Characterization of Mainstream Tobacco Smoke

Analytical Test Report

Labstat®
Since 1976

Prepared for *Philip Morris Products SA*

Project Code: NS531-H

Original Date: February 25, 2020

Revision 1 Date: March 4, 2020

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2 USE OF LABSTAT'S[1] ANALYTICAL REPORTS

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LABSTAT makes no warranties on the CLIENT'S overall product(s). All LABSTAT reports on the results of product testing relate only to the sample(s) received and tested by LABSTAT at the time of testing. LABSTAT warrants that all sample(s) were tested in accordance with its Standard Test Procedures and in accordance with its ISO 17025 accreditation.

Any report or results furnished by LABSTAT is furnished solely for the benefit of CLIENT and any of its Designated Representative(s) and shall be the confidential property of CLIENT. CLIENT shall not at any time misrepresent, amend, or alter the content of any report or other information received from or relating to LABSTAT or its work on behalf of CLIENT.

Unless otherwise required by law, LABSTAT shall provide its report only to the Designated Representative(s).

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CLIENTS that request a re-test agree to pay additional fee if LABSTAT confirms original findings.

The CLIENT further agrees that it shall not release, nor authorize the release of, information in connection with any certificates of analysis for cannabis generated or provided by LABSTAT.

This report is the source document, and is considered to be the only official report of the results contained. Any electronic export of these results must reference this document in full.

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3 REVISION HISTORY

3.1 REVISION 1

The revision was required to address CIR-861-20. The files were split into two reports; one for each regime. The sample descriptions were also updated.

4 ADMINISTRATIVE INFORMATION

4.1 QUOTATION IDENTIFICATION

Quotation Number: 2580 (2)

Date of Quotation: January 22, 2020

Recipient's Name (b) (6)

4.2 CLIENT IDENTIFICATION

Philip Morris Products SA

Quai Jeanrenaud 5

2000 Neuchatel

Switzerland

5 SAMPLE HANDLING

5.1 CHAIN OF CUSTODY

The samples to be tested for project NS531-H were received on March 20, 2019 via DHL and on January 27, 2020 via UPS.

5.2 SAMPLE CHARACTERIZATION AND CODING

5.2.1 SAMPLE CHARACTERISTICS

The shipment received on March 20, 2019 consisted of four cartons of one product. The shipment received on January 27, 2020 consisted of 22 cartons for each of three products. There was no physical damage to cartons. Individual test items were normal in appearance.

5.2.2 SAMPLE IDENTIFICATION

The following sample codes have been used to identify the products associated with the results in each of the tables that are part of this report.

Labstat Product ID	SMP Description	Product Type	Client Product ID	Device
1002	P1M2	Heated Product (HNB, THP) Consumable	P1M2 monitor	IQOS 2.4 Plus
1772396	N/A	Cigarettes	1R6F	N/A
1773011	SMP136145	Heated Product (HNB, THP) Consumable	Marlboro Fresh Menthol HeatSticks	IQOS 3.0 US BOM
1773012	SMP136144	Heated Product (HNB, THP) Consumable	Marlboro HeatSticks	IQOS 3.0 US BOM
1773013	SMP136153	Heated Product (HNB, THP) Consumable	Marlboro Smooth Menthol HeatSticks	IQOS 3.0 US BOM

5.2.3 PHYSICAL MEASUREMENTS

Physical measurements were made on all tobacco products and no unusual findings were noted.

6 PROJECT-SPECIFIC INSTRUCTIONS

No special instructions, with respect to the selection of the test sample and/or compositing, were received. A shipment received on January 28, 2020 via contained the IQOS 3.0 US BOM devices that were used for this project. As requested by the client, Labstat provided the 1R6F research cigarettes (Lot # V062Z53D1) that were used for this project. As requested by the client, Labstat provided the P1M2 monitor (Lot # ZY51714314) that were used for this project.

- iQOS devices activated 30s prior to first puff (device warm-up).

6.1 PLATFORM I TESTING

Test sticks were used in conjunction with a "tobacco heating system" by inserting the consumable (test stick) into a cigarette holder (CH). The CH was used in conjunction with a lighter bar to smoke the test sticks. Therefore, the following requirements of the ISO standard (see section 6.2.3) were either not applicable or could not be fulfilled for technical reasons:

- Air velocity control since the consumable is inserted into the CH.
- Butt length requirement since the heating of the consumable has no effect on the consumable length which remains unchanged after smoking.
- There was no ignition of the cigarette by an external lighter.

