



16.1.9.3 BIOANALYTICAL REPORTS

Determination of HEMA in Human Urine Samples by LC-MS/MS (Study AA99071-05)



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Determination of HEMA in Human Urine Samples from “A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement” by LC-MS/MS

Study: AA99071-05

Bioanalytical Final Report

Philip Morris Products S.A.
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Protocol ZRHR-REXC-03-EU

Report Date: 11-Mar-2015

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HEMA in Human Urine
Celerion Study AA99071-05

STUDY LOCATION

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APPROVAL SIGNATURES

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Bioanalytical Principal Investigator

Kirk Newland, B.S.
Technical Director, Tobacco Sciences

11-Mar-2015

Date

Management

Rafiqul Islam, M.S.
Senior Director, Bioanalytical Services

11-Mar-2015


Date



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SPONSOR
Philip Morris Products, S.A.:

Manager Clinical Science



Christelle Haziza, PhD

13.03.2015

Date



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STATEMENT OF COMPLIANCE

The bioanalytical phase of the study was performed according to applicable GLP requirements and in compliance with Standard Operating Procedures (SOPs) in effect in the bioanalytical laboratory of Celerion, Lincoln, Nebraska. The SOPs are written based on the principles and requirements described in United States Food and Drug Administration Title 21 Code of Federal Regulations (CFR) Part 58, the Guidance for Industry – Bioanalytical Method Validation (CDER, May 2001), and Guideline on Bioanalytical Method Validation (European Medicines Agency [EMA/CHMP/EWP/192217/2009], Effective February 2012).

This production study was conducted in accordance with the guidelines documented in the bioanalytical study plan. To ensure the integrity of the reported data, the bioanalytical laboratory verified all results. The Quality Assurance unit of Celerion, Lincoln, Nebraska, audited the study. A Quality Assurance statement was then issued and is included within this document.

The data summaries, results, and conclusions in this bioanalytical report have been reviewed and were found to be consistent and scientifically rational. All deviations from the protocol and/or significant deviations from SOPs documented in this report have been reviewed and are scientifically valid.

I accept responsibility for the scientific integrity of the data included within this bioanalytical report.

Kirk Newland, B.S.
Technical Director, Tobacco Sciences

11-Mar-2015

Date

HEMA in Human Urine
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Phase Audited	Audit Date(s)	Date Reported to Study Director/ Bioanalytical Principal Investigator	Date Audit Report Signed by Management
Bioanalytical Study Plan	29-Jul-2013	29-Jul-2013	29-Jul-2013
Critical Phase Inspection	25-Sep-2013	26-Sep-2013	12-May-2013
Database EDT File	05, 06-Nov-2013 01-Apr-2014	06-Nov-2013 01-Apr-2014	07-Nov-2013 09-May-2014
Bioanalytical Report (Final Draft)	09, 12-May-2014	12-May-2014	04-Sep-2014
Bioanalytical Report (Final)	10-Mar-2015	10-Mar-2015	10-Mar-2015

Celerion Quality Assurance audited various phases of this study as shown above. This statement confirms that the methods, procedures, and results as presented in this report accurately reflect the raw data of the study.

Jennifer Ortiz Torres, B.S., ASQ-CQA
Quality Assurance Auditor

12 Mar 2015

Date



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1. INTRODUCTION

The purpose of this bioanalytical study (hereafter referred to as study) was to determine the concentration of HEMA in human urine samples by a validated LC-MS/MS method. The study samples were collected in the clinical study ZRHR-REXC-03-EU, entitled, "A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement" [3]. Sample analysis was conducted between 25-Sep-2013 and 30-Oct-2013.

This report provides the results and supporting documentation from the analysis of study samples and includes an evaluation of assay performance.

2. EXPERIMENTAL

2.1. Test Item

The test items are defined in the clinical study protocol [3].

2.2. Reference Items and Internal Standards

	Analyte	Internal Standard (IS)
ID	HEMA DCHA Salt	$^{15}\text{N}^{13}\text{C}_3$ -HEMA DCHA Salt
Source	(b) (4)	(b) (4)
Lot No.	AC0102271A	AC0103004
Purity	99.2%	93.0%
Celerion Assigned Correction Factor	0.6060	0.5004
Expiry Date	05-Sep-2014	04-Oct-2014
Storage Conditions	Refrigerated (5 C), protected from light, desiccant	Refrigerated (5 C), protected from light, desiccant

The certificate(s) of analysis for the reference items and internal standards are presented in [Attachment 6](#).

Reference items and internal standards are retained under the conditions that are specified until they become expired. They will then be removed from the active library or stored for an additional period for the testing of long-term stability.

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2.3. Biological Matrix

Human urine was collected in-house at Celerion, Lincoln, Nebraska. Human urine stored at -20°C may be stored for a period less than 24 months prior to use. Human urine was screened for interference at the retention time and mass transitions of HEMA and $^{15}\text{N}^{13}\text{C}_3$ -HEMA (IS). Individual human urine lots were used to prepare quality control (QC) samples. UriSub[®] (a urine substitute) was purchased from a commercial supplier, stored at 5°C, and used to prepare calibration standards, and as control matrix.

2.4. Test System

2.4.1. Procedure and Instruments

Procedure and Instrumentation	
Extraction Method	Solid phase extraction
Chromatography system	Waters ACQUITY UPLC [®] Binary Solvent Manager [^]
MS/MS system	AB SCIEX API 5000 [™] or QTRAP [®] 5500 [^]
Regression Type	Weighted linear (1/concentration ²)
Quantitation Method	Peak area ratio
Assay Volume	0.300 mL

[^] = Qualified systems

2.4.2. Computer Application Software

Software	
LC-MS/MS software	Applied Biosystems Analyst [®] 1.5.1 [^]
LIMS	Thermo Electron Corporation Watson [™] 7.3 Bioanalytical LIMS 7.3 [^]
LIMS application	Inspector Version 1.1.1 [^]
Laboratory Documentation System	Labnotes [™] Web Client 1.21 [^]
Office applications	Microsoft [®] Office 2007 Package

[^] = Validated systems

2.5. Calibration Standards, Quality Control Samples and Dilution Quality Control Samples

Non-zero calibration standards were prepared fresh daily at the concentration levels of 0.100, 0.200, 0.400, 1.00, 2.00, 5.00, 10.0, 16.0, and 20.0 ng/mL from calibration standard spiking solutions which were prepared in bulk on 23-Sep-2013, 03-Oct-2013, and 21-Oct-2013, aliquoted and stored at -20°C for a period less than 177 days prior to use. The calibration standard spiking solutions were prepared at 20x concentrations. To achieve the required concentration, 0.025 mL of standard spiking solution was added to 0.250 mL of artificial urine.



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Quality control (QC) samples aliquoted into brown polypropylene tubes at the concentration levels of 0.239 ng/mL (low basal level + 0.0730 ng/mL), 1.50 ng/mL (mid basal level + 0.790 ng/mL) and 15.0 ng/mL (mid basal level + 14.2 ng/mL) were prepared in bulk on 20-Sep-2013, aliquoted and stored at -20°C. QC samples were stored under the same conditions as the study samples were stored. The quality control samples were analyzed within the validated stability period of 406 days. Dilution quality control samples, though listed in the study plan, were not required for this study, as no clinical samples required dilution for analysis.

Standard calibrators and quality control samples were prepared from separate stock solutions.

2.6. Study Samples

2.6.1. Sample Source and Date of Receipt

Study samples were collected between 11-Jul-2013 and 18-Sep-2013 and were received frozen on dry ice between 22-Jul-2013 and 18-Oct-2013 from Covance Central Laboratories, Meyrin, Switzerland.

2.6.2. Sample Identification

Study samples were identified based on the subject screening number and time point documented on the sample label.

2.6.3. Sample Storage and Stability

Study samples were stored from sample collection in brown polypropylene tubes to the end of sample analysis at a nominal temperature of -20°C for a duration not exceeding 112 days.

Study samples were analyzed without exceeding long-term, short-term, freeze-thaw, or post-preparative stability. The following evaluations have been conducted:

Stability Summary [5]	
Long-term Stability	262 days in brown polypropylene tubes at -20 C
Short-term Stability	27 hours in clear polypropylene tubes at ambient temperature under white light 4 hours in polypropylene tubes at ambient temperature under UV-shielded light
Cumulative Short-term Stability	53 hours in brown polypropylene tubes at ambient temperature under white light (total of all thaw cycles)
Freeze-thaw Stability	6 freeze (-20 C)-thaw (ambient temperature) cycles in brown polypropylene tubes under white light
Post-preparative Stability	205 hours in a polypropylene 96 well plate at 5 C
Processed Sample Integrity	171 hours in a polypropylene 96 well plate at 5 C
Sample Shipping Stability	8 days in brown polypropylene tubes at -80 C



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2.6.4. Sample Summary

The Sponsor's protocol specifies 160 subjects, with 7 sampling times for the 24-hour urine collections [3]. In study AA99071, a single subject discontinued from the clinical phase after randomization. The samples from this subject were analyzed and the results reported. Additional information regarding the subject discontinuance is provided in Section 8.4.

	No. of Samples
Specified in protocol/received	1120/1135
Analysis not required (subject discontinued from enrollment)	18
Duplicates received	1135
Total number of study samples analyzed	1117

Following analysis, the study samples were kept frozen at -20°C. After submission of the final bioanalytical report the study samples will be further stored under the same conditions for up to 1 month on-site. Then, upon agreement with the Sponsor, the study samples will be destroyed after the completion of the clinical study report and Sponsor notification.

3. SAMPLE ANALYSIS

3.1. Analytical Method

The determination of HEMA in human urine samples was carried out over a calibration range of 0.100 ng/mL to 20.0 ng/mL. The analytical procedure was performed at Celerion, Lincoln, Nebraska and is documented in the Method Validation Report for Celerion Study ZZ38073-01 [5]. The analytical method is documented in BAM SOP ZZ38073-01 [6]. See [Attachment 7](#).

An aliquot of human urine containing the analyte and internal standard was extracted using a solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an AB SCIEX API 5000™ or QTRAP® 5500 triple quadrupole mass spectrometers using an ESI source. Negative ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis ($1/\text{concentration}^2$) of peak area ratios of the analyte and internal standard.

Though listed as a standard, the control blank sample with internal standard (Standard A) was not used to plot the calibration curve.



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3.2. Acceptance Criteria

3.2.1. Analytical Run Acceptance Criteria

An analytical run is acceptable if all of the following criteria are met:

- at least 75% of the non-zero calibration standards were within $\pm 15.0\%$ ($\pm 20.0\%$ for the lower limit of quantification (LLOQ) calibration standard) of their nominal concentration,
- at least two-thirds of the QC samples and at least 50% at each concentration level were within $\pm 15.0\%$ of their nominal concentration,
- at least 50% of the standard zero samples are free of interference at the retention time of the analyte(s) of interest,
- at least 50% of the blank samples are free of interference both at the retention time of the analyte(s) of interest and at the retention time of the IS,
- at least two-thirds of all blank and standard zero samples fulfilled the above described interference criteria.

Interference at the retention time of the analyte of interest is defined as a response greater than 20% of the mean analyte response of the LLOQ calibration standard(s).

Interference at the retention time of the IS is defined as a response greater than 5% of the mean IS response of the LLOQ calibration standard(s).

Individual data of QC samples that were out of their acceptance criteria are flagged appropriately in the study file and in the bioanalytical report. QCs will be excluded from statistics only for analytical reasons (see [Attachment 5](#)).

3.2.2. Acceptance Criteria for System Suitability Testing

The system suitability testing performed with each analytical run is designed to assess the sensitivity, reproducibility of response (absence of response drift based on interpolated concentrations), and carry-over.

- Sensitivity assessed at the start and end of each analytical run is performed by evaluating the signal-to-noise ratio (SNR) of extracted system suitability samples spiked at the lower limit of quantitation. The SNR must be greater than 5:1 unless otherwise specified in the method.
- System stability (reproducibility of response) is performed by replicate injections at the start (5) and the end (2) of the analytical run with pooled high concentration system suitability samples. The percent coefficient of variation (% CV) of the calculated concentration must be less than or equal to 6%. The mean of the calculated concentration of the last 2 replicates or middle replicates (if applicable) of high concentration system suitability samples must be within 15% difference of the mean of the calculated concentration of the first 5 high concentration system suitability samples.

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- The carryover percentage is assessed at the beginning and end of each analytical run. This test is performed by injecting a blank (reconstitution solution) sample immediately after a high concentration system suitability sample. The area counts of the analyte in the blank injection are divided by the analyte area counts in the high concentration system suitability sample and the result is multiplied by 100.

$$\% \text{ carryover} = \left(\frac{\text{area (blank sample)}}{\text{area (high sys suit)}} \right) * 100$$

Analyte	Carryover criteria (needs to be less than)
HEMA	0.1%

3.2.3. Acceptance Criteria for ISR

The % difference was calculated for each pair of original and repeat analyses as follows:

$$\% \text{ difference} = 100 * \frac{|\text{repeat value} - \text{original value}|}{(\text{repeat value} + \text{original value}) / 2}$$

If the % difference was less than or equal to 20%, a pair of results was considered a passing match. Any pair with a % difference of more than 67% (indicating that the repeat value is either less than half or more than twice the original concentration) was considered an event and was investigated. The analytical method will be considered reproducible if at least 67% of the result pairs match. If less than 67% of the pairs match, an event investigation was initiated.

4. RESULTS

Due to rounding procedures, recalculations using the results presented in this report may differ slightly from the reported statistics.

A summary of analytical runs performed is presented in [Table 1](#).

4.1. Quality Control Sample Performance

Between-analytical run precision and accuracy results for QC samples prepared at 0.239, 1.50, and 15.0 ng/mL are summarized in [Table 2](#).

4.2. Calibration Standard Performance

Back-calculated calibration curve standard concentrations are provided in [Table 3](#).

4.3. Standard Curve Parameters

Standard curve parameters from 10 successful analytical runs are provided in [Table 4](#). A representative calibration curve is illustrated in [Figure 1](#).



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4.4. Study Sample Concentrations

Study sample concentrations are provided in [Table 5](#). The column “Split” refers to the “for analysis” or “back-up” sample collected.

Study samples, if any, with no significant peak at the mass transition and retention time of HEMA or with peak area ratios below that of the LLOQ standard, are reported as being below the limit of quantitation (BLQ).

4.5. Reassays

4.5.1. Reassays for Analytical Reasons

Study samples needing re-analysis according to [section 3.2.1](#) are identified in [Table 6](#).

4.5.2. Reassays for Non-analytical Reasons (Value Requiring Confirmation, VRC)

There were no study samples that were reassayed due to non-analytical reasons.

4.5.3. Sponsor Selected Reassays

There were no Sponsor selected reassays.

4.5.4. Incurred Sample Reproducibility

The method for the determination of HEMA was considered reproducible, 96.5% out of 113 repeat analyses met acceptance criteria as defined in [section 3.2.2](#). Results are presented in [Table 7](#).

5. CHROMATOGRAMS

Representative chromatograms are provided in [Attachment 8](#).

6. DEVIATIONS

6.1. Deviation DEV-LNK-13-0534 from ZZ38073-01 BAM SOP v2, Section 7. Extraction Procedure, occurred in which while reconstituting during Step 7, it was noticed that 0.250 mL was used instead of 0.200 mL of reconstitution solution. There was no impact, as the autosampler injection volume was able to be adjusted to account for the small difference in the amount of reconstitution solution on Analytical Run 16.

6.2. Deviation DEV-LNK-14-0232 from Celerion SOP CGSOP.0009 v1, Section 6.1 occurred when an analyst inadvertently did not record reading the BAM SOP prior to processing samples. It was confirmed that the appropriate Sciclone program was used for the analysis. There was no impact from the deviation.



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7. EVENTS

7.1. Event Observation EO-LNK-AA99071-05-13-0513 was initiated when on Analytical Run 15, injections #30, #38, #66, #124, and #133 did not contain any analyte or internal standard peaks. Test injections were performed and the original data was confirmed. An extraction issue was suspected as these samples were ISR testing samples. There was no further impact, as the ISR samples were reassayed and had acceptable values.

7.2. Event Observation EO-LNK-AA99071-05-13-0450 was initiated when on Analytical Run 8 (RI of Analytical Run 3), injection #66 did not contain any analyte or internal standard peaks. There was likely an issue during the extraction processing steps with sample #66 of Analytical Run 8 as the lack of analyte and internal standard peaks confirmed during both injections (Analytical Run 3 and 8). There was no further impact as the sample was reassayed.

8. ANALYTICAL NOTES

8.1. The following analytical runs were not included in the data set.

<u>Run ID</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
1	HEMA	Analytical Run 1 was reassayed as Analytical Run 14 due to an analyst error.
4	HEMA	Analytical Run 4 was reassayed as Analytical Run 9 due to 3 of 3 QC Bs and Cs not meeting acceptance criteria.
5	HEMA	Analytical Run 5 was reassayed as Analytical Run 7 due to an analyst error.
8	HEMA	Analytical Run 8 was reassayed as Analytical Run 10 due to 3 of 3 QC Bs and Cs not meeting acceptance criteria.

8.2. The following analytical run was not included in the data set due to instrumentation issues. The issues were resolved, and the analytical run was reinjected.

<u>Run ID</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
3	HEMA	Analytical Run 3 was reinjected as Analytical Run 8 due to unacceptable chromatography.

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8.3. The following samples from subjects that discontinued from enrollment were inadvertently assayed.

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490001114	6	0211	-1	0	1.10	1	OK	Analyzed in Error	HEMA
05111490001115	6	0211	0	1	3.93	1	OK	Analyzed in Error	HEMA
05111490000421	6	0242	-1	0	1.36	1	OK	Analyzed in Error	HEMA
05111490000422	6	0242	0	1	1.41	1	OK	Analyzed in Error	HEMA
05111490000435	6	0245	-1	0	2.01	1	OK	Analyzed in Error	HEMA
05111490000436	6	0245	0	1	4.42	1	OK	Analyzed in Error	HEMA
05111490000442	6	0247	-1	0	1.38	1	OK	Analyzed in Error	HEMA
05111490000443	6	0247	0	1	1.96	1	OK	Analyzed in Error	HEMA

8.4. During the course of analysis of study AA99077 (ZRHR-REXC-04-JP), it was determined that incomplete documentation of subject consent for further analysis of bioanalytical samples after subject discontinuation existed. A review of the possible impacted studies included ZRHR-REXC-03-EU (AA99071). One subject, 0083, discontinued from the clinical phase post-randomization. Consent for analysis was later confirmed by the Principal Investigator. The results from subject 0083 were included with the final deliverables for this study.

9. ARCHIVES

At a minimum the following records will be retained:

- Study Plan Bioanalysis (and all amendments, if applicable)
- Raw data
- Study related correspondence
- Bioanalytical report (and all amendments, if applicable)

These documents will be kept in the archives of Celerion for at least ten (10) years, taken from the date of Bioanalytical Principal Investigator's signature on the final bioanalytical report. After this time the Sponsor will be contacted to decide if the records should be retained for a further defined time at Celerion, returned to the Sponsor, or disposed of. Study data and documentation are archived at the Celerion Lincoln facility for 90 days, after which the records may be transferred to:

Iron Mountain
1601 Leavenworth
Omaha, Nebraska 68102



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10. CONCLUSION

In this bioanalytical study the concentration was determined in a total of 1117 samples for HEMA in human urine samples collected in the Philip Morris International Research and Development clinical study ZRHR-REXC-03-EU using a validated LC-MS/MS method.

The overall performance of the LC-MS/MS method met acceptance criteria and the results obtained were of the required integrity and quality. These data can be used for further interpretation.

11. REFERENCES

- [1] Guidance for Industry – Bioanalytical Method Validation: US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) May 2001
- [2] OECD Principles on Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 1, OECD Publishing, Paris, France (2003).
- [3] Protocol ZRHR-REXC-03-EU: “A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement”
- [4] Study Plan Bioanalysis: Determination of HEMA in Human Urine Samples from “A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement” by LC-MS/MS, Celerion Study AA99071-05
- [5] Validation of an LC-MS/MS Method for the Determination of HEMA in Human Urine, Celerion Study ZZ38073-01
- [6] Bioanalytical Method SOP for the Determination of HEMA in Human Urine, Celerion Study ZZ38073-01



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RESULT TABLES

Table 1 Summary of Analytical Runs Performed

R ID	Regression Status	Extraction Date	Assay Date	Description	Comment
2	Accepted	10-Oct-2013	11-Oct-2013	SEE WORKLIST FOR SUB AND TIMEPOINTS	OK
4	Rejected	25-Sep-2013	26-Sep-2013	SEE WORKLIST FOR SUBS AND TIMEPOINTS	std/qc fail acceptance
6	Accepted	10-Oct-2013	11-Oct-2013	SEE WORKLIST FOR SUB AND TIMEPOINTS	OK
7	Accepted	14-Oct-2013	15-Oct-2013	RR FAILED BATCH 5	OK
8	Rejected	25-Sep-2013	27-Sep-2013	RI of RUN-003	std/qc fail acceptance
9	Accepted	14-Oct-2013	16-Oct-2013	RR FAILED BATCH 4	OK
10	Accepted	14-Oct-2013	16-Oct-2013	RR FAILED BATCH 8	OK
11	Accepted	16-Oct-2013	16-Oct-2013	SEE WORKLIST FOR SUBS AND TIMEPOINTS	OK
12	Accepted	21-Oct-2013	23-Oct-2013	SEE WORKLIST FOR SUBS AND TIMEPOINTS	OK
13	Accepted	23-Oct-2013	23-Oct-2013	SEE WORKLIST FOR SUB AND TIMEPOINTS	OK
14	Accepted	17-Oct-2013	17-Oct-2013	RR FAILED BATCH 1	OK
15	Accepted	28-Oct-2013	28-Oct-2013	ISRs + REASSAYS	OK
16	Accepted	30-Oct-2013	30-Oct-2013	REASSAY OF 1 RS	OK

"Regression Status" reflects the status of the run with respect to run acceptance criteria



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Table 2 Quality Control Sample Data (Between-Analytical Run Precision and Accuracy)

Assay Date	Run ID	QC A	QC B	QC C
		0.239 ng/mL	1.50 ng/mL	15.0 ng/mL
11-Oct-2013	2	0.254	1.41	14.3
		0.265	1.47	14.9
11-Oct-2013	6	0.247	1.41	14.4
		0.237	1.45	14.2
		0.243	1.42	14.4
15-Oct-2013	7	0.231	1.35	13.9
		0.236	1.34	13.6
		0.229	1.29	14.6
16-Oct-2013	9	0.239	1.39	14.1
		0.248	1.36	13.8
		0.248	1.32	13.2
16-Oct-2013	10	0.240	1.47	13.9
		0.236	1.38	14.2
		0.238	1.43	14.1
16-Oct 2013	11	0.232	1.44	15.7
		0.251	1.47	15.3
		0.224	1.54	15.5
17-Oct-2013	14	0.229	1.63	15.6
		0.213	1.54	15.4
		0.223	1.46	15.7
23-Oct-2013	12	0.242	1.51	15.3
		0.260	1.42	14.8
23-Oct-2013	13	0.234	1.42	14.7
		0.232	1.45	15.2
28-Oct 2013	15	0.247	1.43	15.3
		0.234	1.51	15.1
Mean		0.239	1.44	14.7
S.D.		0.0117	0.0746	0.709
%CV		4.9	5.2	4.8
%Theoretical		100.0	96.0	98.0
%Bias		0.0	-4.0	-2.0
n		26	26	26



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Table 3 Back-calculated Calibration Standard Concentration

Assay Date	Run ID	STD B 0.100 ng/mL	STD C 0.200 ng/mL	STD D 0.400 ng/mL	STD E 1.00 ng/mL	STD F 2.00 ng/mL	STD G 5.00 ng/mL	STD H 10.0 ng/mL	STD I 16.0 ng/mL	STD J 20.0 ng/mL
11-Oct-2013	2	0.101	0.198	0.395	0.983	1.94	5.18	10.1	15.9	20.3
11-Oct-2013	6	0.100	0.201	0.393	0.981	2.00	5.12	9.95	15.8	20.4
15-Oct-2013	7	0.0987	0.206	0.398	0.989	1.95	5.19	10.4	15.9	19.1
16-Oct-2013	9	0.100	0.199	0.403	1.01	1.99	4.99	10.7	15.7	18.8
16-Oct-2013	10	0.100	0.199	0.403	0.994	2.02	5.08	9.90	16.2	19.6
16-Oct-2013	11	0.0988	0.204	0.402	1.00	1.99	4.99	10.0	15.9	19.8
17-Oct-2013	14	0.102	0.195	0.384	1.01	1.92	5.04	10.1	16.5	20.5
23-Oct-2013	12	0.0998	0.202	0.397	0.982	2.09	4.76	10.2	16.3	19.8
23-Oct-2013	13	0.101	0.200	0.393	0.977	1.99	4.88	10.2	16.5	20.1
28 Oct-2013	15	0.101	0.197	0.388	1.00	1.98	5.09	10.3	15.9	19.8
Mea		0.100	0.200	0.396	0.993	1.99	5.03	10.2	16.1	19.8
S.D		0.00103	0.00328	0.00636	0.0121	0.0472	0.134	0.238	0.291	0.549
%CV		1.0	1.6	1.6	1.2	2.4	2.7	2.3	1.8	2.8
%Bias		0.0	0.0	-1.0	0.7	-0.5	0.6	2.0	0.6	-1.0
n		10	10	10	10	10	10	10	10	10



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Table 4 Standard Curve Parameters

Assay Date	Run ID	Slope	Intercept	R-Squared
11-Oct-2013	2	0.590502714	0.000884096762	0.9994
11-Oct-2013	6	0.607692185	0.000630521966	0.9997
15-Oct-2013	7	0.602056495	0.00272047049	0.9989
16-Oct-2013	9	0.620091814	-0.00314776808	0.9985
16-Oct-2013	10	0.561578459	0.000743696837	0.9998
16-Oct-2013	11	0.757218542	-0.00229197817	0.9999
17-Oct-2013	14	0.741339207	0.00524934061	0.9990
23-Oct-2013	12	0.591585811	0.00142684474	0.9991
23-Oct-2013	13	0.675157743	-0.00218119492	0.9995
28 Oct-2013	15	0.745664522	-0.00584517135	0.9995
Mean		0.649288749	0.000725208210	0.9993
S.D.		0.0740658599	0.00311895050	0.0004
%CV		11.4	-430.1	0.0
n		10	10	10



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Table 5 Study Sample Concentrations

