



### **16.1.9.3 BIOANALYTICAL REPORTS**

Determination of Monohydroxy-3-butenyl-mercapturic acid (MHBMA) in Human Urine Samples by LC-MS/MS (Study AA99602-02)



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**Determination of monohydroxy-3-butenyl-mercapturic acid (MHBMA) 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: AA99602-02  
Bioanalytical Report No. AAA99602-02

Bioanalytical Final Report

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

Report Date: 29 August 2014

MHBMA in Human Urine  
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\* Samples were received at Celerion Lincoln and the appropriate aliquots were forwarded from Lincoln to Celerion Switzerland.



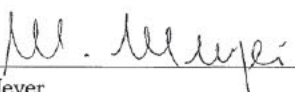
MHBMA in Human Urine  
Celerion Study AA99602-02

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**APPROVAL SIGNATURES**


**TEST FACILITY**  
**Celerion Switzerland AG:**

Bioanalytical Principal Investigator

  
Werner Meyer

  
Date

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MHBMA in Human Urine  
Celerion Study AA99602-02

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Manager Clinical Science

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11.09.2016

Date



MHBMA in Human Urine  
Celerion Study AA99602-02

#### STATEMENT OF COMPLIANCE

Herewith it is confirmed, that the Celerion study AA99602-02, with the exception of test runs (AA99602-02\_T10 and AA99602-02\_T11) was performed according to the standards described in the Swiss Ordinance relating to Good Laboratory Practice, adopted 18 May 2005 [RS 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted 26 November 1997 by decision of the OECD Council [C(97)186/Final] [1].

The OECD Principles of Good Laboratory Practice are accepted by Regulatory Authorities throughout the European Union, the United States of America and Japan.

In addition, the analysis of clinical trial samples including the validation of the applied analytical methods was conducted in accordance with the relevant standards of Good Clinical Practice and Standard Operating Procedures based on the recommendations of the EMA 'Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples' (EMA/INS/GCP/532137/2010) [2] and the EMA 'Guideline on bioanalytical method validation' (EMA/CHMP/EWP/192217/2009) [3].

This 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 audited the study. A Quality Assurance statement was then issued and is included within this document in the following page.

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 validity of the data.

Werner Meyer  
Bioanalytical Principal Investigator

29-Aug-2014  
Date



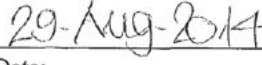
MHBMA in Human Urine  
Celerion Study AA99602-02

**QUALITY ASSURANCE STATEMENT**

Phase Audited	Audit Date(s)	Date Reported to Bioanalytical Principal Investigator	Date Audit Report Signed by Management
Bioanalytical Study Plan	08-Aug-2013	08-Aug-2013	09-Aug-2013
Bioanalytical Study Plan Amendment No. 1	18-Oct-2013	18-Oct-2013	18-Oct-2013
Bioanalytical Study Plan Amendment No.2	12-Nov-2013	12-Nov-2013	12-Nov-2013
Bioanalytical Study Plan Amendment No.3	06-Jan-2014	06-Jan-2014	06-Jan-2014
Study-based inspection / Instrumental analysis and evaluation of results	20, 21-Jan, 03-Feb-2014	03-Feb-2014	07-Aug-2014
Raw Data Audit	06, 11, 12-Feb-2014	12-Feb-2014	27-May-2014
Bioanalytical Report (Final Draft)	04, 10, 11-Jun-2014	11-Jun-2014	07-Aug-2014
Bioanalytical Report (Final)	The date of the QA review of the Final Report is identical to the signature date of the QA Statement.		

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.

  
Diana Bürgin  
for M. Beerli  
QA Auditor

  
Date:

MHBMA in Human Urine  
Celerion Study AA99602-02**TABLE OF CONTENTS**

STUDY LOCATION.....	2
APPROVAL SIGNATURES.....	3
STATEMENT OF COMPLIANCE.....	5
QUALITY ASSURANCE STATEMENT .....	6
TABLE OF CONTENTS.....	7
1. INTRODUCTION.....	10
2. EXPERIMENTAL .....	10
2.1. Test Item .....	10
2.2. Reference Items and Internal Standards.....	10
2.3. Blank Matrix .....	10
2.4. Test System.....	11
2.4.1. Procedure and Instruments.....	11
2.4.2. Computer Application Software .....	11
2.5. Calibration Standards and Quality Control Samples .....	11
2.6. Study Samples.....	11
2.6.1. Sample Source and Date of Receipt.....	11
2.6.2. Sample Identification .....	12
2.6.3. Sample Storage and Stability .....	12
2.6.4. Sample Summary .....	12
3. SAMPLE ANALYSIS.....	13
3.1. Analytical Method.....	13
3.2. Acceptance Criteria.....	13
3.2.1. Analytical Run Acceptance Criteria.....	13
3.2.2. Acceptance Criteria for Sample Dilution.....	13
3.2.3. Acceptance Criteria for ISR.....	13
4. RESULTS.....	14
4.1. Quality Control Sample Performance .....	14
4.2. Calibration Standard Performance .....	14
4.3. Standard Curve Parameters.....	14



MHBMA in Human Urine  
Celerion Study AA99602-02

---

4.4. Study Sample Concentrations .....	14
4.5. Reassays .....	14
4.5.1. Reassays for Analytical Reasons .....	14
4.5.2. Reassays for Non-analytical Reasons (Value requiring confirmation, VRC) .....	15
4.5.3. Sponsor Selected Reassays .....	15
4.5.4. Incurred Sample Reproducibility .....	15
5. CHROMATOGRAMS .....	15
6. DEVIATIONS .....	15
7. EVENTS .....	15
7.1. Event Resolution dated 09-Dec-2013 .....	15
8. ANALYTICAL NOTES .....	16
8.1. Schedule nominal time points .....	16
9. ARCHIVES .....	16
10. CONCLUSION .....	16
11. REFERENCES .....	16
RESULT TABLES .....	18
FIGURES .....	72
ATTACHMENTS .....	73





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MHBMA in Human Urine  
Celerion Study AA99602-02

---

## RESULT TABLES

Table 1	Summary of Analytical Runs Performed .....	18
Table 2	Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for MHBMA .....	20
Table 3	Back-calculated Calibration Standard Concentrations for MHBMA.....	22
Table 4	Standard Curve Parameters for MHBMA .....	24
Table 5	Study Sample Concentrations for MHBMA .....	25
Table 6	Summary of Reassay for Analytical Reasons for MHBMA .....	65
Table 7	Incurred Sample Reproducibility Assessment for MHBMA .....	68

## FIGURES

Figure 1	Calibration Curve for MHBMA in UriSub <sup>®</sup> , Watson Run ID 12 .....	72
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## ATTACHMENTS

Attachment 1	General List of Abbreviations used at Celerion .....	73
Attachment 2	Temperature Definitions at Celerion.....	75
Attachment 3	Procedure for VCR and SSR Reassays and Reporting of Reassay Results ..	76
Attachment 4	General List of Calculation Formulae .....	77
Attachment 5	Reassay Descriptions .....	78
Attachment 6	Statement of GLP Compliance (Swissmedic).....	79
Attachment 7	Certificates of Analysis .....	80
Attachment 8	Summary of the Method Validation Data .....	82
Attachment 9	Chromatograms .....	86

**Total number of pages** **131**

MHBMA in Human Urine  
Celerion Study AA99602-02

## 1. INTRODUCTION

The purpose of this bioanalytical study (hereafter referred to as study) was to determine the concentration of monohydroxy-3-butenyl-mercaptopuric acid (MHBMA) in human urine samples using a validated LC-MS/MS method [4]. 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" [5]. Sample analysis was conducted between 12-Nov-2013 (experimental start) to 27-Jan-2014 (experimental end).

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 item (product name) is defined in the clinical study protocol [5].

### 2.2. Reference Items and Internal Standards

All calculations were based on the purity provided.

	Analyte	Internal Standard (IS)
ID	MHBMA DCHA salt	MHBMA- <sup>15</sup> N- <sup>13</sup> C <sub>3</sub> DCHA salt
Source	(b) (4)	(b) (4)
Lot No.	AC0103094	AC0103111
Purity/Potency (%)	Chromatographic purity 96.5%, Potency 96.1%	Chromatographic purity 86.8%
Retest date	23 May 2015	20 Jun 2015
Storage conditions	5 C	5 C

The certificate of analysis for the reference items and internal standard are presented in [Attachment 7](#). Reference items and internal standards are retained under the conditions that are specified until they become expired.

### 2.3. Blank Matrix

Human urine was collected from volunteers in-house. Human urine, free of significant interference at the retention time and mass transitions of the internal standard was used to prepare quality control (QC) samples. Human urine was stored at -20°C. UriSub<sup>®</sup>, a synthetic urine substitute, was used to prepare calibration standards, as control matrix for blanks and STD 0. UriSub<sup>®</sup> was purchased from (b) (4) stored at room temperature and was used within the given expiry date



MHBMA in Human Urine  
Celerion Study AA99602-02

## 2.4. Test System

### 2.4.1. Procedure and Instruments

#### Procedure and Instrumentation

Extraction Method	Solid-phase extraction
Chromatography system	Perkin Elmer Series 200 Micropump HPLC*
MS/MS system	AB SCIEX QTrap 5500*
Regression Type	Weighted linear regression curve (1/concentration <sup>2</sup> )
Quantitation Method	Area ratio
Assay Volume	0.250 mL

\* = Qualified systems

### 2.4.2. Computer Application Software

#### Software

LC-MS/MS software	Applied Biosystems Analyst® 1.5.2*
LIMS	Thermo Electron Corporation Watson™ 7.3 Bioanalytical LIMS 7.3*
Laboratory Documentation System	Terrington Data Management Labnotes® 5.18, 1.21 (Web application)*
Office applications	Microsoft® Office 2007 and 2010 Package

\* = Validated systems

## 2.5. Calibration Standards and Quality Control Samples

Non-zero calibration standards at the concentration levels of 0.100, 0.200, 0.400, 0.800, 1.50, 3.50, 8.00, 12.0, 16.0 and 20.0 ng/mL of MHBMA were prepared in bulk on 07-Nov-2013 (as part of study AA98876-02 [4]) and on 21-Jan-2014 within this study, aliquoted and stored at -20°C and were used during the validated stability period [4].

Quality control (QC) samples at the concentration levels of 0.310, 1.60 and 15.1 ng/mL of MHBMA were prepared in bulk on 07-Oct-2013 (as part of study AA98876-02 [4]), aliquoted and stored at -20°C and were used during the validated stability period [4]. The actual QC concentration was calculated by adding the basal concentration to the spiked concentrations. QC samples were stored under the same conditions as the study samples were stored.

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 16-Aug-2013 and 22-Nov-2013 from Celerion Lincoln, Nebraska, USA.

MHBMA in Human Urine  
Celerion Study AA99602-02**2.6.2. Sample Identification**

Study samples were identified based on the Watson LIMS custom ID.

**2.6.3. Sample Storage and Stability**

Study samples were stored from sample collection to the end of sample analysis at a nominal temperature of -20°C for a duration not exceeding 200 days.

Up to 6 freeze/thaw cycles and maximum long-term stability of 200 days (including ISR) in urine (for samples) will be evaluated in Celerion study ZZ42382 [6].

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

Stability Summary [4], [7], [8]	MHBMA
Long-term stability	178 days at nominal -20 C in human urine 95 days at nominal -20 C in Urisub®
Short-term stability	24 hours at room temperature
Freeze-thaw stability	4 cycles at nominal -20 C
Post-preparative stability	185 hours at nominal 5 C
Processed sample integrity	153 hours at 5 C
Sample shipping stability	8 days in a polypropylene tubes at -80 C

**2.6.4. Sample Summary**

The Sponsor's protocol specifies 160 subjects, 7 sampling times for 24-hour urine collections [5]. During the study nine subjects (0211, 0242, 0245, 0247, 0269, 0288, 0299, 0309 and 0312) discontinued during the clinical phase. No samples from these subjects were analyzed.

Subject 0085 resigned from the study. Four samples were analyzed and reported for this subject.

	No. of Samples
Number of expected study samples/received in Zurich	1120 (primary samples) and 1120 (back-up samples) / 1117 (primary samples) and 1117 (back-up samples)
Specified "for analysis" samples in protocol/received	1120 primary samples / 1117 primary samples
Time points lost due to subject discontinuance	3
Back-up samples received	1117
Total number of study samples analyzed	1117

Following analysis, the study samples were kept frozen at -20°C and will be destroyed after the completion of the clinical study report and sponsor notification.



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MHBMA in Human Urine  
Celerion Study AA99602-02

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### 3. SAMPLE ANALYSIS

#### 3.1. Analytical Method

The determination of MHBMA in human urine study samples was carried out over a calibration range of 0.100 ng/mL to 20.0 ng/mL (MHBMA) using a system with a single analytical column. The method validation was performed in accordance with Celerion standard procedures, which follow the FDA guidance for the validation of bioanalytical methods [9] and the EMA guideline on bioanalytical method validation [3]. The method validation is described in AA98876-02 [4] and documented in SOP SM1-383A [10] and amendment No. 3 to study plan bioanalysis, PAA99602-02Am 3 [11].

Human urine samples spiked with IS were extracted using a solid phase extraction procedure. The extracted samples were analyzed by LC-MS/MS. Negative ions were monitored in the multiple reaction-monitoring (MRM) mode.

#### 3.2. Acceptance Criteria

##### 3.2.1. Analytical Run Acceptance Criteria

An analytical run was acceptable if all of the following criteria were 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 (including DQCs) 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 Sample Dilution

Not applicable. No dilution quality control samples were used in this study.

##### 3.2.3. Acceptance Criteria for ISR

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





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MHBMA in Human Urine  
Celerion Study AA99602-02

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

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

Data presented in this report derive from the method using a single analytical column system which was, subsequent to the event resolution dated 09-Dec-2013 (see [section 7.1](#)), validated within method validation study AA98876-02 [4].

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 0.310, 1.60 and 15.1 ng/mL are summarized in [Table 2](#) for MHBMA.

##### 4.2. Calibration Standard Performance

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

##### 4.3. Standard Curve Parameters

Standard curve parameters from 20 successful analytical runs using a system with a single analytical column are provided in [Table 4](#) for MHBMA. A representative calibration curve is illustrated in [Figure 1](#) for MHBMA. The standard zero samples (blank samples with IS added) were not used to plot the calibration curve.

##### 4.4. Study Sample Concentrations

Study sample concentrations are provided in [Table 5](#) for MHBMA. 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 MHBMA, respectively, 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 requiring re-analysis according to [Attachment 5](#) for MHBMA in human urine are identified in [Table 6](#). Reassay descriptions are provided in [Attachment 5](#).



MHBMA in Human Urine  
Celerion Study AA99602-02

#### 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 MHBMA in human urine was considered reproducible, 89.6% out of 106 repeat analyses for MHBMA met acceptance criteria as defined in [section 3.2.3](#). Results are presented in [Table 7](#).

### 5. CHROMATOGRAMS

Representative chromatograms from analytical run AA99602-02\_P12 are provided in [Attachment 9](#).

### 6. DEVIATIONS

There were no deviations during the conduct of the study.

### 7. EVENTS

#### 7.1. Event Resolution dated 09-Dec-2013

Within run AA99602-02\_P6, 34 study samples were reanalysed to demonstrate ISR. The difference between repeat and original value for one study sample was >67% and the difference was >20% for 13 of the 34 study samples (ISR pass rate of 61.8%). The occurrence was investigated; different chromatographic properties (different separation of analyte from interfering peak) using the method with two analytical columns in parallel and inconsistencies in peak integration obtained for chromatograms from the two analytical columns by automated peak integration were regarded to be the reason for the data obtained in run AA99602-02\_P6.

Data of the 490 study samples analysed with the system using two analytical columns were considered to be affected and were rejected.

A method using a single analytical column system which was established and additionally evaluated within method validation study AA98876-02 met all corresponding acceptance criteria and was applied for the analysis of all human urine samples collected in the clinical trial ZRHR-REXC-03-EU.



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MHBMA in Human Urine  
Celerion Study AA99602-02

## 8. ANALYTICAL NOTES

### 8.1. Schedule nominal time points

Urine was collected over 24 hours, the following relation exists:

Start day nominal	Nominal time, Nominal Day
-1	0
0	1
1	2
2	3
3	4
4	5
5	6

## 9. ARCHIVES

At a minimum the following records will be retained:

- Study Plan Bioanalysis (and all amendments)
- 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.

## 10. CONCLUSION

In this bioanalytical study the concentration of MHBMA were determined in a total of 1117 human urine samples collected in the Philip Morris International Research and Development clinical study ZRHR-REXC-03-EU by validated LC-MS/MS methods [4] and [7]. The overall performance of the LC-MS/MS methods 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] OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17, OECD, Paris, 1998. (No.1 in OECD Series on Good Laboratory Practice and Compliance Monitoring).
- [2] EMA. GCP Inspectors Working Group. Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples. EMA/INS/GCP/532137/2010 of 28 February 2012.
- [3] EMA. Committee for Medicinal Products for Human Use. Guideline on bioanalytical method validation. EMEA/CHMP/EWP/192217/2009 of 21 July 2011.





MHBMA in Human Urine  
Celerion Study AA99602-02

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- [4] Validation of an LC-MS/MS method for the determination of monohydroxy-3-butenyl-mercapturic acid (MHBMA) in human urine, Celerion Study AA98876-02, Celerion Switzerland AG.
  - [5] 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, Clinical Study Protocol ZRHR-REXC-03-EU, Version number: Final, Revision date: 25 April 2013.
  - [6] Validation of an LC-MS/MS method for the determination of monohydroxy-3-butenyl-mercapturic acid (MHBMA) in human urine, Celerion Switzerland AG, Study ZZ42382.
  - [7] Validation of an LC-MS/MS method for the determination of MHBMA in human urine, Celerion Lincoln, Study ZZ25433-02 Amendment 4 to final report, Report date: 10-Jan-2013.
  - [8] Cross-site validation of an LC-MS/MS method for the determination of MHBMA in human urine, MDS Pharma Services Switzerland AG, Validation Report ZZ00390, Report Date 17-Apr-2008.
  - [9] Guidance for Industry, Bioanalytical Method Validation, U.S. Department of Health and Human Services, Food and Drug Administration, Centre for Drug Evaluation and Research (CDER), May 2001.
  - [10] Determination of monohydroxy-3-butenyl-mercapturic acid (MHBMA) in human urine using LC-MS/MS. Method SOP SM1-383A, Celerion Switzerland AG, dated 01-Oct-2013.
  - [11] Determination of monohydroxy-3-butenyl-mercapturic acid (MHBMA) 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 Switzerland AG, Study Plan Bioanalysis PAA99602-02, effective date 12-Aug-2013, amendment no.1 to the study plan, effective date 23-Oct-2013, amendment no. 2 to the study plan, effective date 12-Nov-2013 and amendment no. 3 to the study plan, effective date 06-Jan-2014.





MHBMA in Human Urine  
Celerion Study AA99602-02

## RESULT TABLES

Table 1 Summary of Analytical Runs Performed

Watson Run ID	Run ID	Regression Status (MHBMA)	Extraction Date	Assay Date	Description	Comment
1	AA99602-02_P1	Rejected <sup>a</sup>	12-Nov-2013	12-Nov-2013	Subj. 0001, 0004, 0008, 0010, 0011, 0013-0017	double column system used
2	AA99602-02_P2	Rejected <sup>a</sup>	13-Nov-2013	13-Nov-2013	Subj. 0020, 0021, 0023, 0025, 0028 to 0031, 0034, 0035	double column system used
3	AA99602-02_P3	Rejected <sup>a</sup>	15-Nov-2013	N/AP	Subj. 0037-0039, 0042, 0044, 0049, 0051 to 0053, 0055	double column system used
4	AA99602-02_P4	Rejected <sup>a</sup>	15-Nov-2013	19-Nov-2013	Subj. 0057, 0060, 0062 to 0064, 0066, 0067, 0069, 0072, 0074	double column system used
5	AA99602-02_P5	Rejected <sup>a</sup>	19-Nov-2013	19-Nov-2013	Subj. 0076, 0080, 0083, 0086 to 0088, 0090, 0093, 0104, 105	double column system used
6	AA99602-02_P6	Rejected <sup>a</sup>	26-Nov-2013	26-Nov-2013	ISR 1 and repeats (Runs 2 and 4)	double column system used
7	AA99602-02_P7	Rejected <sup>a</sup>	21-Nov-2013	21-Nov-2013	Subj. 0037 to 0039, 0042, 0044, 0049, 0051-0053, 0055	double column system used
8	AA99602-02_P8	Rejected <sup>a</sup>	27-Nov-2013	27-Nov-2013	Subj. 0106, 0107, 0110, 0112, 0114, 0117, 0118, 0121-0123	double column system used
9	AA99602-02_P9	Rejected <sup>a</sup>	27-Nov-2013	28-Nov-2013	Subj. 0126-0130, 0133, 0134, 0136, 0137, 0139	double column system used
10	AA99602-02_T10	N/AP	28-Nov-2013	N/AP	Test run	OK
11	AA99602-02_T11	N/AP	10-Dec-2013	N/AP	Test run	OK
12	AA99602-02_P12	Accepted	06-Jan-2014	07-Jan-2014	Subj. 0001, 0004, 0008, 0010, 0011, 0013-0017	OK
13	AA99602-02_P13	Accepted	07-Jan-2014	08-Jan-2014	Subj. 0020, 0021, 0023, 0025, 0028-0031, 0034, 0035	OK
14	AA99602-02_P14	Accepted	07-Jan-2014	09-Jan-2014	Subj. 0037-0039, 0042, 0044, 0049, 0051-0053, 0055	OK
15	AA99602-02_P15	Accepted	08-Jan-2014	10-Jan-2014	Subj. 0057, 0060, 0062-0064, 0066, 0067, 0069, 0072, 0074	OK
16	AA99602-02_P16	Accepted	09-Jan-2014	11-Jan-2014	Subj. 0076, 0080, 0083, 0086-0088, 0090, 0093, 0104, 0105	OK
17	AA99602-02_P17	Accepted	09-Jan-2014	13-Jan-2014	Subj. 0106, 0107, 0110, 0112, 0114, 0117, 0118, 0121-0123	OK
18	AA99602-02_P18	N/AP	15-Jan-2014	N/AP	Subj. 0126-0130, 0133, 0134, 0136, 0137, 0139	ISP (incorrect SPE plate) *
19	AA99602-02_P19	N/AP	14-Jan-2014	N/AP	ISR 2	ISP (no IS added) **
20	AA99602-02_P20	Accepted	16-Jan-2014	16-Jan-2014	Subj. 0140, 0145, 0147-0150, 0152, 0153, 0155, 0156	OK
21	AA99602-02_P21	Accepted	17-Jan-2014	17-Jan-2014	Subj. 0160, 0162, 0167, 0169, 0170, 0177, 0181, 0183, 0185, 0187	OK
22	AA99602-02_P22	Accepted	23-Jan-2014	23-Jan-2014	Subj. 0022, 0071, 0085, 0315, 0318, 0320-0322, 0325, 0328	OK



MHBMA in Human Urine  
Celerion Study AA99602-02

Watson Run ID	Run ID	Regression Status (MHBMA)	Extraction Date	Assay Date	Description	Comment
23	AA99602-02_P23	Accepted	20-Jan-2014	20-Jan-2014	Subj. 0189-0193, 0195-0198, 0200	OK
24	AA99602-02_P24	Accepted	20-Jan-2014	20-Jan-2014	Subj. 0202-0204, 0206, 0210, 0216, 0218, 0220, 0224, 0228	OK
25	AA99602-02_P25	Accepted	21-Jan-2014	21-Jan-2014	Subj. 0229, 0230, 0232, 0234, 0240, 0241, 0244, 0249, 0251, 0252	OK
26	AA99602-02_P26	Accepted	22-Jan-2014	22-Jan-2014	Subj. 0255, 0256, 0262, 0264-0266, 0272, 0273, 0276, 0277	OK
27	AA99602-02_P27	Accepted	23-Jan-2014	23-Jan-2014	Subj. 0278, 0279, 0281-0283, 0285, 0287, 0289, 0291, 0292	OK
28	AA99602-02_P28	Accepted	24-Jan-2014	24-Jan-2014	Subj. 0296, 0298, 0300, 0301, 0306-0308, 0313, 0316, 0317	OK
29	AA99602-02_P29	Accepted	15-Jan-2014	15-Jan-2014	Repeat of ISR 2	OK
30	AA99602-02_P30	Accepted	17-Jan-2014	17-Jan-2014	Subj. 0126-0130, 0133, 0134, 0136, 0137, 0139	OK
31	AA99602-02_E31	Accepted	21-Jan-2014	21-Jan-2014	Spiking check <sup>#</sup>	OK
32	AA99602-02_P32	Accepted	22-Jan-2014	22-Jan-2014	ISR 3	OK
33	AA99602-02_P33	Accepted	24-Jan-2014	24-Jan-2014	Repeats	OK
34	AA99602-02_P34	Accepted	27-Jan-2014	27-Jan-2014	ISR 4 and repeats	OK

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

Rejected<sup>a</sup> for details see section events in paragraph 7.1.

\*: Wrong SPE plate used. The run was considered ISP. Samples were reassayed..

\*\* : IS was not added in the samples. The run was considered ISP. Samples were reassayed.

# : Testing of STDs and QC samples.

Analytical runs (Watson Run IDs 10, 11 and 31) to support study set up or tests that were required during the course of the study did not include any study samples. The content of these runs is described in the raw data.

MHBMA in Human Urine  
Celerion Study AA99602-02Table 2 Quality Control Sample Data (Between-Analytical Run Precision and Accuracy)  
for MHBMA

Assay Date	Watson Run ID	QC 0.3 0.310 ng/mL	QC 1.5 1.60 ng/mL	QC 15 15.1 ng/mL
07-Jan-2014	12	0.337	1.54	15.3
		0.294	1.51	15.3
08-Jan-2014	13	0.306	1.52	15.3
		0.305	1.53	14.0
09-Jan-2014	14	0.309	1.50	14.9
		0.297	1.44	14.8
10-Jan-2014	15	0.302	1.52	14.8
		0.309	1.53	15.6
11-Jan-2014	16	0.301	1.50	15.0
		0.292	1.52	15.2
13-Jan-2014	17	0.324	1.58	15.4
		0.317	1.54	15.0
15-Jan-2014	29	0.306	1.56	15.6
		0.304	1.59	15.2
16-Jan-2014	20	0.302	1.55	15.3
		0.302	1.51	15.0
17-Jan-2014	21	0.313	1.63	16.0
		0.311	1.55	15.5
17-Jan-2014	30	0.309	1.51	14.9
		0.304	1.52	14.7
20-Jan-2014	23	0.299	1.64	15.4
		0.307	1.56	15.9
20-Jan-2014	24	0.295	1.50	15.0
		0.313	1.50	15.2
21-Jan-2014	25	0.300	1.49	14.9
		0.288	1.49	15.1
22-Jan-2014	26	0.294	1.50	14.8
		0.295	1.46	14.6
22-Jan-2014	32	0.309	1.56	15.5
		0.304	1.57	15.5
23-Jan-2014	22	0.304	1.50	14.9
		0.295	1.45	14.0
23-Jan-2014	27	0.297	1.45	14.6
		0.285	1.44	14.6
24-Jan-2014	28	0.324	1.46	14.2
		0.290	1.42	14.2



MHBMA in Human Urine  
Celerion Study AA99602-02

Assay Date	Watson Run ID	QC 0.3 0.310 ng/mL	QC 1.5 1.60 ng/mL	QC 15 15.1 ng/mL
24-Jan-2014	33	0.301	1.47	14.5
		0.295	1.47	14.8
27-Jan-2014	34	0.299	1.46	14.9
		0.287	1.47	14.9
Mean		0.303	1.51	15.0
S.D.		0.011	0.05	0.5
%CV		3.5	3.3	3.1
%Theoretical		97.8	94.6	99.4
n		40	40	40





MHBMA in Human Urine  
Celerion Study AA99602-02

Table 3 Back-calculated Calibration Standard Concentrations for MHBMA

Assay Date	Watson Run ID	STD 0.1 0.100 ng/mL	STD 0.2 0.200 ng/mL	STD 0.4 0.400 ng/mL	STD 0.8 0.800 ng/mL	STD 1.5 1.50 ng/mL	STD 3.5 3.5 ng/mL	STD 8 8.00 ng/mL	STD 12 12.0 ng/mL	STD 16 16.0 ng/mL	STD 20 20.0 ng/mL
07-Jan-2014	12	0.0980	0.209	0.399	0.773	1.53	3.64	7.85	12.0	16.0	19.3
08-Jan-2014	13	0.100	0.196	0.418	0.780	1.52	3.56	7.59	12.0	16.4	19.9
09-Jan-2014	14	0.101	0.200	0.379	0.829	1.51	3.59	8.17	11.8	15.4	20.2
10-Jan-2014	15	0.100	0.200	0.394	0.805	1.53	3.60	8.18	12.0	15.8	19.0
11-Jan-2014	16	0.100	0.200	0.396	0.796	1.48	3.61	8.17	12.0	15.7	19.6
13-Jan-2014	17	*0.116	0.202	0.412	0.707	1.54	3.58	8.00	12.4	16.6	19.1
15-Jan-2014	29	0.0998	0.200	0.403	0.794	1.53	3.50	8.16	11.8	16.0	19.6
16-Jan-2014	20	0.101	0.193	0.400	0.811	1.51	3.50	8.10	11.8	16.3	19.7
17-Jan-2014	21	0.0982	0.208	0.398	0.800	1.47	3.53	7.90	11.9	16.3	19.9
17-Jan-2014	30	0.103	0.191	0.383	0.820	1.51	3.56	7.90	12.1	15.9	20.5
20-Jan-2014	23	0.0999	0.203	0.394	0.800	1.45	3.53	7.85	12.2	16.4	20.1
20-Jan-2014	24	0.0982	0.208	0.399	0.795	1.50	3.48	8.00	**7.34	15.8	20.2
21-Jan-2014	25	0.101	0.196	0.408	0.780	1.51	3.52	8.10	**7.84	15.7	20.2
22-Jan-2014	26	0.0993	0.200	0.405	0.834	1.49	3.46	8.11	11.7	15.8	20.0
22-Jan-2014	32	0.100	0.200	0.399	0.766	1.51	3.58	8.07	12.0	16.0	20.1
23-Jan-2014	22	0.0994	0.202	0.399	0.806	1.50	3.53	8.03	11.8	15.9	20.1
25-Jan-2014	27	0.0981	0.208	0.404	0.797	1.45	3.30	8.16	12.3	16.0	20.3
24-Jan-2014	28	0.100	0.198	0.406	0.822	1.48	3.13	8.35	11.9	16.5	20.5
24-Jan-2014	33	0.101	0.196	0.392	0.802	1.52	3.48	8.17	11.8	16.2	20.0