The use of the CH, in conjunction with the lighter bar for the test samples, required the reference cigarettes to be smoked on an independent run. All reference cigarettes were smoked to the ISO standard requirements for air velocity, butt length and ignition.

6.2 PLATFORM I END POINTS

Test sticks are puffed to a fixed puff number: 12 puffs per stick under Health Canada Intense (HCI) smoking regime[2].

7 EXPERIMENTAL DESIGN AND METHODS

The following is a summary of the instructions that have been received from the client in regard to the smoking and analysis of the tobacco products in this project.

7.1 SAMPLE GENERATION

All tobacco products were conditioned and smoked under the smoking regimes outlined in the following sub-sections.

7.1.1 CIGARETTE BUTT MARKING

Prior to testing, all reference cigarettes were marked with the standard butt length as specified in ISO 4387 (2000) *"Cigarettes -- Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine".*

7.1.2 CIGARETTE CONDITIONING AND SMOKING ENVIRONMENTS

Cigarettes were conditioned and smoked under the environmental conditions specified in ISO 3402 (1999) *"Tobacco and tobacco products – Atmosphere for conditioning and testing".* With respect to conditioning, this document states "*The conditioning atmosphere shall be as follows: temperature 22 ± 1 ℃; relative humidity 60 ± 3%*". Smoking requires an environment in which the temperature is 22 ± 2°C and the relative humidity 60 ± 5%.

Mentholated sticks were conditioned in sealed packs with the cellophane on.

[2] Health Canada Intense: (55.0±0.5)ml puff volume, (30±0.5)s puff frequency, (2.00±0.02)s puff duration, bell-shaped puff profile, no vent blocking; Canadian Tobacco Reporting Regulations: 21 June, 2000, Part 3(6)(b)(iii) - *Canada Gazette Part II, Vol. 134, No. 15*

7.1.3 MACHINE SMOKING CONDITIONS

Smoking of test and reference cigarettes were carried out on either a rotary smoking machine or a linear smoking machine. The smoking parameters and smoking machine specifications which were used are set out in the International Organization for Standardization standard ISO 3308:12, ***Routine analytical cigarette-smoking machine - Definitions and standard conditions*** with modifications as noted in the table below. A single port linear smoking machine was employed in the analysis of NO/NO_x contents of mainstream smoke.

The following table is a summary of the smoking parameters that were employed in this project.

Variable	"ISO"	"Canadian Modified"
Puff Volume (ml)	35	55
Interval (sec)	60	30
Duration (sec)	2	2
Vents[3]	"open"	"fully blocked"

Note: Test samples did not have any vent blocking applied.

Mainstream yields (MS and MH) were obtained under "ISO" and "Canadian Modified" conditions (as defined above). Yields obtained using "ISO" smoking parameters are referred to as "standard" (s) and yields obtained using "Canadian Modified" smoking parameters are referred to as "non-standard" (n). Data files ending in (s) or (n) denote results obtained under the various conditions as noted in the previous sentence and in the above table.

7.2 ANALYTICAL METHODS[4]

7.2.1 SMOKE ANALYSIS

Test methods for the analysis of mainstream tobacco smoke are referenced in the table(s) below and were practiced as written unless otherwise indicated (see "Method Modifications").

[3] Health Canada 100% Vent Blocking Method
Canadian Tobacco Reporting Regulations: 21 June 2000, Part 3(6)(b)(iii) all ventilation holes must be blocked by placing over them a strip of Mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape, and the tape must be cut so that it covers the circumference and is tightly secured from the end of the filter to the tipping overwrap seam, or by another method of equivalent efficiency.

[4] The most current version available at the time of testing was used for all test methods listed.

METHODS FOR THE COLLECTION OF EMISSION DATA ON MAINSTREAM SMOKE[5]