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000001	14	0008	-1	0	1.62	1	OK		HEMA
05111490000002	14	0008	0	1	2.33	1	OK		HEMA
05111490000003	14	0008	1	2	1.12	1	OK		HEMA
05111490000004	14	0008	2	3	0.416	1	OK		HEMA
05111490000005	14	0008	3	4	0.321	1	OK		HEMA
05111490000006	14	0008	4	5	0.524	1	OK		HEMA
05111490000007	14	0008	5	6	0.341	1	OK		HEMA
05111490000008	14	0010	-1	0	3.00	1	OK		HEMA
05111490000009	14	0010	0	1	1.33	1	OK		HEMA
05111490000010	14	0010	1	2	1.63	1	OK		HEMA
05111490000011	14	0010	2	3	1.09	1	OK		HEMA
05111490000012	14	0010	3	4	0.601	1	OK		HEMA
05111490000013	14	0010	4	5	0.847	1	OK		HEMA
05111490000014	14	0010	5	6	0.580	1	OK		HEMA
05111490000015	14	0011	-1	0	0.895	1	OK		HEMA
05111490000016	14	0011	0	1	1.32	1	OK		HEMA
05111490000017	14	0011	1	2	1.18	1	OK		HEMA
05111490000018	14	0011	2	3	0.998	1	OK		HEMA
05111490000019	14	0011	3	4	0.614	1	OK		HEMA
05111490000020	14	0011	4	5	0.835	1	OK		HEMA
05111490000021	14	0011	5	6	0.706	1	OK		HEMA
05111490000022	14	0014	-1	0	1.73	1	OK		HEMA
05111490000023	14	0014	0	1	3.42	1	OK		HEMA
05111490000024	14	0014	1	2	1.07	1	OK		HEMA
05111490000025	14	0014	2	3	0.956	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000026	14	0014	3	4	0.459	1	OK		HEMA
05111490000027	14	0014	4	5	0.511	1	OK		HEMA
05111490000028	14	0014	5	6	0.661	1	OK		HEMA
05111490000029	14	0015	-1	0	4.48	1	OK		HEMA
05111490000030	14	0015	0	1	5.04	1	OK		HEMA
05111490000031	14	0015	1	2	2.32	1	OK		HEMA
05111490000032	14	0015	2	3	2.29	1	OK		HEMA
05111490000033	13	0015	3	4	0.701	1	OK		HEMA
05111490000034	14	0015	4	5	0.874	1	OK		HEMA
05111490000035	14	0015	5	6	0.702	1	OK		HEMA
05111490000036	14	0016	-1	0	6.82	1	OK		HEMA
05111490000037	14	0016	0	1	2.33	1	OK		HEMA
05111490000038	14	0016	1	2	4.99	1	OK		HEMA
05111490000039	14	0016	2	3	2.39	1	OK		HEMA
05111490000040	14	0016	3	4	1.53	1	OK		HEMA
05111490000041	14	0016	4	5	1.86	1	OK		HEMA
05111490000042	14	0016	5	6	1.44	1	OK		HEMA
05111490000043	14	0017	-1	0	1.87	1	OK		HEMA
05111490000044	14	0017	0	1	2.04	1	OK		HEMA
05111490000045	14	0017	1	2	1.67	1	OK		HEMA
05111490000046	14	0017	2	3	2.10	1	OK		HEMA
05111490000047	14	0017	3	4	0.647	1	OK		HEMA
05111490000048	14	0017	4	5	0.997	1	OK		HEMA
05111490000049	14	0017	5	6	0.485	1	OK		HEMA
05111490000050	14	0020	-1	0	11.4	1	OK		HEMA
05111490000051	14	0020	0	1	10.5	1	OK		HEMA
05111490000052	14	0020	1	2	2.96	1	OK		HEMA
05111490000053	14	0020	2	3	1.79	1	OK		HEMA
05111490000054	14	0020	3	4	1.17	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000055	14	0020	4	5	1.79	1	OK		HEMA
05111490000056	14	0020	5	6	0.576	1	OK		HEMA
05111490000057	14	0022	-1	0	1.79	1	OK		HEMA
05111490000058	14	0022	0	1	4.27	1	OK		HEMA
05111490000059	14	0022	1	2	1.48	1	OK		HEMA
05111490000060	14	0022	2	3	0.806	1	OK		HEMA
05111490000061	14	0022	3	4	0.409	1	OK		HEMA
05111490000062	15	0022	4	5	0.390	1	OK		HEMA
05111490000063	10	0022	5	6	0.564	1	OK		HEMA
05111490000064	14	0023	-1	0	2.13	1	OK		HEMA
05111490000065	14	0023	0	1	2.36	1	OK		HEMA
05111490000066	14	0023	1	2	2.05	1	OK		HEMA
05111490000067	14	0023	2	3	2.11	1	OK		HEMA
05111490000068	14	0023	3	4	1.41	1	OK		HEMA
05111490000069	14	0023	4	5	1.27	1	OK		HEMA
05111490000070	14	0023	5	6	1.05	1	OK		HEMA
05111490000071	14	0049	-1	0	2.07	1	OK		HEMA
05111490000072	14	0049	0	1	1.34	1	OK		HEMA
05111490000073	14	0049	1	2	2.32	1	OK		HEMA
05111490000074	14	0049	2	3	1.65	1	OK		HEMA
05111490000075	14	0049	3	4	0.989	1	OK		HEMA
05111490000076	14	0049	4	5	1.07	1	OK		HEMA
05111490000077	14	0049	5	6	0.586	1	OK		HEMA
05111490000085	10	0001	-1	0	0.818	1	OK		HEMA
05111490000086	10	0001	0	1	1.03	1	OK		HEMA
05111490000087	10	0001	1	2	0.592	1	OK		HEMA
05111490000088	10	0001	2	3	0.378	1	OK		HEMA
05111490000089	10	0001	3	4	0.350	1	OK		HEMA
05111490000090	10	0001	4	5	0.340	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000091	10	0001	5	6	0.284	1	OK		HEMA
05111490000092	10	0004	-1	0	2.76	1	OK		HEMA
05111490000093	10	0004	0	1	3.97	1	OK		HEMA
05111490000094	10	0004	1	2	1.17	1	OK		HEMA
05111490000095	10	0004	2	3	0.659	1	OK		HEMA
05111490000096	10	0004	3	4	0.562	1	OK		HEMA
05111490000097	10	0004	4	5	0.654	1	OK		HEMA
05111490000098	10	0004	5	6	0.432	1	OK		HEMA
05111490000099	10	0013	-1	0	3.79	1	OK		HEMA
05111490000100	10	0013	0	1	4.82	1	OK		HEMA
05111490000101	10	0013	1	2	2.14	1	OK		HEMA
05111490000102	10	0013	2	3	1.56	1	OK		HEMA
05111490000103	10	0013	3	4	0.967	1	OK		HEMA
05111490000104	10	0013	4	5	0.965	1	OK		HEMA
05111490000105	10	0013	5	6	1.78	1	OK		HEMA
05111490000106	10	0021	-1	0	1.23	1	OK		HEMA
05111490000107	10	0021	0	1	1.63	1	OK		HEMA
05111490000108	10	0021	1	2	0.573	1	OK		HEMA
05111490000109	10	0021	2	3	2.09	1	OK		HEMA
05111490000110	10	0021	3	4	0.261	1	OK		HEMA
05111490000111	10	0021	4	5	0.295	1	OK		HEMA
05111490000112	10	0021	5	6	0.285	1	OK		HEMA
05111490000113	10	0037	-1	0	3.52	1	OK		HEMA
05111490000114	10	0037	0	1	5.91	1	OK		HEMA
05111490000115	10	0037	1	2	5.11	1	OK		HEMA
05111490000116	10	0037	2	3	4.49	1	OK		HEMA
05111490000117	10	0037	3	4	4.46	1	OK		HEMA
05111490000118	10	0037	4	5	4.91	1	OK		HEMA
05111490000119	10	0037	5	6	4.81	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000120	10	0042	-1	0	3.38	1	OK		HEMA
05111490000121	10	0042	0	1	3.57	1	OK		HEMA
05111490000122	10	0042	1	2	2.48	1	OK		HEMA
05111490000123	10	0042	2	3	0.341	1	OK		HEMA
05111490000124	10	0042	3	4	4.28	1	OK		HEMA
05111490000125	10	0042	4	5	1.80	1	OK		HEMA
05111490000126	10	0042	5	6	2.67	1	OK		HEMA
05111490000127	10	0051	-1	0	1.51	1	OK		HEMA
05111490000128	10	0051	0	1	1.10	1	OK		HEMA
05111490000129	10	0051	1	2	1.68	1	OK		HEMA
05111490000130	10	0051	2	3	1.25	1	OK		HEMA
05111490000131	10	0051	3	4	0.822	1	OK		HEMA
05111490000132	10	0051	4	5	0.744	1	OK		HEMA
05111490000133	10	0051	5	6	1.09	1	OK		HEMA
05111490000134	10	0063	-1	0	1.74	1	OK		HEMA
05111490000135	10	0063	0	1	1.77	1	OK		HEMA
05111490000136	10	0063	1	2	1.13	1	OK		HEMA
05111490000137	10	0063	2	3	0.311	1	OK		HEMA
05111490000138	10	0063	3	4	0.271	1	OK		HEMA
05111490000139	10	0063	4	5	0.292	1	OK		HEMA
05111490000140	10	0063	5	6	0.225	1	OK		HEMA
05111490000141	10	0066	-1	0	1.73	1	OK		HEMA
05111490000142	10	0066	0	1	2.08	1	OK		HEMA
05111490000143	10	0066	1	2	0.579	1	OK		HEMA
05111490000144	10	0066	2	3	0.772	1	OK		HEMA
05111490000145	10	0066	3	4	0.664	1	OK		HEMA
05111490000146	10	0066	4	5	0.368	1	OK		HEMA
05111490000147	10	0066	5	6	0.375	1	OK		HEMA
05111490000148	10	0067	-1	0	1.69	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000149	10	0067	0	1	2.56	1	OK		HEMA
05111490000150	10	0067	1	2	1.78	1	OK		HEMA
05111490000151	10	0067	2	3	1.89	1	OK		HEMA
05111490000152	10	0067	3	4	1.52	1	OK		HEMA
05111490000153	10	0067	4	5	1.36	1	OK		HEMA
05111490000154	10	0067	5	6	1.43	1	OK		HEMA
05111490000155	10	0069	-1	0	6.69	1	OK		HEMA
05111490000156	10	0069	0	1	7.42	1	OK		HEMA
05111490000157	10	0069	1	2	4.32	1	OK		HEMA
05111490000158	10	0069	2	3	1.75	1	OK		HEMA
05111490000159	10	0069	3	4	2.27	1	OK		HEMA
05111490000160	10	0069	4	5	1.81	1	OK		HEMA
05111490000161	10	0069	5	6	1.31	1	OK		HEMA
05111490000162	10	0071	-1	0	3.91	1	OK		HEMA
05111490000163	10	0071	0	1	5.92	1	OK		HEMA
05111490000164	10	0071	1	2	4.68	1	OK		HEMA
05111490000165	10	0071	2	3	2.61	1	OK		HEMA
05111490000166	10	0071	3	4	2.14	1	OK		HEMA
05111490000167	10	0071	4	5	1.61	1	OK		HEMA
05111490000168	10	0071	5	6	1.58	1	OK		HEMA
05111490000169	10	0072	-1	0	1.89	1	OK		HEMA
05111490000170	10	0072	0	1	2.39	1	OK		HEMA
05111490000171	10	0072	1	2	1.88	1	OK		HEMA
05111490000172	10	0072	2	3	2.19	1	OK		HEMA
05111490000173	10	0072	3	4	2.69	1	OK		HEMA
05111490000174	13	0072	4	5	2.16	1	OK		HEMA
05111490000175	10	0072	5	6	1.95	1	OK		HEMA
05111490000176	10	0074	-1	0	4.59	1	OK		HEMA
05111490000177	10	0074	0	1	4.39	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000178	10	0074	1	2	2.49	1	OK		HEMA
05111490000179	10	0074	2	3	1.18	1	OK		HEMA
05111490000180	10	0074	3	4	0.898	1	OK		HEMA
05111490000181	10	0074	4	5	0.758	1	OK		HEMA
05111490000182	10	0074	5	6	0.601	1	OK		HEMA
05111490000183	10	0076	-1	0	0.457	1	OK		HEMA
05111490000184	10	0076	0	1	0.496	1	OK		HEMA
05111490000185	10	0076	1	2	0.624	1	OK		HEMA
05111490000186	10	0076	2	3	0.274	1	OK		HEMA
05111490000187	10	0076	3	4	0.401	1	OK		HEMA
05111490000188	10	0076	4	5	BLQ<(0.100)	1	OK		HEMA
05111490000189	10	0076	5	6	0.220	1	OK		HEMA
05111490000190	10	0080	-1	0	3.32	1	OK		HEMA
05111490000191	10	0080	0	1	3.22	1	OK		HEMA
05111490000192	10	0080	1	2	2.78	1	OK		HEMA
05111490000193	10	0080	2	3	5.11	1	OK		HEMA
05111490000194	10	0080	3	4	1.21	1	OK		HEMA
05111490000195	10	0080	4	5	1.93	1	OK		HEMA
05111490000196	10	0080	5	6	2.47	1	OK		HEMA
05111490000197	10	0083	-1	0	1.23	1	OK		HEMA
05111490000198	10	0083	0	1	1.86	1	OK		HEMA
05111490000199	10	0083	1	2	1.00	1	OK		HEMA
05111490000200	10	0083	2	3	0.525	1	OK		HEMA
05111490000201	10	0083	3	4	0.394	1	OK		HEMA
05111490000202	10	0083	4	5	0.475	1	OK		HEMA
05111490000203	10	0083	5	6	0.359	1	OK		HEMA
05111490000204	10	0085	-1	0	1.94	1	OK		HEMA
05111490000205	10	0085	0	1	2.36	1	OK		HEMA
05111490000206	10	0085	1	2	1.29	1	OK		HEMA



