mentholated		15AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	29AUG2018	VLN non-mentholated		29AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	12SEP2018	VLN non-mentholated		12SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	14SEP2018	VLN non-mentholated		14SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
1029	Screening	26JUL2018	VLN mentholated		26JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 21 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1029	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	11SEP2018	VLN mentholated		11SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

1032	Screening	13AUG2018	VLN mentholated		13AUG2018	Amphetamine	NEGATIVE
------	-----------	-----------	-----------------	--	-----------	-------------	----------

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 22 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1032	Screening	13AUG2018	VLN mentholated		13AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	VLN mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 23 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1032	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1034	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 24 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1034	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	10OCT2018	VLN non-mentholated		10OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1035	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 25 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1035	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1036	Screening	13AUG2018	UB mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	UB mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 26 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1036	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	UB mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	25SEP2018	UB mentholated		25SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	09OCT2018	UB mentholated		09OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	10OCT2018	UB mentholated		10OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
1037	Screening	13AUG2018	UB mentholated		13AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	22AUG2018	UB mentholated		22AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 27 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1037	Start Of Week -1	22AUG2018	UB mentholated		22AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	11SEP2018	UB mentholated		11SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	25SEP2018	UB mentholated		25SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	09OCT2018	UB mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	10OCT2018	UB mentholated		10OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1038	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 28 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1038	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 29 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1038	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1042	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 30 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1042	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1045	Screening	14AUG2018	UB non-mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	22AUG2018	UB non-mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	27AUG2018	UB non-mentholated		27AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	11SEP2018	UB non-mentholated		11SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 31 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1045	End Of Week 4	25SEP2018	UB non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	09OCT2018	UB non-mentholated		09OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	10OCT2018	UB non-mentholated		10OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
1046	Screening	14AUG2018	UB mentholated		14AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	22AUG2018	UB mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 32 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1046	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Opiate	NEGATIVE
	End Of Week 2	11SEP2018	UB mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	UB mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	UB mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	10OCT2018	UB mentholated		10OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1050	Screening	14AUG2018	VLN non-mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 33 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1050	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	10OCT2018	VLN non-mentholated		10OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1051	Screening	14AUG2018	UB mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 34 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1051	Screening	14AUG2018	UB mentholated		14AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	UB mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	27AUG2018	UB mentholated		27AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	11SEP2018	UB mentholated		11SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	25SEP2018	UB mentholated		25SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	09OCT2018	UB mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	10OCT2018	UB mentholated		10OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 35 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1051	End Of Study	10OCT2018	UB mentholated		10OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1052	Screening	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	VLN mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 36 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1052	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1053	Screening	14AUG2018	VLN mentholated		14AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	11SEP2018	VLN mentholated		11SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 37 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1053	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1054	Screening	14AUG2018	UB non-mentholated		14AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	22AUG2018	UB non-mentholated		22AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	27AUG2018	UB non-mentholated		27AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 38 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1054	End Of Week 2	11SEP2018	UB non-mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	25SEP2018	UB non-mentholated		25SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	09OCT2018	UB non-mentholated		09OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	10OCT2018	UB non-mentholated		10OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
1055	Screening	14AUG2018	VLN mentholated		14AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 39 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1055	Start Of Week -1	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
	End Of Week -1	27AUG2018	VLN mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	11SEP2018	VLN mentholated		11SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	25SEP2018	VLN mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1056	Screening	14AUG2018	VLN non-mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 40 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1056	Screening	14AUG2018	VLN non-mentholated		14AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 41 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1056	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Methamphetamine Opiate	NEGATIVE NEGATIVE
1058	Screening	15AUG2018	VLN non-mentholated		15AUG2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	Start Of Week -1	22AUG2018	VLN non-mentholated		22AUG2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week -1	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 2	11SEP2018	VLN non-mentholated		11SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 4	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine Cannabinoids Cocaine	NEGATIVE NEGATIVE NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 42 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1058	End Of Week 6	09OCT2018	VLN non-mentholated		09OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	11OCT2018	VLN non-mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1059						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Screening	27AUG2018	UB non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	UB non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	UB non-mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	25SEP2018	UB non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	09OCT2018	UB non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 43 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1059	End Of Week 4	09OCT2018	UB non-mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	23OCT2018	UB non-mentholated		23OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	24OCT2018	UB non-mentholated		24OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1060	Screening	27AUG2018	VLN mentholated		27AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	05SEP2018	VLN mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	10SEP2018	VLN mentholated		10SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	25SEP2018	VLN mentholated		25SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 44 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1060	End Of Week 2	25SEP2018	VLN mentholated		25SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	23OCT2018	VLN mentholated		23OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	24OCT2018	VLN mentholated		24OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
1063	Screening	27AUG2018	VLN mentholated		27AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	05SEP2018	VLN mentholated		05SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 45 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1063	End Of Week -1	10SEP2018	VLN mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	25SEP2018	VLN mentholated		25SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	09OCT2018	VLN mentholated		09OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	23OCT2018	VLN mentholated		23OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	25OCT2018	VLN mentholated		25OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
1064	Screening	27AUG2018	UB non-mentholated		27AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 46 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1064	Screening	27AUG2018	UB non-mentholated		27AUG2018	Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	UB non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	10SEP2018	UB non-mentholated		10SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	25SEP2018	UB non-mentholated		25SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Opiate	NEGATIVE
1066	Screening	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 47 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1066	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1069	Screening	28AUG2018	UB non-mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 48 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1069	Screening	28AUG2018	UB non-mentholated		28AUG2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	UB non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	10SEP2018	UB non-mentholated		10SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	25SEP2018	UB non-mentholated		25SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	09OCT2018	UB non-mentholated		09OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	23OCT2018	UB non-mentholated		23OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	24OCT2018	UB non-mentholated		24OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 49 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1069	End Of Study	24OCT2018	UB non-mentholated		24OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1070	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Cannabinoids	NEGATIVE
						Amphetamine	NEGATIVE
						Opiate	NEGATIVE
						Methamphetamine	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 50 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1070	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1071	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 51 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1071	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Ethanol	
						Methamphetamine	
1072	Screening	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	VLN mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	VLN mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	25SEP2018	VLN mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 52 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1072	End Of Week 4	09OCT2018	VLN mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	22OCT2018	VLN mentholated		22OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1074	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 53 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1074	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Opiate	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1075	Screening	28AUG2018	UB non-mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	UB non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	UB non-mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 54 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1075	End Of Week -1	10SEP2018	UB non-mentholated		10SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	25SEP2018	UB non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	09OCT2018	UB non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	23OCT2018	UB non-mentholated		23OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	UB non-mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1077	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 55 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1077	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1078	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 56 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1078	Screening	28AUG2018	VLN non-mentholated		28AUG2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 57 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1078	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE
1079	Screening	28AUG2018	VLN mentholated		28AUG2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	Start Of Week -1	05SEP2018	VLN mentholated		05SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week -1	10SEP2018	VLN mentholated		10SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 2	25SEP2018	VLN mentholated		25SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 4	09OCT2018	VLN mentholated		09OCT2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 6	23OCT2018	VLN mentholated		23OCT2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 58 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1079	End Of Week 6	23OCT2018	VLN mentholated		23OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	24OCT2018	VLN mentholated		24OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1082	Screening	30AUG2018	VLN non-mentholated		30AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	05SEP2018	VLN non-mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	10SEP2018	VLN non-mentholated		10SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	25SEP2018	VLN non-mentholated		25SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 59 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1082	End Of Week 4	09OCT2018	VLN non-mentholated		09OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	23OCT2018	VLN non-mentholated		23OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	24OCT2018	VLN non-mentholated		24OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
1083	Screening	04SEP2018	VLN non-mentholated		04SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week -1	17SEP2018	VLN non-mentholated		17SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 60 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1083	End Of Week -1	17SEP2018	VLN non-mentholated		17SEP2018	Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN non-mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	16OCT2018	VLN non-mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	30OCT2018	VLN non-mentholated		30OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN non-mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1084	Screening	04SEP2018	VLN non-mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 61 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1084	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	17SEP2018	VLN non-mentholated		17SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN non-mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	16OCT2018	VLN non-mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Ethanol	
						Methamphetamine	
						Opiate	
1086	Screening	04SEP2018	VLN non-mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 62 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1086	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	17SEP2018	VLN non-mentholated		17SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	02OCT2018	VLN non-mentholated		02OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	16OCT2018	VLN non-mentholated		16OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	30OCT2018	VLN non-mentholated		30OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	31OCT2018	VLN non-mentholated		31OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1088	Screening	04SEP2018	VLN mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 63 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1088	Screening	04SEP2018	VLN mentholated		04SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	16OCT2018	VLN mentholated		16OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 64 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1088	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1089	Screening	04SEP2018	UB non-mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	Start Of Week -1	12SEP2018	UB non-mentholated		12SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	17SEP2018	UB non-mentholated		17SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	02OCT2018	UB non-mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	16OCT2018	UB non-mentholated		16OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	30OCT2018	UB non-mentholated		30OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 65 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1089	End Of Week 6	30OCT2018	UB non-mentholated		30OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	UB non-mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1092	Screening	05SEP2018	VLN mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	02OCT2018	VLN mentholated		02OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 66 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1092	End Of Week 4	16OCT2018	VLN mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
1094	Screening	05SEP2018	VLN mentholated		05SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 67 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1094	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	16OCT2018	VLN mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1095	Screening	07SEP2018	VLN mentholated		07SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 68 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1095	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	16OCT2018	VLN mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1096	Screening	07SEP2018	VLN non-mentholated		07SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 69 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1096	Screening	07SEP2018	VLN non-mentholated		07SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	12SEP2018	VLN non-mentholated		12SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	17SEP2018	VLN non-mentholated		17SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	02OCT2018	VLN non-mentholated		02OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	16OCT2018	VLN non-mentholated		16OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	30OCT2018	VLN non-mentholated		30OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN non-mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 70 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1096	End Of Study	31OCT2018	VLN non-mentholated		31OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1097	Screening	07SEP2018	VLN mentholated		07SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	12SEP2018	VLN mentholated		12SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	17SEP2018	VLN mentholated		17SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	02OCT2018	VLN mentholated		02OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	16OCT2018	VLN mentholated		16OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Cannabinoids	NEGATIVE
						Amphetamine	NEGATIVE
						Opiate	NEGATIVE
						Methamphetamine	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 71 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1097	End Of Week 6	30OCT2018	VLN mentholated		30OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	31OCT2018	VLN mentholated		31OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1098	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 72 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1098	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1099	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 73 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1099	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
1100	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 74 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1100	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Opiate	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1101	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 75 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1101	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 76 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1101	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Methamphetamine Opiate	NEGATIVE NEGATIVE
1103	Screening	18SEP2018	VLN non-mentholated		18SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Amphetamine Cannabinoids Cocaine Ethanol Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Amphetamine Cannabinoids Cocaine	NEGATIVE NEGATIVE NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 77 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1103	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1105	Screening	19SEP2018	VLN non-mentholated		19SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 78 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1105	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
1106	Screening	19SEP2018	UB non-mentholated		19SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	28SEP2018	UB non-mentholated		28SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	03OCT2018	UB non-mentholated		03OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 79 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1106	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	01NOV2018	UB non-mentholated		01NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	15NOV2018	UB non-mentholated		15NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Study	16NOV2018	UB non-mentholated		16NOV2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1107	Screening	21SEP2018	VLN non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 80 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1107	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
1108	Screening	21SEP2018	UB non-mentholated		21SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 81 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1108	Screening	21SEP2018	UB non-mentholated		21SEP2018	Opiate	NEGATIVE
	Start Of Week -1	28SEP2018	UB non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	03OCT2018	UB non-mentholated		03OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	01NOV2018	UB non-mentholated		01NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	15NOV2018	UB non-mentholated		15NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study	16NOV2018	UB non-mentholated		16NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 82 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1108	End Of Study	16NOV2018	UB non-mentholated		16NOV2018	Opiate	NEGATIVE
1109	Screening	21SEP2018	UB non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	28SEP2018	UB non-mentholated		28SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week -1	03OCT2018	UB non-mentholated		03OCT2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	01NOV2018	UB non-mentholated		01NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 6	15NOV2018	UB non-mentholated		15NOV2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 83 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1109	End Of Week 6	15NOV2018	UB non-mentholated		15NOV2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	16NOV2018	UB non-mentholated		16NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
1112						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Screening	21SEP2018	VLN non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 84 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1112	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	15NOV2018	VLN non-mentholated		15NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	16NOV2018	VLN non-mentholated		16NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1114	Screening	24SEP2018	UB non-mentholated		24SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	28SEP2018	UB non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	03OCT2018	UB non-mentholated		03OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 85 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1114	End Of Week 2	18OCT2018	UB non-mentholated		18OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	01NOV2018	UB non-mentholated		01NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Week 6	15NOV2018	UB non-mentholated		15NOV2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	16NOV2018	UB non-mentholated		16NOV2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
1115	Screening	24SEP2018	VLN non-mentholated		24SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	Start Of Week -1	28SEP2018	VLN non-mentholated		28SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 86 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
1115	End Of Week -1	03OCT2018	VLN non-mentholated		03OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	18OCT2018	VLN non-mentholated		18OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	01NOV2018	VLN non-mentholated		01NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Ethanol	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
2002	Screening	29JUN2018	UB mentholated		29JUN2018	Ethanol	
						Methamphetamine	
						Opiate	
						Amphetamine	
						Cannabinoids	
	Start Of Week -1	18JUL2018	UB mentholated		18JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	23JUL2018	UB mentholated		23JUL2018	Cocaine	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Opiate	

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 87 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2002	End Of Week -1	23JUL2018	UB mentholated		23JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	07AUG2018	UB mentholated		07AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	21AUG2018	UB mentholated		21AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	04SEP2018	UB mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2003	Screening	29JUN2018	VLN mentholated		29JUN2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 88 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2003	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2007	Screening	29JUN2018	VLN non-mentholated		29JUN2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN non-mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 89 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2007	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	14AUG2018	VLN non-mentholated		14AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 6	28AUG2018	VLN non-mentholated		28AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study					Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
			VLN non-mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
2008	Screening	06JUL2018	VLN mentholated		06JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018				Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 90 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2008	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2009	Screening	29JUN2018	VLN non-mentholated		29JUN2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN non-mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 91 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2009	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN non-mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated			Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
2010						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Screening	29JUN2018	UB mentholated		29JUN2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	UB mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	UB mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	UB mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 92 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2010	End Of Week 2	31JUL2018	UB mentholated		31JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	UB mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	UB mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2011	Screening	29JUN2018	VLN mentholated		29JUN2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 93 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2011	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2014	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 94 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2014	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
2015	Screening	02JUL2018	UB mentholated		02JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Start Of Week -1	11JUL2018	UB mentholated		11JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	UB mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	31JUL2018	UB mentholated		31JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 95 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2015	End Of Week 2	31JUL2018	UB mentholated		31JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	UB mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	UB mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2016	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 96 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2016	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Cocaine	NEGATIVE
						Methamphetamine	POSITIVE
						Opiate	NEGATIVE
	End Of Study	03AUG2018	VLN mentholated		03AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
2017						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 97 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2017	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
2018						Cocaine	
						Methamphetamine	
						Opiate	
	Screening	02JUL2018	UB mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	UB mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	UB mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	UB mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	UB mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	UB mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 98 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2018	End Of Week 6	28AUG2018	UB mentholated		28AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
2020						Cocaine	
						Methamphetamine	
						Opiate	
	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 99 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2020	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
2021						Cocaine	
						Methamphetamine	
						Opiate	
	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 100 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2021	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
2023						Cocaine	
						Methamphetamine	
						Opiate	
	Screening	02JUL2018	VLN mentholated		02JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	VLN mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	14AUG2018	VLN mentholated		14AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 101 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2023	End Of Week 6	28AUG2018	VLN mentholated		28AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated			Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
				NOT DONE		Opiate	NEGATIVE
						Methamphetamine	
2024	Screening	03JUL2018	UB non-mentholated		03JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	UB non-mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	UB non-mentholated		16JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
2025	Screening	03JUL2018	UB non-mentholated		03JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	UB non-mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	16JUL2018	UB non-mentholated		16JUL2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 102 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2025	End Of Week -1	16JUL2018	UB non-mentholated		16JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	UB non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	14AUG2018	UB non-mentholated		14AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	28AUG2018	UB non-mentholated		28AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2028	Screening	06JUL2018	VLN non-mentholated		06JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	11JUL2018	VLN non-mentholated		11JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 103 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2028	End Of Week -1	16JUL2018	VLN non-mentholated		16JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	31JUL2018	VLN non-mentholated		31JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	14AUG2018	VLN non-mentholated		14AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	28AUG2018	VLN non-mentholated		28AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2029	Screening	09JUL2018	UB mentholated		09JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	18JUL2018	UB mentholated		18JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	23JUL2018	UB mentholated		23JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 104 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2029	End Of Week -1	23JUL2018	UB mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	07AUG2018	UB mentholated		07AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	21AUG2018	UB mentholated		21AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	04SEP2018	UB mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	Screening	13JUL2018	VLN mentholated		13JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
2039	Start Of Week -1	18JUL2018	VLN mentholated		18JUL2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	23JUL2018	VLN mentholated		23JUL2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 105 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2039	End Of Week -1	23JUL2018	VLN mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	07AUG2018	VLN mentholated		07AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	21AUG2018	VLN mentholated		21AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	04SEP2018	VLN mentholated		04SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2050	Screening	20JUL2018	UB mentholated		20JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	02AUG2018	UB mentholated		02AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	07AUG2018	UB mentholated		07AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 106 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2050	End Of Week -1	07AUG2018	UB mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	UB mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	UB mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	UB mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2052	Screening	20JUL2018	VLN mentholated		20JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 107 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2052	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2057	Screening	23JUL2018	VLN mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 108 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2057	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2058	Screening	23JUL2018	VLN mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 109 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2058	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2059	Screening	23JUL2018	UB mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	UB mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	UB mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 110 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2059	End Of Week -1	07AUG2018	UB mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	22AUG2018	UB mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05SEP2018	UB mentholated		05SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	UB mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2060	Screening	23JUL2018	VLN mentholated		23JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 111 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2060	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2064	Screening	23JUL2018	VLN mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 112 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2064	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2066	Screening	23JUL2018	VLN mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 113 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2066	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	VLN mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	VLN mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2067	Screening	23JUL2018	VLN non-mentholated		23JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	VLN non-mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	VLN non-mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 114 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2067	End Of Week -1	07AUG2018	VLN non-mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 2	22AUG2018	VLN non-mentholated		22AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05SEP2018	VLN non-mentholated		05SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19SEP2018	VLN non-mentholated		19SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2075	Screening	30JUL2018	VLN mentholated		30JUL2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	02AUG2018	VLN mentholated		02AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 115 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2075	End Of Week -1	07AUG2018	VLN mentholated		07AUG2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	22AUG2018	VLN mentholated		22AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
2076	Screening	30JUL2018	VLN mentholated		30JUL2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	26AUG2018	VLN mentholated		26AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	31AUG2018	VLN mentholated		31AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	VLN mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 116 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2076	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	13OCT2018	VLN mentholated		13OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
2086	Screening	03AUG2018	VLN non-mentholated		03AUG2018	Opiate	
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	26AUG2018	VLN non-mentholated		26AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	31AUG2018	VLN non-mentholated		31AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	VLN non-mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 117 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2086	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Unscheduled	29SEP2018	VLN non-mentholated		29SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2088	Screening	03AUG2018	VLN mentholated		03AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	26AUG2018	VLN mentholated		26AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	31AUG2018	VLN mentholated		31AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	VLN mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 118 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2088	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	13OCT2018	VLN mentholated		13OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
2092	Screening	06AUG2018	VLN mentholated		06AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	26AUG2018	VLN mentholated		26AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	31AUG2018	VLN mentholated		31AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	VLN mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 119 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2092	End Of Week 4	29SEP2018	VLN mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	13OCT2018	VLN mentholated		13OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2099	Screening	09AUG2018	VLN non-mentholated		09AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	26AUG2018	VLN non-mentholated		26AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	31AUG2018	VLN non-mentholated		31AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	15SEP2018	VLN non-mentholated		15SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 120 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2099	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	13OCT2018	VLN non-mentholated		13OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
2100	Screening	09AUG2018	UB mentholated		09AUG2018	Opiate	
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	26AUG2018	UB mentholated		26AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week -1	31AUG2018	UB mentholated		31AUG2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	UB mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	29SEP2018	UB mentholated		29SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 121 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2100	End Of Week 4	29SEP2018	UB mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	13OCT2018	UB mentholated		13OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2108	Screening	13AUG2018	VLN non-mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	26AUG2018	VLN non-mentholated		26AUG2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	31AUG2018	VLN non-mentholated		31AUG2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	15SEP2018	VLN non-mentholated		15SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 122 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2108	End Of Week 4	29SEP2018	VLN non-mentholated		29SEP2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 6	13OCT2018	VLN non-mentholated		13OCT2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2110	Screening	13AUG2018	UB mentholated		13AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	Start Of Week -1	01SEP2018	UB mentholated		01SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	06SEP2018	UB mentholated		06SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	21SEP2018	UB mentholated		21SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 4	05OCT2018	UB mentholated		05OCT2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 123 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2110	End Of Week 4	05OCT2018	UB mentholated		05OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	UB mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2113	Screening	15AUG2018	VLN mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	01SEP2018	VLN mentholated		01SEP2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	06SEP2018	VLN mentholated		06SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Week 2	21SEP2018	VLN mentholated		21SEP2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 124 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2115	Screening	15AUG2018	VLN mentholated		15AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	VLN mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	VLN mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
2119	Screening	20AUG2018	VLN mentholated		20AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	VLN mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	VLN mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 125 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2119	End Of Week 2	21SEP2018	VLN mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05OCT2018	VLN mentholated		05OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	VLN mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2120	Screening	20AUG2018	VLN non-mentholated		20AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	VLN non-mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	VLN non-mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 126 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2120	End Of Week 2	21SEP2018	VLN non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05OCT2018	VLN non-mentholated		05OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2122	Screening	20AUG2018	UB non-mentholated		20AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	UB non-mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	UB non-mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 127 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2122	End Of Week 2	21SEP2018	UB non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05OCT2018	UB non-mentholated		05OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	UB non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2125	Screening	21AUG2018	UB mentholated		21AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	UB mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	UB mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 128 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2125	End Of Week 2	21SEP2018	UB mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05OCT2018	UB mentholated		05OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	UB mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2126	Screening	21AUG2018	VLN mentholated		21AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	VLN mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	VLN mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 129 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2126	End Of Week 2	21SEP2018	VLN mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	06OCT2018	VLN mentholated		06OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	VLN mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2136	Screening	27AUG2018	VLN non-mentholated		27AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01SEP2018	VLN non-mentholated		01SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06SEP2018	VLN non-mentholated		06SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 130 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2136	End Of Week 2	21SEP2018	VLN non-mentholated		21SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	05OCT2018	VLN non-mentholated		05OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Unscheduled	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2140	Screening	30AUG2018	UB non-mentholated		30AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	18SEP2018	UB non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 131 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2140	End Of Week -1	23SEP2018	UB non-mentholated		23SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08OCT2018	UB non-mentholated		08OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	22OCT2018	UB non-mentholated		22OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	05NOV2018	UB non-mentholated		05NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2142	Screening	31AUG2018	VLN non-mentholated		31AUG2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	18SEP2018	VLN non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 132 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2142	End Of Week -1	23SEP2018	VLN non-mentholated		23SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08OCT2018	VLN non-mentholated		08OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study	08OCT2018	VLN non-mentholated		08OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
2143	Screening	04SEP2018	VLN non-mentholated		04SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	18SEP2018	VLN non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	23SEP2018	VLN non-mentholated		23SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	08OCT2018	VLN non-mentholated		08OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 133 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2143	End Of Week 4	22OCT2018	VLN non-mentholated		22OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	05NOV2018	VLN non-mentholated		05NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2158	Screening	18SEP2018	UB non-mentholated		18SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	UB non-mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	UB non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	UB non-mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 134 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2158	End Of Week 4	17NOV2018	UB non-mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Unscheduled	17NOV2018	UB non-mentholated		17NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	POSITIVE
						Cocaine	NEGATIVE
2159	Screening	19SEP2018	VLN non-mentholated		19SEP2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	Start Of Week -1	14OCT2018	VLN non-mentholated		14OCT2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
	End Of Week -1	19OCT2018	VLN non-mentholated		19OCT2018	Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	VLN non-mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week 4	17NOV2018	VLN non-mentholated		17NOV2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 135 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2159	End Of Week 6	01DEC2018	VLN non-mentholated		01DEC2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	
2164	Screening	27SEP2018	VLN non-mentholated		27SEP2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	Start Of Week -1	14OCT2018	VLN non-mentholated		14OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week -1	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 2	03NOV2018	VLN non-mentholated		03NOV2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week 4	17NOV2018	VLN non-mentholated		17NOV2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 136 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2164	End Of Week 6	01DEC2018	VLN non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2168	Screening	28SEP2018	VLN non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	VLN non-mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	VLN non-mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	VLN non-mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 137 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2168	End Of Week 6	01DEC2018	VLN non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2170	Screening	28SEP2018	UB non-mentholated		28SEP2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	UB non-mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	UB non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	UB non-mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	UB non-mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 138 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2170	End Of Week 6	01DEC2018	UB non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2175	Screening	01OCT2018	UB mentholated		01OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	UB mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	UB mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	UB mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	UB mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 139 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2175	End Of Week 6	01DEC2018	UB mentholated		01DEC2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	
2189	Screening	04OCT2018	VLN mentholated		04OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	Start Of Week -1	14OCT2018	VLN mentholated		14OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Week -1	19OCT2018	VLN mentholated		19OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
	End Of Study	06NOV2018	VLN mentholated		06NOV2018	Amphetamine Cannabinoids Cocaine Methamphetamine Opiate	NEGATIVE NEGATIVE NEGATIVE NEGATIVE NEGATIVE
2211	Screening	10OCT2018	VLN mentholated		10OCT2018	Amphetamine Cannabinoids Cocaine Methamphetamine	NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 140 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2211	Screening	10OCT2018	VLN mentholated		10OCT2018	Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	VLN mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	VLN mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	VLN mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	VLN mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2212	Screening	10OCT2018	UB mentholated		10OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 141 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2212	Screening	10OCT2018	UB mentholated		10OCT2018	Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	UB mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	UB mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	UB mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	UB mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	01DEC2018	UB mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2213	Screening	10OCT2018	VLN mentholated		10OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 142 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2213	Screening	10OCT2018	VLN mentholated		10OCT2018	Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	VLN mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	VLN mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	VLN mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	VLN mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2215	Screening	10OCT2018	UB mentholated		10OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 143 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2215	Screening	10OCT2018	UB mentholated		10OCT2018	Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	UB mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	UB mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	UB mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	UB mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	01DEC2018	UB mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2220	Screening	11OCT2018	VLN non-mentholated		11OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 144 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2220	Screening	11OCT2018	VLN non-mentholated		11OCT2018	Opiate	NEGATIVE
	Start Of Week -1	14OCT2018	VLN non-mentholated		14OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	19OCT2018	VLN non-mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	03NOV2018	VLN non-mentholated		03NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	17NOV2018	VLN non-mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	01DEC2018	VLN non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2235	Screening	19OCT2018	VLN mentholated		19OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 145 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2235	Screening	19OCT2018	VLN mentholated		19OCT2018	Opiate	NEGATIVE
	Start Of Week -1	28OCT2018	VLN mentholated		28OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	02NOV2018	VLN mentholated		02NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	17NOV2018	VLN mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	15DEC2018	VLN mentholated		15DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2244	Screening	25OCT2018	VLN non-mentholated		25OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 146 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2244	Screening	25OCT2018	VLN non-mentholated		25OCT2018	Opiate	NEGATIVE
	Start Of Week -1	28OCT2018	VLN non-mentholated		28OCT2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	02NOV2018	VLN non-mentholated		02NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 2	17NOV2018	VLN non-mentholated		17NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	01DEC2018	VLN non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	15DEC2018	VLN non-mentholated		15DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN non-mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2247	Screening	06NOV2018	VLN mentholated		06NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 147 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2247	Screening	06NOV2018	VLN mentholated		06NOV2018	Opiate	NEGATIVE
	Start Of Week -1	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Week -1	06DEC2018	VLN mentholated		06DEC2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week 2	21DEC2018	VLN mentholated		21DEC2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
	End Of Study	28DEC2018	VLN mentholated		28DEC2018	Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
2251	Screening	09NOV2018	UB non-mentholated		09NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	Start Of Week -1	01DEC2018	UB non-mentholated		01DEC2018	Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
	End Of Week -1	06DEC2018	UB non-mentholated		06DEC2018	Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
						Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 148 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2251	End Of Week -1	06DEC2018	UB non-mentholated		06DEC2018	Opiate	NEGATIVE
	End Of Week 2	21DEC2018	UB non-mentholated		21DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	04JAN2019	UB non-mentholated		04JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	18JAN2019	UB non-mentholated		18JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2257	Screening	14NOV2018	UB non-mentholated		14NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01DEC2018	UB non-mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06DEC2018	UB non-mentholated		06DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 149 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2257	End Of Week -1	06DEC2018	UB non-mentholated		06DEC2018	Opiate	NEGATIVE
	End Of Week 2	21DEC2018	UB non-mentholated		21DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	04JAN2019	UB non-mentholated		04JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	18JAN2019	UB non-mentholated		18JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB non-mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2259	Screening	14NOV2018	UB mentholated		14NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01DEC2018	UB mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06DEC2018	UB mentholated		06DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 150 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2259	End Of Week -1	06DEC2018	UB mentholated		06DEC2018	Opiate	NEGATIVE
	End Of Week 2	21DEC2018	UB mentholated		21DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	04JAN2019	UB mentholated		04JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	18JAN2019	UB mentholated		18JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		UB mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2269	Screening	26NOV2018	VLN mentholated		26NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06DEC2018	VLN mentholated		06DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 151 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2269	End Of Week -1	06DEC2018	VLN mentholated		06DEC2018	Opiate	NEGATIVE
	End Of Week 2	21DEC2018	VLN mentholated		21DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	04JAN2019	VLN mentholated		04JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	18JAN2019	VLN mentholated		18JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Opiate	NEGATIVE
						Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	
2272	Screening	28NOV2018	VLN mentholated		28NOV2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	Start Of Week -1	01DEC2018	VLN mentholated		01DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week -1	06DEC2018	VLN mentholated		06DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.5 Urine Drug Screens (Safety Population)