MHBMA in Human Urine  
Celerion Study AA99602-02

Assay Date	Watson Run ID	STD 0.1 0.100 ng/mL	STD 0.2 0.200 ng/mL	STD 0.4 0.400 ng/mL	STD 0.8 0.800 ng/mL	STD 1.5 1.50ng/mL	STD 3.5 3.5 ng/mL	STD 8 8.00 g/mL	STD 12 12.0 ng/mL	STD 16 16.0 ng/mL	STD 20 20.0 ng/mL
27-Jan-2014	34	0.100	0.200	0.400	0.806	1.47	3.49	8.07	11.9	15.9	20.5
Mean		0.100	0.200	0.399	0.796	1.50	3.51	8.05	12.0	16.0	19.9
S.D.		0.001	0.005	0.009	0.027	0.03	0.12	0.17	0.2	0.3	0.4
%CV		1.3	2.5	2.2	3.4	1.8	3.3	2.1	1.7	2.0	2.2
%Bias		0.0	0.2	-0.1	-0.5	0.1	0.2	0.6	-0.3	0.1	-0.3
n		19	20	20	20	20	20	20	18	20	20

\* rejected STD due to interference in blank/STD 0

\*\* rejected STD, conc. outside 85.0 to 115.0%



MHBMA in Human Urine  
Celerion Study AA99602-02

Table 4 Standard Curve Parameters for MHBMA

Assay Date	Watson Run ID	Slope	Intercept	R-Squared
07-Jan-2014	12	0.1470	-0.0001336	0.9990
08-Jan-2014	13	0.1491	0.0004333	0.9990
09-Jan-2014	14	0.1534	-0.0003165	0.9989
10-Jan-2014	15	0.1465	0.0002750	0.9993
11-Jan-2014	16	0.1499	0.0006051	0.9997
13-Jan-2014	17	0.1483	-0.001065	0.9967
15-Jan-2014	29	0.1610	0.0004684	0.9998
16-Jan-2014	20	0.1520	-0.000001401	0.9996
17-Jan-2014	21	0.2878	-0.0005433	0.9996
17-Jan-2014	30	0.1518	-0.0005395	0.9991
20-Jan-2014	23	0.2802	0.001679	0.9996
20-Jan-2014	24	0.1516	-0.001078	0.9996
21-Jan-2014	25	0.1465	0.0003534	0.9997
22-Jan-2014	26	0.2995	0.001320	0.9995
22-Jan-2014	32	0.1489	-0.0001582	0.9996
23-Jan-2014	22	0.3048	-0.0005554	0.9999
23-Jan-2014	27	0.1597	0.0003813	0.9988
24-Jan-2014	28	0.2938	0.00009858	0.9977
24-Jan-2014	33	0.1519	-0.0002771	0.9997
27-Jan-2014	34	0.1527	-0.0001909	0.9998
Mean		0.1868	0.00003774	0.9992
S.D.		0.0633	0.0006924	0.0008
%CV		33.9	1834.5	0.1
n		20	20	20