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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000207	10	0085	2	3	1.10	1	OK		HEMA
05111490000211	10	0086	-1	0	5.63	1	OK		HEMA
05111490000212	10	0086	0	1	6.62	1	OK		HEMA
05111490000213	10	0086	1	2	3.21	1	OK		HEMA
05111490000214	10	0086	2	3	1.98	1	OK		HEMA
05111490000215	10	0086	3	4	1.81	1	OK		HEMA
05111490000216	10	0086	4	5	1.84	1	OK		HEMA
05111490000217	10	0086	5	6	1.80	1	OK		HEMA
05111490000218	10	0087	-1	0	7.90	1	OK		HEMA
05111490000219	10	0087	0	1	7.66	1	OK		HEMA
05111490000220	10	0087	1	2	5.69	1	OK		HEMA
05111490000221	10	0087	2	3	6.29	1	OK		HEMA
05111490000222	10	0087	3	4	6.18	1	OK		HEMA
05111490000223	10	0087	4	5	4.20	1	OK		HEMA
05111490000224	10	0087	5	6	2.03	1	OK		HEMA
05111490000225	10	0088	-1	0	1.40	1	OK		HEMA
05111490000226	10	0088	0	1	0.916	1	OK		HEMA
05111490000227	10	0088	1	2	0.913	1	OK		HEMA
05111490000228	10	0088	2	3	0.590	1	OK		HEMA
05111490000229	10	0088	3	4	0.711	1	OK		HEMA
05111490000230	10	0088	4	5	0.418	1	OK		HEMA
05111490000231	10	0088	5	6	0.555	1	OK		HEMA
05111490000232	10	0090	-1	0	0.597	1	OK		HEMA
05111490000233	10	0090	0	1	0.688	1	OK		HEMA
05111490000234	10	0090	1	2	0.616	1	OK		HEMA
05111490000235	10	0090	2	3	0.522	1	OK		HEMA
05111490000236	10	0090	3	4	0.619	1	OK		HEMA
05111490000237	10	0090	4	5	0.364	1	OK		HEMA
05111490000238	10	0090	5	6	0.281	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000239	9	0093	-1	0	3.16	1	OK		HEMA
05111490000240	9	0093	0	1	4.44	1	OK		HEMA
05111490000241	9	0093	1	2	1.88	1	OK		HEMA
05111490000242	9	0093	2	3	0.780	1	OK		HEMA
05111490000243	9	0093	3	4	0.755	1	OK		HEMA
05111490000244	9	0093	4	5	0.546	1	OK		HEMA
05111490000245	9	0093	5	6	0.505	1	OK		HEMA
05111490000246	9	0104	-1	0	4.65	1	OK		HEMA
05111490000247	9	0104	0	1	5.61	1	OK		HEMA
05111490000248	9	0104	1	2	2.37	1	OK		HEMA
05111490000249	9	0104	2	3	1.56	1	OK		HEMA
05111490000250	9	0104	3	4	1.15	1	OK		HEMA
05111490000251	9	0104	4	5	1.45	1	OK		HEMA
05111490000252	9	0104	5	6	0.669	1	OK		HEMA
05111490000253	9	0105	-1	0	7.17	1	OK		HEMA
05111490000254	9	0105	0	1	7.16	1	OK		HEMA
05111490000255	9	0105	1	2	10.5	1	OK		HEMA
05111490000256	9	0105	2	3	9.18	1	OK		HEMA
05111490000257	9	0105	3	4	6.18	1	OK		HEMA
05111490000258	9	0105	4	5	4.97	1	OK		HEMA
05111490000259	9	0105	5	6	2.66	1	OK		HEMA
05111490000260	9	0106	-1	0	0.580	1	OK		HEMA
05111490000261	9	0106	0	1	0.940	1	OK		HEMA
05111490000262	9	0106	1	2	0.493	1	OK		HEMA
05111490000263	9	0106	2	3	0.364	1	OK		HEMA
05111490000264	9	0106	3	4	0.355	1	OK		HEMA
05111490000265	9	0106	4	5	0.263	1	OK		HEMA
05111490000266	9	0106	5	6	0.270	1	OK		HEMA
05111490000267	9	0107	-1	0	5.82	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000268	9	0107	0	1	3.92	1	OK		HEMA
05111490000269	9	0107	1	2	2.85	1	OK		HEMA
05111490000270	9	0107	2	3	1.32	1	OK		HEMA
05111490000271	9	0107	3	4	2.96	1	OK		HEMA
05111490000272	9	0107	4	5	1.36	1	OK		HEMA
05111490000273	9	0107	5	6	0.826	1	OK		HEMA
05111490000274	9	0110	-1	0	2.78	1	OK		HEMA
05111490000275	9	0110	0	1	5.35	1	OK		HEMA
05111490000276	9	0110	1	2	1.95	1	OK		HEMA
05111490000277	9	0110	2	3	1.94	1	OK		HEMA
05111490000278	9	0110	3	4	1.53	1	OK		HEMA
05111490000279	9	0110	4	5	1.30	1	OK		HEMA
05111490000280	9	0110	5	6	1.34	1	OK		HEMA
05111490000281	9	0112	-1	0	2.19	1	OK		HEMA
05111490000282	9	0112	0	1	1.82	1	OK		HEMA
05111490000283	9	0112	1	2	0.875	1	OK		HEMA
05111490000284	9	0112	2	3	0.488	1	OK		HEMA
05111490000285	9	0112	3	4	0.525	1	OK		HEMA
05111490000286	9	0112	4	5	0.473	1	OK		HEMA
05111490000287	9	0112	5	6	0.647	1	OK		HEMA
05111490000288	9	0114	-1	0	4.79	1	OK		HEMA
05111490000289	9	0114	0	1	6.33	1	OK		HEMA
05111490000290	9	0114	1	2	4.18	1	OK		HEMA
05111490000291	9	0114	2	3	1.65	1	OK		HEMA
05111490000292	9	0114	3	4	1.31	1	OK		HEMA
05111490000293	9	0114	4	5	1.03	1	OK		HEMA
05111490000294	9	0114	5	6	1.42	1	OK		HEMA
05111490000295	9	0117	-1	0	6.20	1	OK		HEMA
05111490000296	9	0117	0	1	9.93	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000297	9	0117	1	2	8.78	1	OK		HEMA
05111490000298	9	0117	2	3	11.3	1	OK		HEMA
05111490000299	9	0117	3	4	9.02	1	OK		HEMA
05111490000300	9	0117	4	5	6.21	1	OK		HEMA
05111490000301	9	0117	5	6	3.80	1	OK		HEMA
05111490000302	9	0118	-1	0	1.24	1	OK		HEMA
05111490000303	9	0118	0	1	1.21	1	OK		HEMA
05111490000304	9	0118	1	2	0.973	1	OK		HEMA
05111490000305	9	0118	2	3	0.950	1	OK		HEMA
05111490000306	9	0118	3	4	1.23	1	OK		HEMA
05111490000307	9	0118	4	5	0.850	1	OK		HEMA
05111490000308	9	0118	5	6	1.06	1	OK		HEMA
05111490000309	9	0121	-1	0	3.15	1	OK		HEMA
05111490000310	9	0121	0	1	5.50	1	OK		HEMA
05111490000311	9	0121	1	2	2.81	1	OK		HEMA
05111490000312	9	0121	2	3	3.02	1	OK		HEMA
05111490000313	9	0121	3	4	2.47	1	OK		HEMA
05111490000314	9	0121	4	5	2.26	1	OK		HEMA
05111490000315	9	0121	5	6	2.10	1	OK		HEMA
05111490000316	9	0122	-1	0	5.25	1	OK		HEMA
05111490000317	9	0122	0	1	3.24	1	OK		HEMA
05111490000318	9	0122	1	2	1.75	1	OK		HEMA
05111490000319	9	0122	2	3	1.54	1	OK		HEMA
05111490000320	9	0122	3	4	1.01	1	OK		HEMA
05111490000321	9	0122	4	5	1.10	1	OK		HEMA
05111490000322	9	0122	5	6	0.618	1	OK		HEMA
05111490000323	9	0123	-1	0	0.500	1	OK		HEMA
05111490000324	9	0123	0	1	0.981	1	OK		HEMA
05111490000325	9	0123	1	2	0.851	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000326	9	0123	2	3	0.544	1	OK		HEMA
05111490000327	9	0123	3	4	0.656	1	OK		HEMA
05111490000328	9	0123	4	5	0.495	1	OK		HEMA
05111490000329	9	0.23	5	6	0.437	1	OK		HEMA
05111490000330	11	0181	-1	0	2.83	1	OK		HEMA
05111490000331	7	0181	0	1	3.72	1	OK		HEMA
05111490000332	7	0181	1	2	1.38	1	OK		HEMA
05111490000333	7	0181	2	3	0.455	1	OK		HEMA
05111490000334	7	0181	3	4	0.569	1	OK		HEMA
05111490000335	7	0181	4	5	0.542	1	OK		HEMA
05111490000336	7	0181	5	6	0.332	1	OK		HEMA
05111490000337	7	0189	-1	0	2.28	1	OK		HEMA
05111490000338	7	0189	0	1	2.67	1	OK		HEMA
05111490000339	7	0189	1	2	0.724	1	OK		HEMA
05111490000340	7	0189	2	3	0.693	1	OK		HEMA
05111490000341	7	0189	3	4	0.541	1	OK		HEMA
05111490000342	7	0189	4	5	0.796	1	OK		HEMA
05111490000343	7	0189	5	6	0.533	1	OK		HEMA
05111490000344	6	0216	-1	0	5.16	1	OK		HEMA
05111490000345	6	0216	0	1	6.97	1	OK		HEMA
05111490000346	6	0216	1	2	3.17	1	OK		HEMA
05111490000347	6	0216	2	3	1.20	1	OK		HEMA
05111490000348	12	0216	3	4	0.981	1	OK		HEMA
05111490000349	12	0216	4	5	1.31	1	OK		HEMA
05111490000350	12	0216	5	6	0.761	1	OK		HEMA
05111490000351	6	0218	-1	0	1.52	1	OK		HEMA
05111490000352	6	0218	0	1	3.76	1	OK		HEMA
05111490000353	6	0218	1	2	1.66	1	OK		HEMA
05111490000354	6	0218	2	3	1.79	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000355	12	0218	3	4	1.84	1	OK		HEMA
05111490000356	15	0218	4	5	1.61	1	OK		HEMA
05111490000357	12	0218	5	6	1.04	1	OK		HEMA
05111490000358	6	0220	-1	0	2.00	1	OK		HEMA
05111490000359	6	0220	0	1	3.05	1	OK		HEMA
05111490000360	6	0220	1	2	1.09	1	OK		HEMA
05111490000361	6	0220	2	3	0.756	1	OK		HEMA
05111490000362	12	0220	3	4	0.939	1	OK		HEMA
05111490000363	12	0220	4	5	0.955	1	OK		HEMA
05111490000364	12	0220	5	6	0.502	1	OK		HEMA
05111490000365	6	0224	-1	0	10.1	1	OK		HEMA
05111490000366	6	0224	0	1	12.8	1	OK		HEMA
05111490000367	6	0224	1	2	9.09	1	OK		HEMA
05111490000368	6	0224	2	3	10.7	1	OK		HEMA
05111490000369	12	0224	3	4	10.2	1	OK		HEMA
05111490000370	12	0224	4	5	15.5	1	OK		HEMA
05111490000371	12	0224	5	6	10.4	1	OK		HEMA
05111490000372	6	0228	-1	0	2.28	1	OK		HEMA
05111490000373	6	0228	0	1	3.39	1	OK		HEMA
05111490000374	6	0228	1	2	1.84	1	OK		HEMA
05111490000375	6	0228	2	3	0.795	1	OK		HEMA
05111490000376	12	0228	3	4	1.20	1	OK		HEMA
05111490000377	12	0228	4	5	1.80	1	OK		HEMA
05111490000378	12	0228	5	6	0.972	1	OK		HEMA
05111490000379	6	0229	-1	0	1.46	1	OK		HEMA
05111490000380	6	0229	0	1	1.36	1	OK		HEMA
05111490000381	6	0229	1	2	1.82	1	OK		HEMA
05111490000382	6	0229	2	3	1.42	1	OK		HEMA
05111490000383	12	0229	3	4	2.52	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000384	12	0229	4	5	2.71	1	OK		HEMA
05111490000385	12	0229	5	6	1.80	1	OK		HEMA
05111490000386	6	0230	-1	0	0.913	1	OK		HEMA
05111490000387	6	0230	0	1	1.24	1	OK		HEMA
05111490000388	6	0230	1	2	0.985	1	OK		HEMA
05111490000389	6	0230	2	3	1.28	1	OK		HEMA
05111490000390	12	0230	3	4	1.04	1	OK		HEMA
05111490000391	12	0230	4	5	1.51	1	OK		HEMA
05111490000392	12	0230	5	6	0.974	1	OK		HEMA
05111490000393	6	0232	-1	0	3.67	1	OK		HEMA
05111490000394	6	0232	0	1	2.87	1	OK		HEMA
05111490000395	6	0232	1	2	0.976	1	OK		HEMA
05111490000396	6	0232	2	3	0.634	1	OK		HEMA
05111490000397	12	0232	3	4	0.924	1	OK		HEMA
05111490000398	12	0232	4	5	0.988	1	OK		HEMA
05111490000399	12	0232	5	6	0.682	1	OK		HEMA
05111490000400	6	0234	-1	0	0.963	1	OK		HEMA
05111490000401	6	0234	0	1	2.15	1	OK		HEMA
05111490000402	6	0234	1	2	0.750	1	OK		HEMA
05111490000403	6	0234	2	3	0.437	1	OK		HEMA
05111490000404	12	0234	3	4	0.515	1	OK		HEMA
05111490000405	12	0234	4	5	0.562	1	OK		HEMA
05111490000406	12	0234	5	6	0.414	1	OK		HEMA
05111490000407	6	0240	-1	0	11.9	1	OK		HEMA
05111490000408	6	0240	0	1	12.9	1	OK		HEMA
05111490000409	6	0240	1	2	6.20	1	OK		HEMA
05111490000410	6	0240	2	3	1.89	1	OK		HEMA
05111490000411	12	0240	3	4	1.88	1	OK		HEMA
05111490000412	12	0240	4	5	3.90	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000413	12	0240	5	6	2.52	1	OK		HEMA
05111490000414	6	0241	-1	0	5.50	1	OK		HEMA
05111490000415	6	0241	0	1	7.65	1	OK		HEMA
05111490000416	6	0241	1	2	3.90	1	OK		HEMA
05111490000417	6	0241	2	3	2.13	1	OK		HEMA
05111490000418	12	0241	3	4	1.47	1	OK		HEMA
05111490000419	12	0241	4	5	2.31	1	OK		HEMA
05111490000420	12	0241	5	6	1.73	1	OK		HEMA
05111490000428	6	0244	-1	0	3.92	1	OK		HEMA
05111490000429	6	0244	0	1	4.75	1	OK		HEMA
05111490000430	6	0244	1	2	1.91	1	OK		HEMA
05111490000431	6	0244	2	3	1.27	1	OK		HEMA
05111490000432	12	0244	3	4	1.12	1	OK		HEMA
05111490000433	12	0244	4	5	2.47	1	OK		HEMA
05111490000434	12	0244	5	6	1.07	1	OK		HEMA
05111490000449	6	0249	-1	0	6.37	1	OK		HEMA
05111490000450	6	0249	0	1	5.34	1	OK		HEMA
05111490000451	6	0249	1	2	2.21	1	OK		HEMA
05111490000452	6	0249	2	3	1.05	1	OK		HEMA
05111490000453	12	0249	3	4	1.28	1	OK		HEMA
05111490000454	12	0249	4	5	1.49	1	OK		HEMA
05111490000455	12	0249	5	6	1.37	1	OK		HEMA
05111490000456	6	0251	-1	0	2.62	1	OK		HEMA
05111490000457	6	0251	0	1	2.04	1	OK		HEMA
05111490000458	6	0251	1	2	0.823	1	OK		HEMA
05111490000459	6	0251	2	3	0.565	1	OK		HEMA
05111490000460	12	0251	3	4	0.613	1	OK		HEMA
05111490000461	12	0251	4	5	0.768	1	OK		HEMA
05111490000462	12	0251	5	6	0.522	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000463	6	0252	-1	0	5.12	1	OK		HEMA
05111490000464	6	0252	0	1	5.49	1	OK		HEMA
05111490000465	6	0252	1	2	3.07	1	OK		HEMA
05111490000466	6	0252	2	3	2.41	1	OK		HEMA
05111490000467	12	0252	3	4	1.68	1	OK		HEMA
05111490000468	12	0252	4	5	2.94	1	OK		HEMA
05111490000469	12	0252	5	6	2.94	1	OK		HEMA
05111490000470	6	0255	-1	0	4.07	1	OK		HEMA
05111490000471	6	0255	0	1	3.69	1	OK		HEMA
05111490000472	6	0255	1	2	1.45	1	OK		HEMA
05111490000473	6	0255	2	3	1.01	1	OK		HEMA
05111490000474	12	0255	3	4	0.906	1	OK		HEMA
05111490000475	12	0255	4	5	1.58	1	OK		HEMA
05111490000476	12	0255	5	6	1.44	1	OK		HEMA
05111490000477	6	0256	-1	0	6.05	1	OK		HEMA
05111490000478	6	0256	0	1	8.67	1	OK		HEMA
05111490000479	6	0256	1	2	3.88	1	OK		HEMA
05111490000480	6	0256	2	3	2.05	1	OK		HEMA
05111490000481	12	0256	3	4	1.62	1	OK		HEMA
05111490000482	12	0256	4	5	2.25	1	OK		HEMA
05111490000483	12	0256	5	6	1.91	1	OK		HEMA
05111490000484	6	0262	-1	0	0.597	1	OK		HEMA
05111490000485	6	0262	0	1	0.610	1	OK		HEMA
05111490000486	6	0262	1	2	0.755	1	OK		HEMA
05111490000487	6	0262	2	3	0.571	1	OK		HEMA
05111490000488	12	0262	3	4	0.706	1	OK		HEMA
05111490000489	12	0262	4	5	1.11	1	OK		HEMA
05111490000490	12	0262	5	6	0.414	1	OK		HEMA
05111490000491	6	0264	-1	0	2.51	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000492	6	0264	0	1	2.82	1	OK		HEMA
05111490000493	6	0264	1	2	1.65	1	OK		HEMA
05111490000494	6	0264	2	3	1.07	1	OK		HEMA
05111490000495	12	0264	3	4	1.22	1	OK		HEMA
05111490000496	12	0264	4	5	1.59	1	OK		HEMA
05111490000497	12	0264	5	6	1.08	1	OK		HEMA
05111490000498	6	0265	-1	0	1.13	1	OK		HEMA
05111490000499	6	0265	0	1	1.03	1	OK		HEMA
05111490000500	6	0265	1	2	1.28	1	OK		HEMA
05111490000501	6	0265	2	3	0.522	1	OK		HEMA
05111490000502	12	0265	3	4	0.893	1	OK		HEMA
05111490000503	12	0265	4	5	0.767	1	OK		HEMA
05111490000504	12	0265	5	6	0.537	1	OK		HEMA
05111490000505	11	0266	-1	0	4.24	1	OK		HEMA
05111490000506	11	0266	0	1	4.02	1	OK		HEMA
05111490000507	11	0266	1	2	3.26	1	OK		HEMA
05111490000508	11	0266	2	3	1.97	1	OK		HEMA
05111490000509	15	0266	3	4	1.31	1	OK		HEMA
05111490000510	13	0266	4	5	2.08	1	OK		HEMA
05111490000511	13	0266	5	6	1.48	1	OK		HEMA
05111490000512		0269	-1	0		1	Other	Analysis not required	HEMA
05111490000513		0269	0	1		1	Other	Analysis not required	HEMA
05111490000519	11	0272	-1	0	1.15	1	OK		HEMA
05111490000520	11	0272	0	1	1.02	1	OK		HEMA
05111490000521	11	0272	1	2	0.608	1	OK		HEMA
05111490000522	11	0272	2	3	1.00	1	OK		HEMA
05111490000523	13	0272	3	4	0.957	1	OK		HEMA
05111490000524	13	0272	4	5	0.383	1	OK		HEMA
05111490000525	13	0272	5	6	0.526	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000526	11	0273	-1	0	5.54	1	OK		HEMA
05111490000527	11	0273	0	1	7.08	1	OK		HEMA
05111490000528	11	0273	1	2	3.42	1	OK		HEMA
05111490000529	11	0273	2	3	1.72	1	OK		HEMA
05111490000530	13	0273	3	4	1.30	1	OK		HEMA
05111490000531	13	0273	4	5	1.20	1	OK		HEMA
05111490000532	13	0273	5	6	0.768	1	OK		HEMA
05111490000533	11	0276	-1	0	4.21	1	OK		HEMA
05111490000534	11	0276	0	1	5.94	1	OK		HEMA
05111490000535	11	0276	1	2	4.46	1	OK		HEMA
05111490000536	11	0276	2	3	3.66	1	OK		HEMA
05111490000537	13	0276	3	4	2.29	1	OK		HEMA
05111490000538	13	0276	4	5	2.93	1	OK		HEMA
05111490000539	13	0276	5	6	2.44	1	OK		HEMA
05111490000540	11	0277	-1	0	2.45	1	OK		HEMA
05111490000541	11	0277	0	1	2.88	1	OK		HEMA
05111490000542	11	0277	1	2	1.20	1	OK		HEMA
05111490000543	11	0277	2	3	0.819	1	OK		HEMA
05111490000544	13	0277	3	4	0.589	1	OK		HEMA
05111490000545	13	0277	4	5	0.551	1	OK		HEMA
05111490000546	13	0277	5	6	0.444	1	OK		HEMA
05111490000547	11	0278	-1	0	8.75	1	OK		HEMA
05111490000548	11	0278	0	1	9.79	1	OK		HEMA
05111490000549	11	0278	1	2	11.5	1	OK		HEMA
05111490000550	11	0278	2	3	13.0	1	OK		HEMA
05111490000551	13	0278	3	4	9.82	1	OK		HEMA
05111490000552	13	0278	4	5	7.65	1	OK		HEMA
05111490000553	13	0278	5	6	5.15	1	OK		HEMA
05111490000554	11	0279	-1	0	3.91	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000555	11	0279	0	1	3.49	1	OK		HEMA
05111490000556	11	0279	1	2	2.22	1	OK		HEMA
05111490000557	11	0279	2	3	1.27	1	OK		HEMA
05111490000558	13	0279	3	4	1.20	1	OK		HEMA
05111490000559	13	0279	4	5	0.915	1	OK		HEMA
05111490000560	13	0279	5	6	0.677	1	OK		HEMA
05111490000561	11	0281	-1	0	3.45	1	OK		HEMA
05111490000562	11	0281	0	1	2.20	1	OK		HEMA
05111490000563	11	0281	1	2	1.29	1	OK		HEMA
05111490000564	11	0281	2	3	0.557	1	OK		HEMA
05111490000565	13	0281	3	4	0.612	1	OK		HEMA
05111490000566	13	0281	4	5	0.441	1	OK		HEMA
05111490000567	13	0281	5	6	0.591	1	OK		HEMA
05111490000568	11	0282	-1	0	3.50	1	OK		HEMA
05111490000569	11	0282	0	1	3.60	1	OK		HEMA
05111490000570	11	0282	1	2	1.19	1	OK		HEMA
05111490000571	11	0282	2	3	0.749	1	OK		HEMA
05111490000572	13	0282	3	4	0.514	1	OK		HEMA
05111490000573	13	0282	4	5	0.543	1	OK		HEMA
05111490000574	13	0282	5	6	0.224	1	OK		HEMA
05111490000575	11	0283	-1	0	2.08	1	OK		HEMA
05111490000576	11	0283	0	1	2.48	1	OK		HEMA
05111490000577	11	0283	1	2	1.95	1	OK		HEMA
05111490000578	11	0283	2	3	2.30	1	OK		HEMA
05111490000579	13	0283	3	4	2.35	1	OK		HEMA
05111490000580	13	0283	4	5	2.23	1	OK		HEMA
05111490000581	13	0283	5	6	1.42	1	OK		HEMA
05111490000582	11	0285	-1	0	8.43	1	OK		HEMA
05111490000583	11	0285	0	1	16.8	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000584	11	0285	1	2	12.6	1	OK		HEMA
05111490000585	11	0285	2	3	18.9	1	OK		HEMA
05111490000586	13	0285	3	4	11.5	1	OK		HEMA
05111490000587	13	0285	4	5	9.16	1	OK		HEMA
05111490000588	13	0285	5	6	10.1	1	OK		HEMA
05111490000589	11	0287	-1	0	7.34	1	OK		HEMA
05111490000590	11	0287	0	1	6.93	1	OK		HEMA
05111490000591	11	0287	1	2	3.86	1	OK		HEMA
05111490000592	11	0287	2	3	1.38	1	OK		HEMA
05111490000593	13	0287	3	4	1.15	1	OK		HEMA
05111490000594	13	0287	4	5	1.30	1	OK		HEMA
05111490000595	13	0287	5	6	1.07	1	OK		HEMA
05111490000596		0288	-1	0		1	Other	Analysis not required	HEMA
05111490000597		0288	0	1		1	Other	Analysis not required	HEMA
05111490000603	11	0289	-1	0	12.4	1	OK		HEMA
05111490000604	11	0289	0	1	12.8	1	OK		HEMA
05111490000605	11	0289	1	2	7.79	1	OK		HEMA
05111490000606	11	0289	2	3	5.55	1	OK		HEMA
05111490000607	13	0289	3	4	3.48	1	OK		HEMA
05111490000608	13	0289	4	5	3.37	1	OK		HEMA
05111490000609	13	0289	5	6	1.86	1	OK		HEMA
05111490000610	11	0291	-1	0	2.32	1	OK		HEMA
05111490000611	11	0291	0	1	2.23	1	OK		HEMA
05111490000612	11	0291	1	2	1.07	1	OK		HEMA
05111490000613	11	0291	2	3	1.03	1	OK		HEMA
05111490000614	13	0291	3	4	0.679	1	OK		HEMA
05111490000615	13	0291	4	5	1.11	1	OK		HEMA
05111490000616	13	0291	5	6	0.332	1	OK		HEMA
05111490000617	11	0292	-1	0	2.23	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000618	11	0292	0	1	3.30	1	OK		HEMA
05111490000619	11	0292	1	2	4.76	1	OK		HEMA
05111490000620	11	0292	2	3	1.92	1	OK		HEMA
05111490000621	13	0292	3	4	2.02	1	OK		HEMA
05111490000622	13	0292	4	5	1.95	1	OK		HEMA
05111490000623	13	0292	5	6	1.17	1	OK		HEMA
05111490000624	11	0296	-1	0	7.96	1	OK		HEMA
05111490000625	11	0296	0	1	7.04	1	OK		HEMA
05111490000626	11	0296	1	2	2.72	1	OK		HEMA
05111490000627	11	0296	2	3	3.47	1	OK		HEMA
05111490000628	13	0296	3	4	2.21	1	OK		HEMA
05111490000629	13	0296	4	5	3.03	1	OK		HEMA
05111490000630	13	0296	5	6	1.69	1	OK		HEMA
05111490000631	11	0298	-1	0	14.7	1	OK		HEMA
05111490000632	11	0298	0	1	18.1	1	OK		HEMA
05111490000633	11	0298	1	2	15.5	1	OK		HEMA
05111490000634	11	0298	2	3	11.9	1	OK		HEMA
05111490000635	13	0298	3	4	7.68	1	OK		HEMA
05111490000636	13	0298	4	5	9.06	1	OK		HEMA
05111490000637	13	0298	5	6	8.22	1	OK		HEMA
05111490000638		0299	-1	0		1	Other	Analysis not required	HEMA
05111490000639		0299	0	1		1	Other	Analysis not required	HEMA
05111490000645	11	0300	-1	0	8.48	1	OK		HEMA
05111490000646	11	0300	0	1	7.97	1	OK		HEMA
05111490000647	11	0300	1	2	3.28	1	OK		HEMA
05111490000648	11	0300	2	3	3.01	1	OK		HEMA
05111490000649	13	0300	3	4	2.44	1	OK		HEMA
05111490000650	13	0300	4	5	3.44	1	OK		HEMA
05111490000651	13	0300	5	6	2.19	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000652	11	0301	-1	0	1.07	1	OK		HEMA
05111490000653	11	0301	0	1	1.90	1	OK		HEMA
05111490000654	11	0301	1	2	0.850	1	OK		HEMA
05111490000655	11	0301	2	3	0.885	1	OK		HEMA
05111490000656	13	0301	3	4	1.09	1	OK		HEMA
05111490000657	13	0301	4	5	0.900	1	OK		HEMA
05111490000658	13	0301	5	6	0.593	1	OK		HEMA
05111490000659	11	0306	-1	0	1.15	1	OK		HEMA
05111490000660	11	0306	0	1	1.46	1	OK		HEMA
05111490000661	11	0306	1	2	0.925	1	OK		HEMA
05111490000662	11	0306	2	3	0.603	1	OK		HEMA
05111490000663	13	0306	3	4	0.581	1	OK		HEMA
05111490000664	13	0306	4	5	0.494	1	OK		HEMA
05111490000665	13	0306	5	6	0.592	1	OK		HEMA
05111490000666	11	0307	-1	0	10.4	1	OK		HEMA
05111490000667	11	0307	0	1	9.06	1	OK		HEMA
05111490000668	11	0307	1	2	4.61	1	OK		HEMA
05111490000669	11	0307	2	3	3.38	1	OK		HEMA
05111490000670	13	0307	3	4	2.79	1	OK		HEMA
05111490000671	13	0307	4	5	2.05	1	OK		HEMA
05111490000672	13	0307	5	6	1.75	1	OK		HEMA
05111490000673	11	0308	-1	0	1.38	1	OK		HEMA
05111490000674	11	0308	0	1	1.83	1	OK		HEMA
05111490000675	11	0308	1	2	1.27	1	OK		HEMA
05111490000676	11	0308	2	3	1.01	1	OK		HEMA
05111490000677	13	0308	3	4	0.769	1	OK		HEMA
05111490000678	13	0308	4	5	0.733	1	OK		HEMA
05111490000679	13	0308	5	6	0.914	1	OK		HEMA
05111490000680		0312	-1	0		1	Other	Analysis not required	HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000681		0312	0	1		1	Other	Analysis not required	HEMA
05111490000687	11	0313	-1	0	5.79	1	OK		HEMA
05111490000688	11	0313	0	1	6.65	1	OK		HEMA
05111490000689	11	0313	1	2	7.69	1	OK		HEMA
05111490000690	11	0313	2	3	6.11	1	OK		HEMA
05111490000691	13	0313	3	4	5.29	1	OK		HEMA
05111490000692	13	0313	4	5	6.20	1	OK		HEMA
05111490000693	13	0313	5	6	3.24	1	OK		HEMA
05111490000694	14	0025	-1	0	1.09	1	OK		HEMA
05111490000695	14	0025	0	1	1.36	1	OK		HEMA
05111490000696	14	0025	1	2	1.57	1	OK		HEMA
05111490000697	14	0025	2	3	2.82	1	OK		HEMA
05111490000698	14	0025	3	4	1.78	1	OK		HEMA
05111490000699	14	0025	4	5	2.27	1	OK		HEMA
05111490000700	14	0025	5	6	1.19	1	OK		HEMA
05111490000701	14	0028	-1	0	1.71	1	OK		HEMA
05111490000702	14	0028	0	1	2.43	1	OK		HEMA
05111490000703	14	0028	1	2	0.996	1	OK		HEMA
05111490000704	14	0028	2	3	1.58	1	OK		HEMA
05111490000705	14	0028	3	4	0.612	1	OK		HEMA
05111490000706	14	0028	4	5	0.772	1	OK		HEMA
05111490000707	14	0028	5	6	0.431	1	OK		HEMA
05111490000708	14	0029	-1	0	1.88	1	OK		HEMA
05111490000709	14	0029	0	1	1.22	1	OK		HEMA
05111490000710	14	0029	1	2	2.25	1	OK		HEMA
05111490000711	14	0029	2	3	2.76	1	OK		HEMA
05111490000712	14	0029	3	4	1.79	1	OK		HEMA
05111490000713	14	0029	4	5	0.498	1	OK		HEMA
05111490000714	14	0029	5	6	1.14	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000715	14	0030	-1	0	0.503	1	OK		HEMA
05111490000716	14	0030	0	1	1.14	1	OK		HEMA
05111490000717	14	0030	1	2	0.570	1	OK		HEMA
05111490000718	14	0030	2	3	0.488	1	OK		HEMA
05111490000719	14	0030	3	4	0.167	1	OK		HEMA
05111490000720	14	0030	4	5	0.450	1	OK		HEMA
05111490000721	14	0030	5	6	0.244	1	OK		HEMA
05111490000722	14	0031	-1	0	1.57	1	OK		HEMA
05111490000723	14	0031	0	1	3.20	1	OK		HEMA
05111490000724	14	0031	1	2	2.06	1	OK		HEMA
05111490000725	14	0031	2	3	1.87	1	OK		HEMA
05111490000726	14	0031	3	4	0.917	1	OK		HEMA
05111490000727	14	0031	4	5	0.936	1	OK		HEMA
05111490000728	14	0031	5	6	0.622	1	OK		HEMA
05111490000729	14	0034	-1	0	3.91	1	OK		HEMA
05111490000730	14	0034	0	1	4.17	1	OK		HEMA
05111490000731	14	0034	1	2	3.23	1	OK		HEMA
05111490000732	14	0034	2	3	2.19	1	OK		HEMA
05111490000733	14	0034	3	4	1.43	1	OK		HEMA
05111490000734	14	0034	4	5	1.83	1	OK		HEMA
05111490000735	14	0034	5	6	0.567	1	OK		HEMA
05111490000736	14	0035	-1	0	2.90	1	OK		HEMA
05111490000737	14	0035	0	1	3.49	1	OK		HEMA
05111490000738	14	0035	1	2	3.65	1	OK		HEMA
05111490000739	14	0035	2	3	4.11	1	OK		HEMA
05111490000740	10	0035	3	4	3.01	1	OK		HEMA
05111490000741	10	0035	4	5	3.98	1	OK		HEMA
05111490000742	10	0035	5	6	3.99	1	OK		HEMA
05111490000743	14	0038	-1	0	2.91	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000744	14	0038	0	1	2.27	1	OK		HEMA
05111490000745	14	0038	1	2	1.81	1	OK		HEMA
05111490000746	14	0038	2	3	0.871	1	OK		HEMA
05111490000747	14	0038	3	4	0.605	1	OK		HEMA
05111490000748	14	0038	4	5	0.913	1	OK		HEMA
05111490000749	14	0038	5	6	0.997	1	OK		HEMA
05111490000750	14	0039	-1	0	1.26	1	OK		HEMA
05111490000751	14	0039	0	1	1.21	1	OK		HEMA
05111490000752	14	0039	1	2	1.91	1	OK		HEMA
05111490000753	14	0039	2	3	1.20	1	OK		HEMA
05111490000754	10	0039	3	4	1.09	1	OK		HEMA
05111490000755	14	0039	4	5	1.99	1	OK		HEMA
05111490000756	14	0039	5	6	0.950	1	OK		HEMA
05111490000757	14	0044	-1	0	2.07	1	OK		HEMA
05111490000758	14	0044	0	1	3.51	1	OK		HEMA
05111490000759	14	0044	1	2	2.02	1	OK		HEMA
05111490000760	14	0044	2	3	1.40	1	OK		HEMA
05111490000761	14	0044	3	4	0.956	1	OK		HEMA
05111490000762	14	0044	4	5	1.29	1	OK		HEMA
05111490000763	14	0044	5	6	0.777	1	OK		HEMA
05111490000764	2	0052	-1	0	1.58	1	OK		HEMA
05111490000765	2	0052	0	1	2.46	1	OK		HEMA
05111490000766	2	0052	1	2	2.60	1	OK		HEMA
05111490000767	2	0052	2	3	4.21	1	OK		HEMA
05111490000768	2	0052	3	4	0.723	1	OK		HEMA
05111490000769	2	0052	4	5	1.50	1	OK		HEMA
05111490000770	2	0052	5	6	1.39	1	OK		HEMA
05111490000771	2	0053	-1	0	5.07	1	OK		HEMA
05111490000772	2	0053	0	1	3.31	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000773	2	0053	1	2	3.76	1	OK		HEMA
05111490000774	2	0053	2	3	5.09	1	OK		HEMA
05111490000775	2	0053	3	4	3.24	1	OK		HEMA
05111490000776	2	0053	4	5	3.58	1	OK		HEMA
05111490000777	2	0053	5	6	3.25	1	OK		HEMA
05111490000778	2	0055	-1	0	0.964	1	OK		HEMA
05111490000779	2	0055	0	1	0.539	1	OK		HEMA
05111490000780	2	0055	1	2	0.600	1	OK		HEMA
05111490000781	2	0055	2	3	0.717	1	OK		HEMA
05111490000782	2	0055	3	4	0.474	1	OK		HEMA
05111490000783	2	0055	4	5	0.606	1	OK		HEMA
05111490000784	2	0055	5	6	0.649	1	OK		HEMA
05111490000785	2	0057	-1	0	2.41	1	OK		HEMA
05111490000786	2	0057	0	1	1.64	1	OK		HEMA
05111490000787	2	0057	1	2	1.33	1	OK		HEMA
05111490000788	2	0057	2	3	0.518	1	OK		HEMA
05111490000789	2	0057	3	4	0.436	1	OK		HEMA
05111490000790	9	0057	4	5	0.531	1	OK		HEMA
05111490000791	13	0057	5	6	0.353	1	OK		HEMA
05111490000792	2	0060	-1	0	1.51	1	OK		HEMA
05111490000793	2	0060	0	1	3.30	1	OK		HEMA
05111490000794	2	0060	1	2	1.86	1	OK		HEMA
05111490000795	2	0060	2	3	1.64	1	OK		HEMA
05111490000796	2	0060	3	4	0.765	1	OK		HEMA
05111490000797	2	0060	4	5	1.38	1	OK		HEMA
05111490000798	2	0060	5	6	0.752	1	OK		HEMA
05111490000799	2	0062	-1	0	0.949	1	OK		HEMA
05111490000800	2	0062	0	1	1.54	1	OK		HEMA
05111490000801	2	0062	1	2	2.37	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000802	2	0062	2	3	0.934	1	OK		HEMA
05111490000803	2	0062	3	4	0.708	1	OK		HEMA
05111490000804	2	0062	4	5	0.483	1	OK		HEMA
05111490000805	9	0062	5	6	0.470	1	OK		HEMA
05111490000806	2	0064	-1	0	0.508	1	OK		HEMA
05111490000807	2	0064	0	1	2.44	1	OK		HEMA
05111490000808	2	0064	1	2	1.25	1	OK		HEMA
05111490000809	2	0064	2	3	1.55	1	OK		HEMA
05111490000810	10	0064	3	4	1.29	1	OK		HEMA
05111490000811	2	0064	4	5	1.22	1	OK		HEMA
05111490000812	2	0064	5	6	1.42	1	OK		HEMA
05111490000813	9	0126	-1	0	3.49	1	OK		HEMA
05111490000814	9	0126	0	1	3.79	1	OK		HEMA
05111490000815	9	0126	1	2	3.84	1	OK		HEMA
05111490000816	9	0126	2	3	2.59	1	OK		HEMA
05111490000817	9	0126	3	4	3.30	1	OK		HEMA
05111490000818	9	0126	4	5	3.09	1	OK		HEMA
05111490000819	9	0126	5	6	2.25	1	OK		HEMA
05111490000820	9	0127	-1	0	2.60	1	OK		HEMA
05111490000821	9	0127	0	1	0.603	1	OK		HEMA
05111490000822	9	0127	1	2	0.306	1	OK		HEMA
05111490000823	9	0127	2	3	0.202	1	OK		HEMA
05111490000824	9	0127	3	4	0.183	1	OK		HEMA
05111490000825	9	0127	4	5	0.201	1	OK		HEMA
05111490000826	9	0127	5	6	0.201	1	OK		HEMA
05111490000827	9	0128	-1	0	4.59	1	OK		HEMA
05111490000828	9	0128	0	1	3.66	1	OK		HEMA
05111490000829	9	0128	1	2	3.42	1	OK		HEMA
05111490000830	9	0128	2	3	2.20	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000831	9	0128	3	4	1.75	1	OK		HEMA
05111490000832	9	0128	4	5	1.72	1	OK		HEMA
05111490000833	9	0128	5	6	1.96	1	OK		HEMA
05111490000834	9	0129	-1	0	1.17	1	OK		HEMA
05111490000835	9	0129	0	1	1.40	1	OK		HEMA
05111490000836	9	0129	1	2	0.982	1	OK		HEMA
05111490000837	9	0129	2	3	0.640	1	OK		HEMA
05111490000838	9	0129	3	4	0.621	1	OK		HEMA
05111490000839	9	0129	4	5	0.711	1	OK		HEMA
05111490000840	9	0129	5	6	0.489	1	OK		HEMA
05111490000841	9	0130	-1	0	4.56	1	OK		HEMA
05111490000842	9	0130	0	1	4.16	1	OK		HEMA
05111490000843	9	0130	1	2	1.48	1	OK		HEMA
05111490000844	9	0130	2	3	0.707	1	OK		HEMA
05111490000845	9	0130	3	4	1.08	1	OK		HEMA
05111490000846	9	0130	4	5	1.34	1	OK		HEMA
05111490000847	9	0130	5	6	0.687	1	OK		HEMA
05111490000848	9	0133	-1	0	1.28	1	OK		HEMA
05111490000849	7	0133	0	1	2.98	1	OK		HEMA
05111490000850	7	0133	1	2	2.12	1	OK		HEMA
05111490000851	7	0133	2	3	0.441	1	OK		HEMA
05111490000852	7	0133	3	4	0.515	1	OK		HEMA
05111490000853	7	0133	4	5	0.383	1	OK		HEMA
05111490000854	7	0133	5	6	0.405	1	OK		HEMA
05111490000855	9	0134	-1	0	1.31	1	OK		HEMA
05111490000856	7	0134	0	1	0.911	1	OK		HEMA
05111490000857	7	0134	1	2	0.653	1	OK		HEMA
05111490000858	7	0134	2	3	0.464	1	OK		HEMA
05111490000859	7	0134	3	4	0.481	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000860	7	0134	4	5	0.553	1	OK		HEMA
05111490000861	7	0134	5	6	0.474	1	OK		HEMA
05111490000862	9	0136	-1	0	5.51	1	OK		HEMA
05111490000863	7	0136	0	1	3.81	1	OK		HEMA
05111490000864	7	0136	1	2	2.49	1	OK		HEMA
05111490000865	7	0136	2	3	1.01	1	OK		HEMA
05111490000866	7	0136	3	4	1.09	1	OK		HEMA
05111490000867	7	0136	4	5	0.659	1	OK		HEMA
05111490000868	7	0136	5	6	0.509	1	OK		HEMA
05111490000869	9	0137	-1	0	1.49	1	OK		HEMA
05111490000870	7	0137	0	1	1.12	1	OK		HEMA
05111490000871	7	0137	1	2	0.853	1	OK		HEMA
05111490000872	7	0137	2	3	0.465	1	OK		HEMA
05111490000873	7	0137	3	4	0.398	1	OK		HEMA
05111490000874	7	0137	4	5	0.338	1	OK		HEMA
05111490000875	7	0137	5	6	0.290	1	OK		HEMA
05111490000876	9	0139	-1	0	7.12	1	OK		HEMA
05111490000877	7	0139	0	1	11.5	1	OK		HEMA
05111490000878	7	0139	1	2	5.93	1	OK		HEMA
05111490000879	7	0139	2	3	6.81	1	OK		HEMA
05111490000880	7	0139	3	4	8.04	1	OK		HEMA
05111490000881	7	0139	4	5	7.21	1	OK		HEMA
05111490000882	7	0139	5	6	7.54	1	OK		HEMA
05111490000883	9	0140	-1	0	10.6	1	OK		HEMA
05111490000884	7	0140	0	1	11.0	1	OK		HEMA
05111490000885	7	0140	1	2	9.93	1	OK		HEMA
05111490000886	7	0140	2	3	10.4	1	OK		HEMA
05111490000887	7	0140	3	4	10.8	1	OK		HEMA
05111490000888	7	0140	4	5	8.69	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000889	7	0140	5	6	5.38	1	OK		HEMA
05111490000890	9	0145	-1	0	3.52	1	OK		HEMA
05111490000891	7	0145	0	1	3.41	1	OK		HEMA
05111490000892	7	0145	1	2	1.68	1	OK		HEMA
05111490000893	7	0145	2	3	0.571	1	OK		HEMA
05111490000894	7	0145	3	4	0.418	1	OK		HEMA
05111490000895	7	0145	4	5	0.532	1	OK		HEMA
05111490000896	7	0145	5	6	0.496	1	OK		HEMA
05111490000897	9	0147	-1	0	6.63	1	OK		HEMA
05111490000898	7	0147	0	1	8.40	1	OK		HEMA
05111490000899	7	0147	1	2	3.76	1	OK		HEMA
05111490000900	7	0147	2	3	1.27	1	OK		HEMA
05111490000901	7	0147	3	4	1.36	1	OK		HEMA
05111490000902	7	0147	4	5	2.00	1	OK		HEMA
05111490000903	7	0147	5	6	0.993	1	OK		HEMA
05111490000904	9	0148	-1	0	2.92	1	OK		HEMA
05111490000905	7	0148	0	1	2.33	1	OK		HEMA
05111490000906	7	0148	1	2	2.01	1	OK		HEMA
05111490000907	7	0148	2	3	1.54	1	OK		HEMA
05111490000908	7	0148	3	4	1.60	1	OK		HEMA
05111490000909	7	0148	4	5	1.69	1	OK		HEMA
05111490000910	7	0148	5	6	1.19	1	OK		HEMA
05111490000911	9	0149	-1	0	1.12	1	OK		HEMA
05111490000912	7	0149	0	1	0.666	1	OK		HEMA
05111490000913	7	0149	1	2	0.416	1	OK		HEMA
05111490000914	7	0149	2	3	0.385	1	OK		HEMA
05111490000915	7	0149	3	4	0.495	1	OK		HEMA
05111490000916	7	0149	4	5	0.482	1	OK		HEMA
05111490000917	7	0149	5	6	0.331	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000918	9	0150	-1	0	1.78	1	OK		HEMA
05111490000919	7	0150	0	1	1.09	1	OK		HEMA
05111490000920	7	0150	1	2	1.50	1	OK		HEMA
05111490000921	7	0150	2	3	1.25	1	OK		HEMA
05111490000922	7	0150	3	4	0.714	1	OK		HEMA
05111490000923	7	0150	4	5	0.638	1	OK		HEMA
05111490000924	7	0150	5	6	0.790	1	OK		HEMA
05111490000925	9	0152	-1	0	0.865	1	OK		HEMA
05111490000926	7	0152	0	1	0.911	1	OK		HEMA
05111490000927	7	0152	1	2	1.30	1	OK		HEMA
05111490000928	7	0152	2	3	1.33	1	OK		HEMA
05111490000929	7	0152	3	4	1.20	1	OK		HEMA
05111490000930	7	0152	4	5	1.38	1	OK		HEMA
05111490000931	7	0152	5	6	0.828	1	OK		HEMA
05111490000932	9	0153	-1	0	2.61	1	OK		HEMA
05111490000933	7	0153	0	1	2.43	1	OK		HEMA
05111490000934	7	0153	1	2	1.96	1	OK		HEMA
05111490000935	7	0153	2	3	1.14	1	OK		HEMA
05111490000936	7	0153	3	4	0.999	1	OK		HEMA
05111490000937	7	0153	4	5	1.36	1	OK		HEMA
05111490000938	7	0153	5	6	0.804	1	OK		HEMA
05111490000939	9	0155	-1	0	5.37	1	OK		HEMA
05111490000940	7	0155	0	1	7.31	1	OK		HEMA
05111490000941	7	0155	1	2	4.56	1	OK		HEMA
05111490000942	7	0155	2	3	2.60	1	OK		HEMA
05111490000943	7	0155	3	4	1.68	1	OK		HEMA
05111490000944	7	0155	4	5	2.16	1	OK		HEMA
05111490000945	7	0155	5	6	1.44	1	OK		HEMA
05111490000946	9	0156	-1	0	3.31	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000947	7	0156	0	1	3.95	1	OK		HEMA
05111490000948	7	0156	1	2	3.74	1	OK		HEMA
05111490000949	7	0156	2	3	3.43	1	OK		HEMA
05111490000950	7	0156	3	4	3.13	1	OK		HEMA
05111490000951	7	0156	4	5	4.61	1	OK		HEMA
05111490000952	7	0156	5	6	2.28	1	OK		HEMA
05111490000953	9	0160	-1	0	7.25	1	OK		HEMA
05111490000954	7	0160	0	1	6.63	1	OK		HEMA
05111490000955	7	0160	1	2	5.21	1	OK		HEMA
05111490000956	7	0160	2	3	5.49	1	OK		HEMA
05111490000957	7	0160	3	4	5.20	1	OK		HEMA
05111490000958	7	0160	4	5	5.71	1	OK		HEMA
05111490000959	7	0160	5	6	4.91	1	OK		HEMA
05111490000960	9	0162	-1	0	3.14	1	OK		HEMA
05111490000961	7	0162	0	1	3.44	1	OK		HEMA
05111490000962	7	0162	1	2	1.63	1	OK		HEMA
05111490000963	7	0162	2	3	1.13	1	OK		HEMA
05111490000964	7	0162	3	4	1.33	1	OK		HEMA
05111490000965	7	0162	4	5	0.979	1	OK		HEMA
05111490000966	7	0162	5	6	0.723	1	OK		HEMA
05111490000967	9	0167	-1	0	2.63	1	OK		HEMA
05111490000968	7	0167	0	1	3.21	1	OK		HEMA
05111490000969	7	0167	1	2	2.27	1	OK		HEMA
05111490000970	7	0167	2	3	1.59	1	OK		HEMA
05111490000971	7	0167	3	4	1.69	1	OK		HEMA
05111490000972	7	0167	4	5	1.52	1	OK		HEMA
05111490000973	7	0167	5	6	1.04	1	OK		HEMA
05111490000974	9	0169	-1	0	1.74	1	OK		HEMA
05111490000975	7	0169	0	1	1.49	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490000976	7	0169	1	2	1.48	1	OK		HEMA
05111490000977	7	0169	2	3	0.533	1	OK		HEMA
05111490000978	7	0169	3	4	0.536	1	OK		HEMA
05111490000979	7	0169	4	5	0.293	1	OK		HEMA
05111490000980	7	0169	5	6	0.390	1	OK		HEMA
05111490000981	9	0170	-1	0	3.08	1	OK		HEMA
05111490000982	7	0170	0	1	2.46	1	OK		HEMA
05111490000983	7	0170	1	2	1.07	1	OK		HEMA
05111490000984	7	0170	2	3	0.621	1	OK		HEMA
05111490000985	7	0170	3	4	0.453	1	OK		HEMA
05111490000986	7	0170	4	5	0.659	1	OK		HEMA
05111490000987	7	0170	5	6	0.452	1	OK		HEMA
05111490000988	9	0177	-1	0	2.56	1	OK		HEMA
05111490000989	7	0177	0	1	2.44	1	OK		HEMA
05111490000990	7	0177	1	2	0.956	1	OK		HEMA
05111490000991	7	0177	2	3	0.414	1	OK		HEMA
05111490000992	7	0177	3	4	0.387	1	OK		HEMA
05111490000993	7	0177	4	5	0.344	1	OK		HEMA
05111490000994	7	0177	5	6	0.386	1	OK		HEMA
05111490000995	9	0183	-1	0	1.36	1	OK		HEMA
05111490000996	7	0183	0	1	1.11	1	OK		HEMA
05111490000997	7	0183	1	2	0.518	1	OK		HEMA
05111490000998	7	0183	2	3	0.379	1	OK		HEMA
05111490000999	7	0183	3	4	0.235	1	OK		HEMA
05111490001000	7	0183	4	5	0.207	1	OK		HEMA
05111490001001	7	0183	5	6	0.249	1	OK		HEMA
05111490001002	9	0185	-1	0	16.1	1	OK		HEMA
05111490001003	7	0185	0	1	7.92	1	OK		HEMA
05111490001004	7	0185	1	2	6.13	1	OK		HEMA