Page 152 of 152

Subject Number	Visit		Product Group	Was the Urine Sample Collected?	Date of Collection	Test Name	Result
	Name	Date					
2272	End Of Week -1	06DEC2018	VLN mentholated		06DEC2018	Opiate	NEGATIVE
	End Of Week 2	21DEC2018	VLN mentholated		21DEC2018	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 4	04JAN2019	VLN mentholated		04JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Week 6	18JAN2019	VLN mentholated		18JAN2019	Amphetamine	NEGATIVE
						Cannabinoids	NEGATIVE
						Cocaine	NEGATIVE
						Methamphetamine	NEGATIVE
						Opiate	NEGATIVE
	End Of Study		VLN mentholated	NOT DONE		Amphetamine	
						Cannabinoids	
						Cocaine	
						Methamphetamine	
						Opiate	

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-DG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit	Product Group	Collection Date	Test Type	Test Result
	Name				
1001	Screening	VLN non-mentholated	02JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	19JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	24JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	08AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	22AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	05SEP2018	URINE	NEGATIVE
1013	Screening	VLN non-mentholated	16JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	12SEP2018	URINE	NEGATIVE
1014	Screening	VLN mentholated	16JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	12SEP2018	URINE	NEGATIVE
1015	Screening	VLN mentholated	16JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	12SEP2018	URINE	NEGATIVE
1017	Screening	UB mentholated	17JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	UB mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	UB mentholated	31JUL2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
1017	End Of Week 2	UB mentholated	UB mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	UB mentholated	UB mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	UB mentholated	UB mentholated	12SEP2018	URINE	NEGATIVE
1018	Screening	VLN mentholated	VLN mentholated	17JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	31JUL2018	URINE	NEGATIVE
1020	Screening	VLN non-mentholated	VLN non-mentholated	17JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	12SEP2018	URINE	NEGATIVE
1021	Screening	UB non-mentholated	UB non-mentholated	17JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	UB non-mentholated	UB non-mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	UB non-mentholated	UB non-mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	UB non-mentholated	UB non-mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	UB non-mentholated	UB non-mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	UB non-mentholated	UB non-mentholated	12SEP2018	URINE	NEGATIVE
1023	Screening	VLN non-mentholated	VLN non-mentholated	17JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	26JUL2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	15AUG2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	29AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	12SEP2018	URINE	NEGATIVE
1029	Screening	VLN mentholated	VLN mentholated	26JUL2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	22AUG2018	BLOOD	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
1029	End Of Week -1	VLN mentholated	VLN mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	09OCT2018	URINE	NEGATIVE
1032	Screening	VLN mentholated	VLN mentholated	13AUG2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	09OCT2018	URINE	NEGATIVE
1036	Screening	UB mentholated	UB mentholated	13AUG2018	BLOOD	NEGATIVE
	Start Of Week -1	UB mentholated	UB mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1	UB mentholated	UB mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2	UB mentholated	UB mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4	UB mentholated	UB mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	UB mentholated	UB mentholated	09OCT2018	URINE	NEGATIVE
1038	Screening	VLN non-mentholated	VLN non-mentholated	13AUG2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	09OCT2018	URINE	NEGATIVE
1050	Screening	VLN non-mentholated	VLN non-mentholated	14AUG2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	25SEP2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
1050	End Of Week 6		VLN non-mentholated	09OCT2018	URINE	NEGATIVE
1051	Screening		UB mentholated	14AUG2018	BLOOD	NEGATIVE
	Start Of Week -1		UB mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1		UB mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2		UB mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4		UB mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6		UB mentholated	09OCT2018	URINE	NEGATIVE
1055	Screening		VLN mentholated	14AUG2018	BLOOD	NEGATIVE
	Start Of Week -1		VLN mentholated	22AUG2018	BLOOD	NEGATIVE
	End Of Week -1		VLN mentholated	27AUG2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	11SEP2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	09OCT2018	URINE	NEGATIVE
1069	Screening		UB non-mentholated	28AUG2018	BLOOD	NEGATIVE
	Start Of Week -1		UB non-mentholated	05SEP2018	BLOOD	NEGATIVE
	End Of Week -1		UB non-mentholated	10SEP2018	URINE	NEGATIVE
	End Of Week 2		UB non-mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6		UB non-mentholated	23OCT2018	URINE	NEGATIVE
1075	Screening		UB non-mentholated	28AUG2018	BLOOD	NEGATIVE
	Start Of Week -1		UB non-mentholated	05SEP2018	BLOOD	NEGATIVE
	End Of Week -1		UB non-mentholated	10SEP2018	URINE	NEGATIVE
	End Of Week 2		UB non-mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6		UB non-mentholated	23OCT2018	URINE	NEGATIVE
1077	Screening		VLN non-mentholated	28AUG2018	BLOOD	NEGATIVE
	Start Of Week -1		VLN non-mentholated	05SEP2018	BLOOD	NEGATIVE
	End Of Week -1		VLN non-mentholated	10SEP2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Page 5 of 13

Subject Number	Visit	Product Group	Collection Date	Test Type	Test Result
	----- Name				
1077	End Of Week 2	VLN non-mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	23OCT2018	URINE	NEGATIVE
1078	Screening	VLN non-mentholated	28AUG2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	05SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	10SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	25SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	23OCT2018	URINE	NEGATIVE
1083	Screening	VLN non-mentholated	04SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	12SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	17SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	02OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	16OCT2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	30OCT2018	URINE	NEGATIVE
1089	Screening	UB non-mentholated	04SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	UB non-mentholated	12SEP2018	BLOOD	NEGATIVE
	End Of Week -1	UB non-mentholated	17SEP2018	URINE	NEGATIVE
	End Of Week 2	UB non-mentholated	02OCT2018	URINE	NEGATIVE
	End Of Week 4	UB non-mentholated	16OCT2018	URINE	NEGATIVE
1092	Screening	VLN mentholated	05SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN mentholated	12SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	17SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	02OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	16OCT2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	30OCT2018	URINE	NEGATIVE
1095	Screening	VLN mentholated	07SEP2018	BLOOD	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
1095	Start Of Week -1	VLN mentholated	VLN mentholated	12SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	17SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	02OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	16OCT2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	30OCT2018	URINE	NEGATIVE
1096	Screening	VLN non-mentholated	VLN non-mentholated	07SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	12SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	17SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	02OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	16OCT2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	30OCT2018	URINE	NEGATIVE
1099	Screening	VLN non-mentholated	VLN non-mentholated	18SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	28SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	03OCT2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	18OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	01NOV2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	15NOV2018	URINE	NEGATIVE
1105	Screening	VLN non-mentholated	VLN non-mentholated	19SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	28SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	03OCT2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	18OCT2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	01NOV2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	15NOV2018	URINE	NEGATIVE
1112	Screening	VLN non-mentholated	VLN non-mentholated	21SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	28SEP2018	BLOOD	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	03OCT2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	18OCT2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
1112	End Of Week 4	VLN non-mentholated	VLN non-mentholated	01NOV2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	15NOV2018	URINE	NEGATIVE
1114	Screening	UB non-mentholated	UB non-mentholated	24SEP2018	BLOOD	NEGATIVE
	Start Of Week -1	UB non-mentholated	UB non-mentholated	28SEP2018	BLOOD	NEGATIVE
	End Of Week -1	UB non-mentholated	UB non-mentholated	03OCT2018	URINE	NEGATIVE
	End Of Week 2	UB non-mentholated	UB non-mentholated	18OCT2018	URINE	NEGATIVE
	End Of Week 4	UB non-mentholated	UB non-mentholated	01NOV2018	URINE	NEGATIVE
	End Of Week 6	UB non-mentholated	UB non-mentholated	15NOV2018	URINE	NEGATIVE
2003	Screening	VLN mentholated	VLN mentholated	29JUN2018	URINE	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	28AUG2018	URINE	NEGATIVE
2007	Screening	VLN non-mentholated	VLN non-mentholated	29JUN2018	URINE	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	28AUG2018	URINE	NEGATIVE
2011	Screening	VLN mentholated	VLN mentholated	29JUN2018	URINE	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	28AUG2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2015	Screening		UB mentholated	02JUL2018	URINE	NEGATIVE
	Start Of Week -1		UB mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1		UB mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2		UB mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4		UB mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6		UB mentholated	28AUG2018	URINE	NEGATIVE
2016	Screening		VLN mentholated	02JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	31JUL2018	URINE	NEGATIVE
2018	Screening		UB mentholated	02JUL2018	URINE	NEGATIVE
	Start Of Week -1		UB mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1		UB mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2		UB mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4		UB mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6		UB mentholated	28AUG2018	URINE	NEGATIVE
2020	Screening		VLN mentholated	02JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	11JUL2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	16JUL2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	31JUL2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	14AUG2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	28AUG2018	URINE	NEGATIVE
2039	Screening		VLN mentholated	13JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	18JUL2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	23JUL2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	07AUG2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	21AUG2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2039	End Of Week 6		VLN mentholated	04SEP2018	URINE	NEGATIVE
2058	Screening		VLN mentholated	23JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	02AUG2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	07AUG2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	22AUG2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	05SEP2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	19SEP2018	URINE	NEGATIVE
2059	Screening		UB mentholated	23JUL2018	URINE	NEGATIVE
	Start Of Week -1		UB mentholated	02AUG2018	URINE	NEGATIVE
	End Of Week -1		UB mentholated	07AUG2018	URINE	NEGATIVE
	End Of Week 2		UB mentholated	22AUG2018	URINE	NEGATIVE
	End Of Week 4		UB mentholated	05SEP2018	URINE	NEGATIVE
	End Of Week 6		UB mentholated	19SEP2018	URINE	NEGATIVE
2060	Screening		VLN mentholated	23JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	02AUG2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	07AUG2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	22AUG2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	05SEP2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	19SEP2018	URINE	NEGATIVE
2066	Screening		VLN mentholated	23JUL2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	02AUG2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	07AUG2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	22AUG2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	05SEP2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	19SEP2018	URINE	NEGATIVE
2088	Screening		VLN mentholated	03AUG2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2088	Start Of Week -1	VLN mentholated	VLN mentholated	26AUG2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	31AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	15SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	29SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	13OCT2018	URINE	NEGATIVE
2092	Screening	VLN mentholated	VLN mentholated	06AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	26AUG2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	31AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	15SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN mentholated	VLN mentholated	29SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN mentholated	VLN mentholated	13OCT2018	URINE	NEGATIVE
2100	Screening	UB mentholated	UB mentholated	09AUG2018	URINE	NEGATIVE
	Start Of Week -1	UB mentholated	UB mentholated	26AUG2018	URINE	NEGATIVE
	End Of Week -1	UB mentholated	UB mentholated	31AUG2018	URINE	NEGATIVE
	End Of Week 2	UB mentholated	UB mentholated	15SEP2018	URINE	NEGATIVE
	End Of Week 4	UB mentholated	UB mentholated	29SEP2018	URINE	NEGATIVE
	End Of Week 6	UB mentholated	UB mentholated	13OCT2018	URINE	NEGATIVE
2108	Screening	VLN non-mentholated	VLN non-mentholated	13AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	26AUG2018	URINE	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	31AUG2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	15SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	29SEP2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	13OCT2018	URINE	NEGATIVE
2110	Screening	UB mentholated	UB mentholated	13AUG2018	URINE	NEGATIVE
	Start Of Week -1	UB mentholated	UB mentholated	01SEP2018	URINE	NEGATIVE
	End Of Week -1	UB mentholated	UB mentholated	06SEP2018	URINE	NEGATIVE
	End Of Week 2	UB mentholated	UB mentholated	21SEP2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2110	End Of Week 4	UB mentholated	UB mentholated	05OCT2018	URINE	NEGATIVE
	End Of Week 6	UB mentholated	UB mentholated	19OCT2018	URINE	NEGATIVE
2113	Screening	VLN mentholated	VLN mentholated	15AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	01SEP2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	06SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	21SEP2018	URINE	NEGATIVE
2115	Screening	VLN mentholated	VLN mentholated	15AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN mentholated	VLN mentholated	01SEP2018	URINE	NEGATIVE
	End Of Week -1	VLN mentholated	VLN mentholated	06SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN mentholated	VLN mentholated	21SEP2018	URINE	NEGATIVE
2120	Screening	VLN non-mentholated	VLN non-mentholated	20AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	01SEP2018	URINE	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	06SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	21SEP2018	URINE	NEGATIVE
	End Of Week 4	VLN non-mentholated	VLN non-mentholated	05OCT2018	URINE	NEGATIVE
	End Of Week 6	VLN non-mentholated	VLN non-mentholated	19OCT2018	URINE	NEGATIVE
2140	Screening	UB non-mentholated	UB non-mentholated	30AUG2018	URINE	NEGATIVE
	Start Of Week -1	UB non-mentholated	UB non-mentholated	18SEP2018	URINE	NEGATIVE
	End Of Week -1	UB non-mentholated	UB non-mentholated	23SEP2018	URINE	NEGATIVE
	End Of Week 2	UB non-mentholated	UB non-mentholated	08OCT2018	URINE	NEGATIVE
	End Of Week 4	UB non-mentholated	UB non-mentholated	22OCT2018	URINE	NEGATIVE
	End Of Week 6	UB non-mentholated	UB non-mentholated	05NOV2018	URINE	NEGATIVE
2142	Screening	VLN non-mentholated	VLN non-mentholated	31AUG2018	URINE	NEGATIVE
	Start Of Week -1	VLN non-mentholated	VLN non-mentholated	18SEP2018	URINE	NEGATIVE
	End Of Week -1	VLN non-mentholated	VLN non-mentholated	23SEP2018	URINE	NEGATIVE
	End Of Week 2	VLN non-mentholated	VLN non-mentholated	08OCT2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2158	Screening		UB non-mentholated	18SEP2018	URINE	NEGATIVE
	Start Of Week -1		UB non-mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		UB non-mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		UB non-mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		UB non-mentholated	17NOV2018	URINE	NEGATIVE
2164	Screening		VLN non-mentholated	27SEP2018	URINE	NEGATIVE
	Start Of Week -1		VLN non-mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		VLN non-mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		VLN non-mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		VLN non-mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 6		VLN non-mentholated	01DEC2018	URINE	NEGATIVE
2168	Screening		VLN non-mentholated	28SEP2018	URINE	NEGATIVE
	Start Of Week -1		VLN non-mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		VLN non-mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		VLN non-mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		VLN non-mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 6		VLN non-mentholated	01DEC2018	URINE	NEGATIVE
2170	Screening		UB non-mentholated	28SEP2018	URINE	NEGATIVE
	Start Of Week -1		UB non-mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		UB non-mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		UB non-mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		UB non-mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 6		UB non-mentholated	01DEC2018	URINE	NEGATIVE
2175	Screening		UB mentholated	01OCT2018	URINE	NEGATIVE
	Start Of Week -1		UB mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		UB mentholated	19OCT2018	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.6 Pregnancy Tests (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test Type	Test Result
	-----	-----				
2211	Screening		VLN mentholated	10OCT2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	01DEC2018	URINE	NEGATIVE
2215	Screening		UB mentholated	10OCT2018	URINE	NEGATIVE
	Start Of Week -1		UB mentholated	14OCT2018	URINE	NEGATIVE
	End Of Week -1		UB mentholated	19OCT2018	URINE	NEGATIVE
	End Of Week 2		UB mentholated	03NOV2018	URINE	NEGATIVE
	End Of Week 4		UB mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 6		UB mentholated	01DEC2018	URINE	NEGATIVE
2235	Screening		VLN mentholated	19OCT2018	URINE	NEGATIVE
	Start Of Week -1		VLN mentholated	28OCT2018	URINE	NEGATIVE
	End Of Week -1		VLN mentholated	02NOV2018	URINE	NEGATIVE
	End Of Week 2		VLN mentholated	17NOV2018	URINE	NEGATIVE
	End Of Week 4		VLN mentholated	01DEC2018	URINE	NEGATIVE
	End Of Week 6		VLN mentholated	15DEC2018	URINE	NEGATIVE
2257	Screening		UB non-mentholated	14NOV2018	URINE	NEGATIVE
	Start Of Week -1		UB non-mentholated	01DEC2018	URINE	NEGATIVE
	End Of Week -1		UB non-mentholated	06DEC2018	URINE	NEGATIVE
	End Of Week 2		UB non-mentholated	21DEC2018	URINE	NEGATIVE
	End Of Week 4		UB non-mentholated	04JAN2019	URINE	NEGATIVE
	End Of Week 6		UB non-mentholated	18JAN2019	URINE	NEGATIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PG.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.7 Serum FSH (Safety Population)

Subject Number	Visit		Product Group	Was Serum FSH Collected?	Was Postmenopausal Status Confirmed	Collection Date
	Name	Date				
1001	Screening	02JUL2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	02JUL2018
1032	Screening	13AUG2018	VLN mentholated	Yes	SURGICALLY STERILE	13AUG2018
1077	Screening	28AUG2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	28AUG2018
1078	Screening	28AUG2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	28AUG2018
1083	Screening	04SEP2018	VLN non-mentholated	Yes	SURGICALLY STERILE	04SEP2018
1095	Screening	07SEP2018	VLN mentholated	Yes	POST-MENOPAUSAL	07SEP2018
1112	Screening	21SEP2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	21SEP2018
2007	Screening	29JUN2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	29JUN2018
2015	Screening	02JUL2018	UB mentholated	Yes	POST-MENOPAUSAL	02JUL2018
2039	Screening	13JUL2018	VLN mentholated	Yes	POST-MENOPAUSAL	13JUL2018
2108	Screening	13AUG2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	13AUG2018
2113	Screening	15AUG2018	VLN mentholated	Yes	POST-MENOPAUSAL	15AUG2018
2164	Screening	27SEP2018	VLN non-mentholated	Yes	POST-MENOPAUSAL	27SEP2018
2215	Screening	10OCT2018	UB mentholated	Yes	POST-MENOPAUSAL	10OCT2018
2257	Screening	14NOV2018	UB non-mentholated	Yes	POST-MENOPAUSAL	14NOV2018

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-FSH.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1001	SCREENING	02JUL2018	VLN non-mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	Positive
1002	SCREENING	02JUL2018	VLN non-mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	Positive
1003	SCREENING	03JUL2018	VLN mentholated	Yes	03JUL2018	Positive
	START OF WEEK -1	19JUL2018	VLN mentholated	Yes	19JUL2018	Positive
1007	SCREENING	12JUL2018	VLN non-mentholated	Yes	12JUL2018	Positive
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	Positive
1008	SCREENING	12JUL2018	VLN mentholated	Yes	12JUL2018	Positive
	START OF WEEK -1	19JUL2018	VLN mentholated	Yes	19JUL2018	Positive
1010	SCREENING	13JUL2018	UB mentholated	Yes	13JUL2018	Positive
	START OF WEEK -1	19JUL2018	UB mentholated	Yes	19JUL2018	Positive
1011	SCREENING	13JUL2018	UB non-mentholated	Yes	13JUL2018	Positive
	START OF WEEK -1	19JUL2018	UB non-mentholated	Yes	19JUL2018	Positive
1013	SCREENING	16JUL2018	VLN non-mentholated	Yes	16JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	Positive
1014	SCREENING	16JUL2018	VLN mentholated	Yes	16JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	Positive
1015	SCREENING	16JUL2018	VLN mentholated	Yes	16JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1016	SCREENING	16JUL2018	UB non-mentholated	Yes	16JUL2018	Positive
	START OF WEEK -1	26JUL2018	UB non-mentholated	Yes	26JUL2018	Positive
1017	SCREENING	17JUL2018	UB mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	UB mentholated	Yes	26JUL2018	Positive
1018	SCREENING	17JUL2018	VLN mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	Positive
1019	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	Positive
1020	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	Positive
1021	SCREENING	17JUL2018	UB non-mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	UB non-mentholated	Yes	26JUL2018	Positive
1023	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	Positive
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	Positive
1029	SCREENING	26JUL2018	VLN mentholated	Yes	26JUL2018	Positive
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	Positive
1032	SCREENING	13AUG2018	VLN mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	Positive
1034	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1035	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1036	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	Positive
1037	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	Positive
1038	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1042	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1045	SCREENING	14AUG2018	UB non-mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB non-mentholated	Yes	22AUG2018	Positive
1046	SCREENING	14AUG2018	UB mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	Positive
1050	SCREENING	14AUG2018	VLN non-mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1051	SCREENING	14AUG2018	UB mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	Positive
1052	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1053	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	Positive
1054	SCREENING	14AUG2018	UB non-mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	UB non-mentholated	Yes	22AUG2018	Positive
1055	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	Positive
1056	SCREENING	14AUG2018	VLN non-mentholated	Yes	14AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1058	SCREENING	15AUG2018	VLN non-mentholated	Yes	15AUG2018	Positive
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	Positive
1059	SCREENING	27AUG2018	UB non-mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	Positive
1060	SCREENING	27AUG2018	VLN mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
1063	SCREENING	27AUG2018	VLN mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
1064	SCREENING	27AUG2018	UB non-mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	Positive
1066	SCREENING	27AUG2018	VLN non-mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1069	SCREENING	28AUG2018	UB non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	Positive
1070	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive
1071	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive
1072	SCREENING	28AUG2018	VLN mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
1074	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive
1075	SCREENING	28AUG2018	UB non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	Positive
1077	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive
1078	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive
1079	SCREENING	28AUG2018	VLN mentholated	Yes	28AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
1082	SCREENING	30AUG2018	VLN non-mentholated	Yes	30AUG2018	Positive
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1083	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	Positive
1084	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	Positive
1086	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	Positive
1088	SCREENING	04SEP2018	VLN mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	Positive
1089	SCREENING	04SEP2018	UB non-mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	12SEP2018	UB non-mentholated	Yes	12SEP2018	Positive
1092	SCREENING	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	Positive
1094	SCREENING	05SEP2018	VLN mentholated	Yes	05SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	Positive
1095	SCREENING	07SEP2018	VLN mentholated	Yes	07SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	Positive
1096	SCREENING	07SEP2018	VLN non-mentholated	Yes	07SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	Positive
1097	SCREENING	07SEP2018	VLN mentholated	Yes	07SEP2018	Positive
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1098	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1099	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1100	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1101	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1103	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1105	SCREENING	19SEP2018	VLN non-mentholated	Yes	19SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1106	SCREENING	19SEP2018	UB non-mentholated	Yes	19SEP2018	Positive
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	Positive
1107	SCREENING	21SEP2018	VLN non-mentholated	Yes	21SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1108	SCREENING	21SEP2018	UB non-mentholated	Yes	21SEP2018	Positive
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	Positive
1109	SCREENING	21SEP2018	UB non-mentholated	Yes	21SEP2018	Positive
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
1112	SCREENING	21SEP2018	VLN non-mentholated	Yes	21SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
1114	SCREENING	24SEP2018	UB non-mentholated	Yes	24SEP2018	Positive
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	Positive
1115	SCREENING	24SEP2018	VLN non-mentholated	Yes	24SEP2018	Positive
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
2002	SCREENING	29JUN2018	UB mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	18JUL2018	UB mentholated	Yes	18JUL2018	Positive
2003	SCREENING	29JUN2018	VLN mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2007	SCREENING	29JUN2018	VLN non-mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	Positive
2008	SCREENING	06JUL2018	VLN mentholated	Yes	06JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2009	SCREENING	29JUN2018	VLN non-mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	Positive
2010	SCREENING	29JUN2018	UB mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	Positive
2011	SCREENING	29JUN2018	VLN mentholated	Yes	29JUN2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2014	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2015	SCREENING	02JUL2018	UB mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	Positive
2016	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2017	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2018	SCREENING	02JUL2018	UB mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	Positive
2020	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2021	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2023	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	Positive
2024	SCREENING	03JUL2018	UB non-mentholated	Yes	03JUL2018	Positive
	START OF WEEK -1	11JUL2018	UB non-mentholated	Yes	11JUL2018	Positive
2025	SCREENING	03JUL2018	UB non-mentholated	Yes	03JUL2018	Positive
	START OF WEEK -1	11JUL2018	UB non-mentholated	Yes	11JUL2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2028	SCREENING	06JUL2018	VLN non-mentholated	Yes	06JUL2018	Positive
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	Positive
2029	SCREENING	09JUL2018	UB mentholated	Yes	09JUL2018	Positive
	START OF WEEK -1	18JUL2018	UB mentholated	Yes	18JUL2018	Positive
2039	SCREENING	13JUL2018	VLN mentholated	Yes	13JUL2018	Positive
	START OF WEEK -1	18JUL2018	VLN mentholated	Yes	18JUL2018	Positive
2050	SCREENING	20JUL2018	UB mentholated	Yes	20JUL2018	Positive
	START OF WEEK -1	02AUG2018	UB mentholated	Yes	02AUG2018	Positive
2052	SCREENING	20JUL2018	VLN mentholated	Yes	20JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2057	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2058	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2059	SCREENING	23JUL2018	UB mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	UB mentholated	Yes	02AUG2018	Positive
2060	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2064	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2066	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2067	SCREENING	23JUL2018	VLN non-mentholated	Yes	23JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN non-mentholated	Yes	02AUG2018	Positive
2075	SCREENING	30JUL2018	VLN mentholated	Yes	30JUL2018	Positive
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	Positive
2076	SCREENING	30JUL2018	VLN mentholated	Yes	30JUL2018	Positive
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	Positive
2086	SCREENING	03AUG2018	VLN non-mentholated	Yes	03AUG2018	Positive
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	Positive
2088	SCREENING	03AUG2018	VLN mentholated	Yes	03AUG2018	Positive
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	Positive
2092	SCREENING	06AUG2018	VLN mentholated	Yes	06AUG2018	Positive
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	Positive
2099	SCREENING	09AUG2018	VLN non-mentholated	Yes	09AUG2018	Positive
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	Positive
2100	SCREENING	09AUG2018	UB mentholated	Yes	09AUG2018	Positive
	START OF WEEK -1	26AUG2018	UB mentholated	Yes	26AUG2018	Positive
2108	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2110	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	Positive
	START OF WEEK -1	01SEP2018	UB mentholated	Yes	01SEP2018	Positive
2113	SCREENING	15AUG2018	VLN mentholated	Yes	15AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	Positive
2115	SCREENING	15AUG2018	VLN mentholated	Yes	15AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	Positive
2119	SCREENING	20AUG2018	VLN mentholated	Yes	20AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	Positive
2120	SCREENING	20AUG2018	VLN non-mentholated	Yes	20AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN non-mentholated	Yes	01SEP2018	Positive
2122	SCREENING	20AUG2018	UB non-mentholated	Yes	20AUG2018	Positive
	START OF WEEK -1	01SEP2018	UB non-mentholated	Yes	01SEP2018	Positive
2125	SCREENING	21AUG2018	UB mentholated	Yes	21AUG2018	Positive
	START OF WEEK -1	01SEP2018	UB mentholated	Yes	01SEP2018	Positive
2126	SCREENING	21AUG2018	VLN mentholated	Yes	21AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	Positive
2136	SCREENING	27AUG2018	VLN non-mentholated	Yes	27AUG2018	Positive
	START OF WEEK -1	01SEP2018	VLN non-mentholated	Yes	01SEP2018	Positive
2140	SCREENING	30AUG2018	UB non-mentholated	Yes	30AUG2018	Positive
	START OF WEEK -1	18SEP2018	UB non-mentholated	Yes	18SEP2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2142	SCREENING	31AUG2018	VLN non-mentholated	Yes	31AUG2018	Positive
	START OF WEEK -1	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
2143	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	Positive
	START OF WEEK -1	18SEP2018	VLN non-mentholated	Yes	18SEP2018	Positive
2158	SCREENING	18SEP2018	UB non-mentholated	Yes	18SEP2018	Positive
	START OF WEEK -1	14OCT2018	UB non-mentholated	Yes	14OCT2018	Positive
2159	SCREENING	19SEP2018	VLN non-mentholated	Yes	19SEP2018	Positive
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	Positive
2164	SCREENING	27SEP2018	VLN non-mentholated	Yes	27SEP2018	Positive
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	Positive
2168	SCREENING	28SEP2018	VLN non-mentholated	Yes	28SEP2018	Positive
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	Positive
2170	SCREENING	28SEP2018	UB non-mentholated	Yes	28SEP2018	Positive
	START OF WEEK -1	14OCT2018	UB non-mentholated	Yes	14OCT2018	Positive
2175	SCREENING	01OCT2018	UB mentholated	Yes	01OCT2018	Positive
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	Positive
2189	SCREENING	04OCT2018	VLN mentholated	Yes	04OCT2018	Positive
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	Positive
2211	SCREENING	10OCT2018	VLN mentholated	Yes	10OCT2018	Positive
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2212	SCREENING	10OCT2018	UB mentholated	Yes	10OCT2018	Positive
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	Positive
2213	SCREENING	10OCT2018	VLN mentholated	Yes	10OCT2018	Positive
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	Positive
2215	SCREENING	10OCT2018	UB mentholated	Yes	10OCT2018	Positive
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	Positive
2220	SCREENING	11OCT2018	VLN non-mentholated	Yes	11OCT2018	Positive
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	Positive
2235	SCREENING	19OCT2018	VLN mentholated	Yes	19OCT2018	Positive
	START OF WEEK -1	28OCT2018	VLN mentholated	Yes	28OCT2018	Positive
2244	SCREENING	25OCT2018	VLN non-mentholated	Yes	25OCT2018	Positive
	START OF WEEK -1	28OCT2018	VLN non-mentholated	Yes	28OCT2018	Positive
2247	SCREENING	06NOV2018	VLN mentholated	Yes	06NOV2018	Positive
	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	Positive
2251	SCREENING	09NOV2018	UB non-mentholated	Yes	09NOV2018	Positive
	START OF WEEK -1	01DEC2018	UB non-mentholated	Yes	01DEC2018	Positive
2257	SCREENING	14NOV2018	UB non-mentholated	Yes	14NOV2018	Positive
	START OF WEEK -1	01DEC2018	UB non-mentholated	Yes	01DEC2018	Positive
2259	SCREENING	14NOV2018	UB mentholated	Yes	14NOV2018	Positive
	START OF WEEK -1	01DEC2018	UB mentholated	Yes	01DEC2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.8 Urine Cotinine Screens (Safety Population)

Subject Number	Visit		Product Group	Was the Urine Cotinine Sample Collected?	Date of Collection	Is Result Positive* for Urine Cotinine?
	Name	Date				
2269	SCREENING	26NOV2018	VLN mentholated	Yes	26NOV2018	Positive
	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	Positive
2272	SCREENING	28NOV2018	VLN mentholated	Yes	28NOV2018	Positive
	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	Positive

Note: \*Positive = greater than or equal to 500 ng/mL  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-COTIN.SAS 18JUN2019 11:11