Item	Emission	Labstat Method	Method Description
1.	Ammonia	TMS-00101 Appendix E	*Determination of Ammonia in Mainstream Tobacco Smoke*
2.	*(a)* Formaldehyde *(b)* Acetaldehyde *(c)* Acrolein *(d)* Crotonaldehyde	TMS-00104	*Determination of Selected Carbonyls in Mainstream Tobacco Smoke*
3.	*(a)* NFDPM *(b)* Nicotine *(c)* Carbon Monoxide *(d)* Water	TMS-00115a Appendix E	*Determination of "NFDPM", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke*
4.	Benzo(a)pyrene	TMS-00120 Appendix H	*Determination of Selected Polynuclear Aromatic Hydrocarbons in Mainstream Tobacco Smoke*
5.	*(a)* 1,3-Butadiene *(b)* Isoprene *(c)* Acrylonitrile *(d)* Benzene *(e)* Toluene	TMS-00124 Appendix G	*Determination of Vinyl Chloride, 1,3-Butadiene, Isoprene, Acrylonitrile, Benzene, Toluene, Styrene, and Acetamide in Mainstream Tobacco Smoke (expanded list)*
6.	*(a)* 1- aminonaphthalene *(b)* 2- aminonaphthalene *(c)* 4- aminobiphenyl	TMS-00128 Appendix G	*Determination of Aromatic Amines in Mainstream Tobacco Smoke (expanded list)*
7.	*(a)* *N*-nitrosonornicotine *(b)* 4-(*N*-nitrosomethylamino)-1-(3-pyridyl)-1-butanone	TMS-00135	*Determination of Tobacco Specific Nitrosamines in Mainstream Tobacco Smoke by High-Performance Liquid Chromatography-Tandem Mass Spectrometry*

[5] Regulations Amending the Tobacco Reporting Regulations: SOR/2019-64, March 4, 2019 Canada Gazette Part II, Volume 153, Number 6 (http://gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors64-eng.html)

Test Method numbers refer to Health Canada methodologies as listed in Tobacco Reporting Regulations referenced above and also in Consolidation Tobacco Reporting Regulations (SOR/2000-273) Current to November 19, 2019 (https://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-273/index.html

7.2.2 METHOD REFERENCES AND SYNOPSES

7.2.2.1 AMMONIA (T-101/TMS-00101)

7.2.2.1.1 METHOD SYNOPSIS

Five conditioned sticks (cigarettes) were smoked on a standard rotary smoking machine. The mainstream smoke was passed through a conditioned, pre-weighed 92mm glass fiber filter disk (pad) and then into two impingers placed in series after the pad, each containing 15mL of 0.1N sulfuric acid. The pad, after being weighed to determine the mainstream total particulate matter (TPM), was extracted with the contents of the two impingers. The mixture was then filtered through a 0.45 µm syringe filter into an auto-sampler vial and analyzed by cation exchange chromatography using an external standard calibration.

For this project, “heat-not-burn” products were “smoked” on a standard 20 port linear smoking machine using two impingers per port as smoked on a rotary machine.

7.2.2.2 CARBONYLS (T-104/TMS-00104)

7.2.2.2.1 METHOD SYNOPSIS

Two conditioned sticks (cigarettes) were smoked on a standard 20 port linear smoking machine that was fitted with Drechsel-type bottles or traps with fritted impingers. The unfiltered mainstream tobacco smoke was scrubbed of volatile carbonyls by passing each puff through an impinger into a trap containing 80mL of an acidified solution of 2,4-dinitrophenylhydrazine in acetonitrile. An aliquot of the reacted DNPH-smoke extract was then syringe-filtered and diluted with 1% trizma base in aqueous acetonitrile. The samples were subjected to reverse phase high performance liquid chromatography (HPLC) and quantified via ultra violet detection.

For the analysis of “heat-not-burn” products, no additional changes to the sample generation, collection or sample preparation of the base method for cigarettes were required.

7.2.2.3 NFDPM, NICOTINE AND CARBON MONOXIDE (T-115/TMS-00115A)

7.2.2.3.1 METHOD SYNOPSIS

Five conditioned sticks (cigarettes) were smoked using a standard 20 port linear smoking machine equipped with a CO analyzer, onto a conditioned, pre-weighed 44mm glass fiber filter disc (pad). The gas phase was collected into a Vapour Phase (VP) collection bag and then introduced into a Non-Dispersive Infra-Red (NDIR) analyzer and the % CO determined. The pad was re-weighed with the difference calculated as the Total Particulate Matter (TPM). The pad was extracted with isopropanol (IPA) containing the internal standards (trans-anethole for nicotine and methanol for water), and the extract analyzed for nicotine and water by gas chromatography (flame ionization detector (FID) for nicotine and thermal conductivity detector (TCD) for water). The nicotine-free dry particulate matter (NFDPM) value was determined by subtracting the water and nicotine from the TPM result.

For the analysis of "heat-not-burn" products, no additional changes to the sample generation, collection or sample preparation of the base method for cigarettes were required.