MHBMA in Human Urine  
Celerion Study AA99602-02

Table 5 Study Sample Concentrations for MHBMA

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000414	12	0001	Urine	-1	0	0.706	1	OK	
05113210000415	12	0001	Urine	0	1	1.02	1	OK	
05113210000416	12	0001	Urine	1	2	0.274	1	OK	
05113210000417	12	0001	Urine	2	3	0.139	1	OK	
05113210000418	12	0001	Urine	3	4	0.105	1	OK	
05113210000419	12	0001	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000420	12	0001	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000428	12	0004	Urine	-1	0	2.30	1	OK	
05113210000429	12	0004	Urine	0	1	2.83	1	OK	
05113210000430	12	0004	Urine	1	2	0.660	1	OK	
05113210000431	12	0004	Urine	2	3	0.182	1	OK	
05113210000432	12	0004	Urine	3	4	0.122	1	OK	
05113210000433	12	0004	Urine	4	5	0.128	1	OK	
05113210000434	12	0004	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000001	12	0008	Urine	-1	0	4.97	1	OK	
05113210000002	12	0008	Urine	0	1	5.32	1	OK	
05113210000003	12	0008	Urine	1	2	2.24	1	OK	
05113210000004	12	0008	Urine	2	3	0.277	1	OK	
05113210000005	12	0008	Urine	3	4	0.165	1	OK	
05113210000006	12	0008	Urine	4	5	0.187	1	OK	
05113210000007	12	0008	Urine	5	6	0.127	1	OK	
05113210000008	12	0010	Urine	-1	0	4.90	1	OK	
05113210000009	12	0010	Urine	0	1	1.67	1	OK	
05113210000010	12	0010	Urine	1	2	0.789	1	OK	
05113210000011	12	0010	Urine	2	3	0.174	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000012	12	0010	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000013	12	0010	Urine	4	5	0.125	1	OK	
05113210000014	12	0010	Urine	5	6	0.105	1	OK	
05113210000015	12	0011	Urine	-1	0	0.446	1	OK	
05113210000016	12	0011	Urine	0	1	0.691	1	OK	
05113210000017	12	0011	Urine	1	2	0.331	1	OK	
05113210000018	12	0011	Urine	2	3	0.159	1	OK	
05113210000019	12	0011	Urine	3	4	0.139	1	OK	
05113210000020	12	0011	Urine	4	5	0.155	1	OK	
05113210000021	12	0011	Urine	5	6	0.128	1	OK	
05113210000442	12	0013	Urine	-1	0	1.45	1	OK	
05113210000443	12	0013	Urine	0	1	2.58	1	OK	
05113210000444	12	0013	Urine	1	2	0.331	1	OK	
05113210000445	12	0013	Urine	2	3	0.208	1	OK	
05113210000446	12	0013	Urine	3	4	0.135	1	OK	
05113210000447	12	0013	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000448	12	0013	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000022	12	0014	Urine	-1	0	1.69	1	OK	
05113210000023	12	0014	Urine	0	1	2.41	1	OK	
05113210000024	12	0014	Urine	1	2	0.458	1	OK	
05113210000025	12	0014	Urine	2	3	0.198	1	OK	
05113210000026	12	0014	Urine	3	4	0.125	1	OK	
05113210000027	12	0014	Urine	4	5	0.139	1	OK	
05113210000028	12	0014	Urine	5	6	0.127	1	OK	
05113210000029	12	0015	Urine	-1	0	4.97	1	OK	
05113210000030	12	0015	Urine	0	1	3.04	1	OK	
05113210000031	12	0015	Urine	1	2	0.674	1	OK	
05113210000032	12	0015	Urine	2	3	0.224	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000033	12	0015	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000034	12	0015	Urine	4	5	0.154	1	OK	
05113210000035	12	0015	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000036	12	0016	Urine	-1	0	1.86	1	OK	
05113210000037	12	0016	Urine	0	1	0.716	1	OK	
05113210000038	12	0016	Urine	1	2	0.254	1	OK	
05113210000039	12	0016	Urine	2	3	BLQ<(0.100)	1	OK	
05113210000040	12	0016	Urine	3	4	0.107	1	OK	
05113210000041	12	0016	Urine	4	5	0.121	1	OK	
05113210000042	12	0016	Urine	5	6	0.129	1	OK	
05113210000043	12	0017	Urine	-1	0	0.907	1	OK	
05113210000044	12	0017	Urine	0	1	1.13	1	OK	
05113210000045	12	0017	Urine	1	2	0.408	1	OK	
05113210000046	12	0017	Urine	2	3	0.202	1	OK	
05113210000047	12	0017	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000048	12	0017	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000049	12	0017	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000050	13	0020	Urine	-1	0	3.24	1	OK	
05113210000051	13	0020	Urine	0	1	3.38	1	OK	
05113210000052	13	0020	Urine	1	2	0.500	1	OK	
05113210000053	13	0020	Urine	2	3	0.146	1	OK	
05113210000054	13	0020	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000055	13	0020	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000056	13	0020	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000456	13	0021	Urine	-1	0	1.73	1	OK	
05113210000457	13	0021	Urine	0	1	2.37	1	OK	
05113210000458	13	0021	Urine	1	2	0.552	1	OK	
05113210000459	13	0021	Urine	2	3	2.86	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000460	13	0021	Urine	3	4	0.121	1	OK	
05113210000461	13	0021	Urine	4	5	0.112	1	OK	
05113210000462	13	0021	Urine	5	6	0.112	1	OK	
05113210000057	22	0022	Urine	-1	0	2.61	1	OK	
05113210000058	22	0022	Urine	0	1	3.83	1	OK	
05113210000059	22	0022	Urine	1	2	0.736	1	OK	
05113210000060	22	0022	Urine	2	3	0.176	1	OK	
05113210000061	22	0022	Urine	3	4	0.133	1	OK	
05113210000062	22	0022	Urine	4	5	0.125	1	OK	
05113210000259	22	0022	Urine	5	6	0.121	2	OK	
05113210000064	13	0023	Urine	-1	0	0.334	1	OK	
05113210000065	13	0023	Urine	0	1	0.350	1	OK	
05113210000066	13	0023	Urine	1	2	0.276	1	OK	
05113210000067	13	0023	Urine	2	3	0.135	1	OK	
05113210000068	13	0023	Urine	3	4	0.102	1	OK	
05113210000069	13	0023	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000070	13	0023	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000071	13	0025	Urine	-1	0	0.766	1	OK	
05113210000072	13	0025	Urine	0	1	1.05	1	OK	
05113210000073	13	0025	Urine	1	2	1.06	1	OK	
05113210000074	13	0025	Urine	2	3	0.846	1	OK	
05113210000075	13	0025	Urine	3	4	0.787	1	OK	
05113210000076	13	0025	Urine	4	5	0.972	1	OK	
05113210000077	13	0025	Urine	5	6	0.645	1	OK	
05113210000078	13	0028	Urine	-1	0	1.67	1	OK	
05113210000079	13	0028	Urine	0	1	1.99	1	OK	
05113210000080	13	0028	Urine	1	2	0.508	1	OK	
05113210000081	33	0028	Urine	2	3	0.253	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000082	33	0028	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000083	13	0028	Urine	4	5	0.105	1	OK	
05113210000084	13	0028	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000085	13	0029	Urine	-1	0	2.64	1	OK	
05113210000086	13	0029	Urine	0	1	1.13	1	OK	
05113210000087	13	0029	Urine	1	2	2.17	1	OK	
05113210000088	13	0029	Urine	2	3	2.04	1	OK	
05113210000089	13	0029	Urine	3	4	1.51	1	OK	
05113210000090	13	0029	Urine	4	5	1.76	1	OK	
05113210000091	13	0029	Urine	5	6	1.92	1	OK	
05113210000092	13	0030	Urine	-1	0	1.23	1	OK	
05113210000093	13	0030	Urine	0	1	1.39	1	OK	
05113210000094	13	0030	Urine	1	2	0.308	1	OK	
05113210000095	13	0030	Urine	2	3	BLQ<(0.100)	1	OK	
05113210000096	13	0030	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000097	13	0030	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000098	13	0030	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000099	13	0031	Urine	-1	0	0.256	1	OK	
05113210000100	13	0031	Urine	0	1	0.365	1	OK	
05113210000101	13	0031	Urine	1	2	0.143	1	OK	
05113210000102	13	0031	Urine	2	3	0.134	1	OK	
05113210000103	13	0031	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000104	13	0031	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000105	13	0031	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000106	13	0034	Urine	-1	0	1.15	1	OK	
05113210000107	13	0034	Urine	0	1	1.11	1	OK	
05113210000108	13	0034	Urine	1	2	0.484	1	OK	
05113210000109	13	0034	Urine	2	3	0.126	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000110	13	0034	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000111	13	0034	Urine	4	5	0.122	1	OK	
05113210000112	13	0034	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000113	13	0035	Urine	-1	0	2.23	1	OK	
05113210000114	13	0035	Urine	0	1	2.59	1	OK	
05113210000115	13	0035	Urine	1	2	2.38	1	OK	
05113210000116	13	0035	Urine	2	3	1.68	1	OK	
05113210000117	13	0035	Urine	3	4	1.68	1	OK	
05113210000118	13	0035	Urine	4	5	2.21	1	OK	
05113210000119	13	0035	Urine	5	6	2.53	1	OK	
05113210000470	14	0037	Urine	-1	0	3.24	1	OK	
05113210000471	14	0037	Urine	0	1	4.07	1	OK	
05113210000472	14	0037	Urine	1	2	3.50	1	OK	
05113210000473	14	0037	Urine	2	3	2.91	1	OK	
05113210000474	14	0037	Urine	3	4	3.48	1	OK	
05113210000475	14	0037	Urine	4	5	3.65	1	OK	
05113210000476	14	0037	Urine	5	6	3.57	1	OK	
05113210000120	14	0038	Urine	-1	0	2.18	1	OK	
05113210000121	14	0038	Urine	0	1	2.08	1	OK	
05113210000122	14	0038	Urine	1	2	0.576	1	OK	
05113210000123	14	0038	Urine	2	3	0.105	1	OK	
05113210000124	14	0038	Urine	3	4	0.115	1	OK	
05113210000125	14	0038	Urine	4	5	0.151	1	OK	
05113210000126	14	0038	Urine	5	6	0.133	1	OK	
05113210000127	14	0039	Urine	-1	0	0.144	1	OK	
05113210000128	14	0039	Urine	0	1	0.173	1	OK	
05113210000129	14	0039	Urine	1	2	0.141	1	OK	
05113210000130	14	0039	Urine	2	3	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000131	14	0039	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000132	14	0039	Urine	4	5	0.128	1	OK	
05113210000133	14	0039	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000477	14	0042	Urine	-1	0	1.61	2	OK	
05113210000485	14	0042	Urine	0	1	2.27	1	OK	
05113210000486	14	0042	Urine	1	2	2.29	1	OK	
05113210000487	14	0042	Urine	2	3	0.161	1	OK	
05113210000488	14	0042	Urine	3	4	4.43	1	OK	
05113210000489	14	0042	Urine	4	5	1.87	1	OK	
05113210000490	14	0042	Urine	5	6	2.34	1	OK	
05113210000134	14	0044	Urine	-1	0	0.736	1	OK	
05113210000135	14	0044	Urine	0	1	1.16	1	OK	
05113210000136	14	0044	Urine	1	2	0.414	1	OK	
05113210000137	14	0044	Urine	2	3	0.134	1	OK	
05113210000138	14	0044	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000139	14	0044	Urine	4	5	0.110	1	OK	
05113210000140	14	0044	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000141	14	0049	Urine	-1	0	1.97	1	OK	
05113210000142	14	0049	Urine	0	1	0.779	1	OK	
05113210000143	14	0049	Urine	1	2	0.851	1	OK	
05113210000144	14	0049	Urine	2	3	0.145	1	OK	
05113210000145	14	0049	Urine	3	4	0.162	1	OK	
05113210000146	14	0049	Urine	4	5	0.135	1	OK	
05113210000147	14	0049	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000498	14	0051	Urine	-1	0	0.104	1	OK	
05113210000499	14	0051	Urine	0	1	BLQ<(0.100)	1	OK	
05113210000500	14	0051	Urine	1	2	BLQ<(0.100)	1	OK	
05113210000501	14	0051	Urine	2	3	BLQ<(0.100)	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000502	14	0051	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000503	14	0051	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000504	14	0051	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000148	14	0052	Urine	-1	0	0.159	1	OK	
05113210000149	14	0052	Urine	0	1	0.199	1	OK	
05113210000150	14	0052	Urine	1	2	0.108	1	OK	
05113210000151	14	0052	Urine	2	3	0.269	1	OK	
05113210000152	14	0052	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000153	14	0052	Urine	4	5	0.169	1	OK	
05113210000154	14	0052	Urine	5	6	0.154	1	OK	
05113210000155	14	0053	Urine	-1	0	2.46	1	OK	
05113210000156	14	0053	Urine	0	1	2.77	1	OK	
05113210000353	14	0053	Urine	1	2	3.63	2	OK	
05113210000158	14	0053	Urine	2	3	2.49	1	OK	
05113210000159	14	0053	Urine	3	4	2.83	1	OK	
05113210000160	14	0053	Urine	4	5	2.03	1	OK	
05113210000161	14	0053	Urine	5	6	2.90	1	OK	
05113210000162	14	0055	Urine	-1	0	0.575	1	OK	
05113210000163	14	0055	Urine	0	1	BLQ<(0.100)	1	OK	
05113210000164	14	0055	Urine	1	2	0.422	1	OK	
05113210000165	14	0055	Urine	2	3	0.463	1	OK	
05113210000166	14	0055	Urine	3	4	0.296	1	OK	
05113210000167	14	0055	Urine	4	5	0.425	1	OK	
05113210000168	14	0055	Urine	5	6	0.700	1	OK	
05113210000169	15	0057	Urine	-1	0	1.49	1	OK	
05113210000170	15	0057	Urine	0	1	0.967	1	OK	
05113210000171	15	0057	Urine	1	2	0.415	1	OK	
05113210000172	15	0057	Urine	2	3	0.114	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000173	15	0057	Urine	3	4	0.113	1	OK	
05113210000174	15	0057	Urine	4	5	0.103	1	OK	
05113210000175	15	0057	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000176	15	0060	Urine	-1	0	1.10	1	OK	
05113210000177	15	0060	Urine	0	1	1.19	1	OK	
05113210000178	15	0060	Urine	1	2	0.246	1	OK	
05113210000179	15	0060	Urine	2	3	0.142	1	OK	
05113210000180	15	0060	Urine	3	4	0.142	1	OK	
05113210000181	15	0060	Urine	4	5	0.169	1	OK	
05113210000182	15	0060	Urine	5	6	0.106	1	OK	
05113210000183	15	0062	Urine	-1	0	0.533	1	OK	
05113210000184	15	0062	Urine	0	1	0.729	1	OK	
05113210000185	15	0062	Urine	1	2	0.188	1	OK	
05113210000186	15	0062	Urine	2	3	BLQ<(0.100)	1	OK	
05113210000187	15	0062	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000188	33	0062	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000189	15	0062	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000512	15	0063	Urine	-1	0	2.33	1	OK	
05113210000513	15	0063	Urine	0	1	3.08	1	OK	
05113210000514	15	0063	Urine	1	2	0.715	1	OK	
05113210000515	15	0063	Urine	2	3	BLQ<(0.100)	1	OK	
05113210000516	15	0063	Urine	3	4	0.104	1	OK	
05113210000517	15	0063	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000518	15	0063	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000190	15	0064	Urine	-1	0	0.706	1	OK	
05113210000191	15	0064	Urine	0	1	1.51	1	OK	
05113210000192	15	0064	Urine	1	2	0.702	1	OK	
05113210000193	15	0064	Urine	2	3	0.587	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000194	15	0064	Urine	3	4	0.739	1	OK	
05113210000195	15	0064	Urine	4	5	0.679	1	OK	
05113210000196	15	0064	Urine	5	6	1.05	1	OK	
05113210000526	15	0066	Urine	-1	0	1.02	1	OK	
05113210000527	15	0066	Urine	0	1	1.33	1	OK	
05113210000528	15	0066	Urine	1	2	0.235	1	OK	
05113210000529	15	0066	Urine	2	3	0.156	1	OK	
05113210000530	15	0066	Urine	3	4	0.121	1	OK	
05113210000531	15	0066	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000532	15	0066	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000540	15	0067	Urine	-1	0	1.60	1	OK	
05113210000541	15	0067	Urine	0	1	2.50	1	OK	
05113210000542	15	0067	Urine	1	2	1.39	1	OK	
05113210000543	15	0067	Urine	2	3	1.21	1	OK	
05113210000544	15	0067	Urine	3	4	1.21	1	OK	
05113210000545	15	0067	Urine	4	5	0.985	1	OK	
05113210000546	15	0067	Urine	5	6	1.09	1	OK	
05113210000554	15	0069	Urine	-1	0	1.62	1	OK	
05113210000555	15	0069	Urine	0	1	1.67	1	OK	
05113210000556	15	0069	Urine	1	2	0.501	1	OK	
05113210000557	15	0069	Urine	2	3	0.171	1	OK	
05113210000558	15	0069	Urine	3	4	0.155	1	OK	
05113210000559	15	0069	Urine	4	5	0.102	1	OK	
05113210000560	15	0069	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000568	22	0071	Urine	-1	0	0.887	1	OK	
05113210000569	22	0071	Urine	0	1	0.749	1	OK	
05113210000570	22	0071	Urine	1	2	0.377	1	OK	
05113210000571	22	0071	Urine	2	3	0.209	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000572	22	0071	Urine	3	4	0.152	1	OK	
05113210000573	22	0071	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000574	22	0071	Urine	5	6	0.108	1	OK	
05113210000582	15	0072	Urine	-1	0	3.12	1	OK	
05113210000583	15	0072	Urine	0	1	2.54	1	OK	
05113210000584	15	0072	Urine	1	2	3.05	1	OK	
05113210000585	15	0072	Urine	2	3	3.94	1	OK	
05113210000586	15	0072	Urine	3	4	4.19	1	OK	
05113210000587	15	0072	Urine	4	5	3.27	1	OK	
05113210000588	15	0072	Urine	5	6	2.65	1	OK	
05113210000596	15	0074	Urine	-1	0	6.43	1	OK	
05113210000597	15	0074	Urine	0	1	6.12	1	OK	
05113210000598	15	0074	Urine	1	2	1.15	1	OK	
05113210000599	15	0074	Urine	2	3	0.324	1	OK	
05113210000600	15	0074	Urine	3	4	0.213	1	OK	
05113210000601	15	0074	Urine	4	5	0.131	1	OK	
05113210000602	15	0074	Urine	5	6	0.133	1	OK	
05113210000610	16	0076	Urine	-1	0	1.36	1	OK	
05113210000611	16	0076	Urine	0	1	1.19	1	OK	
05113210000612	16	0076	Urine	1	2	0.669	1	OK	
05113210000613	16	0076	Urine	2	3	0.167	1	OK	
05113210000614	16	0076	Urine	3	4	0.140	1	OK	
05113210000615	16	0076	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000616	16	0076	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000624	16	0080	Urine	-1	0	2.70	1	OK	
05113210000625	16	0080	Urine	0	1	2.45	1	OK	
05113210000626	16	0080	Urine	1	2	2.64	1	OK	
05113210000627	16	0080	Urine	2	3	3.14	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000628	16	0080	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000629	16	0080	Urine	4	5	1.58	1	OK	
05113210000630	16	0080	Urine	5	6	1.89	1	OK	
05113210000638	16	0083	Urine	-1	0	2.10	1	OK	
05113210000639	16	0083	Urine	0	1	1.72	1	OK	
05113210000640	16	0083	Urine	1	2	0.377	1	OK	
05113210000641	16	0083	Urine	2	3	0.157	1	OK	
05113210000642	16	0083	Urine	3	4	0.105	1	OK	
05113210000643	16	0083	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000644	16	0083	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000652	22	0085	Urine	-1	0	0.951	1	OK	
05113210000653	22	0085	Urine	0	1	0.965	1	OK	
05113210000654	22	0085	Urine	1	2	0.297	1	OK	
05113210000655	22	0085	Urine	2	3	0.154	1	OK	
05113210000666	16	0086	Urine	-1	0	1.58	1	OK	
05113210000667	16	0086	Urine	0	1	1.99	1	OK	
05113210000668	16	0086	Urine	1	2	0.556	1	OK	
05113210000669	16	0086	Urine	2	3	0.180	1	OK	
05113210000670	16	0086	Urine	3	4	0.223	1	OK	
05113210000671	16	0086	Urine	4	5	0.123	1	OK	
05113210000672	16	0086	Urine	5	6	0.181	1	OK	
05113210000680	16	0087	Urine	-1	0	3.41	1	OK	
05113210000681	16	0087	Urine	0	1	2.95	1	OK	
05113210000682	16	0087	Urine	1	2	3.32	1	OK	
05113210000683	16	0087	Urine	2	3	2.85	1	OK	
05113210000684	16	0087	Urine	3	4	2.96	1	OK	
05113210000685	16	0087	Urine	4	5	1.68	1	OK	
05113210000686	16	0087	Urine	5	6	1.10	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000694	16	0088	Urine	-1	0	0.155	1	OK	
05113210000695	16	0088	Urine	0	1	0.160	1	OK	
05113210000696	16	0088	Urine	1	2	BLQ<(0.100)	1	OK	
05113210000697	16	0088	Urine	2	3	0.107	1	OK	
05113210000698	16	0088	Urine	3	4	0.113	1	OK	
05113210000699	16	0088	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000700	16	0088	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000708	16	0090	Urine	-1	0	0.163	1	OK	
05113210000709	16	0090	Urine	0	1	0.208	1	OK	
05113210000710	16	0090	Urine	1	2	0.158	1	OK	
05113210000711	16	0090	Urine	2	3	0.129	1	OK	
05113210000712	16	0090	Urine	3	4	0.138	1	OK	
05113210000713	16	0090	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000714	16	0090	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000722	16	0093	Urine	-1	0	2.63	1	OK	
05113210000723	16	0093	Urine	0	1	3.53	1	OK	
05113210000724	16	0093	Urine	1	2	0.800	1	OK	
05113210000725	16	0093	Urine	2	3	0.212	1	OK	
05113210000726	16	0093	Urine	3	4	0.106	1	OK	
05113210000727	16	0093	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000728	16	0093	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000736	16	0104	Urine	-1	0	0.723	1	OK	
05113210000737	16	0104	Urine	0	1	0.882	1	OK	
05113210000738	16	0104	Urine	1	2	0.289	1	OK	
05113210000739	16	0104	Urine	2	3	0.113	1	OK	
05113210000740	16	0104	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000741	16	0104	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000742	16	0104	Urine	5	6	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000750	16	0105	Urine	-1	0	1.17	1	OK	
05113210000751	16	0105	Urine	0	1	1.44	1	OK	
05113210000752	16	0105	Urine	1	2	1.27	1	OK	
05113210000753	16	0105	Urine	2	3	1.51	1	OK	
05113210000754	16	0105	Urine	3	4	1.17	1	OK	
05113210000755	16	0105	Urine	4	5	0.827	1	OK	
05113210000756	16	0105	Urine	5	6	0.671	1	OK	
05113210000764	17	0106	Urine	-1	0	1.07	1	OK	
05113210000765	17	0106	Urine	0	1	1.39	1	OK	
05113210000766	17	0106	Urine	1	2	0.305	1	OK	
05113210000767	33	0106	Urine	2	3	0.138	1	OK	
05113210000768	33	0106	Urine	3	4	0.109	1	OK	
05113210000769	33	0106	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000770	33	0106	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000778	17	0107	Urine	-1	0	2.97	1	OK	
05113210000779	17	0107	Urine	0	1	1.98	1	OK	
05113210000780	17	0107	Urine	1	2	0.471	1	OK	
05113210000781	33	0107	Urine	2	3	0.113	1	OK	
05113210000782	17	0107	Urine	3	4	2.31	1	OK	
05113210000783	33	0107	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000784	33	0107	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000792	17	0110	Urine	-1	0	2.01	1	OK	
05113210000793	17	0110	Urine	0	1	2.67	1	OK	
05113210000794	17	0110	Urine	1	2	0.836	1	OK	
05113210000795	17	0110	Urine	2	3	0.441	1	OK	
05113210000796	33	0110	Urine	3	4	0.178	1	OK	
05113210000797	33	0110	Urine	4	5	0.117	1	OK	
05113210000798	33	0110	Urine	5	6	0.129	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000806	17	0112	Urine	-1	0	1.36	1	OK	
05113210000807	17	0112	Urine	0	1	1.40	1	OK	
05113210000808	17	0112	Urine	1	2	0.292	1	OK	
05113210000809	33	0112	Urine	2	3	0.128	1	OK	
05113210000810	33	0112	Urine	3	4	0.137	1	OK	
05113210000811	33	0112	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000812	33	0112	Urine	5	6	0.104	1	OK	
05113210000820	17	0114	Urine	-1	0	2.41	1	OK	
05113210000821	17	0114	Urine	0	1	4.00	1	OK	
05113210000822	17	0114	Urine	1	2	0.877	1	OK	
05113210000823	17	0114	Urine	2	3	0.260	1	OK	
05113210000824	17	0114	Urine	3	4	0.244	1	OK	
05113210000825	33	0114	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000826	33	0114	Urine	5	6	0.115	1	OK	
05113210000834	17	0117	Urine	-1	0	1.09	1	OK	
05113210000835	17	0117	Urine	0	1	1.50	1	OK	
05113210000836	17	0117	Urine	1	2	2.25	1	OK	
05113210000837	17	0117	Urine	2	3	3.08	1	OK	
05113210000838	17	0117	Urine	3	4	2.15	1	OK	
05113210000839	17	0117	Urine	4	5	1.21	1	OK	
05113210000840	17	0117	Urine	5	6	0.868	1	OK	
05113210000848	17	0118	Urine	-1	0	0.219	1	OK	
05113210000849	17	0118	Urine	0	1	0.345	1	OK	
05113210000850	17	0118	Urine	1	2	0.255	1	OK	
05113210000851	33	0118	Urine	2	3	0.209	1	OK	
05113210000852	17	0118	Urine	3	4	0.348	1	OK	
05113210000853	33	0118	Urine	4	5	0.174	1	OK	
05113210000854	17	0118	Urine	5	6	0.203	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000862	17	0121	Urine	-1	0	2.27	1	OK	
05113210000863	33	0121	Urine	0	1	2.00	1	OK	
05113210000864	17	0121	Urine	1	2	1.25	1	OK	
05113210000865	17	0121	Urine	2	3	1.54	1	OK	
05113210000866	17	0121	Urine	3	4	1.69	1	OK	
05113210000867	33	0121	Urine	4	5	0.867	1	OK	
05113210000868	17	0121	Urine	5	6	1.04	1	OK	
05113210000876	33	0122	Urine	-1	0	0.125	1	OK	
05113210000877	33	0122	Urine	0	1	0.122	1	OK	
05113210000878	33	0122	Urine	1	2	BLQ<(0.100)	1	OK	
05113210000879	33	0122	Urine	2	3	BLQ<(0.100)	1	OK	
05113210000880	33	0122	Urine	3	4	BLQ<(0.100)	1	OK	
05113210000881	33	0122	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000882	33	0122	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000890	33	0123	Urine	-1	0	0.108	1	OK	
05113210000891	33	0123	Urine	0	1	0.185	1	OK	
05113210000892	33	0123	Urine	1	2	0.142	1	OK	
05113210000893	33	0123	Urine	2	3	0.100	1	OK	
05113210000894	33	0123	Urine	3	4	0.138	1	OK	
05113210000895	33	0123	Urine	4	5	BLQ<(0.100)	1	OK	
05113210000896	33	0123	Urine	5	6	BLQ<(0.100)	1	OK	
05113210000904	30	0126	Urine	-1	0	1.08	1	OK	
05113210000905	30	0126	Urine	0	1	1.86	1	OK	
05113210000906	30	0126	Urine	1	2	1.90	1	OK	
05113210000907	30	0126	Urine	2	3	1.15	1	OK	
05113210000908	30	0126	Urine	3	4	1.10	1	OK	
05113210000909	30	0126	Urine	4	5	1.08	1	OK	
05113210000910	30	0126	Urine	5	6	0.862	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000918	30	0127	Urine	-1	0	4.50	1	OK	
05113210000919	30	0127	Urine	0	1	4.06	1	OK	
05113210000920	30	0127	Urine	1	2	0.909	1	OK	
05113210000921	30	0127	Urine	2	3	0.308	1	OK	
05113210000922	30	0127	Urine	3	4	0.254	1	OK	
05113210000923	30	0127	Urine	4	5	0.208	1	OK	
05113210000924	30	0127	Urine	5	6	0.273	1	OK	
05113210000932	30	0128	Urine	-1	0	0.423	1	OK	
05113210000933	30	0128	Urine	0	1	0.332	1	OK	
05113210000934	30	0128	Urine	1	2	0.383	1	OK	
05113210000935	30	0128	Urine	2	3	0.185	1	OK	
05113210000936	30	0128	Urine	3	4	0.274	1	OK	
05113210000937	30	0128	Urine	4	5	0.193	1	OK	
05113210000938	30	0128	Urine	5	6	0.227	1	OK	
05113210000946	30	0129	Urine	-1	0	0.256	1	OK	
05113210000947	30	0129	Urine	0	1	0.295	1	OK	
05113210000948	30	0129	Urine	1	2	0.167	1	OK	
05113210000949	30	0129	Urine	2	3	0.176	1	OK	
05113210000950	30	0129	Urine	3	4	0.174	1	OK	
05113210000951	30	0129	Urine	4	5	0.123	1	OK	
05113210000952	30	0129	Urine	5	6	0.109	1	OK	
05113210000960	30	0130	Urine	-1	0	1.14	1	OK	
05113210000961	30	0130	Urine	0	1	1.44	1	OK	
05113210000962	30	0130	Urine	1	2	0.312	1	OK	
05113210000963	30	0130	Urine	2	3	0.156	1	OK	
05113210000964	30	0130	Urine	3	4	0.193	1	OK	
05113210000965	30	0130	Urine	4	5	0.166	1	OK	
05113210000966	30	0130	Urine	5	6	0.101	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210000974	30	0133	Urine	-1	0	3.70	1	OK	
05113210000975	30	0133	Urine	0	1	3.89	1	OK	
05113210000976	30	0133	Urine	1	2	0.907	1	OK	
05113210000977	30	0133	Urine	2	3	0.127	1	OK	
05113210000978	30	0133	Urine	3	4	0.153	1	OK	
05113210000979	30	0133	Urine	4	5	0.120	1	OK	
05113210000980	30	0133	Urine	5	6	0.197	1	OK	
05113210000988	30	0134	Urine	-1	0	0.764	1	OK	
05113210000989	30	0134	Urine	0	1	0.958	1	OK	
05113210000990	30	0134	Urine	1	2	0.287	1	OK	
05113210000991	30	0134	Urine	2	3	0.196	1	OK	
05113210000992	30	0134	Urine	3	4	0.165	1	OK	
05113210000993	30	0134	Urine	4	5	0.204	1	OK	
05113210000994	30	0134	Urine	5	6	0.131	1	OK	
05113210001002	30	0136	Urine	-1	0	4.51	1	OK	
05113210001003	30	0136	Urine	0	1	3.00	1	OK	
05113210001004	30	0136	Urine	1	2	1.05	1	OK	
05113210001005	30	0136	Urine	2	3	0.309	1	OK	
05113210001006	30	0136	Urine	3	4	0.346	1	OK	
05113210001007	30	0136	Urine	4	5	0.169	1	OK	
05113210001008	30	0136	Urine	5	6	0.173	1	OK	
05113210001016	30	0137	Urine	-1	0	2.16	1	OK	
05113210001017	30	0137	Urine	0	1	1.70	1	OK	
05113210001018	30	0137	Urine	1	2	0.589	1	OK	
05113210001019	30	0137	Urine	2	3	0.199	1	OK	
05113210001020	30	0137	Urine	3	4	0.160	1	OK	
05113210001021	30	0137	Urine	4	5	0.113	1	OK	
05113210001022	30	0137	Urine	5	6	0.115	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001030	30	0139	Urine	-1	0	2.63	1	OK	
05113210001031	30	0139	Urine	0	1	4.36	1	OK	
05113210001032	30	0139	Urine	1	2	2.68	1	OK	
05113210001033	30	0139	Urine	2	3	2.44	1	OK	
05113210001034	30	0139	Urine	3	4	3.73	1	OK	
05113210001035	30	0139	Urine	4	5	2.85	1	OK	
05113210001036	30	0139	Urine	5	6	2.62	1	OK	
05113210001044	20	0140	Urine	-1	0	0.901	1	OK	
05113210001045	20	0140	Urine	0	1	1.16	1	OK	
05113210001046	20	0140	Urine	1	2	0.967	1	OK	
05113210001047	20	0140	Urine	2	3	1.17	1	OK	
05113210001048	20	0140	Urine	3	4	1.39	1	OK	
05113210001049	20	0140	Urine	4	5	1.10	1	OK	
05113210001050	20	0140	Urine	5	6	0.844	1	OK	
05113210001058	20	0145	Urine	-1	0	1.63	1	OK	
05113210001059	20	0145	Urine	0	1	2.01	1	OK	
05113210001060	20	0145	Urine	1	2	0.775	1	OK	
05113210001061	20	0145	Urine	2	3	0.162	1	OK	
05113210001062	20	0145	Urine	3	4	BLQ<(0.100)	1	OK	
05113210001063	20	0145	Urine	4	5	BLQ<(0.100)	1	OK	
05113210001064	20	0145	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001072	20	0147	Urine	-1	0	2.81	1	OK	
05113210001073	20	0147	Urine	0	1	3.27	1	OK	
05113210001074	20	0147	Urine	1	2	0.602	1	OK	
05113210001075	20	0147	Urine	2	3	0.179	1	OK	
05113210001076	20	0147	Urine	3	4	0.136	1	OK	
05113210001077	20	0147	Urine	4	5	0.187	1	OK	
05113210001078	20	0147	Urine	5	6	0.104	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001086	20	0148	Urine	-1	0	1.04	1	OK	
05113210001087	20	0148	Urine	0	1	1.04	1	OK	
05113210001088	20	0148	Urine	1	2	1.05	1	OK	
05113210001089	20	0148	Urine	2	3	0.783	1	OK	
05113210001090	20	0148	Urine	3	4	0.906	1	OK	
05113210001091	20	0148	Urine	4	5	0.800	1	OK	
05113210001092	20	0148	Urine	5	6	0.705	1	OK	
05113210001100	20	0149	Urine	-1	0	0.205	1	OK	
05113210001101	20	0149	Urine	0	1	0.193	1	OK	
05113210001102	20	0149	Urine	1	2	BLQ<(0.100)	1	OK	
05113210001103	20	0149	Urine	2	3	0.104	1	OK	
05113210001104	20	0149	Urine	3	4	0.141	1	OK	
05113210001105	20	0149	Urine	4	5	0.108	1	OK	
05113210001106	20	0149	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001114	20	0150	Urine	-1	0	0.340	1	OK	
05113210001115	20	0150	Urine	0	1	0.350	1	OK	
05113210001116	20	0150	Urine	1	2	0.383	1	OK	
05113210001117	20	0150	Urine	2	3	0.392	1	OK	
05113210001118	20	0150	Urine	3	4	0.251	1	OK	
05113210001119	20	0150	Urine	4	5	0.203	1	OK	
05113210001120	20	0150	Urine	5	6	0.250	1	OK	
05113210001128	20	0152	Urine	-1	0	1.01	1	OK	
05113210001129	20	0152	Urine	0	1	1.06	1	OK	
05113210001130	20	0152	Urine	1	2	1.62	1	OK	
05113210001131	20	0152	Urine	2	3	1.22	1	OK	
05113210001132	20	0152	Urine	3	4	1.40	1	OK	
05113210001133	20	0152	Urine	4	5	0.956	1	OK	
05113210001134	20	0152	Urine	5	6	0.974	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001142	20	0153	Urine	-1	0	0.159	1	OK	
05113210001143	20	0153	Urine	0	1	0.232	1	OK	
05113210001144	20	0153	Urine	1	2	BLQ<(0.100)	1	OK	
05113210001145	20	0153	Urine	2	3	BLQ<(0.100)	1	OK	
05113210001146	20	0153	Urine	3	4	BLQ<(0.100)	1	OK	
05113210001147	20	0153	Urine	4	5	BLQ<(0.100)	1	OK	
05113210001148	20	0153	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001156	20	0155	Urine	-1	0	1.22	1	OK	
05113210001157	20	0155	Urine	0	1	1.45	1	OK	
05113210001158	20	0155	Urine	1	2	0.424	1	OK	
05113210001159	20	0155	Urine	2	3	0.186	1	OK	
05113210001160	20	0155	Urine	3	4	0.153	1	OK	
05113210001161	20	0155	Urine	4	5	0.147	1	OK	
05113210001162	20	0155	Urine	5	6	0.138	1	OK	
05113210001170	20	0156	Urine	-1	0	3.70	1	OK	
05113210001171	20	0156	Urine	0	1	5.22	1	OK	
05113210001172	20	0156	Urine	1	2	4.91	1	OK	
05113210001173	20	0156	Urine	2	3	4.42	1	OK	
05113210001174	20	0156	Urine	3	4	4.74	1	OK	
05113210001175	20	0156	Urine	4	5	5.35	1	OK	
05113210001176	20	0156	Urine	5	6	3.94	1	OK	
05113210001184	21	0160	Urine	-1	0	3.35	1	OK	
05113210001185	21	0160	Urine	0	1	4.63	1	OK	
05113210001186	21	0160	Urine	1	2	4.23	1	OK	
05113210001187	21	0160	Urine	2	3	3.18	1	OK	
05113210001188	21	0160	Urine	3	4	4.12	1	OK	
05113210001189	21	0160	Urine	4	5	3.36	1	OK	
05113210001190	21	0160	Urine	5	6	3.39	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001198	21	0162	Urine	-1	0	1.13	1	OK	
05113210001199	21	0162	Urine	0	1	1.76	1	OK	
05113210001200	21	0162	Urine	1	2	0.473	1	OK	
05113210001201	21	0162	Urine	2	3	0.300	1	OK	
05113210001202	21	0162	Urine	3	4	0.357	1	OK	
05113210001203	21	0162	Urine	4	5	0.232	1	OK	
05113210001204	21	0162	Urine	5	6	0.201	1	OK	
05113210001212	21	0167	Urine	-1	0	0.754	1	OK	
05113210001213	21	0167	Urine	0	1	0.872	1	OK	
05113210001214	21	0167	Urine	1	2	0.427	1	OK	
05113210001215	21	0167	Urine	2	3	0.263	1	OK	
05113210001216	21	0167	Urine	3	4	0.252	1	OK	
05113210001217	21	0167	Urine	4	5	0.235	1	OK	
05113210001218	21	0167	Urine	5	6	0.166	1	OK	
05113210001226	21	0169	Urine	-1	0	1.16	1	OK	
05113210001227	21	0169	Urine	0	1	0.958	1	OK	
05113210001228	21	0169	Urine	1	2	0.586	1	OK	
05113210001229	21	0169	Urine	2	3	0.182	1	OK	
05113210001230	21	0169	Urine	3	4	0.187	1	OK	
05113210001231	21	0169	Urine	4	5	BLQ<(0.100)	1	OK	
05113210001232	21	0169	Urine	5	6	0.129	1	OK	
05113210001240	21	0170	Urine	-1	0	3.44	1	OK	
05113210001241	21	0170	Urine	0	1	2.85	1	OK	
05113210001242	21	0170	Urine	1	2	0.475	1	OK	
05113210001243	21	0170	Urine	2	3	0.219	1	OK	
05113210001244	21	0170	Urine	3	4	0.164	1	OK	
05113210001245	21	0170	Urine	4	5	0.185	1	OK	
05113210001246	21	0170	Urine	5	6	0.171	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001254	21	0177	Urine	-1	0	4.34	1	OK	
05113210001255	21	0177	Urine	0	1	4.08	1	OK	
05113210001256	21	0177	Urine	1	2	1.08	1	OK	
05113210001257	21	0177	Urine	2	3	0.252	1	OK	
05113210001258	21	0177	Urine	3	4	0.233	1	OK	
05113210001259	21	0177	Urine	4	5	0.148	1	OK	
05113210001260	21	0177	Urine	5	6	0.197	1	OK	
05113210001352	21	0181	Urine	-1	0	4.63	1	OK	
05113210001353	21	0181	Urine	0	1	4.18	1	OK	
05113210001354	21	0181	Urine	1	2	0.958	1	OK	
05113210001355	21	0181	Urine	2	3	0.240	1	OK	
05113210001356	21	0181	Urine	3	4	0.264	1	OK	
05113210001357	21	0181	Urine	4	5	0.216	1	OK	
05113210001358	21	0181	Urine	5	6	0.145	1	OK	
05113210001268	21	0183	Urine	-1	0	3.08	1	OK	
05113210001269	21	0183	Urine	0	1	2.64	1	OK	
05113210001270	21	0183	Urine	1	2	0.657	1	OK	
05113210001271	21	0183	Urine	2	3	0.336	1	OK	
05113210001272	21	0183	Urine	3	4	0.216	1	OK	
05113210001273	21	0183	Urine	4	5	0.173	1	OK	
05113210001274	21	0183	Urine	5	6	0.178	1	OK	
05113210001282	21	0185	Urine	-1	0	4.89	1	OK	
05113210001283	21	0185	Urine	0	1	2.83	1	OK	
05113210001284	21	0185	Urine	1	2	0.736	1	OK	
05113210001285	21	0185	Urine	2	3	0.268	1	OK	
05113210001286	21	0185	Urine	3	4	0.255	1	OK	
05113210001287	21	0185	Urine	4	5	0.194	1	OK	
05113210001288	21	0185	Urine	5	6	0.228	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001296	21	0187	Urine	-1	0	1.63	1	OK	
05113210001297	21	0187	Urine	0	1	1.11	1	OK	
05113210001298	21	0187	Urine	1	2	1.04	1	OK	
05113210001299	21	0187	Urine	2	3	1.79	1	OK	
05113210001300	21	0187	Urine	3	4	2.20	1	OK	
05113210001301	21	0187	Urine	4	5	1.57	1	OK	
05113210001302	21	0187	Urine	5	6	1.08	1	OK	
05113210001366	23	0189	Urine	-1	0	2.31	1	OK	
05113210001367	23	0189	Urine	0	1	2.27	1	OK	
05113210001368	23	0189	Urine	1	2	0.469	1	OK	
05113210001369	23	0189	Urine	2	3	0.224	1	OK	
05113210001370	23	0189	Urine	3	4	0.139	1	OK	
05113210001371	23	0189	Urine	4	5	0.234	1	OK	
05113210001372	23	0189	Urine	5	6	0.168	1	OK	
05113210001310	23	0190	Urine	-1	0	0.252	1	OK	
05113210001311	23	0190	Urine	0	1	0.271	1	OK	
05113210001312	23	0190	Urine	1	2	0.239	1	OK	
05113210001313	23	0190	Urine	2	3	0.169	1	OK	
05113210001314	23	0190	Urine	3	4	0.157	1	OK	
05113210001315	23	0190	Urine	4	5	0.125	1	OK	
05113210001316	23	0190	Urine	5	6	0.128	1	OK	
05113210001324	23	0191	Urine	-1	0	1.74	1	OK	
05113210001325	23	0191	Urine	0	1	1.83	1	OK	
05113210001326	23	0191	Urine	1	2	1.86	1	OK	
05113210001327	23	0191	Urine	2	3	1.75	1	OK	
05113210001328	23	0191	Urine	3	4	2.20	1	OK	
05113210001329	23	0191	Urine	4	5	1.71	1	OK	
05113210001330	23	0191	Urine	5	6	1.25	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001338	23	0192	Urine	-1	0	2.48	1	OK	
05113210001339	23	0192	Urine	0	1	2.46	1	OK	
05113210001340	23	0192	Urine	1	2	0.440	1	OK	
05113210001341	23	0192	Urine	2	3	0.264	1	OK	
05113210001342	23	0192	Urine	3	4	0.206	1	OK	
05113210001343	23	0192	Urine	4	5	0.130	1	OK	
05113210001344	23	0192	Urine	5	6	0.164	1	OK	
05113210001380	23	0193	Urine	-1	0	1.55	1	OK	
05113210001381	23	0193	Urine	0	1	4.15	1	OK	
05113210001382	23	0193	Urine	1	2	0.505	1	OK	
05113210001383	23	0193	Urine	2	3	0.168	1	OK	
05113210001384	23	0193	Urine	3	4	0.216	1	OK	
05113210001385	23	0193	Urine	4	5	0.170	1	OK	
05113210001386	23	0193	Urine	5	6	0.176	1	OK	
05113210001394	23	0195	Urine	-1	0	0.730	1	OK	
05113210001395	23	0195	Urine	0	1	0.949	1	OK	
05113210001396	23	0195	Urine	1	2	0.275	1	OK	
05113210001397	23	0195	Urine	2	3	0.159	1	OK	
05113210001398	23	0195	Urine	3	4	0.167	1	OK	
05113210001399	23	0195	Urine	4	5	0.163	1	OK	
05113210001400	23	0195	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001408	23	0196	Urine	-1	0	0.451	1	OK	
05113210001409	23	0196	Urine	0	1	0.589	1	OK	
05113210001410	23	0196	Urine	1	2	0.257	1	OK	
05113210001411	23	0196	Urine	2	3	BLQ<(0.100)	1	OK	
05113210001412	23	0196	Urine	3	4	BLQ<(0.100)	1	OK	
05113210001413	23	0196	Urine	4	5	0.112	1	OK	
05113210001414	23	0196	Urine	5	6	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001422	23	0197	Urine	-1	0	2.73	1	OK	
05113210001423	23	0197	Urine	0	1	6.09	1	OK	
05113210001424	23	0197	Urine	1	2	0.931	1	OK	
05113210001425	23	0197	Urine	2	3	0.334	1	OK	
05113210001426	23	0197	Urine	3	4	0.216	1	OK	
05113210001427	23	0197	Urine	4	5	0.206	1	OK	
05113210001428	23	0197	Urine	5	6	0.157	1	OK	
05113210001436	23	0198	Urine	-1	0	3.31	1	OK	
05113210001437	23	0198	Urine	0	1	6.81	1	OK	
05113210001438	23	0198	Urine	1	2	5.63	1	OK	
05113210001439	23	0198	Urine	2	3	7.10	1	OK	
05113210001440	23	0198	Urine	3	4	6.62	1	OK	
05113210001441	23	0198	Urine	4	5	7.61	1	OK	
05113210001442	23	0198	Urine	5	6	5.66	1	OK	
05113210001450	23	0200	Urine	-1	0	1.10	1	OK	
05113210001451	23	0200	Urine	0	1	1.60	1	OK	
05113210001452	23	0200	Urine	1	2	1.38	1	OK	
05113210001453	23	0200	Urine	2	3	1.02	1	OK	
05113210001454	23	0200	Urine	3	4	1.50	1	OK	
05113210001455	23	0200	Urine	4	5	1.53	1	OK	
05113210001456	23	0200	Urine	5	6	0.711	1	OK	
05113210001464	24	0202	Urine	-1	0	0.633	1	OK	
05113210001465	24	0202	Urine	0	1	0.829	1	OK	
05113210001466	24	0202	Urine	1	2	0.678	1	OK	
05113210001467	24	0202	Urine	2	3	0.320	1	OK	
05113210001468	24	0202	Urine	3	4	0.172	1	OK	
05113210001469	24	0202	Urine	4	5	0.102	1	OK	
05113210001470	24	0202	Urine	5	6	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001478	24	0203	Urine	-1	0	1.12	1	OK	
05113210001479	24	0203	Urine	0	1	1.33	1	OK	
05113210001480	24	0203	Urine	1	2	0.279	1	OK	
05113210001481	24	0203	Urine	2	3	0.135	1	OK	
05113210001482	24	0203	Urine	3	4	0.121	1	OK	
05113210001483	24	0203	Urine	4	5	0.101	1	OK	
05113210001484	24	0203	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001492	24	0204	Urine	-1	0	0.414	1	OK	
05113210001493	24	0204	Urine	0	1	0.876	1	OK	
05113210001494	24	0204	Urine	1	2	0.896	1	OK	
05113210001495	24	0204	Urine	2	3	0.557	1	OK	
05113210001496	24	0204	Urine	3	4	0.876	1	OK	
05113210001497	24	0204	Urine	4	5	0.880	1	OK	
05113210001498	24	0204	Urine	5	6	0.637	1	OK	
05113210001506	24	0206	Urine	-1	0	0.972	1	OK	
05113210001507	24	0206	Urine	0	1	2.12	1	OK	
05113210001508	24	0206	Urine	1	2	0.496	1	OK	
05113210001509	24	0206	Urine	2	3	0.190	1	OK	
05113210001510	24	0206	Urine	3	4	0.184	1	OK	
05113210001511	24	0206	Urine	4	5	0.170	1	OK	
05113210001512	24	0206	Urine	5	6	0.131	1	OK	
05113210001520	24	0210	Urine	-1	0	2.23	1	OK	
05113210001521	24	0210	Urine	0	1	1.76	1	OK	
05113210001522	24	0210	Urine	1	2	0.456	1	OK	
05113210001523	24	0210	Urine	2	3	0.148	1	OK	
05113210001524	24	0210	Urine	3	4	0.159	1	OK	
05113210001525	24	0210	Urine	4	5	0.198	1	OK	
05113210001526	24	0210	Urine	5	6	BLQ<(0.100)	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001548	24	0216	Urine	-1	0	2.05	1	OK	
05113210001549	24	0216	Urine	0	1	2.28	1	OK	
05113210001550	24	0216	Urine	1	2	0.756	1	OK	
05113210001551	24	0216	Urine	2	3	0.206	1	OK	
05113210001552	24	0216	Urine	3	4	0.166	1	OK	
05113210001553	24	0216	Urine	4	5	0.129	1	OK	
05113210001554	24	0216	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001562	24	0218	Urine	-1	0	0.412	1	OK	
05113210001563	24	0218	Urine	0	1	0.378	1	OK	
05113210001564	24	0218	Urine	1	2	0.163	1	OK	
05113210001565	24	0218	Urine	2	3	0.231	1	OK	
05113210001566	24	0218	Urine	3	4	0.280	1	OK	
05113210001567	24	0218	Urine	4	5	0.159	1	OK	
05113210001568	24	0218	Urine	5	6	0.140	1	OK	
05113210001576	24	0220	Urine	-1	0	1.56	1	OK	
05113210001577	24	0220	Urine	0	1	1.94	1	OK	
05113210001578	24	0220	Urine	1	2	0.294	1	OK	
05113210001579	24	0220	Urine	2	3	0.178	1	OK	
05113210001580	24	0220	Urine	3	4	0.156	1	OK	
05113210001581	24	0220	Urine	4	5	0.113	1	OK	
05113210001582	24	0220	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001590	24	0224	Urine	-1	0	1.88	1	OK	
05113210001591	24	0224	Urine	0	1	2.62	1	OK	
05113210001592	24	0224	Urine	1	2	2.07	1	OK	
05113210001593	24	0224	Urine	2	3	2.08	1	OK	
05113210001594	24	0224	Urine	3	4	2.40	1	OK	
05113210001595	24	0224	Urine	4	5	2.56	1	OK	
05113210001596	24	0224	Urine	5	6	1.61	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001604	24	0228	Urine	-1	0	0.196	1	OK	
05113210001605	24	0228	Urine	0	1	0.293	1	OK	
05113210001606	24	0228	Urine	1	2	0.127	1	OK	
05113210001607	24	0228	Urine	2	3	BLQ<(0.100)	1	OK	
05113210001608	24	0228	Urine	3	4	0.120	1	OK	
05113210001609	24	0228	Urine	4	5	BLQ<(0.100)	1	OK	
05113210001610	24	0228	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001618	25	0229	Urine	-1	0	1.53	1	OK	
05113210001619	25	0229	Urine	0	1	1.41	1	OK	
05113210001620	25	0229	Urine	1	2	2.08	1	OK	
05113210001621	25	0229	Urine	2	3	1.94	1	OK	
05113210001622	25	0229	Urine	3	4	2.38	1	OK	
05113210001623	25	0229	Urine	4	5	2.45	1	OK	
05113210001624	25	0229	Urine	5	6	1.18	1	OK	
05113210001632	25	0230	Urine	-1	0	1.07	1	OK	
05113210001633	25	0230	Urine	0	1	2.34	1	OK	
05113210001634	25	0230	Urine	1	2	1.64	1	OK	
05113210001635	25	0230	Urine	2	3	1.36	1	OK	
05113210001636	25	0230	Urine	3	4	1.41	1	OK	
05113210001637	25	0230	Urine	4	5	1.53	1	OK	
05113210001638	25	0230	Urine	5	6	1.22	1	OK	
05113210001646	25	0232	Urine	-1	0	1.41	1	OK	
05113210001647	25	0232	Urine	0	1	1.57	1	OK	
05113210001648	25	0232	Urine	1	2	0.242	1	OK	
05113210001649	25	0232	Urine	2	3	0.113	1	OK	
05113210001650	25	0232	Urine	3	4	0.112	1	OK	
05113210001651	25	0232	Urine	4	5	0.101	1	OK	
05113210001652	25	0232	Urine	5	6	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001660	25	0234	Urine	-1	0	1.18	1	OK	
05113210001661	25	0234	Urine	0	1	2.05	1	OK	
05113210001662	25	0234	Urine	1	2	0.521	1	OK	
05113210001663	25	0234	Urine	2	3	0.185	1	OK	
05113210001664	25	0234	Urine	3	4	0.176	1	OK	
05113210001665	25	0234	Urine	4	5	0.139	1	OK	
05113210001666	25	0234	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001674	25	0240	Urine	-1	0	1.84	1	OK	
05113210001675	25	0240	Urine	0	1	2.02	1	OK	
05113210001676	25	0240	Urine	1	2	0.377	1	OK	
05113210001677	25	0240	Urine	2	3	0.104	1	OK	
05113210001678	25	0240	Urine	3	4	0.113	1	OK	
05113210001679	25	0240	Urine	4	5	0.109	1	OK	
05113210001680	25	0240	Urine	5	6	0.115	1	OK	
05113210001688	25	0241	Urine	-1	0	1.62	1	OK	
05113210001689	25	0241	Urine	0	1	1.95	1	OK	
05113210001690	25	0241	Urine	1	2	0.409	1	OK	
05113210001691	25	0241	Urine	2	3	0.170	1	OK	
05113210001692	25	0241	Urine	3	4	0.192	1	OK	
05113210001693	25	0241	Urine	4	5	0.152	1	OK	
05113210001694	25	0241	Urine	5	6	0.118	1	OK	
05113210001716	25	0244	Urine	-1	0	2.16	1	OK	
05113210001717	25	0244	Urine	0	1	1.76	1	OK	
05113210001718	25	0244	Urine	1	2	0.507	1	OK	
05113210001719	25	0244	Urine	2	3	0.191	1	OK	
05113210001720	25	0244	Urine	3	4	0.178	1	OK	
05113210001721	25	0244	Urine	4	5	0.199	1	OK	
05113210001722	25	0244	Urine	5	6	BLQ<(0.100)	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001758	25	0249	Urine	-1	0	4.73	1	OK	
05113210001759	25	0249	Urine	0	1	4.49	1	OK	
05113210001760	25	0249	Urine	1	2	0.785	1	OK	
05113210001761	25	0249	Urine	2	3	0.227	1	OK	
05113210001762	25	0249	Urine	3	4	0.428	1	OK	
05113210001763	25	0249	Urine	4	5	0.193	1	OK	
05113210001764	25	0249	Urine	5	6	0.210	1	OK	
05113210001772	25	0251	Urine	-1	0	1.17	1	OK	
05113210001773	25	0251	Urine	0	1	1.08	1	OK	
05113210001774	25	0251	Urine	1	2	0.274	1	OK	
05113210001775	25	0251	Urine	2	3	0.131	1	OK	
05113210001776	25	0251	Urine	3	4	0.107	1	OK	
05113210001777	25	0251	Urine	4	5	BLQ<(0.100)	1	OK	
05113210001778	25	0251	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001786	25	0252	Urine	-1	0	1.46	1	OK	
05113210001787	25	0252	Urine	0	1	1.78	1	OK	
05113210001788	25	0252	Urine	1	2	0.292	1	OK	
05113210001789	25	0252	Urine	2	3	0.201	1	OK	
05113210001790	25	0252	Urine	3	4	0.147	1	OK	
05113210001791	25	0252	Urine	4	5	0.146	1	OK	
05113210001792	25	0252	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001800	26	0255	Urine	-1	0	1.84	1	OK	
05113210001801	26	0255	Urine	0	1	2.05	1	OK	
05113210001802	26	0255	Urine	1	2	0.343	1	OK	
05113210001803	26	0255	Urine	2	3	0.224	1	OK	
05113210001804	26	0255	Urine	3	4	0.162	1	OK	
05113210001805	26	0255	Urine	4	5	0.225	1	OK	
05113210001806	26	0255	Urine	5	6	0.170	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001814	26	0256	Urine	-1	0	2.25	1	OK	
05113210001815	26	0256	Urine	0	1	2.49	1	OK	
05113210001816	26	0256	Urine	1	2	0.521	1	OK	
05113210001817	26	0256	Urine	2	3	0.253	1	OK	
05113210001818	26	0256	Urine	3	4	0.222	1	OK	
05113210001819	26	0256	Urine	4	5	0.218	1	OK	
05113210001820	26	0256	Urine	5	6	0.175	1	OK	
05113210001828	26	0262	Urine	-1	0	0.134	1	OK	
05113210001829	26	0262	Urine	0	1	0.192	1	OK	
05113210001830	26	0262	Urine	1	2	0.162	1	OK	
05113210001831	26	0262	Urine	2	3	0.189	1	OK	
05113210001832	26	0262	Urine	3	4	0.242	1	OK	
05113210001833	26	0262	Urine	4	5	0.240	1	OK	
05113210001834	26	0262	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001842	26	0264	Urine	-1	0	1.12	1	OK	
05113210001843	26	0264	Urine	0	1	0.961	1	OK	
05113210001844	26	0264	Urine	1	2	0.382	1	OK	
05113210001845	26	0264	Urine	2	3	0.119	1	OK	
05113210001846	26	0264	Urine	3	4	0.173	1	OK	
05113210001847	26	0264	Urine	4	5	0.134	1	OK	
05113210001848	26	0264	Urine	5	6	BLQ<(0.100)	1	OK	
05113210001856	26	0265	Urine	-1	0	0.393	1	OK	
05113210001857	26	0265	Urine	0	1	0.596	1	OK	
05113210001858	26	0265	Urine	1	2	0.282	1	OK	
05113210001859	26	0265	Urine	2	3	0.174	1	OK	
05113210001860	26	0265	Urine	3	4	0.191	1	OK	
05113210001861	26	0265	Urine	4	5	0.169	1	OK	
05113210001862	26	0265	Urine	5	6	0.146	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001870	26	0266	Urine	-1	0	0.322	1	OK	
05113210001871	26	0266	Urine	0	1	0.266	1	OK	
05113210001872	26	0266	Urine	1	2	0.197	1	OK	
05113210001873	26	0266	Urine	2	3	0.141	1	OK	
05113210001874	26	0266	Urine	3	4	0.120	1	OK	
05113210001875	26	0266	Urine	4	5	0.173	1	OK	
05113210001876	26	0266	Urine	5	6	0.177	1	OK	
05113210001898	26	0272	Urine	-1	0	0.677	1	OK	
05113210001899	26	0272	Urine	0	1	0.699	1	OK	
05113210001900	26	0272	Urine	1	2	0.345	1	OK	
05113210001901	26	0272	Urine	2	3	0.458	1	OK	
05113210001902	26	0272	Urine	3	4	0.459	1	OK	
05113210001903	26	0272	Urine	4	5	0.213	1	OK	
05113210001904	26	0272	Urine	5	6	0.267	1	OK	
05113210001912	26	0273	Urine	-1	0	1.36	1	OK	
05113210001913	26	0273	Urine	0	1	1.80	1	OK	
05113210001914	26	0273	Urine	1	2	0.329	1	OK	
05113210001915	26	0273	Urine	2	3	0.184	1	OK	
05113210001916	26	0273	Urine	3	4	0.161	1	OK	
05113210001917	26	0273	Urine	4	5	0.133	1	OK	
05113210001918	26	0273	Urine	5	6	0.111	1	OK	
05113210001926	26	0276	Urine	-1	0	0.416	1	OK	
05113210001927	26	0276	Urine	0	1	0.593	1	OK	
05113210001928	26	0276	Urine	1	2	0.273	1	OK	
05113210001929	26	0276	Urine	2	3	0.196	1	OK	
05113210001930	26	0276	Urine	3	4	0.238	1	OK	
05113210001931	26	0276	Urine	4	5	0.225	1	OK	
05113210001932	26	0276	Urine	5	6	0.248	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001940	26	0277	Urine	-1	0	1.72	1	OK	
05113210001941	26	0277	Urine	0	1	2.06	1	OK	
05113210001942	26	0277	Urine	1	2	0.564	1	OK	
05113210001943	26	0277	Urine	2	3	0.254	1	OK	
05113210001944	26	0277	Urine	3	4	0.198	1	OK	
05113210001945	26	0277	Urine	4	5	0.155	1	OK	
05113210001946	26	0277	Urine	5	6	0.134	1	OK	
05113210001954	27	0278	Urine	-1	0	1.69	1	OK	
05113210001955	27	0278	Urine	0	1	1.60	1	OK	
05113210001956	27	0278	Urine	1	2	2.40	1	OK	
05113210001957	27	0278	Urine	2	3	1.97	1	OK	
05113210001958	27	0278	Urine	3	4	1.99	1	OK	
05113210001959	27	0278	Urine	4	5	1.54	1	OK	
05113210001960	27	0278	Urine	5	6	1.12	1	OK	
05113210001968	27	0279	Urine	-1	0	2.09	1	OK	
05113210001969	27	0279	Urine	0	1	1.21	1	OK	
05113210001970	27	0279	Urine	1	2	0.452	1	OK	
05113210001971	27	0279	Urine	2	3	0.246	1	OK	
05113210001972	27	0279	Urine	3	4	0.300	1	OK	
05113210001973	27	0279	Urine	4	5	0.174	1	OK	
05113210001974	27	0279	Urine	5	6	0.147	1	OK	
05113210001982	27	0281	Urine	-1	0	4.56	1	OK	
05113210001983	27	0281	Urine	0	1	4.62	1	OK	
05113210001984	27	0281	Urine	1	2	1.11	1	OK	
05113210001985	27	0281	Urine	2	3	0.333	1	OK	
05113210001986	27	0281	Urine	3	4	0.400	1	OK	
05113210001987	27	0281	Urine	4	5	0.228	1	OK	
05113210001988	27	0281	Urine	5	6	0.302	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210001996	27	0282	Urine	-1	0	2.19	1	OK	
05113210001997	27	0282	Urine	0	1	3.47	1	OK	
05113210001998	27	0282	Urine	1	2	0.565	1	OK	
05113210001999	27	0282	Urine	2	3	0.174	1	OK	
05113210002000	27	0282	Urine	3	4	0.156	1	OK	
05113210002001	27	0282	Urine	4	5	0.118	1	OK	
05113210002002	27	0282	Urine	5	6	BLQ<(0.100)	1	OK	
05113210002010	27	0283	Urine	-1	0	1.09	1	OK	
05113210002011	27	0283	Urine	0	1	1.33	1	OK	
05113210002012	27	0283	Urine	1	2	1.17	1	OK	
05113210002013	27	0283	Urine	2	3	1.26	1	OK	
05113210002014	27	0283	Urine	3	4	1.29	1	OK	
05113210002015	27	0283	Urine	4	5	0.982	1	OK	
05113210002016	27	0283	Urine	5	6	0.793	1	OK	
05113210002024	27	0285	Urine	-1	0	1.30	1	OK	
05113210002025	27	0285	Urine	0	1	2.49	1	OK	
05113210002026	27	0285	Urine	1	2	2.54	1	OK	
05113210002027	27	0285	Urine	2	3	2.80	1	OK	
05113210002028	27	0285	Urine	3	4	2.43	1	OK	
05113210002029	27	0285	Urine	4	5	1.41	1	OK	
05113210002030	27	0285	Urine	5	6	2.40	1	OK	
05113210002038	27	0287	Urine	-1	0	2.16	1	OK	
05113210002039	27	0287	Urine	0	1	2.27	1	OK	
05113210002040	27	0287	Urine	1	2	0.665	1	OK	
05113210002041	27	0287	Urine	2	3	0.198	1	OK	
05113210002042	27	0287	Urine	3	4	0.233	1	OK	
05113210002043	27	0287	Urine	4	5	0.184	1	OK	
05113210002044	27	0287	Urine	5	6	0.207	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210002066	27	0289	Urine	-1	0	1.13	1	OK	
05113210002067	27	0289	Urine	0	1	1.07	1	OK	
05113210002068	27	0289	Urine	1	2	0.440	1	OK	
05113210002069	27	0289	Urine	2	3	0.222	1	OK	
05113210002070	27	0289	Urine	3	4	0.158	1	OK	
05113210002071	27	0289	Urine	4	5	0.142	1	OK	
05113210002072	27	0289	Urine	5	6	BLQ<(0.100)	1	OK	
05113210002080	27	0291	Urine	-1	0	1.47	1	OK	
05113210002081	27	0291	Urine	0	1	1.26	1	OK	
05113210002082	27	0291	Urine	1	2	0.273	1	OK	
05113210002083	27	0291	Urine	2	3	0.192	1	OK	
05113210002084	27	0291	Urine	3	4	0.191	1	OK	
05113210002085	27	0291	Urine	4	5	0.231	1	OK	
05113210002086	27	0291	Urine	5	6	BLQ<(0.100)	1	OK	
05113210002094	27	0292	Urine	-1	0	0.302	1	OK	
05113210002095	27	0292	Urine	0	1	0.422	1	OK	
05113210002096	27	0292	Urine	1	2	0.377	1	OK	
05113210002097	27	0292	Urine	2	3	0.156	1	OK	
05113210002098	27	0292	Urine	3	4	0.197	1	OK	
05113210002099	27	0292	Urine	4	5	0.116	1	OK	
05113210002100	27	0292	Urine	5	6	0.128	1	OK	
05113210002108	28	0296	Urine	-1	0	3.03	1	OK	
05113210002109	28	0296	Urine	0	1	3.30	1	OK	
05113210002110	28	0296	Urine	1	2	0.619	1	OK	
05113210002111	28	0296	Urine	2	3	0.500	1	OK	
05113210002112	28	0296	Urine	3	4	0.314	1	OK	
05113210002113	28	0296	Urine	4	5	0.341	1	OK	
05113210002114	28	0296	Urine	5	6	0.287	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210002122	28	0298	Urine	-1	0	1.52	1	OK	
05113210002123	28	0298	Urine	0	1	2.24	1	OK	
05113210002124	28	0298	Urine	1	2	2.64	1	OK	
05113210002125	28	0298	Urine	2	3	1.51	1	OK	
05113210002126	28	0298	Urine	3	4	1.51	1	OK	
05113210002127	28	0298	Urine	4	5	1.21	1	OK	
05113210002128	28	0298	Urine	5	6	1.81	1	OK	
05113210002150	28	0300	Urine	-1	0	0.875	1	OK	
05113210002151	28	0300	Urine	0	1	0.623	1	OK	
05113210002152	28	0300	Urine	1	2	0.191	1	OK	
05113210002153	28	0300	Urine	2	3	0.150	1	OK	
05113210002154	28	0300	Urine	3	4	0.262	1	OK	
05113210002155	28	0300	Urine	4	5	0.156	1	OK	
05113210002156	28	0300	Urine	5	6	0.149	1	OK	
05113210002164	28	0301	Urine	-1	0	0.252	1	OK	
05113210002165	28	0301	Urine	0	1	0.353	1	OK	
05113210002166	28	0301	Urine	1	2	0.138	1	OK	
05113210002167	28	0301	Urine	2	3	0.180	1	OK	
05113210002168	28	0301	Urine	3	4	0.299	1	OK	
05113210002169	28	0301	Urine	4	5	0.208	1	OK	
05113210002170	28	0301	Urine	5	6	0.145	1	OK	
05113210002178	28	0306	Urine	-1	0	0.382	1	OK	
05113210002179	28	0306	Urine	0	1	0.372	1	OK	
05113210002180	28	0306	Urine	1	2	0.193	1	OK	
05113210002181	28	0306	Urine	2	3	0.204	1	OK	
05113210002182	28	0306	Urine	3	4	0.237	1	OK	
05113210002183	28	0306	Urine	4	5	0.280	1	OK	
05113210002184	28	0306	Urine	5	6	0.234	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210002192	28	0307	Urine	-1	0	1.95	1	OK	
05113210002193	28	0307	Urine	0	1	2.35	1	OK	
05113210002194	28	0307	Urine	1	2	0.537	1	OK	
05113210002195	28	0307	Urine	2	3	0.313	1	OK	
05113210002196	28	0307	Urine	3	4	0.337	1	OK	
05113210002197	28	0307	Urine	4	5	0.224	1	OK	
05113210002198	28	0307	Urine	5	6	0.220	1	OK	
05113210002206	28	0308	Urine	-1	0	0.267	1	OK	
05113210002207	28	0308	Urine	0	1	0.367	1	OK	
05113210002208	28	0308	Urine	1	2	0.150	1	OK	
05113210002209	28	0308	Urine	2	3	0.181	1	OK	
05113210002210	28	0308	Urine	3	4	0.193	1	OK	
05113210002211	28	0308	Urine	4	5	0.142	1	OK	
05113210002212	28	0308	Urine	5	6	0.199	1	OK	
05113210002248	28	0313	Urine	-1	0	1.04	1	OK	
05113210002249	28	0313	Urine	0	1	1.21	1	OK	
05113210002250	28	0313	Urine	1	2	1.73	1	OK	
05113210002251	28	0313	Urine	2	3	1.03	1	OK	
05113210002252	28	0313	Urine	3	4	1.29	1	OK	
05113210002253	28	0313	Urine	4	5	1.00	1	OK	
05113210002254	28	0313	Urine	5	6	0.941	1	OK	
05113210002262	22	0315	Urine	-1	0	1.33	1	OK	
05113210002263	22	0315	Urine	0	1	1.53	1	OK	
05113210002264	22	0315	Urine	1	2	1.25	1	OK	
05113210002265	22	0315	Urine	2	3	1.43	1	OK	
05113210002266	22	0315	Urine	3	4	1.22	1	OK	
05113210002267	22	0315	Urine	4	5	0.997	1	OK	
05113210002268	22	0315	Urine	5	6	1.18	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210002276	28	0316	Urine	-1	0	0.632	1	OK	
05113210002277	28	0316	Urine	0	1	0.770	1	OK	
05113210002278	28	0316	Urine	1	2	0.257	1	OK	
05113210002279	28	0316	Urine	2	3	0.157	1	OK	
05113210002280	28	0316	Urine	3	4	0.162	1	OK	
05113210002281	28	0316	Urine	4	5	0.174	1	OK	
05113210002282	28	0316	Urine	5	6	0.110	1	OK	
05113210002290	28	0317	Urine	-1	0	1.41	1	OK	
05113210002291	28	0317	Urine	0	1	1.27	1	OK	
05113210002292	28	0317	Urine	1	2	0.523	1	OK	
05113210002293	28	0317	Urine	2	3	0.257	1	OK	
05113210002294	28	0317	Urine	3	4	0.199	1	OK	
05113210002295	28	0317	Urine	4	5	0.155	1	OK	
05113210002296	28	0317	Urine	5	6	0.144	1	OK	
05113210002304	22	0318	Urine	-1	0	0.254	1	OK	
05113210002305	22	0318	Urine	0	1	0.305	1	OK	
05113210002306	22	0318	Urine	1	2	0.367	1	OK	
05113210002307	22	0318	Urine	2	3	0.428	1	OK	
05113210002308	22	0318	Urine	3	4	0.487	1	OK	
05113210002309	22	0318	Urine	4	5	0.503	1	OK	
05113210002310	22	0318	Urine	5	6	0.538	1	OK	
05113210002318	22	0320	Urine	-1	0	5.09	1	OK	
05113210002319	22	0320	Urine	0	1	5.53	1	OK	
05113210002320	22	0320	Urine	1	2	1.36	1	OK	
05113210002321	22	0320	Urine	2	3	0.358	1	OK	
05113210002322	22	0320	Urine	3	4	0.323	1	OK	
05113210002323	22	0320	Urine	4	5	0.277	1	OK	
05113210002324	22	0320	Urine	5	6	0.226	1	OK	