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1001	Screening	02JUL2018	VLN non-mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE
1002	Screening	02JUL2018	VLN non-mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE
1003	Screening	03JUL2018	VLN mentholated	03JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE
1007	Screening	12JUL2018	VLN non-mentholated	12JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE
1008	Screening	12JUL2018	VLN mentholated	12JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE NON-REACTIVE
1010	Screening	13JUL2018	UB mentholated	13JUL2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1010	Screening	13JUL2018	UB mentholated	13JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE  NON-REACTIVE
1011	Screening	13JUL2018	UB non-mentholated	13JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1013	Screening	16JUL2018	VLN non-mentholated	16JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1014	Screening	16JUL2018	VLN mentholated	16JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1015	Screening	16JUL2018	VLN mentholated	16JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1016	Screening	16JUL2018	UB non-mentholated	16JUL2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1016	Screening	16JUL2018	UB non-mentholated	16JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1017	Screening	17JUL2018	UB mentholated	17JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1018	Screening	17JUL2018	VLN mentholated	17JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1019	Screening	17JUL2018	VLN non-mentholated	17JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1020	Screening	17JUL2018	VLN non-mentholated	17JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1021	Screening	17JUL2018	UB non-mentholated	17JUL2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1021	Screening	17JUL2018	UB non-mentholated	17JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1023	Screening	17JUL2018	VLN non-mentholated	17JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1029	Screening	26JUL2018	VLN mentholated	26JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1032	Screening	13AUG2018	VLN mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1034	Screening	13AUG2018	VLN non-mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1035	Screening	13AUG2018	VLN non-mentholated	13AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1035	Screening	13AUG2018	VLN non-mentholated	13AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE  NON-REACTIVE
1036	Screening	13AUG2018	UB mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1037	Screening	13AUG2018	UB mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1038	Screening	13AUG2018	VLN non-mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1042	Screening	13AUG2018	VLN non-mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1045	Screening	14AUG2018	UB non-mentholated	14AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1045	Screening	14AUG2018	UB non-mentholated	14AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1046	Screening	14AUG2018	UB mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1050	Screening	14AUG2018	VLN non-mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1051	Screening	14AUG2018	UB mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1052	Screening	14AUG2018	VLN mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1053	Screening	14AUG2018	VLN mentholated	14AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1053	Screening	14AUG2018	VLN mentholated	14AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1054	Screening	14AUG2018	UB non-mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1055	Screening	14AUG2018	VLN mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1056	Screening	14AUG2018	VLN non-mentholated	14AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1058	Screening	15AUG2018	VLN non-mentholated	15AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1059	Screening	27AUG2018	UB non-mentholated	27AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1059	Screening	27AUG2018	UB non-mentholated	27AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1060	Screening	27AUG2018	VLN mentholated	27AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1063	Screening	27AUG2018	VLN mentholated	27AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1064	Screening	27AUG2018	UB non-mentholated	27AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1066	Screening	27AUG2018	VLN non-mentholated	27AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1069	Screening	28AUG2018	UB non-mentholated	28AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1069	Screening	28AUG2018	UB non-mentholated	28AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1070	Screening	28AUG2018	VLN non-mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1071	Screening	28AUG2018	VLN non-mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1072	Screening	28AUG2018	VLN mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1074	Screening	28AUG2018	VLN non-mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1075	Screening	29AUG2018	UB non-mentholated	29AUG2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1075	Screening	29AUG2018	UB non-mentholated	29AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1077	Screening	28AUG2018	VLN non-mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1078	Screening	28AUG2018	VLN non-mentholated	28AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1079	Screening	29AUG2018	VLN mentholated	29AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1082	Screening	30AUG2018	VLN non-mentholated	30AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1083	Screening	04SEP2018	VLN non-mentholated	04SEP2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1083	Screening	04SEP2018	VLN non-mentholated	04SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1084	Screening	04SEP2018	VLN non-mentholated	04SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1086	Screening	04SEP2018	VLN non-mentholated	04SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1088	Screening	04SEP2018	VLN mentholated	04SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1089	Screening	04SEP2018	UB non-mentholated	04SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1092	Screening	05SEP2018	VLN mentholated	05SEP2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Page 12 of 29

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1092	Screening	05SEP2018	VLN mentholated	05SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1094	Screening	05SEP2018	VLN mentholated	05SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1095	Screening	07SEP2018	VLN mentholated	07SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1096	Screening	07SEP2018	VLN non-mentholated	07SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1097	Screening	07SEP2018	VLN mentholated	07SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1098	Screening	18SEP2018	VLN non-mentholated	18SEP2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1098	Screening	18SEP2018	VLN non-mentholated	18SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1099	Screening	18SEP2018	VLN non-mentholated	18SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1100	Screening	18SEP2018	VLN non-mentholated	18SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1101	Screening	18SEP2018	VLN non-mentholated	18SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1103	Screening	18SEP2018	VLN non-mentholated	18SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1105	Screening	19SEP2018	VLN non-mentholated	19SEP2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1105	Screening	19SEP2018	VLN non-mentholated	19SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE
1106	Screening	19SEP2018	UB non-mentholated	19SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1107	Screening	21SEP2018	VLN non-mentholated	21SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1108	Screening	21SEP2018	UB non-mentholated	21SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1109	Screening	21SEP2018	UB non-mentholated	21SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1112	Screening	21SEP2018	VLN non-mentholated	21SEP2018	HIV Antibody	NON-REACTIVE

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
1112	Screening	21SEP2018	VLN non-mentholated	21SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE  NON-REACTIVE
1114	Screening	24SEP2018	UB non-mentholated	24SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
1115	Screening	24SEP2018	VLN non-mentholated	24SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	NON-REACTIVE NON-REACTIVE NON-REACTIVE
2002	Screening	29JUN2018	UB mentholated	29JUN2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2003	Screening	29JUN2018	VLN mentholated	29JUN2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2007	Screening	29JUN2018	VLN non-mentholated	29JUN2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2007	Screening	29JUN2018	VLN non-mentholated	29JUN2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative <0.1
2008	Screening	06JUL2018	VLN mentholated	06JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2009	Screening	29JUN2018	VLN non-mentholated	29JUN2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2010	Screening	29JUN2018	UB mentholated	29JUN2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2011	Screening	29JUN2018	VLN mentholated	29JUN2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2014	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2014	Screening	02JUL2018	VLN mentholated	02JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative <0.1
2015	Screening	02JUL2018	UB mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2016	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2017	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2018	Screening	02JUL2018	UB mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2020	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2020	Screening	02JUL2018	VLN mentholated	02JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative <0.1
2021	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2023	Screening	02JUL2018	VLN mentholated	02JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2024	Screening	03JUL2018	UB non-mentholated	03JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2025	Screening	03JUL2018	UB non-mentholated	03JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2028	Screening	06JUL2018	VLN non-mentholated	06JUL2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2028	Screening	06JUL2018	VLN non-mentholated	06JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative <0.1
2029	Screening	09JUL2018	UB mentholated	09JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2039	Screening	13JUL2018	VLN mentholated	13JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2050	Screening	20JUL2018	UB mentholated	20JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2052	Screening	20JUL2018	VLN mentholated	20JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2057	Screening	23JUL2018	VLN mentholated	23JUL2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2057	Screening	23JUL2018	VLN mentholated	23JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2058	Screening	23JUL2018	VLN mentholated	23JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2059	Screening	23JUL2018	UB mentholated	23JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2060	Screening	23JUL2018	VLN mentholated	23JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2064	Screening	23JUL2018	VLN mentholated	23JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2066	Screening	23JUL2018	VLN mentholated	23JUL2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2066	Screening	23JUL2018	VLN mentholated	23JUL2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2067	Screening	23JUL2018	VLN non-mentholated	23JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2075	Screening	30JUL2018	VLN mentholated	30JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2076	Screening	30JUL2018	VLN mentholated	30JUL2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2086	Screening	03AUG2018	VLN non-mentholated	03AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2088	Screening	03AUG2018	VLN mentholated	03AUG2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2088	Screening	03AUG2018	VLN mentholated	03AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative <0.1
2092	Screening	06AUG2018	VLN mentholated	06AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2099	Screening	09AUG2018	VLN non-mentholated	09AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2100	Screening	09AUG2018	UB mentholated	09AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2108	Screening	13AUG2018	VLN non-mentholated	13AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative <0.1
2110	Screening	13AUG2018	UB mentholated	13AUG2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2110	Screening	13AUG2018	UB mentholated	13AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2113	Screening	15AUG2018	VLN mentholated	15AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  0.2
2115	Screening	15AUG2018	VLN mentholated	15AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  0.1
2119	Screening	20AUG2018	VLN mentholated	20AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2120	Screening	20AUG2018	VLN non-mentholated	20AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2122	Screening	20AUG2018	UB non-mentholated	20AUG2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2122	Screening	20AUG2018	UB non-mentholated	20AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2125	Screening	21AUG2018	UB mentholated	21AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2126	Screening	21AUG2018	VLN mentholated	21AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2136	Screening	27AUG2018	VLN non-mentholated	27AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  0.5
2140	Screening	30AUG2018	UB non-mentholated	30AUG2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2142	Screening	31AUG2018	VLN non-mentholated	31AUG2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2142	Screening	31AUG2018	VLN non-mentholated	31AUG2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2143	Screening	04SEP2018	VLN non-mentholated	04SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2158	Screening	18SEP2018	UB non-mentholated	18SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2159	Screening	19SEP2018	VLN non-mentholated	19SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2164	Screening	27SEP2018	VLN non-mentholated	27SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2168	Screening	28SEP2018	VLN non-mentholated	28SEP2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2168	Screening	28SEP2018	VLN non-mentholated	28SEP2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2170	Screening	28SEP2018	UB non-mentholated	28SEP2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2175	Screening	01OCT2018	UB mentholated	01OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2189	Screening	04OCT2018	VLN mentholated	04OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2211	Screening	10OCT2018	VLN mentholated	10OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2212	Screening	10OCT2018	UB mentholated	10OCT2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2212	Screening	10OCT2018	UB mentholated	10OCT2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2213	Screening	10OCT2018	VLN mentholated	10OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2215	Screening	10OCT2018	UB mentholated	10OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2220	Screening	11OCT2018	VLN non-mentholated	11OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2235	Screening	19OCT2018	VLN mentholated	19OCT2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2244	Screening	25OCT2018	VLN non-mentholated	25OCT2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2244	Screening	25OCT2018	VLN non-mentholated	25OCT2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2247	Screening	06NOV2018	VLN mentholated	06NOV2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2251	Screening	09NOV2018	UB non-mentholated	09NOV2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2257	Screening	14NOV2018	UB non-mentholated	14NOV2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2259	Screening	14NOV2018	UB mentholated	14NOV2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1
2269	Screening	26NOV2018	VLN mentholated	26NOV2018	HIV Antibody	Non Reactive

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.9 Serology Sample Collection (Safety Population)

Subject Number	Visit		Product Group	Collection Date	Test	Result
	Name	Date				
2269	Screening	26NOV2018	VLN mentholated	26NOV2018	Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Negative  <0.1
2272	Screening	28NOV2018	VLN mentholated	28NOV2018	HIV Antibody Hepatitis B Virus Surface Antigen Hepatitis C Virus Antibody	Non Reactive Negative  <0.1

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-SEROL.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1001	SCREENING	02JUL2018	VLN non-mentholated	Yes	02JUL2018	21
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	26
1002	SCREENING	02JUL2018	VLN non-mentholated	Yes	02JUL2018	42
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	42
1003	SCREENING	03JUL2018	VLN mentholated	Yes	03JUL2018	23
	START OF WEEK -1	19JUL2018	VLN mentholated	Yes	19JUL2018	32
1007	SCREENING	12JUL2018	VLN non-mentholated	Yes	12JUL2018	14
	START OF WEEK -1	19JUL2018	VLN non-mentholated	Yes	19JUL2018	23
1008	SCREENING	12JUL2018	VLN mentholated	Yes	12JUL2018	18
	START OF WEEK -1	19JUL2018	VLN mentholated	Yes	19JUL2018	20
1010	SCREENING	13JUL2018	UB mentholated	Yes	13JUL2018	33
	START OF WEEK -1	19JUL2018	UB mentholated	Yes	19JUL2018	26
1011	SCREENING	13JUL2018	UB non-mentholated	Yes	13JUL2018	28
	START OF WEEK -1	19JUL2018	UB non-mentholated	Yes	19JUL2018	33
1013	SCREENING	16JUL2018	VLN non-mentholated	Yes	16JUL2018	35
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	36
1014	SCREENING	16JUL2018	VLN mentholated	Yes	16JUL2018	38
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	33
1015	SCREENING	16JUL2018	VLN mentholated	Yes	16JUL2018	14
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	13
1016	SCREENING	16JUL2018	UB non-mentholated	Yes	16JUL2018	22

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1016	START OF WEEK -1	26JUL2018	UB non-mentholated	Yes	26JUL2018	19
1017	SCREENING	17JUL2018	UB mentholated	Yes	17JUL2018	33
	START OF WEEK -1	26JUL2018	UB mentholated	Yes	26JUL2018	20
1018	SCREENING	17JUL2018	VLN mentholated	Yes	17JUL2018	29
	START OF WEEK -1	26JUL2018	VLN mentholated	Yes	26JUL2018	36
1019	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	38
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	24
1020	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	43
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	31
1021	SCREENING	17JUL2018	UB non-mentholated	Yes	17JUL2018	17
	START OF WEEK -1	26JUL2018	UB non-mentholated	Yes	26JUL2018	5
1023	SCREENING	17JUL2018	VLN non-mentholated	Yes	17JUL2018	33
	START OF WEEK -1	26JUL2018	VLN non-mentholated	Yes	26JUL2018	16
1029	SCREENING	26JUL2018	VLN mentholated	Yes	26JUL2018	19
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	15
1032	SCREENING	13AUG2018	VLN mentholated	Yes	13AUG2018	28
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	44
1034	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	53
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	32
1035	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	41
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	29

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1036	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	19
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	7
1037	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	36
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	49
1038	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	25
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	16
1042	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	14
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	23
1045	SCREENING	14AUG2018	UB non-mentholated	Yes	14AUG2018	28
	START OF WEEK -1	22AUG2018	UB non-mentholated	Yes	22AUG2018	27
1046	SCREENING	14AUG2018	UB mentholated	Yes	14AUG2018	12
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	12
1050	SCREENING	14AUG2018	VLN non-mentholated	Yes	14AUG2018	24
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	16
1051	SCREENING	14AUG2018	UB mentholated	Yes	14AUG2018	28
	START OF WEEK -1	22AUG2018	UB mentholated	Yes	22AUG2018	16
1052	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	41
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	29
1053	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	20
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	20
1054	SCREENING	14AUG2018	UB non-mentholated	Yes	14AUG2018	24

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1054	START OF WEEK -1	22AUG2018	UB non-mentholated	Yes	22AUG2018	22
1055	SCREENING	14AUG2018	VLN mentholated	Yes	14AUG2018	25
	START OF WEEK -1	22AUG2018	VLN mentholated	Yes	22AUG2018	19
1056	SCREENING	14AUG2018	VLN non-mentholated	Yes	14AUG2018	31
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	18
1058	SCREENING	15AUG2018	VLN non-mentholated	Yes	15AUG2018	38
	START OF WEEK -1	22AUG2018	VLN non-mentholated	Yes	22AUG2018	17
1059	SCREENING	27AUG2018	UB non-mentholated	Yes	27AUG2018	23
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	41
1060	SCREENING	27AUG2018	VLN mentholated	Yes	27AUG2018	21
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	26
1063	SCREENING	27AUG2018	VLN mentholated	Yes	27AUG2018	22
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	16
1064	SCREENING	27AUG2018	UB non-mentholated	Yes	27AUG2018	37
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	38
1066	SCREENING	27AUG2018	VLN non-mentholated	Yes	27AUG2018	25
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	32
1069	SCREENING	28AUG2018	UB non-mentholated	Yes	28AUG2018	12
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	18
1070	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	36
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	38

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1071	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	20
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	27
1072	SCREENING	28AUG2018	VLN mentholated	Yes	28AUG2018	22
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	20
1074	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	17
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	26
1075	SCREENING	28AUG2018	UB non-mentholated	Yes	28AUG2018	15
	START OF WEEK -1	05SEP2018	UB non-mentholated	Yes	05SEP2018	24
1077	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	27
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	22
1078	SCREENING	28AUG2018	VLN non-mentholated	Yes	28AUG2018	23
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	28
1079	SCREENING	28AUG2018	VLN mentholated	Yes	28AUG2018	17
	START OF WEEK -1	05SEP2018	VLN mentholated	Yes	05SEP2018	7
1082	SCREENING	30AUG2018	VLN non-mentholated	Yes	30AUG2018	22
	START OF WEEK -1	05SEP2018	VLN non-mentholated	Yes	05SEP2018	33
1083	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	30
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	33
1084	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	15
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	21
1086	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	25

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1086	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	27
1088	SCREENING	04SEP2018	VLN mentholated	Yes	04SEP2018	26
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	24
1089	SCREENING	04SEP2018	UB non-mentholated	Yes	04SEP2018	26
	START OF WEEK -1	12SEP2018	UB non-mentholated	Yes	12SEP2018	22
1092	SCREENING	05SEP2018	VLN mentholated	Yes	05SEP2018	26
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	25
1094	SCREENING	05SEP2018	VLN mentholated	Yes	05SEP2018	24
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	14
1095	SCREENING	07SEP2018	VLN mentholated	Yes	07SEP2018	30
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	23
1096	SCREENING	07SEP2018	VLN non-mentholated	Yes	07SEP2018	12
	START OF WEEK -1	12SEP2018	VLN non-mentholated	Yes	12SEP2018	31
1097	SCREENING	07SEP2018	VLN mentholated	Yes	07SEP2018	33
	START OF WEEK -1	12SEP2018	VLN mentholated	Yes	12SEP2018	29
1098	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	18
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	13
1099	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	17
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	25
1100	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	30
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	15

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
1101	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	35
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	37
1103	SCREENING	18SEP2018	VLN non-mentholated	Yes	18SEP2018	36
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	23
1105	SCREENING	19SEP2018	VLN non-mentholated	Yes	19SEP2018	17
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	15
1106	SCREENING	19SEP2018	UB non-mentholated	Yes	19SEP2018	17
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	20
1107	SCREENING	21SEP2018	VLN non-mentholated	Yes	21SEP2018	27
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	5
1108	SCREENING	21SEP2018	UB non-mentholated	Yes	21SEP2018	19
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	27
1109	SCREENING	21SEP2018	UB non-mentholated	Yes	21SEP2018	30
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	15
1112	SCREENING	21SEP2018	VLN non-mentholated	Yes	21SEP2018	21
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	15
1114	SCREENING	24SEP2018	UB non-mentholated	Yes	24SEP2018	33
	START OF WEEK -1	28SEP2018	UB non-mentholated	Yes	28SEP2018	28
1115	SCREENING	24SEP2018	VLN non-mentholated	Yes	24SEP2018	32
	START OF WEEK -1	28SEP2018	VLN non-mentholated	Yes	28SEP2018	17
2002	SCREENING	29JUN2018	UB mentholated	Yes	29JUN2018	32

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2002	START OF WEEK -1	18JUL2018	UB mentholated	Yes	18JUL2018	47
2003	SCREENING	29JUN2018	VLN mentholated	Yes	29JUN2018	39
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	34
2007	SCREENING	29JUN2018	VLN non-mentholated	Yes	29JUN2018	27
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	29
2008	SCREENING	06JUL2018	VLN mentholated	Yes	06JUL2018	48
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	25
2009	SCREENING	29JUN2018	VLN non-mentholated	Yes	29JUN2018	11
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	14
2010	SCREENING	29JUN2018	UB mentholated	Yes	29JUN2018	24
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	20
2011	SCREENING	29JUN2018	VLN mentholated	Yes	29JUN2018	11
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	21
2014	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	59
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	54
2015	SCREENING	02JUL2018	UB mentholated	Yes	02JUL2018	17
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	23
2016	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	21
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	27
2017	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	26
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	27

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11



## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2018	SCREENING	02JUL2018	UB mentholated	Yes	02JUL2018	76
	START OF WEEK -1	11JUL2018	UB mentholated	Yes	11JUL2018	28
2020	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	24
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	41
2021	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	16
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	16
2023	SCREENING	02JUL2018	VLN mentholated	Yes	02JUL2018	29
	START OF WEEK -1	11JUL2018	VLN mentholated	Yes	11JUL2018	25
2024	SCREENING	03JUL2018	UB non-mentholated	Yes	03JUL2018	18
	START OF WEEK -1	11JUL2018	UB non-mentholated	Yes	11JUL2018	21
2025	SCREENING	03JUL2018	UB non-mentholated	Yes	03JUL2018	36
	START OF WEEK -1	11JUL2018	UB non-mentholated	Yes	11JUL2018	41
2028	SCREENING	06JUL2018	VLN non-mentholated	Yes	06JUL2018	45
	START OF WEEK -1	11JUL2018	VLN non-mentholated	Yes	11JUL2018	34
2029	SCREENING	09JUL2018	UB mentholated	Yes	09JUL2018	13
	START OF WEEK -1	18JUL2018	UB mentholated	Yes	18JUL2018	19
2039	SCREENING	13JUL2018	VLN mentholated	Yes	13JUL2018	21
	START OF WEEK -1	18JUL2018	VLN mentholated	Yes	18JUL2018	25
2050	SCREENING	20JUL2018	UB mentholated	Yes	20JUL2018	36
	START OF WEEK -1	02AUG2018	UB mentholated	Yes	02AUG2018	25
2052	SCREENING	20JUL2018	VLN mentholated	Yes	20JUL2018	20

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2052	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	22
2057	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	17
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	17
2058	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	14
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02SEP2018	8
2059	SCREENING	23JUL2018	UB mentholated	Yes	23JUL2018	25
	START OF WEEK -1	02AUG2018	UB mentholated	Yes	02AUG2018	29
2060	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	31
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	34
2064	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	40
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	35
2066	SCREENING	23JUL2018	VLN mentholated	Yes	23JUL2018	20
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	23
2067	SCREENING	23JUL2018	VLN non-mentholated	Yes	23JUL2018	12
	START OF WEEK -1	02AUG2018	VLN non-mentholated	Yes	02AUG2018	18
2075	SCREENING	30JUL2018	VLN mentholated	Yes	30JUL2018	23
	START OF WEEK -1	02AUG2018	VLN mentholated	Yes	02AUG2018	18
2076	SCREENING	30JUL2018	VLN mentholated	Yes	30JUL2018	22
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	21
2086	SCREENING	03AUG2018	VLN non-mentholated	Yes	03AUG2018	23
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	26

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2088	SCREENING	03AUG2018	VLN mentholated	Yes	03AUG2018	24
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	21
2092	SCREENING	06AUG2018	VLN mentholated	Yes	06AUG2018	11
	START OF WEEK -1	26AUG2018	VLN mentholated	Yes	26AUG2018	18
2099	SCREENING	09AUG2018	VLN non-mentholated	Yes	09AUG2018	11
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	12
2100	SCREENING	09AUG2018	UB mentholated	Yes	09AUG2018	28
	START OF WEEK -1	26AUG2018	UB mentholated	Yes	26AUG2018	20
2108	SCREENING	13AUG2018	VLN non-mentholated	Yes	13AUG2018	27
	START OF WEEK -1	26AUG2018	VLN non-mentholated	Yes	26AUG2018	36
2110	SCREENING	13AUG2018	UB mentholated	Yes	13AUG2018	18
	START OF WEEK -1	01SEP2018	UB mentholated	Yes	01SEP2018	31
2113	SCREENING	15AUG2018	VLN mentholated	Yes	15AUG2018	36
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	47
2115	SCREENING	15AUG2018	VLN mentholated	Yes	15AUG2018	25
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	23
2119	SCREENING	20AUG2018	VLN mentholated	Yes	20AUG2018	12
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	16
2120	SCREENING	20AUG2018	VLN non-mentholated	Yes	20AUG2018	31
	START OF WEEK -1	01SEP2018	VLN non-mentholated	Yes	01SEP2018	39
2122	SCREENING	20AUG2018	UB non-mentholated	Yes	20AUG2018	34

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2122	START OF WEEK -1	01SEP2018	UB non-mentholated	Yes	01SEP2018	60
2125	SCREENING	21AUG2018	UB mentholated	Yes	21AUG2018	34
	START OF WEEK -1	01SEP2018	UB mentholated	Yes	01SEP2018	34
2126	SCREENING	21AUG2018	VLN mentholated	Yes	21AUG2018	20
	START OF WEEK -1	01SEP2018	VLN mentholated	Yes	01SEP2018	25
2136	SCREENING	27AUG2018	VLN non-mentholated	Yes	27AUG2018	14
	START OF WEEK -1	01SEP2018	VLN non-mentholated	Yes	01SEP2018	19
2140	SCREENING	30AUG2018	UB non-mentholated	Yes	30AUG2018	15
	START OF WEEK -1	18SEP2018	UB non-mentholated	Yes	18SEP2018	12
2142	SCREENING	31AUG2018	VLN non-mentholated	Yes	31AUG2018	27
	START OF WEEK -1	18SEP2018	VLN non-mentholated	Yes	18SEP2018	39
2143	SCREENING	04SEP2018	VLN non-mentholated	Yes	04SEP2018	55
	START OF WEEK -1	18SEP2018	VLN non-mentholated	Yes	18SEP2018	59
2158	SCREENING	18SEP2018	UB non-mentholated	Yes	18SEP2018	25
	START OF WEEK -1	14OCT2018	UB non-mentholated	Yes	14OCT2018	32
2159	SCREENING	19SEP2018	VLN non-mentholated	Yes	19SEP2018	49
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	52
2164	SCREENING	27SEP2018	VLN non-mentholated	Yes	27SEP2018	35
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	24
2168	SCREENING	28SEP2018	VLN non-mentholated	Yes	28SEP2018	24
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	33

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2170	SCREENING	28SEP2018	UB non-mentholated	Yes	28SEP2018	22
	START OF WEEK -1	14OCT2018	UB non-mentholated	Yes	14OCT2018	35
2175	SCREENING	01OCT2018	UB mentholated	Yes	01OCT2018	21
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	29
2189	SCREENING	04OCT2018	VLN mentholated	Yes	04OCT2018	25
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	14
2211	SCREENING	10OCT2018	VLN mentholated	Yes	10OCT2018	24
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	22
2212	SCREENING	10OCT2018	UB mentholated	Yes	10OCT2018	34
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	25
2213	SCREENING	10OCT2018	VLN mentholated	Yes	10OCT2018	44
	START OF WEEK -1	14OCT2018	VLN mentholated	Yes	14OCT2018	24
2215	SCREENING	10OCT2018	UB mentholated	Yes	10OCT2018	28
	START OF WEEK -1	14OCT2018	UB mentholated	Yes	14OCT2018	27
2220	SCREENING	11OCT2018	VLN non-mentholated	Yes	11OCT2018	22
	START OF WEEK -1	14OCT2018	VLN non-mentholated	Yes	14OCT2018	21
2235	SCREENING	19OCT2018	VLN mentholated	Yes	19OCT2018	17
	START OF WEEK -1	28OCT2018	VLN mentholated	Yes	28OCT2018	20
2244	SCREENING	25OCT2018	VLN non-mentholated	Yes	25OCT2018	31
	START OF WEEK -1	28OCT2018	VLN non-mentholated	Yes	28OCT2018	26
2247	SCREENING	06NOV2018	VLN mentholated	Yes	06NOV2018	18

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.1.10 Exhaled CO Measurement (Safety Population)

Subject Number	Visit		Product Group	Was Exhaled CO Measurement Performed?	Date of Collection	Exhaled CO Measurement (ppm)
	Name	Date				
2247	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	25
2251	SCREENING	09NOV2018	UB non-mentholated	Yes	09NOV2018	29
	START OF WEEK -1	01DEC2018	UB non-mentholated	Yes	01DEC2018	27
2257	SCREENING	14NOV2018	UB non-mentholated	Yes	14NOV2018	21
	START OF WEEK -1	01DEC2018	UB non-mentholated	Yes	01DEC2018	23
2259	SCREENING	14NOV2018	UB mentholated	Yes	14NOV2018	14
	START OF WEEK -1	01DEC2018	UB mentholated	Yes	01DEC2018	19
2269	SCREENING	26NOV2018	VLN mentholated	Yes	26NOV2018	15
	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	15
2272	SCREENING	28NOV2018	VLN mentholated	Yes	28NOV2018	11
	START OF WEEK -1	01DEC2018	VLN mentholated	Yes	01DEC2018	15

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-CO.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1001	SCREENING		VLN non-mentholated	02JUL2018	10:02			126/78		88	16	97.9
	START OF WEEK -1		VLN non-mentholated	19JUL2018	7:49			118/76		92	18	98.6
	END OF WEEK -1		VLN non-mentholated	24JUL2018	16:36			126/83		91	18	98.4
	END OF WEEK 2		VLN non-mentholated	08AUG2018	16:29			119/75		85	14	99.4
	END OF WEEK 4		VLN non-mentholated	22AUG2018	8:24			120/80		86	16	98
	END OF WEEK 6		VLN non-mentholated	05SEP2018	16:35			128/83		96	16	98.9
	END OF STUDY		VLN non-mentholated	07SEP2018	12:06			121/71		85	22	99
1002	SCREENING		VLN non-mentholated	02JUL2018	10:26			121/84		72	16	97.9
	START OF WEEK -1		VLN non-mentholated	19JUL2018	7:50			116/77		74	20	97.9
	END OF WEEK -1		VLN non-mentholated	24JUL2018	16:38			121/79		68	16	98
	END OF WEEK 2		VLN non-mentholated	08AUG2018	16:32			123/79		72	16	98.1
	END OF WEEK 4		VLN non-mentholated	22AUG2018	8:14			134/81		76	14	97.7
	END OF WEEK 6		VLN non-mentholated	05SEP2018	16:33			111/73		72	14	98.1
	END OF STUDY		VLN non-mentholated	07SEP2018	12:09			122/79		64	24	98.1
1003	SCREENING		VLN mentholated	03JUL2018	9:56			115/82		73	14	98.1
	START OF WEEK -1		VLN mentholated	19JUL2018	7:45			107/69		65	18	98
	END OF WEEK -1		VLN mentholated	24JUL2018	16:30			112/72		78	18	98.3
	END OF WEEK 2		VLN mentholated	08AUG2018	16:27			109/69		77	16	98.2
	END OF WEEK 4		VLN mentholated	22AUG2018	8:16			115/78		69	12	97.7
	END OF WEEK 6		VLN mentholated	05SEP2018	16:27			102/66		77	12	98.3
	END OF STUDY		VLN mentholated	07SEP2018	11:58			107/67		65	21	98.4
1007	SCREENING		VLN non-mentholated	12JUL2018	8:31			120/81		64	14	98.5
	START OF WEEK -1		VLN non-mentholated	19JUL2018	7:51			121/86		74	22	98.5
	END OF WEEK -1		VLN non-mentholated	24JUL2018	16:40			122/85		75	16	98.5
	END OF WEEK 2		VLN non-mentholated	08AUG2018	16:30			120/78		73	20	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name						(mmHg)			
1007	END OF WEEK 4	VLN non-mentholated	22AUG2018	8:07			123/85	66	14	98.1
	END OF WEEK 6	VLN non-mentholated	05SEP2018	16:37			116/75	98	12	98.5
	END OF STUDY	VLN non-mentholated	07SEP2018	12:11			129/83	71	21	98.2
1008	SCREENING	VLN mentholated	12JUL2018	9:20			128/88	71	14	98.6
	START OF WEEK -1	VLN mentholated	19JUL2018	7:46			135/86	70	14	98.5
	END OF WEEK -1	VLN mentholated	24JUL2018	16:32			132/82	80	16	98.4
	END OF WEEK 2	VLN mentholated	08AUG2018	16:36			134/78	64	16	98.2
	END OF WEEK 4	VLN mentholated	22AUG2018	8:18			132/86	69	14	97.8
	END OF WEEK 6	VLN mentholated	05SEP2018	16:29			124/75	73	16	98.4
	END OF STUDY	VLN mentholated	07SEP2018	12:01			127/78	61	20	98.5
1010	SCREENING	UB mentholated	13JUL2018	11:35			139/89	64	16	98.7
	START OF WEEK -1	UB mentholated	19JUL2018	7:48			127/80	62	10	98.7
	END OF WEEK -1	UB mentholated	24JUL2018	16:34			130/85	83	18	98.7
	END OF WEEK 2	UB mentholated	08AUG2018	16:38			130/80	71	16	98.9
	END OF WEEK 4	UB mentholated	22AUG2018	8:09			130/84	71	16	98.4
	END OF WEEK 6	UB mentholated	05SEP2018	16:31			120/76	84	14	98.7
	END OF STUDY	UB mentholated	06SEP2018	20:58			129/83	60	12	98.5
1011	SCREENING	UB non-mentholated	13JUL2018	11:45			139/95	74	14	98.1
	START OF WEEK -1	UB non-mentholated	19JUL2018	7:52			125/58	88	18	98.2
	END OF WEEK -1	UB non-mentholated	24JUL2018	16:42			125/88	92	20	98.5
	END OF WEEK 2	UB non-mentholated	08AUG2018	16:34			130/87	89	18	98.4
	END OF WEEK 4	UB non-mentholated	22AUG2018	8:11			130/91	74	16	98.1
	END OF WEEK 6	UB non-mentholated	05SEP2018	16:39			129/84	96	16	98.4
	END OF STUDY	UB non-mentholated	06SEP2018	21:01			134/82	82	12	98.6