HEMA in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490001005	7	0185	2	3	2.14	1	OK		HEMA
05111490001006	7	0185	3	4	1.99	1	OK		HEMA
05111490001007	7	0185	4	5	2.08	1	OK		HEMA
05111490001008	7	0185	5	6	1.69	1	OK		HEMA
05111490001009	9	0187	-1	0	4.77	1	OK		HEMA
05111490001010	7	0187	0	1	3.44	1	OK		HEMA
05111490001011	7	0187	1	2	3.63	1	OK		HEMA
05111490001012	7	0187	2	3	4.17	1	OK		HEMA
05111490001013	7	0187	3	4	6.20	1	OK		HEMA
05111490001014	7	0187	4	5	3.91	1	OK		HEMA
05111490001015	7	0187	5	6	2.47	1	OK		HEMA
05111490001016	9	0190	-1	0	2.86	1	OK		HEMA
05111490001017	6	0190	0	1	2.34	1	OK		HEMA
05111490001018	6	0190	1	2	2.60	1	OK		HEMA
05111490001019	6	0190	2	3	1.72	1	OK		HEMA
05111490001020	6	0190	3	4	1.31	1	OK		HEMA
05111490001021	6	0190	4	5	1.62	1	OK		HEMA
05111490001022	6	0190	5	6	0.987	1	OK		HEMA
05111490001023	9	0191	-1	0	1.44	1	OK		HEMA
05111490001024	6	0191	0	1	1.26	1	OK		HEMA
05111490001025	6	0191	1	2	1.21	1	OK		HEMA
05111490001026	6	0191	2	3	1.22	1	OK		HEMA
05111490001027	6	0191	3	4	1.78	1	OK		HEMA
05111490001028	6	0191	4	5	1.54	1	OK		HEMA
05111490001029	6	0191	5	6	0.954	1	OK		HEMA
05111490001030	9	0192	-1	0	17.9	1	OK		HEMA
05111490001031	6	0192	0	1	18.0	1	OK		HEMA
05111490001032	6	0192	1	2	4.61	1	OK		HEMA
05111490001033	6	0192	2	3	3.37	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490001034	6	0192	3	4	2.91	1	OK		HEMA
05111490001035	6	0192	4	5	2.60	1	OK		HEMA
05111490001036	6	0192	5	6	2.74	1	OK		HEMA
05111490001037	6	0193	-1	0	2.98	1	OK		HEMA
05111490001038	6	0193	0	1	4.63	1	OK		HEMA
05111490001039	6	0193	1	2	1.61	1	OK		HEMA
05111490001040	6	0193	2	3	0.819	1	OK		HEMA
05111490001041	11	0193	3	4	0.875	1	OK		HEMA
05111490001042	11	0193	4	5	1.31	1	OK		HEMA
05111490001043	11	0193	5	6	1.02	1	OK		HEMA
05111490001044	6	0195	-1	0	1.32	1	OK		HEMA
05111490001045	6	0195	0	1	1.54	1	OK		HEMA
05111490001046	6	0195	1	2	0.725	1	OK		HEMA
05111490001047	6	0195	2	3	0.553	1	OK		HEMA
05111490001048	11	0195	3	4	0.361	1	OK		HEMA
05111490001049	11	0195	4	5	0.855	1	OK		HEMA
05111490001050	11	0195	5	6	0.284	1	OK		HEMA
05111490001051	6	0196	-1	0	0.892	1	OK		HEMA
05111490001052	6	0196	0	1	0.898	1	OK		HEMA
05111490001053	6	0196	1	2	0.689	1	OK		HEMA
05111490001054	6	0196	2	3	0.566	1	OK		HEMA
05111490001055	11	0196	3	4	0.251	1	OK		HEMA
05111490001056	11	0196	4	5	0.766	1	OK		HEMA
05111490001057	11	0196	5	6	0.483	1	OK		HEMA
05111490001058	6	0197	-1	0	2.47	1	OK		HEMA
05111490001059	6	0197	0	1	4.24	1	OK		HEMA
05111490001060	6	0197	1	2	2.23	1	OK		HEMA
05111490001061	6	0197	2	3	1.29	1	OK		HEMA
05111490001062	11	0197	3	4	0.644	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490001063	11	0197	4	5	1.18	1	OK		HEMA
05111490001064	11	0197	5	6	0.611	1	OK		HEMA
05111490001065	6	0198	-1	0	2.18	1	OK		HEMA
05111490001066	6	0198	0	1	5.44	1	OK		HEMA
05111490001067	6	0198	1	2	3.69	1	OK		HEMA
05111490001068	6	0198	2	3	5.91	1	OK		HEMA
05111490001069	11	0198	3	4	4.59	1	OK		HEMA
05111490001070	11	0198	4	5	6.21	1	OK		HEMA
05111490001071	11	0198	5	6	4.14	1	OK		HEMA
05111490001072	6	0200	-1	0	2.79	1	OK		HEMA
05111490001073	6	0200	0	1	2.73	1	OK		HEMA
05111490001074	6	0200	1	2	1.80	1	OK		HEMA
05111490001075	6	0200	2	3	1.57	1	OK		HEMA
05111490001076	11	0200	3	4	2.00	1	OK		HEMA
05111490001077	11	0200	4	5	1.65	1	OK		HEMA
05111490001078	11	0200	5	6	1.57	1	OK		HEMA
05111490001079	6	0202	-1	0	BLQ<(0.100)	1	OK		HEMA
05111490001080	6	0202	0	1	BLQ<(0.100)	1	OK		HEMA
05111490001081	6	0202	1	2	BLQ<(0.100)	1	OK		HEMA
05111490001082	6	0202	2	3	BLQ<(0.100)	1	OK		HEMA
05111490001083	11	0202	3	4	BLQ<(0.100)	1	OK		HEMA
05111490001084	11	0202	4	5	BLQ<(0.100)	1	OK		HEMA
05111490001085	11	0202	5	6	BLQ<(0.100)	1	OK		HEMA
05111490001086	6	0203	-1	0	1.79	1	OK		HEMA
05111490001087	6	0203	0	1	1.89	1	OK		HEMA
05111490001088	6	0203	1	2	1.00	1	OK		HEMA
05111490001089	6	0203	2	3	0.819	1	OK		HEMA
05111490001090	11	0203	3	4	0.483	1	OK		HEMA
05111490001091	11	0203	4	5	0.867	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490001092	11	0203	5	6	0.568	1	OK		HEMA
05111490001093	6	0204	-1	0	3.18	1	OK		HEMA
05111490001094	6	0204	0	1	4.61	1	OK		HEMA
05111490001095	6	0204	1	2	4.62	1	OK		HEMA
05111490001096	6	0204	2	3	3.24	1	OK		HEMA
05111490001097	11	0204	3	4	5.07	1	OK		HEMA
05111490001098	11	0204	4	5	4.47	1	OK		HEMA
05111490001099	11	0204	5	6	5.00	1	OK		HEMA
05111490001100	6	0206	-1	0	3.62	1	OK		HEMA
05111490001101	6	0206	0	1	6.15	1	OK		HEMA
05111490001102	6	0206	1	2	3.83	1	OK		HEMA
05111490001103	6	0206	2	3	1.90	1	OK		HEMA
05111490001104	12	0206	3	4	1.42	1	OK		HEMA
05111490001105	12	0206	4	5	1.68	1	OK		HEMA
05111490001106	12	0206	5	6	1.08	1	OK		HEMA
05111490001107	6	0210	-1	0	7.63	1	OK		HEMA
05111490001108	6	0210	0	1	8.99	1	OK		HEMA
05111490001109	6	0210	1	2	6.01	1	OK		HEMA
05111490001110	6	0210	2	3	2.94	1	OK		HEMA
05111490001111	12	0210	3	4	2.08	1	OK		HEMA
05111490001112	12	0210	4	5	2.88	1	OK		HEMA
05111490001113	12	0210	5	6	1.30	1	OK		HEMA
05111490002248	11	0315	-1	0	1.93	1	OK		HEMA
05111490002249	11	0315	0	1	3.08	1	OK		HEMA
05111490002250	11	0315	1	2	2.14	1	OK		HEMA
05111490002251	11	0315	2	3	2.96	1	OK		HEMA
05111490002252	13	0315	3	4	2.13	1	OK		HEMA
05111490002253	13	0315	4	5	1.80	1	OK		HEMA
05111490002254	13	0315	5	6	1.46	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490002262	11	0316	-1	0	3.65	1	OK		HEMA
05111490002263	11	0316	0	1	2.99	1	OK		HEMA
05111490002264	11	0316	1	2	3.21	1	OK		HEMA
05111490002265	11	0316	2	3	2.48	1	OK		HEMA
05111490002266	13	0316	3	4	1.72	1	OK		HEMA
05111490002267	13	0316	4	5	1.83	1	OK		HEMA
05111490002268	13	0316	5	6	1.08	1	OK		HEMA
05111490002276	11	0317	-1	0	1.62	1	OK		HEMA
05111490002277	11	0317	0	1	1.77	1	OK		HEMA
05111490002278	11	0317	1	2	1.81	1	OK		HEMA
05111490002279	11	0317	2	3	1.50	1	OK		HEMA
05111490002280	13	0317	3	4	0.720	1	OK		HEMA
05111490002281	13	0317	4	5	0.683	1	OK		HEMA
05111490002282	13	0317	5	6	0.364	1	OK		HEMA
05111490002290	11	0318	-1	0	1.03	1	OK		HEMA
05111490002291	11	0318	0	1	1.17	1	OK		HEMA
05111490002292	11	0318	1	2	0.938	1	OK		HEMA
05111490002293	11	0318	2	3	1.04	1	OK		HEMA
05111490002294	13	0318	3	4	0.941	1	OK		HEMA
05111490002295	13	0318	4	5	1.25	1	OK		HEMA
05111490002296	13	0318	5	6	1.62	1	OK		HEMA
05111490002304	11	0320	-1	0	7.77	1	OK		HEMA
05111490002305	11	0320	0	1	9.30	1	OK		HEMA
05111490002306	11	0320	1	2	2.80	1	OK		HEMA
05111490002307	11	0320	2	3	1.49	1	OK		HEMA
05111490002308	13	0320	3	4	1.35	1	OK		HEMA
05111490002309	13	0320	4	5	1.47	1	OK		HEMA
05111490002310	13	0320	5	6	0.689	1	OK		HEMA
05111490002318	11	0321	-1	0	4.95	1	OK		HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05111490002319	11	0321	0	1	6.57	1	OK		HEMA
05111490002320	11	0321	1	2	2.05	1	OK		HEMA
05111490002321	11	0321	2	3	1.67	1	OK		HEMA
05111490002322	13	0321	3	4	1.32	1	OK		HEMA
05111490002323	13	0321	4	5	1.43	1	OK		HEMA
05111490002324	13	0321	5	6	1.28	1	OK		HEMA
05111490002332	11	0322	-1	0	1.27	1	OK		HEMA
05111490002333	11	0322	0	1	1.51	1	OK		HEMA
05111490002334	11	0322	1	2	0.944	1	OK		HEMA
05111490002335	11	0322	2	3	1.52	1	OK		HEMA
05111490002336	13	0322	3	4	1.29	1	OK		HEMA
05111490002337	13	0322	4	5	1.13	1	OK		HEMA
05111490002338	13	0322	5	6	0.736	1	OK		HEMA
05111490002346	11	0325	-1	0	2.87	1	OK		HEMA
05111490002347	11	0325	0	1	2.02	1	OK		HEMA
05111490002348	11	0325	1	2	3.42	1	OK		HEMA
05111490002349	11	0325	2	3	2.47	1	OK		HEMA
05111490002350	13	0325	3	4	1.96	1	OK		HEMA
05111490002351	13	0325	4	5	1.25	1	OK		HEMA
05111490002352	13	0325	5	6	1.22	1	OK		HEMA
05111490002360	11	0328	-1	0	1.45	1	OK		HEMA
05111490002361	11	0328	0	1	1.84	1	OK		HEMA
05111490002362	11	0328	1	2	0.823	1	OK		HEMA
05111490002363	11	0328	2	3	1.16	1	OK		HEMA
05111490002364	13	0328	3	4	0.978	1	OK		HEMA
05111490002365	13	0328	4	5	0.911	1	OK		HEMA
05111490002366	13	0328	5	6	0.679	1	OK		HEMA
05111490002374		0309	-1	0		1	Other	Analysis not required	HEMA
05111490002375		0309	0	1		1	Other	Analysis not required	HEMA



HEMA in Human Urine
Celerion Study AA99071-05

Table 6 Summary of Reassay for Analytical Reasons

Run ID	Reason	Sample Name
4	Fail	AA99071-05 05111490000239 0093 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000241 0093 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000242 0093 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000243 0093 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000244 0093 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000245 0093 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000246 0104 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000247 0104 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000248 0104 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000249 0104 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000250 0104 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000251 0104 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000252 0104 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000253 0105 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000254 0105 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000255 0105 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000256 0105 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000257 0105 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000258 0105 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000259 0105 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000260 0106 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000261 0106 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000262 0106 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000263 0106 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000264 0106 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000265 0106 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000266 0106 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000267 0107 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000268 0107 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000269 0107 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000270 0107 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000271 0107 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000272 0107 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000273 0107 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000274 0110 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000275 0110 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000276 0110 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000277 0110 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000278 0110 N/A P1 Day 4 URN-1



HEMA in Human Urine
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Run ID	Reason	Sample Name
4	Fail	AA99071-05 05111490000279 0110 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000280 0110 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000281 0112 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000282 0112 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000283 0112 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000284 0112 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000285 0112 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000286 0112 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000287 0112 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000288 0114 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000289 0114 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000290 0114 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000291 0114 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000292 0114 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000293 0114 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000294 0114 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000295 0117 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000297 0117 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000298 0117 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000299 0117 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000300 0117 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000301 0117 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000302 0118 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000303 0118 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000304 0118 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000305 0118 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000306 0118 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000307 0118 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000309 0121 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000310 0121 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000311 0121 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000312 0121 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000313 0121 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000314 0121 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000315 0121 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000316 0122 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000317 0122 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000318 0122 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000319 0122 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000320 0122 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000321 0122 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000322 0122 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000323 0123 N/A P1 Day 0 URN-1



HEMA in Human Urine
Celerion Study AA99071-05

Run ID	Reason	Sample Name
4	Fail	AA99071-05 05111490000324 0123 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000325 0123 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000326 0123 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000327 0123 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000328 0123 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000329 0123 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000813 0126 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000820 0127 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000827 0128 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000834 0129 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000841 0130 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000848 0133 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000855 0134 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000862 0136 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000869 0137 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000876 0139 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000883 0140 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000890 0145 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000897 0147 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000904 0148 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000911 0149 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000918 0150 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000925 0152 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000932 0153 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000939 0155 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000946 0156 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000953 0160 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000960 0162 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000967 0167 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000974 0169 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000981 0170 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000988 0177 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000995 0183 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490001002 0185 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490001009 0187 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490001016 0190 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490001023 0191 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490001030 0192 N/A P1 Day 0 URN-1
4	Fail	AA99071-05 05111490000790 0057 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000805 0062 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000240 0093 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000296 0117 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000308 0118 N/A P1 Day 6 URN-1



HEMA in Human Urine
Celerion Study AA99071-05

Run ID	Reason	Sample Name
4	Fail	AA99071-05 05111490000814 0126 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000815 0126 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000816 0126 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000817 0126 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000818 0126 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000819 0126 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000821 0127 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000822 0127 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000823 0127 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000824 0127 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000825 0127 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000826 0127 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000828 0128 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000829 0128 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000830 0128 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000831 0128 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000832 0128 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000833 0128 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000835 0129 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000836 0129 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000837 0129 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000838 0129 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000839 0129 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000840 0129 N/A P1 Day 6 URN-1
4	Fail	AA99071-05 05111490000842 0130 N/A P1 Day 1 URN-1
4	Fail	AA99071-05 05111490000843 0130 N/A P1 Day 2 URN-1
4	Fail	AA99071-05 05111490000844 0130 N/A P1 Day 3 URN-1
4	Fail	AA99071-05 05111490000845 0130 N/A P1 Day 4 URN-1
4	Fail	AA99071-05 05111490000846 0130 N/A P1 Day 5 URN-1
4	Fail	AA99071-05 05111490000847 0130 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000085 0001 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000086 0001 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000087 0001 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000088 0001 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000089 0001 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000090 0001 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000091 0001 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000092 0004 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000093 0004 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000094 0004 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000095 0004 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000096 0004 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000097 0004 N/A P1 Day 5 URN-1



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Run ID	Reason	Sample Name
8	Fail	AA99071-05 05111490000098 0004 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000099 0013 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000100 0013 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000101 0013 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000102 0013 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000103 0013 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000104 0013 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000105 0013 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000106 0021 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000107 0021 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000108 0021 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000109 0021 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000110 0021 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000111 0021 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000112 0021 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000740 0035 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000741 0035 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000742 0035 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000113 0037 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000114 0037 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000115 0037 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000116 0037 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000117 0037 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000118 0037 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000119 0037 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000754 0039 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000120 0042 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000121 0042 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000122 0042 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000123 0042 N/A P1 Day 3 URN-1
8	UISR/Fail	AA99071-05 05111490000124 0042 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000125 0042 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000126 0042 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000127 0051 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000128 0051 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000129 0051 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000130 0051 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000131 0051 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000132 0051 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000133 0051 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000134 0063 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000135 0063 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000136 0063 N/A P1 Day 2 URN-1



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Run ID	Reason	Sample Name
8	Fail	AA99071-05 05111490000137 0063 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000138 0063 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000139 0063 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000140 0063 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000810 0064 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000141 0066 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000142 0066 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000143 0066 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000144 0066 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000145 0066 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000146 0066 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000147 0066 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000148 0067 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000149 0067 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000150 0067 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000151 0067 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000152 0067 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000153 0067 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000154 0067 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000155 0069 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000156 0069 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000157 0069 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000158 0069 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000159 0069 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000160 0069 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000161 0069 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000162 0071 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000163 0071 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000164 0071 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000165 0071 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000166 0071 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000167 0071 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000168 0071 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000169 0072 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000170 0072 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000171 0072 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000172 0072 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000173 0072 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000175 0072 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000176 0074 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000177 0074 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000178 0074 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000179 0074 N/A P1 Day 3 URN-1



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Run ID	Reason	Sample Name
8	Fail	AA99071-05 05111490000180 0074 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000181 0074 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000182 0074 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000183 0076 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000184 0076 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000185 0076 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000186 0076 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000187 0076 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000188 0076 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000189 0076 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000190 0080 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000191 0080 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000192 0080 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000193 0080 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000194 0080 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000195 0080 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000196 0080 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000197 0083 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000198 0083 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000199 0083 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000200 0083 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000201 0083 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000202 0083 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000203 0083 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000204 0085 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000205 0085 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000206 0085 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000207 0085 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000211 0086 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000212 0086 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000213 0086 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000214 0086 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000215 0086 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000216 0086 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000217 0086 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000218 0087 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000219 0087 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000220 0087 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000221 0087 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000222 0087 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000223 0087 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000224 0087 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000225 0088 N/A P1 Day 0 URN-1



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Run ID	Reason	Sample Name
8	Fail	AA99071-05 05111490000226 0088 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000227 0088 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000228 0088 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000229 0088 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000230 0088 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000231 0088 N/A P1 Day 6 URN-1
8	Fail	AA99071-05 05111490000232 0090 N/A P1 Day 0 URN-1
8	Fail	AA99071-05 05111490000233 0090 N/A P1 Day 1 URN-1
8	Fail	AA99071-05 05111490000234 0090 N/A P1 Day 2 URN-1
8	Fail	AA99071-05 05111490000235 0090 N/A P1 Day 3 URN-1
8	Fail	AA99071-05 05111490000236 0090 N/A P1 Day 4 URN-1
8	Fail	AA99071-05 05111490000237 0090 N/A P1 Day 5 URN-1
8	Fail	AA99071-05 05111490000238 0090 N/A P1 Day 6 URN-1
12	UISR	AA99071-05 05111490000356 0218 N/A P1 Day 5 URN-1
13	UISR	AA99071-05 05111490000509 0266 N/A P1 Day 4 URN-1
15	UISR	AA99071-05 05111490000065 0023 N/A P1 Day 1 URN-1
15	UISR	AA99071-05 05111490000120 0042 N/A P1 Day 0 URN-1
15	UISR	AA99071-05 05111490000310 0121 N/A P1 Day 1 URN-1
15	UISR	AA99071-05 05111490000630 0296 N/A P1 Day 6 URN-1
15	UISR	AA99071-05 05111490002268 0316 N/A P1 Day 6 URN-1



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Table 7. Incurred Sample Reproducibility Assessment

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0008	1	Day 1	HEMA	ng/mL	2.33	2.30	2.32	1.29	Pass	No	96.5
0008	1	Day 6	HEMA	ng/mL	0.341	0.374	0.358	9.22	Pass	No	
0014	1	Day 1	HEMA	ng/mL	3.42	3.26	3.34	4.79	Pass	No	
0015	1	Day 6	HEMA	ng/mL	0.702	0.724	0.713	3.09	Pass	No	
0016	1	Day 0	HEMA	ng/mL	6.82	6.67	6.75	2.22	Pass	No	
0017	1	Day 6	HEMA	ng/mL	0.485	0.481	0.483	0.83	Pass	No	
0022	1	Day 4	HEMA	ng/mL	0.409	0.428	0.419	4.53	Pass	No	
0023	1	Day 6	HEMA	ng/mL	1.05	1.02	1.04	2.88	Pass	No	
0049	1	Day 2	HEMA	ng/mL	2.32	2.40	2.36	3.39	Pass	No	
0004	1	Day 1	HEMA	ng/mL	3.97	3.97	3.97	0.00	Pass	No	
0013	1	Day 1	HEMA	ng/mL	4.82	4.91	4.87	1.85	Pass	No	
0021	1	Day 5	HEMA	ng/mL	0.295	0.290	0.293	1.71	Pass	No	
0063	1	Day 1	HEMA	ng/mL	1.77	1.96	1.87	10.16	Pass	No	
0067	1	Day 1	HEMA	ng/mL	2.56	2.43	2.50	5.20	Pass	No	
0069	1	Day 6	HEMA	ng/mL	1.31	1.37	1.34	4.48	Pass	No	
0071	1	Day 6	HEMA	ng/mL	1.58	1.52	1.55	3.87	Pass	No	
0076	1	Day 4	HEMA	ng/mL	0.401	0.358	0.380	11.32	Pass	No	
0080	1	Day 3	HEMA	ng/mL	5.11	4.91	5.01	3.99	Pass	No	
0080	1	Day 4	HEMA	ng/mL	1.21	1.45	1.33	18.05	Pass	No	
0083	1	Day 1	HEMA	ng/mL	1.86	1.88	1.87	1.07	Pass	No	
0085	1	Day 3	HEMA	ng/mL	1.10	1.16	1.13	5.31	Pass	No	
0087	1	Day 0	HEMA	ng/mL	7.90	7.78	7.84	1.53	Pass	No	
0088	1	Day 5	HEMA	ng/mL	0.418	0.418	0.418	0.00	Pass	No	
0105	1	Day 3	HEMA	ng/mL	9.18	9.56	9.37	4.06	Pass	No	



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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0105	1	Day 6	HEMA	ng/mL	2.66	2.63	2.65	1.13	Pass	No	
0106	1	Day 5	HEMA	ng/mL	0.263	0.256	0.260	2.69	Pass	No	
0110	1	Day 1	HEMA	ng/mL	5.35	5.72	5.54	6.68	Pass	No	
0114	1	Day 1	HEMA	ng/mL	6.33	6.72	6.53	5.97	Pass	No	
0118	1	Day 5	HEMA	ng/mL	0.850	0.919	0.885	7.80	Pass	No	
0122	1	Day 0	HEMA	ng/mL	5.25	5.13	5.19	2.31	Pass	No	
0123	1	Day 6	HEMA	ng/mL	0.437	0.479	0.458	9.17	Pass	No	
0181	1	Day 6	HEMA	ng/mL	0.332	0.354	0.343	6.41	Pass	No	
0216	1	Day 1	HEMA	ng/mL	6.97	7.64	7.31	9.17	Pass	No	
0218	1	Day 1	HEMA	ng/mL	3.76	4.21	3.99	11.28	Pass	No	
0220	1	Day 6	HEMA	ng/mL	0.502	0.431	0.467	15.20	Pass	No	
0224	1	Day 6	HEMA	ng/mL	10.4	10.9	10.7	4.67	Pass	No	
0229	1	Day 5	HEMA	ng/mL	2.71	3.07	2.89	12.46	Pass	No	
0230	1	Day 0	HEMA	ng/mL	0.913	0.873	0.893	4.48	Pass	No	
0232	1	Day 0	HEMA	ng/mL	3.67	3.62	3.65	1.37	Pass	No	
0234	1	Day 6	HEMA	ng/mL	0.414	0.420	0.417	1.44	Pass	No	
0251	1	Day 6	HEMA	ng/mL	0.522	0.542	0.532	3.76	Pass	No	
0252	1	Day 4	HEMA	ng/mL	1.68	1.83	1.76	8.52	Pass	No	
0256	1	Day 1	HEMA	ng/mL	8.67	8.98	8.83	3.51	Pass	No	
0256	1	Day 4	HEMA	ng/mL	1.62	1.58	1.60	2.50	Pass	No	
0262	1	Day 5	HEMA	ng/mL	1.11	1.13	1.12	1.79	Pass	No	
0262	1	Day 6	HEMA	ng/mL	0.414	0.403	0.409	2.69	Pass	No	
0265	1	Day 2	HEMA	ng/mL	1.28	1.27	1.28	0.78	Pass	No	
0266	1	Day 0	HEMA	ng/mL	4.24	4.43	4.34	4.38	Pass	No	
0272	1	Day 0	HEMA	ng/mL	1.15	1.16	1.16	0.86	Pass	No	
0276	1	Day 4	HEMA	ng/mL	2.29	2.21	2.25	3.56	Pass	No	
0277	1	Day 6	HEMA	ng/mL	0.444	0.444	0.444	0.00	Pass	No	



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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0278	1	Day 6	HEMA	ng/mL	5.15	4.95	5.05	3.96	Pass	No	
0279	1	Day 0	HEMA	ng/mL	3.91	3.87	3.89	1.03	Pass	No	
0281	1	Day 0	HEMA	ng/mL	3.45	2.96	3.21	15.26	Pass	No	
0282	1	Day 5	HEMA	ng/mL	0.543	0.577	0.560	6.07	Pass	No	
0283	1	Day 6	HEMA	ng/mL	1.42	1.15	1.29	20.93	Fail	No	
0285	1	Day 1	HEMA	ng/mL	16.8	13.4	15.1	22.52	Fail	No	
0287	1	Day 6	HEMA	ng/mL	1.07	1.06	1.07	0.93	Pass	No	
0289	1	Day 0	HEMA	ng/mL	12.4	12.5	12.5	0.80	Pass	No	
0291	1	Day 0	HEMA	ng/mL	2.32	2.59	2.46	10.98	Pass	No	
0298	1	Day 1	HEMA	ng/mL	18.1	17.8	18.0	1.67	Pass	No	
0298	1	Day 4	HEMA	ng/mL	7.68	7.63	7.66	0.65	Pass	No	
0300	1	Day 6	HEMA	ng/mL	2.19	2.28	2.24	4.02	Pass	No	
0307	1	Day 0	HEMA	ng/mL	10.4	10.1	10.3	2.91	Pass	No	
0307	1	Day 6	HEMA	ng/mL	1.75	1.74	1.75	0.57	Pass	No	
0313	1	Day 2	HEMA	ng/mL	7.69	8.12	7.91	5.44	Pass	No	
0313	1	Day 6	HEMA	ng/mL	3.24	3.42	3.33	5.41	Pass	No	
0025	1	Day 3	HEMA	ng/mL	2.82	2.38	2.60	16.92	Pass	No	
0028	1	Day 6	HEMA	ng/mL	0.431	0.452	0.442	4.75	Pass	No	
0034	1	Day 6	HEMA	ng/mL	0.567	0.567	0.567	0.00	Pass	No	
0035	1	Day 3	HEMA	ng/mL	4.11	4.21	4.16	2.40	Pass	No	
0039	1	Day 4	HEMA	ng/mL	1.09	1.10	1.10	0.91	Pass	No	
0044	1	Day 1	HEMA	ng/mL	3.51	3.71	3.61	5.54	Pass	No	
0052	1	Day 3	HEMA	ng/mL	4.21	5.48	4.85	26.19	Fail	No	
0053	1	Day 4	HEMA	ng/mL	3.24	4.03	3.64	21.70	Fail	No	
0055	1	Day 0	HEMA	ng/mL	0.964	0.918	0.941	4.89	Pass	No	
0055	1	Day 4	HEMA	ng/mL	0.474	0.502	0.488	5.74	Pass	No	
0060	1	Day 2	HEMA	ng/mL	1.86	1.79	1.83	3.83	Pass	No	



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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0064	1	Day 0	HEMA	ng/mL	0.508	0.487	0.498	4.22	Pass	No	
0064	1	Day 1	HEMA	ng/mL	2.44	2.50	2.47	2.43	Pass	No	
0127	1	Day 2	HEMA	ng/mL	0.306	0.335	0.321	9.03	Pass	No	
0128	1	Day 0	HEMA	ng/mL	4.59	4.43	4.51	3.55	Pass	No	
0129	1	Day 1	HEMA	ng/mL	1.40	1.26	1.33	10.53	Pass	No	
0130	1	Day 0	HEMA	ng/mL	4.56	3.97	4.27	13.82	Pass	No	
0133	1	Day 6	HEMA	ng/mL	0.405	0.444	0.425	9.18	Pass	No	
0137	1	Day 0	HEMA	ng/mL	1.49	1.51	1.50	1.33	Pass	No	
0145	1	Day 0	HEMA	ng/mL	3.52	3.63	3.58	3.07	Pass	No	
0145	1	Day 6	HEMA	ng/mL	0.496	0.455	0.476	8.61	Pass	No	
0148	1	Day 0	HEMA	ng/mL	2.92	2.90	2.91	0.69	Pass	No	
0149	1	Day 0	HEMA	ng/mL	1.12	1.12	1.12	0.00	Pass	No	
0160	1	Day 0	HEMA	ng/mL	7.25	6.21	6.73	15.45	Pass	No	
0170	1	Day 6	HEMA	ng/mL	0.452	0.464	0.458	2.62	Pass	No	
0183	1	Day 3	HEMA	ng/mL	0.379	0.396	0.388	4.38	Pass	No	
0187	1	Day 6	HEMA	ng/mL	2.47	2.50	2.49	1.20	Pass	No	
0190	1	Day 6	HEMA	ng/mL	0.987	1.10	1.04	10.87	Pass	No	
0191	1	Day 0	HEMA	ng/mL	1.44	1.51	1.48	4.73	Pass	No	
0193	1	Day 3	HEMA	ng/mL	0.819	0.833	0.826	1.69	Pass	No	
0195	1	Day 4	HEMA	ng/mL	0.361	0.359	0.360	0.56	Pass	No	
0197	1	Day 6	HEMA	ng/mL	0.611	0.650	0.631	6.18	Pass	No	
0200	1	Day 6	HEMA	ng/mL	1.57	1.40	1.49	11.41	Pass	No	
0206	1	Day 6	HEMA	ng/mL	1.08	1.12	1.10	3.64	Pass	No	
0315	1	Day 0	HEMA	ng/mL	1.93	1.96	1.95	1.54	Pass	No	
0321	1	Day 6	HEMA	ng/mL	1.28	1.28	1.28	0.00	Pass	No	
0322	1	Day 3	HEMA	ng/mL	1.52	1.43	1.48	6.08	Pass	No	
0325	1	Day 2	HEMA	ng/mL	3.42	3.36	3.39	1.77	Pass	No	

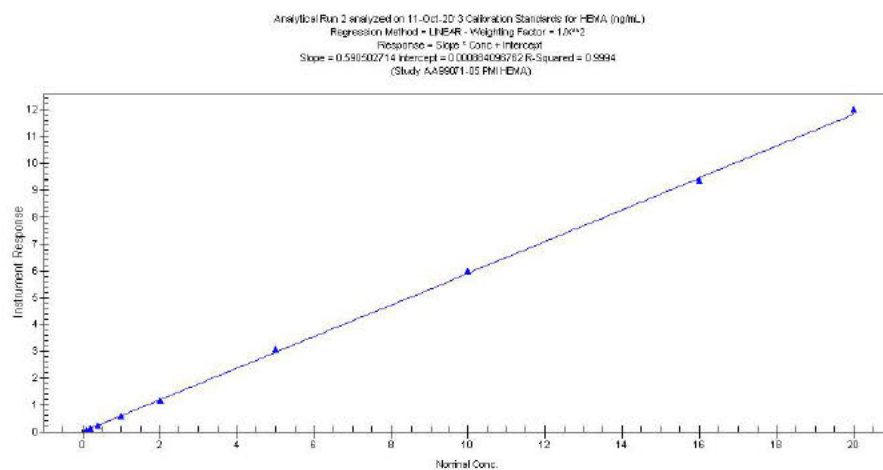


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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0325	1	Day 6	HEMA	ng/mL	1.22	1.11	1.17	9.40	Pass	No	
0328	1	Day 1	HEMA	ng/mL	1.84	1.88	1.86	2.15	Pass	No	
0328	1	Day 6	HEMA	ng/mL	0.679	0.698	0.689	2.76	Pass	No	
0023	1	Day 1	HEMA	ng/mL	2.36	2.18	2.27	7.93	Pass	No	
0042	1	Day 0	HEMA	ng/mL	3.38	3.23	3.31	4.53	Pass	No	
0121	1	Day 1	HEMA	ng/mL	5.50	5.58	5.54	1.44	Pass	No	
0296	1	Day 6	HEMA	ng/mL	1.69	1.50	1.60	11.88	Pass	No	
0316	1	Day 6	HEMA	ng/mL	1.08	1.08	1.08	0.00	Pass	No	

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FIGURES

Figure 1 Calibration Curve for HEMA in Control Matrix, Watson Run ID 2¹

¹ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



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ATTACHMENTS

Attachment 1 General List of Abbreviations used at Celerion

Abbreviations are used in this document as applicable.