MHBMA in Human Urine  
Celerion Study AA99602-02

Custom ID	Watson Run ID	Subject	Biological Matrix	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments
05113210002332	22	0321	Urine	-1	0	1.56	1	OK	
05113210002333	22	0321	Urine	0	1	2.05	1	OK	
05113210002334	22	0321	Urine	1	2	0.412	1	OK	
05113210002335	22	0321	Urine	2	3	0.252	1	OK	
05113210002336	22	0321	Urine	3	4	0.243	1	OK	
05113210002337	22	0321	Urine	4	5	0.194	1	OK	
05113210002338	34	0321	Urine	5	6	0.245	1	OK	
05113210002346	22	0322	Urine	-1	0	1.63	1	OK	
05113210002347	22	0322	Urine	0	1	1.72	1	OK	
05113210002348	22	0322	Urine	1	2	1.39	1	OK	
05113210002349	22	0322	Urine	2	3	1.48	1	OK	
05113210002350	22	0322	Urine	3	4	1.32	1	OK	
05113210002351	22	0322	Urine	4	5	1.03	1	OK	
05113210002352	22	0322	Urine	5	6	1.03	1	OK	
05113210002360	22	0325	Urine	-1	0	0.734	1	OK	
05113210002361	22	0325	Urine	0	1	0.723	1	OK	
05113210002362	22	0325	Urine	1	2	0.712	1	OK	
05113210002363	22	0325	Urine	2	3	0.611	1	OK	
05113210002364	22	0325	Urine	3	4	0.526	1	OK	
05113210002365	22	0325	Urine	4	5	0.305	1	OK	
05113210002366	22	0325	Urine	5	6	0.270	1	OK	
05113210002374	22	0328	Urine	-1	0	0.943	1	OK	
05113210002375	22	0328	Urine	0	1	1.26	1	OK	
05113210002376	22	0328	Urine	1	2	0.721	1	OK	
05113210002377	22	0328	Urine	2	3	0.924	1	OK	
05113210002378	22	0328	Urine	3	4	0.882	1	OK	
05113210002379	22	0328	Urine	4	5	0.674	1	OK	
05113210002380	22	0328	Urine	5	6	0.791	1	OK	



MHBMA in Human Urine  
Celerion Study AA99602-02

Table 6 Summary of Reassay for Analytical Reasons for MHBMA

Watson Run ID	Reason*	Sample Name	
		(Custom ID Subject Treatment Period Matrix-Split Nominal Time)	
13	ISP	05113210000081	0028 N/A P1 URN-1 Day 3
13	ISP	05113210000082	0028 N/A P1 URN-1 Day 4
15	UCR	05113210000188	0062 N/A P1 URN-1 Day 5
17	LSR	05113210000767	0106 N/A P1 URN-1 Day 3
17	LSR	05113210000768	0106 N/A P1 URN-1 Day 4
17	LSR	05113210000769	0106 N/A P1 URN-1 Day 5
17	LSR	05113210000770	0106 N/A P1 URN-1 Day 6
17	LSR	05113210000781	0107 N/A P1 URN-1 Day 3
17	LSR	05113210000783	0107 N/A P1 URN-1 Day 5
17	LSR	05113210000784	0107 N/A P1 URN-1 Day 6
17	LSR	05113210000796	0110 N/A P1 URN-1 Day 4
17	LSR	05113210000797	0110 N/A P1 URN-1 Day 5
17	LSR	05113210000798	0110 N/A P1 URN-1 Day 6
17	LSR	05113210000809	0112 N/A P1 URN-1 Day 3
17	LSR	05113210000810	0112 N/A P1 URN-1 Day 4
17	LSR	05113210000811	0112 N/A P1 URN-1 Day 5
17	LSR	05113210000812	0112 N/A P1 URN-1 Day 6
17	LSR	05113210000825	0114 N/A P1 URN-1 Day 5
17	LSR	05113210000826	0114 N/A P1 URN-1 Day 6
17	UCR for IS	05113210000851	0118 N/A P1 URN-1 Day 3
17	LSR	05113210000853	0118 N/A P1 URN-1 Day 5
17	UCR for IS	05113210000863	0121 N/A P1 URN-1 Day 1
17	UCR for IS	05113210000867	0121 N/A P1 URN-1 Day 5
17	LSR	05113210000876	0122 N/A P1 URN-1 Day 0
17	LSR	05113210000877	0122 N/A P1 URN-1 Day 1
17	LSR	05113210000878	0122 N/A P1 URN-1 Day 2
17	LSR	05113210000879	0122 N/A P1 URN-1 Day 3
17	LSR	05113210000880	0122 N/A P1 URN-1 Day 4
17	UCR for IS	05113210000881	0122 N/A P1 URN-1 Day 5
17	LSR	05113210000882	0122 N/A P1 URN-1 Day 6
17	LSR	05113210000890	0123 N/A P1 URN-1 Day 0
17	LSR	05113210000891	0123 N/A P1 URN-1 Day 1
17	LSR	05113210000892	0123 N/A P1 URN-1 Day 2
17	LSR	05113210000893	0123 N/A P1 URN-1 Day 3
17	LSR	05113210000894	0123 N/A P1 URN-1 Day 4
17	UCR for IS	05113210000895	0123 N/A P1 URN-1 Day 5
17	LSR	05113210000896	0123 N/A P1 URN-1 Day 6
18	ISP	05113210000904	0126 N/A P1 URN-1 Day 0
18	ISP	05113210000905	0126 N/A P1 URN-1 Day 1
18	ISP	05113210000906	0126 N/A P1 URN-1 Day 2
18	ISP	05113210000907	0126 N/A P1 URN-1 Day 3
18	ISP	05113210000908	0126 N/A P1 URN-1 Day 4
18	ISP	05113210000909	0126 N/A P1 URN-1 Day 5
18	ISP	05113210000910	0126 N/A P1 URN-1 Day 6



MHBMA in Human Urine  
Celerion Study AA99602-02

Watson Run ID	Reason*	Sample Name	
		(Custom ID Subject Treatment Period Matrix-Split Nominal Time)	
18	ISP	05113210000918 0127 N/A P1 URN-1	Day 0
18	ISP	05113210000919 0127 N/A P1 URN-1	Day 1
18	ISP	05113210000920 0127 N/A P1 URN-1	Day 2
18	ISP	05113210000921 0127 N/A P1 URN-1	Day 3
18	ISP	05113210000922 0127 N/A P1 URN-1	Day 4
18	ISP	05113210000923 0127 N/A P1 URN-1	Day 5
18	ISP	05113210000924 0127 N/A P1 URN-1	Day 6
18	ISP	05113210000932 0128 N/A P1 URN-1	Day 0
18	ISP	05113210000933 0128 N/A P1 URN-1	Day 1
18	ISP	05113210000934 0128 N/A P1 URN-1	Day 2
18	ISP	05113210000935 0128 N/A P1 URN-1	Day 3
18	ISP	05113210000936 0128 N/A P1 URN-1	Day 4
18	ISP	05113210000937 0128 N/A P1 URN-1	Day 5
18	ISP	05113210000938 0128 N/A P1 URN-1	Day 6
18	ISP	05113210000946 0129 N/A P1 URN-1	Day 0
18	ISP	05113210000947 0129 N/A P1 URN-1	Day 1
18	ISP	05113210000948 0129 N/A P1 URN-1	Day 2
18	ISP	05113210000949 0129 N/A P1 URN-1	Day 3
18	ISP	05113210000950 0129 N/A P1 URN-1	Day 4
18	ISP	05113210000951 0129 N/A P1 URN-1	Day 5
18	ISP	05113210000952 0129 N/A P1 URN-1	Day 6
18	ISP	05113210000960 0130 N/A P1 URN-1	Day 0
18	ISP	05113210000961 0130 N/A P1 URN-1	Day 1
18	ISP	05113210000962 0130 N/A P1 URN-1	Day 2
18	ISP	05113210000963 0130 N/A P1 URN-1	Day 3
18	ISP	05113210000964 0130 N/A P1 URN-1	Day 4
18	ISP	05113210000965 0130 N/A P1 URN-1	Day 5
18	ISP	05113210000966 0130 N/A P1 URN-1	Day 6
18	ISP	05113210000974 0133 N/A P1 URN-1	Day 0
18	ISP	05113210000975 0133 N/A P1 URN-1	Day 1
18	ISP	05113210000976 0133 N/A P1 URN-1	Day 2
18	ISP	05113210000977 0133 N/A P1 URN-1	Day 3
18	ISP	05113210000978 0133 N/A P1 URN-1	Day 4
18	ISP	05113210000979 0133 N/A P1 URN-1	Day 5
18	ISP	05113210000980 0133 N/A P1 URN-1	Day 6
18	ISP	05113210000988 0134 N/A P1 URN-1	Day 0
18	ISP	05113210000989 0134 N/A P1 URN-1	Day 1
18	ISP	05113210000990 0134 N/A P1 URN-1	Day 2
18	ISP	05113210000991 0134 N/A P1 URN-1	Day 3
18	ISP	05113210000992 0134 N/A P1 URN-1	Day 4
18	ISP	05113210000993 0134 N/A P1 URN-1	Day 5
18	ISP	05113210000994 0134 N/A P1 URN-1	Day 6
18	ISP	05113210001002 0136 N/A P1 URN-1	Day 0
18	ISP	05113210001003 0136 N/A P1 URN-1	Day 1
18	ISP	05113210001004 0136 N/A P1 URN-1	Day 2
18	ISP	05113210001005 0136 N/A P1 URN-1	Day 3
18	ISP	05113210001006 0136 N/A P1 URN-1	Day 4





MHBMA in Human Urine  
Celerion Study AA99602-02

Watson Run ID	Reason*	Sample Name	
		(Custom ID Subject Treatment Period Matrix-Split Nominal Time)	
18	ISP	05113210001007 0136 N/A P1 URN-1	Day 5
18	ISP	05113210001008 0136 N/A P1 URN-1	Day 6
18	ISP	05113210001016 0137 N/A P1 URN-1	Day 0
18	ISP	05113210001017 0137 N/A P1 URN-1	Day 1
18	ISP	05113210001018 0137 N/A P1 URN-1	Day 2
18	ISP	05113210001019 0137 N/A P1 URN-1	Day 3
18	ISP	05113210001020 0137 N/A P1 URN-1	Day 4
18	ISP	05113210001021 0137 N/A P1 URN-1	Day 5
18	ISP	05113210001022 0137 N/A P1 URN-1	Day 6
18	ISP	05113210001030 0139 N/A P1 URN-1	Day 0
18	ISP	05113210001031 0139 N/A P1 URN-1	Day 1
18	ISP	05113210001032 0139 N/A P1 URN-1	Day 2
18	ISP	05113210001033 0139 N/A P1 URN-1	Day 3
18	ISP	05113210001034 0139 N/A P1 URN-1	Day 4
18	ISP	05113210001035 0139 N/A P1 URN-1	Day 5
18	ISP	05113210001036 0139 N/A P1 URN-1	Day 6
19	ISP	05113210000017 0011 N/A P1 URN-1	Day 2
19	ISP	05113210000444 0013 N/A P1 URN-1	Day 2
19	ISP	05113210000045 0017 N/A P1 URN-1	Day 2
19	ISP	05113210000024 0014 N/A P1 URN-1	Day 2
19	ISP	05113210000094 0030 N/A P1 URN-1	Day 2
19	ISP	05113210000064 0023 N/A P1 URN-1	Day 0
19	ISP	05113210000100 0031 N/A P1 URN-1	Day 1
19	ISP	05113210000136 0044 N/A P1 URN-1	Day 2
19	ISP	05113210000164 0055 N/A P1 URN-1	Day 2
19	ISP	05113210000122 0038 N/A P1 URN-1	Day 2
19	ISP	05113210000142 0049 N/A P1 URN-1	Day 1
19	ISP	05113210000640 0083 N/A P1 URN-1	Day 2
19	ISP	05113210000668 0086 N/A P1 URN-1	Day 2
19	ISP	05113210000612 0076 N/A P1 URN-1	Day 2
19	ISP	05113210000008 0010 N/A P1 URN-1	Day 0
19	ISP	05113210000029 0015 N/A P1 URN-1	Day 0
19	ISP	05113210000002 0008 N/A P1 URN-1	Day 1
19	ISP	05113210000114 0035 N/A P1 URN-1	Day 1
19	ISP	05113210000085 0029 N/A P1 URN-1	Day 0
19	ISP	05113210000459 0021 N/A P1 URN-1	Day 3
19	ISP	05113210000051 0020 N/A P1 URN-1	Day 1
19	ISP	05113210000353 0053 N/A P1 URN-2	Day 2
19	ISP	05113210000471 0037 N/A P1 URN-1	Day 1
19	ISP	05113210000488 0042 N/A P1 URN-1	Day 4
19	ISP	05113210000638 0083 N/A P1 URN-1	Day 0
19	ISP	05113210000627 0080 N/A P1 URN-1	Day 3
19	ISP	05113210000680 0087 N/A P1 URN-1	Day 0
19	ISP	05113210000723 0093 N/A P1 URN-1	Day 1
22	UCR	05113210002338 0321 N/A P1 URN-1	Day 6

\*: See [Attachment 5](#) for reassay descriptions.