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia				
1013	SCREENING	VLN non-mentholated	16JUL2018	11:08			111/69		71	14	98
	START OF WEEK -1	VLN non-mentholated	26JUL2018	7:55			106/68		70	16	98.1
	END OF WEEK -1	VLN non-mentholated	31JUL2018	16:56			106/70		70	16	98.8
	END OF WEEK 2	VLN non-mentholated	15AUG2018	16:38			102/61		81	14	98.5
	END OF WEEK 4	VLN non-mentholated	29AUG2018	8:26			104/63		74	16	98.3
	END OF WEEK 6	VLN non-mentholated	12SEP2018	16:37			124/70		80	18	98.6
	END OF STUDY	VLN non-mentholated	14SEP2018	12:05			109/70		62	14	98.1
1014	SCREENING	VLN mentholated	16JUL2018	11:03			117/80		84	16	98.2
	START OF WEEK -1	VLN mentholated	26JUL2018	7:43			121/83		74	14	98.4
	END OF WEEK -1	VLN mentholated	31JUL2018	16:46			116/78		92	18	98.5
	END OF WEEK 2	VLN mentholated	15AUG2018	16:30			99/64		84	12	98.2
	END OF WEEK 4	VLN mentholated	29AUG2018	8:29			117/75		76	18	98.3
	END OF WEEK 6	VLN mentholated	12SEP2018	16:38			118/75		79	16	98.3
	END OF STUDY	VLN mentholated	14SEP2018	11:57			110/74		76	16	98.2
1015	SCREENING	VLN mentholated	16JUL2018	11:25			142/91		61	14	97.6
	START OF WEEK -1	VLN mentholated	26JUL2018	7:37			119/77		74	16	98.2
	END OF WEEK -1	VLN mentholated	31JUL2018	16:40			129/88		80	18	98.2
	END OF WEEK 2	VLN mentholated	15AUG2018	16:42			124/79		85	14	98.1
	END OF WEEK 4	VLN mentholated	29AUG2018	8:28			111/77		65	12	98.3
	END OF WEEK 6	VLN mentholated	12SEP2018	16:49			111/76		84	16	98
	END OF STUDY	VLN mentholated	14SEP2018	11:55			107/72		74	14	98.3
1016	SCREENING	UB non-mentholated	16JUL2018	11:30			160 NCS/108 NCS		69	12	98.1
	UNSCHEDULED	UB non-mentholated	16JUL2018	11:36			163 NCS/108 NCS		62		
	UNSCHEDULED	UB non-mentholated	16JUL2018	11:39			145/91		61		
	START OF WEEK -1	UB non-mentholated	26JUL2018	7:57			165 NCS/96 NCS		82	14	98.4

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1016	UNSCHEDULED		UB non-mentholated	26JUL2018	8:01			139/93		81		
	END OF WEEK -1		UB non-mentholated	31JUL2018	16:58			161 NCS/119 NCS		78	18	98.3
	UNSCHEDULED		UB non-mentholated	31JUL2018	17:08			163 NCS/106 NCS		82		
	UNSCHEDULED		UB non-mentholated	31JUL2018	17:18			153 NCS/100 NCS		76		
	UNSCHEDULED		UB non-mentholated	01AUG2018	9:21			128/84		84		
	END OF WEEK 2		UB non-mentholated	15AUG2018	16:39			175 NCS/111 NCS		73	10	98.2
	UNSCHEDULED		UB non-mentholated	15AUG2018	16:50			161 NCS/93		70		
	UNSCHEDULED		UB non-mentholated	15AUG2018	16:52			168 NCS/105 NCS		76		
	UNSCHEDULED		UB non-mentholated	16AUG2018	7:14			143/90		80		
	END OF WEEK 4		UB non-mentholated	29AUG2018	8:24			149/91		96	14	98.6
	END OF WEEK 6		UB non-mentholated	12SEP2018	16:35			150/101 NCS		91	16	98.9
	UNSCHEDULED		UB non-mentholated	12SEP2018	16:45			161 NCS/108 NCS		78		
	UNSCHEDULED		UB non-mentholated	12SEP2018	16:55			151 NCS/103 NCS		79		
	UNSCHEDULED		UB non-mentholated	13SEP2018	6:51			185 NCS/116 NCS		67		
	UNSCHEDULED		UB non-mentholated	13SEP2018	6:58			196 NCS/113 NCS		67		
	END OF STUDY		UB non-mentholated	13SEP2018	21:12			174 NCS/110 NCS		73	16	98.7
	UNSCHEDULED		UB non-mentholated	13SEP2018	21:22			178 NCS/112 NCS		73		
	UNSCHEDULED		UB non-mentholated	13SEP2018	21:34			176 NCS/114 NCS		70		
1017	SCREENING		UB mentholated	17JUL2018	11:50			113/79		69	14	98.7
	START OF WEEK -1		UB mentholated	26JUL2018	7:39			117/81		80	14	98.6
	END OF WEEK -1		UB mentholated	31JUL2018	16:42			112/75		79	18	98.8
	END OF WEEK 2		UB mentholated	15AUG2018	16:44			113/75		91	14	98.6
	END OF WEEK 4		UB mentholated	29AUG2018	8:11			103/72		75	18	99.3
	END OF WEEK 6		UB mentholated	12SEP2018	16:39			112/76		87	16	98.4
	END OF STUDY		UB mentholated	13SEP2018	21:00			114/78		68	18	98.3
1018	SCREENING		VLN mentholated	17JUL2018	11:48			140/100		71	14	98.3

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	Name						-----	Sys/Dia			
1018	UNSCCHEDULED		VLN mentholated	17JUL2018	11:54				143/94	77		
	START OF WEEK -1		VLN mentholated	26JUL2018	7:41				144/96 NCS	87	18	98.4
	UNSCCHEDULED		VLN mentholated	26JUL2018	7:51				148/97 NCS	86		
	UNSCCHEDULED		VLN mentholated	26JUL2018	7:58				135/93	93		
	END OF WEEK -1		VLN mentholated	31JUL2018	16:44				145/91	93	16	98.5
	END OF STUDY		VLN mentholated	15AUG2018	20:10				132/85	96	14	98.3
1019	SCREENING		VLN non-mentholated	17JUL2018	12:06				112/77	60	20	98.5
	START OF WEEK -1		VLN non-mentholated	26JUL2018	7:45				136/72	69	16	98.2
	END OF WEEK -1		VLN non-mentholated	31JUL2018	16:48				107/69	77	16	98.9
	UNSCCHEDULED		VLN non-mentholated	02AUG2018	8:17				76/52	49 NCS		
	UNSCCHEDULED		VLN non-mentholated	02AUG2018	8:26				109/72	60		
	END OF WEEK 2		VLN non-mentholated	15AUG2018	16:31				108/68	66	10	98.2
	END OF WEEK 4		VLN non-mentholated	29AUG2018	8:19				120/74	72	16	97.9
	END OF WEEK 6		VLN non-mentholated	12SEP2018	16:43				104/67	68	14	98.8
	END OF STUDY		VLN non-mentholated	14SEP2018	12:00				108/71	45 NCS	12	98.2
1020	SCREENING		VLN non-mentholated	17JUL2018	12:42				111/80	64	16	98.5
	START OF WEEK -1		VLN non-mentholated	26JUL2018	7:49				101/66	62	18	98.3
	END OF WEEK -1		VLN non-mentholated	31JUL2018	16:52				111/77	62	18	98.6
	END OF WEEK 2		VLN non-mentholated	15AUG2018	16:34				105/73	66	12	98.2
	END OF WEEK 4		VLN non-mentholated	29AUG2018	8:16				102/67	68	16	98.6
	END OF WEEK 6		VLN non-mentholated	12SEP2018	16:48				102/70	70	16	98.2
	END OF STUDY		VLN non-mentholated	14SEP2018	12:01				105/73	56	12	98.3
1021	SCREENING		UB non-mentholated	17JUL2018	13:04				118/84	68	14	98.3
	START OF WEEK -1		UB non-mentholated	26JUL2018	7:47				107/75	65	16	98.2
	END OF WEEK -1		UB non-mentholated	31JUL2018	16:50				117/79	73	16	98.4

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1021	END OF WEEK 2		UB non-mentholated	15AUG2018	16:33			119/79		78	14	98.6
	END OF WEEK 4		UB non-mentholated	29AUG2018	8:13			118/78		72	16	98.5
	END OF WEEK 6		UB non-mentholated	12SEP2018	16:41			108/74		77	16	98.1
	END OF STUDY		UB non-mentholated	13SEP2018	21:11			117/80		67	14	98.6
1023	SCREENING		VLN non-mentholated	17JUL2018	12:35			111/76		64	16	98.3
	START OF WEEK -1		VLN non-mentholated	26JUL2018	7:53			103/69		65	14	98.2
	END OF WEEK -1		VLN non-mentholated	31JUL2018	16:54			97/64		76	18	98.3
	END OF WEEK 2		VLN non-mentholated	15AUG2018	16:36			99/63		70	12	98.2
	END OF WEEK 4		VLN non-mentholated	29AUG2018	8:31			96/64		66	14	98.1
	END OF WEEK 6		VLN non-mentholated	12SEP2018	16:51			95/65		70	16	98.2
	END OF STUDY		VLN non-mentholated	14SEP2018	12:03			96/63		65	14	97.5
1029	SCREENING		VLN mentholated	26JUL2018	10:06			131/96		74	16	98.5
	UNSCHEDULED		VLN mentholated	26JUL2018	10:11			138/88		81		
	START OF WEEK -1		VLN mentholated	22AUG2018	7:21			135/83		79	18	97.9
	END OF WEEK -1		VLN mentholated	27AUG2018	16:13			130/88		80	14	98.3
	END OF WEEK 2		VLN mentholated	11SEP2018	16:18			146/94		77	14	98.2
	END OF WEEK 4		VLN mentholated	25SEP2018	7:30			124/78		64	12	97.8
	END OF WEEK 6		VLN mentholated	09OCT2018	16:00			125/78		77	16	97.5
	END OF STUDY		VLN mentholated	11OCT2018	11:25			124/75		62	16	97.7
1032	SCREENING		VLN mentholated	13AUG2018	9:45			126/84		61	18	97.9
	START OF WEEK -1		VLN mentholated	22AUG2018	7:23			104/68		59	14	98.3
	END OF WEEK -1		VLN mentholated	27AUG2018	16:22			105/67		81	14	99.2
	END OF WEEK 2		VLN mentholated	11SEP2018	16:14			116/68		72	14	98.9
	END OF WEEK 4		VLN mentholated	25SEP2018	7:43			103/67		56	12	98.4
	END OF WEEK 6		VLN mentholated	09OCT2018	16:06			92/57		59	16	98.6

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1032	END OF STUDY		VLN mentholated	11OCT2018	11:28			104/64		54	12	98.3
1034	SCREENING		VLN non-mentholated	13AUG2018	9:48			136/84		69	16	98.3
	START OF WEEK -1		VLN non-mentholated	22AUG2018	7:45			126/76		64	10	98.6
	END OF WEEK -1		VLN non-mentholated	27AUG2018	16:10			143/83		83	14	98.8
	END OF WEEK 2		VLN non-mentholated	11SEP2018	16:16			147/83		77	12	99.1
	END OF WEEK 4		VLN non-mentholated	25SEP2018	7:53			129/80		80	12	98.2
	END OF WEEK 6		VLN non-mentholated	09OCT2018	16:33			137/85		72	12	98.9
	END OF STUDY		VLN non-mentholated	10OCT2018	20:37			124/78		54	14	98.5
1035	SCREENING		VLN non-mentholated	13AUG2018	9:58			122/87		77	16	97.9
	START OF WEEK -1		VLN non-mentholated	22AUG2018	7:33			128/83		76	12	97.8
	END OF WEEK -1		VLN non-mentholated	27AUG2018	16:30			117/82		91	12	99.1
	END OF WEEK 2		VLN non-mentholated	11SEP2018	16:42			116/81		99	12	98.7
	END OF WEEK 4		VLN non-mentholated	25SEP2018	7:57			124/86		75	12	98.1
	END OF WEEK 6		VLN non-mentholated	09OCT2018	16:25			132/87		76	12	98.9
	END OF STUDY		VLN non-mentholated	11OCT2018	11:50			121/82		86	12	98.4
1036	SCREENING		UB mentholated	13AUG2018	10:12			134/90		85	14	97.8
	START OF WEEK -1		UB mentholated	22AUG2018	7:22			128/84		89	14	98.8
	END OF WEEK -1		UB mentholated	27AUG2018	16:31			135/88		82	16	98.9
	END OF WEEK 2		UB mentholated	11SEP2018	16:45			126/84		87	12	99
	END OF WEEK 4		UB mentholated	25SEP2018	8:05			131/85		83	16	98.1
	END OF WEEK 6		UB mentholated	09OCT2018	16:08			139/88		94	16	99.1
	END OF STUDY		UB mentholated	10OCT2018	20:26			142/92		81	12	98.9
1037	SCREENING		UB mentholated	13AUG2018	10:26			132/86		68	14	98
	START OF WEEK -1		UB mentholated	22AUG2018	7:38			125/85		75	12	98.3

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
1037	END OF WEEK -1	UB mentholated	27AUG2018	16:28				146/79		82	14	99.2
	END OF WEEK 2	UB mentholated	11SEP2018	16:21				133/73		86	14	98.4
	END OF WEEK 4	UB mentholated	25SEP2018	7:58				117/73		56	14	98
	END OF WEEK 6	UB mentholated	09OCT2018	16:20				119/69		66	12	98.4
	END OF STUDY	UB mentholated	10OCT2018	20:30				118/73		66	14	98.3
1038	SCREENING	VLN non-mentholated	13AUG2018	10:16				111/82		85	14	97.9
	START OF WEEK -1	VLN non-mentholated	22AUG2018	7:53				116/78		74	12	98.3
	END OF WEEK -1	VLN non-mentholated	27AUG2018	16:29				111/76	NCS	101	16	98.4
	UNSCHEDULED	VLN non-mentholated	27AUG2018	16:39				111/74		94		
	END OF WEEK 2	VLN non-mentholated	11SEP2018	16:39				117/75		97	16	98.6
	END OF WEEK 4	VLN non-mentholated	25SEP2018	8:02				122/78		83	14	98.2
	END OF WEEK 6	VLN non-mentholated	09OCT2018	16:29				122/79	NCS	101	16	98.5
	UNSCHEDULED	VLN non-mentholated	09OCT2018	16:39				111/77		91		
	END OF STUDY	VLN non-mentholated	11OCT2018	11:49				121/82		86	12	98.4
1042	SCREENING	VLN non-mentholated	13AUG2018	10:21				154/105		53	16	97.9
	UNSCHEDULED	VLN non-mentholated	13AUG2018	10:30				144/94		64		
	START OF WEEK -1	VLN non-mentholated	22AUG2018	7:51				131/85		76	16	97.8
	END OF WEEK -1	VLN non-mentholated	27AUG2018	16:34				153 NCS/84		88	14	98.4
	END OF WEEK 2	VLN non-mentholated	11SEP2018	16:34				161 NCS/88		72	12	97.9
	UNSCHEDULED	VLN non-mentholated	11SEP2018	16:48				141/94		76		
	END OF WEEK 4	VLN non-mentholated	25SEP2018	8:00				134/87		69	12	97.9
	END OF WEEK 6	VLN non-mentholated	09OCT2018	16:24				122/82		73	14	98.5
	END OF STUDY	VLN non-mentholated	11OCT2018	11:43				127/86		64	12	98.4
1045	SCREENING	UB non-mentholated	14AUG2018	10:24				129/89		83	16	98.4
	START OF WEEK -1	UB non-mentholated	22AUG2018	7:41				121/78		68	16	98.4

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----			
Name								Sys/Dia			
1045	END OF WEEK -1	UB non-mentholated	27AUG2018	16:23				123/80	90	12	98.7
	END OF WEEK 2	UB non-mentholated	11SEP2018	16:27				116/75	80	14	98.6
	END OF WEEK 4	UB non-mentholated	25SEP2018	7:55				115/79	71	12	98.1
	END OF WEEK 6	UB non-mentholated	09OCT2018	16:28				132/85	86	10	98.8
	END OF STUDY	UB non-mentholated	10OCT2018	20:40				136/75	83	16	98.1
1046	SCREENING	UB mentholated	14AUG2018	10:50				117/81	73	16	98.3
	START OF WEEK -1	UB mentholated	22AUG2018	7:34				112/76	78	16	98.1
	END OF WEEK -1	UB mentholated	27AUG2018	16:16				113/71	84	16	98.4
	END OF WEEK 2	UB mentholated	11SEP2018	16:24				103/70	96	16	98.8
	END OF WEEK 4	UB mentholated	25SEP2018	7:47				109/73	74	12	98
	END OF WEEK 6	UB mentholated	09OCT2018	16:22				110/72	83	12	97.8
	END OF STUDY	UB mentholated	10OCT2018	20:31				111/75	78	14	97.7
1050	SCREENING	VLN non-mentholated	14AUG2018	10:19				107/74	72	16	98.5
	START OF WEEK -1	VLN non-mentholated	22AUG2018	7:54				108/72	75	10	97.6
	END OF WEEK -1	VLN non-mentholated	27AUG2018	16:19				114/75	84	14	98.5
	END OF WEEK 2	VLN non-mentholated	11SEP2018	16:13				108/71	64	14	97.7
	END OF WEEK 4	VLN non-mentholated	25SEP2018	7:49				106/69	73	14	97.7
	END OF WEEK 6	VLN non-mentholated	09OCT2018	16:31				107/67	80	16	98
	END OF STUDY	VLN non-mentholated	10OCT2018	20:46				114/75	63	14	98.2
1051	SCREENING	UB mentholated	14AUG2018	10:43				130/87	87	18	98.6
	START OF WEEK -1	UB mentholated	22AUG2018	7:29				127/86	77	16	98.6
	END OF WEEK -1	UB mentholated	27AUG2018	16:08				124/86	90	16	98.4
	END OF WEEK 2	UB mentholated	11SEP2018	16:37				121/81	88	14	98.4
	END OF WEEK 4	UB mentholated	25SEP2018	7:46				125/81	75	14	98.2
	END OF WEEK 6	UB mentholated	09OCT2018	16:14				120/82	86	16	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name						Sys/Dia			
1051	END OF STUDY	UB mentholated	10OCT2018	20:28			136/84	81	14	98.1
1052	SCREENING	VLN mentholated	14AUG2018	10:45			118/78	58	16	98.4
	START OF WEEK -1	VLN mentholated	22AUG2018	7:26			111/63	67	12	98
	END OF WEEK -1	VLN mentholated	27AUG2018	16:26			115/64	73	14	98.1
	END OF WEEK 2	VLN mentholated	11SEP2018	16:28			118/75	67	12	98.4
	END OF WEEK 4	VLN mentholated	25SEP2018	7:38			109/65	66	12	98.2
	END OF WEEK 6	VLN mentholated	09OCT2018	16:13			126/78	90	14	98
	END OF STUDY	VLN mentholated	11OCT2018	11:39			121/64	72	14	98.2
1053	SCREENING	VLN mentholated	14AUG2018	11:04			138/96	76	14	98.6
	UNSCHEDULED	VLN mentholated	14AUG2018	11:11			136/89	87		
	START OF WEEK -1	VLN mentholated	22AUG2018	7:27			143/86	92	14	98.3
	END OF WEEK -1	VLN mentholated	27AUG2018	16:25			143/93	96	12	98.2
	END OF WEEK 2	VLN mentholated	11SEP2018	16:46			135/85	85	16	98.3
	END OF WEEK 4	VLN mentholated	25SEP2018	7:41			135/88	89	10	98.3
	END OF WEEK 6	VLN mentholated	09OCT2018	16:10			147/100 NCS	94	12	98.5
	UNSCHEDULED	VLN mentholated	09OCT2018	16:16			136/89	86		
	END OF STUDY	VLN mentholated	11OCT2018	11:38			103/69	76	12	97.6
1054	SCREENING	UB non-mentholated	14AUG2018	10:53			126/80	73	16	98.6
	START OF WEEK -1	UB non-mentholated	22AUG2018	7:47			130/77	66	12	97.7
	END OF WEEK -1	UB non-mentholated	27AUG2018	16:33			125/80	82	14	98.7
	END OF WEEK 2	UB non-mentholated	11SEP2018	16:31			128/77	87	18	98.5
	END OF WEEK 4	UB non-mentholated	25SEP2018	7:51			101/67	74	10	98.2
	END OF WEEK 6	UB non-mentholated	09OCT2018	16:34			132/81	86	14	98
	END OF STUDY	UB non-mentholated	10OCT2018	20:47			138/85	76	14	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
	-----	-----						-----			
	Name							Sys/Dia			
1055	SCREENING	VLN mentholated	14AUG2018	10:58				102/70	53	14	98.8
	START OF WEEK -1	VLN mentholated	22AUG2018	7:31				99/62	69	14	98.8
	END OF WEEK -1	VLN mentholated	27AUG2018	16:15				125/76	62	18	99
	END OF WEEK 2	VLN mentholated	11SEP2018	16:19				105/67	68	16	98.6
	END OF WEEK 4	VLN mentholated	25SEP2018	7:36				109/69	77	14	98.5
	END OF WEEK 6	VLN mentholated	09OCT2018	16:18				106/70	78	18	99
	END OF STUDY	VLN mentholated	11OCT2018	11:41				102/66	65	16	98.7
1056	SCREENING	VLN non-mentholated	14AUG2018	11:14				143/90	101 NCS	12	97.9
	UNSCHEDULED	VLN non-mentholated	14AUG2018	11:19				142/95	103 NCS		
	UNSCHEDULED	VLN non-mentholated	14AUG2018	11:49				145/93	93		
	START OF WEEK -1	VLN non-mentholated	22AUG2018	7:43				133/85	83	12	98.3
	END OF WEEK -1	VLN non-mentholated	27AUG2018	16:20				136/85	97	12	98.1
	END OF WEEK 2	VLN non-mentholated	11SEP2018	16:11				121/82	86	16	98.4
	END OF WEEK 4	VLN non-mentholated	25SEP2018	7:34				119/79	79	14	98.2
	END OF WEEK 6	VLN non-mentholated	09OCT2018	16:04				118/76	79	14	98.1
	END OF STUDY	VLN non-mentholated	11OCT2018	11:56				112/71	71	12	98.3
1058	SCREENING	VLN non-mentholated	15AUG2018	9:54				113/77	74	18	97.9
	START OF WEEK -1	VLN non-mentholated	22AUG2018	7:49				116/78	67	14	97.8
	END OF WEEK -1	VLN non-mentholated	27AUG2018	16:04				127/75	83	14	98
	END OF WEEK 2	VLN non-mentholated	11SEP2018	16:32				147/84	62	14	98.3
	END OF WEEK 4	VLN non-mentholated	25SEP2018	7:32				115/72	79	12	98.1
	END OF WEEK 6	VLN non-mentholated	09OCT2018	16:02				136/75	87	12	98
	END OF STUDY	VLN non-mentholated	11OCT2018	11:46				128/78	64	16	97.8
1059	SCREENING	UB non-mentholated	27AUG2018	10:26				118/82	87	16	98
	START OF WEEK -1	UB non-mentholated	05SEP2018	7:28				110/74	85	12	97.7

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1059	END OF WEEK -1		UB non-mentholated	10SEP2018	15:58			122/80		90		98.6
	END OF WEEK 2		UB non-mentholated	25SEP2018	16:08			107/74		98		98.6
	END OF WEEK 4		UB non-mentholated	09OCT2018	7:40			111/77		96		98.1
	END OF WEEK 6		UB non-mentholated	23OCT2018	16:06			119/73		105 NCS	10	98.6
	UNSCHEDULED		UB non-mentholated	23OCT2018	16:24			104/70		102 NCS		
	UNSCHEDULED		UB non-mentholated	23OCT2018	16:34			136/73		99		
	END OF STUDY		UB non-mentholated	24OCT2018	20:31			109/75		80	12	97.9
1060	SCREENING		VLN mentholated	27AUG2018	10:31			124/86		59	16	97.9
	START OF WEEK -1		VLN mentholated	05SEP2018	7:24			109/71		64	14	98
	END OF WEEK -1		VLN mentholated	10SEP2018	16:00			108/72		79	16	99.1
	END OF WEEK 2		VLN mentholated	25SEP2018	16:04			107/66		76	10	98.7
	END OF WEEK 4		VLN mentholated	09OCT2018	7:45			112/74		64	16	98.4
	END OF WEEK 6		VLN mentholated	23OCT2018	16:02			115/74		84	14	98.7
	END OF STUDY		VLN mentholated	24OCT2018	20:27			117/82		76	12	98.3
1063	SCREENING		VLN mentholated	27AUG2018	11:24			108/76		80	18	97.9
	START OF WEEK -1		VLN mentholated	05SEP2018	7:20			107/70		66	12	98
	END OF WEEK -1		VLN mentholated	10SEP2018	16:04			120/77		89	14	98.5
	END OF WEEK 2		VLN mentholated	25SEP2018	16:00			111/73		66	14	97.9
	END OF WEEK 4		VLN mentholated	09OCT2018	7:32			102/67		70	14	98.1
	END OF WEEK 6		VLN mentholated	23OCT2018	16:12			105/67		76	12	98.1
	END OF STUDY		VLN mentholated	25OCT2018	11:21			117/74		70	16	98.2
1064	SCREENING		UB non-mentholated	27AUG2018	11:40			117/82		68	16	98.1
	START OF WEEK -1		UB non-mentholated	05SEP2018	10:53			113/80		82	16	98.2
	END OF WEEK -1		UB non-mentholated	10SEP2018	16:22			120/83		89	14	98.3
	END OF WEEK 2		UB non-mentholated	25SEP2018	16:12			134/79		80	12	98.4

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
1064	END OF STUDY	UB non-mentholated	22OCT2018		NOT DONE	SUBJECT IS LOST TO FOLLOW UP	/			
1066	SCREENING	VLN non-mentholated	27AUG2018	11:17			149/94	66	14	98.2
	START OF WEEK -1	VLN non-mentholated	05SEP2018	8:00			142/90	62	14	97.7
	END OF WEEK -1	VLN non-mentholated	10SEP2018	16:15			133/83	76	12	98.7
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:16			128/74	61	14	98.4
	END OF WEEK 4	VLN non-mentholated	09OCT2018	7:51			145/91	60	16	98.2
	END OF WEEK 6	VLN non-mentholated	23OCT2018	16:10			130/81	71	12	98.1
	END OF STUDY	VLN non-mentholated	24OCT2018	20:35			142/83	59	12	98.3
1069	SCREENING	UB non-mentholated	28AUG2018	10:40			116/82	72	14	99.1
	START OF WEEK -1	UB non-mentholated	05SEP2018	7:40			108/72	75	14	98.3
	END OF WEEK -1	UB non-mentholated	10SEP2018	16:08			116/75	71	12	99.1
	END OF WEEK 2	UB non-mentholated	25SEP2018	16:20			104/70	79	16	98.6
	END OF WEEK 4	UB non-mentholated	09OCT2018	7:57			128/80	78	16	98.8
	END OF WEEK 6	UB non-mentholated	23OCT2018	16:16			105/71	76	16	98.7
	END OF STUDY	UB non-mentholated	24OCT2018	20:39			114/75	80	14	98.8
1070	SCREENING	VLN non-mentholated	28AUG2018	10:08			150/101 NCS	88	16	98.2
	UNSCHEDULED	VLN non-mentholated	28AUG2018	10:13			142/89	88		
	START OF WEEK -1	VLN non-mentholated	05SEP2018	7:36			135/88	77	14	98.3
	END OF WEEK -1	VLN non-mentholated	10SEP2018	15:55			154 NCS/94	97	14	98.4
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:18			141/81	97	16	98.1
	END OF WEEK 4	VLN non-mentholated	09OCT2018	7:54			151 NCS/78	111 NCS	16	98
	UNSCHEDULED	VLN non-mentholated	09OCT2018	8:09			147/91	98		
	END OF WEEK 6	VLN non-mentholated	23OCT2018	16:14			118/79	97	10	98.3