Abbreviation	Description
°C	Degree Celsius (centigrade)
µg	Microgram
AAR	Above the acceptable range
AB	Applied Biosystems
API	Atmospheric pressure ionization
ASCII	American standard code for information interchange
BAM	Bioanalytical method
BLK	Blank
BLQ	Below limit of quantification
CC	Conventional Cigarette
CDER	Center for Drug Evaluation and Research
CFR	Code of Federal Regulations
CRO	Contract research organisation
CV	Coefficient of variation
Da	Dalton
DCU	Diluted concentration unreliable
DFNR	Dilution factor not reliable
DQC	Dilution quality control sample
ELISA	Enzyme-linked immunosorbent assay
EDTA	Ethylenediaminetetraacetic acid
EQB	Exceeding quadratic bounds
EXT	Extraction
fg	Femtogram
g	Gram
GLP	Good laboratory practices
h	Hour
HDPE	High density polyethylene
HPLC	High performance liquid chromatography

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Abbreviation	Description
HSR	High standard removed
ID	Identifier
INC	Incongruous
INS	Instrumentation
IS	Internal standard
ISA	Insufficient volume for full analysis
ISP	Incomplete sample processing
ISR	Incurred sample reproducibility
ISV	Insufficient volume
IVR	Insufficient volume to reassay
L	Litre, liter
LLOQ	Lower limit of quantitation
LNK	Celerion, Lincoln site
M	Molar
mg	Milligram
mL	Millilitre, milliliter
mol	Mole
MS	Mass spectrometry
MW	Molecular weight
n	Number of data points
N/AP	Not applicable
N/AV	Not available
NFV	Not full volume
ng	Nanogram
No	Number
NU	Not used
OECD	Organization for Economic Cooperation and Development
PD	Period
pg	Picogram
QC	Quality control
QCs	Quality control samples
R E	Relative error
REF	Reference

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Abbreviation	Description
RI	Reinjection
RIA	Rarioimmunoassay
RT	Room temperature
RR	Reanalysis
RVL	Remaining volume low
S A	Smoking Abstinence
S D	Standard deviation
SOP	Standard operating procedure
SPE	Solid-phase extraction
SST	System suitability test
STD	Standard
Sub	Subject
SVD	Sample volume depleted
TBD	To be determined
Temp	Temperature
THS	Tobacco Heating System
UCR	Unacceptable chromatography
UISR	Unacceptable internal standard response
ULOQ	Upper limit of quantitation
U S FDA	United States Food and Drug Administration
USP	US pharmacopeia
\bar{x}	Mean



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Attachment 2 Temperature Definitions at Celerion

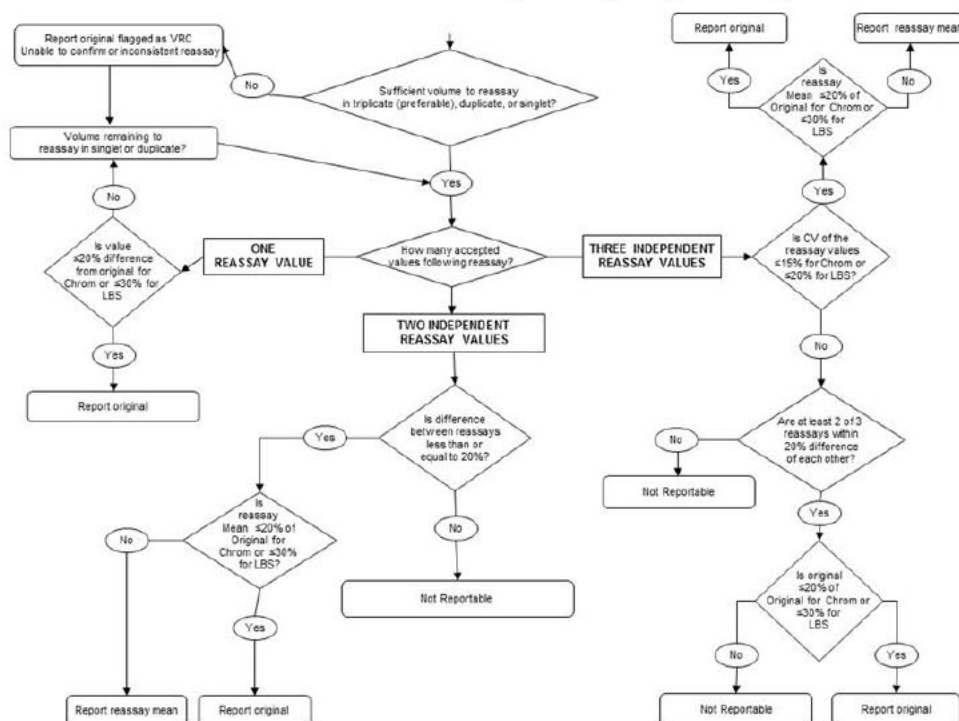
Values for temperatures are nominal temperatures representing the following temperature ranges:

Nominal temperature	Temperature Range
-80 C	-65 C to -90 C
-20 C	-10 C to -30 C
5 C	2 C to 8 C
Room temperature	15 C to 25 C
24 C	22 C to 26 C



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Attachment 3 Procedure for VRC and SSR Reassays and Reporting of Reassay Results



To compare reassays:

$$\frac{|\text{Re assay Value 1} - \text{Re assay Value 2}|}{\text{Mean of Re assay Value 1 and 2}} * 100\%$$

To compare to original:

$$\frac{|\text{Mean of Re assays} - \text{Original Value}|}{\text{Original Value}} * 100\%$$

An LC-MS/MS value as outlined in the decision tree is obtained from a single determination

If BLQ is obtained for a value, the nominal concentration of the LLOQ is used when comparing reassays in this decision tree.

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Attachment 4 General List of Calculation Formulae

Mean:

$$x_{\text{Mean}} = \frac{1}{n} \sum_{i=1}^n x_i$$

Standard Deviation (SD):

$$SD = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (x_i - x_{\text{Mean}})^2}$$

Precision (RSD, CV):

$$CV \% = \left(\frac{SD}{x_{\text{Mean}}} \right) * 100$$

Accuracy (% Theoretical):

$$\text{Accuracy \%} = \left(\frac{x}{x_{\text{Nominal}}} \right) * 100$$

$$\text{Accuracy of Mean \%} = \left(\frac{x_{\text{Mean}}}{x_{\text{Nominal}}} \right) * 100$$

Inaccuracy (% Bias, % RE):

$$\text{Bias \%} = \left(\frac{(x - x_{\text{Nominal}})}{x_{\text{Nominal}}} \right) * 100$$

$$\text{Bias of Mean \%} = \left(\frac{(x_{\text{Mean}} - x_{\text{Nominal}})}{x_{\text{Nominal}}} \right) * 100$$

x = value (e.g. analyte concentration, OD value, cpm value, peak signal)

n = number of values

$$\text{Potency} = \frac{100 - \left(\frac{\% \text{ Salts Determined By Assay} + \% \text{ Water Content} + \% \text{ Residual Solvent} + \% \text{ Other Impurity}}{100} \right)}{100} * \frac{\% \text{ Chromatographic Purity}}{100} * \frac{\% \text{ Chiral Purity}}{100} * \frac{\% \text{ Isotopic Purity}}{100} * \frac{\% \text{ Other Purity}}{100} * \frac{\text{MW Free Base}}{\text{MW Salt}}$$

$$\% \text{ Difference} = \left[\frac{\left| \frac{(\text{Re assay} - \text{Original})}{2} \right|}{\left(\frac{\text{Re assay} + \text{Original}}{2} \right)} \right] * 100$$

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Attachment 5 Reassay Descriptions

Analytical Reason (Code)	Description
Above the Accepted Range (AAR)	Identifies a study sample whose calculated concentration is greater than the upper limit of quantitation (ULOQ). This study sample will be diluted before being reassayed.
Diluted Concentration Unreliable (DCU)	Identifies a study sample that has been diluted and determined to have a concentration below LLOQ (BLQ, below limit of quantification) before correction for the final dilution factor.
Dilution Factor Not Reliable (DFNR)	Identifies a study sample that has been diluted, and determined to have a measurable concentration, however >50% of the dilution QC samples (having the same dilution factor) did not meet their acceptance criteria. Identifies a dilution QC sample that does not fulfil the acceptance criterion and is excluded from the DQC statistics.
Highest / Lowest Standard Removed (HSR / LSR)	If the working range of the method is truncated as a result of - the ULOQ calibration standard being rejected or unavailable (e.g. incomplete sample processing or incomplete instrument analysis, unacceptable chromatography), all study samples with concentrations greater than the highest acceptable standard are identified as 'highest standard removed' (HSR). - the calibration standard at the LLOQ being rejected or unavailable (e.g. incomplete sample processing or incomplete instrument analysis, unacceptable chromatography), all study samples with concentrations below the lowest acceptable standard are identified as 'lowest standard removed' (LSR).
Incomplete Sample Processing (ISP)	Identifies a study sample, calibration standard, or QC sample for which data could not be obtained due to processing problems that occurred during the extraction or assay documented by the analyst prior to instrumental analysis.
Insufficient Volume for Reassay (IVR)	Identified a study sample that has insufficient sample volume for reanalysis (including all received splits)
Incomplete Instrument Analysis (IIA)	Identifies a study sample, calibration standard, or QC sample for which data could not be obtained due to processing problems that occurred during HPLC injection or instrumental analysis and were documented by the analyst.
Unacceptable Chromatography (UCR)	Identifies a study sample, calibration standard, or QC sample judged to demonstrate unacceptable chromatography according to the applicable Celerion procedures (e.g. split peak, poor peak symmetry, unseparated interference).



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Attachment 6 Certificates of Analysis



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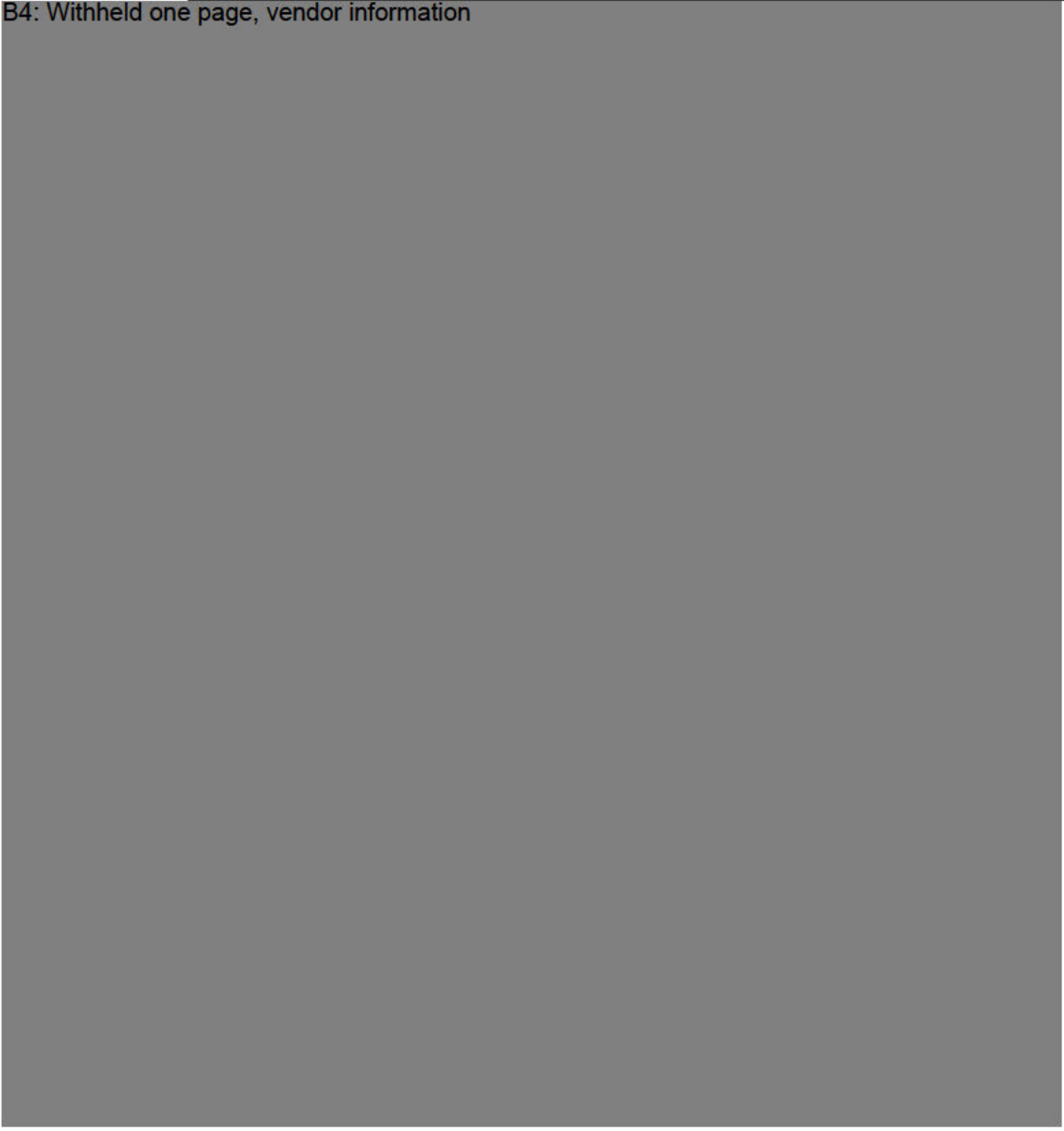


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Attachment 7 Bioanalytical Method Summary



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BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_CM000496 - CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: HEMA		Matrix: Urine	
MVR/SOP no. & date: ZZ38073-01/ 30-Oct-2014		CRO/Laboratory: Celerion-Lincoln	
LLOQ: 0.100 ng/mL		ULOQ: 20.0 ng/mL	
Validation	<input checked="" type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Cross Comments (required for Partial/Cross):		
Assay:	<input checked="" type="checkbox"/> Chromatographic <input type="checkbox"/> Ligand binding <input type="checkbox"/> Enzymatic <input type="checkbox"/> Other describe: <input type="checkbox"/> LC/MS <input checked="" type="checkbox"/> LC/MS/MS <input type="checkbox"/> GC/MS <input type="checkbox"/> GC/MS/MS <input type="checkbox"/> ELISA		
Equipment and short description of extraction and analysis: An aliquot of human urine containing the analyte and internal standard was extracted using a solid-phase extraction procedure. The extracted samples were analyzed by an UPLC equipped with an AB SCIEX API 5000™ and a QTRAP® 5500 mass spectrometer. Negative ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.			
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in any of the 10 human urine lots that were fortified at low concentration and in any of the 10 human urine lots that were fortified at high concentration.		
Accuracy:	Intra-batch: -5.4 to 9.8% R.E. Inter-batch: -2.0 to 4.9% R.E.		
Precision:	Intra-batch: 2.2 to 5.8% CV Inter-batch: 3.2 to 6.1% CV		
Recovery:	64% recovery at 0.200 ng/mL in human urine 74% recovery at 2.00 ng/mL in human urine 79% recovery at 16.0 ng/mL in human urine		
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in brown polypropylene tubes at -20°C under white light		
Short-term temperature stability:	Short-Term Stability: 27 hours in brown polypropylene tubes at ambient temperature under white light Cumulative Short-Term Stability: 53 hours in brown polypropylene tubes at ambient temperature under white light (total of all thaw cycles) Short-Term Stability: 4 hours in polypropylene tubes at ambient temperature under UV-shielded light		
Long-term stability:	406 days in brown polypropylene tubes at -20°C		
Stock solution stability:	258 days at approximately 100 µg/mL in methanol in a polypropylene container at -20°C		
Post-preparative stability:	205 hours in a polypropylene 96 well plate at 5°C		

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PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOP_QM000498 - CR204A2

Version N°: 2.0

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Stability of Analyte During Sample Collection and Handling:	2 days in human urine in amber high-density polyethylene containers at 5°C in a refrigerator, 4 hours in human urine in brown polypropylene tubes at ambient temperature under white light Up to 96 hours in smoker and non-smoker human urine in high-density polyethylene containers at 5°C and 20°C under UV-shielded light, up to 48 hours in smoker and non-smoker human urine in high-density polyethylene containers at 40°C under UV-shielded light	
Accreditation/ GLP compliance/ QA statements:	GLP Compliance as Assay Validation conforms to Celerion Standard Operating Procedures which were written in compliance with FDA: Guidance to Industry "Bioanalytical Method Validation"	
BMS completed by:		
Name:	Date:	Signature:
Erica Nach.	31 Oct 2014	Erica J. Nach.



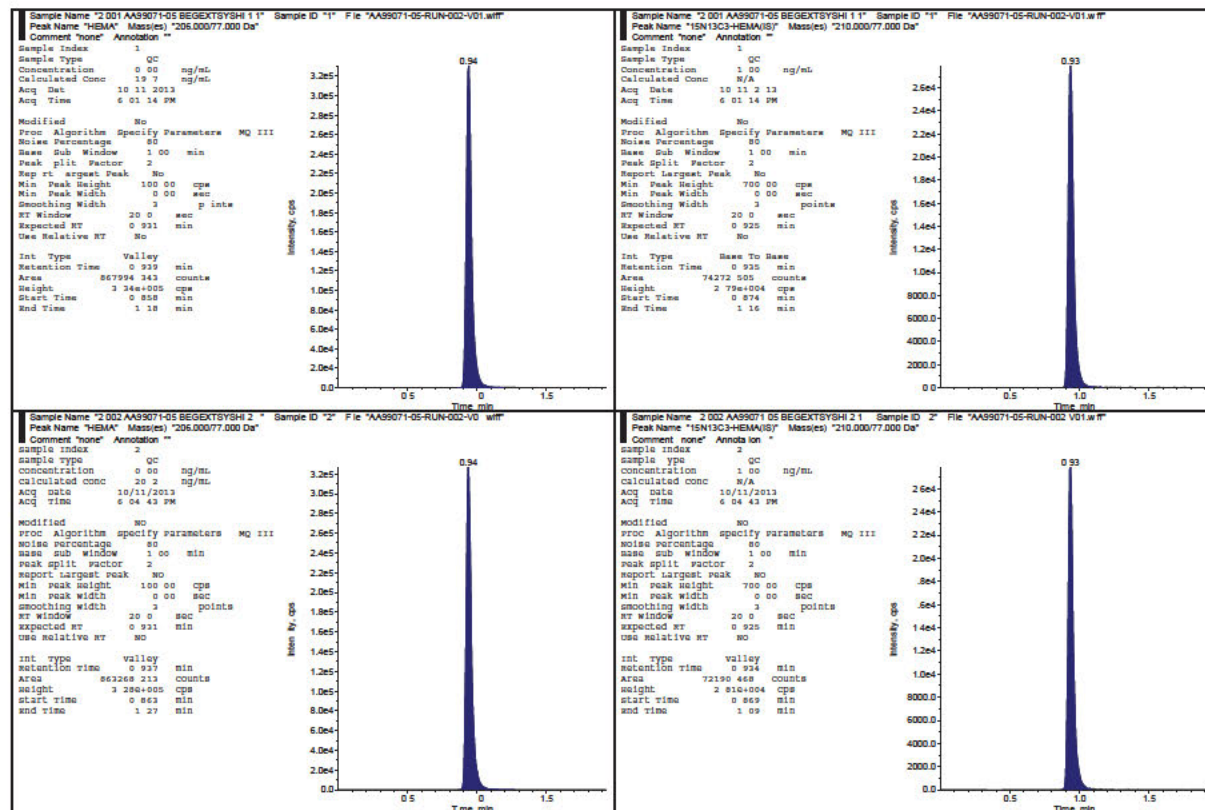
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Attachment 8 Chromatograms

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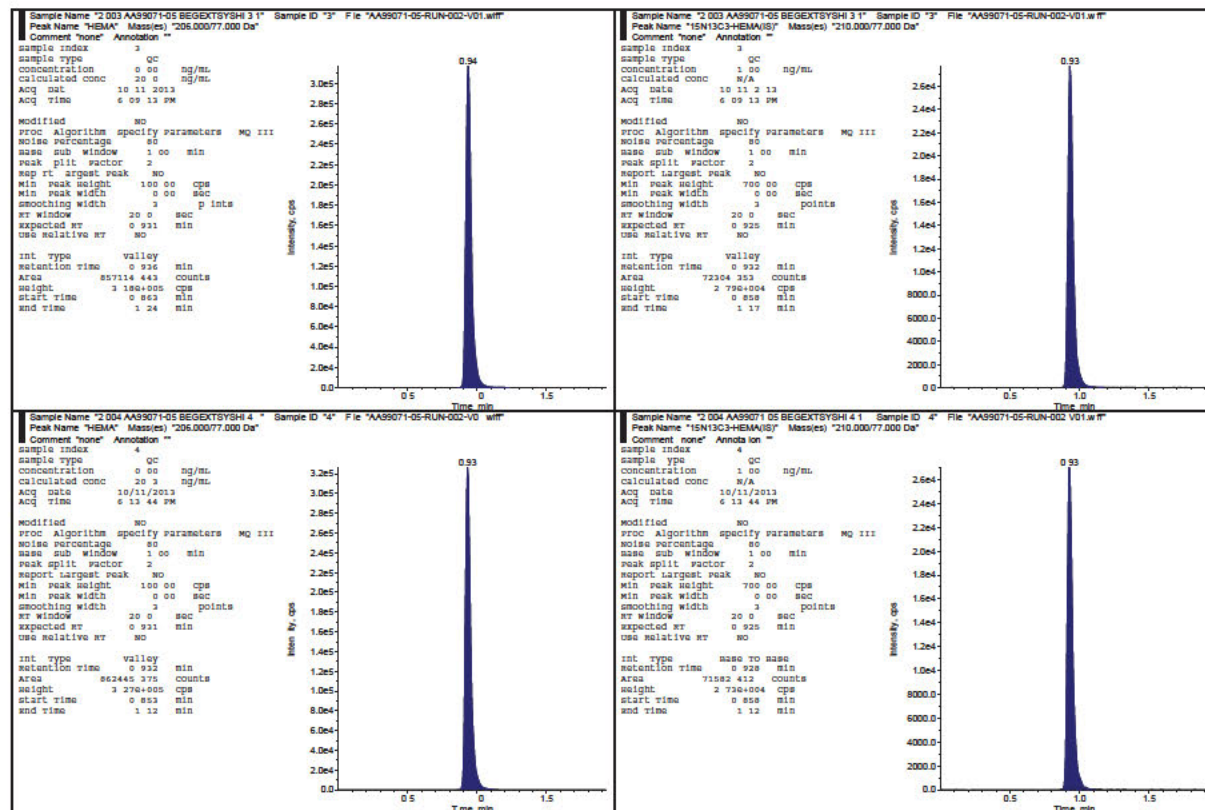


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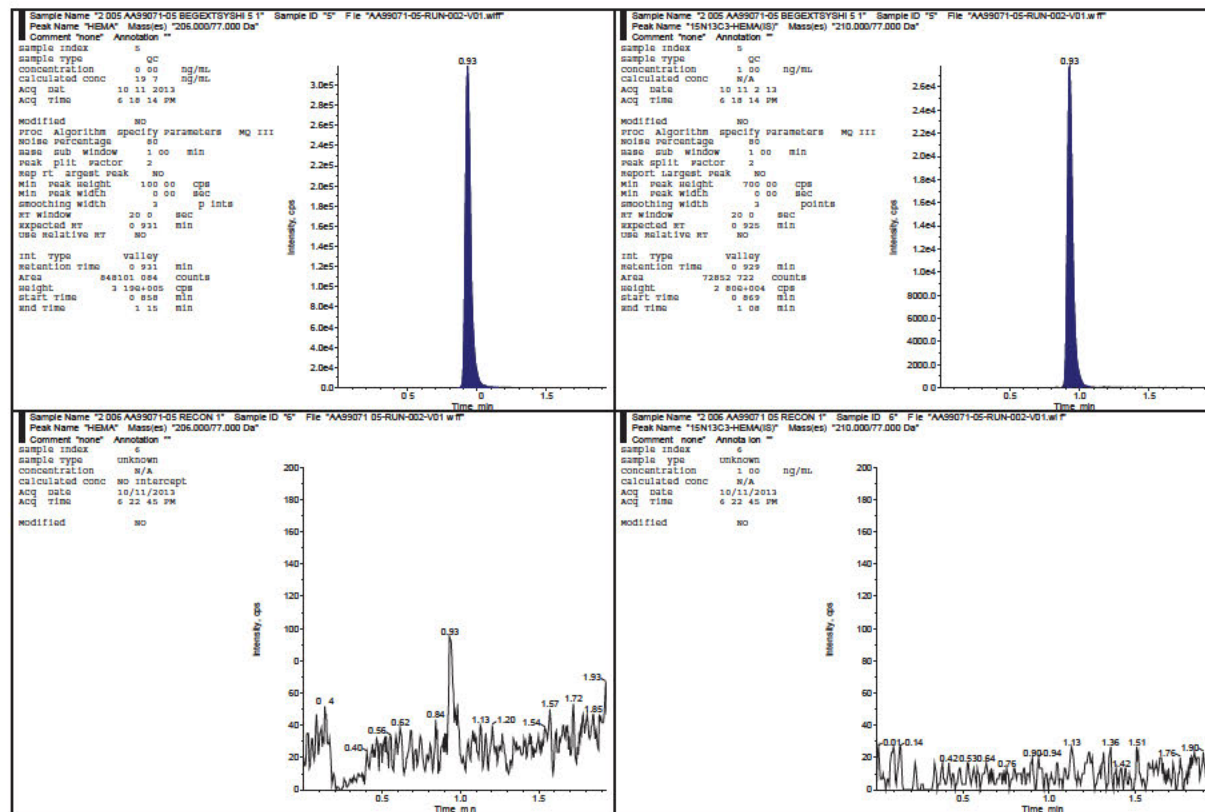


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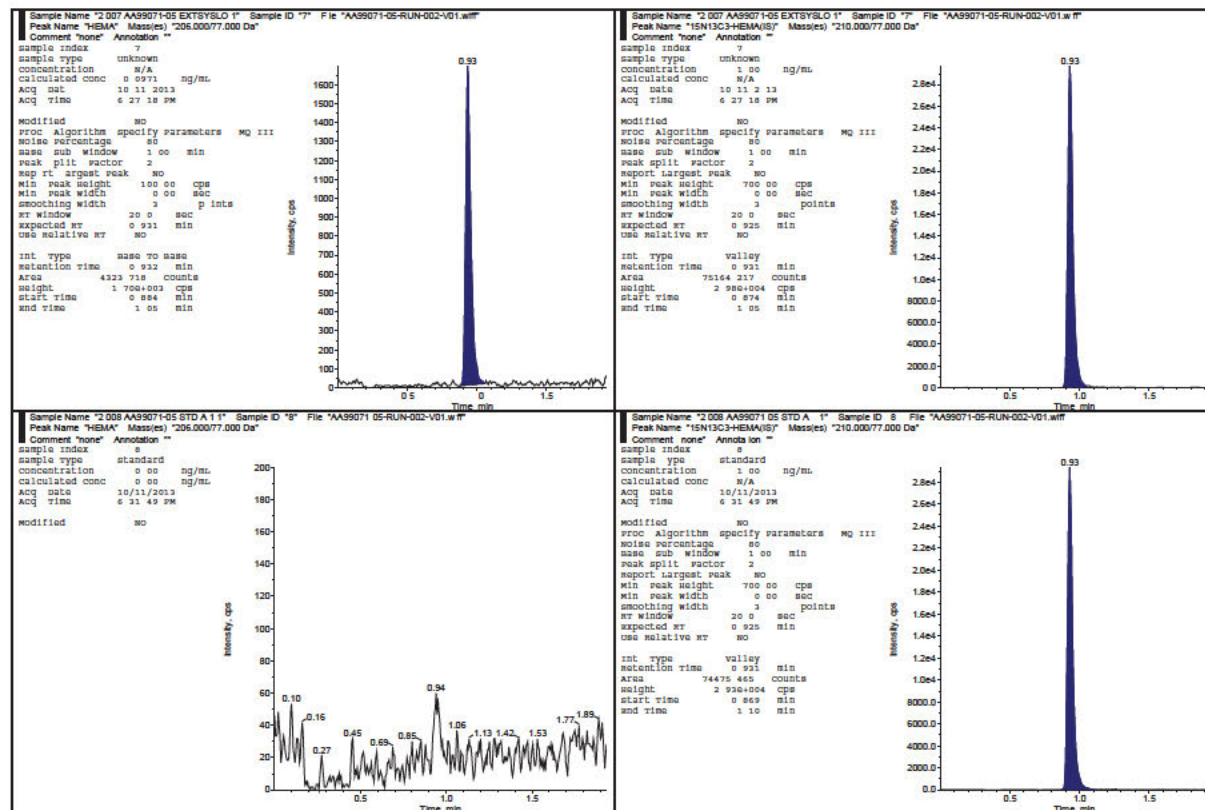


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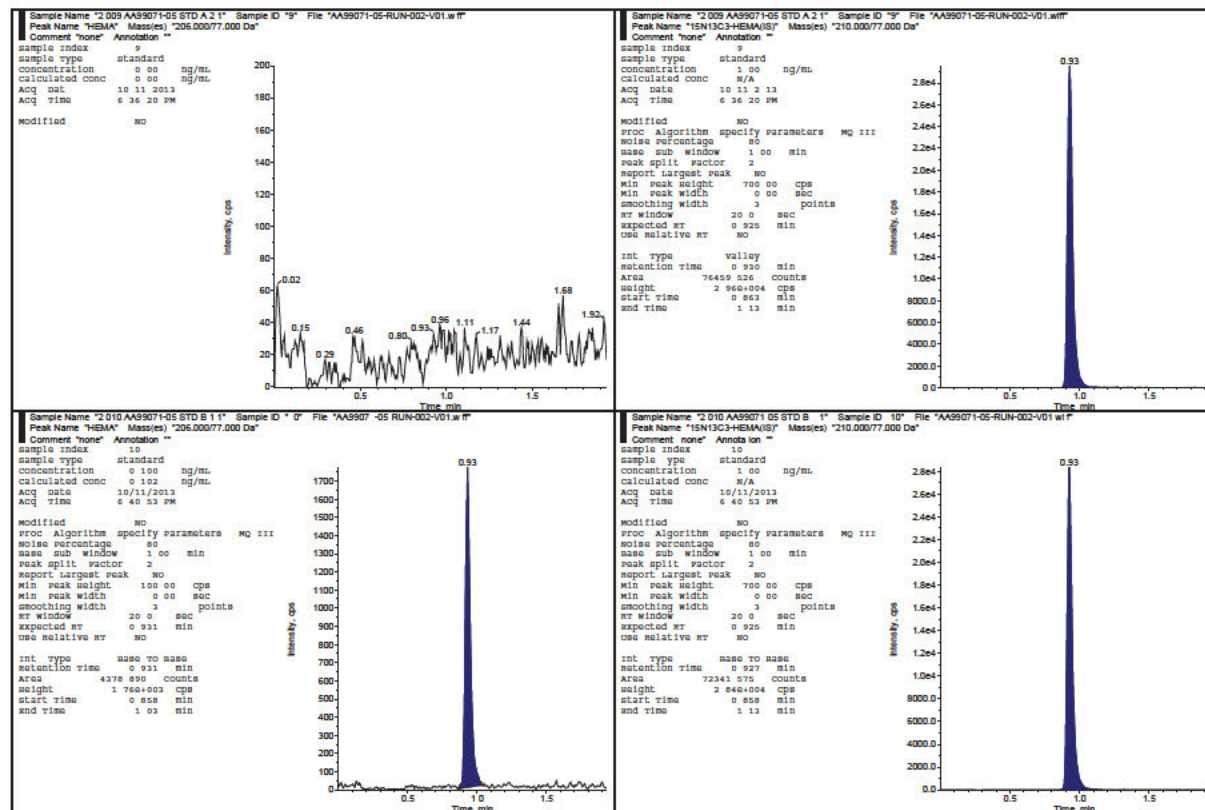