7.2.2.4 POLYNUCLEAR AROMATIC HYDROCARBONS (LABSTAT METHOD TMS-00120)

7.2.2.4.1 METHOD SYNOPSIS

Ten conditioned sticks (cigarettes) were smoked using a standard rotary smoking machine, onto a conditioned, pre-weighed 92mm glass fiber filter disc (pad). The pad was spiked with internal standards (d_{12}-benzo[a]pyrene, d_{14}-dibenz[a,h]anthracene, d_{10}-anthracene and d_{10}-pyrene) and extracted with 50 mL of methanol. The methanol extracts were filtered through a filter paper. A portion of filtered extract was cleaned up by Solid Phase Extraction (SPE) using a RapidTrace SPE Workstation and analyzed by gas chromatography-mass spectrometry for quantification. The mass detector was operated under Selected Ion Monitoring (SIM) mode. The ions of interest (i.e. molecular ions and in some cases specific fragment ions) were mass-selected and used for quantification.

For this project, combustible and "heat-not-burn" products were "smoked" on a standard 20 port linear smoking machine using a 44mm pad instead of a rotary smoking machine. After adding the internal standards solution to the pad, the pad was extracted with 20mL of methanol. The sample was then analyzed by GC/MS as described above.

7.2.2.5 VOLATILE ORGANICS (LABSTAT METHOD TMS-00124)

7.2.2.5.1 METHOD SYNOPSIS

Ten conditioned sticks (cigarettes) were smoked on a standard rotary smoking machine. The mainstream smoke was passed through a conditioned, pre-weighed 92mm glass fiber filter disc (pad) and then into two cryogenic traps placed in series after the pad, each containing 10mL of methanol. An aliquot of the solution from the two traps was spiked with the internal standards (d_6-benzene, d_6-vinyl acetate and d_4-furan) and analyzed by gas chromatography – mass spectrometry (GC/MS) with ion trap under full scan mode.

A second aliquot of the solution from the two traps was derivatized with 48% hydrobromic acid, then spiked with internal standards (d_4-2-bromorthanol) and analyzed for ethylene oxide via gas chromatography – mass spectrometry (GC/MS) operating under selective ion monitoring (SIM) mode.

For this project, combustible and "heat-not-burn" products were "smoked" on a standard 20 port linear smoking machine using a 44mm pad instead of a rotary smoking machine. The pad was replaced after five sticks were smoked per port for HCI smoking conditions (two pads per replicate for HCI). Lower calibrations standards were prepared and analysis of the trapping solution was done by gas chromatography – mass spectrometry (GC/MS) using a single quadrupole mass detector operating under selective ion monitoring (SIM) mode.

For the ethylene oxide analysis, a second aliquot of the trapping solution was dried on anhydrous sodium sulphate, derivatized with 48% hydrobromic acid, neutralized with sodium carbonate and spiked with the internal standards (d_4-2-bromorthanol). After centrifugation, the supernatant was analyzed with a capillary column by GC/MS operating under selective ion monitoring (SIM) mode.

7.2.2.6 AROMATIC AMINES (LABSTAT METHOD TMS-00128)

7.2.2.6.1 METHOD SYNOPSIS

Ten conditioned sticks (cigarettes) were smoked on a standard rotary smoking machine. The mainstream total particulate matter (TPM) was collected on a conditioned, pre-weighed 92mm glass fiber filter disc (pad). The pad was quartered and extracted with 100mL of 5% hydrochloric acid solution. The extraction flask was shaken for 30 minutes on a wrist-action shaker and the contents filtered into a 500mL separatory funnel. The internal standards (d_7-1-aminonaphthalene, d_7-2-aminonaphthalene, d_9-4-aminonabiphenyl, d_9-toluidine, d_8-benzidine, d_7-o-anisidine, d_5-o-aniline and d_6-2,6-dimethylaniline) were spiked into the solution. The filtrate was washed with dichloromethane, made basic with sodium hydroxide solution and extracted with hexane. The hexane extracts were dried with sodium sulphate, derivatized with pentafluoropropionic acid anhydride (PFPA) and trimethylamine, concentrated by rotary evaporation, passed through a florisil column, and quantified using gas chromatography – mass spectrometry (GC/MS) with ion trap under full scan mode.