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
1070	END OF STUDY	VLN non-mentholated	24OCT2018	20:37			129/83	94	12	98.4
1071	SCREENING	VLN non-mentholated	28AUG2018	10:30			117/81	66	14	98.2
	START OF WEEK -1	VLN non-mentholated	05SEP2018	7:30			128/76	70	14	98.2
	END OF WEEK -1	VLN non-mentholated	10SEP2018	15:57			148/78	89	14	98.8
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:10			141/80	101 NCS	14	98.6
	UNSCHEDULED	VLN non-mentholated	25SEP2018	16:25			125/79	76		
	END OF WEEK 4	VLN non-mentholated	09OCT2018	7:43			130/78	68	12	97.9
	END OF STUDY	VLN non-mentholated	23OCT2018		NOT DONE	SUBJECT DROPPED FROM STUDY	/			
1072	SCREENING	VLN mentholated	28AUG2018	10:16			126/82	61	14	98.8
	START OF WEEK -1	VLN mentholated	05SEP2018	7:22			106/70	74	14	98.2
	END OF WEEK -1	VLN mentholated	10SEP2018	16:06			136/72	101 NCS	16	98.6
	UNSCHEDULED	VLN mentholated	10SEP2018	16:12			148/74	98		
	END OF WEEK 2	VLN mentholated	25SEP2018	16:02			120/72	73	18	98.6
	END OF WEEK 4	VLN mentholated	09OCT2018	7:35			131/80	76	16	98.3
	END OF STUDY	VLN mentholated	22OCT2018	11:58			144/74	78	16	98.1
1074	SCREENING	VLN non-mentholated	28AUG2018	10:45			136/92	85	16	98.2
	START OF WEEK -1	VLN non-mentholated	05SEP2018	7:46			143/93	76	14	97.6
	END OF WEEK -1	VLN non-mentholated	10SEP2018	16:19			145/92	81	16	98.1
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:26			148/101 NCS	83	22	98.3
	UNSCHEDULED	VLN non-mentholated	25SEP2018	16:36			150/102 NCS	89		
	UNSCHEDULED	VLN non-mentholated	25SEP2018	16:47			148/93	80		
	END OF WEEK 4	VLN non-mentholated	09OCT2018	8:05			146/99 NCS	77	18	97.7
	UNSCHEDULED	VLN non-mentholated	09OCT2018	8:10			137/93	73		

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia				
1074	END OF WEEK 6	VLN non-mentholated	23OCT2018	16:21			137/93		73	10	97.8
	END OF STUDY	VLN non-mentholated	24OCT2018	20:46			149/95		71	12	97.5
1075	SCREENING	UB non-mentholated	28AUG2018	10:49			106/71		61	14	98.6
	START OF WEEK -1	UB non-mentholated	05SEP2018	7:47			104/70		70	14	98.1
	END OF WEEK -1	UB non-mentholated	10SEP2018	16:17			115/73		58	14	97.9
	END OF WEEK 2	UB non-mentholated	25SEP2018	16:28			96/62		77	20	98.4
	END OF WEEK 4	UB non-mentholated	09OCT2018	8:07			104/69		71	12	98.3
	END OF WEEK 6	UB non-mentholated	23OCT2018	16:23			103/70		74	14	98.2
	END OF STUDY	UB non-mentholated	24OCT2018	20:48			100/67		71	10	98.5
1077	SCREENING	VLN non-mentholated	28AUG2018	11:01			120/86		75	16	98.8
	START OF WEEK -1	VLN non-mentholated	05SEP2018	7:45			118/78		90	12	97.9
	END OF WEEK -1	VLN non-mentholated	10SEP2018	16:10			127/81		97	16	98.1
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:23			113/75		82	16	98.2
	END OF WEEK 4	VLN non-mentholated	09OCT2018	8:03			109/76		81	20	98.8
	END OF WEEK 6	VLN non-mentholated	23OCT2018	16:20			129/81		98	14	98.2
	END OF STUDY	VLN non-mentholated	24OCT2018	20:44			124/84		86	10	98.6
1078	SCREENING	VLN non-mentholated	28AUG2018	11:05			105/73		80	14	98.2
	START OF WEEK -1	VLN non-mentholated	05SEP2018	7:33			119/82		65	14	98
	END OF WEEK -1	VLN non-mentholated	10SEP2018	16:24			113/82		69	14	98.3
	END OF WEEK 2	VLN non-mentholated	25SEP2018	16:14			120/80		67	20	98.4
	END OF WEEK 4	VLN non-mentholated	09OCT2018	7:49			114/79		75	12	98
	END OF WEEK 6	VLN non-mentholated	23OCT2018	16:08			121/81		84	14	98.1
	END OF STUDY	VLN non-mentholated	24OCT2018	20:33			110/73		69	10	98
1079	SCREENING	VLN mentholated	28AUG2018	11:15			130/83		78	14	98.6

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
1079	START OF WEEK -1	-1	VLN mentholated	05SEP2018	7:26			126/80		92		98.2
	END OF WEEK -1	-1	VLN mentholated	10SEP2018	17:06			137/76		114 NCS	16	98.6
	UNSCHEDULED		VLN mentholated	10SEP2018	17:11			107/76		106 NCS		
	UNSCHEDULED		VLN mentholated	10SEP2018	17:18			103/71		90		
	END OF WEEK 2		VLN mentholated	25SEP2018	16:06			127/78		90	8 NCS	98.5
	END OF WEEK 4		VLN mentholated	09OCT2018	7:38			127/85		77	14	98.1
	END OF WEEK 6		VLN mentholated	23OCT2018	16:04			125/88		89	16	98.3
	END OF STUDY		VLN mentholated	24OCT2018	20:29			122/80		87	12	98.2
1082	SCREENING		VLN non-mentholated	30AUG2018	8:28			126/80		63	18	98.4
	START OF WEEK -1	-1	VLN non-mentholated	05SEP2018	7:50			112/71		60	12	98.2
	END OF WEEK -1	-1	VLN non-mentholated	10SEP2018	16:02			110/69		76	14	98.7
	END OF WEEK 2		VLN non-mentholated	25SEP2018	16:22			106/71		60	14	98.6
	END OF WEEK 4		VLN non-mentholated	09OCT2018	7:59			111/74		60	16	97.9
	END OF WEEK 6		VLN non-mentholated	23OCT2018	16:18			116/68		72	14	98.5
	END OF STUDY		VLN non-mentholated	24OCT2018	20:41			119/77		60	16	98.4
1083	SCREENING		VLN non-mentholated	04SEP2018	10:14			120/80		69	14	98.8
	START OF WEEK -1	-1	VLN non-mentholated	12SEP2018	8:03			125/84		67	20	98.1
	END OF WEEK -1	-1	VLN non-mentholated	17SEP2018	16:38			132/78		79	18	98.3
	END OF WEEK 2		VLN non-mentholated	02OCT2018	16:30			113/74		88	14	98.4
	END OF WEEK 4		VLN non-mentholated	16OCT2018	8:16			119/76		67	16	98.3
	END OF WEEK 6		VLN non-mentholated	30OCT2018	16:43			125/81		73	12	98
	END OF STUDY		VLN non-mentholated	31OCT2018	21:07			126/81		56	16	98.2
1084	SCREENING		VLN non-mentholated	04SEP2018	10:51			142/93		71	22	98.7
	START OF WEEK -1	-1	VLN non-mentholated	12SEP2018	8:07			119/85		70	16	98.3
	END OF WEEK -1	-1	VLN non-mentholated	17SEP2018	16:39			117/77		76	16	98.5

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
1084	END OF WEEK 2		VLN non-mentholated	02OCT2018	16:24			128/86		75	16	98.1
	END OF WEEK 4		VLN non-mentholated	16OCT2018	8:18			113/83		87	14	98.6
	END OF STUDY		VLN non-mentholated	16OCT2018		NOT DONE	SUBJECT DROPPED FROM STUDY	/				
1086	SCREENING		VLN non-mentholated	04SEP2018	10:08			151 NCS/92		69	12	97.8
	UNSCHEDULED		VLN non-mentholated	04SEP2018	10:21			140/97 NCS		77		
	UNSCHEDULED		VLN non-mentholated	04SEP2018	10:36			146/96 NCS		75		
	START OF WEEK -1		VLN non-mentholated	12SEP2018	8:09			128/84		78	18	97.9
	END OF WEEK -1		VLN non-mentholated	17SEP2018	16:31			143/88		86	16	97.7
	END OF WEEK 2		VLN non-mentholated	02OCT2018	16:42			131/80		93	22	98
	END OF WEEK 4		VLN non-mentholated	16OCT2018	8:20			123/83		76	20	98.2
	END OF WEEK 6		VLN non-mentholated	30OCT2018	16:45			128/88		90	14	97.4
	END OF STUDY		VLN non-mentholated	31OCT2018	21:09			145/81		81	16	98.3
1088	SCREENING		VLN mentholated	04SEP2018	10:33			127/84		90	14	97.9
	START OF WEEK -1		VLN mentholated	12SEP2018	7:52			122/83		74	20	98.3
	END OF WEEK -1		VLN mentholated	17SEP2018	16:30			129/78		86	18	98.5
	END OF WEEK 2		VLN mentholated	02OCT2018	16:22			133/86		80	18	98.1
	END OF WEEK 4		VLN mentholated	16OCT2018	8:06			122/71		66	16	98
	END OF WEEK 6		VLN mentholated	30OCT2018	16:32			147/68		90	14	97.8
	END OF STUDY		VLN mentholated	31OCT2018	20:57			122/77		67	20	98.4
1089	SCREENING		UB non-mentholated	04SEP2018	11:00			122/72		69	18	98.2
	START OF WEEK -1		UB non-mentholated	12SEP2018	9:23			111/69		63	16	97.5
	END OF WEEK -1		UB non-mentholated	17SEP2018	16:41			112/71		81	16	98.9
	END OF WEEK 2		UB non-mentholated	02OCT2018	16:43			107/68		78	16	98.6

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	----- Name						(mmHg) ----- Sys/Dia			
1089	END OF WEEK 4	UB non-mentholated	16OCT2018	8:14			120/74	64	18	98.3
	END OF WEEK 6	UB non-mentholated	30OCT2018	16:38			116/75	78	12	98.4
	END OF STUDY	UB non-mentholated	31OCT2018	21:05			115/71	58	18	98.2
1092	SCREENING	VLN mentholated	05SEP2018	9:12			150/109 NCS	77	16	98.1
	UNSCHEDULED	VLN mentholated	05SEP2018	9:14			139/102 NCS	83		
	UNSCHEDULED	VLN mentholated	05SEP2018	9:18			139/95	82		
	START OF WEEK -1	VLN mentholated	12SEP2018	7:54			141/101 NCS	79	16	98.8
	UNSCHEDULED	VLN mentholated	12SEP2018	7:56			140/99 NCS	79		
	UNSCHEDULED	VLN mentholated	12SEP2018	7:58			139/91	82		
	END OF WEEK -1	VLN mentholated	17SEP2018	16:37			145/92	108 NCS	18	98.9
	UNSCHEDULED	VLN mentholated	17SEP2018	16:48			148/95	93		
	END OF WEEK 2	VLN mentholated	02OCT2018	16:34			138/93	102 NCS	20	98.8
	UNSCHEDULED	VLN mentholated	02OCT2018	16:48			143/97 NCS	99		
	UNSCHEDULED	VLN mentholated	02OCT2018	16:58			140/95	98		
	END OF WEEK 4	VLN mentholated	16OCT2018	8:09			133/91	84	18	98.6
	END OF WEEK 6	VLN mentholated	30OCT2018	16:41			131/90	92	14	98.3
	END OF STUDY	VLN mentholated	31OCT2018	20:59			137/96 NCS	80	20	98.5
	UNSCHEDULED	VLN mentholated	31OCT2018	21:10			141/100 NCS	81		
1094	SCREENING	VLN mentholated	05SEP2018	9:57			143/96 NCS	83	18	98
	UNSCHEDULED	VLN mentholated	05SEP2018	10:00			143/97 NCS	85		
	UNSCHEDULED	VLN mentholated	05SEP2018	10:05			131/89	83		
	START OF WEEK -1	VLN mentholated	12SEP2018	7:50			127/84	68	16	98.3
	END OF WEEK -1	VLN mentholated	17SEP2018	16:34			124/77	116 NCS	18	98.8
	UNSCHEDULED	VLN mentholated	17SEP2018	16:44			125/80	111 NCS		
	UNSCHEDULED	VLN mentholated	17SEP2018	16:55			129/83	108 NCS		
	END OF WEEK 2	VLN mentholated	02OCT2018	16:27			127/83	91	16	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia			
1094	END OF WEEK 4	VLN mentholated	16OCT2018	8:03			137/87	69	18	98.5
	END OF WEEK 6	VLN mentholated	30OCT2018	16:30			110/81	79	12	98.3
	END OF STUDY	VLN mentholated	31OCT2018	20:55			126/77	66	18	98.4
1095	SCREENING	VLN mentholated	07SEP2018	8:42			133/86	66	16	98.5
	START OF WEEK -1	VLN mentholated	12SEP2018	8:01			116/77	73	16	98.2
	END OF WEEK -1	VLN mentholated	17SEP2018	17:57			145/91	62	14	98.4
	END OF WEEK 2	VLN mentholated	02OCT2018	16:46			132/77	81	10	98.7
	END OF WEEK 4	VLN mentholated	16OCT2018	8:26			126/81	79	16	98.4
	END OF WEEK 6	VLN mentholated	30OCT2018	17:05			133/79	60	12	97.9
	END OF STUDY	VLN mentholated	31OCT2018	21:03			153 NCS/83	57	18	98.2
1096	SCREENING	VLN non-mentholated	07SEP2018	8:32			108/75	85	16	98.8
	START OF WEEK -1	VLN non-mentholated	12SEP2018	8:13			123/82	79	16	98.1
	END OF WEEK -1	VLN non-mentholated	17SEP2018	16:35			114/78	99	16	98.5
	END OF WEEK 2	VLN non-mentholated	02OCT2018	16:40			105/72	97	16	98.4
	END OF WEEK 4	VLN non-mentholated	16OCT2018	8:23			112/79	87	16	98.8
	END OF WEEK 6	VLN non-mentholated	30OCT2018	16:47			108/71	90	10	98.2
	END OF STUDY	VLN non-mentholated	31OCT2018	21:12			116/83	80	16	98.3
1097	SCREENING	VLN mentholated	07SEP2018	9:36			124/83	72	16	97.7
	START OF WEEK -1	VLN mentholated	12SEP2018	9:42			111/74	72	22	97.8
	END OF WEEK -1	VLN mentholated	17SEP2018	16:32			113/69	70	20	98.7
	END OF WEEK 2	VLN mentholated	02OCT2018	16:37			100/63	77	18	97.6
	END OF WEEK 4	VLN mentholated	16OCT2018	8:11			102/67	73	14	97.8
	END OF WEEK 6	VLN mentholated	30OCT2018	16:36			116/70	69	12	97.7
	END OF STUDY	VLN mentholated	31OCT2018	21:01			101/62	56	18	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia			
1098	SCREENING	VLN non-mentholated	18SEP2018	10:35			126/83	58	16	97.7
	START OF WEEK -1	VLN non-mentholated	28SEP2018	7:54			120/79	57	10	97.7
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:28			106/67	73	16	98
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:32			124/81	60	16	97.7
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:04			130/77	58	14	98.2
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:45			125/81	60	16	98
	END OF STUDY	VLN non-mentholated	16NOV2018	20:57			131/75	57	16	98
1099	SCREENING	VLN non-mentholated	18SEP2018	10:38			112/77	71	14	98
	START OF WEEK -1	VLN non-mentholated	28SEP2018	8:14			110/73	89	12	98.6
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:25			114/76	85	14	98
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:52			115/77	82	18	98.2
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:22			111/76	80	14	98.1
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:34			121/81	82	20	98.1
	END OF STUDY	VLN non-mentholated	16NOV2018	21:14			115/77	72	18	97.9
1100	SCREENING	VLN non-mentholated	18SEP2018	11:18			134/87	62	14	98.3
	START OF WEEK -1	VLN non-mentholated	28SEP2018	7:56			133/88	72	12	98.2
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:43			132/86	77	14	98.5
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:36			137/88	78	14	98.5
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:06			129/85	69	12	98.1
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:43			149/98 NCS	85	18	97.9
	UNSCHEDULED	VLN non-mentholated	15NOV2018	16:53			155 NCS/94	83		
	END OF STUDY	VLN non-mentholated	16NOV2018	20:59			138/91	75	12	98.1
1101	SCREENING	VLN non-mentholated	18SEP2018	11:23			131/89	78	18	99.4
	START OF WEEK -1	VLN non-mentholated	28SEP2018	8:00			120/78	98	12	98.5
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:49			155 NCS/92	92	14	99.3

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name						Sys/Dia			
1101	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:40			152 NCS/94	89	16	98.8
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:10			135/88	82	18	98.5
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:40			168 NCS/95	91	20	98.2
	UNSCHEDULED	VLN non-mentholated	15NOV2018	16:50			160 NCS/90	93		
	UNSCHEDULED	VLN non-mentholated	15NOV2018	17:00			153 NCS/93	90		
	END OF STUDY	VLN non-mentholated	16NOV2018	21:02			126/84	76	16	98.2
1103	SCREENING	VLN non-mentholated	18SEP2018	11:14			119/79	59	14	97.9
	START OF WEEK -1	VLN non-mentholated	28SEP2018	7:58			117/74	60	10	97.9
	END OF WEEK -1	VLN non-mentholated	03OCT2018	17:03			130/73	79	12	98.5
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:38			130/80	65	14	98.2
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:08			108/72	65	10	98.4
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:42			122/78	60	16	98.1
	END OF STUDY	VLN non-mentholated	16NOV2018	21:01			126/78	55	12	98.5
1105	SCREENING	VLN non-mentholated	19SEP2018	10:41			103/67	70	16	97.5
	START OF WEEK -1	VLN non-mentholated	28SEP2018	8:12			106/75	72	8 NCS	98.1
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:41			105/73	84	14	98.1
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:49			102/69	73	18	97.8
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:20			110/74	65	14	97.9
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:32			102/66	74	16	97.9
	END OF STUDY	VLN non-mentholated	16NOV2018	21:12			105/73	67	12	98.1
1106	SCREENING	UB non-mentholated	19SEP2018	10:25			130/91	90	18	98.1
	START OF WEEK -1	UB non-mentholated	28SEP2018	7:52			130/84	87	10	98.3
	END OF WEEK -1	UB non-mentholated	03OCT2018	16:39			134/81	93	10	98.4
	END OF WEEK 2	UB non-mentholated	18OCT2018	16:34			126/77	97	16	98.1
	END OF WEEK 4	UB non-mentholated	01NOV2018	8:02			125/78	86	18	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
1106	END OF WEEK 6	UB non-mentholated	15NOV2018	16:46				137/92	85	20	97.8	
	END OF STUDY	UB non-mentholated	16NOV2018	20:55				130/82	92	14	98.5	
1107	SCREENING	VLN non-mentholated	21SEP2018	10:07				139/90	75	14	97.8	
	START OF WEEK -1	VLN non-mentholated	28SEP2018	8:06				142/90	71	10	98.2	
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:45				120/83	78	12	98.2	
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:44				139/88	76	16	98.2	
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:14				141/88	73	14	98.1	
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:37				134/87	75	18	97.7	
	END OF STUDY	VLN non-mentholated	16NOV2018	21:06				138/88	73	16	97.9	
1108	SCREENING	UB non-mentholated	21SEP2018	10:09				144/87	60	16	98	
	START OF WEEK -1	UB non-mentholated	28SEP2018	8:02				121/81	73	16	97.9	
	END OF WEEK -1	UB non-mentholated	03OCT2018	16:46				135/83	73	12	98.3	
	END OF WEEK 2	UB non-mentholated	18OCT2018	16:42				112/74	92	16	98.1	
	END OF WEEK 4	UB non-mentholated	01NOV2018	8:12				116/76	80	14	98.2	
	END OF WEEK 6	UB non-mentholated	15NOV2018	16:39				123/81	93	20	98.1	
	END OF STUDY	UB non-mentholated	16NOV2018	21:04				128/85	67	10	98.4	
1109	SCREENING	UB non-mentholated	21SEP2018	10:36				143/90	71	14	99	
	START OF WEEK -1	UB non-mentholated	28SEP2018	8:08				120/78	63	10	98	
	END OF WEEK -1	UB non-mentholated	03OCT2018	16:30				102/68	76	12	98.8	
	END OF WEEK 2	UB non-mentholated	18OCT2018	16:46				129/84	63	14	98.9	
	END OF WEEK 4	UB non-mentholated	01NOV2018	8:16				111/70	64	16	98.1	
	END OF WEEK 6	UB non-mentholated	15NOV2018	16:36				132/79	77	16	98.3	
	END OF STUDY	UB non-mentholated	16NOV2018	21:09				123/84	60	14	98.4	
1112	SCREENING	VLN non-mentholated	21SEP2018	10:34				108/74	67	14	98	

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
1112	START OF WEEK -1	VLN non-mentholated	28SEP2018	8:17			103/64	69	10	98.2
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:27			104/68	71	14	98.5
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:54			111/66	71	20	98.9
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:24			125/76	72	12	98.3
	END OF WEEK 6	VLN non-mentholated	15NOV2018	16:35			102/67	76	18	98.6
	END OF STUDY	VLN non-mentholated	16NOV2018	21:16			117/73	65	10	98.5
1114	SCREENING	UB non-mentholated	24SEP2018	9:57			110/78	86	12	98.2
	START OF WEEK -1	UB non-mentholated	28SEP2018	8:10			116/83	88	10	98.2
	END OF WEEK -1	UB non-mentholated	03OCT2018	16:35			113/82	120 NCS	12	98.2
	UNSCHEDULED	UB non-mentholated	03OCT2018	17:06			118/82	103 NCS		
	UNSCHEDULED	UB non-mentholated	03OCT2018	17:15			115/82	103 NCS		
	UNSCHEDULED	UB non-mentholated	04OCT2018	7:20			122/78	91	14	97.9
	END OF WEEK 2	UB non-mentholated	18OCT2018	16:48			112/81	99	16	98.1
	END OF WEEK 4	UB non-mentholated	01NOV2018	8:18			108/75	87	12	98.4
	END OF WEEK 6	UB non-mentholated	15NOV2018	16:30			120/88	98	18	98.5
	END OF STUDY	UB non-mentholated	16NOV2018	21:10			115/82	82	10	98.5
1115	SCREENING	VLN non-mentholated	24SEP2018	9:52			124/86	87	14	98.6
	START OF WEEK -1	VLN non-mentholated	28SEP2018	7:50			126/84	79	14	98.3
	END OF WEEK -1	VLN non-mentholated	03OCT2018	16:32			127/86	99	12	98
	END OF WEEK 2	VLN non-mentholated	18OCT2018	16:30			130/79	83	14	98.1
	END OF WEEK 4	VLN non-mentholated	01NOV2018	8:00			129/83	82	12	98
	END OF STUDY	VLN non-mentholated	14NOV2018		NOT DONE	SUBJECT DROPPED FROM STUDY	/			
2002	SCREENING	UB mentholated	29JUN2018	9:35			134/82	57	16	98.4

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
2002	START OF WEEK -1	UB mentholated	18JUL2018	10:25				130/74	92	16	98.2	
	END OF WEEK -1	UB mentholated	23JUL2018	13:55				140/74	90	16	98.4	
	END OF WEEK 2	UB mentholated	07AUG2018	14:28				130/76	84	16	98.8	
	END OF WEEK 4	UB mentholated	21AUG2018	12:52				117/77	87	12	98.1	
	END OF WEEK 6	UB mentholated	04SEP2018	13:35				135/75	71	12	98.5	
	END OF STUDY	UB mentholated	05SEP2018	7:25				114/74	54	17	98.2	
2003	SCREENING	VLN mentholated	29JUN2018	9:54				94/61	64	16	98.1	
	START OF WEEK -1	VLN mentholated	11JUL2018	8:35				99/63	67	16	98.4	
	END OF WEEK -1	VLN mentholated	16JUL2018	13:54				118/71	80	16	98.5	
	END OF WEEK 2	VLN mentholated	31JUL2018	14:24				102/66	65	16	98	
	END OF WEEK 4	VLN mentholated	14AUG2018	13:41				106/69	63	14	98.4	
	END OF WEEK 6	VLN mentholated	28AUG2018	13:29				117/69	80	16	98.1	
	END OF STUDY	VLN mentholated	29AUG2018	7:00				99/66	55	18	98.2	
2007	SCREENING	VLN non-mentholated	29JUN2018	11:47				103/67	66	16	97.7	
	START OF WEEK -1	VLN non-mentholated	11JUL2018	8:46				103/69	71	16	98.1	
	END OF WEEK -1	VLN non-mentholated	16JUL2018	13:59				103/69	66	14	98	
	END OF WEEK 2	VLN non-mentholated	31JUL2018	14:37				97/63	68	16	98.3	
	END OF WEEK 4	VLN non-mentholated	14AUG2018	10:05				94/62	62	17	98	
	END OF WEEK 6	VLN non-mentholated	28AUG2018	13:30				90/56	68	14	98.7	
	END OF STUDY	VLN non-mentholated	29AUG2018	7:07				88 NCS/60	72	20	97.5	
	UNSCHEDULED	VLN non-mentholated	29AUG2018	7:15				91/64	71	20		
2008	SCREENING	VLN mentholated	06JUL2018	9:44				126/83	71	16	98.1	
	START OF WEEK -1	VLN mentholated	11JUL2018	11:12				113/75	87	14	99.5	
	END OF WEEK -1	VLN mentholated	16JUL2018	7:36				115/74	70	18	98.5	
	END OF WEEK 2	VLN mentholated	31JUL2018	14:40				112/72	66	14	98.1	

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						Sys/Dia	-----			
2008	END OF WEEK 4		VLN mentholated	14AUG2018	10:10			102/69		66	16	98.3
	END OF WEEK 6		VLN mentholated	28AUG2018	13:49			108/67		80	18	98.6
	END OF STUDY		VLN mentholated	29AUG2018	7:03			102/66		62	16	98.4
2009	SCREENING		VLN non-mentholated	29JUN2018	12:03			104/70		67	16	97.9
	START OF WEEK -1		VLN non-mentholated	11JUL2018	8:48			105/71		73	12	98.1
	END OF WEEK -1		VLN non-mentholated	16JUL2018	14:04			100/58		80	16	98.4
	END OF WEEK 2		VLN non-mentholated	31JUL2018	14:11			97/62		76	16	98.3
	END OF WEEK 4		VLN non-mentholated	14AUG2018	8:34			98/63		74	19	98.7
	END OF STUDY		VLN non-mentholated	14AUG2018		NOT DONE	SUBJECT REFUSED EARLY TERM PROCEDURES	/				
2010	SCREENING		UB mentholated	29JUN2018	12:06			111/79		67	16	98.8
	START OF WEEK -1		UB mentholated	11JUL2018	8:52			108/74		75	16	98
	END OF WEEK -1		UB mentholated	16JUL2018	14:09			101/66		92	18	98.5
	END OF WEEK 2		UB mentholated	31JUL2018	14:34			99/65		80	16	98.1
	END OF WEEK 4		UB mentholated	14AUG2018	9:16			113/77		81	16	98.5
	END OF WEEK 6		UB mentholated	28AUG2018	13:34			123/77		90	16	98.4
	END OF STUDY		UB mentholated	29AUG2018	7:36			110/77		66	17	98.4
2011	SCREENING		VLN mentholated	29JUN2018	12:13			120/84		80	14	98.2
	START OF WEEK -1		VLN mentholated	11JUL2018	8:32			120/80		89	16	98.4
	END OF WEEK -1		VLN mentholated	16JUL2018	14:12			103/71		89	14	98.6
	END OF WEEK 2		VLN mentholated	31JUL2018	14:46			113/77		71	16	98.7
	END OF WEEK 4		VLN mentholated	14AUG2018	9:05			128/85		79	17	98.5
	END OF WEEK 6		VLN mentholated	28AUG2018	13:36			112/76		81	12	98.7