MHBMA in Human Urine  
Celerion Study AA99602-02

Table 7 Incurred Sample Reproducibility Assessment for MHBMA

Subject	Day Nominal	Custom ID	Original analysis		ISR analysis		%Diff	Match
			Result (ng/mL)	Watson Run ID	Result (ng/mL)	Watson Run ID		
0008	Day 1	05113210000002	5.32	12	5.58	29	4.7	Yes
0010	Day 0	05113210000008	4.90	12	5.08	29	3.7	Yes
0011	Day 2	05113210000017	0.331	12	0.334	29	0.8	Yes
0013	Day 2	05113210000444	0.331	12	0.315	29	5.1	Yes
0014	Day 2	05113210000024	0.458	12	0.457	29	0.3	Yes
0015	Day 0	05113210000029	4.97	12	5.09	29	2.5	Yes
0017	Day 2	05113210000045	0.408	12	0.420	29	2.9	Yes
0020	Day 1	05113210000051	3.38	13	3.50	29	3.4	Yes
0021	Day 3	05113210000459	2.86	13	2.98	29	4.2	Yes
0022	Day 0	05113210000057	2.61	22	2.49	34	4.9	Yes
0023	Day 0	05113210000064	0.334	13	0.366	29	9.0	Yes
0029	Day 0	05113210000085	2.64	13	2.71	29	2.7	Yes
0030	Day 2	05113210000094	0.308	13	0.316	29	2.5	Yes
0031	Day 1	05113210000100	0.365	13	0.402	29	9.7	Yes
0035	Day 1	05113210000114	2.59	13	2.58	29	0.5	Yes
0037	Day 1	05113210000471	4.07	14	4.25	29	4.2	Yes
0038	Day 2	05113210000122	0.576	14	0.639	29	10.4	Yes
0042	Day 4	05113210000488	4.43	14	4.76	29	7.3	Yes
0044	Day 2	05113210000136	0.414	14	0.471	29	12.8	Yes
0049	Day 1	05113210000142	0.779	14	0.802	29	3.0	Yes
0053	Day 2	05113210000353	3.63	14	4.09	29	11.9	Yes
0055	Day 2	05113210000164	0.422	14	0.532	29	23.0	No
0057	Day 2	05113210000171	0.415	15	0.377	32	9.7	Yes
0062	Day 0	05113210000183	0.533	15	0.569	32	6.4	Yes
0063	Day 1	05113210000513	3.08	15	2.95	32	4.3	Yes
0069	Day 2	05113210000556	0.501	15	0.518	32	3.4	Yes
0071	Day 2	05113210000570	0.377	22	0.312	34	18.7	Yes



MHBMA in Human Urine  
Celerion Study AA99602-02

Subject	Day Nominal	Custom ID	Original analysis		ISR analysis		%Diff	Match
			Result (ng/mL)	Watson Run ID	Result (ng/mL)	Watson Run ID		
0072	Day 4	05113210000586	4.19	15	4.45	32	5.9	Yes
0074	Day 0	05113210000596	6.43	15	6.59	32	2.3	Yes
0074	Day 3	05113210000599	0.324	15	0.350	32	7.6	Yes
0076	Day 2	05113210000612	0.669	16	0.788	29	16.4	Yes
0080	Day 3	05113210000627	3.14	16	3.35	29	6.6	Yes
0083	Day 0	05113210000638	2.10	16	1.99	29	5.6	Yes
0083	Day 2	05113210000640	0.377	16	0.418	29	10.3	Yes
0086	Day 2	05113210000668	0.556	16	0.644	29	14.6	Yes
0087	Day 0	05113210000680	3.41	16	3.45	29	1.2	Yes
0093	Day 1	05113210000723	3.53	16	3.78	29	6.9	Yes
0106	Day 2	05113210000766	0.305	17	0.301	32	1.4	Yes
0107	Day 0	05113210000778	2.97	17	2.98	32	0.5	Yes
0114	Day 1	05113210000821	4.00	17	2.36	32	51.5	No
0117	Day 3	05113210000837	3.08	17	1.79	32	53.0	No
0118	Day 1	05113210000849	0.345	17	0.237	32	37.4	No
0127	Day 0	05113210000918	4.50	30	4.02	32	11.4	Yes
0127	Day 3	05113210000921	0.308	30	0.224	32	31.7	No
0130	Day 2	05113210000962	0.312	30	0.284	32	9.5	Yes
0136	Day 0	05113210001002	4.51	30	3.45	32	26.7	No
0136	Day 3	05113210001005	0.309	30	0.327	32	5.8	Yes
0139	Day 1	05113210001031	4.36	30	3.05	32	35.2	No
0145	Day 1	05113210001059	2.01	20	1.97	32	2.1	Yes
0147	Day 1	05113210001073	3.27	20	3.20	32	2.4	Yes
0147	Day 2	05113210001074	0.602	20	0.557	32	7.7	Yes
0150	Day 0	05113210001114	0.340	20	0.295	32	14.2	Yes
0155	Day 2	05113210001158	0.424	20	0.387	32	9.1	Yes
0156	Day 5	05113210001175	5.35	20	5.14	32	3.9	Yes
0160	Day 1	05113210001185	4.63	21	4.07	32	12.8	Yes
0162	Day 3	05113210001201	0.300	21	0.260	32	14.4	Yes
0167	Day 2	05113210001214	0.427	21	0.312	32	31.3	No



MHBMA in Human Urine  
Celerion Study AA99602-02

Subject	Day Nominal	Custom ID	Original analysis		ISR analysis		%Diff	Match
			Result (ng/mL)	Watson Run ID	Result (ng/mL)	Watson Run ID		
0177	Day 0	05113210001254	4.34	21	3.79	32	13.5	Yes
0181	Day 0	05113210001352	4.63	21	3.89	32	17.4	Yes
0183	Day 3	05113210001271	0.336	21	0.233	32	36.5	No
0185	Day 0	05113210001282	4.89	21	4.18	32	15.7	Yes
0192	Day 2	05113210001340	0.440	23	0.373	32	16.6	Yes
0193	Day 1	05113210001381	4.15	23	3.58	32	14.5	Yes
0196	Day 0	05113210001408	0.451	23	0.385	32	15.7	Yes
0197	Day 1	05113210001423	6.09	23	5.57	32	8.8	Yes
0197	Day 3	05113210001425	0.334	23	0.276	32	19.1	Yes
0198	Day 5	05113210001441	7.61	23	6.79	32	11.3	Yes
0202	Day 3	05113210001467	0.320	24	0.323	32	1.1	Yes
0204	Day 0	05113210001492	0.414	24	0.421	32	1.7	Yes
0210	Day 0	05113210001520	2.23	24	2.24	32	0.2	Yes
0210	Day 2	05113210001522	0.456	24	0.427	32	6.4	Yes
0216	Day 1	05113210001549	2.28	24	2.21	32	2.9	Yes
0218	Day 1	05113210001563	0.378	24	0.404	32	6.6	Yes
0224	Day 1	05113210001591	2.62	24	3.05	32	15.2	Yes
0229	Day 4	05113210001622	2.38	25	2.35	34	1.0	Yes
0230	Day 1	05113210001633	2.34	25	2.26	34	3.5	Yes
0240	Day 2	05113210001676	0.377	25	0.352	34	6.9	Yes
0241	Day 2	05113210001690	0.409	25	0.388	34	5.2	Yes
0244	Day 0	05113210001716	2.16	25	2.10	34	3.0	Yes
0249	Day 0	05113210001758	4.73	25	4.63	34	2.2	Yes
0249	Day 4	05113210001762	0.428	25	0.379	34	12.3	Yes
0255	Day 1	05113210001801	2.05	26	2.03	34	0.8	Yes
0255	Day 2	05113210001802	0.343	26	0.320	34	7.2	Yes
0256	Day 1	05113210001815	2.49	26	2.36	34	5.3	Yes
0266	Day 0	05113210001870	0.322	26	0.273	34	16.3	Yes
0273	Day 2	05113210001914	0.329	26	0.321	34	2.4	Yes
0277	Day 1	05113210001941	2.06	26	1.91	34	7.2	Yes



MHBMA in Human Urine  
Celerion Study AA99602-02

Subject	Day Nominal	Custom ID	Original analysis		ISR analysis		%Diff	Match
			Result (ng/mL)	Watson Run ID	Result (ng/mL)	Watson Run ID		
0279	Day 2	05113210001970	0.452	27	0.479	34	5.6	Yes
0281	Day 1	05113210001983	4.62	27	4.81	34	4.2	Yes
0281	Day 6	05113210001988	0.302	27	0.308	34	2.2	Yes
0282	Day 1	05113210001997	3.47	27	3.46	34	0.4	Yes
0285	Day 3	05113210002027	2.80	27	2.92	34	4.3	Yes
0289	Day 2	05113210002068	0.440	27	0.439	34	0.4	Yes
0292	Day 0	05113210002094	0.302	27	0.302	34	0.2	Yes
0296	Day 1	05113210002109	3.30	28	3.22	34	2.6	Yes
0296	Day 4	05113210002112	0.314	28	0.289	34	8.4	Yes
0298	Day 2	05113210002124	2.64	28	2.51	34	5.2	Yes
0301	Day 1	05113210002165	0.353	28	0.281	34	22.7	No
0307	Day 1	05113210002193	2.35	28	2.30	34	2.5	Yes
0307	Day 3	05113210002195	0.313	28	0.281	34	10.8	Yes
0313	Day 2	05113210002250	1.73	28	1.71	34	1.1	Yes
0318	Day 1	05113210002305	0.305	22	0.233	34	26.7	No
0320	Day 1	05113210002319	5.53	22	5.45	34	1.6	Yes
0320	Day 4	05113210002322	0.323	22	0.285	34	12.5	Yes
0321	Day 1	05113210002333	2.05	22	1.92	34	6.6	Yes
0325	Day 5	05113210002365	0.305	22	0.258	34	16.8	Yes
<b>n</b>							106	95
<b>Matches (%)</b>								89.6

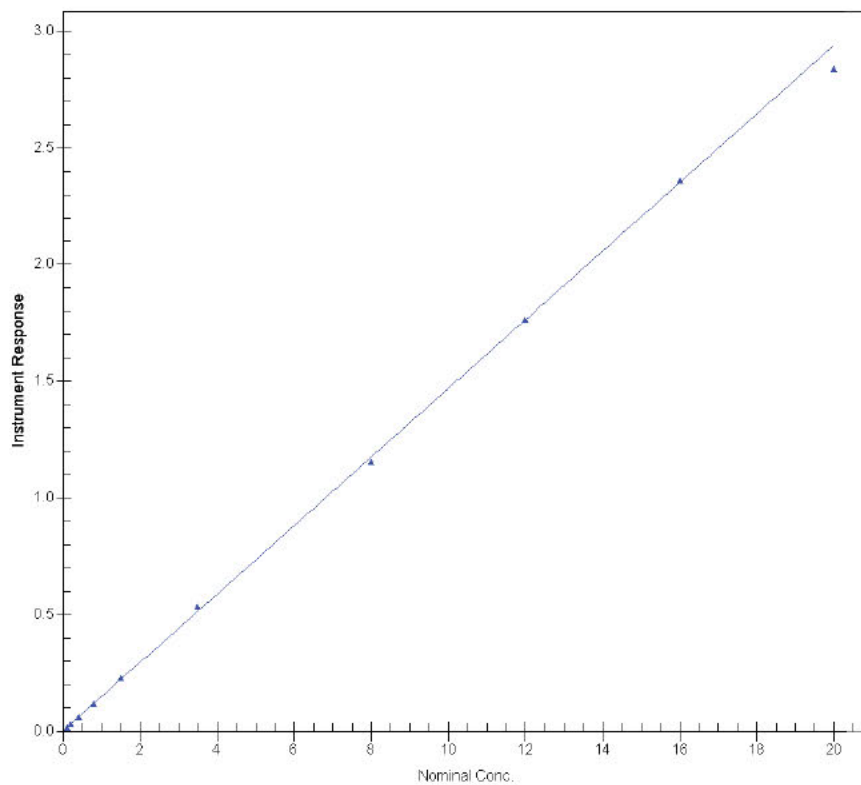


MHBMA in Human Urine  
Celerion Study AA99602-02

## FIGURES

Figure 1 Calibration Curve for MHBMA in UriSub<sup>®</sup>, Watson Run ID 12

Analytical Run 12 analyzed on 07-Jan-2014: Calibration Standards for MHBMA (ng/mL)  
Regression Method = LINEAR - Weighting Factor = 1/X\*\*2  
Response = Slope \* Conc + Intercept  
Slope = 0.147007318 Intercept = -0.000133575071 R-Squared = 0.9990  
(Study ZRHR-REXC-03-EU, MHBMA)



MHBMA in Human Urine  
Celerion Study AA99602-02**ATTACHMENTS**

## Attachment 1 General List of Abbreviations used at Celerion

Abbreviations are used in this document as applicable.

Abbreviation	Description
AAR	Above the accepted range
ASCII	American standard code for information interchange
API	Atmospheric pressure ionisation
BLQ	Below limit of quantification
BSA	Bovine serum albumin
CC	Conventional Cigarette
cpm	counts per minute
CRO	Contract research organisation
CV	Coefficient of variation
DCU	Diluted concentration unreliable
DFNR	Dilution factor not reliable
DQC	Dilution quality control sample
ELISA	Enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EQB	Exceeding quadratic bounds
FDA	Food and Drug Administration (U.S. Department of Health and Human Services)
GLP	Good laboratory practice
HPLC	High performance liquid chromatography
HSR	Highest standard removed
IIA	Incomplete instrument analysis
ID	Identifier
IS	Internal standard
ISA	Insufficient Sample for Analysis
ISP	Incomplete sample processing
ISR	Incurred sample reproducibility
IVR	Insufficient Sample Volume for Reanalysis
LBS	Ligand binding services
LC-MS/MS	Liquid chromatography-tandem mass spectrometry
LIMS	Laboratory information management system
LLOQ	Lower limit of quantification
LSR	Lowest standard removed

MHBMA in Human Urine  
Celerion Study AA99602-02

Abbreviation	Description
MRM	Multiple-reaction-monitoring
MW	Molecular weight
n	Number of data points
N/AP	Not applicable
N/AV	Not available
No.	Number
NR	Not reportable
OD	Optical Density
OECD	Organisation for economic cooperation and development
QC	Quality control
QMV	Questionable multiple values
RE	Relative error
RIA	Radioimmunoassay
RIP	Radioimmunoprecipitation
RSD	Relative standard deviation
RT	Room temperature
SA	Smoking Abstinence
SD	Standard deviation
SOP	Standard operating procedure
STD	Calibration standard
THS	Tobacco Heating System
TMB	3,3',5,5'-Tetramethylbenzidine
UCR	Unacceptable chromatography
UISR	Unacceptable internal standard response
ULOQ	Upper limit of quantification



MHBMA in Human Urine  
Celerion Study AA99602-02

#### Attachment 2 Temperature Definitions at Celerion

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

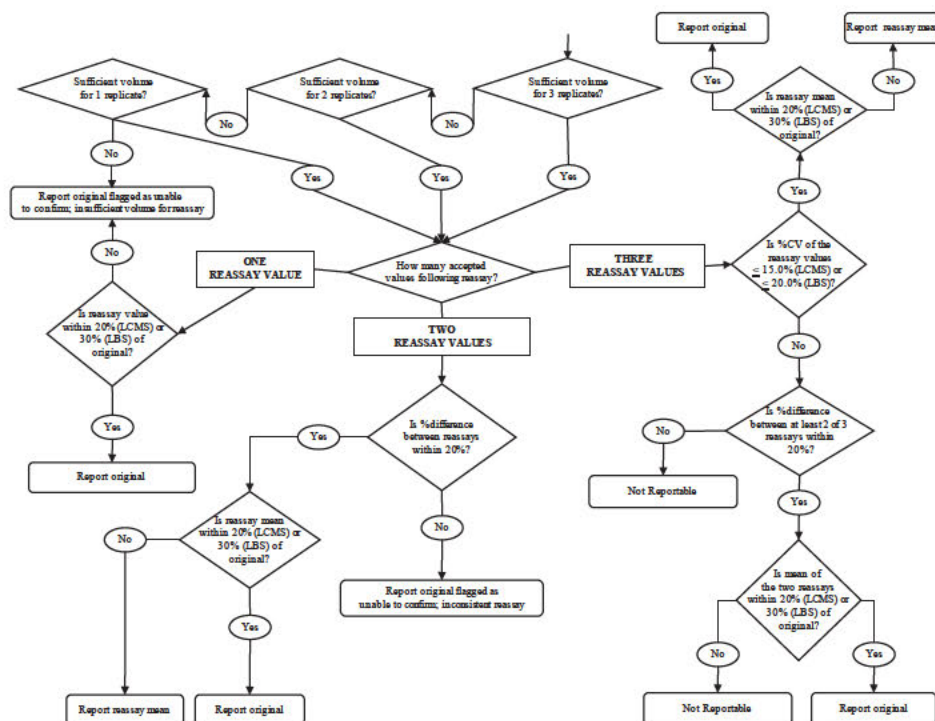
Nominal temperature	Temperature Range
-80 C	-65 C to -90 C
-20 C	-10 C to -30 C
5 C	2 C to 8 C
Room temperature	15 C to 25 C
24 C	22 C to 26 C





MHBMA in Human Urine  
Celerion Study AA99602-02

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



To compare reassays:

$$\frac{|\text{Reassay Value 1} - \text{Reassay Value 2}|}{\text{Mean of Reassay Value 1 and 2}} \times 100\%$$

To compare to original:

$$\frac{|\text{Mean of Reassays} - \text{Original Value}|}{\text{Original Value}} \times 100\%$$

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.

MHBMA in Human Urine  
Celerion Study AA99602-02

## Attachment 4 General List of Calculation Formulae

Mean:

$$\bar{X} = \frac{1}{n} \sum_{i=1}^n X_i$$

Standard Deviation (SD):

$$s = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (X_i - \bar{X})^2}$$

Precision (RSD, CV):

$$CV \% = (SD / X_{Mean}) * 100$$

Accuracy (% Theoretical):

$$Accuracy \% = (X / X_{Nominal}) * 100$$

$$Accuracy \text{ of Mean } \% = (X_{Mean} / X_{Nominal}) * 100$$

Inaccuracy (% Bias, % RE):

$$Bias \% = ((X - X_{nominal}) / X_{nominal}) * 100$$

$$Bias \text{ of Mean } \% = ((X_{Mean} - X_{nominal}) / X_{nominal}) * 100$$

X = value (e.g. analyte concentration, OD value, cpm value, peak signal)  
n = number of values X



MHBMA in Human Urine  
Celerion Study AA99602-02



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.
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).



MHBMA in Human Urine  
Celerion Study AA99602-02

Attachment 6 Statement of GLP Compliance (Swissmedic)

The Swiss GLP Monitoring Authorities		
	Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra Swiss Confederation	Federal Department of Home Affairs DHA Federal Office of Public Health FOPH  Federal Department of the Environment, Transport, Energy and Communications DETEC Federal Office for the Environment FOEN
		 <b>swissmedic</b> Swiss Agency for Therapeutic Products

## Statement of GLP Compliance

According to Article 14 paragraph 3 Ordinance on Good Laboratory Practice [OGLP, SR 813.112.1]

The notification authority for chemicals confirms that the following test facility was inspected with respect to the compliance with the Swiss Ordinance on Good Laboratory Practice, adopted on 18th May 2005 [OGLP, SR 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted on 28th November 1997 by decision of the OECD Council [C(97)186/Final].

Unequivocal name and address of the test facility:	Area of expertise according to article 3 paragraph 1 letter d OGLP:
Celerion Switzerland Ltd Allmendstrasse 32 8320 Fehraltorf, Switzerland	8. analytic and clinical chemistry testing.

Inspection authority: Swiss Agency for Therapeutic Products (Swissmedic)

Date of inspection: 13 to 14 May 2013

Date of decision: 27 June 2013

Based on the above mentioned decision it can be confirmed that the above mentioned test facility is able to conduct studies according to the aforementioned area of expertise in compliance with the principles of GLP. The above mentioned test facility is listed in the register and GLP list according to the Article 14 OGLP and is inspected on a regular basis according to Article 6 paragraph 2 OGLP.

Swiss Federal Office of Public Health  
Consumer protection directorate  
Notification authority for chemicals  
CH-3003 Bern



*Dag Kappes*

Bern, 14 August 2013, The Head, Dr. Dag Kappes.

The notification authority for chemicals is the coordination and decision authority for the good laboratory practice (GLP) for the FOEN, the FOPH and Swissmedic.

Swiss Federal Office of Public Health, Consumer protection directorate, Notification authority for chemicals, CH-3003 Bern.

[www.glp.admin.ch](http://www.glp.admin.ch), Phone: +41 (0)31 322 73 05, Fax: +41 (0)31 322 54 86





MHBMA in Human Urine  
Celerion Study AA99602-02

Attachment 7 Certificates of Analysis

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MHBMA in Human Urine  
Celerion Study AA99602-02

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MHBMA in Human Urine  
Celerion Study AA99602-02

## Attachment 8 Summary of the Method Validation Data

 PMI RESEARCH & DEVELOPMENT

**BIOANALYTICAL METHOD SUMMARY (BMS)**

Doc No: FOR\_QM300496 - CR204A2 Version R": 2.0 Page 1 of 2

<b>Biomarker: Monohydroxy-3-butenyl-mercaptopuric acid (MHBMA)</b>		<b>Matrix: Human urine</b>
<b>MVR/SOP no. &amp; date: SOP SM1-363A / 01-Oct-2013</b>		<b>CRO/Laboratory: Celerion Switzerland</b>
<b>LLOQ: 0.100 ng/mL</b>		<b>ULOQ: 20.0 ng/mL</b>
<b>Validation</b>	<input type="checkbox"/> Full <input checked="" type="checkbox"/> Partial <input type="checkbox"/> Cross Comments (required for Partial/Cross):	
<b>Assay:</b>	<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	
<b>Equipment and short description of extraction and analysis:</b> An aliquot of human urine containing the analyte and internal standard (assay volume of 250 µL) was extracted using a solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an Applied Biosystems/MDS SCIEX API QTrap 5500 mass spectrometer. Negative ions were monitored in the multiple reaction monitoring (MRM) mode. Quantification was performed using the peak area ratios of analyte versus IS for each pair of analyte and IS. The calibration curve fitting was done by $1/\text{concentration}^2$ -weighted linear regression.		
<b>Selectivity/Sensitivity/Matrix effect:</b>	Comments: No significant interference at the retention time and mass transition of MHBMA-15N-13C3 (IS) in all six human urine lots. Matrix effect within acceptance for all six human urine lots spiked near the low (0.300 ng/mL) and high (20.0 ng/mL) concentration level.	
<b>Accuracy:</b>	Intra-run: -5.6 – 0.1% R.E. Inter-run: -2.1 – 10.6% R.E.	
<b>Precision:</b>	Intra-run: 1.2 – 2.4% C.V. Inter-run: 2.1 – 13.8% C.V.	
<b>Recovery:</b>	N/A	
<b>Freeze and thaw stability:</b>	4 cycles in UV shielded polypropylene tubes at -20°C 3 cycles in UV shielded polypropylene tubes at -80°C	
<b>Short-term temperature stability:</b>	24 hours at room temperature in UV shielded polypropylene tubes	
<b>Long-term stability:</b>	8 day at -80°C in UV shielded polypropylene tubes	
<b>Stock solution stability:</b>	24 hours at 500 µg/mL in methanol for MHBMA in silanized glass at room temperature 24 hours at 500 µg/mL in methanol for MHBMA- <sup>15</sup> N- <sup>13</sup> C <sub>3</sub> (IS) in silanized glass at room temperature	
<b>Post-preparative stability:</b>	N/A; processed sample integrity up to 122 hours at 5°C demonstrated	
<b>Accreditation/ GLP compliance/ QA statements:</b>	GLP Compliance as Assay Validation conforms to Celerion Standard Operating Procedures which were written in compliance with FDA: "Guidance to Industry " Bioanalytical Method Validation"	



MHBMA in Human Urine  
Celerion Study AA99602-02

 PMI RESEARCH & DEVELOPMENT

**BIOANALYTICAL METHOD SUMMARY (BMS)**

Doc No: FOR\_QM00496 - CR204A2 Version R: 2.6 Page 2 of 2

<b>BMS completed by:</b>		
Name:	Date:	Signature:
Werner Meyer	12 NOV 2013	





MHBMA in Human Urine  
Celerion Study AA99602-02



PMI RESEARCH &amp; DEVELOPMENT

## BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_L0M000496 - CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: Monohydroxybutenyl mercapturic acid	Matrix: Urine
MVR/SOP no. & date: ZZ25433-02 / 10-Jan-2013	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 HPLC equipped with an AB SCIEX API 5000™ mass spectrometer. Negative ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration <sup>2</sup> ) of peak area ratios of the analyte and internal standard.	
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in 9 of the 10 human urine lots that were spiked near the concentration of the LLOQ and in 9 of the 10 human urine lots that were spiked near the concentration of the high QC
Accuracy:	Intra-batch: -2.7 to 11.0% R.E. Inter-batch: -1.3 to 6.0% R.E.
Precision:	Intra-batch: 0.8 to 27.9% C.V. Inter-batch: 2.4 to 14.7% C.V.
Recovery:	83% at 0.200 ng/mL in human urine 82% at 1.50 ng/mL in human urine 100% at 12.0 ng/mL in human urine
Freeze and thaw stability:	4 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under yellow light, 4 freeze (-20°C)-thaw (5°C) cycles in polypropylene tubes in the absence of light, 4 freeze (-80°C) thaw (5°C) cycles in polypropylene tubes under UV-shielded light
Short-term temperature stability:	20 hours in polypropylene tubes at ambient temperature under yellow light (total of all thaw cycles), 112 hours in polypropylene tubes at 5°C in the absence of light (QCs stored at -20°C), 93 hours in polypropylene tubes at 5°C under UV-shielded light (total of all thaw cycles) (QCs stored at -80°C)
Long-term stability:	Long-Term Stability: 178 days in polypropylene tubes at -20°C, 158 days (low QC) and 159 days (medium and dilution QC) in polypropylene tubes at -80°C
Stock solution stability:	716 days at approximately 750 µg/mL in methanol in polypropylene container at -20°C
Post-preparative stability:	185 hours in amber injection vials with deactivated glass inserts at 5°C
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"



MHBMA in Human Urine  
Celerion Study AA99602-02



PMI RESEARCH &amp; DEVELOPMENT

## BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_OM000498 – CR204A2

Version R1: 2.0

Page 2 of 2

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Name:	Date:	Signature:
Erica Naele	14-MAY-2013	<i>Erica Naele</i>



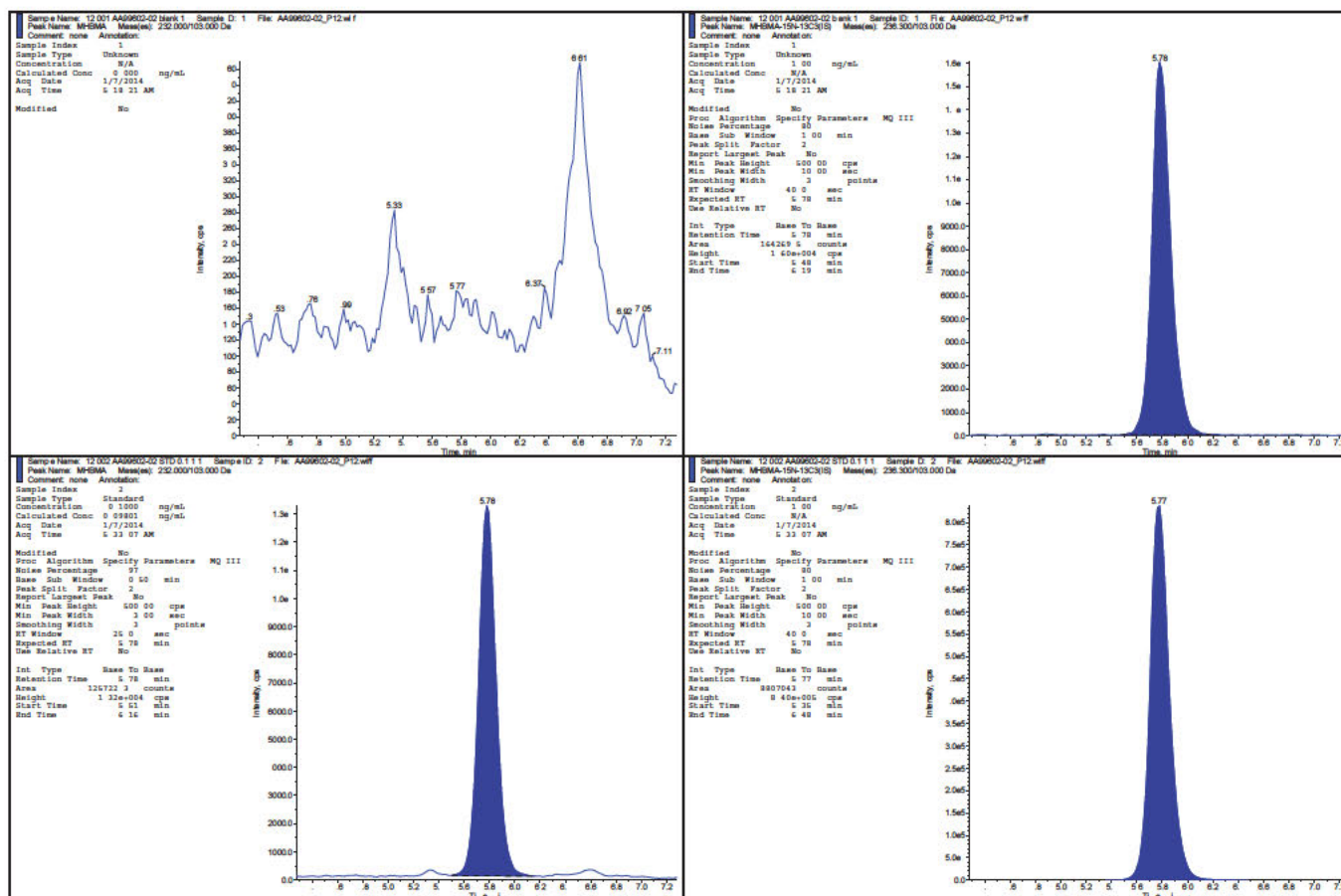
MHBMA in Human Urine  
Celerion Study AA99602-02

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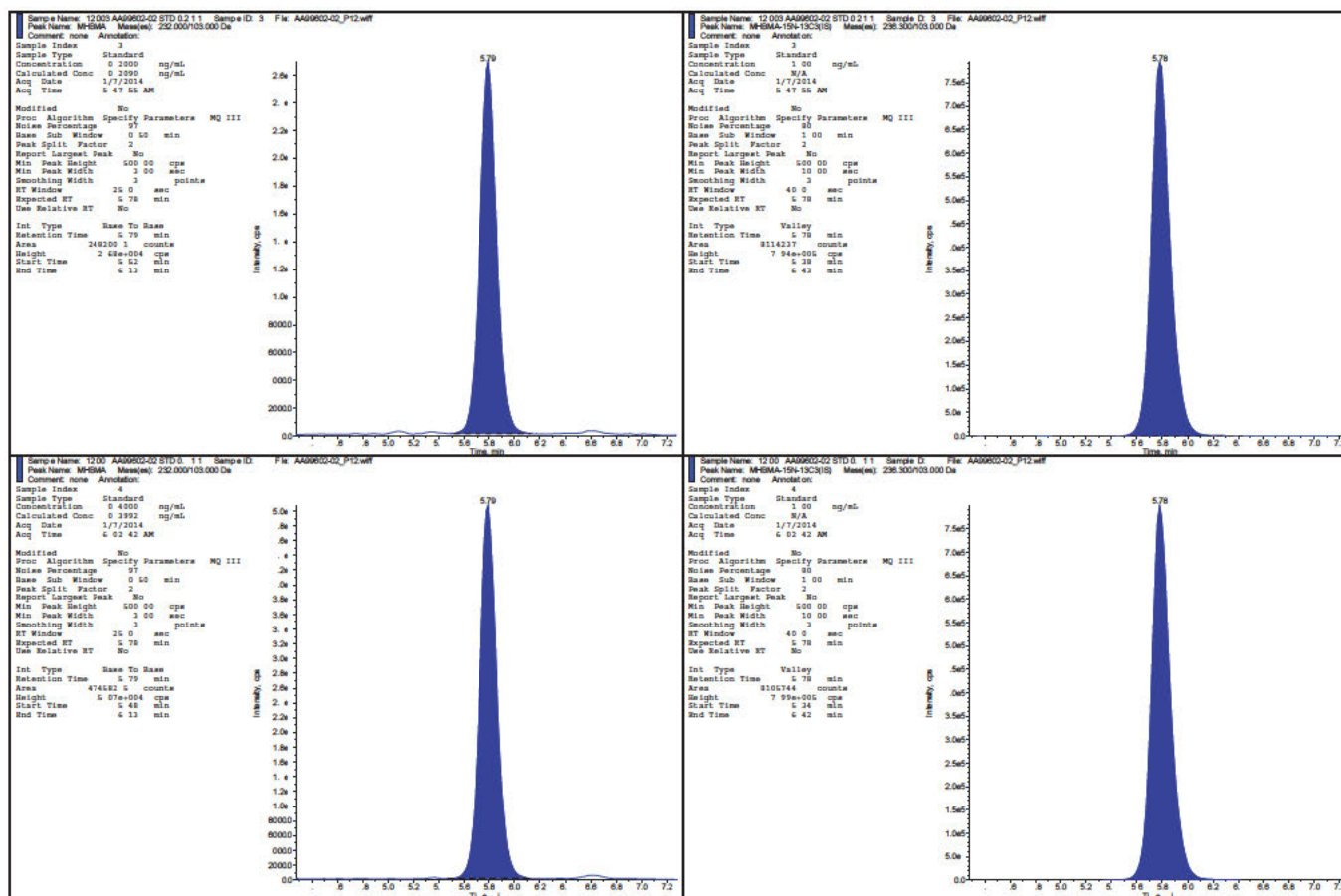
#### Attachment 9 Chromatograms

Representative chromatograms from analytical run AA99602-02\_P12.