For this project, combustible and "heat-not-burn" products were "smoked" on a standard 20 port linear smoking machine and a 44mm pad was used instead of a rotary smoking machine. The 44mm pad was replaced after five sticks were smoked per port for HCI smoking conditions (two pads per replicate for HCI). Quantification was achieved using negative chemical ionization (NCI) gas chromatography – mass spectrometry (GC/MS) operating in selective ion monitoring (SIM) mode.

7.2.2.7 TOBACCO SPECIFIC NITROSAMINES (LABSTAT METHOD TMS-00135)

7.2.2.7.1 METHOD SYNOPSIS

Five conditioned sticks (cigarettes) were smoked per port on a standard 20 port linear smoking machine. The mainstream total particulate matter (TPM) was collected on a conditioned, pre-weighed 44mm glass fiber filter disc (pad). The pad was spiked with a deuterium labeled internal standard solution (containing d_4-NNN, d_4-NAT, d_4-NAB and d_4-NNK) and then extracted with a 100mM ammonium acetate solution. The extract was then filtered and subject to LC-MS/MS analysis with positive electrospray ionization (ESI). Two mass transition pairs for each analyte can be used to assist analyte confirmation and quantification. The most intense pairs are used for quantification while the less intense transition pairs are used as qualifiers for further compound confirmation.

For the analysis of "heat-not-burn" products, no additional changes to the sample generation, collection or sample preparation of the base method for cigarettes were required.

7.3 METHOD MODIFICATIONS

Methods were followed as written (see Section 6).

8 ACCEPTANCE OF DATA

8.1 EVALUATION OF RESULTS FROM CONTROL MATERIALS

Data obtained using control materials are deemed acceptable if the data are in keeping with Labstat's database for the control material and the specific method of analysis[6]. This is not a simple problem since there is no "yes" or "no" answer but rather one which is phrased in terms of probabilities. In the approach taken by Labstat, the measure of random variation in the procedure is taken to be the sample standard deviation (S.D. or "s").

To evaluate control data accuracy, a "*Z score*" statistic is determined as follows:

$$Z\text{ - }score = \frac{\text{Sample Average - Historical Average}}{\text{Historical Standard Deviation}}$$

To evaluate control data precision, a "*Chi-square*" statistic is determined as follows:

$$Chi\text{ - }square = (\text{Sample Size - 1}) \times \frac{(\text{Sample Standard Deviation})^2}{(\text{Historical Standard Deviation})^2}$$

P values are generated and the cut-off point (α) chosen in such a way as to minimize the chance of rejecting data which are legitimate members of the set (i.e. type 1 error). Thus, in most cases where the number of observed control samples is greater than or equal to 5, z-score p-values are generated from the Standard Normal distribution.

The standard deviation rather than the standard error for the mean has been chosen when determining the 'Z score'. This allows for both project-to-project variation, which is inherent in the historical data, and the 'normal' run-to-run variability, which is present in the data set. The cut-off point for P values is a matter of judgment and has been set at 0.005 assuming the probability of falsely rejecting a data point is 0.5% (i.e. α=0.01) or less for a two tailed test.

In instances where expected values are not known, a decision to accept the data is made based on observed levels of precision in comparison with that determined for similar analyses. Also, there are circumstances where the expected value may be "Below Detection Limits". In this case the decision to accept or reject the data is made upon the ability of the method to recover the analyte of interest either in the form of a laboratory fortified blank (LFB) or laboratory fortified matrix (LFM). Acceptable recoveries are close to 100%, but vary depending on the analyte.

[6] A minimum of 30 results is normally required for the purpose of this comparison.

8.2 IDENTIFICATION OF OUTLIERS[7]

8.2.1 OUTLIER DEFINITION

An outlying observation, or "outlier," is one that appears to deviate markedly from other members of the sample in which it occurs. In this case, there are two alternatives:

1. An outlying observation may be merely an extreme manifestation of the random variability inherent in the data. If this is true, the value is retained and processed in the same manner as the other observations in the sample.
2. The observation may be the result of gross deviation from prescribed experimental procedure or an error in calculating or recording the numerical value. In such cases, an investigation must be carried out. When the experimenter is clearly aware that a gross deviation from prescribed experimental procedure has taken place, the resultant observation is discarded (assignable cause) without recourse to a statistical test. A statistical test may always be used to support a judgment that a physical reason does actually exist for an outlier, or the statistical criterion may be used routinely as a basis to initiate action to find a physical cause.