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name						----- Sys/Dia			
2011	END OF STUDY	VLN mentholated	29AUG2018	7:10			113/78	74	18	98.1
2014	SCREENING	VLN mentholated	02JUL2018	9:48			109/75	67	18	98.4
	START OF WEEK -1	VLN mentholated	11JUL2018	10:25			108/71	78	14	98.8
	END OF WEEK -1	VLN mentholated	16JUL2018	14:20			118/72	81	16	98.6
	END OF WEEK 2	VLN mentholated	31JUL2018	14:49			111/71	65	18	98.4
	END OF WEEK 4	VLN mentholated	14AUG2018	9:57			106/70	85	16	98.6
	END OF WEEK 6	VLN mentholated	28AUG2018	13:42			109/69	80	16	99.3
	END OF STUDY	VLN mentholated	29AUG2018	7:21			103/69	65	12	99.2
2015	SCREENING	UB mentholated	02JUL2018	10:25			136/89	69	18	97.5
	START OF WEEK -1	UB mentholated	11JUL2018	10:22			122/80	80	16	98.2
	END OF WEEK -1	UB mentholated	16JUL2018	14:26			124/84	67	18	98.1
	UNSCHEDULED	UB mentholated	17JUL2018	13:26			65 CS/33 CS	112 CS	16	97.4
	UNSCHEDULED	UB mentholated	17JUL2018	13:36			110/72	75	16	
	UNSCHEDULED	UB mentholated	17JUL2018	13:42			127/86	84	16	
	UNSCHEDULED	UB mentholated	17JUL2018	13:45			132/92	93	14	
	END OF WEEK 2	UB mentholated	31JUL2018	14:54			114/78	76	16	97.9
	END OF WEEK 4	UB mentholated	14AUG2018	10:06			132/88	73	16	97.9
	END OF WEEK 6	UB mentholated	28AUG2018	13:46			108/72	91	16	98
END OF STUDY	UB mentholated	29AUG2018	7:12			123/80	68	20	98.2	
2016	SCREENING	VLN mentholated	02JUL2018	10:05			130/77	59	16	97.9
	START OF WEEK -1	VLN mentholated	11JUL2018	10:15			146/78	78	14	98.2
	END OF WEEK -1	VLN mentholated	16JUL2018	14:28			116/75	85	14	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
2016	END OF WEEK 2	VLN mentholated	31JUL2018		NOT DONE	SUBJECT WAS DISCONTINUED PRIOR TO THIS ASSESSMENT	/			
	END OF STUDY	VLN mentholated	03AUG2018	8:57			132/80	71	16	98.2
2017	SCREENING	VLN mentholated	02JUL2018	10:08			118/73	65	16	98.1
	START OF WEEK -1	VLN mentholated	11JUL2018	10:35			120/68	70	12	98
	END OF WEEK -1	VLN mentholated	16JUL2018	14:43			122/84	76	16	98.4
	END OF WEEK 2	VLN mentholated	31JUL2018	14:56			114/67	77	16	98
	END OF WEEK 4	VLN mentholated	14AUG2018	10:53			135/84	91	19	97.3
	END OF WEEK 6	VLN mentholated	28AUG2018	13:48			117/85	73	14	98.1
	END OF STUDY	VLN mentholated	29AUG2018	7:11			117/74	55	17	98
2018	SCREENING	UB mentholated	02JUL2018	11:08			106/74	81	18	97.9
	START OF WEEK -1	UB mentholated	11JUL2018	10:10			104/71	85	12	98.5
	END OF WEEK -1	UB mentholated	16JUL2018	14:32			102/69	82	16	98.2
	END OF WEEK 2	UB mentholated	31JUL2018	15:02			100/69	74	12	98.6
	END OF WEEK 4	UB mentholated	14AUG2018	9:12			118/83	101 NCS	16	98
	UNSCHEDULED	UB mentholated	14AUG2018	9:25			103/71	91	16	97.9
	END OF WEEK 6	UB mentholated	28AUG2018	14:10			99/64	94	18	98.1
	END OF STUDY	UB mentholated	29AUG2018	7:24			95/64	85	16	98.1
2020	SCREENING	VLN mentholated	02JUL2018	11:11			131/81	71	18	97.7
	START OF WEEK -1	VLN mentholated	11JUL2018	10:52			129/79	74	12	97.8
	END OF WEEK -1	VLN mentholated	16JUL2018	14:38			130/75	77	16	98.8
	END OF WEEK 2	VLN mentholated	31JUL2018	15:03			113/76	76	16	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia			
2020	END OF WEEK 4	VLN mentholated	14AUG2018	10:23			143/77	76	18	98.3
	END OF WEEK 6	VLN mentholated	28AUG2018	13:50			114/71	90	12	99.4
	END OF STUDY	VLN mentholated	29AUG2018	7:26			112/67	67	16	98.4
2021	SCREENING	VLN mentholated	02JUL2018	11:37			122/78	61	16	98.2
	START OF WEEK -1	VLN mentholated	11JUL2018	10:28			146/78	78	16	98.2
	END OF WEEK -1	VLN mentholated	16JUL2018	14:46			110/71	85	16	98.7
	END OF WEEK 2	VLN mentholated	31JUL2018	15:01			113/69	57	16	98.1
	END OF WEEK 4	VLN mentholated	14AUG2018	10:08			129/81	62	18	98
	END OF WEEK 6	VLN mentholated	28AUG2018	13:55			108/73	60	16	98.1
	END OF STUDY	VLN mentholated	29AUG2018	7:19			107/73	52	18	98.4
2023	SCREENING	VLN mentholated	02JUL2018	11:55			113/77	65	18	98.1
	START OF WEEK -1	VLN mentholated	11JUL2018	10:38			129/82	72	16	98
	END OF WEEK -1	VLN mentholated	16JUL2018	14:49			104/71	80	16	97.1
	END OF WEEK 2	VLN mentholated	31JUL2018	14:59			104/72	67	14	98.4
	END OF WEEK 4	VLN mentholated	14AUG2018	10:14			112/78	75	18	97.8
	END OF WEEK 6	VLN mentholated	28AUG2018	13:56			104/68	94	16	98.5
	END OF STUDY	VLN mentholated	29AUG2018	7:21			103/72	65	18	98.3
2024	SCREENING	UB non-mentholated	03JUL2018	10:09			129/78	71	18	98.2
	START OF WEEK -1	UB non-mentholated	11JUL2018	10:54			127/75	71	12	98.2
	END OF WEEK -1	UB non-mentholated	16JUL2018	14:59			102/65	62	14	98.2
2025	SCREENING	UB non-mentholated	03JUL2018	10:14			110/71	64	16	98.1
	START OF WEEK -1	UB non-mentholated	11JUL2018	10:49			106/67	71	14	98.3
	END OF WEEK -1	UB non-mentholated	16JUL2018	14:53			116/73	61	16	98.8
	END OF WEEK 2	UB non-mentholated	31JUL2018	14:47			119/76	76	16	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	Name						-----	Sys/Dia			
2025	UNSCHEDULED		UB non-mentholated	01AUG2018	10:40			/				97.7
	END OF WEEK 4		UB non-mentholated	14AUG2018	8:28			118/79	73	17		98.1
	END OF WEEK 6		UB non-mentholated	28AUG2018	13:39			113/74	67	14		98.4
	END OF STUDY		UB non-mentholated	29AUG2018	7:33			118/74	64	16		97.5
2028	SCREENING		VLN non-mentholated	06JUL2018	11:34			101/64	52	16		98.1
	START OF WEEK -1		VLN non-mentholated	11JUL2018	10:46			105/73	79	16		98.7
	END OF WEEK -1		VLN non-mentholated	16JUL2018	15:03			115/76	69	16		98.1
	END OF WEEK 2		VLN non-mentholated	31JUL2018	14:34			109/65	50	16		98.2
	END OF WEEK 4		VLN non-mentholated	14AUG2018	10:45			115/70	58	16		98.4
	END OF WEEK 6		VLN non-mentholated	28AUG2018	14:07			119/75	79	16		98.7
	END OF STUDY		VLN non-mentholated	29AUG2018	7:38			98/62	68	18		98.2
2029	SCREENING		UB mentholated	09JUL2018	10:46			131/82	65	16		97.6
	START OF WEEK -1		UB mentholated	18JUL2018	10:34			120/81	73	16		98.7
	END OF WEEK -1		UB mentholated	23JUL2018	14:03			124/81	66	14		99
	END OF WEEK 2		UB mentholated	07AUG2018	14:28			126/80	68	16		97.8
	UNSCHEDULED		UB mentholated	08AUG2018	13:39			109/71	83	16		98.6
	END OF WEEK 4		UB mentholated	21AUG2018	8:42			132/92	79	16		98
	END OF WEEK 6		UB mentholated	04SEP2018	13:38			118/79	79	14		98.3
	END OF STUDY		UB mentholated	05SEP2018	7:26			115/79	70	14		98.2
2039	SCREENING		VLN mentholated	13JUL2018	9:58			108/73	68	12		98.3
	START OF WEEK -1		VLN mentholated	18JUL2018	11:30			106/72	71	14		98.3
	END OF WEEK -1		VLN mentholated	23JUL2018	14:15			101/66	78	16		98.5
	END OF WEEK 2		VLN mentholated	07AUG2018	14:27			95/63	61	14		98
	END OF WEEK 4		VLN mentholated	21AUG2018	8:43			94/59	76	12		98.8
	END OF WEEK 6		VLN mentholated	04SEP2018	14:02			94/62	77	16		98.8

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia			
2039	END OF STUDY		VLN mentholated	05SEP2018	7:27			91/61	64	17	97.8
2050	SCREENING		UB mentholated	20JUL2018	10:27			110/71	52	16	97.5
	START OF WEEK -1		UB mentholated	02AUG2018	10:27			120/75	68	16	97.9
	END OF WEEK -1		UB mentholated	07AUG2018	13:47			104/66	77	16	98
	END OF WEEK 2		UB mentholated	22AUG2018	13:55			117/67	60	14	98.4
	END OF WEEK 4		UB mentholated	05SEP2018	8:30			122/71	67	14	98
	END OF WEEK 6		UB mentholated	19SEP2018	13:45			113/64	81	14	98.1
	END OF STUDY		UB mentholated	20SEP2018	7:33			123/78	67	14	98.4
2052	SCREENING		VLN mentholated	20JUL2018	10:49			139/83	70	14	98.5
	START OF WEEK -1		VLN mentholated	02AUG2018	10:37			125/83	91	16	98.3
	END OF WEEK -1		VLN mentholated	07AUG2018	14:20			122/77	84	14	98.7
	END OF WEEK 2		VLN mentholated	22AUG2018	14:13			129/82	98	16	98.5
	END OF WEEK 4		VLN mentholated	05SEP2018	8:42			145/88	75	16	98
	END OF WEEK 6		VLN mentholated	19SEP2018	13:54			131/78	88	16	99.1
	END OF STUDY		VLN mentholated	20SEP2018	7:35			122/81	64	15	97.8
2057	SCREENING		VLN mentholated	23JUL2018	9:39			118/77	59	18	97.5
	START OF WEEK -1		VLN mentholated	02AUG2018	10:09			114/71	73	16	98.2
	END OF WEEK -1		VLN mentholated	07AUG2018	14:00			120/79	80	14	98.3
	END OF WEEK 2		VLN mentholated	22AUG2018	14:04			106/68	69	16	98.4
	END OF WEEK 4		VLN mentholated	05SEP2018	8:48			122/75	70	16	98.8
	END OF WEEK 6		VLN mentholated	19SEP2018	13:55			108/70	69	16	98.6
	END OF STUDY		VLN mentholated	20SEP2018	7:37			109/72	67	16	98.4
2058	SCREENING		VLN mentholated	23JUL2018	9:58			93/64	66	17	98.4
	START OF WEEK -1		VLN mentholated	02AUG2018	10:21			94/61	88	16	98.7

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name						-----			
2058	END OF WEEK -1	VLN mentholated	07AUG2018	14:01			97/66	76	12	98.6
	END OF WEEK 2	VLN mentholated	22AUG2018	14:07			101/65	75	18	98.1
	END OF WEEK 4	VLN mentholated	05SEP2018	9:48			101/59	74	16	98.9
	END OF WEEK 6	VLN mentholated	19SEP2018	13:59			94/65	73	14	98.4
	END OF STUDY	VLN mentholated	20SEP2018	7:54			95/64	65	12	98.9
2059	SCREENING	UB mentholated	23JUL2018	10:09			126/80	59	19	98.4
	START OF WEEK -1	UB mentholated	02AUG2018	9:35			103/69	58	12	98.1
	END OF WEEK -1	UB mentholated	07AUG2018	14:02			90/62	56	14	98.7
	END OF WEEK 2	UB mentholated	22AUG2018	14:25			107/68	61	16	98.6
	END OF WEEK 4	UB mentholated	05SEP2018	9:48			95/60	64	16	97.5
	END OF WEEK 6	UB mentholated	19SEP2018	14:16			103/68	60	14	98.4
	END OF STUDY	UB mentholated	20SEP2018	7:43			94/61	56	15	98.3
2060	SCREENING	VLN mentholated	23JUL2018	10:18			121/81	62	18	98.1
	START OF WEEK -1	VLN mentholated	02AUG2018	11:35			126/78	82	16	98.1
	END OF WEEK -1	VLN mentholated	07AUG2018	14:07			114/73	73	14	98.4
	END OF WEEK 2	VLN mentholated	22AUG2018	13:58			114/73	73	16	98.4
	END OF WEEK 4	VLN mentholated	05SEP2018	16:22			134/86	71	16	98.9
	END OF WEEK 6	VLN mentholated	19SEP2018	14:14			116/72	78	16	98.3
	END OF STUDY	VLN mentholated	20SEP2018	7:54			120/81	63	16	97.9
2064	SCREENING	VLN mentholated	23JUL2018	10:47			125/86	71	16	97.8
	START OF WEEK -1	VLN mentholated	02AUG2018	11:36			112/77	74	14	98.4
	END OF WEEK -1	VLN mentholated	07AUG2018	14:14			101/62	80	16	98.7
	END OF WEEK 2	VLN mentholated	22AUG2018	13:53			116/73	82	16	98.7
	END OF WEEK 4	VLN mentholated	05SEP2018	9:15			113/77	77	16	98.4
	END OF WEEK 6	VLN mentholated	19SEP2018	14:07			116/71	76	16	98.2

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	Name						-----	Sys/Dia			
2064	END OF STUDY		VLN mentholated	20SEP2018	7:29				116/79	69	14	97.5
2066	SCREENING		VLN mentholated	23JUL2018	11:12				125/87	68	19	97.5
	START OF WEEK -1		VLN mentholated	02AUG2018	11:35				119/86	93	14	98.1
	END OF WEEK -1		VLN mentholated	07AUG2018	14:35				114/77	90	16	98.6
	END OF WEEK 2		VLN mentholated	22AUG2018	13:50				129/89	83	16	98.3
	END OF WEEK 4		VLN mentholated	05SEP2018	10:08				111/75	70	16	98
	END OF WEEK 6		VLN mentholated	19SEP2018	14:11				124/84	69	14	98.6
	END OF STUDY		VLN mentholated	20SEP2018	7:51				124/78	69	14	98.2
2067	SCREENING		VLN non-mentholated	23JUL2018	11:57				129/83	62	18	97.5
	START OF WEEK -1		VLN non-mentholated	02AUG2018	10:36				144/89	64	16	98.2
	END OF WEEK -1		VLN non-mentholated	07AUG2018	14:16				137/76	66	18	98.7
	END OF WEEK 2		VLN non-mentholated	22AUG2018	14:12				119/74	73	18	98.1
	END OF WEEK 4		VLN non-mentholated	05SEP2018	10:01				127/82	59	18	98.6
	END OF WEEK 6		VLN non-mentholated	19SEP2018	14:03				129/82	71	16	98
	END OF STUDY		VLN non-mentholated	20SEP2018	7:44				116/77	63	14	99.1
2075	SCREENING		VLN mentholated	30JUL2018	10:32				130/80	78	18	98.1
	START OF WEEK -1		VLN mentholated	02AUG2018	10:23				120/76	80	16	99
	END OF WEEK -1		VLN mentholated	07AUG2018	14:17				120/89	101 NCS	16	98.4
	UNSCHEDULED		VLN mentholated	07AUG2018	14:24				126/78	101 NCS		
	UNSCHEDULED		VLN mentholated	07AUG2018	17:00				136/75	108 NCS		
	END OF WEEK 2		VLN mentholated	22AUG2018	14:10				121/71	98	16	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
2075	END OF STUDY		VLN mentholated	22AUG2018		NOT DONE	SUBJECT DIS ON DAY 14 PLEASE USE DAY 14 VITALS	/				
2076	SCREENING		VLN mentholated	30JUL2018	10:38			118/78		64	17	98.1
	START OF WEEK -1		VLN mentholated	26AUG2018	8:21			123/82		56	18	98.7
	END OF WEEK -1		VLN mentholated	31AUG2018	13:50			113/66		51	18	98.7
	END OF WEEK 2		VLN mentholated	15SEP2018	14:08			120/77	NCS	44	20	98.1
	END OF WEEK 4		VLN mentholated	29SEP2018	8:28			121/80		66	14	97.7
	END OF WEEK 6		VLN mentholated	13OCT2018	13:25			130/86		60	16	98.3
	END OF STUDY		VLN mentholated	14OCT2018	7:32			120/80		59	14	98.1
2086	SCREENING		VLN non-mentholated	03AUG2018	11:31			115/73		52	14	97.5
	START OF WEEK -1		VLN non-mentholated	26AUG2018	11:26			111/75		73	16	97.7
	END OF WEEK -1		VLN non-mentholated	31AUG2018	15:04			102/69		65	16	98.3
	END OF WEEK 2		VLN non-mentholated	15SEP2018	14:18			117/78		55	18	97.4
	END OF WEEK 4		VLN non-mentholated	29SEP2018	10:27			121/79		67	16	98.7
	END OF STUDY		VLN non-mentholated	29SEP2018	11:05			128/79		55	16	97.4
2088	SCREENING		VLN mentholated	03AUG2018	11:49			122/87		64	16	97.8
	START OF WEEK -1		VLN mentholated	26AUG2018	10:01			148/102	NCS	81	18	97.8
	UNSCHEDULED		VLN mentholated	26AUG2018	10:07			133/92		77	16	
	END OF WEEK -1		VLN mentholated	31AUG2018	15:55			114/79		82	16	98.2
	END OF WEEK 2		VLN mentholated	15SEP2018	13:50			120/83		67	16	98.8
	END OF WEEK 4		VLN mentholated	29SEP2018	9:27			121/81		80	14	98.8
	END OF WEEK 6		VLN mentholated	13OCT2018	13:48			125/83		71	16	99.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
2088	END OF STUDY		VLN mentholated	14OCT2018	7:31			138/93		58	18	99.1
2092	SCREENING		VLN mentholated	06AUG2018	10:02			123/84		72	14	98
	START OF WEEK -1		VLN mentholated	26AUG2018	9:17			124/83		76	18	98.2
	END OF WEEK -1		VLN mentholated	31AUG2018	13:48			128/88		89	17	98.3
	END OF WEEK 2		VLN mentholated	15SEP2018	13:49			135/85		83	20	98.2
	END OF WEEK 4		VLN mentholated	29SEP2018	8:17			121/78	101 NCS	101	14	98.1
	UNSCHEDULED		VLN mentholated	29SEP2018	8:31			119/80		93		
	END OF WEEK 6		VLN mentholated	13OCT2018	13:30			136/84		97	14	98.9
	END OF STUDY		VLN mentholated	14OCT2018	7:34			106/73		73	14	98.2
2099	SCREENING		VLN non-mentholated	09AUG2018	9:55			139/94		71	16	98
	START OF WEEK -1		VLN non-mentholated	26AUG2018	9:45			144/84		77	16	97.9
	END OF WEEK -1		VLN non-mentholated	31AUG2018	13:55			138/84		82	18	98.4
	END OF WEEK 2		VLN non-mentholated	15SEP2018	13:43			132/83		75	16	98.3
	END OF WEEK 4		VLN non-mentholated	29SEP2018	9:34			143/84		79	18	97.7
	END OF WEEK 6		VLN non-mentholated	13OCT2018	13:28			146/93		81	16	98.1
	END OF STUDY		VLN non-mentholated	14OCT2018	7:35			138/93		75	14	98.4
2100	SCREENING		UB mentholated	09AUG2018	10:25			141/90		67	14	98.3
	START OF WEEK -1		UB mentholated	26AUG2018	9:43			141/94		88	16	98.4
	END OF WEEK -1		UB mentholated	31AUG2018	13:56			123/84		75	14	98.4
	END OF WEEK 2		UB mentholated	15SEP2018	14:14			134/88		78	20	98.2
	END OF WEEK 4		UB mentholated	29SEP2018	8:31			123/85		84	16	98.8
	END OF WEEK 6		UB mentholated	13OCT2018	13:39			120/85		83	16	98
	END OF STUDY		UB mentholated	14OCT2018	7:35			133/87		75	16	98
2108	SCREENING		VLN non-mentholated	13AUG2018	9:53			139/90		65	18	97.9

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
	-----	-----						-----			
	Name							Sys/Dia			
2108	START OF WEEK -1	VLN non-mentholated	26AUG2018	8:40				131/79	65	16	99
	END OF WEEK -1	VLN non-mentholated	31AUG2018	14:00				107/73	78	14	98.5
	END OF WEEK 2	VLN non-mentholated	15SEP2018	14:06				99/65	68	18	98.1
	END OF WEEK 4	VLN non-mentholated	29SEP2018	9:35				112/74	80	16	98.3
	END OF WEEK 6	VLN non-mentholated	13OCT2018	13:37				113/74	76	16	99
	END OF STUDY	VLN non-mentholated	14OCT2018	7:31				116/76	58	16	98
2110	SCREENING	UB mentholated	13AUG2018	10:09				114/78	84	19	97.9
	START OF WEEK -1	UB mentholated	01SEP2018	9:27				112/77	80	16	98.4
	END OF WEEK -1	UB mentholated	06SEP2018	13:56				114/78	80	12	98.6
	END OF WEEK 2	UB mentholated	21SEP2018	13:44				116/80	80	12	98.6
	END OF WEEK 4	UB mentholated	05OCT2018	8:29				121/78	90	12	98.2
	END OF WEEK 6	UB mentholated	19OCT2018	14:00				122/81	87	14	98.5
	END OF STUDY	UB mentholated	20OCT2018	7:54				108/75	75	18	98.2
2113	SCREENING	VLN mentholated	15AUG2018	10:32				121/82	69	16	99.3
	START OF WEEK -1	VLN mentholated	01SEP2018	9:27				120/83	72	14	99.2
	END OF WEEK -1	VLN mentholated	06SEP2018	13:57				115/77	65	14	98.1
	END OF WEEK 2	VLN mentholated	21SEP2018	14:18				96/71	72	12	99.3
2115	SCREENING	VLN mentholated	15AUG2018	11:01				123/80	65	16	98.2
	START OF WEEK -1	VLN mentholated	01SEP2018	10:21				113/78	74	17	98.2
	END OF WEEK -1	VLN mentholated	06SEP2018	14:00				115/81	72	16	98
	END OF WEEK 2	VLN mentholated	21SEP2018	14:32				119/82	74	12	98.4
2119	SCREENING	VLN mentholated	20AUG2018	10:01				125/87	83	17	98.6
	START OF WEEK -1	VLN mentholated	01SEP2018	9:43				135/87	84	18	98.1
	END OF WEEK -1	VLN mentholated	06SEP2018	14:01				124/83	90	14	98.5

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
2119	END OF WEEK 2		VLN mentholated	21SEP2018	14:32			154 NCS/100 NCS		101 NCS	16	98.4
	UNSCHEDULED		VLN mentholated	21SEP2018	14:42			146/94		94		
	END OF WEEK 4		VLN mentholated	05OCT2018	8:21			136/91		91	14	98.4
	END OF WEEK 6		VLN mentholated	19OCT2018	14:06			127/84		81	16	98.5
	END OF STUDY		VLN mentholated	20OCT2018	7:49			134/90		81	17	98.3
2120	SCREENING		VLN non-mentholated	20AUG2018	10:10			143/79		51	16	97.4
	START OF WEEK -1		VLN non-mentholated	01SEP2018	9:44			108/73		60	14	97.8
	END OF WEEK -1		VLN non-mentholated	06SEP2018	14:10			106/68		58	12	98.1
	END OF WEEK 2		VLN non-mentholated	21SEP2018	13:48			118/74		62	14	98
	END OF WEEK 4		VLN non-mentholated	05OCT2018	8:56			156/80		57	14	98.3
	UNSCHEDULED		VLN non-mentholated	05OCT2018	9:15			160 NCS/92 NCS		54	14	97.7
	END OF WEEK 6		VLN non-mentholated	19OCT2018	14:12			103/63		57	14	97.8
	END OF STUDY		VLN non-mentholated	20OCT2018	7:57			113/73		66	16	97.5
2122	SCREENING		UB non-mentholated	20AUG2018	11:09			162 NCS/90		65	14	97.9
	UNSCHEDULED		UB non-mentholated	20AUG2018	11:20			150/90		64	14	
	START OF WEEK -1		UB non-mentholated	01SEP2018	9:30			148/82		83	16	98.1
	END OF WEEK -1		UB non-mentholated	06SEP2018	14:09			146/81		81	14	98.4
	END OF WEEK 2		UB non-mentholated	21SEP2018	13:49			149/73		80	16	99.4
	END OF WEEK 4		UB non-mentholated	05OCT2018	9:43			128/83		75	16	98.3
	END OF WEEK 6		UB non-mentholated	19OCT2018	14:18			149/82		80	16	98.7
	END OF STUDY		UB non-mentholated	20OCT2018	7:54			133/76		68	17	98.1
2125	SCREENING		UB mentholated	21AUG2018	10:44			108/73		47 NCS	12	98.2
	START OF WEEK -1		UB mentholated	01SEP2018	9:54			117/74		51	12	98.6
	END OF WEEK -1		UB mentholated	06SEP2018	14:09			143/78		49 NCS	16	98.5
	END OF WEEK 2		UB mentholated	21SEP2018	13:55			134/69		80	12	98.6

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg) Sys/Dia	Pulse (bpm)	Respiration (rpm)	Temperature (°F)
2125	END OF WEEK 4	UB mentholated	05OCT2018	8:02			119/80	55	14	98.5
	END OF WEEK 6	UB mentholated	19OCT2018	14:42			123/71	71	16	99.4
	END OF STUDY	UB mentholated	20OCT2018	7:48			122/75	50	17	98
2126	SCREENING	VLN mentholated	21AUG2018	10:54			153 NCS/99 NCS	99	14	98.4
	UNSCHEDULED	VLN mentholated	21AUG2018	11:06			135/91	72		
	START OF WEEK -1	VLN mentholated	01SEP2018	9:50			127/91	71	12	98
	END OF WEEK -1	VLN mentholated	06SEP2018	14:13			136/88	78	16	98.3
	END OF WEEK 2	VLN mentholated	21SEP2018	13:47			135/89	69	16	98.2
	END OF WEEK 4	VLN mentholated	06OCT2018	10:48			129/89	84	18	98.1
	END OF WEEK 6	VLN mentholated	19OCT2018	14:30			135/89	61	16	98.3
	END OF STUDY	VLN mentholated	20OCT2018	7:52			134/84	69	16	98.1
2136	SCREENING	VLN non-mentholated	27AUG2018	10:32			137/88	69	20	98.8
	START OF WEEK -1	VLN non-mentholated	01SEP2018	9:31			161 NCS/93	76	16	98.2
	UNSCHEDULED	VLN non-mentholated	01SEP2018	11:34			163 NCS/94	69		
	END OF WEEK -1	VLN non-mentholated	06SEP2018	14:22			126/85	86	16	98.3
	END OF WEEK 2	VLN non-mentholated	21SEP2018	13:52			136/90	103 NCS	18	98.5
	UNSCHEDULED	VLN non-mentholated	21SEP2018	14:02			127/85	103 NCS		
	UNSCHEDULED	VLN non-mentholated	21SEP2018	20:00			109/71	99		
	END OF WEEK 4	VLN non-mentholated	05OCT2018	9:47			159 NCS/90	76	14	98.2
	UNSCHEDULED	VLN non-mentholated	05OCT2018	10:00			155/93	77		
	END OF WEEK 6	VLN non-mentholated	19OCT2018	14:37			144/83	86	16	98
	END OF STUDY	VLN non-mentholated	19OCT2018		NOT DONE	VITALS WERE DONE ON SAME DAY FOR DAY 42 VISIT	/			

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----			
Name								Sys/Dia			
2140	SCREENING	UB non-mentholated	30AUG2018	10:25				131/90	74	18	98.1
	START OF WEEK -1	UB non-mentholated	18SEP2018	8:59				122/87	71	16	98.4
	END OF WEEK -1	UB non-mentholated	23SEP2018	13:48				125/85	71	14	98.3
	END OF WEEK 2	UB non-mentholated	08OCT2018	13:42				119/82	75	17	98.4
	END OF WEEK 4	UB non-mentholated	22OCT2018	9:55				116/80	85	14	97.9
	END OF WEEK 6	UB non-mentholated	05NOV2018	14:50				116/82	70	16	98.4
	END OF STUDY	UB non-mentholated	06NOV2018	7:15				109/78	69	12	97.8
2142	SCREENING	VLN non-mentholated	31AUG2018	10:52				127/93	98	17	98.3
	START OF WEEK -1	VLN non-mentholated	18SEP2018	9:39				139/88	91	16	98.8
	END OF WEEK -1	VLN non-mentholated	23SEP2018	13:50				141/94	92	16	99
	END OF WEEK 2	VLN non-mentholated	08OCT2018	13:43				159 NCS/104 NCS	101 NCS	18	99.4
	END OF STUDY	VLN non-mentholated	08OCT2018	14:40				155 NCS/92	97	14	98.7
2143	SCREENING	VLN non-mentholated	04SEP2018	9:46				100/64	55	10	97.9
	START OF WEEK -1	VLN non-mentholated	18SEP2018	9:39				100/64	64	16	97.7
	END OF WEEK -1	VLN non-mentholated	23SEP2018	13:59				101/62	67	12	98.3
	END OF WEEK 2	VLN non-mentholated	08OCT2018	13:40				103/67	65	12	98.6
	END OF WEEK 4	VLN non-mentholated	22OCT2018	9:33				102/64	55	16	97.9
	END OF WEEK 6	VLN non-mentholated	05NOV2018	14:39				104/59	62	14	98.2
	END OF STUDY	VLN non-mentholated	06NOV2018	7:15				99/63	66	16	98.2
2158	SCREENING	UB non-mentholated	18SEP2018	11:48				123/77	80	17	98.2
	START OF WEEK -1	UB non-mentholated	14OCT2018	8:42				110/74	81	16	98.2
	END OF WEEK -1	UB non-mentholated	19OCT2018	11:57				105/69	87	18	98.4
	END OF WEEK 2	UB non-mentholated	03NOV2018	12:26				111/73	84	14	98.7

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
2158	END OF WEEK 4		UB non-mentholated	17NOV2018		NOT DONE	SUBJECT WAS DISCONTINUED DUE TO POSITIVE UDS	/				
2159	SCREENING		VLN non-mentholated	19SEP2018	10:24			127/91		73	14	98.4
	START OF WEEK -1		VLN non-mentholated	14OCT2018	10:03			102/67		76	16	98.7
	END OF WEEK -1		VLN non-mentholated	19OCT2018	11:25			129/85		72	17	98.4
	END OF WEEK 2		VLN non-mentholated	03NOV2018	12:27			130/79		81	14	98.6
	END OF WEEK 4		VLN non-mentholated	17NOV2018	11:42			117/83		85	12	98.4
	END OF WEEK 6		VLN non-mentholated	01DEC2018	14:12			124/80		77	14	99.1
	END OF STUDY		VLN non-mentholated	02DEC2018	6:39			128/83		65	14	98.4
2164	SCREENING		VLN non-mentholated	27SEP2018	10:40			113/75		72	14	98
	START OF WEEK -1		VLN non-mentholated	14OCT2018	8:34			106/69		87	16	97.9
	END OF WEEK -1		VLN non-mentholated	19OCT2018	11:27			111/74		80	17	97.6
	END OF WEEK 2		VLN non-mentholated	03NOV2018	12:22			116/74		91	14	98.4
	END OF WEEK 4		VLN non-mentholated	17NOV2018	11:34			108/67		96	16	98.2
	END OF WEEK 6		VLN non-mentholated	01DEC2018	14:14			116/74		83	16	97.4
	END OF STUDY		VLN non-mentholated	02DEC2018	6:39			104/66		98	16	98.2
2168	SCREENING		VLN non-mentholated	28SEP2018	10:07			101/74		80	14	98.1
	START OF WEEK -1		VLN non-mentholated	14OCT2018	8:53			100/69		81	14	98
	END OF WEEK -1		VLN non-mentholated	19OCT2018	11:40			122/79		78	17	98.2
	END OF WEEK 2		VLN non-mentholated	03NOV2018	12:32			100/67		89	14	98.1
	END OF WEEK 4		VLN non-mentholated	17NOV2018	12:47			110/74		90	14	98
	END OF WEEK 6		VLN non-mentholated	01DEC2018	14:36			106/71		83	14	98.8
	END OF STUDY		VLN non-mentholated	02DEC2018	6:41			96/63		75	16	97.8