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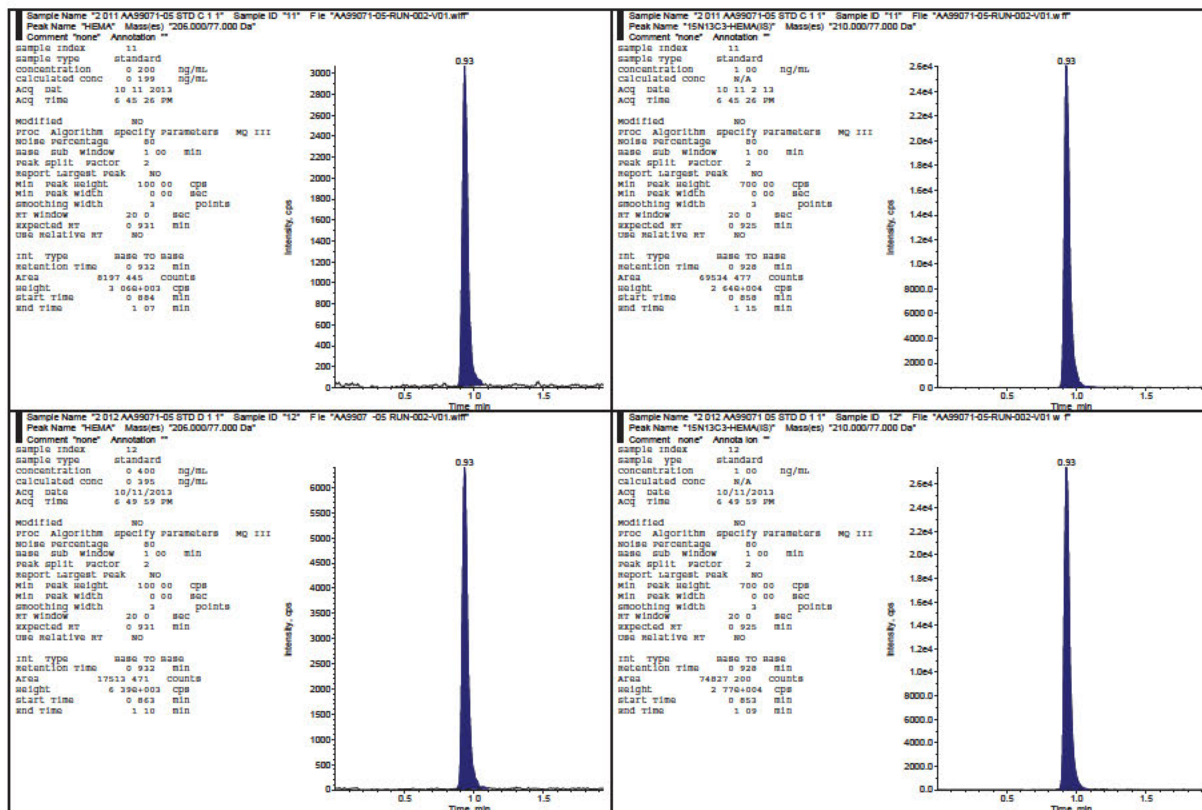


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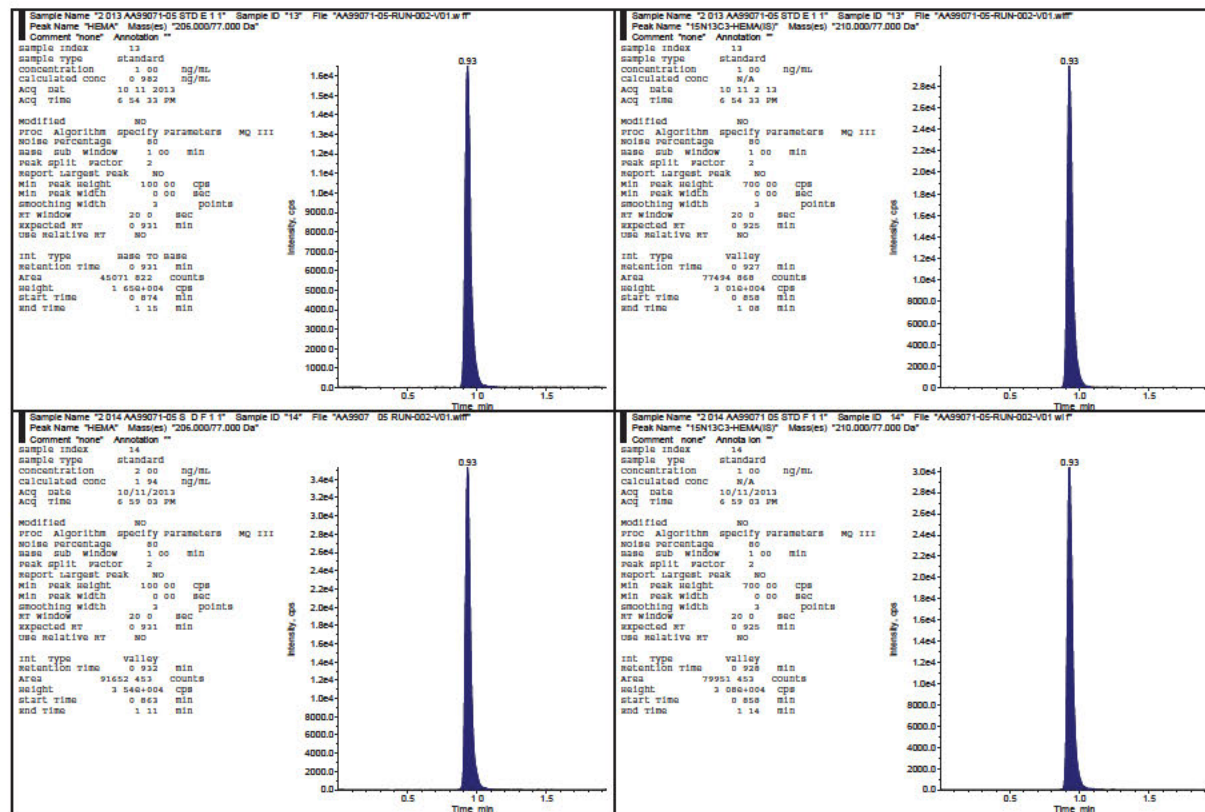


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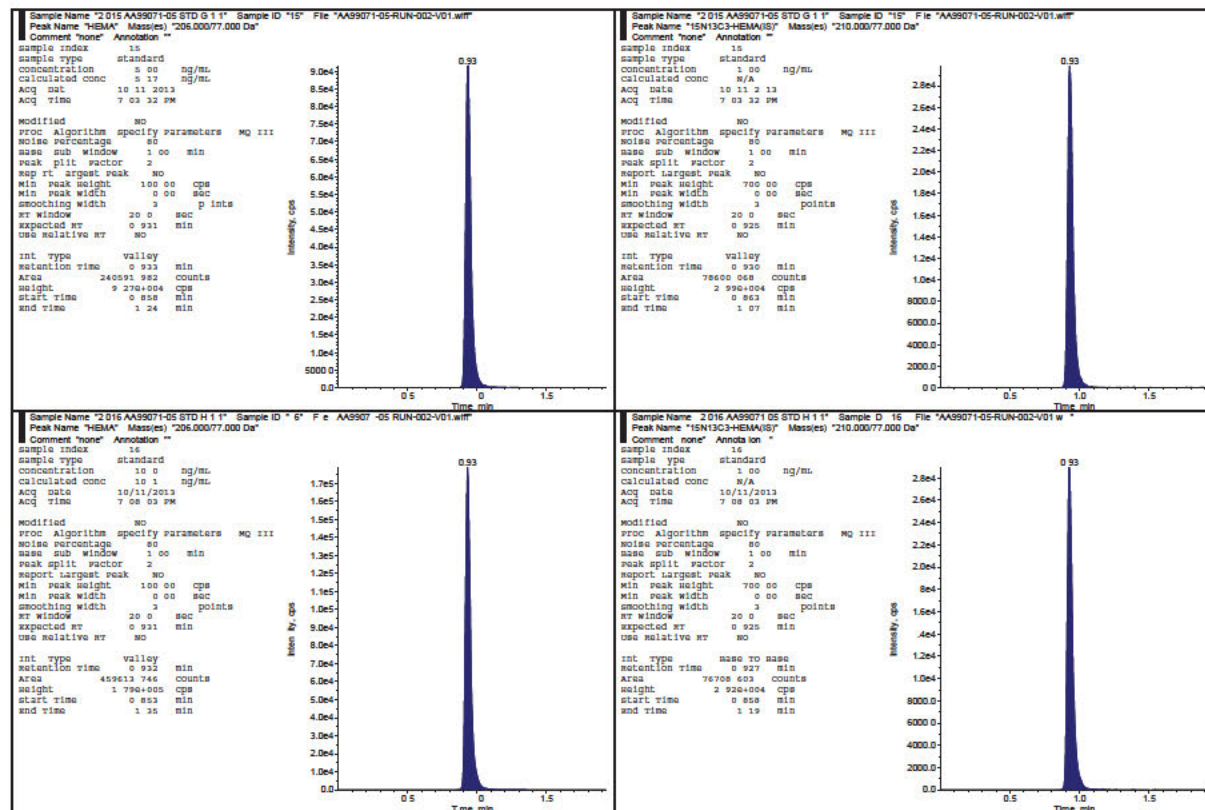


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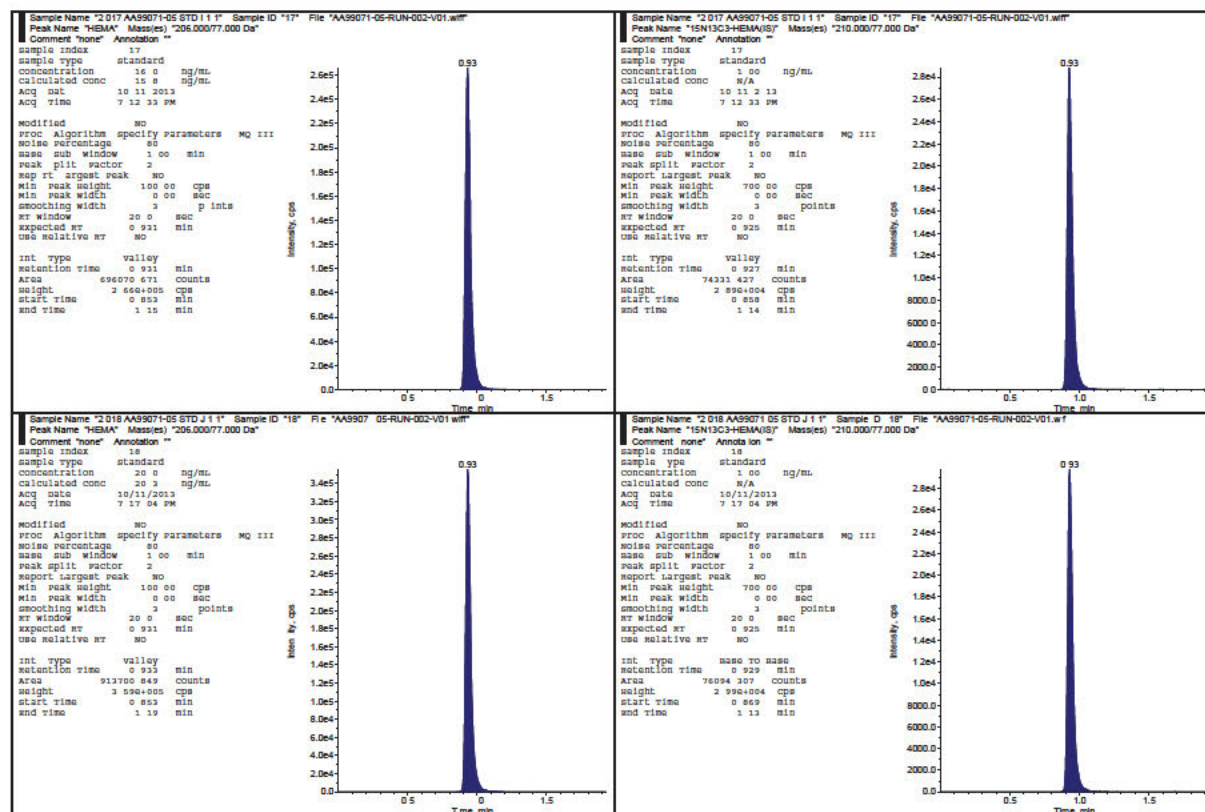


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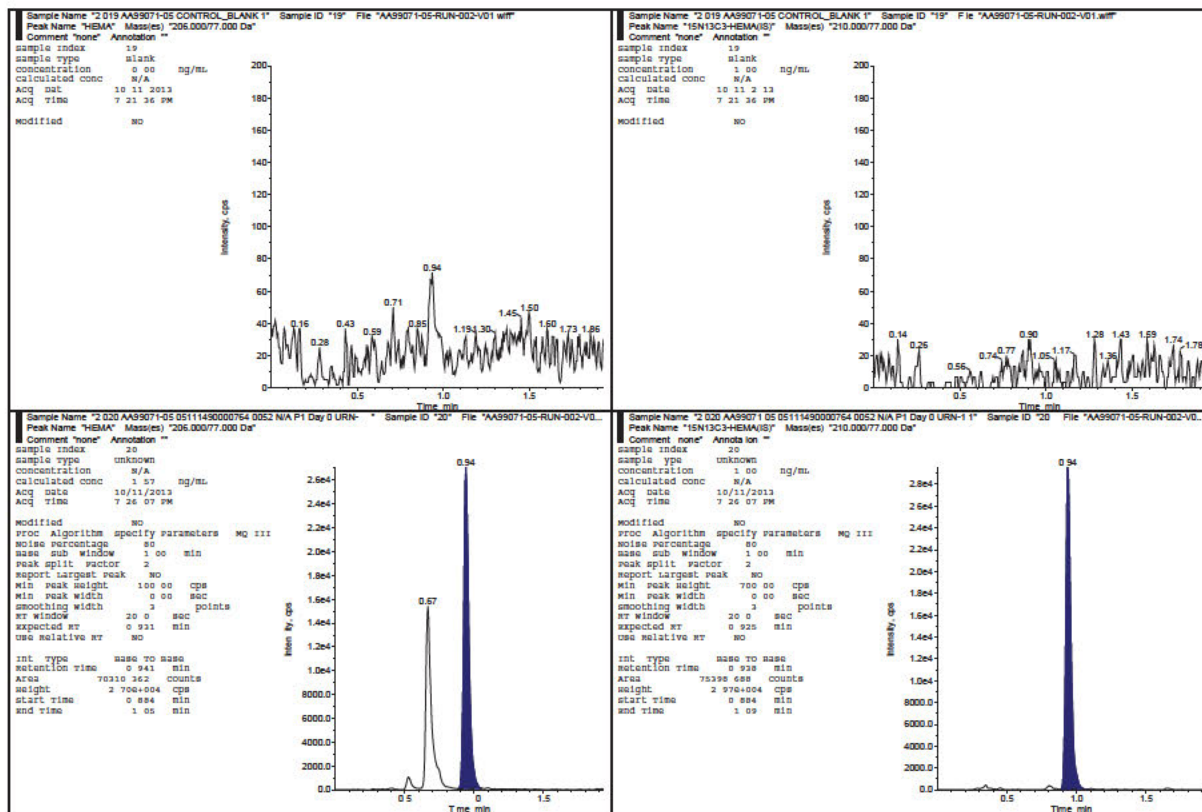


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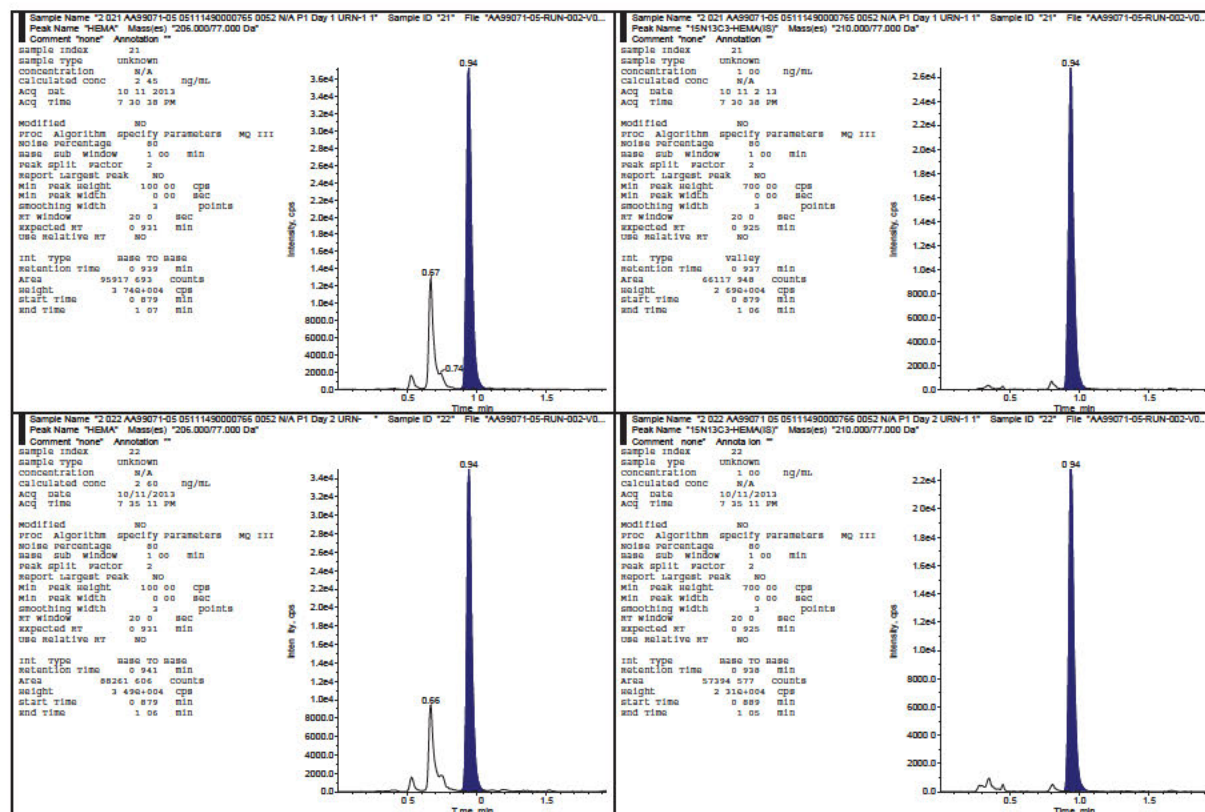


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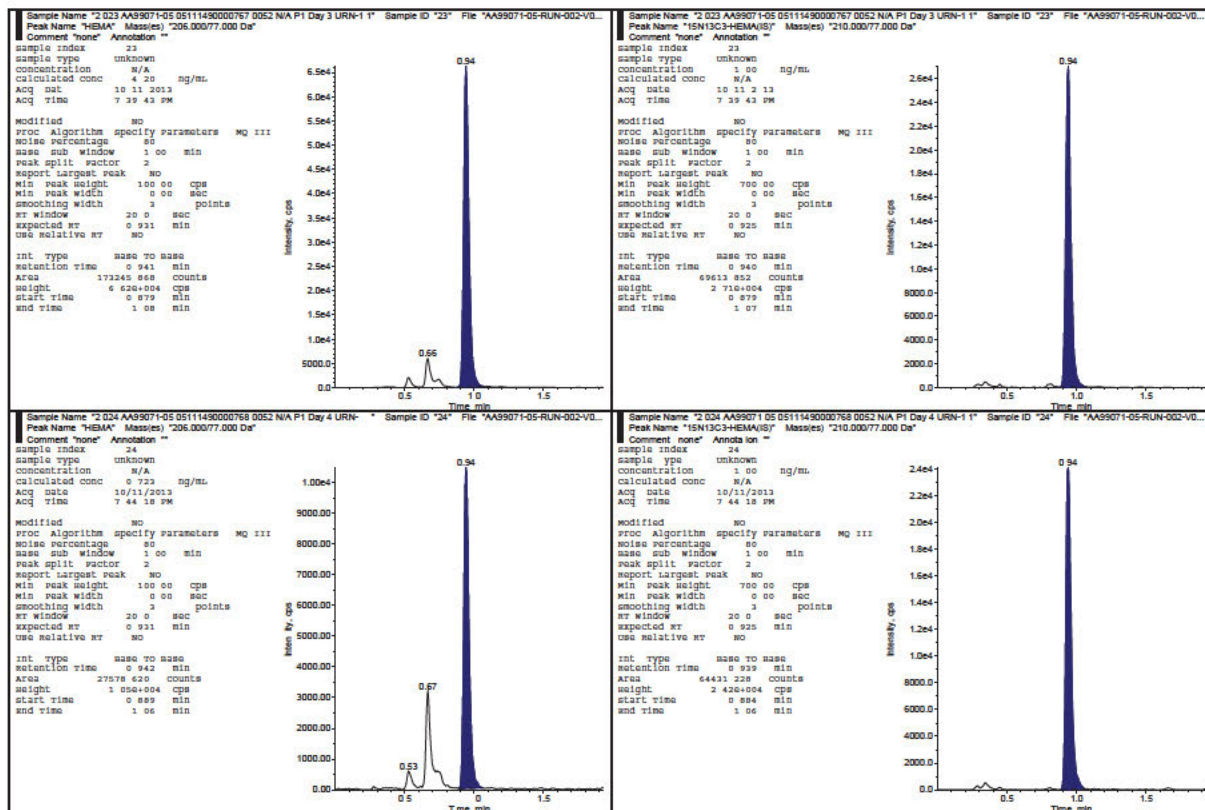


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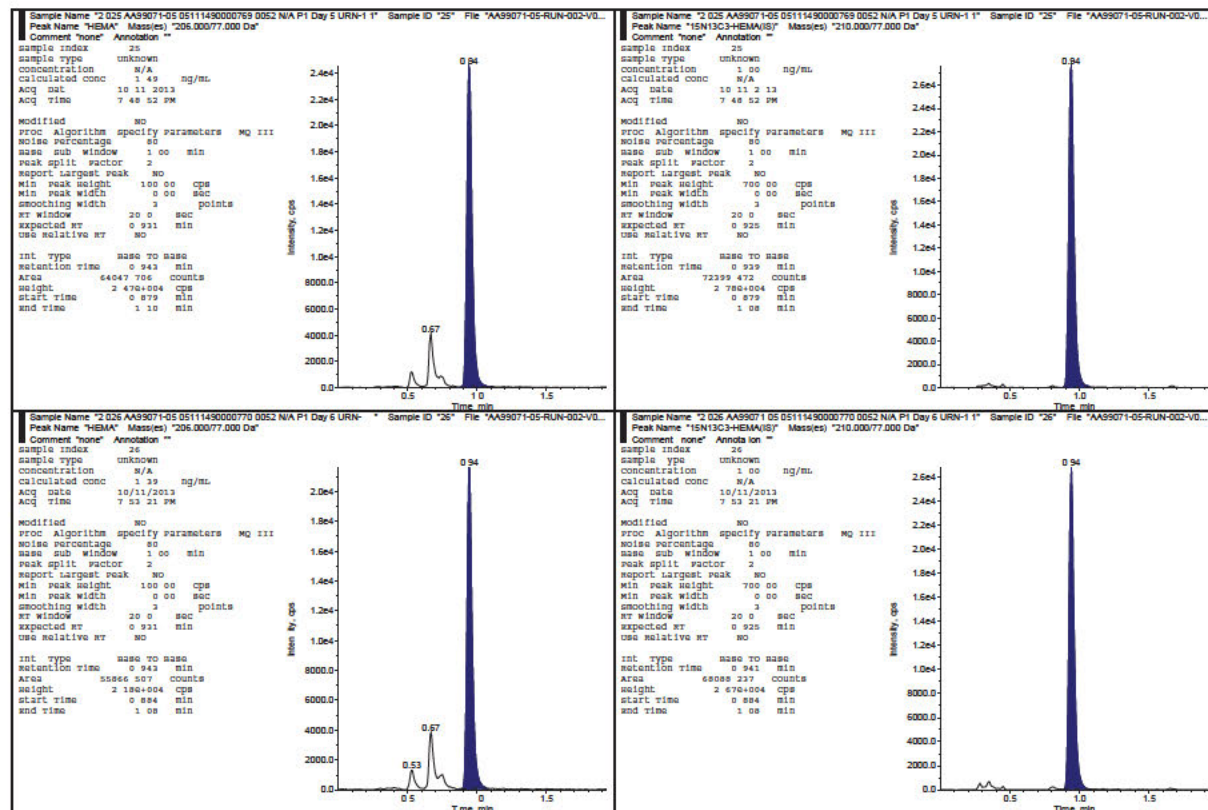


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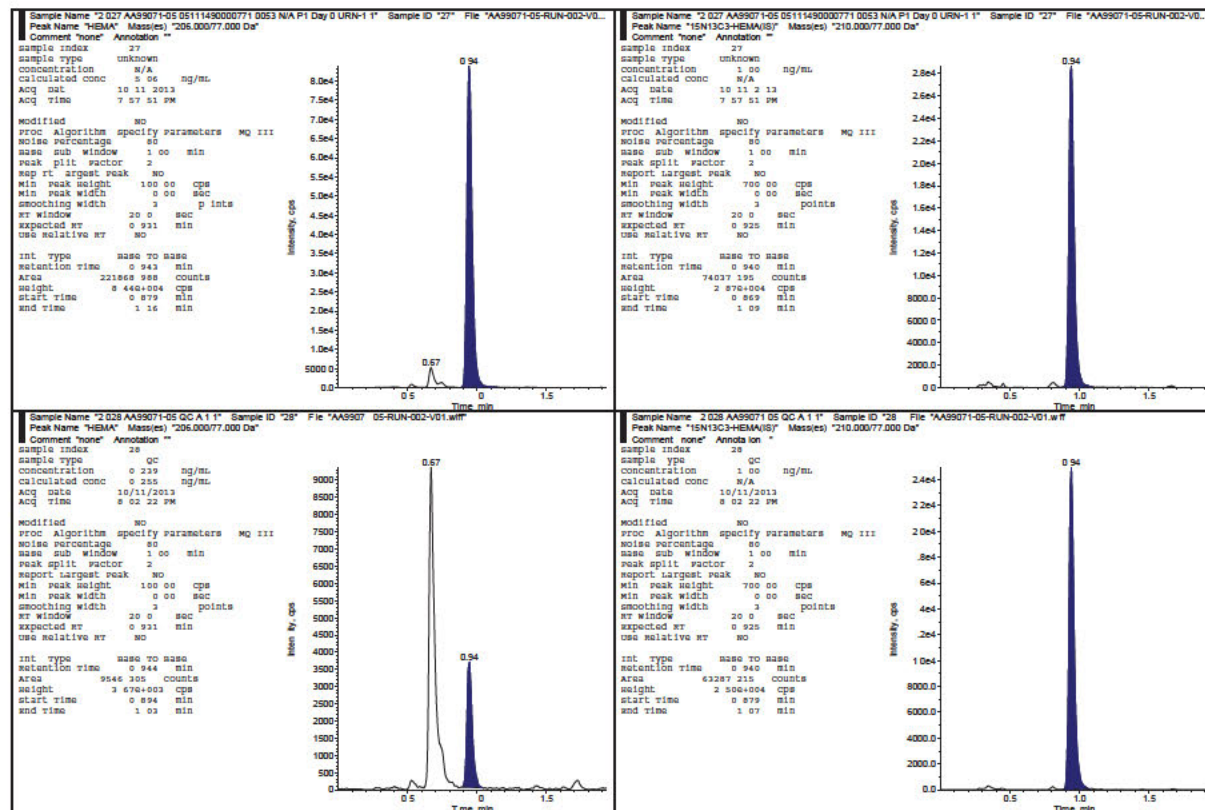


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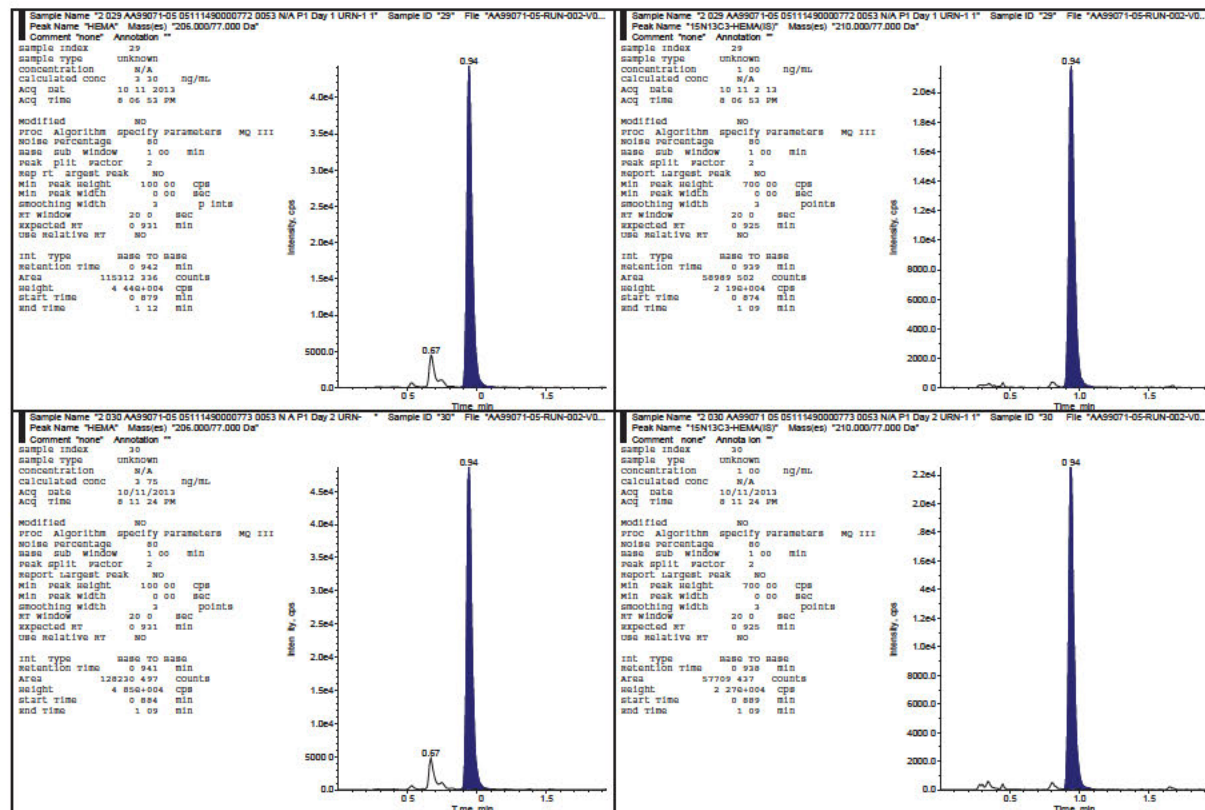