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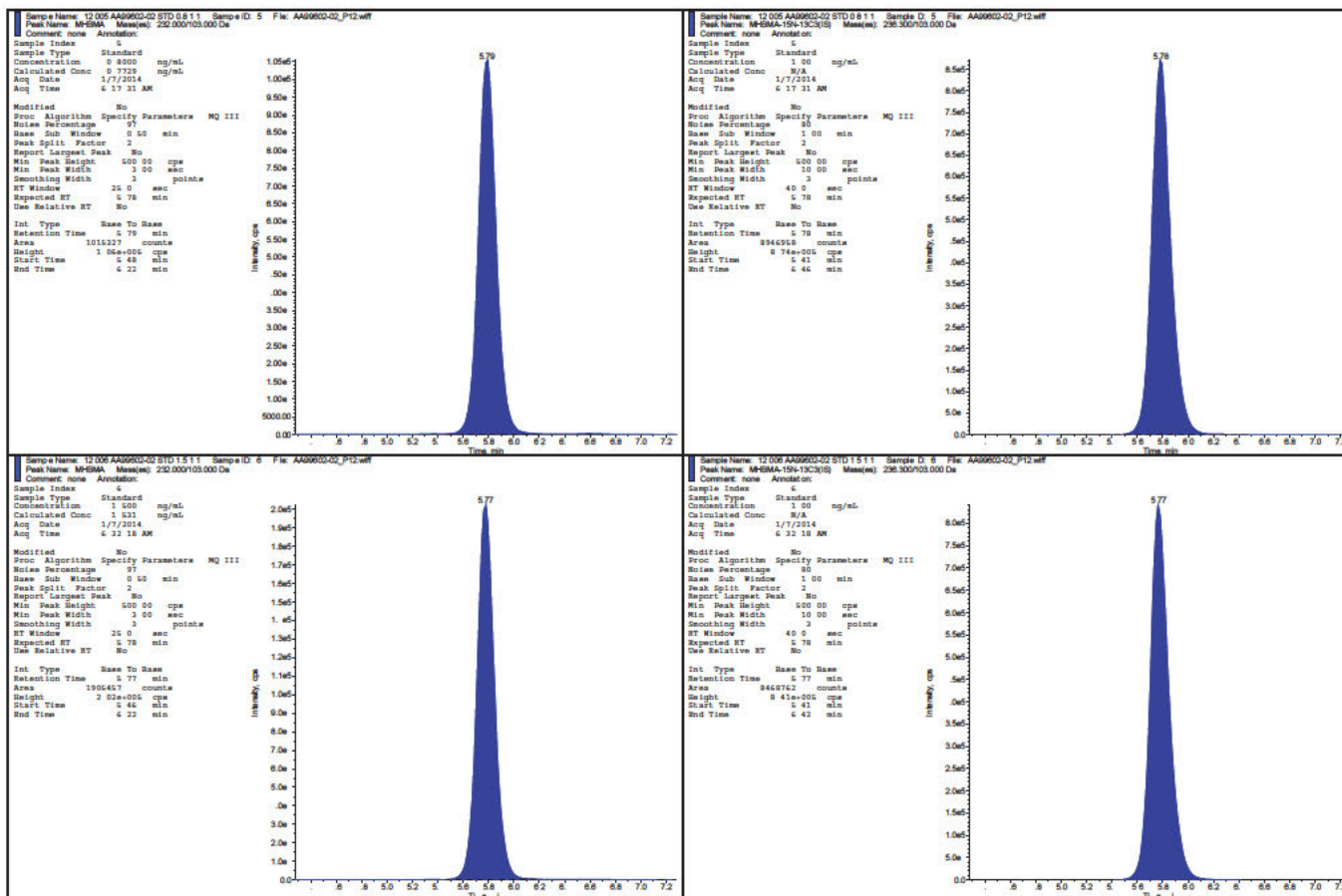




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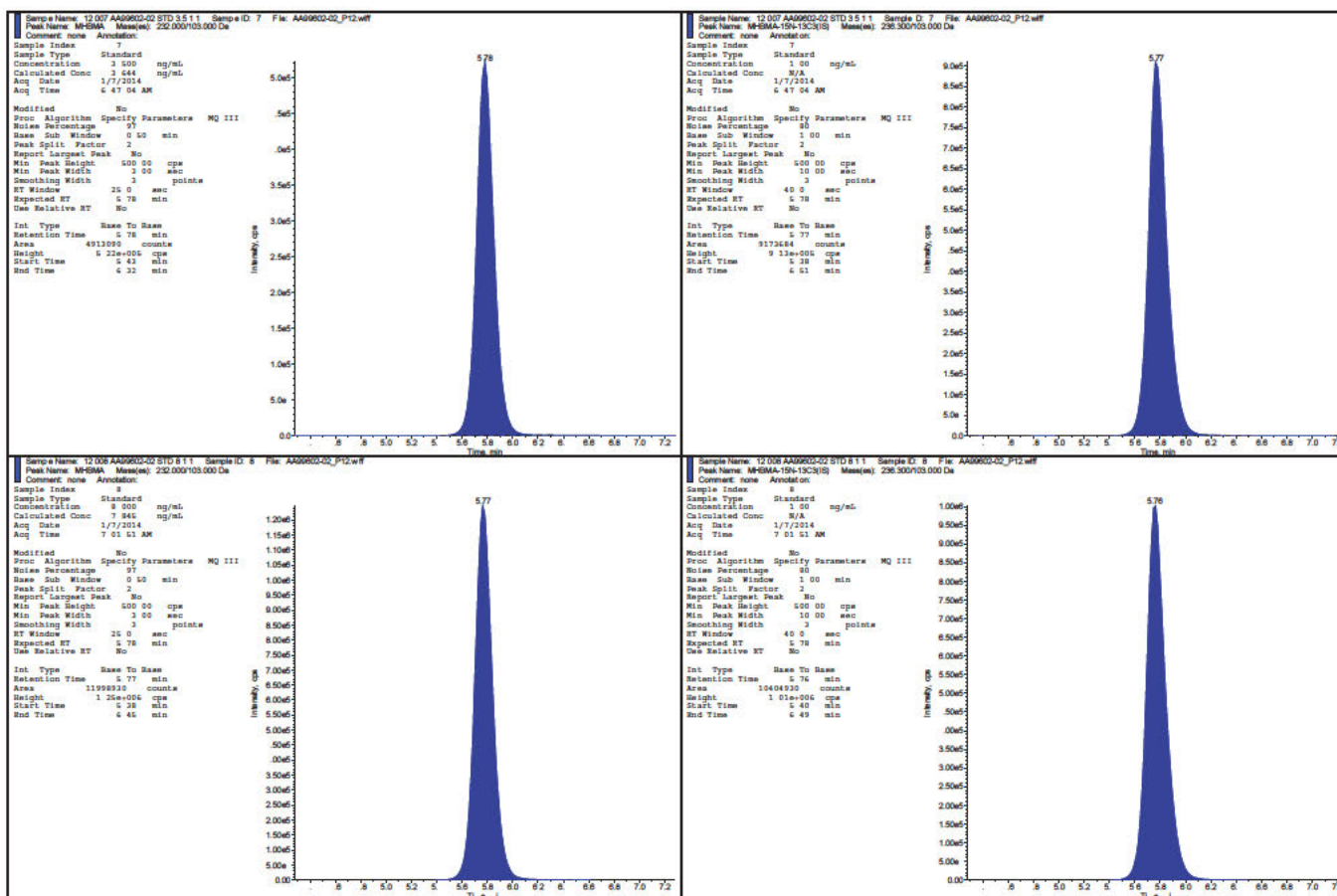
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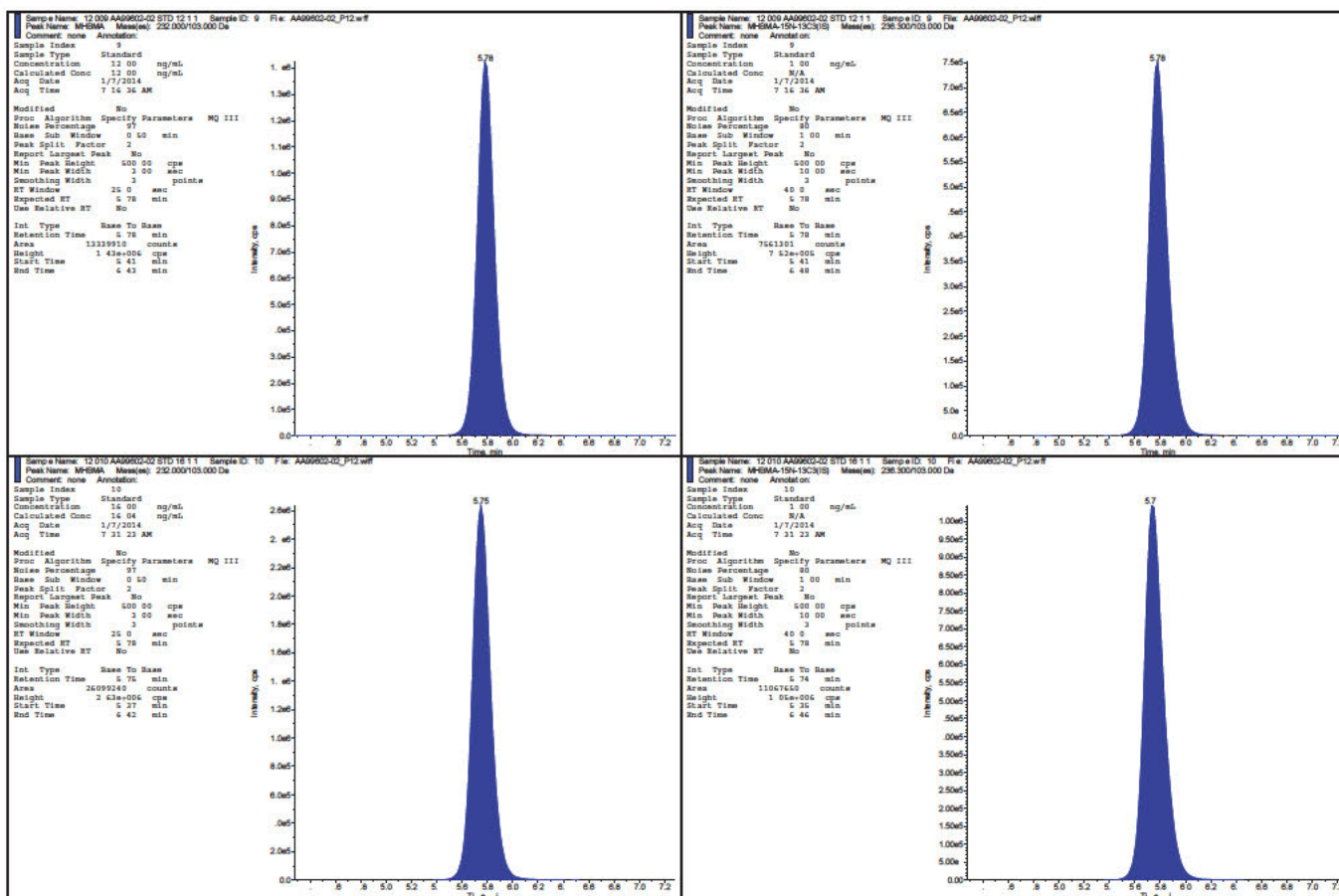
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Page 4 of 45

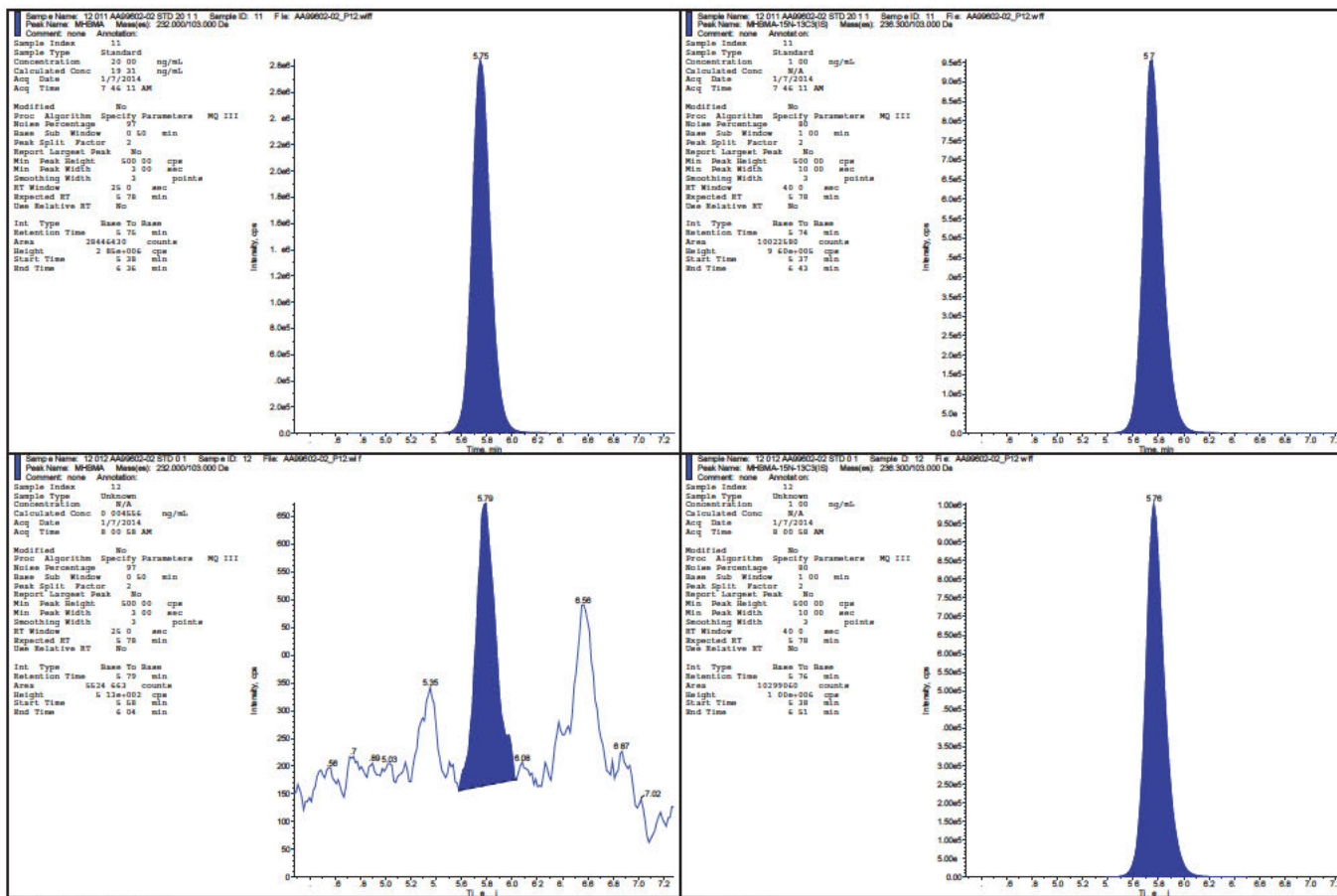


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Page 5 of 45

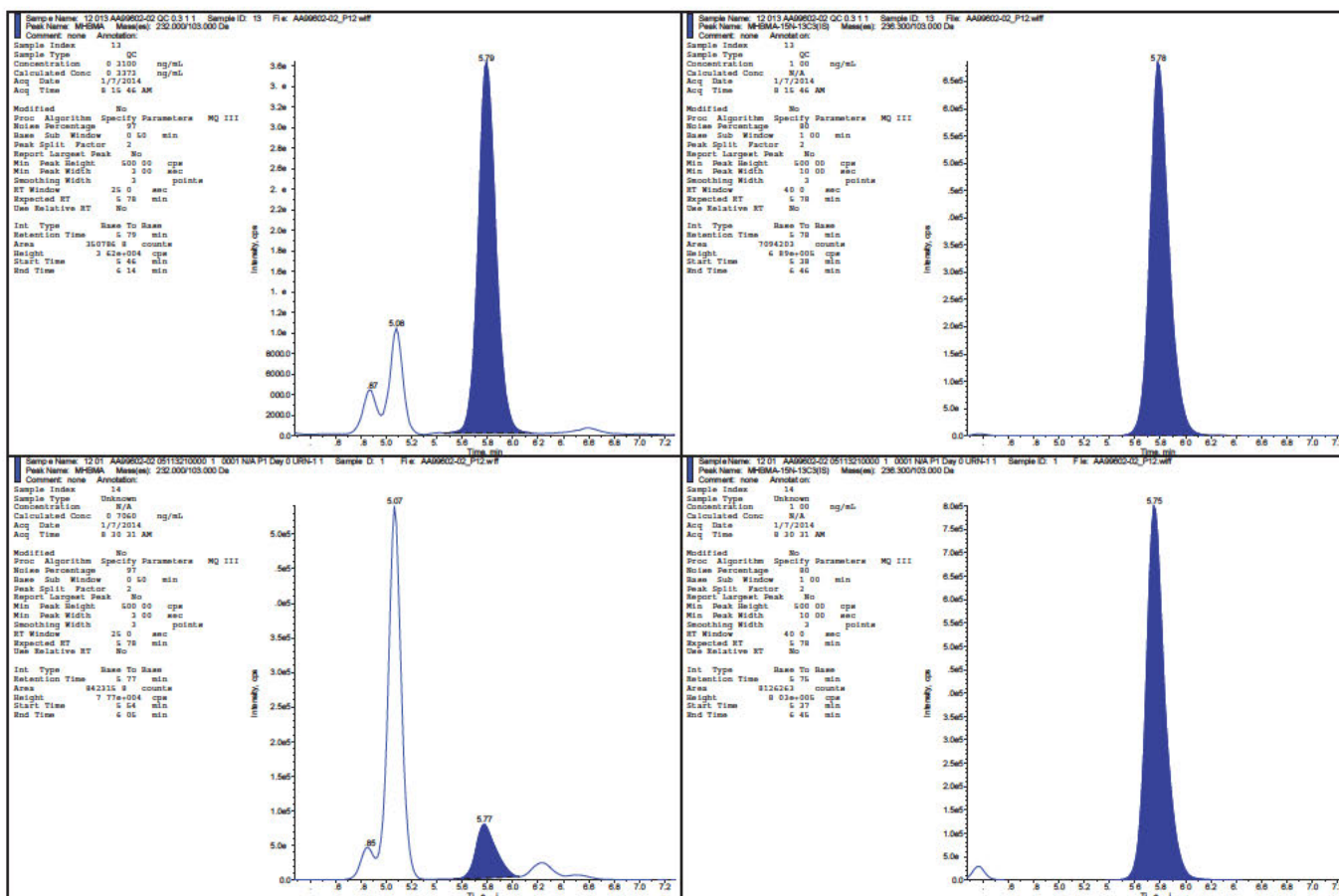




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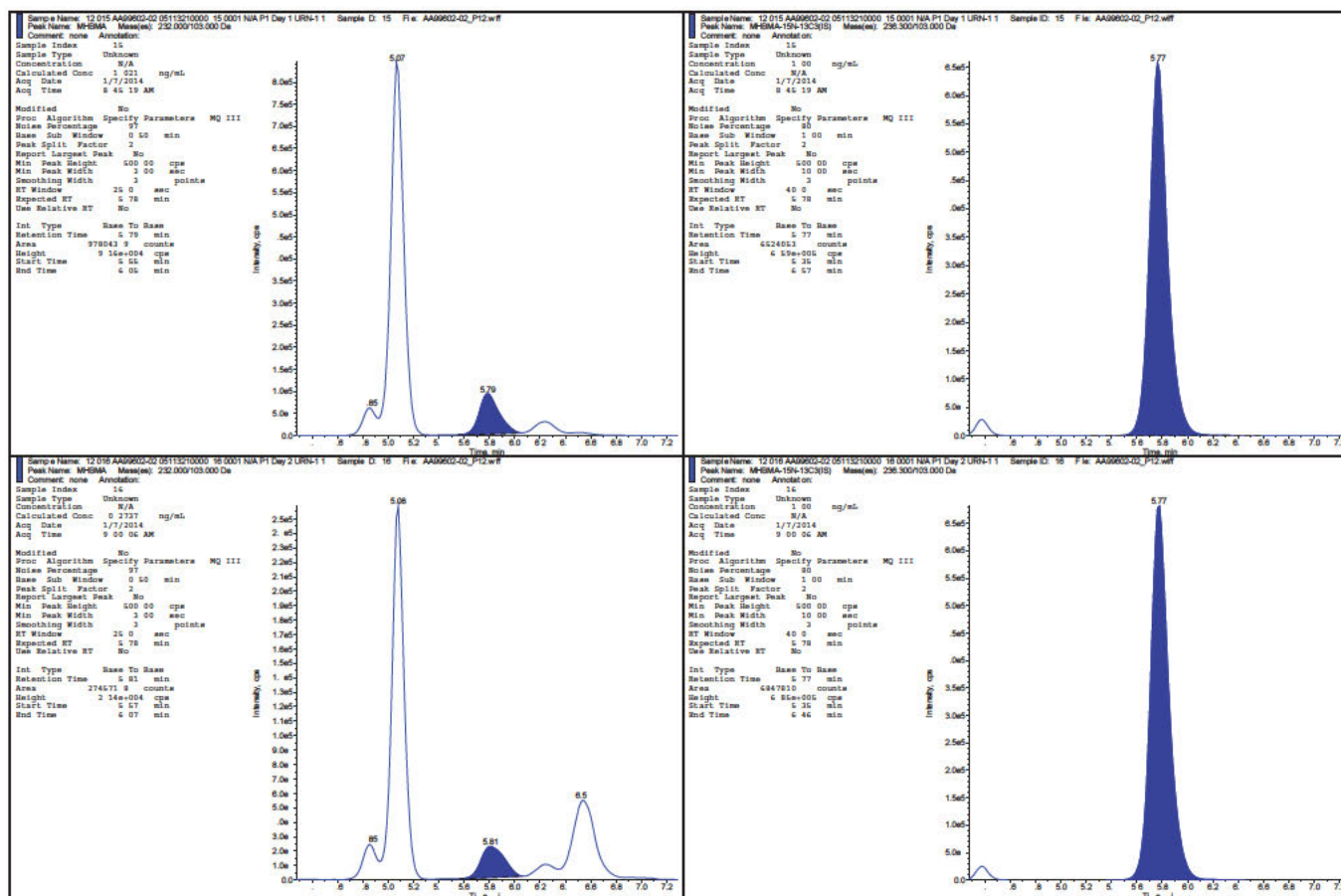
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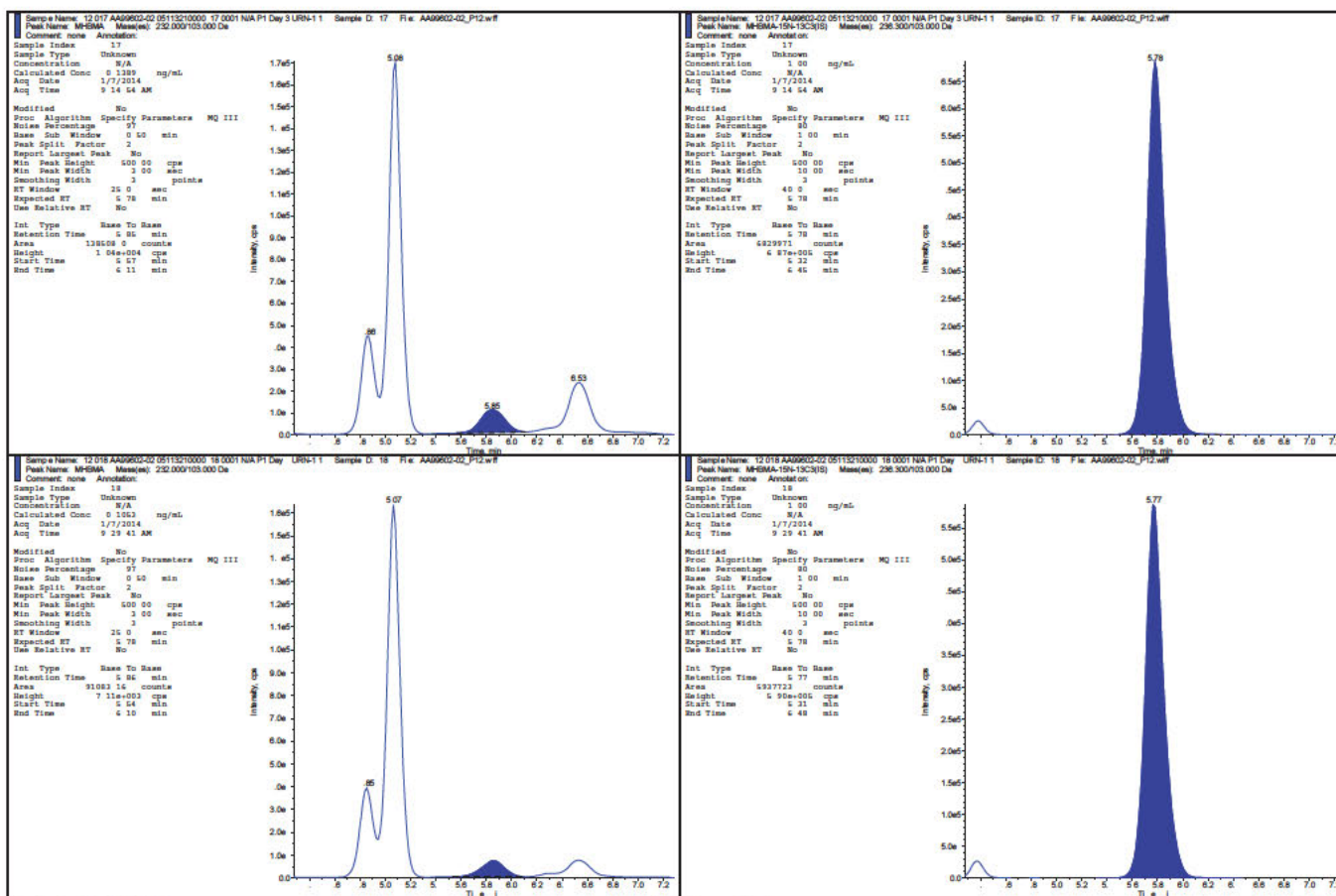
Page 7 of 45