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	Name						-----	Sys/Dia			
2170	SCREENING		UB non-mentholated	28SEP2018	10:51				114/73	79	14	98.2
	START OF WEEK -1		UB non-mentholated	14OCT2018	10:40				116/86	67	17	97.5
	END OF WEEK -1		UB non-mentholated	19OCT2018	11:53				110/76	72	18	98.4
	END OF WEEK 2		UB non-mentholated	03NOV2018	12:35				102/63	80	14	98.2
	END OF WEEK 4		UB non-mentholated	17NOV2018	10:44				115/71	73	14	98.3
	END OF WEEK 6		UB non-mentholated	01DEC2018	14:20				109/71	85	14	98.7
	END OF STUDY		UB non-mentholated	02DEC2018	6:41				102/69	94	15	98.3
2175	SCREENING		UB mentholated	01OCT2018	11:06				124/78	78	16	98.3
	START OF WEEK -1		UB mentholated	14OCT2018	9:48				109/73	69	14	98.1
	END OF WEEK -1		UB mentholated	19OCT2018	11:45				106/73	75	17	98.5
	END OF WEEK 2		UB mentholated	03NOV2018	12:32				119/86	77	14	98.2
	END OF WEEK 4		UB mentholated	17NOV2018	12:00				113/78	69	12	98.2
	END OF WEEK 6		UB mentholated	01DEC2018	14:40				108/75	83	14	98.9
	END OF STUDY		UB mentholated	02DEC2018	6:43				107/74	76	16	98.1
2189	SCREENING		VLN mentholated	04OCT2018	10:57				119/74	76	12	97.7
	START OF WEEK -1		VLN mentholated	14OCT2018	9:11				127/80	96	16	98.9
	END OF WEEK -1		VLN mentholated	19OCT2018	12:10				121/80	101 NCS	18	98.5
	UNSCHEDULED		VLN mentholated	19OCT2018	12:20				135/83	108 NCS	19	98.4
	UNSCHEDULED		VLN mentholated	19OCT2018	14:46				/	96		
	END OF STUDY		VLN mentholated	06NOV2018	13:14				112/77	66	14	98
2211	SCREENING		VLN mentholated	10OCT2018	11:25				121/89	88	12	98.1
	START OF WEEK -1		VLN mentholated	14OCT2018	10:30				115/80	80	16	97.7
	END OF WEEK -1		VLN mentholated	19OCT2018	12:15				106/72	96	17	98.3
	END OF WEEK 2		VLN mentholated	03NOV2018	12:28				99/66	73	16	98.7
	END OF WEEK 4		VLN mentholated	17NOV2018	11:15				117/80	71	16	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	-----	-----						-----	-----			
Name								Sys/Dia				
2211	END OF WEEK 6	VLN mentholated	01DEC2018	14:22				106/69	98	12	98.2	
	END OF STUDY	VLN mentholated	02DEC2018	6:44				100/68	65	16	98.2	
2212	SCREENING	UB mentholated	10OCT2018	12:12				117/70	57	14	98	
	START OF WEEK -1	UB mentholated	14OCT2018	10:51				126/71	66	17	98.1	
	END OF WEEK -1	UB mentholated	19OCT2018	12:17				113/71	56	17	98	
	END OF WEEK 2	UB mentholated	03NOV2018	15:59				120/79	66	12	97.5	
	END OF WEEK 4	UB mentholated	17NOV2018	15:05				107/71	57	12	98.4	
	END OF WEEK 6	UB mentholated	01DEC2018	15:51				103/65	62	16	98.3	
	END OF STUDY	UB mentholated	02DEC2018	6:44				102/73	59	18	98.2	
2213	SCREENING	VLN mentholated	10OCT2018	12:17				118/78	71	17	98.5	
	START OF WEEK -1	VLN mentholated	14OCT2018	11:29				108/73	80	16	97.9	
	END OF WEEK -1	VLN mentholated	19OCT2018	12:18				114/74	81	17	98.1	
	END OF WEEK 2	VLN mentholated	03NOV2018	12:35				119/78	83	16	98.5	
	END OF WEEK 4	VLN mentholated	17NOV2018	12:19				139/84	89		98.4	
	END OF WEEK 6	VLN mentholated	01DEC2018	14:23				109/74	85	16	98.6	
	END OF STUDY	VLN mentholated	02DEC2018	6:49				107/56	77	16	98.4	
2215	SCREENING	UB mentholated	10OCT2018	12:38				117/78	80	16	98.1	
	START OF WEEK -1	UB mentholated	14OCT2018	8:39				135/79	73	14	98.4	
	END OF WEEK -1	UB mentholated	19OCT2018	12:19				113/71	80	14	98.3	
	UNSCHEDULED	UB mentholated	19OCT2018	19:30				113/73	81	16	98.3	
	END OF WEEK 2	UB mentholated	03NOV2018	12:39				138/83	80	12	97.4	
	END OF WEEK 4	UB mentholated	17NOV2018	11:31				118/78	76	14	98.1	
	END OF WEEK 6	UB mentholated	01DEC2018	14:38				105/77	82	16	98.3	
	END OF STUDY	UB mentholated	02DEC2018	6:48				108/74	70	16	97.8	

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
2220	SCREENING		VLN non-mentholated	11OCT2018	9:44			116/73		61	18	99.3
	START OF WEEK -1		VLN non-mentholated	14OCT2018	12:22			123/81		61	16	98.1
	END OF WEEK -1		VLN non-mentholated	19OCT2018	18:46			117/77		77	16	98.7
	END OF WEEK 2		VLN non-mentholated	03NOV2018	12:43			114/72		57	14	98.1
	END OF WEEK 4		VLN non-mentholated	17NOV2018	13:40			120/75		70	14	98.2
	END OF WEEK 6		VLN non-mentholated	01DEC2018	14:40			107/66		71	12	98
	END OF STUDY		VLN non-mentholated	02DEC2018	6:53			104/63		65	18	97.6
2235	SCREENING		VLN mentholated	19OCT2018	10:26			123/82		69	16	98.8
	START OF WEEK -1		VLN mentholated	28OCT2018	8:54			117/77		81	14	98.3
	END OF WEEK -1		VLN mentholated	02NOV2018	15:15			115/75		73	12	98.5
	END OF WEEK 2		VLN mentholated	17NOV2018	13:36			116/71		78	14	98
	END OF WEEK 4		VLN mentholated	01DEC2018	12:49			131/84		62	14	98.2
	END OF WEEK 6		VLN mentholated	15DEC2018	17:34			118/74		73	16	98.1
	END OF STUDY		VLN mentholated	16DEC2018	7:33			107/75		63	14	98.3
2244	SCREENING		VLN non-mentholated	25OCT2018	10:00			126/86		87	16	98.1
	START OF WEEK -1		VLN non-mentholated	28OCT2018	8:57			112/74		101	12	98.1
	UNSCHEDULED		VLN non-mentholated	28OCT2018	9:48			119/81		93		
	END OF WEEK -1		VLN non-mentholated	02NOV2018	15:20			115/75		100	16	98.7
	UNSCHEDULED		VLN non-mentholated	02NOV2018	20:20			117/81		98		
	END OF WEEK 2		VLN non-mentholated	17NOV2018	17:18			112/73		93	12	98.2
	END OF WEEK 4		VLN non-mentholated	01DEC2018	12:27			115/80		93	16	98
	END OF WEEK 6		VLN non-mentholated	15DEC2018	17:36			124/76		96	14	98.3
	END OF STUDY		VLN non-mentholated	16DEC2018	7:37			110/75		91	16	97.7
2247	SCREENING		VLN mentholated	06NOV2018	9:40			116/78		82	16	96.8
	START OF WEEK -1		VLN mentholated	01DEC2018	10:44			117/79		84	16	98

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11



## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit		Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)		Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
	Name							Sys/Dia				
2247	END OF WEEK -1		VLN mentholated	06DEC2018	13:51			128/82		81	14	98.1
	END OF WEEK 2		VLN mentholated	21DEC2018	13:46			106/70		84	16	97.9
	END OF STUDY		VLN mentholated	28DEC2018	17:44			126/85		88	14	98.1
2251	SCREENING		UB non-mentholated	09NOV2018	10:41			133/88		65	16	98.1
	START OF WEEK -1		UB non-mentholated	01DEC2018	8:39			113/72		66	16	98.3
	END OF WEEK -1		UB non-mentholated	06DEC2018	13:53			120/73		69	14	97.5
	END OF WEEK 2		UB non-mentholated	21DEC2018	13:50			126/76		72	14	97.8
	END OF WEEK 4		UB non-mentholated	04JAN2019	9:09			126/79		80	12	98.4
	END OF WEEK 6		UB non-mentholated	18JAN2019	13:47			124/75		77	12	97.7
	END OF STUDY		UB non-mentholated	19JAN2019	7:28			112/74		83	16	98.3
2257	SCREENING		UB non-mentholated	14NOV2018	10:36			111/76		65	14	98.1
	START OF WEEK -1		UB non-mentholated	01DEC2018	11:00			114/78		69	14	98.2
	END OF WEEK -1		UB non-mentholated	06DEC2018	14:28			125/80		73	16	97.6
	END OF WEEK 2		UB non-mentholated	21DEC2018	14:21			111/70		81	12	97.9
	END OF WEEK 4		UB non-mentholated	04JAN2019	15:23			106/67		77	12	97.9
	END OF WEEK 6		UB non-mentholated	18JAN2019	14:43			112/75		82	18	97.4
	END OF STUDY		UB non-mentholated	19JAN2019	7:35			91/58		71	14	97.7
2259	SCREENING		UB mentholated	14NOV2018	11:26			151 NCS/90		66	16	98.5
	UNSCHEDULED		UB mentholated	14NOV2018	11:54			138/82		70		
	START OF WEEK -1		UB mentholated	01DEC2018	11:02			119/74		73	18	98.3
	END OF WEEK -1		UB mentholated	06DEC2018	13:56			132/80		72	16	97.3
	END OF WEEK 2		UB mentholated	21DEC2018	13:53			118/78		77	14	98
	END OF WEEK 4		UB mentholated	04JAN2019	10:00			118/72		79	20	98.6
	END OF WEEK 6		UB mentholated	18JAN2019	15:30			122/77		77	16	98
	END OF STUDY		UB mentholated	19JAN2019	7:29			116/76		82	16	97.8

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
 mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
 VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.2 Vital Signs (Safety Population)

Subject Number	Visit Name	Product Group	Date	Time	Not Done?	Reason for Not Done	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (rpm)	Temper- ature (°F)
							Sys/Dia			
2269	SCREENING	VLN mentholated	26NOV2018	10:02			124/80	70	16	98.2
	START OF WEEK -1	VLN mentholated	01DEC2018	8:28			129/84	77	16	98.6
	END OF WEEK -1	VLN mentholated	06DEC2018	13:48			126/81	75	16	98
	END OF WEEK 2	VLN mentholated	21DEC2018	13:44			130/73	90	16	98.2
	END OF WEEK 4	VLN mentholated	04JAN2019	9:53			123/76	78	14	98.1
	END OF WEEK 6	VLN mentholated	18JAN2019	13:57			117/75	92	14	98.6
	END OF STUDY	VLN mentholated	19JAN2019	7:31			123/78	76	16	98
2272	SCREENING	VLN mentholated	28NOV2018	10:15			113/75	54	16	98.4
	START OF WEEK -1	VLN mentholated	01DEC2018	9:40			114/73	78	14	98.6
	END OF WEEK -1	VLN mentholated	06DEC2018	14:29			113/74	68	16	98.5
	END OF WEEK 2	VLN mentholated	21DEC2018	14:26			114/78	62	14	98.3
	END OF WEEK 4	VLN mentholated	04JAN2019	9:09			103/74	67	16	98.8
	END OF WEEK 6	VLN mentholated	18JAN2019	14:02			134/66	69	16	98.3
	END OF STUDY	VLN mentholated	19JAN2019	7:28			101/67	56	14	98.1

Note: Sys = Systolic, Dia = Diastolic, CS = Clinically Significant, DIS = Discontinued  
mmHg = millimeter of mercury, bpm = beats per minute, rpm = respiration per minute, NCS = Not Clinically Significant  
VLN non-mentholated = Non-mentholated VLN cigarettes  
VLN mentholated = Mentholated VLN cigarettes  
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-VIT.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1001	SCREENING	VLN non-mentholated	02JUL2018	10:20:00	YES	NORMAL	90	150	670	74	382	437	
	END OF STUDY	VLN non-mentholated	07SEP2018	11:45:00	YES	NORMAL	86	146	700	74	388	437	
1002	SCREENING	VLN non-mentholated	02JUL2018	10:42:00	YES	NORMAL	66	150	910	98	422	436	
	END OF STUDY	VLN non-mentholated	07SEP2018	11:49:00	YES	NORMAL	58	144	1040	98	446	441	
1003	SCREENING	VLN mentholated	03JUL2018	10:10:00	YES	NORMAL	67	162	900	102	400	415	
	END OF STUDY	VLN mentholated	07SEP2018	11:41:00	YES	NORMAL	67	142	890	104	388	403	
1007	SCREENING	VLN non-mentholated	12JUL2018	8:15:00	YES	NORMAL	62	150	970	96	402	406	
	END OF STUDY	VLN non-mentholated	07SEP2018	11:51:00	YES	NORMAL	63	146	950	96	416	423	
1008	SCREENING	VLN mentholated	12JUL2018	9:41:00	YES	ABNORMAL	66	148	910	104	410	423	LEFT ANTERIOR HEMIBLOCK/ FASCICULAR BLOCK
	END OF STUDY	VLN mentholated	07SEP2018	11:44:00	YES	ABNORMAL	62	142	970	104	402	406	LEFT ANTERIOR HEMIBLOCK/ FASCICULAR BLOCK
1010	SCREENING	UB mentholated	13JUL2018	11:47:00	YES	NORMAL	61	190	980	98	418	420	
	END OF STUDY	UB mentholated	06SEP2018	20:46:00	YES	NORMAL	61	184	990	98	422	424	
1011	SCREENING	UB non-mentholated	13JUL2018	11:32:00	YES	NORMAL	69	158	870	100	398	417	
	END OF STUDY	UB non-mentholated	06SEP2018	20:52:00	YES	NORMAL	76	162	790	100	372	402	
1013	SCREENING	VLN non-mentholated	16JUL2018	11:34:00	YES	NORMAL	60	164	1000	84	424	424	
	END OF STUDY	VLN non-mentholated	14SEP2018	11:50:00	YES	NORMAL	61	178	990	86	420	422	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1014	SCREENING	VLN mentholated	16JUL2018	11:17:00	YES	NORMAL	76	154	790	80	380	411	
	END OF STUDY	VLN mentholated	14SEP2018	11:42:00	YES	NORMAL	65	150	920	80	420	431	
1015	SCREENING	VLN mentholated	16JUL2018	11:39:00	YES	NORMAL	60	154	1000	92	426	426	
	END OF STUDY	VLN mentholated	14SEP2018	11:40:00	YES	NORMAL	63	166	950	90	416	423	
1016	SCREENING	UB non-mentholated	16JUL2018	11:58:00	YES	NORMAL	56	172	1070	98	440	430	
	END OF STUDY	UB non-mentholated	13SEP2018	21:01:00	YES	NORMAL	65	168	920	102	402	413	
1017	SCREENING	UB mentholated	17JUL2018	11:36:00	YES	NORMAL	68	146	880	100	406	423	
	END OF STUDY	UB mentholated	13SEP2018	20:46:00	YES	NORMAL	67	154	890	102	392	407	
1018	SCREENING	VLN mentholated	17JUL2018	11:30:00	YES	NORMAL	69	122	870	84	390	409	
	END OF STUDY	VLN mentholated	15AUG2018	20:22:00	YES	NORMAL	92	118	650	84	354	408	
1019	SCREENING	VLN non-mentholated	17JUL2018	11:51:00	YES	NORMAL	61	156	990	108	420	422	
	END OF STUDY	VLN non-mentholated	14SEP2018	11:44:00	YES	NORMAL	48	158	1240	106	428	397	
1020	SCREENING	VLN non-mentholated	17JUL2018	12:29:00	YES	NORMAL	45	206	1320	88	446	405	
	END OF STUDY	VLN non-mentholated	14SEP2018	11:46:00	YES	NORMAL	57	208	1060	96	446	438	@
1021	SCREENING	UB non-mentholated	17JUL2018	12:45:00	YES	NORMAL	67	156	900	82	422	438	
	END OF STUDY	UB non-mentholated	13SEP2018	20:58:00	YES	NORMAL	73	156	820	82	400	427	
1023	SCREENING	VLN non-mentholated	17JUL2018	12:56:00	YES	NORMAL	63	150	960	84	422	429	
	END OF STUDY	VLN non-mentholated	14SEP2018	11:48:00	YES	NORMAL	65	146	930	86	398	409	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1029	SCREENING	VLN mentholated	26JUL2018	10:38:00	YES	NORMAL	66	140	910	86	404	417	
	END OF STUDY	VLN mentholated	11OCT2018	11:13:00	YES	NORMAL	63	144	960	106	392	398	
1032	SCREENING	VLN mentholated	13AUG2018	10:05:00	YES	NORMAL	56	180	1080	98	428	418	
	END OF STUDY	VLN mentholated	11OCT2018	11:16:00	YES	NORMAL	54	184	1120	100	424	409	
1034	SCREENING	VLN non-mentholated	13AUG2018	10:20:00	YES	NORMAL	72	128	830	94	400	425	
	END OF STUDY	VLN non-mentholated	10OCT2018	20:24:00	YES	ABNORMAL	56	108	1070	104	428	418	SHORT PR INTERVAL
1035	SCREENING	VLN non-mentholated	13AUG2018	10:27:00	YES	NORMAL	69	140	870	108	390	409	
	END OF STUDY	VLN non-mentholated	11OCT2018	11:37:00	YES	NORMAL	65	130	920	102	386	396	
1036	SCREENING	UB mentholated	13AUG2018	9:51:00	YES	NORMAL	79	162	760	80	374	410	
	END OF STUDY	UB mentholated	10OCT2018	20:05:00	YES	NORMAL	90	152	670	80	350	401	
1037	SCREENING	UB mentholated	13AUG2018	10:11:00	YES	NORMAL	65	174	920	98	396	407	
	END OF STUDY	UB mentholated	10OCT2018	20:10:00	YES	NORMAL	63	176	950	96	382	388	
1038	SCREENING	VLN non-mentholated	13AUG2018	9:58:00	YES	NORMAL	73	170	820	78	396	423	
	END OF STUDY	VLN non-mentholated	11OCT2018	11:40:00	YES	NORMAL	76	160	790	76	390	422	
1042	SCREENING	VLN non-mentholated	13AUG2018	11:07:00	YES	NORMAL	59	164	1020	100	450	447	
	END OF STUDY	VLN non-mentholated	11OCT2018	11:32:00	YES	NORMAL	64	156	940	106	414	423	
1045	SCREENING	UB non-mentholated	14AUG2018	10:50:00	YES	NORMAL	69	178	870	98	390	409	
	END OF STUDY	UB non-mentholated	10OCT2018	20:26:00	YES	NORMAL	79	176	760	100	368	403	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1046	SCREENING	UB mentholated	14AUG2018	10:30:00	YES	NORMAL	60	166	1000	102	428	428	
	END OF STUDY	UB mentholated	10OCT2018	20:19:00	YES	NORMAL	67	162	900	88	392	407	
1050	SCREENING	VLN non-mentholated	14AUG2018	10:31:00	YES	NORMAL	52	148	1150	106	438	418	
	END OF STUDY	VLN non-mentholated	10OCT2018	20:29:00	YES	NORMAL	63	150	960	106	424	431	
1051	SCREENING	UB mentholated	14AUG2018	11:31:00	YES	NORMAL	63	138	960	100	384	390	
	END OF STUDY	UB mentholated	10OCT2018	20:15:00	YES	NORMAL	86	136	700	94	354	399	
1052	SCREENING	VLN mentholated	14AUG2018	11:05:00	YES	NORMAL	61	148	980	86	388	390	
	END OF STUDY	VLN mentholated	11OCT2018	11:19:00	YES	ABNORMAL	73	128	820	86	384	410	ECTOPIC ATRIAL RHYTHM
1053	SCREENING	VLN mentholated	14AUG2018	10:46:00	YES	NORMAL	77	124	780	100	348	378	
	END OF STUDY	VLN mentholated	11OCT2018	11:26:00	YES	NORMAL	76	126	790	90	344	372	
1054	SCREENING	UB non-mentholated	14AUG2018	11:15:00	YES	ABNORMAL	65	178	920	118	416	427	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC. LEFT ANTERIOR HEMIBLOCK/ FASCICULAR BLOCK

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Page 5 of 20

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1054	END OF STUDY	UB non-mentholated	10OCT2018	20:31:00	YES	ABNORMAL	74	180	810	110	398	427	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC. LEFT ANTERIOR HEMIBLOCK/ FASCICULAR BLOCK
1055	SCREENING	VLN mentholated	14AUG2018	11:20:00	YES	NORMAL	55	154	1090	92	418	406	
	END OF STUDY	VLN mentholated	11OCT2018	11:28:00	YES	NORMAL	54	160	1110	92	434	419	
1056	SCREENING	VLN non-mentholated	14AUG2018	11:02:00	YES	NORMAL	79	164	760	82	372	408	
	END OF STUDY	VLN non-mentholated	11OCT2018	11:42:00	YES	NORMAL	64	138	940	82	392	401	
1058	SCREENING	VLN non-mentholated	15AUG2018	10:06:00	YES	NORMAL	63	146	950	96	408	415	
	END OF STUDY	VLN non-mentholated	11OCT2018	11:34:00	YES	NORMAL	51	148	1170	100	412	390	
1059	SCREENING	UB non-mentholated	27AUG2018	10:15:00	YES	NORMAL	71	160	850	98	402	425	
	END OF STUDY	UB non-mentholated	24OCT2018	20:16:00	YES	NORMAL	81	148	740	96	374	413	
1060	SCREENING	VLN mentholated	27AUG2018	10:11:00	YES	ABNORMAL	56	204	1080	98	442	432	NONSPECIFIC T WAVE ABNORMALITY
	END OF STUDY	VLN mentholated	24OCT2018	20:12:00	YES	NORMAL	56	186	1070	94	438	428	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1063	SCREENING	VLN mentholated	27AUG2018	11:42:00	YES	ABNORMAL	63	192	960	112	420	427	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	VLN mentholated	25OCT2018	11:10:00	YES	NORMAL	70	188	860	106	390	411	
1064	SCREENING	UB non-mentholated	27AUG2018	11:27:00	YES	NORMAL	63	170	960	88	396	402	
	END OF STUDY	UB non-mentholated	22OCT2018		ND								
1066	SCREENING	VLN non-mentholated	27AUG2018	11:38:00	YES	NORMAL	63	196	950	90	392	398	
	END OF STUDY	VLN non-mentholated	24OCT2018	20:21:00	YES	NORMAL	60	202	1000	88	396	396	
1069	SCREENING	UB non-mentholated	28AUG2018	10:24:00	YES	NORMAL	69	138	870	92	406	425	
	END OF STUDY	UB non-mentholated	24OCT2018	20:24:00	YES	NORMAL	81	154	740	100	370	409	
1070	SCREENING	VLN non-mentholated	28AUG2018	10:37:00	YES	ABNORMAL	79	142	760	114	394	432	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	VLN non-mentholated	24OCT2018	20:22:00	YES	NORMAL	77	152	780	90	376	409	
1071	SCREENING	VLN non-mentholated	28AUG2018	10:11:00	YES	NORMAL	63	152	950	100	426	433	
	END OF STUDY	VLN non-mentholated	23OCT2018		ND								
1072	SCREENING	VLN mentholated	28AUG2018	10:30:00	YES	NORMAL	61	154	980	84	420	422	
	END OF STUDY	VLN mentholated	22OCT2018	12:24:00	YES	NORMAL	68	140	880	76	406	423	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11



## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Page 7 of 20

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1074	SCREENING	VLN non-mentholated	28AUG2018	10:58:00	YES	ABNORMAL	69	232	870	100	418	438	FIRST DEGREE ATRIO- VENTRICULAR BLOCK
	END OF STUDY	VLN non-mentholated	24OCT2018	20:32:00	YES	ABNORMAL	67	240	900	106	408	423	FIRST DEGREE ATRIO- VENTRICULAR BLOCK
1075	SCREENING	UB non-mentholated	28AUG2018	11:03:00	YES	NORMAL	59	148	1020	86	430	428	
	END OF STUDY	UB non-mentholated	24OCT2018	20:33:00	YES	NORMAL	62	144	970	88	400	404	
1077	SCREENING	VLN non-mentholated	28AUG2018	10:44:00	YES	NORMAL	77	158	780	100	370	402	
	END OF STUDY	VLN non-mentholated	24OCT2018	20:28:00	YES	NORMAL	75	162	800	100	352	379	
1078	SCREENING	VLN non-mentholated	28AUG2018	10:50:00	YES	NORMAL	62	146	970	94	430	435	
	END OF STUDY	VLN non-mentholated	24OCT2018	20:19:00	YES	NORMAL	59	148	1020	96	428	426	
1079	SCREENING	VLN mentholated	28AUG2018	11:44:00	YES	NORMAL	75	132	800	96	372	401	
	END OF STUDY	VLN mentholated	24OCT2018	20:14:00	YES	NORMAL	80	126	750	100	362	398	
1082	SCREENING	VLN non-mentholated	30AUG2018	8:40:00	YES	NORMAL	59	136	1020	100	422	420	
	END OF STUDY	VLN non-mentholated	24OCT2018	20:26:00	YES	NORMAL	58	132	1030	104	412	407	
1083	SCREENING	VLN non-mentholated	04SEP2018	10:25:00	YES	NORMAL	61	140	990	92	398	400	
	END OF STUDY	VLN non-mentholated	31OCT2018	20:50:00	YES	NORMAL	61	144	990	94	396	398	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1084	SCREENING	VLN non-mentholated	04SEP2018	10:10:00	YES	NORMAL	66	178	910	108	394	407	
	END OF STUDY	VLN non-mentholated	16OCT2018		ND								
1086	SCREENING	VLN non-mentholated	04SEP2018	11:20:00	YES	NORMAL	61	144	990	102	426	428	
	END OF STUDY	VLN non-mentholated	31OCT2018	20:51:00	YES	NORMAL	72	146	830	102	382	406	
1088	SCREENING	VLN mentholated	04SEP2018	10:45:00	YES	NORMAL	61	172	980	108	394	396	
	END OF STUDY	VLN mentholated	31OCT2018	20:37:00	YES	ABNORMAL	65	164	930	110	386	396	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
1089	SCREENING	UB non-mentholated	04SEP2018	10:39:00	YES	NORMAL	62	110	970	76	422	427	
	END OF STUDY	UB non-mentholated	31OCT2018	20:45:00	YES	ABNORMAL	63	108	950	76	424	431	SHORT PR INTERVAL
1092	SCREENING	VLN mentholated	05SEP2018	9:29:00	YES	NORMAL	70	172	860	82	386	406	
	END OF STUDY	VLN mentholated	31OCT2018	20:40:00	YES	NORMAL	72	172	830	88	364	387	
1094	SCREENING	VLN mentholated	05SEP2018	10:19:00	YES	NORMAL	76	168	790	86	366	396	
	END OF STUDY	VLN mentholated	31OCT2018	20:35:00	YES	NORMAL	69	170	870	82	378	396	
1095	SCREENING	VLN mentholated	07SEP2018	8:53:00	YES	NORMAL	57	158	1060	102	440	433	
	END OF STUDY	VLN mentholated	31OCT2018	20:49:00	YES	NORMAL	61	158	980	106	418	420	
1096	SCREENING	VLN non-mentholated	07SEP2018	9:21:00	YES	NORMAL	78	140	770	92	402	439	
	END OF STUDY	VLN non-mentholated	31OCT2018	20:54:00	YES	NORMAL	81	136	740	84	364	402	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product ----- Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1097	SCREENING	VLN mentholated	07SEP2018	9:49:00	YES	NORMAL	60	124	1000	86	392	392	
	END OF STUDY	VLN mentholated	31OCT2018	20:42:00	YES	NORMAL	57	130	1060	90	392	385	
1098	SCREENING	VLN non-mentholated	18SEP2018	10:54:00	YES	ABNORMAL	51	156	1170	98	478	453	# PROLONGED QTC INTERVAL
	END OF STUDY	VLN non-mentholated	16NOV2018	20:46:00	YES	ABNORMAL	59	144	1020	106	456	453	# PROLONGED QTC INTERVAL
1099	SCREENING	VLN non-mentholated	18SEP2018	10:49:00	YES	NORMAL	71	156	840	100	384	406	
	END OF STUDY	VLN non-mentholated	16NOV2018	21:05:00	YES	NORMAL	71	162	850	106	380	402	
1100	SCREENING	VLN non-mentholated	18SEP2018	11:41:00	YES	NORMAL	61	156	980	90	408	410	
	END OF STUDY	VLN non-mentholated	16NOV2018	20:48:00	YES	NORMAL	70	144	860	92	374	394	
1101	SCREENING	VLN non-mentholated	18SEP2018	11:48:00	YES	NORMAL	70	122	860	100	402	423	
	END OF STUDY	VLN non-mentholated	16NOV2018	20:52:00	YES	NORMAL	82	116	730	80	388	431	
1103	SCREENING	VLN non-mentholated	18SEP2018	11:31:00	YES	ABNORMAL	61	182	990	112	400	402	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	VLN non-mentholated	16NOV2018	20:49:00	YES	ABNORMAL	62	172	970	110	396	400	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
1105	SCREENING	VLN non-mentholated	19SEP2018	11:04:00	YES	NORMAL	66	176	910	86	408	421	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Page 10 of 20