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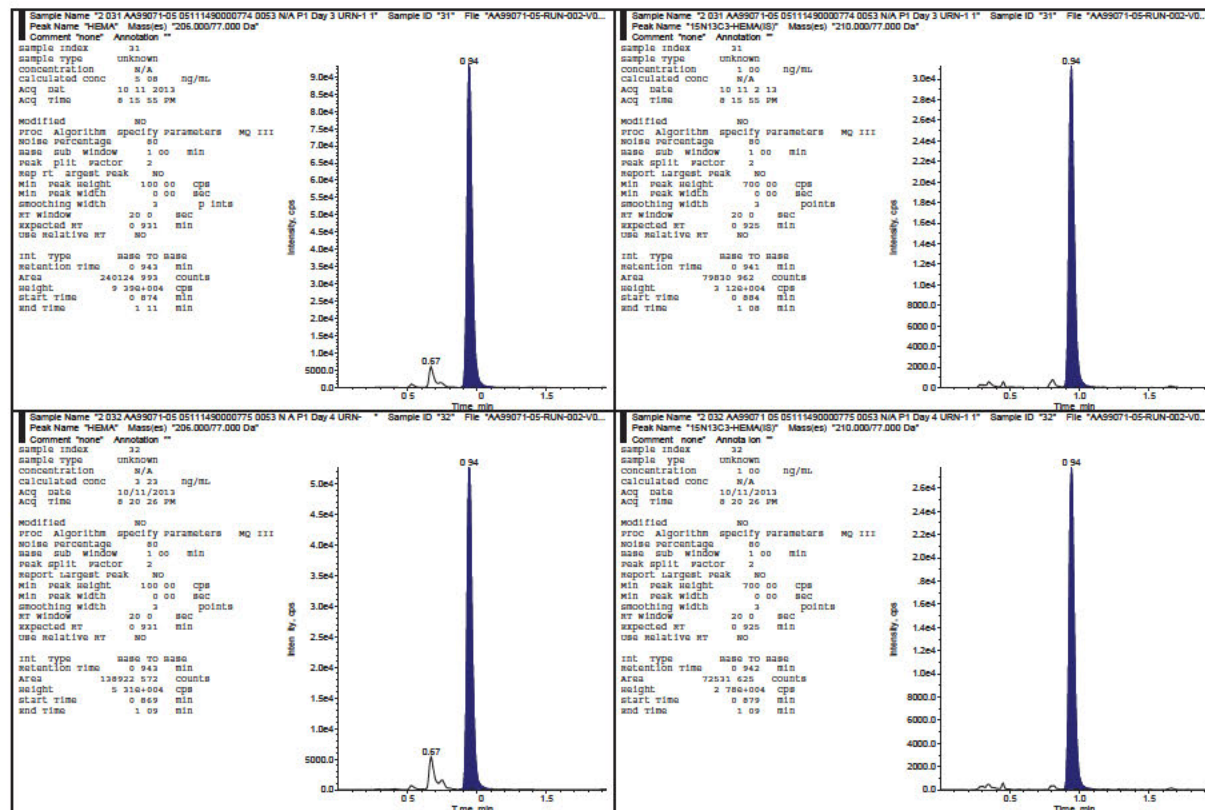


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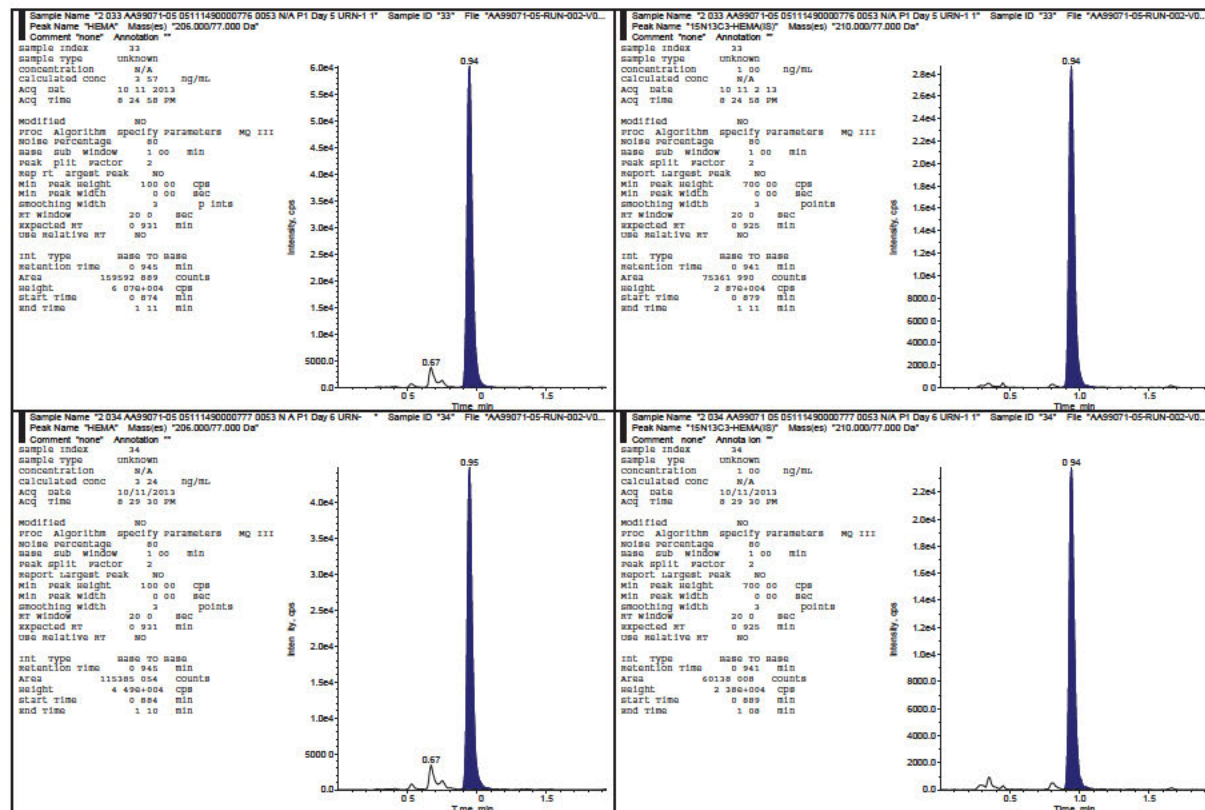


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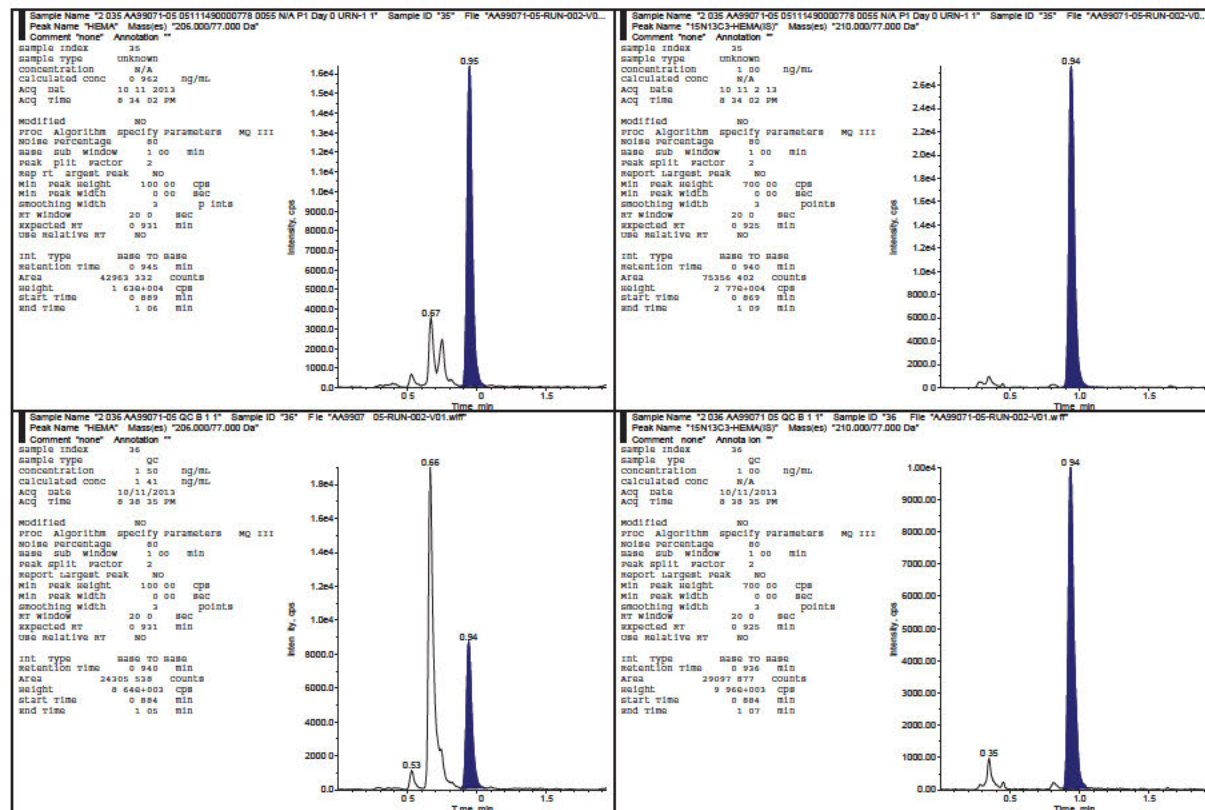


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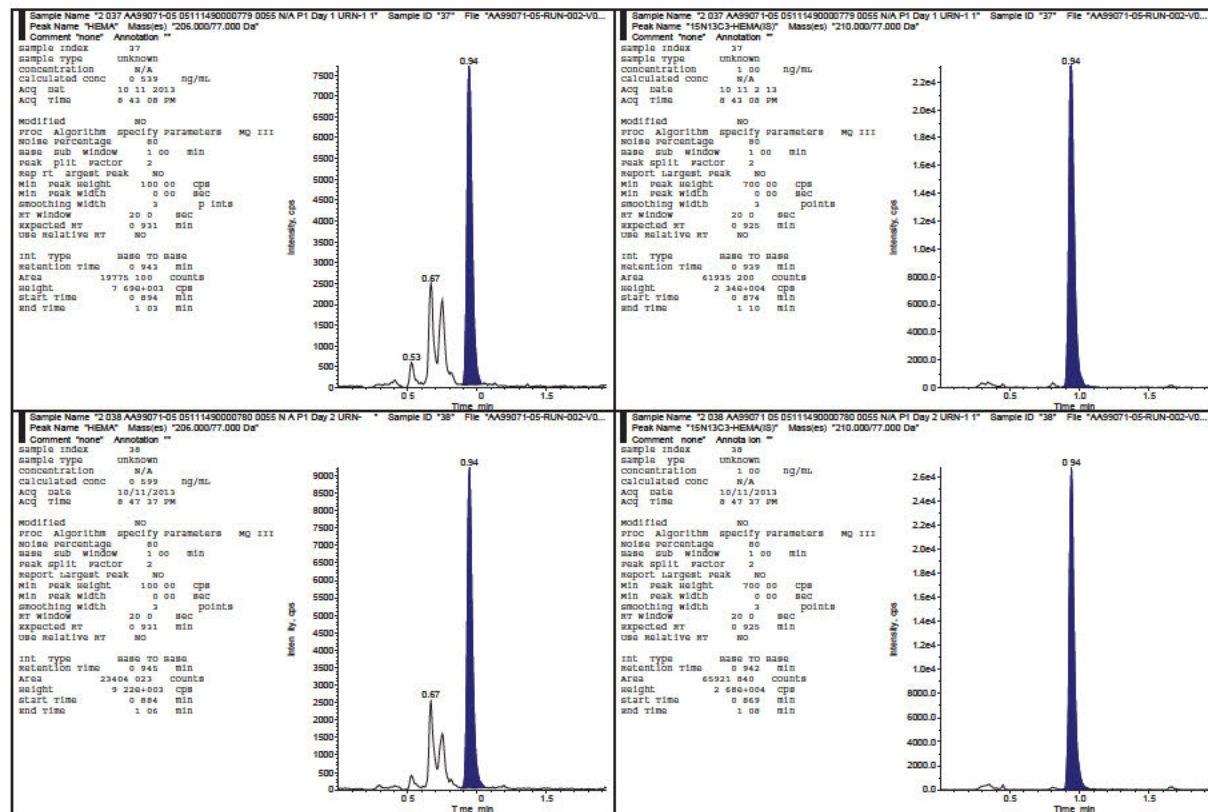


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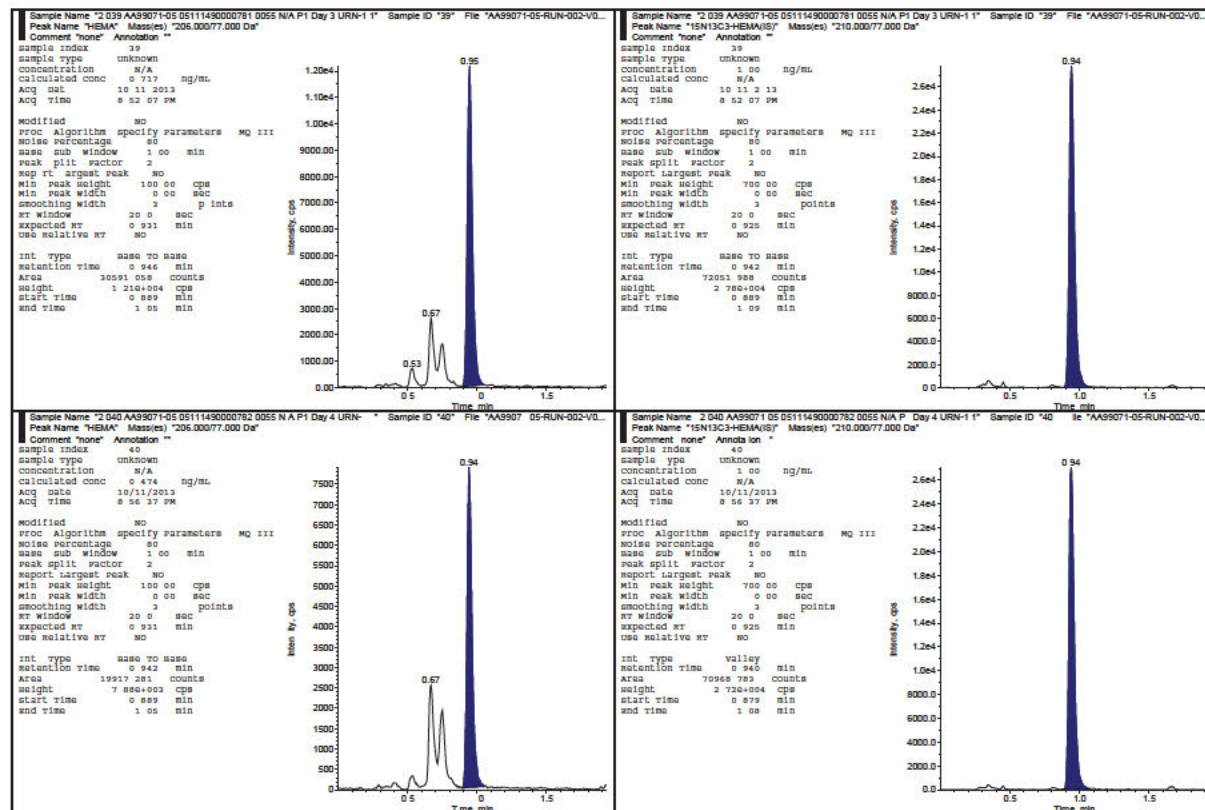


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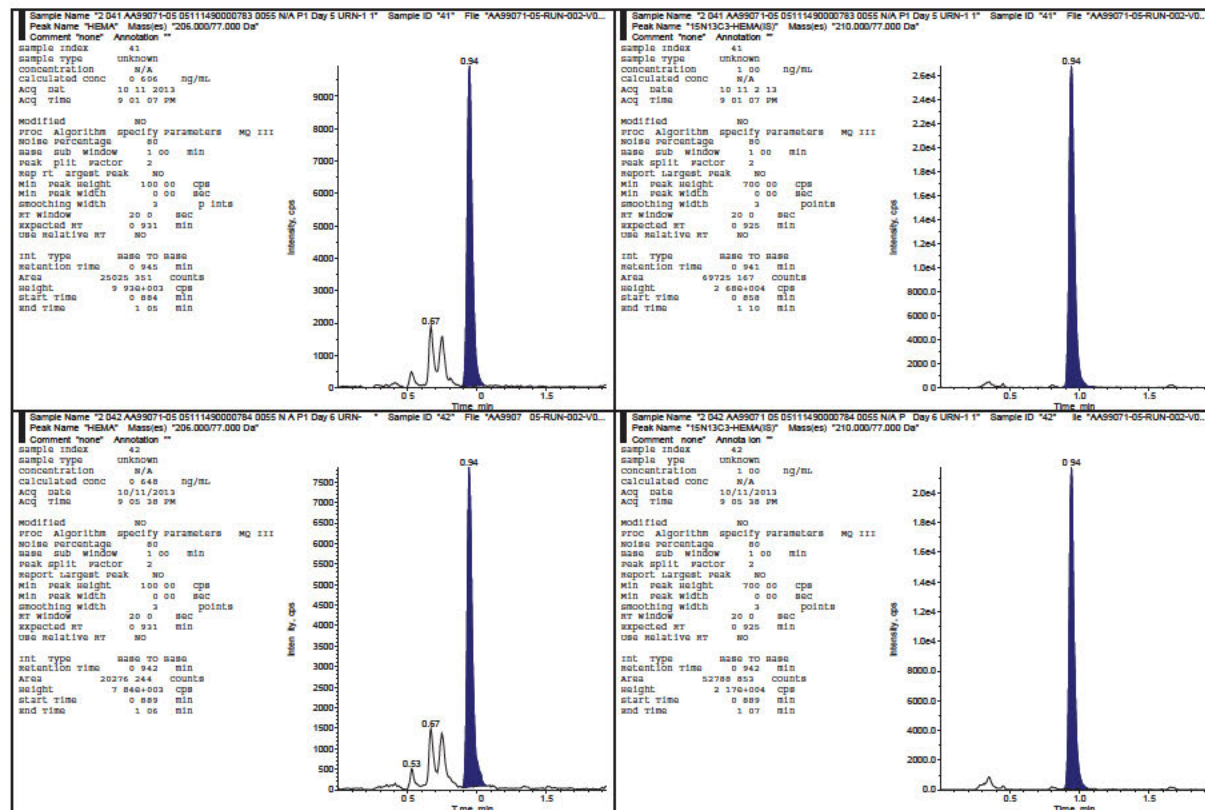


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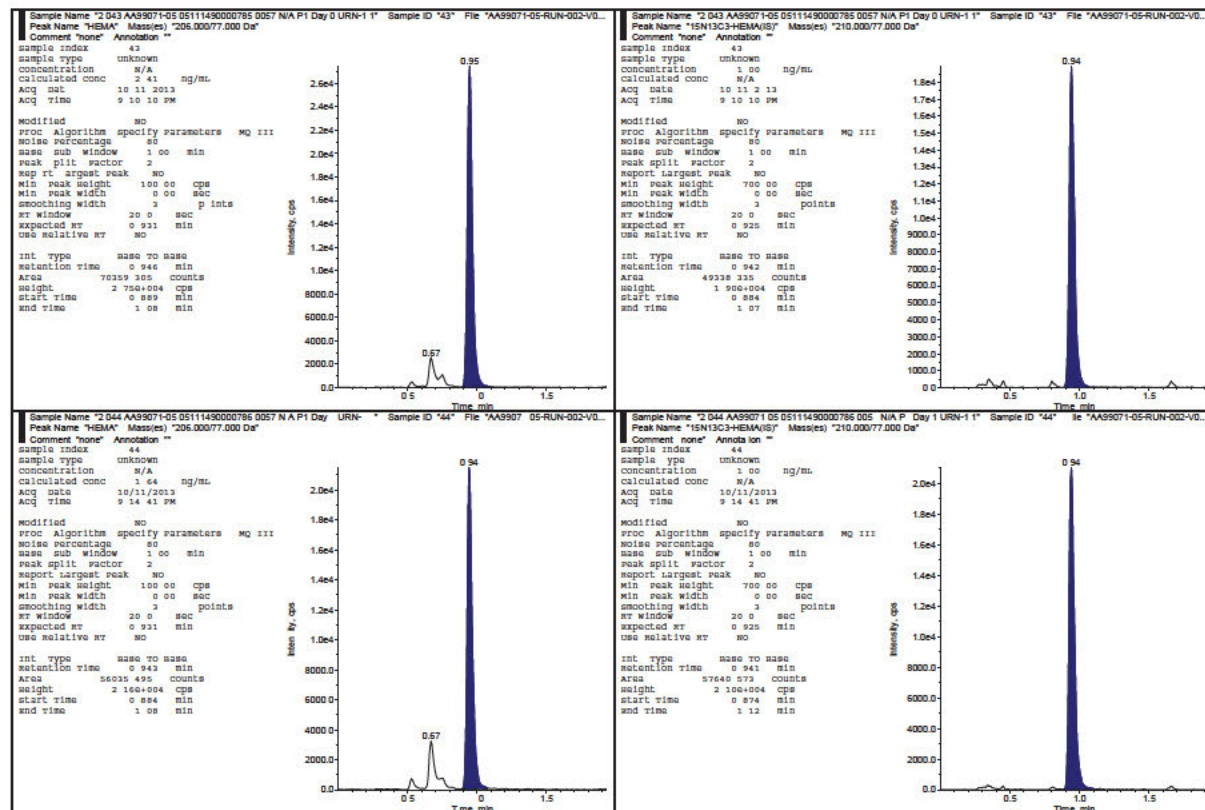


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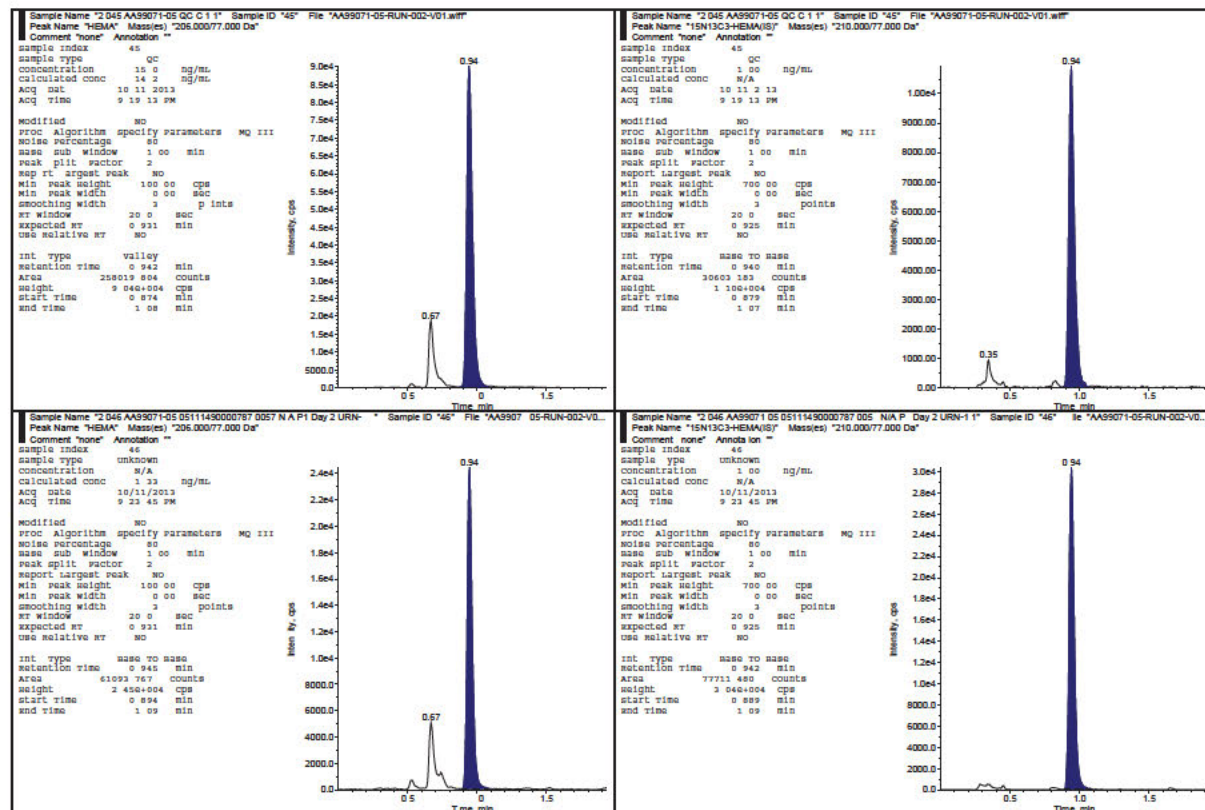


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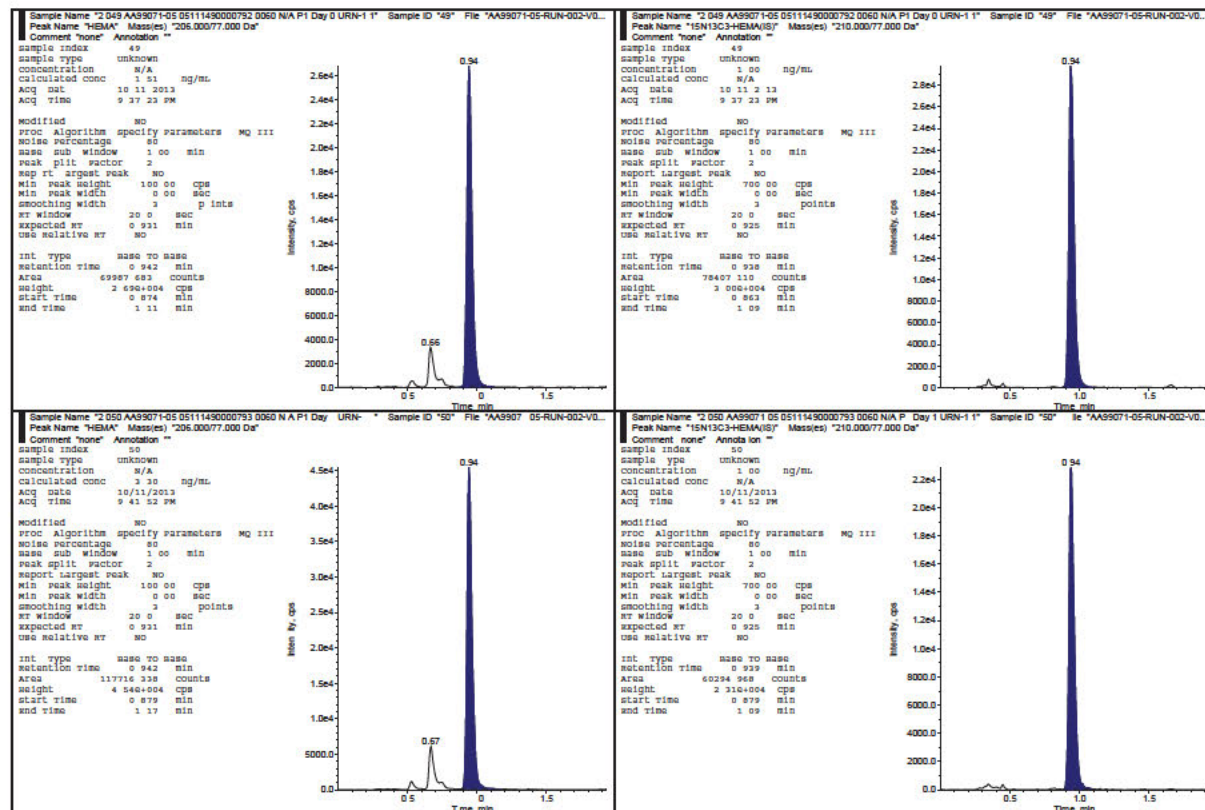


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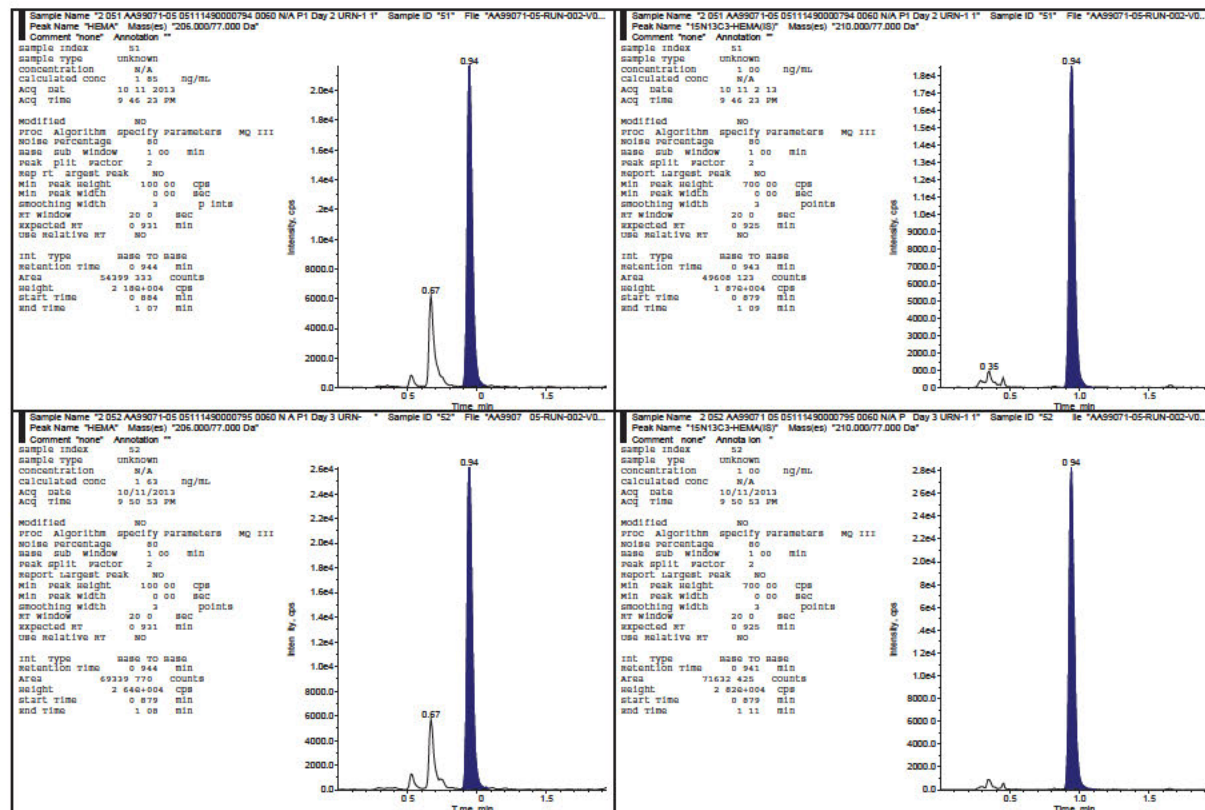


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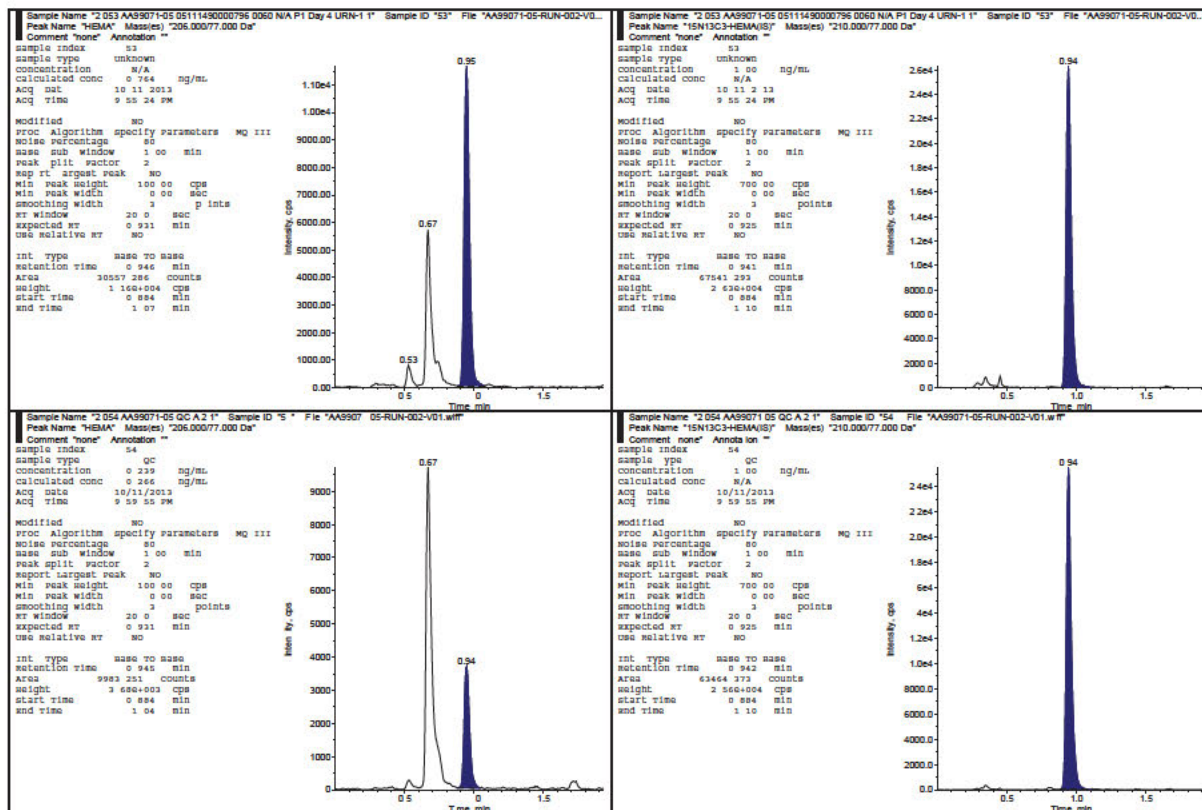