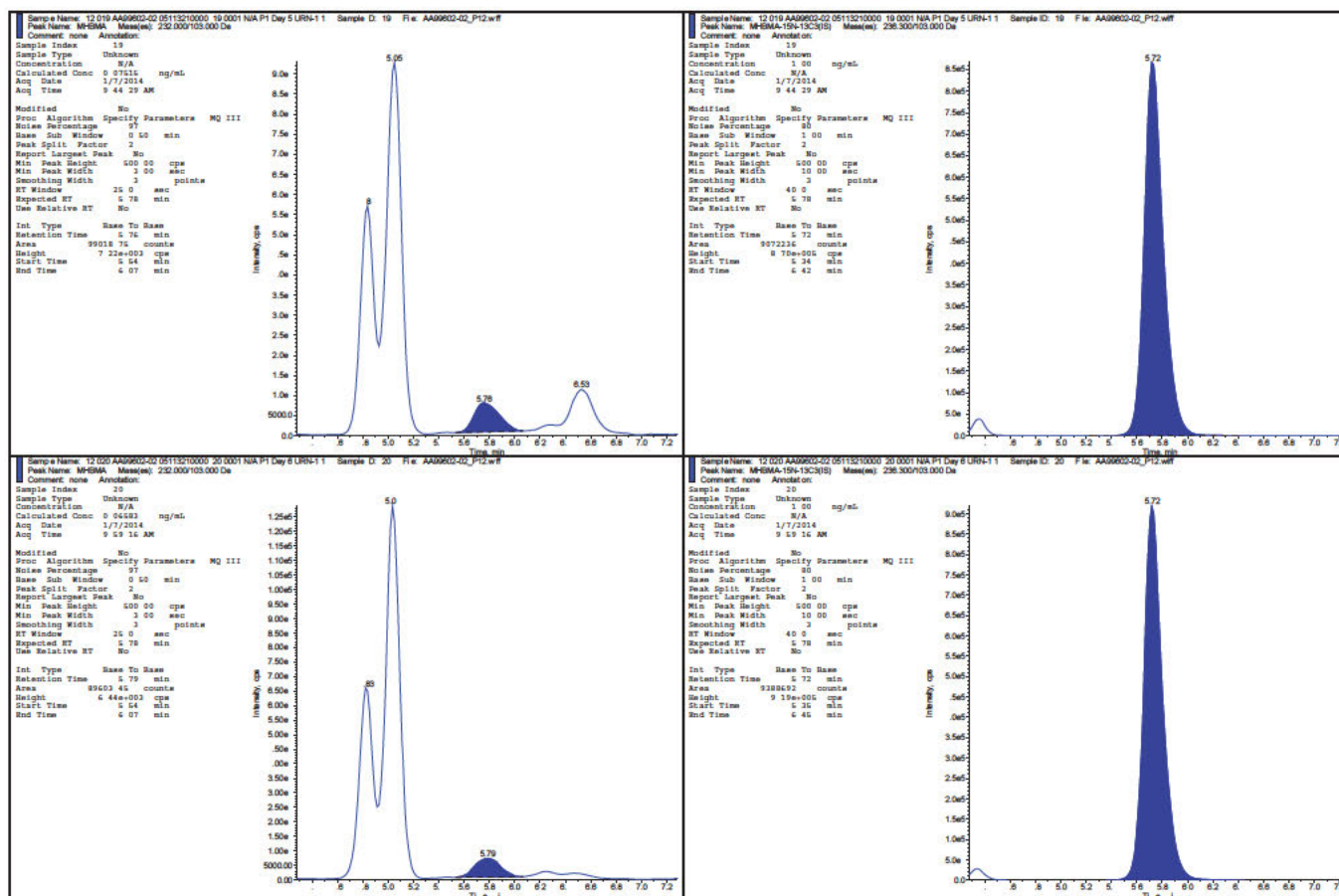
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Page 8 of 45



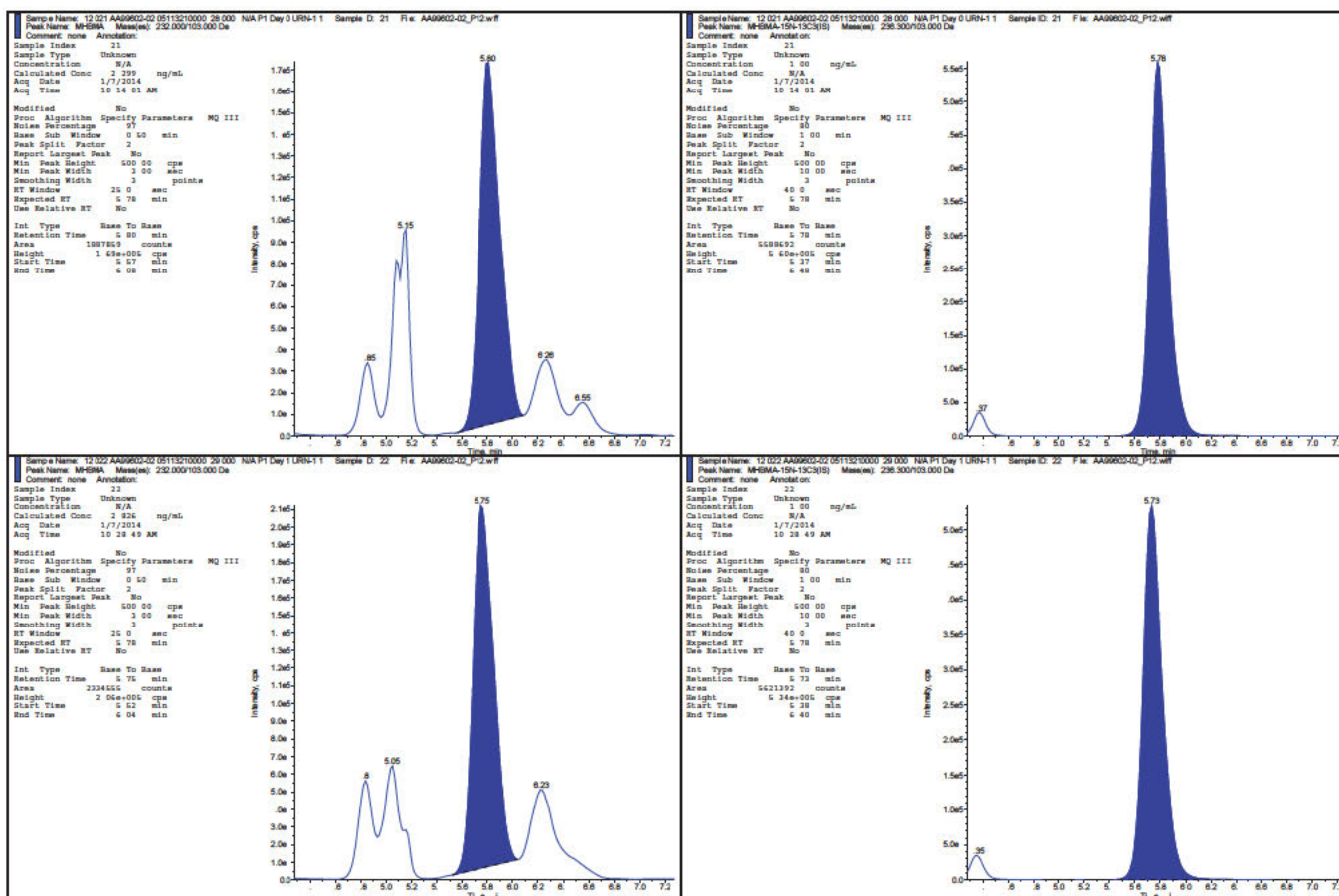




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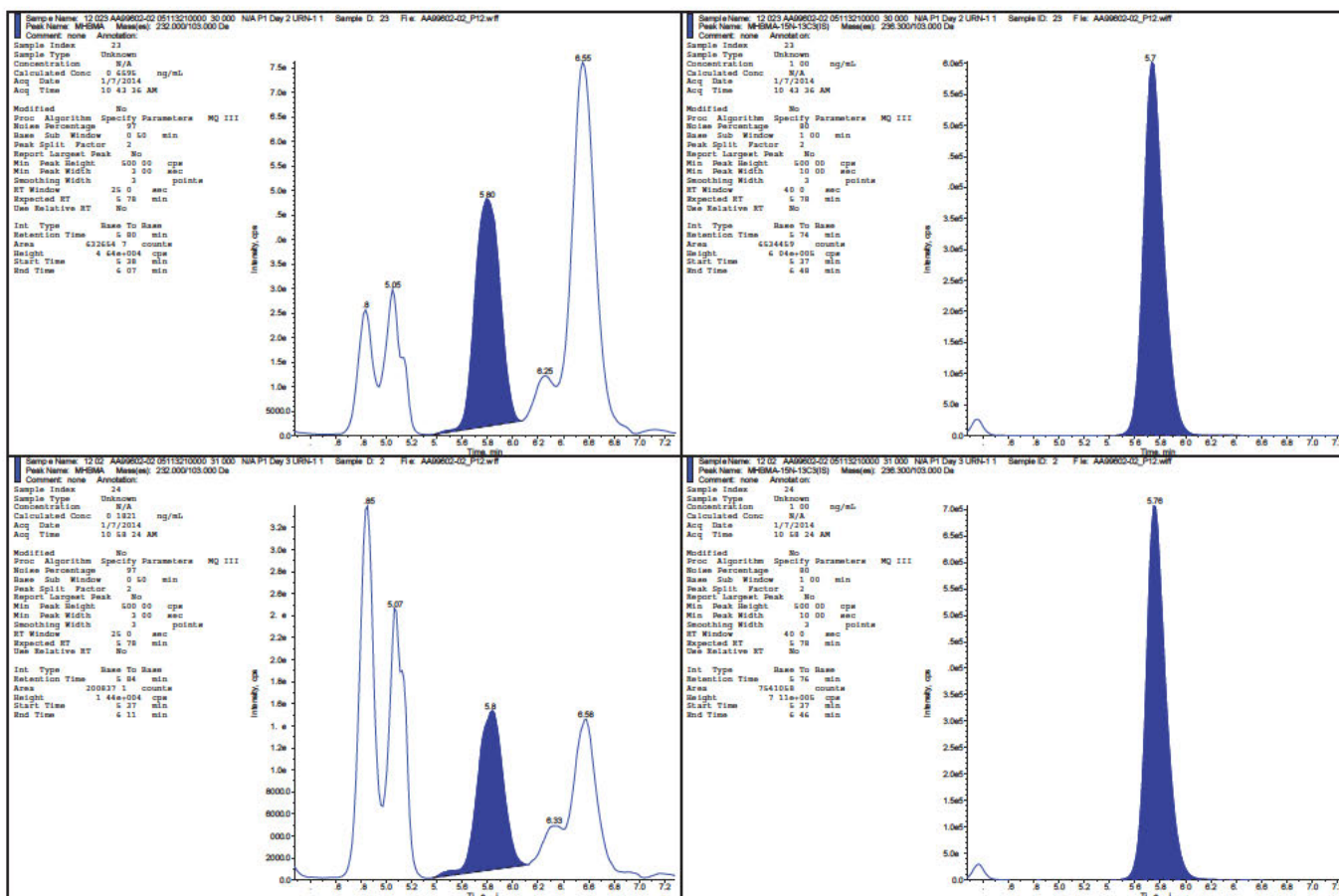
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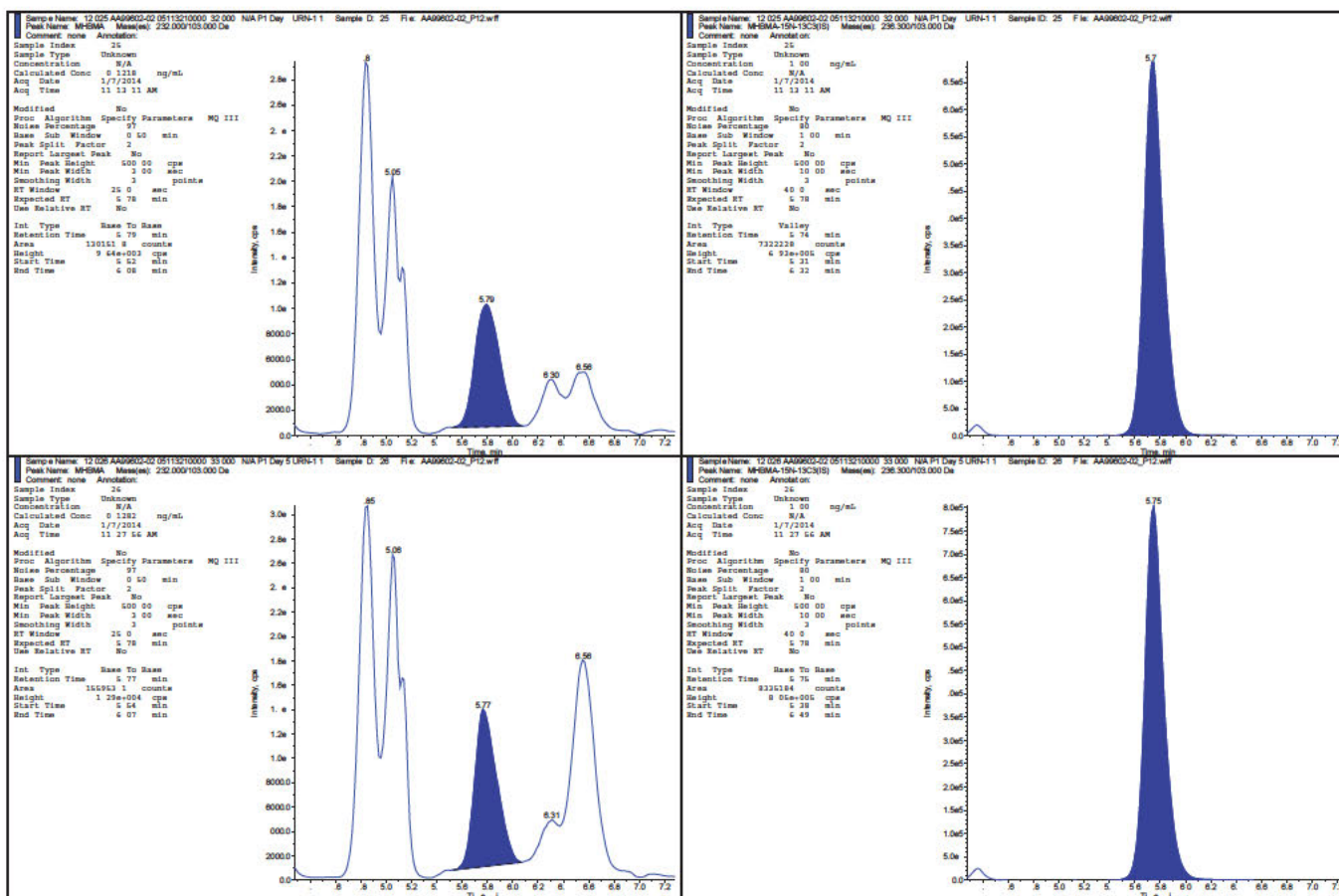
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Page 12 of 45

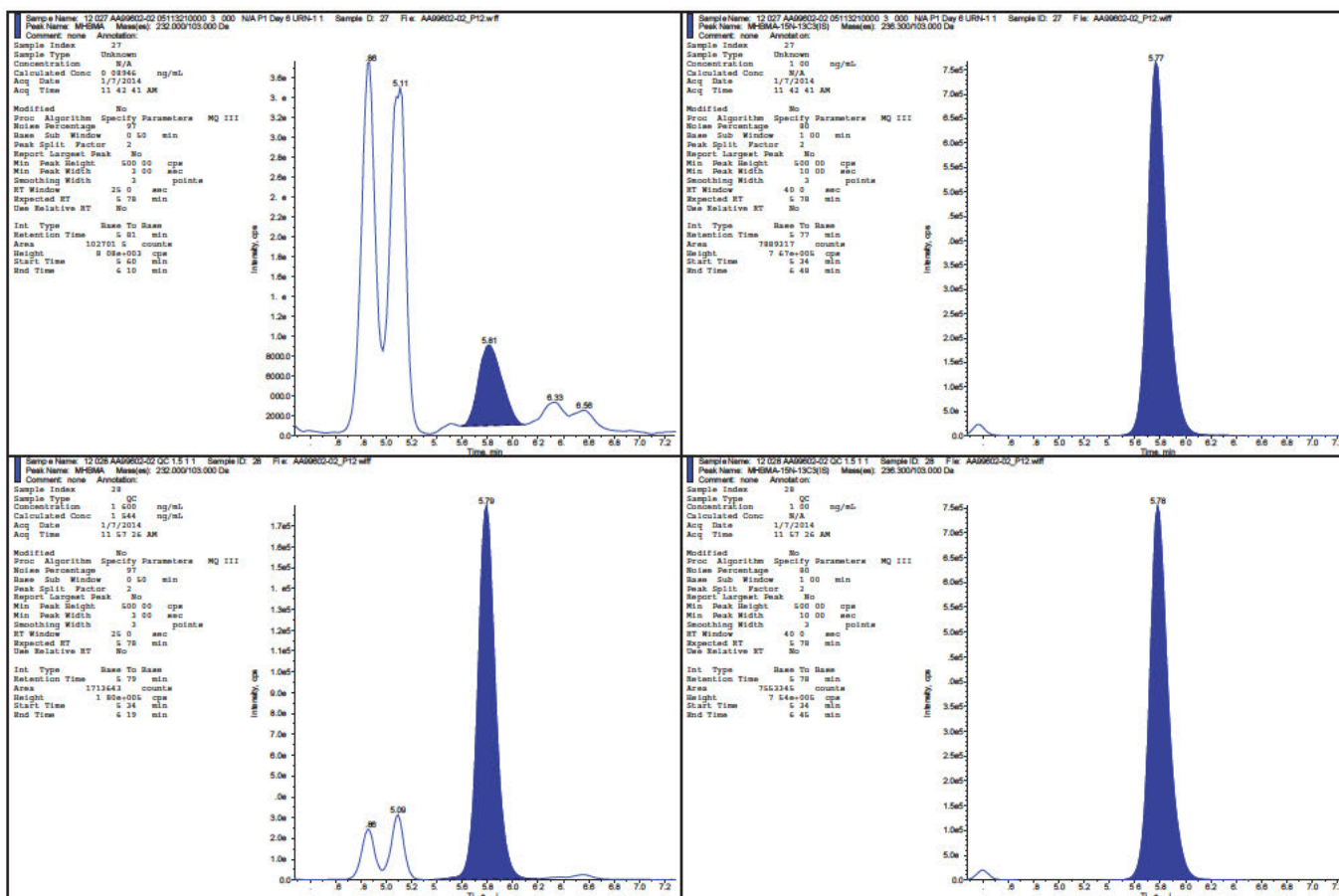


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Page 13 of 45

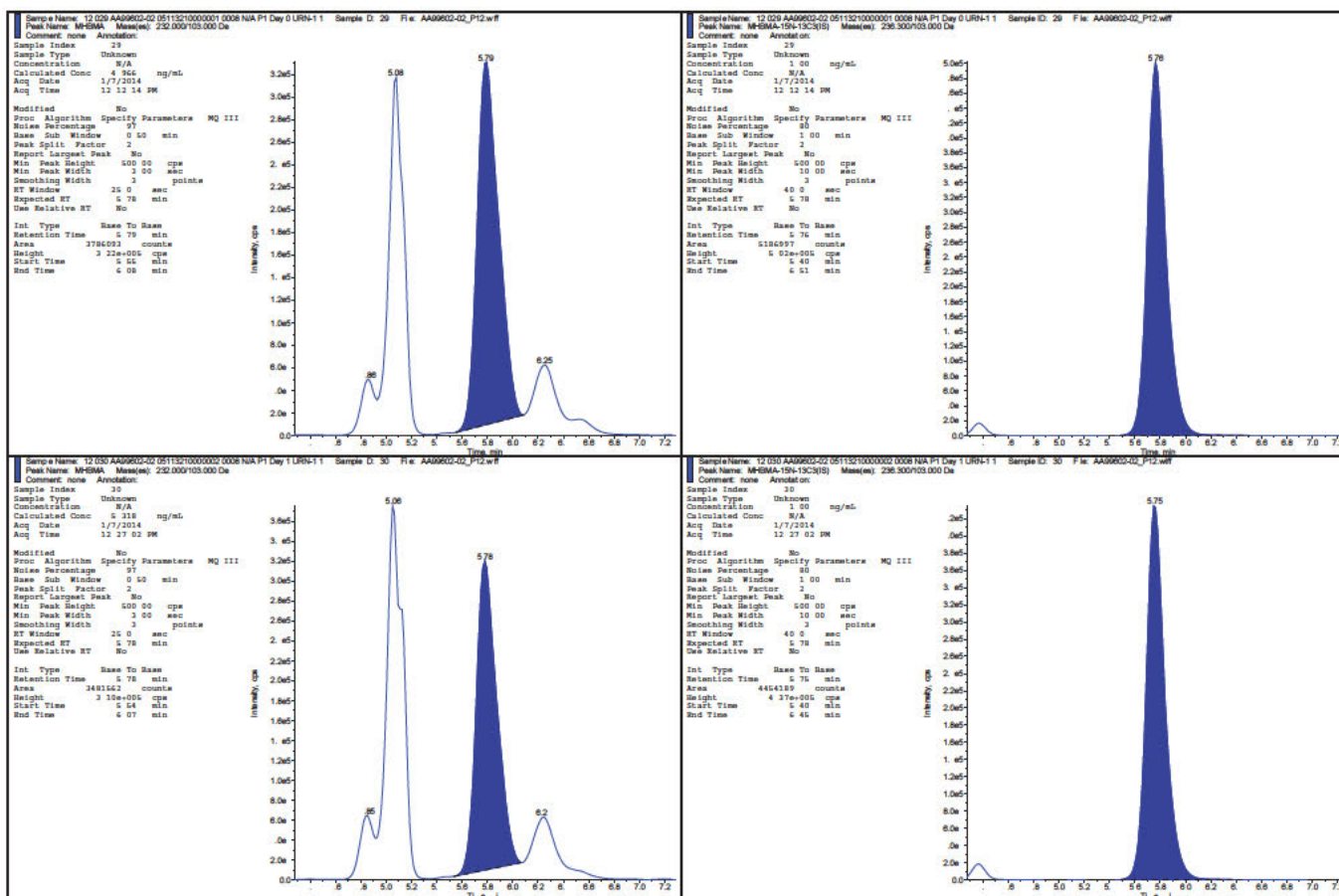




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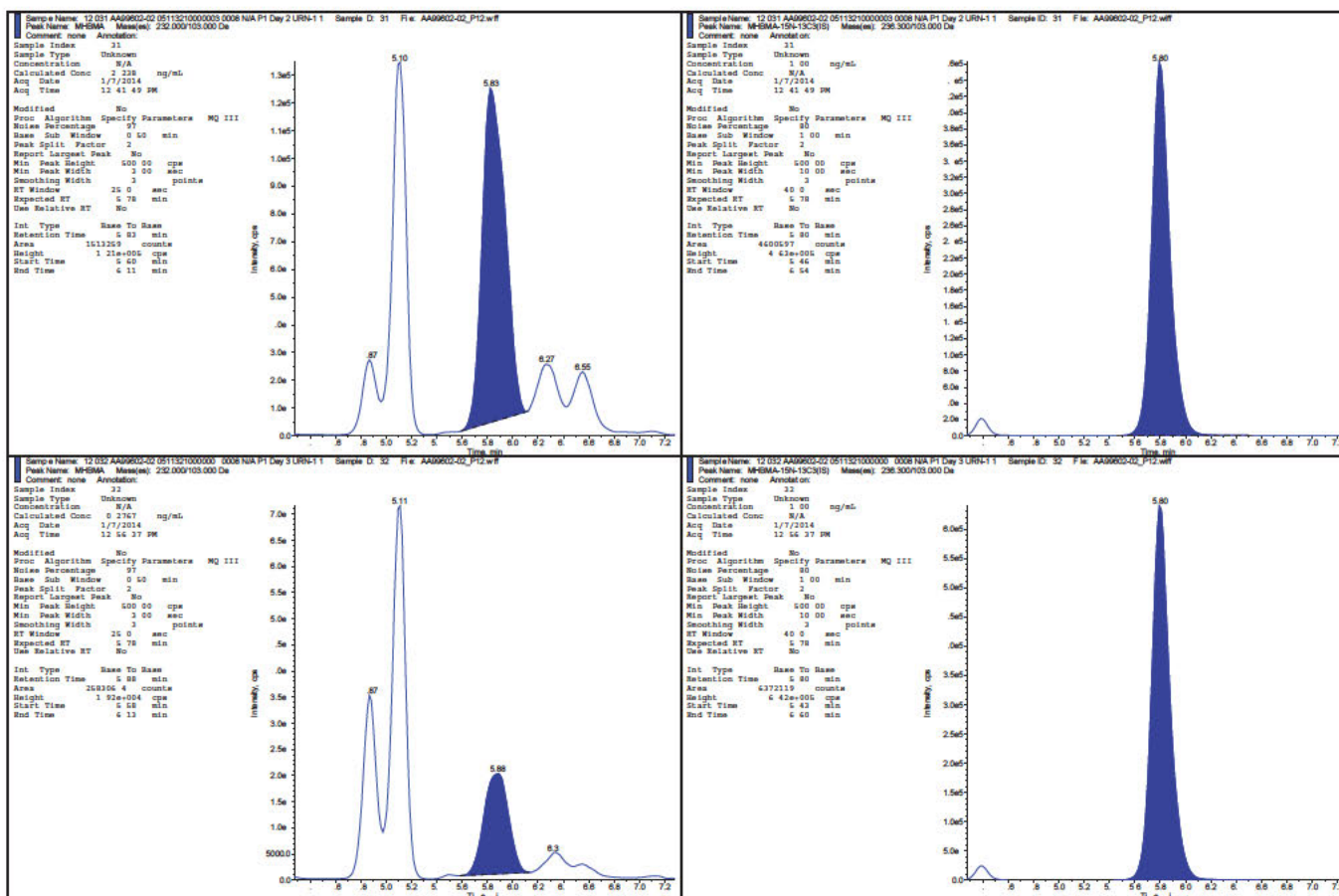
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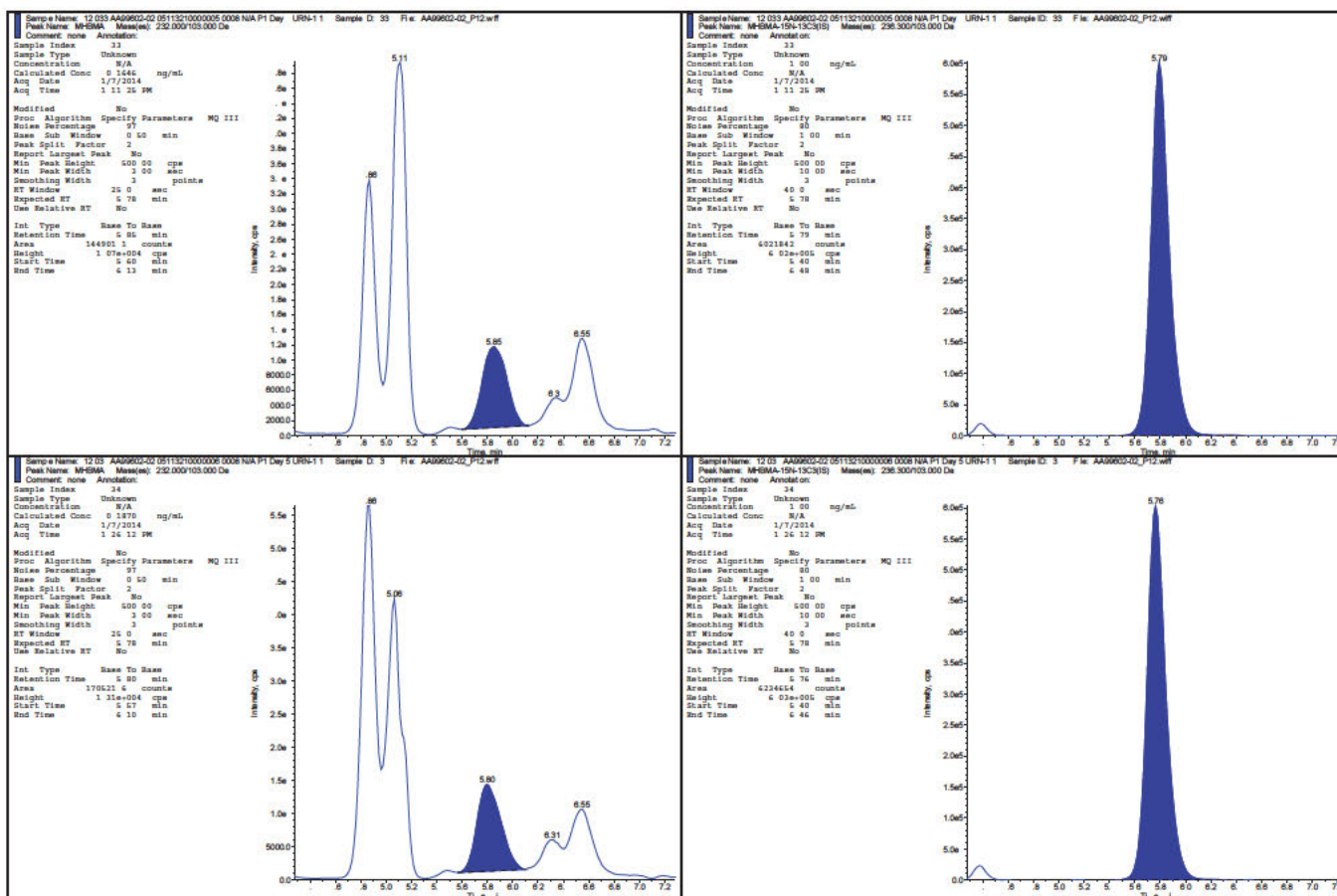
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Page 16 of 45