8.2.2 STATISTICAL CRITERIA

There are a number of criteria for testing outliers. In all of these, the doubtful observation is included in the calculation of the numerical value of a sample criterion (or statistic) that is then compared with a critical value. The critical value is that which would be exceeded by chance with some specified (small) probability on the assumption that all the observations did indeed constitute a random sample from a single parent population, distribution or universe. The specified small probability is called the "significance level" and can be thought of as the risk of erroneously rejecting a good observation. A level of significance of 0.02 has been chosen in conjunction with the statistical test and tables described in ASTM E178-08[8].

Significant departures from the expected results (i.e. “outliers”) are viewed seriously, requiring an investigation for an assignable cause. This is a documented procedure that, at a minimum, consists of the following steps:

1. Review of all associated calculations to ensure that arithmetic errors have not been made
2. Review of linearity range for any standards
3. Assessment of instrument status
4. Review of reagents, columns, standards etc. to ensure that contamination or decomposition has not occurred
5. Review of sample preparation and handling procedures as they relate to the result in question

[7] The term "outlier" has been defined in International Standard ISO 3534-1:2006 entitled "*Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability*"

[8] ASTM Designation: E178-08. Standard Practice for Dealing with Outlying Observations

If the outlier is present in the analyte data and an assignable cause is found, the test result is removed from the data set but recorded in the quality control section of the laboratory's record of test results for that project. The analysis must then be repeated. If the outlier is present in the ancillary[9] data and an assignable cause is found, the test result is not removed, but rather the outlying observation is replaced by the designation "AC" (Assignable Cause). If this investigation fails to determine an assignable cause, the test result is assumed to be a legitimate member of the data set and is included in all subsequent calculations.

9 RESULTS

9.1 QUALITY CONTROL

The control results for the variables of interest were acceptable as defined in section 7.1. Consequently, it is reasonable to assume that the values determined for the test samples are reflective of the characteristics of the products as received and tested as described in the Analytical Methods section.

9.2 ANALYTICAL DATA

Individual results and the corresponding sample statistics (consisting of means, standard deviations, and coefficients of variation or 95% confidence limits) may be found in the data files, labeled *NS531-H_mh_dataCF_HCI.xls*, *NS531-H_mh_dataCF_ISO.xls*, *NS531-H_mh_controlsCF_HCI.xls*, *NS531-H_mh_controlsCF_ISO.xls*, *NS531-H_ms_dataCF_HCI.xls* and *NS531-H_ms_dataCF_ISO.xls*, which accompany this report.

9.2.1 SAMPLE STATISTIC CALCULATIONS

In cases where a sample result is below the limit of detection (LOD), the average of the value zero (0) and the LOD is used in the sample statistic calculation. In cases where a sample result is between the LOD and the limit of quantification (LOQ), the average of the LOD and the LOQ is used in the sample statistic calculation.

[9] Data, which are related, but not normally required as part of the reporting process (e.g. puff counts, TPM, cigarette weights etc.). Outliers in the analyte data that have an assignable cause are always repeated.

10 ACCREDITATION

Labstat International Inc. has been accredited by the Standards Council of Canada to International Standard ISO/IEC 17025:2017 "*General requirements for the competence of testing and calibration laboratories*" with a scope[10] that includes all of the mandated tobacco-related Health Canada methods (see Tobacco Reporting Regulations dated 04 March 2019, Canada Gazette, Part II, Volume 153, Number 6, Schedules 1, 2 and 3). The testing included in this report is within the scope of this accreditation, unless otherwise noted.

Accredited LAB 368

(SCC Accreditation & Design Mark is an Official Mark of the Standards Council of Canada, used under license)

11 AUTHORIZATION

11.1 ORIGINAL

This report has been reviewed by me and is certified, to the best of my knowledge, to be a true and accurate description of the procedures, protocols and test methods used to arrive at the data and/or findings that accompany this report.

Dated: February 25, 2020

(b) (6)

Mingliang Bao, Ph.D.

Principal Scientist

Labstat International Inc.

[10] Labstat's accreditation scope is available on Standards Council of Canada website at: http://palcan.scc.ca/specs/pdf/180_e.pdf

11.2 REVISION 1

This report has been reviewed by me and is certified, to the best of my knowledge, to be a true and accurate description of the procedures, protocols and test methods used to arrive at the data and/or findings that accompany this report.

Dated: March 4, 2020

(b) (6)

Mingliang Bao, Ph.D.

Principal Scientist

Labstat International Inc.

12 APPENDIX A: "RAW" DATA AND SUMMARY STATISTICS

See Accompanying Data Files or Enclosed CD