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1105	END OF STUDY	VLN non-mentholated	16NOV2018	21:02:00	YES	NORMAL	66	182	910	96	400	413	
1106	SCREENING	UB non-mentholated	19SEP2018	10:47:00	YES	NORMAL	77	128	780	86	378	411	
	END OF STUDY	UB non-mentholated	16NOV2018	20:41:00	YES	NORMAL	88	138	680	80	344	391	
1107	SCREENING	VLN non-mentholated	21SEP2018	10:39:00	YES	ABNORMAL	65	150	920	114	402	413	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	VLN non-mentholated	16NOV2018	20:56:00	YES	ABNORMAL	71	146	840	116	384	406	
1108	SCREENING	UB non-mentholated	21SEP2018	10:48:00	YES	NORMAL	53	172	1140	86	438	420	
	END OF STUDY	UB non-mentholated	16NOV2018	20:54:00	YES	NORMAL	63	172	950	92	406	413	
1109	SCREENING	UB non-mentholated	21SEP2018	10:20:00	YES	ABNORMAL	60	170	1000	118	440	440	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	UB non-mentholated	16NOV2018	20:58:00	YES	NORMAL	63	166	960	108	408	415	
1112	SCREENING	VLN non-mentholated	21SEP2018	11:08:00	YES	NORMAL	62	150	970	80	424	429	
	END OF STUDY	VLN non-mentholated	16NOV2018	21:07:00	YES	NORMAL	63	142	960	80	418	425	
1114	SCREENING	UB non-mentholated	24SEP2018	10:15:00	YES	NORMAL	74	186	810	88	388	416	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
1114	END OF STUDY	UB non-mentholated	16NOV2018	21:00:00	YES	NORMAL	73	166	820	86	362	386	
1115	SCREENING	VLN non-mentholated	24SEP2018	10:05:00	YES	ABNORMAL	81	162	740	118	360	398	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC
	END OF STUDY	VLN non-mentholated	14NOV2018		ND								
2002	SCREENING	UB mentholated	29JUN2018	9:48:00	YES	NORMAL	53	166	1120	78	408	392	
	END OF STUDY	UB mentholated	05SEP2018	7:54:00	YES	NORMAL	50	167	1186	80	414	391	
2003	SCREENING	VLN mentholated	29JUN2018	10:07:00	YES	NORMAL	57	145	1052	102	431	423	
	END OF STUDY	VLN mentholated	29AUG2018	7:13:00	YES	NORMAL	53	152	1126	102	419	402	
2007	SCREENING	VLN non-mentholated	29JUN2018	12:02:00	YES	NORMAL	59	162	1011	101	441	439	
	END OF STUDY	VLN non-mentholated	29AUG2018	8:00:00	YES	NORMAL	61	163	981	95	405	407	
2008	SCREENING	VLN mentholated	06JUL2018	9:57:00	YES	NORMAL	68	150	879	86	405	422	
	END OF STUDY	VLN mentholated	29AUG2018	7:17:00	YES	NORMAL	61	161	981	82	416	418	
2009	SCREENING	VLN non-mentholated	29JUN2018	12:14:00	YES	NORMAL	54	169	1099	92	422	408	
	END OF STUDY	VLN non-mentholated	14AUG2018		ND								
2010	SCREENING	UB mentholated	29JUN2018	12:23:00	YES	NORMAL	76	199	781	82	354	384	
	END OF STUDY	UB mentholated	29AUG2018	7:59:00	YES	NORMAL	58	197	1026	86	381	377	
2011	SCREENING	VLN mentholated	29JUN2018	12:25:00	YES	NORMAL	70	148	849	82	384	405	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2011	END OF STUDY	VLN mentholated	29AUG2018	7:22:00	YES	NORMAL	73	152	812	80	385	412	
2014	SCREENING	VLN mentholated	02JUL2018	10:03:00	YES	ABNORMAL	68	216	874	95	379	396	sinus rhythm with first degree AV block, ST. elevation probably early repolarization, non specific T wave abnormality; ncs
	END OF STUDY	VLN mentholated	29AUG2018	7:42:00	YES	ABNORMAL	62	190	965	97	394	398	sinus rhythm, ST elevation, probably early repolarization, non specific T wave abnormality; ncs
2015	SCREENING	UB mentholated	02JUL2018	10:39:00	YES	NORMAL	62	132	955	85	436	442	
	END OF STUDY	UB mentholated	29AUG2018	7:32:00	YES	NORMAL	61	131	970	90	427	431	
2016	SCREENING	VLN mentholated	02JUL2018	10:20:00	YES	NORMAL	60	151	999	89	394	394	
	END OF STUDY	VLN mentholated	03AUG2018	9:14:00	YES	NORMAL	68	150	872	94	383	400	
2017	SCREENING	VLN mentholated	02JUL2018	10:25:00	YES	NORMAL	58	155	1020	90	394	391	
	END OF STUDY	VLN mentholated	29AUG2018	7:22:00	YES	NORMAL	58	159	1017	90	401	398	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2018	SCREENING	UB mentholated	02JUL2018	11:36:00	YES	NORMAL	66	161	906	90	393	406	
	END OF STUDY	UB mentholated	29AUG2018	7:52:00	YES	NORMAL	67	182	890	85	388	403	
2020	SCREENING	VLN mentholated	02JUL2018	11:25:00	YES	NORMAL	70	164	857	85	387	407	
	END OF STUDY	VLN mentholated	29AUG2018	7:43:00	YES	NORMAL	66	165	906	90	391	404	
2021	SCREENING	VLN mentholated	02JUL2018	11:49:00	YES	NORMAL	60	155	995	89	373	373	
	END OF STUDY	VLN mentholated	29AUG2018	7:32:00	YES	ABNORMAL	48	167	1227	91	409	382	sinus bradycardia
2023	SCREENING	VLN mentholated	02JUL2018	12:14:00	YES	NORMAL	68	172	880	85	387	403	
	END OF STUDY	VLN mentholated	29AUG2018	7:36:00	YES	NORMAL	68	175	881	92	390	406	
2024	SCREENING	UB non-mentholated	03JUL2018	10:21:00	YES	NORMAL	67	147	889	101	396	411	
	END OF STUDY	UB non-mentholated	29AUG2018	7:50:00	YES	NORMAL	58	182	1026	86	433	429	
2025	SCREENING	UB non-mentholated	03JUL2018	10:27:00	YES	NORMAL	61	193	979	82	410	412	
	END OF STUDY	UB non-mentholated	29AUG2018	7:50:00	YES	NORMAL	58	182	1026	86	433	429	
2028	SCREENING	VLN non-mentholated	06JUL2018	11:45:00	YES	NORMAL	58	156	1027	99	403	399	
	END OF STUDY	VLN non-mentholated	29AUG2018	8:04:00	YES	NORMAL	59	157	1012	100	416	414	
2029	SCREENING	UB mentholated	09JUL2018	10:58:00	YES	NORMAL	62	175	956	98	408	414	
	END OF STUDY	UB mentholated	05SEP2018	8:05:00	YES	NORMAL	65	194	917	95	397	408	
2039	SCREENING	VLN mentholated	13JUL2018	10:12:00	YES	NORMAL	68	165	873	80	392	410	
	END OF STUDY	VLN mentholated	05SEP2018	8:12:00	YES	NORMAL	59	145	1008	82	409	407	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2050	SCREENING	UB mentholated	20JUL2018	10:45:00	YES	ABNORMAL	53	195	1120	101	386	371	sinus bradycardia, nonspecific ST & T wave abnormality sinus rhythm, nonspecific T wave abnormality; ncs
	END OF STUDY	UB mentholated	20SEP2018	7:49:00	YES	ABNORMAL	69	162	860	97	357	375	
2052	SCREENING	VLN mentholated	20JUL2018	11:02:00	YES	NORMAL	63	171	947	98	411	418	
	END OF STUDY	VLN mentholated	20SEP2018	7:53:00	YES	NORMAL	60	191	991	97	418	419	
2057	SCREENING	VLN mentholated	23JUL2018	9:53:00	YES	NORMAL	60	197	997	92	401	401	
	END OF STUDY	VLN mentholated	20SEP2018	7:57:00	YES	NORMAL	57	197	1046	97	418	411	
2058	SCREENING	VLN mentholated	23JUL2018	10:10:00	YES	NORMAL	63	184	948	96	390	397	
	END OF STUDY	VLN mentholated	20SEP2018	8:19:00	YES	NORMAL	71	189	837	80	375	397	
2059	SCREENING	UB mentholated	23JUL2018	10:25:00	YES	NORMAL	54	137	1110	83	448	432	
	END OF STUDY	UB mentholated	20SEP2018	8:05:00	YES	NORMAL	53	139	1127	77	452	434	
2060	SCREENING	VLN mentholated	23JUL2018	10:34:00	YES	NORMAL	62	185	961	88	415	420	
	END OF STUDY	VLN mentholated	20SEP2018	8:25:00	YES	NORMAL	59	194	1003	89	416	415	
2064	SCREENING	VLN mentholated	23JUL2018	10:59:00	YES	NORMAL	74	194	803	93	391	420	
	END OF STUDY	VLN mentholated	20SEP2018	8:01:00	YES	NORMAL	66	203	902	88	409	423	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11



## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2066	SCREENING	VLN mentholated	23JUL2018	11:25:00	YES	ABNORMAL	68	148	874	109	393	411	sinus rhythm with sinus arrhythmia, incomplete right bundle branch block; ncs sinus rhythm, RST (QR) IN V1/ V2 consistent with right ventricular conduction delay; ncs
	END OF STUDY	VLN mentholated	20SEP2018	8:12:00	YES	ABNORMAL	62	140	955	105	388	394	
2067	SCREENING	VLN non-mentholated	23JUL2018	12:09:00	YES	NORMAL	53	170	1117	86	428	412	
	END OF STUDY	VLN non-mentholated	20SEP2018	8:04:00	YES	NORMAL	61	172	978	85	398	400	
2075	SCREENING	VLN mentholated	30JUL2018	10:46:00	YES	NORMAL	64	184	931	101	388	397	
	END OF STUDY	VLN mentholated	22AUG2018	19:31:00	YES	NORMAL	71	184	844	102	374	395	
2076	SCREENING	VLN mentholated	30JUL2018	10:59:00	YES	NORMAL	51	158	1154	89	422	402	
	END OF STUDY	VLN mentholated	14OCT2018	7:43:00	YES	NORMAL	52	171	1147	106	421	402	
2086	SCREENING	VLN non-mentholated	03AUG2018	11:55:00	YES	NORMAL	49	140	1211	96	388	364	
	END OF STUDY	VLN non-mentholated	29SEP2018	11:18:00	YES	NORMAL	50	169	1194	102	379	357	
2088	SCREENING	VLN mentholated	03AUG2018	12:06:00	YES	NORMAL	59	159	1006	89	412	411	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2088	END OF STUDY	VLN mentholated	14OCT2018	9:06:00	YES	NORMAL	62	145	967	87	414	418	
2092	SCREENING	VLN mentholated	06AUG2018	10:17:00	YES	NORMAL	74	124	805	92	369	396	
	END OF STUDY	VLN mentholated	14OCT2018	7:52:00	YES	NORMAL	68	113	876	99	405	423	
2099	SCREENING	VLN non-mentholated	09AUG2018	10:08:00	YES	NORMAL	67	189	885	81	398	414	
	END OF STUDY	VLN non-mentholated	14OCT2018	7:51:00	YES	NORMAL	73	168	812	90	382	409	
2100	SCREENING	UB mentholated	09AUG2018	10:36:00	YES	NORMAL	71	187	840	93	394	417	
	END OF STUDY	UB mentholated	14OCT2018	7:56:00	YES	NORMAL	68	148	873	94	410	428	
2108	SCREENING	VLN non-mentholated	13AUG2018	10:08:00	YES	NORMAL	63	150	949	94	410	417	
	END OF STUDY	VLN non-mentholated	14OCT2018	7:45:00	YES	ABNORMAL	54	151	1102	94	429	415	sinus bradycardia, T Wave abnormality; ncs
2110	SCREENING	UB mentholated	13AUG2018	10:33:00	YES	NORMAL	86	148	692	102	345	390	
	END OF STUDY	UB mentholated	20OCT2018	8:01:00	YES	NORMAL	69	132	865	92	363	380	
2113	SCREENING	VLN mentholated	15AUG2018	10:44:00	YES	NORMAL	59	148	1008	82	409	407	
2115	SCREENING	VLN mentholated	15AUG2018	11:17:00	YES	NORMAL	56	168	1068	102	441	431	
2119	SCREENING	VLN mentholated	20AUG2018	10:13:00	YES	NORMAL	73	125	819	92	370	395	
	END OF STUDY	VLN mentholated	20OCT2018	8:08:00	YES	NORMAL	77	129	770	94	362	394	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2120	SCREENING	VLN non-mentholated	20AUG2018	10:21:00	YES	ABNORMAL	58	214	1031	86	412	407	sinus bradycardia with first degree AV block
	END OF STUDY	VLN non-mentholated	20OCT2018	8:18:00	YES	ABNORMAL	66	203	898	89	394	408	borderline first degree av block
2122	SCREENING	UB non-mentholated	20AUG2018	11:43:00	YES	NORMAL	62	176	960	97	386	391	
	END OF STUDY	UB non-mentholated	20OCT2018	8:17:00	YES	NORMAL	62	179	966	100	379	383	
2125	SCREENING	UB mentholated	21AUG2018	11:01:00	YES	ABNORMAL	41	146	1439	85	407	360	sinus bradycardia; QR in V1/ V2 consistent with right ventricular conduction delay
	END OF STUDY	UB mentholated	20OCT2018	8:01:00	YES	NORMAL	52	158	1146	81	384	366	
2126	SCREENING	VLN mentholated	21AUG2018	11:25:00	YES	NORMAL	62	157	958	86	400	405	
	END OF STUDY	VLN mentholated	20OCT2018	8:13:00	YES	NORMAL	58	158	1018	89	419	416	
2136	SCREENING	VLN non-mentholated	27AUG2018	10:45:00	YES	NORMAL	64	174	937	101	406	414	
	END OF STUDY	VLN non-mentholated	19OCT2018	15:26:00	YES	NORMAL	75	174	797	99	368	396	
2140	SCREENING	UB non-mentholated	30AUG2018	10:41:00	YES	NORMAL	70	182	854	100	430	453	#

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Page 18 of 20

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2140	END OF STUDY	UB non-mentholated	06NOV2018	7:28:00	YES	ABNORMAL	64	206	936	96	417	426	sinus rhythm, nonspecific T wave abnormality; ncs
2142	SCREENING	VLN non-mentholated	31AUG2018	11:06:00	YES	NORMAL	86	155	693	85	366	413	
	END OF STUDY	VLN non-mentholated	08OCT2018	14:22:00	YES	NORMAL	94	148	638	85	355	412	
2143	SCREENING	VLN non-mentholated	04SEP2018	10:05:00	YES	NORMAL	54	196	1105	89	425	411	
	END OF STUDY	VLN non-mentholated	06NOV2018	7:30:00	YES	ABNORMAL	63	212	948	84	396	403	sinus rhythm with first degree AV block; ncs
2158	SCREENING	UB non-mentholated	18SEP2018	12:00:00	YES	NORMAL	59	140	1014	89	430	428	
2159	SCREENING	VLN non-mentholated	19SEP2018	10:37:00	YES	NORMAL	63	113	939	81	395	403	
	END OF STUDY	VLN non-mentholated	02DEC2018	7:48:00	YES	NORMAL	57	113	1052	88	434	426	
2164	SCREENING	VLN non-mentholated	27SEP2018	11:00:00	YES	NORMAL	73	182	815	89	403	431	
	END OF STUDY	VLN non-mentholated	02DEC2018	7:10:00	YES	NORMAL	82	178	724	93	388	432	
2168	SCREENING	VLN non-mentholated	28SEP2018	10:17:00	YES	ABNORMAL	69	121	858	101	400	420	Incomplete right bundle branch block;ncs
	END OF STUDY	VLN non-mentholated	02DEC2018	7:16:00	YES	NORMAL	72	140	833	108	391	415	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2170	SCREENING	UB non-mentholated	28SEP2018	11:03:00	YES	NORMAL	74	174	805	88	391	420	
	END OF STUDY	UB non-mentholated	02DEC2018	7:25:00	YES	NORMAL	76	186	787	102	400	433	
2175	SCREENING	UB mentholated	01OCT2018	11:25:00	YES	NORMAL	55	156	1084	93	414	403	
	END OF STUDY	UB mentholated	02DEC2018	7:26:00	YES	NORMAL	70	172	856	106	405	426	
2189	SCREENING	VLN mentholated	04OCT2018	11:14:00	YES	NORMAL	65	159	916	90	391	402	
	END OF STUDY	VLN mentholated	06NOV2018	13:25:00	YES	NORMAL	67	167	894	81	382	396	
2211	SCREENING	VLN mentholated	10OCT2018	11:36:00	YES	NORMAL	75	117	793	93	379	409	
	END OF STUDY	VLN mentholated	02DEC2018	7:36:00	YES	NORMAL	58	120	1032	93	402	397	
2212	SCREENING	UB mentholated	10OCT2018	12:24:00	YES	NORMAL	52	171	1140	87	422	403	
	END OF STUDY	UB mentholated	02DEC2018	7:36:00	YES	NORMAL	55	169	1074	84	405	395	
2213	SCREENING	VLN mentholated	10OCT2018	12:30:00	YES	NORMAL	56	162	1067	86	418	409	
	END OF STUDY	VLN mentholated	02DEC2018	7:24:00	YES	NORMAL	56	170	1060	92	392	384	
2215	SCREENING	UB mentholated	10OCT2018	12:52:00	YES	NORMAL	61	153	977	80	389	392	
	END OF STUDY	UB mentholated	02DEC2018	8:06:00	YES	NORMAL	60	163	987	84	399	400	
2220	SCREENING	VLN non-mentholated	11OCT2018	9:57:00	YES	NORMAL	54	170	1101	91	423	409	
	END OF STUDY	VLN non-mentholated	02DEC2018	7:30:00	YES	NORMAL	54	167	1104	90	412	398	
2235	SCREENING	VLN mentholated	19OCT2018	10:54:00	YES	NORMAL	58	146	1028	99	414	410	
	END OF STUDY	VLN mentholated	16DEC2018	7:44:00	YES	NORMAL	64	154	929	98	392	401	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.3 12-Lead Electrocardiogram (Safety Population)

Subject Number	Visit ----- Name	Product Group	Date	Time	Was EG Per\$	Overall Result	Heart Rate (bpm)	PR (msec)	RR (msec)	QRS (msec)	QT (msec)	QTcF* (msec)	If Abnormal, Specify
2244	SCREENING	VLN non-mentholated	25OCT2018	10:13:00	YES	NORMAL	75	173	790	92	370	400	
	END OF STUDY	VLN non-mentholated	16DEC2018	7:50:00	YES	NORMAL	86	175	694	93	352	397	
2247	SCREENING	VLN mentholated	06NOV2018	9:53:00	YES	NORMAL	71	152	839	89	394	417	
	END OF STUDY	VLN mentholated	28DEC2018	14:58:00	YES	NORMAL	82	145	723	84	356	396	
2251	SCREENING	UB non-mentholated	09NOV2018	10:59:00	YES	NORMAL	53	136	1118	110	420	404	
	END OF STUDY	UB non-mentholated	19JAN2019	7:39:00	YES	NORMAL	66	144	900	108	384	397	
2257	SCREENING	UB non-mentholated	14NOV2018	10:54:00	YES	ABNORMAL	63	152	948	91	388	394	RSR (QR) IN V1/ V2 CONSISTENT WITH RIGHT VENTRICULAR CONDUCTION DELAY
	END OF STUDY	UB non-mentholated	19JAN2019	7:46:00	YES	NORMAL	61	166	969	92	379	382	
2259	SCREENING	UB mentholated	14NOV2018	12:08:00	YES	NORMAL	64	146	925	98	385	395	
	END OF STUDY	UB mentholated	19JAN2019	7:39:00	YES	NORMAL	71	143	845	94	374	395	
2269	SCREENING	VLN mentholated	26NOV2018	10:15:00	YES	NORMAL	71	180	835	89	375	398	
	END OF STUDY	VLN mentholated	19JAN2019	7:46:00	YES	ABNORMAL	73	202	820	86	376	401	borderline 1st degree AV block
2272	SCREENING	VLN mentholated	28NOV2018	10:37:00	YES	ABNORMAL	49	164	1224	106	393	367	SINUS BRADYCARDIA
	END OF STUDY	VLN mentholated	19JAN2019	7:42:00	YES	NORMAL	56	178	1058	87	376	368	

Note: QTcF\* = QT corrected for heart rate using Fridericia's correction.

NCS = Not Clinically Significant, \$Per = Performed?, ND = Not Done

bpm = beats per minute, msec = millisecond, Baseline is the screen value

# = QTc value greater than 450 msec, @ = QTc change from baseline greater than 30 msec.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-ECG.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
1001	FOLLOW-UP CALL	14SEP2018	VLN non-mentholate	14SEP2018	Yes	No
1002	FOLLOW-UP CALL	14SEP2018	VLN non-mentholate	14SEP2018	Yes	No
1003	FOLLOW-UP CALL	14SEP2018	VLN mentholated	14SEP2018	Yes	No
1007	FOLLOW-UP CALL	14SEP2018	VLN non-mentholate	14SEP2018	Yes	No
1008	FOLLOW-UP CALL	14SEP2018	VLN mentholated	14SEP2018	Yes	No
1010	FOLLOW-UP CALL	14SEP2018	UB mentholated	14SEP2018	Yes	No
1011	FOLLOW-UP CALL	14SEP2018	UB non-mentholated	14SEP2018	Yes	No
1013	FOLLOW-UP CALL	21SEP2018	VLN non-mentholate	21SEP2018	Yes	No
1014	FOLLOW-UP CALL	21SEP2018	VLN mentholated	21SEP2018	Yes	No
1015	FOLLOW-UP CALL	21SEP2018	VLN mentholated	21SEP2018	Yes	No
1016	FOLLOW-UP CALL	21SEP2018	UB non-mentholated	21SEP2018	Yes	No
1017	FOLLOW-UP CALL	21SEP2018	UB mentholated	21SEP2018	Yes	No
1019	FOLLOW-UP CALL	21SEP2018	VLN non-mentholate	21SEP2018	Yes	No
1020	FOLLOW-UP CALL	21SEP2018	VLN non-mentholate	21SEP2018	Yes	No
1021	FOLLOW-UP CALL	21SEP2018	UB non-mentholated	21SEP2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
1023	FOLLOW-UP CALL	21SEP2018	VLN non-mentholate	21SEP2018	Yes	No
1029	FOLLOW-UP CALL	18OCT2018	VLN mentholated	18OCT2018	Yes	No
1032	FOLLOW-UP CALL	18OCT2018	VLN mentholated	18OCT2018	Yes	No
1034	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1035	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1036	FOLLOW-UP CALL	18OCT2018	UB mentholated	18OCT2018	Yes	No
1037	FOLLOW-UP CALL	18OCT2018	UB mentholated	18OCT2018	Yes	No
1038	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1042	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1045	FOLLOW-UP CALL	18OCT2018	UB non-mentholated	18OCT2018	Yes	No
1046	FOLLOW-UP CALL	18OCT2018	UB mentholated	18OCT2018	Yes	No
1050	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1051	FOLLOW-UP CALL	18OCT2018	UB mentholated	18OCT2018	Yes	No
1052	FOLLOW-UP CALL	18OCT2018	VLN mentholated	18OCT2018	Yes	No
1053	FOLLOW-UP CALL	18OCT2018	VLN mentholated	18OCT2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11



## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
1054	FOLLOW-UP CALL	18OCT2018	UB non-mentholated	18OCT2018	Yes	No
1055	FOLLOW-UP CALL	18OCT2018	VLN mentholated	18OCT2018	Yes	No
1056	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1058	FOLLOW-UP CALL	18OCT2018	VLN non-mentholate	18OCT2018	Yes	No
1059	FOLLOW-UP CALL	01NOV2018	UB non-mentholated	01NOV2018	Yes	No
1060	FOLLOW-UP CALL	01NOV2018	VLN mentholated	01NOV2018	Yes	No
1063	FOLLOW-UP CALL	01NOV2018	VLN mentholated	01NOV2018	Yes	No
1066	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1069	FOLLOW-UP CALL	01NOV2018	UB non-mentholated	01NOV2018	Yes	No
1070	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1074	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1075	FOLLOW-UP CALL	01NOV2018	UB non-mentholated	01NOV2018	Yes	No
1077	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1078	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1079	FOLLOW-UP CALL	01NOV2018	VLN mentholated	01NOV2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
1082	FOLLOW-UP CALL	01NOV2018	VLN non-mentholate	01NOV2018	Yes	No
1083	FOLLOW-UP CALL	08NOV2018	VLN non-mentholate	08NOV2018	Yes	No
1086	FOLLOW-UP CALL	08NOV2018	VLN non-mentholate	08NOV2018	Yes	No
1088	FOLLOW-UP CALL	08NOV2018	VLN mentholated	08NOV2018	Yes	No
1089	FOLLOW-UP CALL	08NOV2018	UB non-mentholated	08NOV2018	Yes	No
1092	FOLLOW-UP CALL	08NOV2018	VLN mentholated	08NOV2018	Yes	No
1094	FOLLOW-UP CALL	08NOV2018	VLN mentholated	08NOV2018	Yes	No
1095	FOLLOW-UP CALL	08NOV2018	VLN mentholated	08NOV2018	Yes	No
1096	FOLLOW-UP CALL	08NOV2018	VLN non-mentholate	08NOV2018	Yes	No
1097	FOLLOW-UP CALL	08NOV2018	VLN mentholated	08NOV2018	Yes	No
1098	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1099	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1100	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1101	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1103	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
1105	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1106	FOLLOW-UP CALL	24NOV2018	UB non-mentholated	24NOV2018	Yes	No
1107	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1108	FOLLOW-UP CALL	24NOV2018	UB non-mentholated	24NOV2018	Yes	No
1109	FOLLOW-UP CALL	24NOV2018	UB non-mentholated	24NOV2018	Yes	No
1112	FOLLOW-UP CALL	24NOV2018	VLN non-mentholate	24NOV2018	Yes	No
1114	FOLLOW-UP CALL	24NOV2018	UB non-mentholated	24NOV2018	Yes	No
2002	FOLLOW-UP CALL	12SEP2018	UB mentholated	12SEP2018	Yes	No
2003	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2007	FOLLOW-UP CALL	05SEP2018	VLN non-mentholate	05SEP2018	Yes	No
2008	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2010	FOLLOW-UP CALL	05SEP2018	UB mentholated	05SEP2018	Yes	No
2011	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2014	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2015	FOLLOW-UP CALL	05SEP2018	UB mentholated	05SEP2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
2016	FOLLOW-UP CALL	10AUG2018	VLN mentholated	10AUG2018	Yes	No
2017	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2018	FOLLOW-UP CALL	05SEP2018	UB mentholated	05SEP2018	Yes	No
2020	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2021	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2023	FOLLOW-UP CALL	05SEP2018	VLN mentholated	05SEP2018	Yes	No
2025	FOLLOW-UP CALL	05SEP2018	UB non-mentholated	05SEP2018	Yes	No
2028	FOLLOW-UP CALL	05SEP2018	VLN non-mentholate	05SEP2018	Yes	No
2029	FOLLOW-UP CALL	12SEP2018	UB mentholated	12SEP2018	Yes	No
2039	FOLLOW-UP CALL	12SEP2018	VLN mentholated	12SEP2018	Yes	No
2050	FOLLOW-UP CALL	27SEP2018	UB mentholated	27SEP2018	Yes	No
2052	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2057	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2058	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2059	FOLLOW-UP CALL	27SEP2018	UB mentholated	27SEP2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
2060	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2064	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2066	FOLLOW-UP CALL	27SEP2018	VLN mentholated	27SEP2018	Yes	No
2067	FOLLOW-UP CALL	27SEP2018	VLN non-mentholate	27SEP2018	Yes	No
2076	FOLLOW-UP CALL	21OCT2018	VLN mentholated	21OCT2018	Yes	No
2086	FOLLOW-UP CALL	09OCT2018	VLN non-mentholate	09OCT2018	Yes	No
2088	FOLLOW-UP CALL	21OCT2018	VLN mentholated	21OCT2018	Yes	No
2092	FOLLOW-UP CALL	21OCT2018	VLN mentholated	21OCT2018	Yes	No
2099	FOLLOW-UP CALL	21OCT2018	VLN non-mentholate	21OCT2018	Yes	No
2100	FOLLOW-UP CALL	21OCT2018	UB mentholated	21OCT2018	Yes	No
2108	FOLLOW-UP CALL	21OCT2018	VLN non-mentholate	21OCT2018	Yes	No
2110	FOLLOW-UP CALL	27OCT2018	UB mentholated	27OCT2018	Yes	No
2119	FOLLOW-UP CALL	27OCT2018	VLN mentholated	27OCT2018	Yes	No
2120	FOLLOW-UP CALL	27OCT2018	VLN non-mentholate	27OCT2018	Yes	No
2122	FOLLOW-UP CALL	27OCT2018	UB non-mentholated	27OCT2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
2125	FOLLOW-UP CALL	27OCT2018	UB mentholated	27OCT2018	Yes	No
2126	FOLLOW-UP CALL	27OCT2018	VLN mentholated	27OCT2018	Yes	No
2140	FOLLOW-UP CALL	13NOV2018	UB non-mentholated	13NOV2018	Yes	No
2143	FOLLOW-UP CALL	13NOV2018	VLN non-mentholate	13NOV2018	Yes	No
2159	FOLLOW-UP CALL	09DEC2018	VLN non-mentholate	09DEC2018	Yes	No
2164	FOLLOW-UP CALL	09DEC2018	VLN non-mentholate	09DEC2018	Yes	No
2168	FOLLOW-UP CALL	09DEC2018	VLN non-mentholate	09DEC2018	Yes	No
2170	FOLLOW-UP CALL	09DEC2018	UB non-mentholated	09DEC2018	Yes	No
2175	FOLLOW-UP CALL	09DEC2018	UB mentholated	09DEC2018	Yes	No
2189	FOLLOW-UP CALL	13NOV2018	VLN mentholated	13NOV2018	Yes	No
2211	FOLLOW-UP CALL	09DEC2018	VLN mentholated	09DEC2018	Yes	No
2212	FOLLOW-UP CALL	09DEC2018	UB mentholated	09DEC2018	Yes	No
2213	FOLLOW-UP CALL	09DEC2018	VLN mentholated	09DEC2018	Yes	No
2215	FOLLOW-UP CALL	09DEC2018	UB mentholated	09DEC2018	Yes	No
2220	FOLLOW-UP CALL	09DEC2018	VLN non-mentholate	09DEC2018	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11

## Appendix 16.2.8.4 Phone Call (Safety Population)

Subject Number	Visit		Product Group	Date of Call	Was Tobacco Cessation Information Provided?	Did Subject Need to Return to the Clinic for a Symptom Driven Physical Exam?
	Name	Date of Call				
2235	FOLLOW-UP CALL	23DEC2018	VLN mentholated	23DEC2018	Yes	No
2244	FOLLOW-UP CALL	23DEC2018	VLN non-mentholate	23DEC2018	Yes	No
2247	FOLLOW-UP CALL	04JAN2019	VLN mentholated	04JAN2019	Yes	No
2251	FOLLOW-UP CALL	26JAN2019	UB non-mentholated	26JAN2019	Yes	No
2257	FOLLOW-UP CALL	26JAN2019	UB non-mentholated	26JAN2019	Yes	No
2259	FOLLOW-UP CALL	26JAN2019	UB mentholated	26JAN2019	Yes	No
2269	FOLLOW-UP CALL	26JAN2019	VLN mentholated	26JAN2019	Yes	No
2272	FOLLOW-UP CALL	26JAN2019	VLN mentholated	26JAN2019	Yes	No

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas\_prg/stsas/sdtm-lis/SDTM-LIS-PHO.SAS 18JUN2019 11:11