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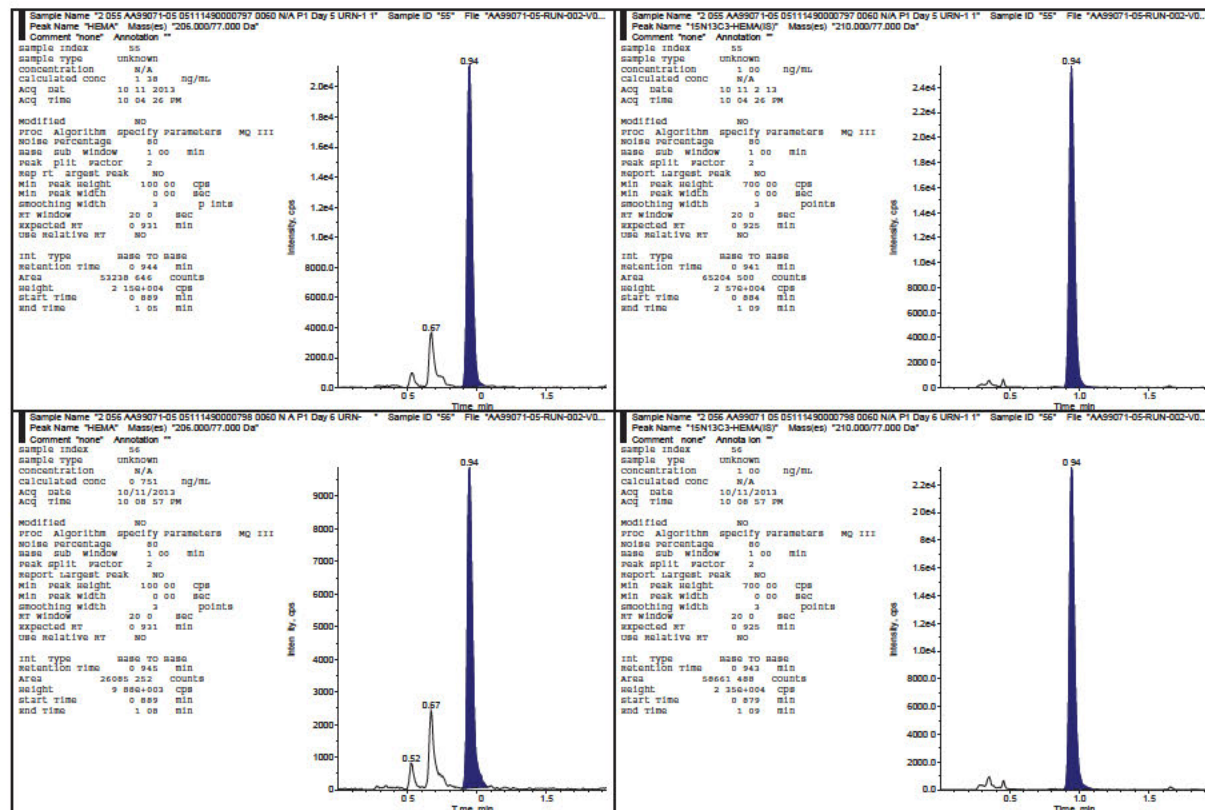


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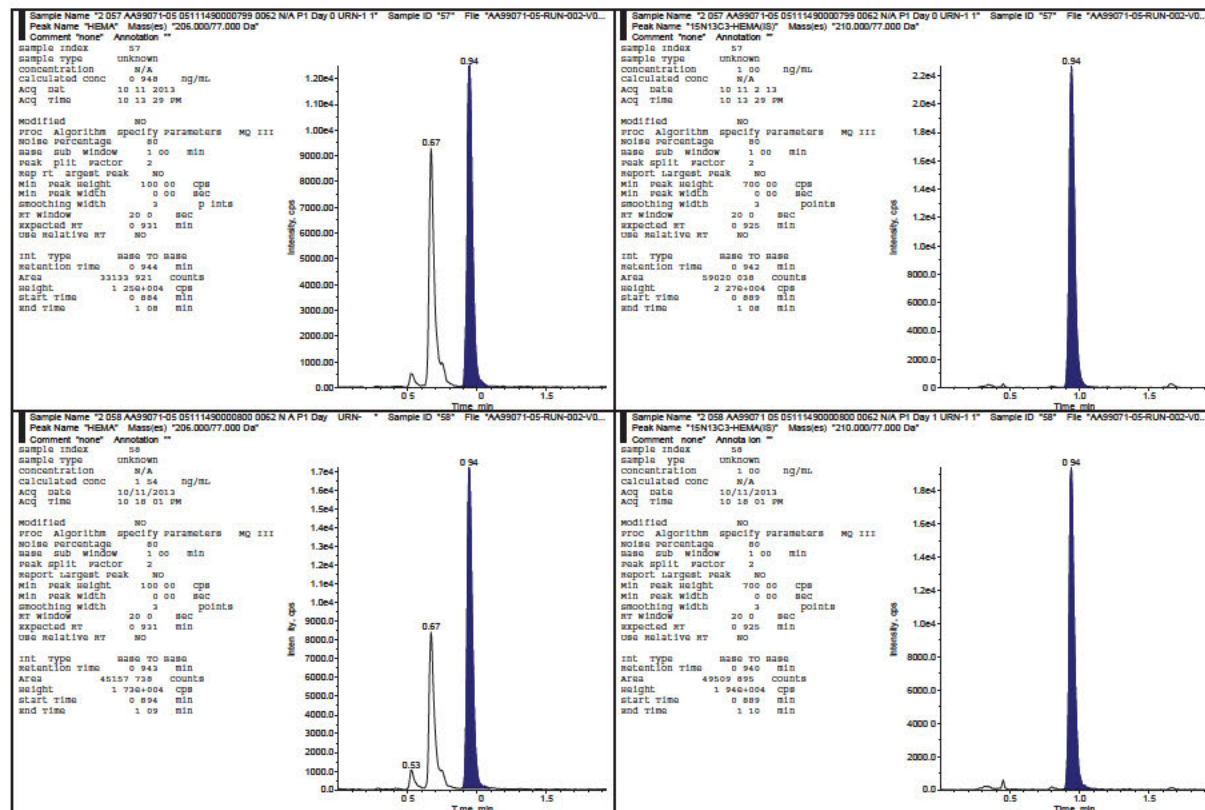


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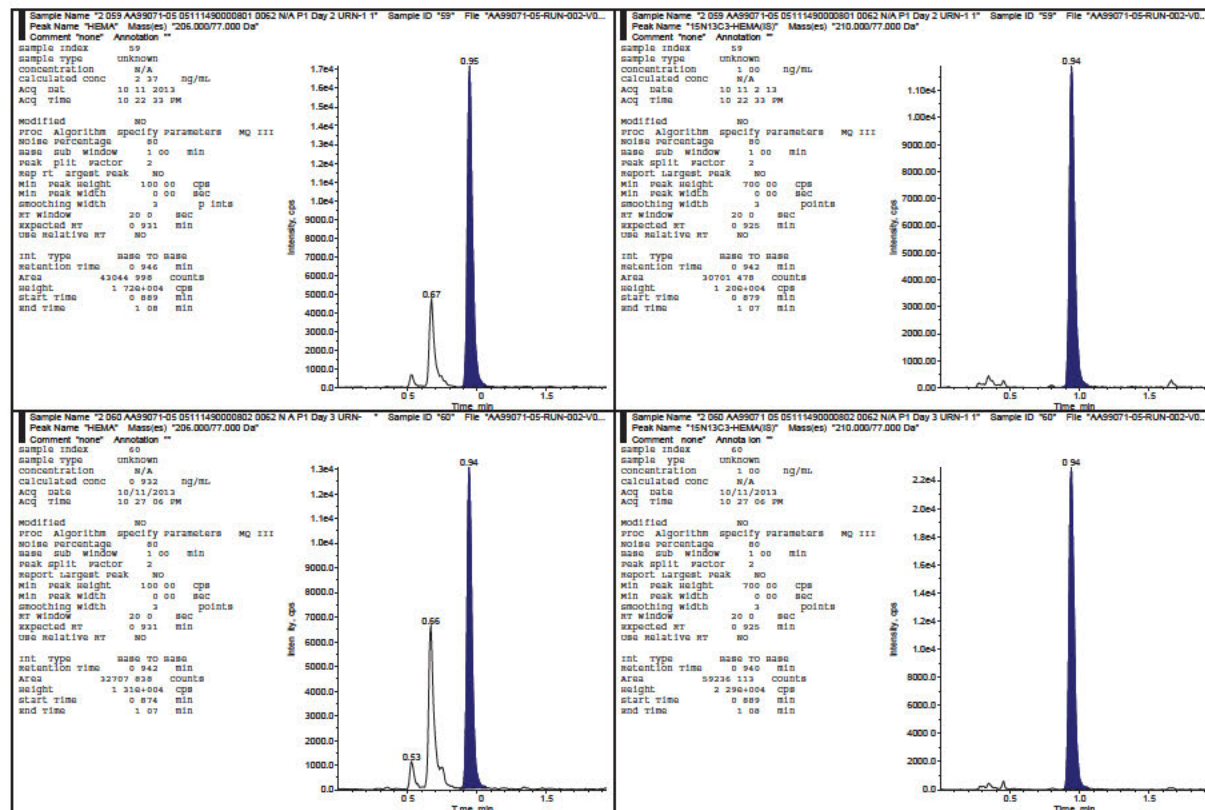


HEMA in Human Urine
Celerion Study AA99071-05



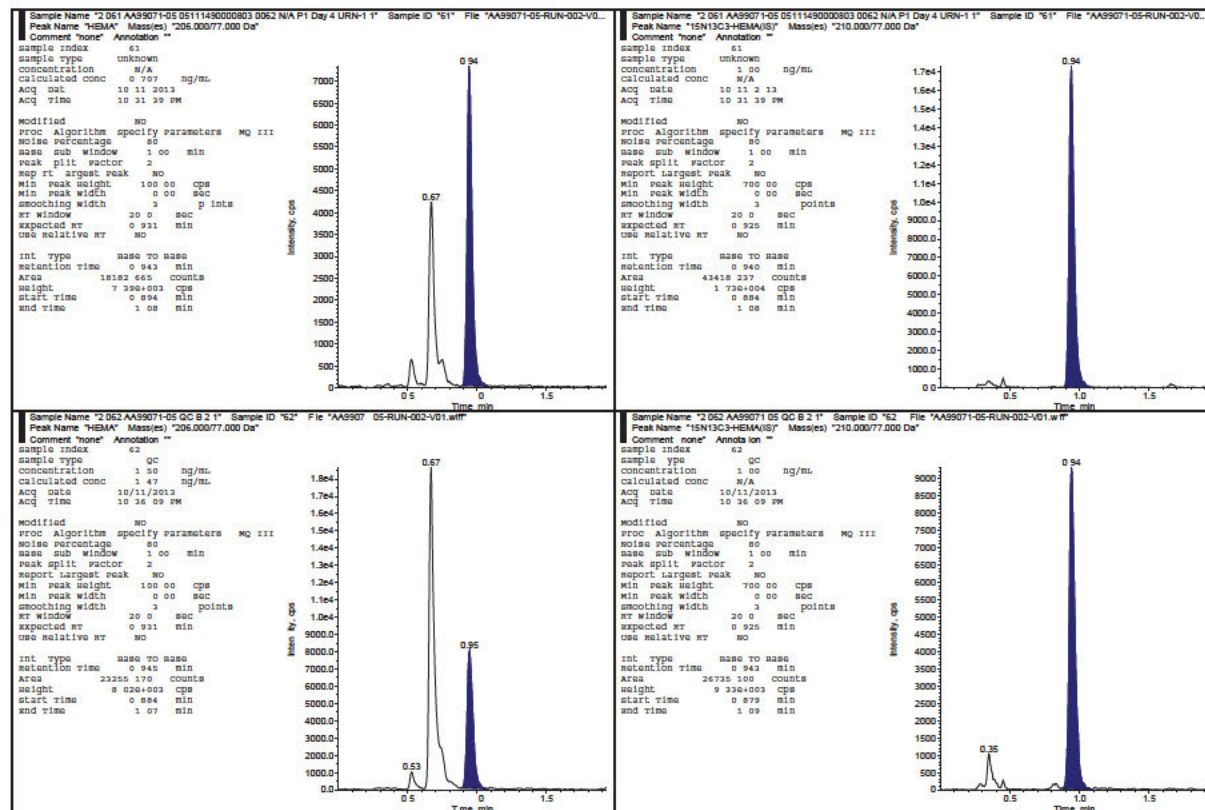


HEMA in Human Urine
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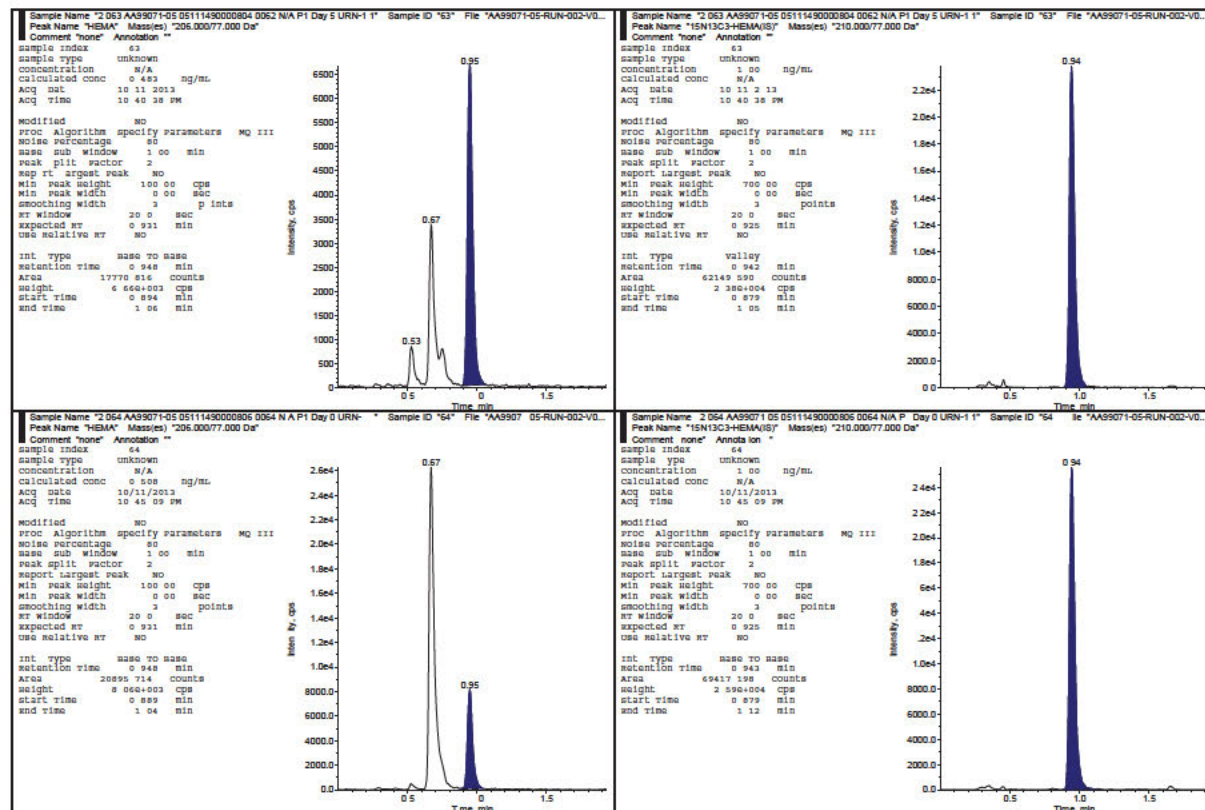


HEMA in Human Urine
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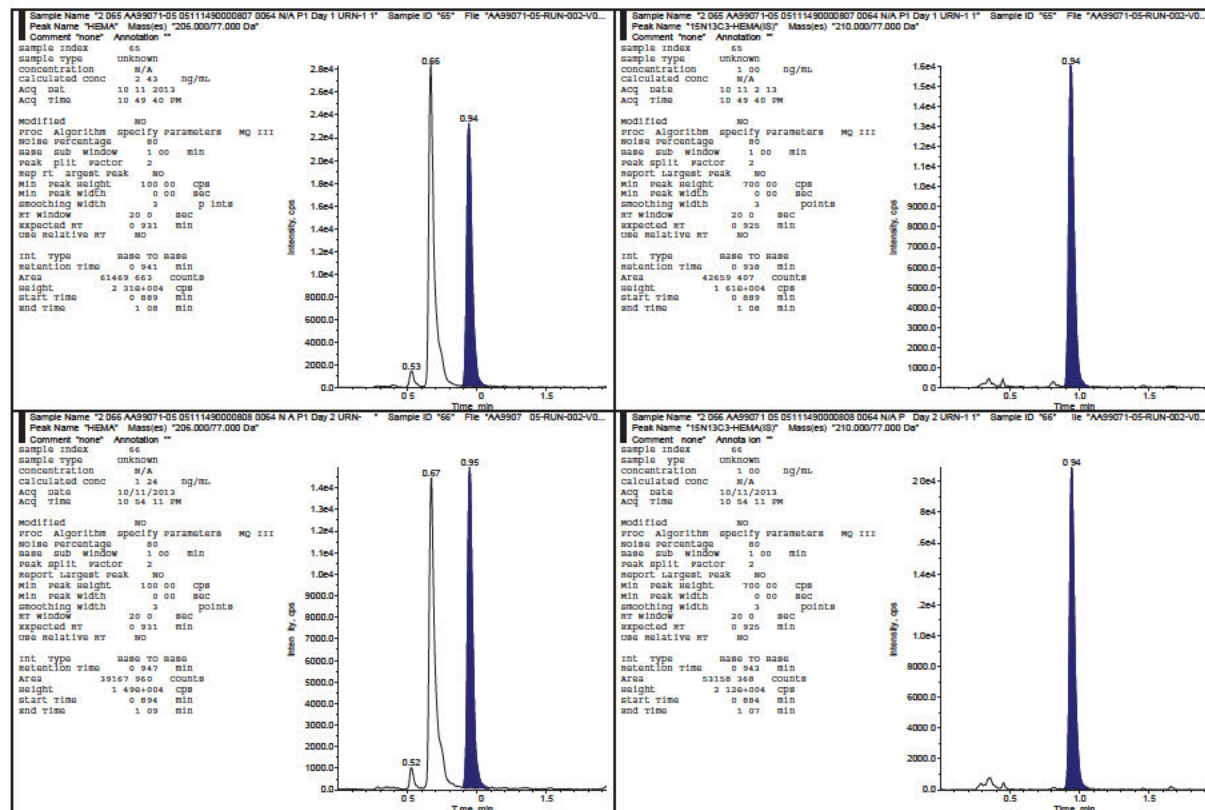


HEMA in Human Urine
Celerion Study AA99071-05



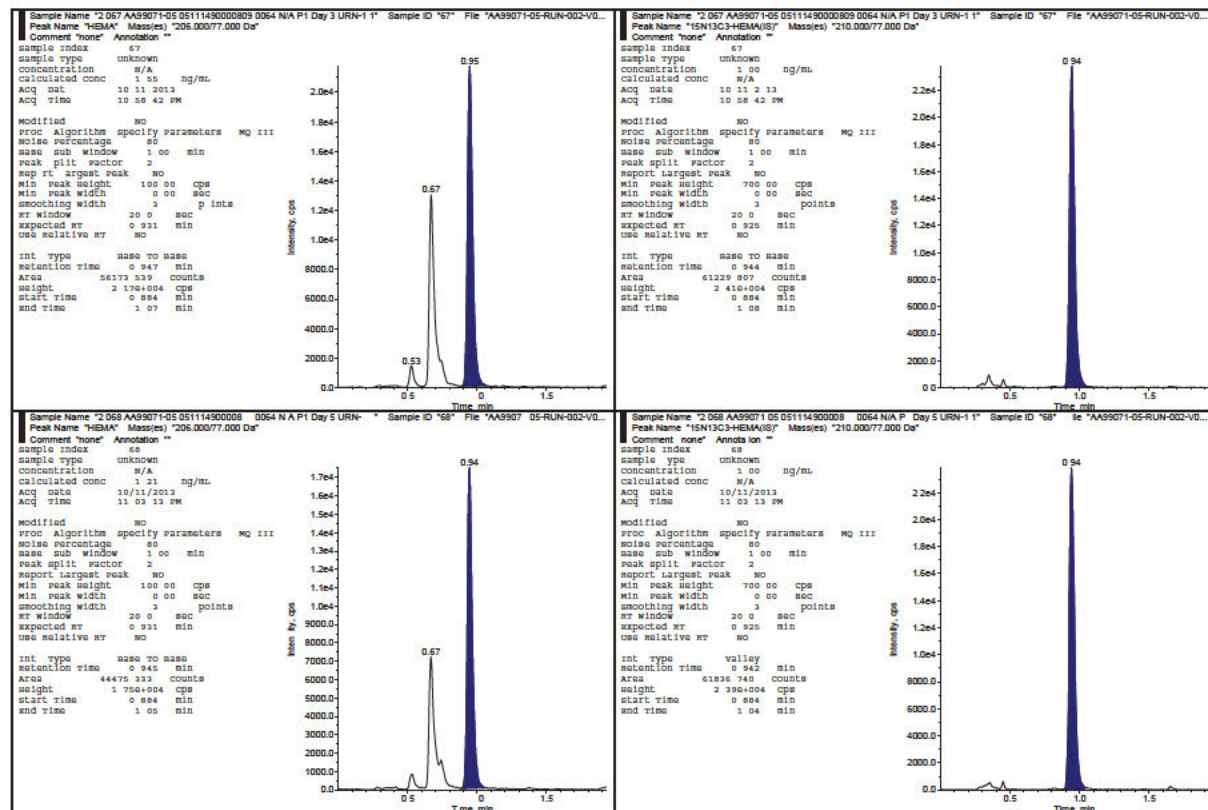


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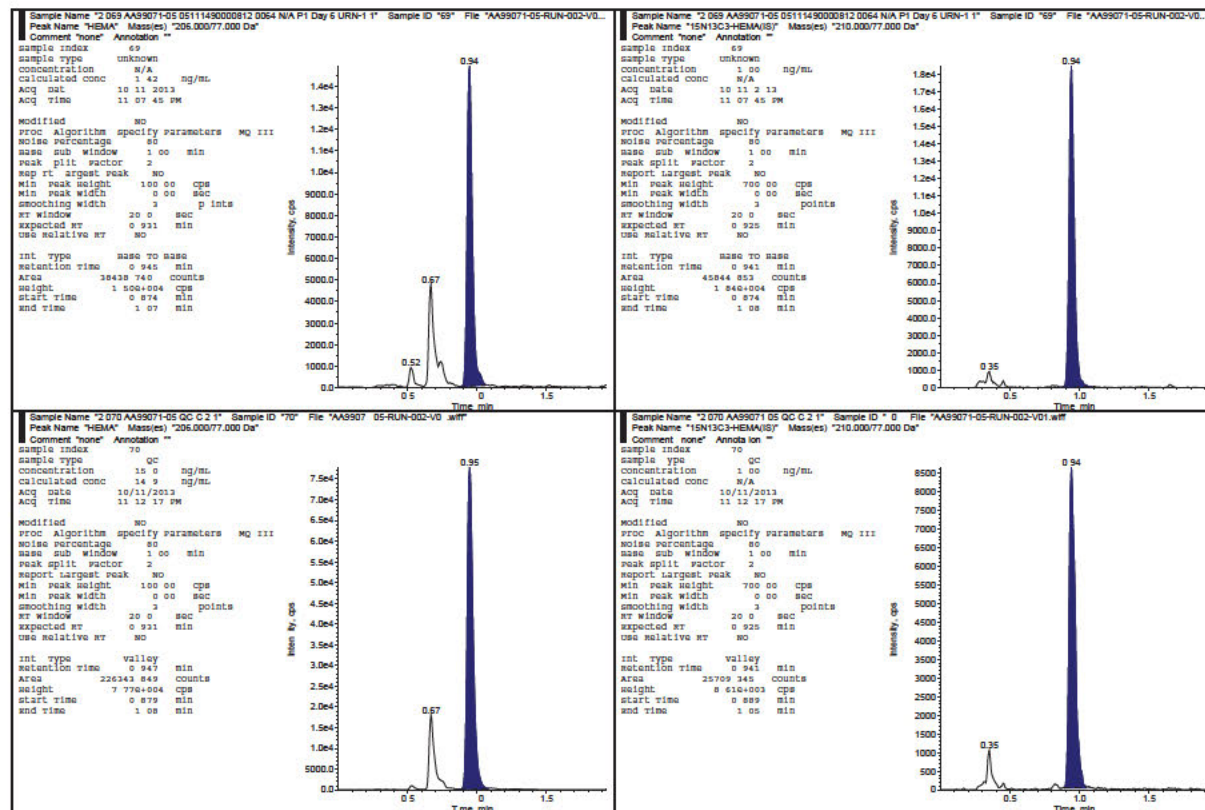


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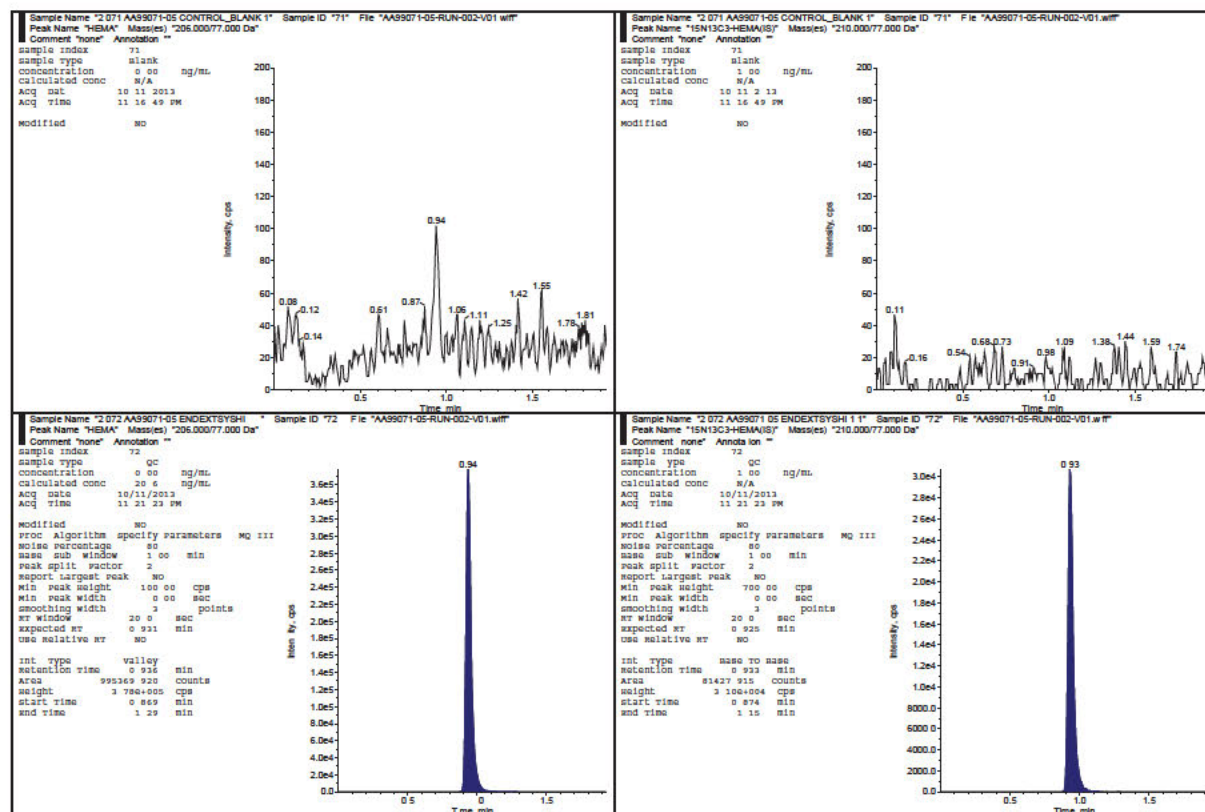


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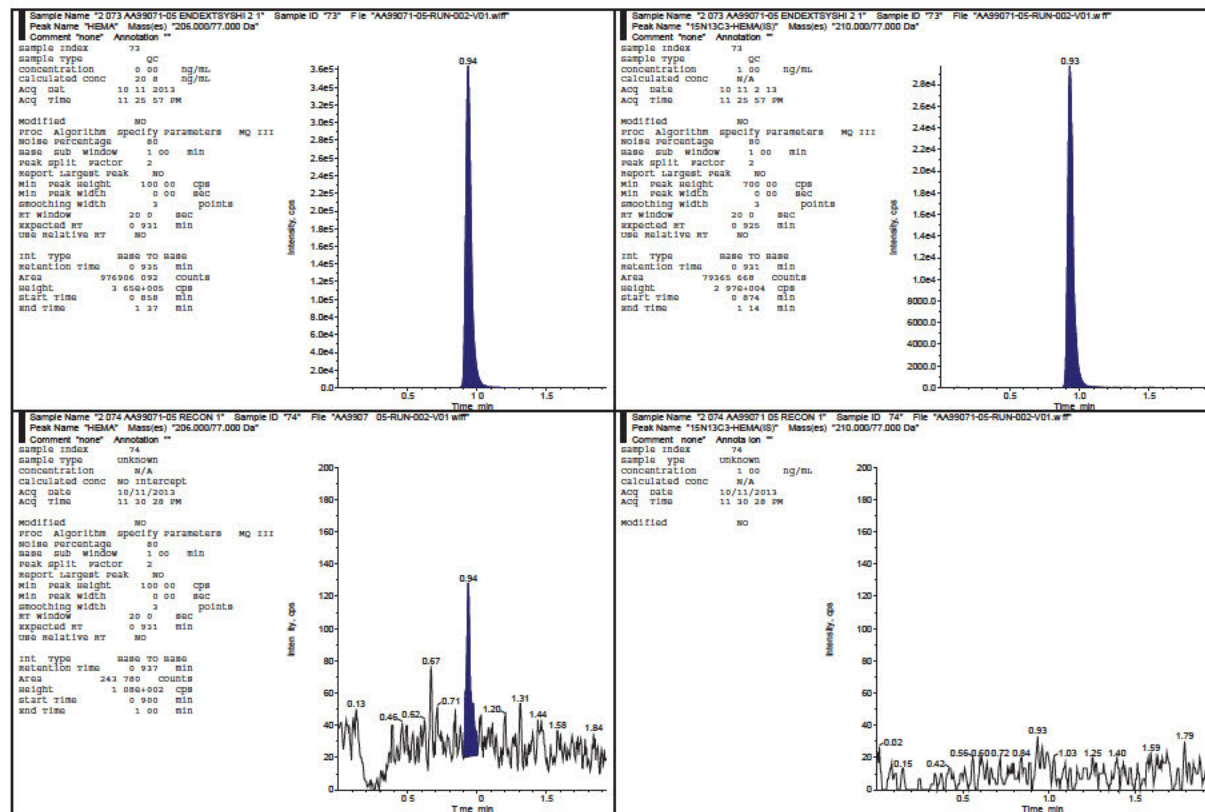


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