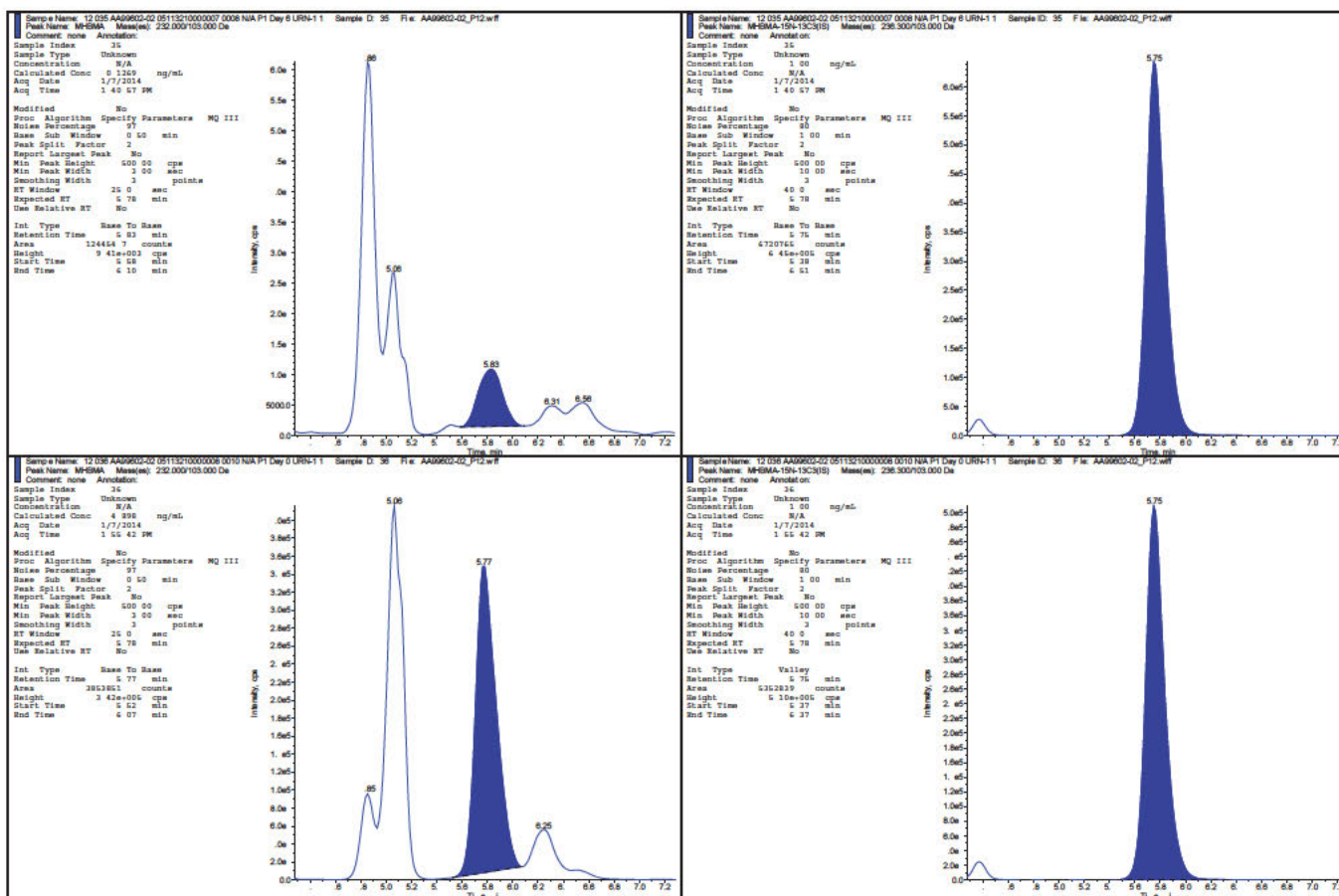


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Page 17 of 45

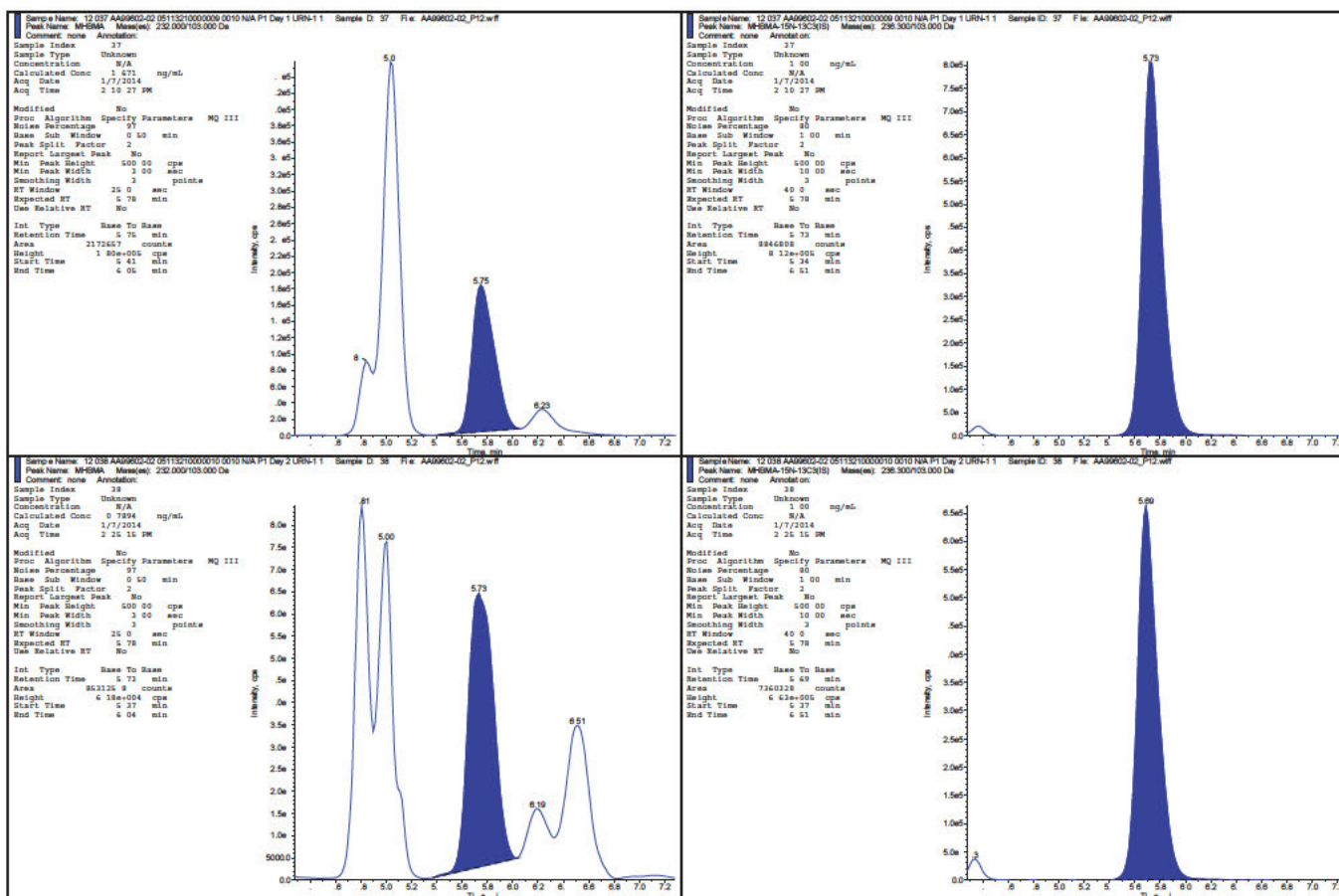




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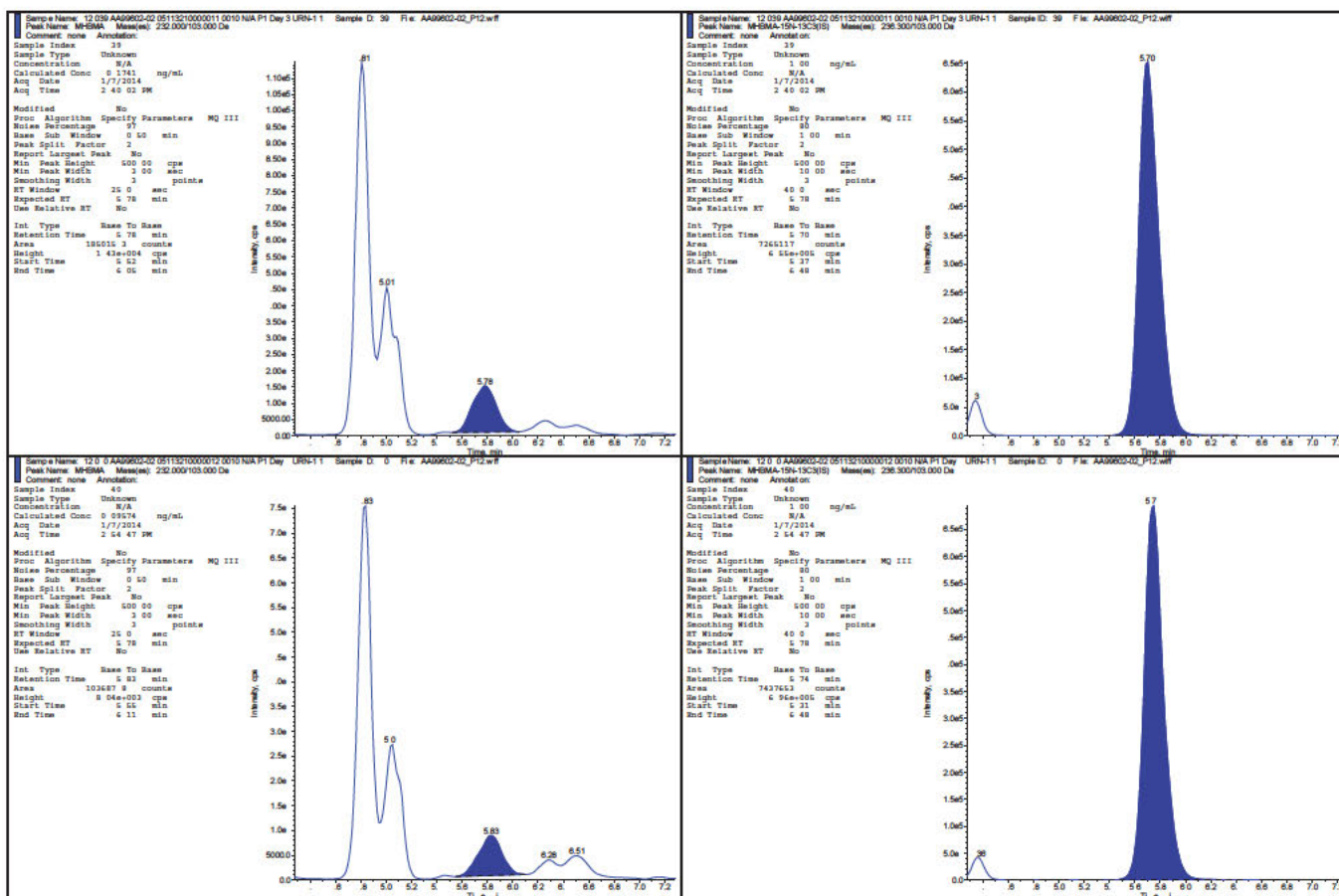
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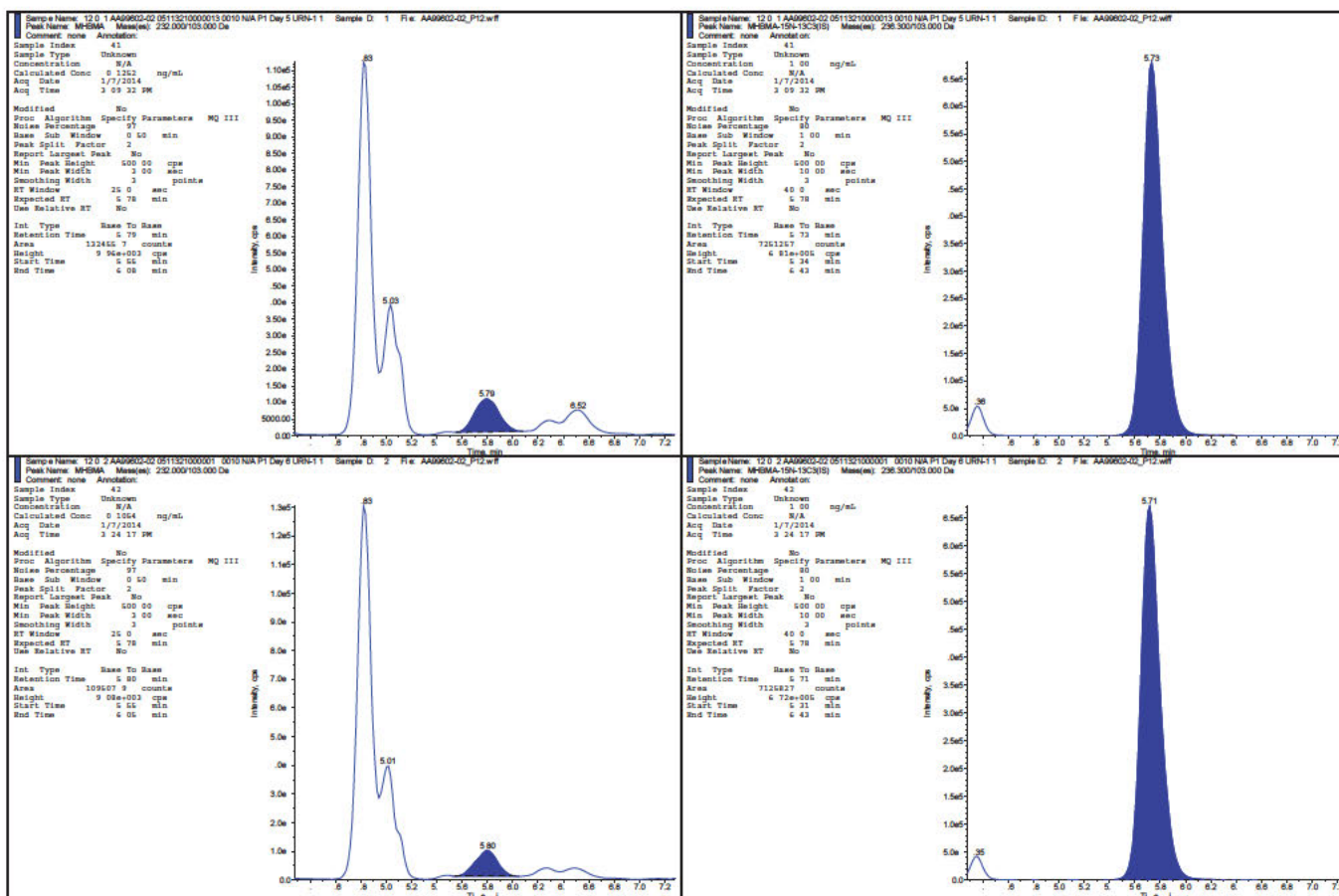
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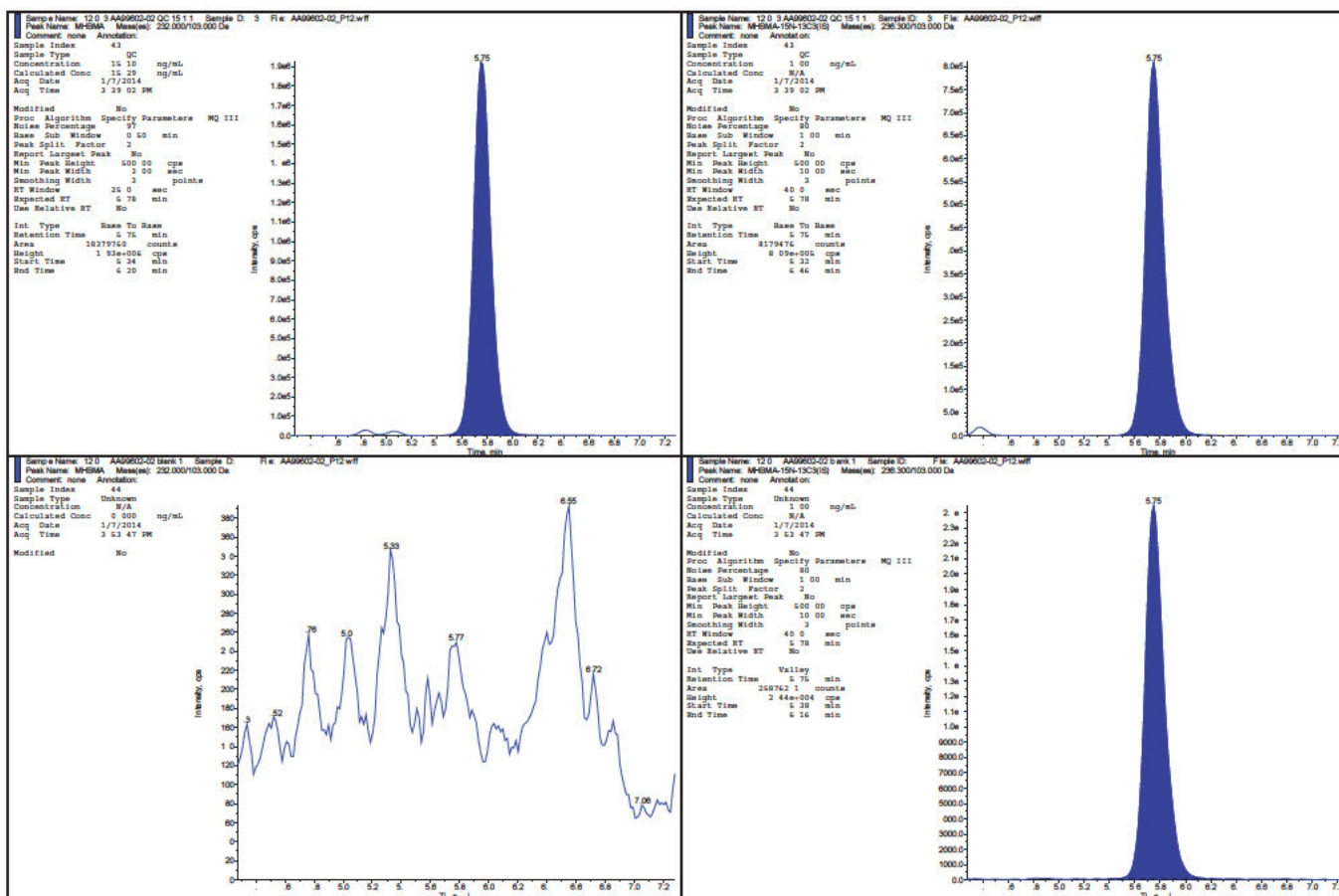
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Page 20 of 45



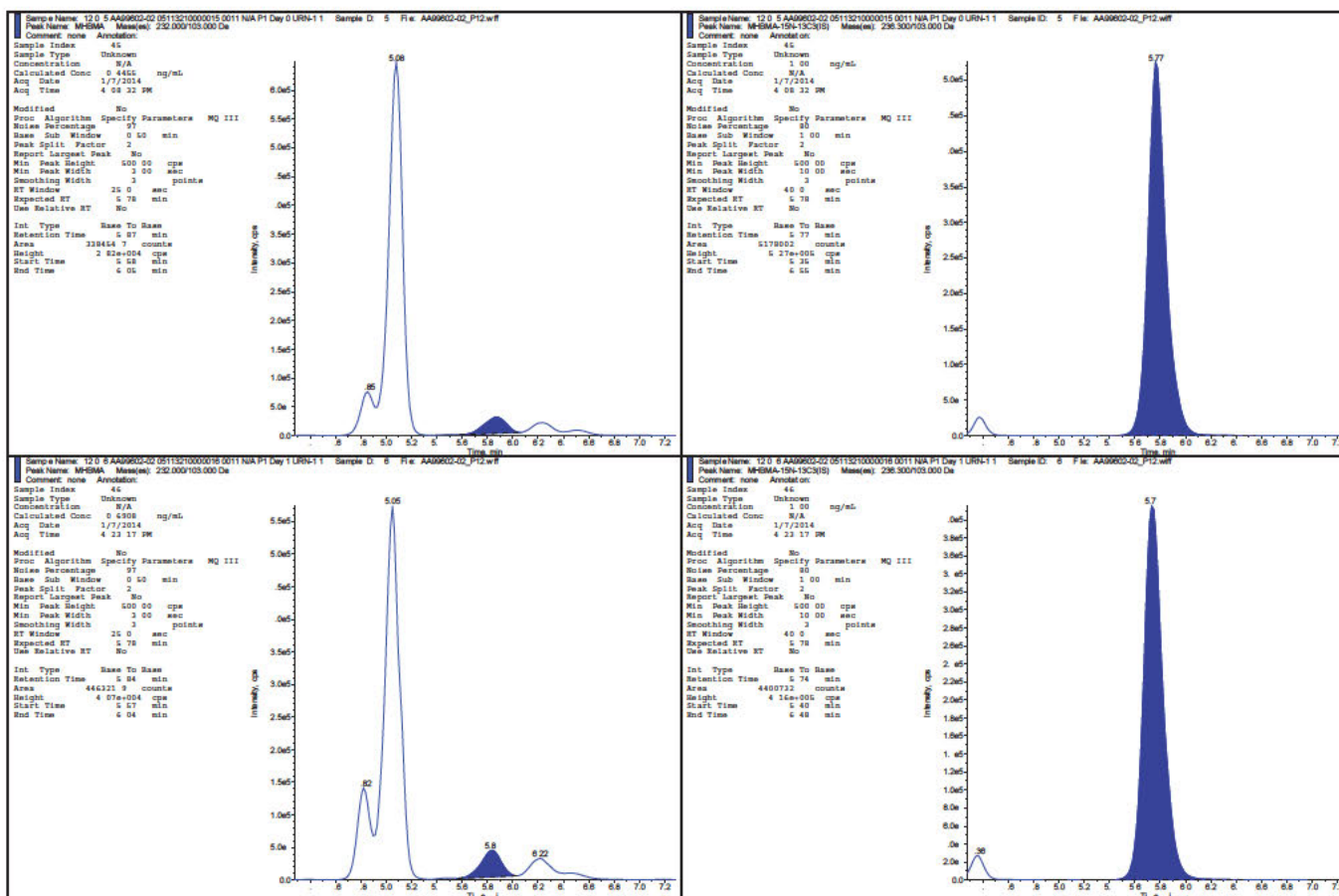




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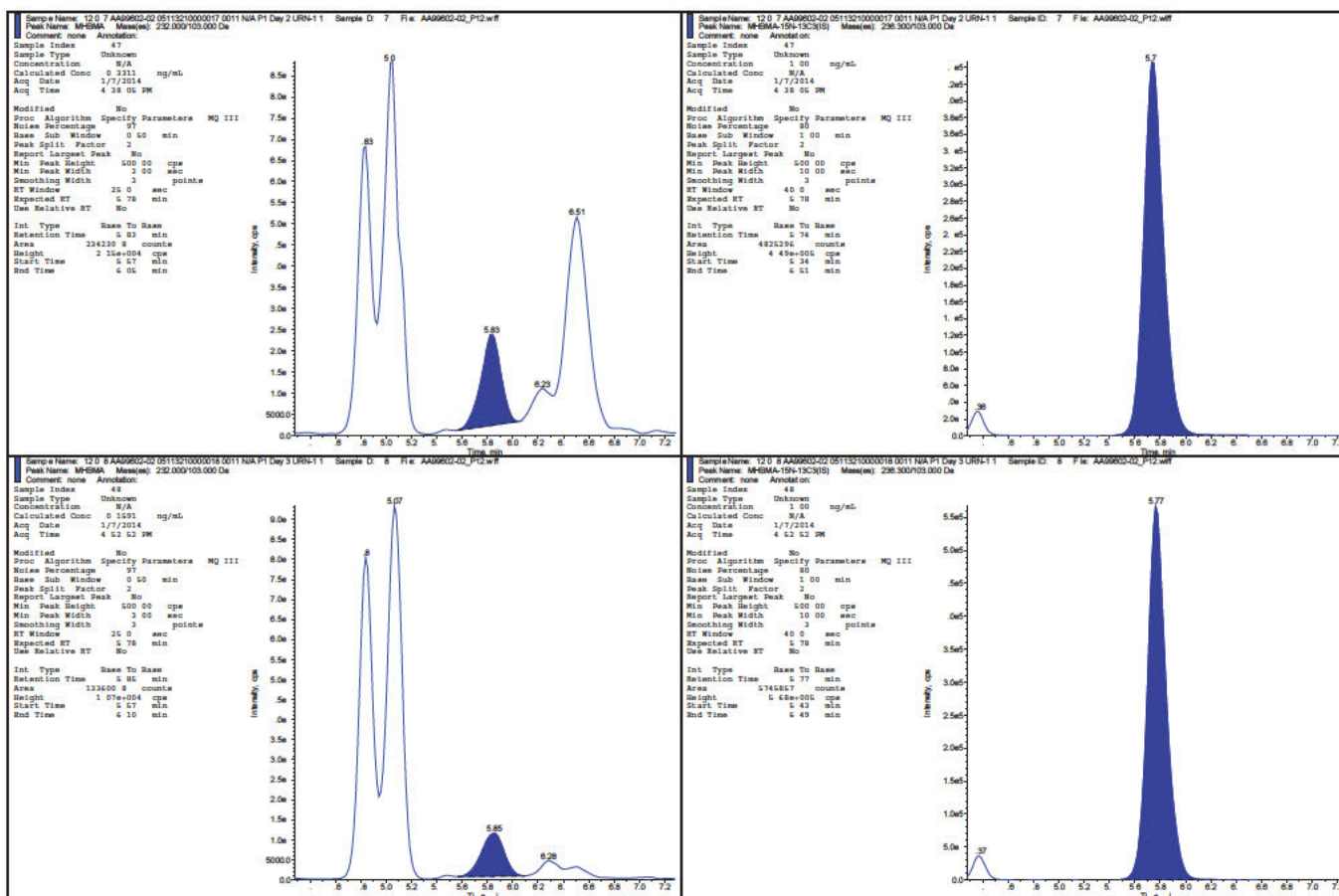
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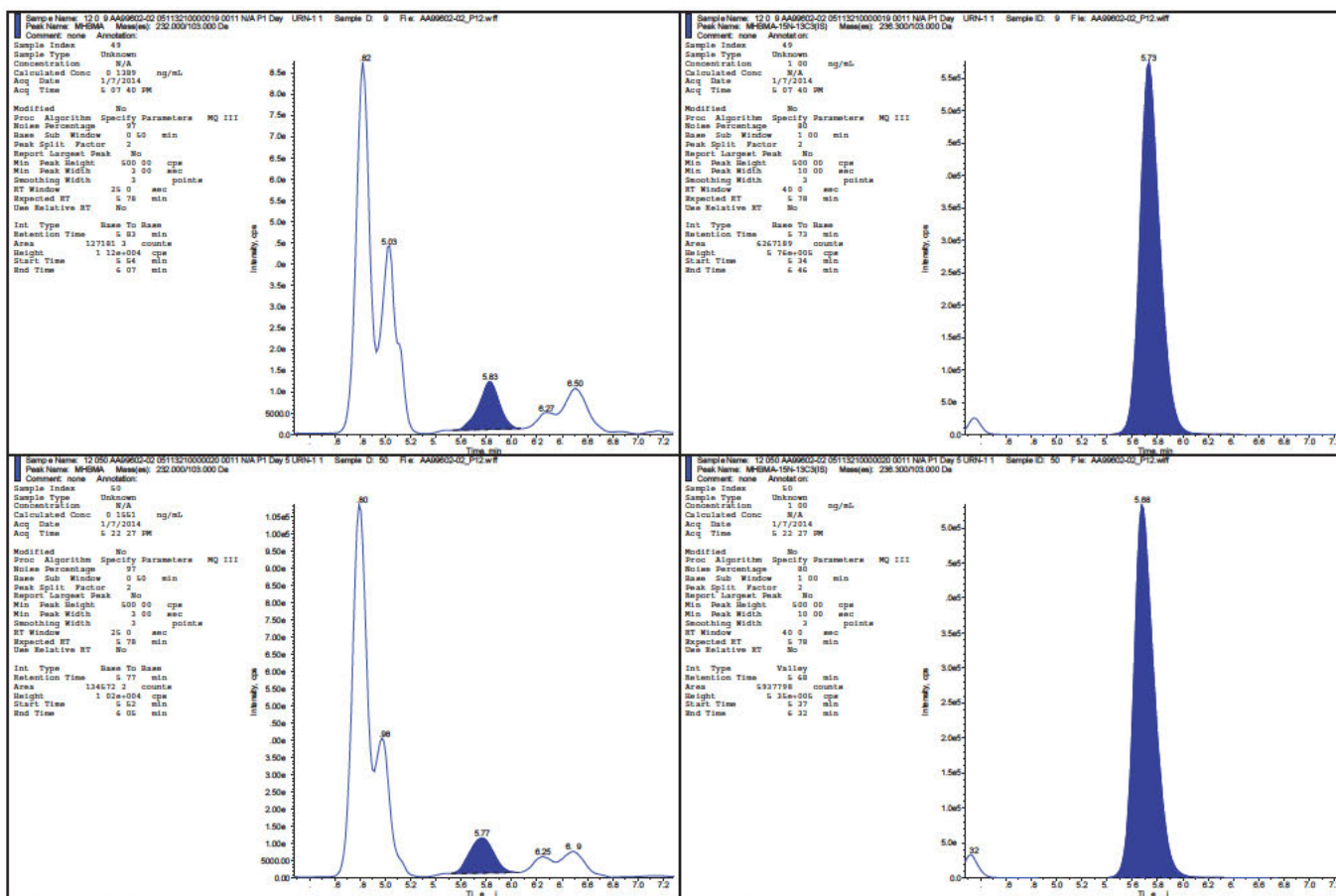


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Page 23 of 45



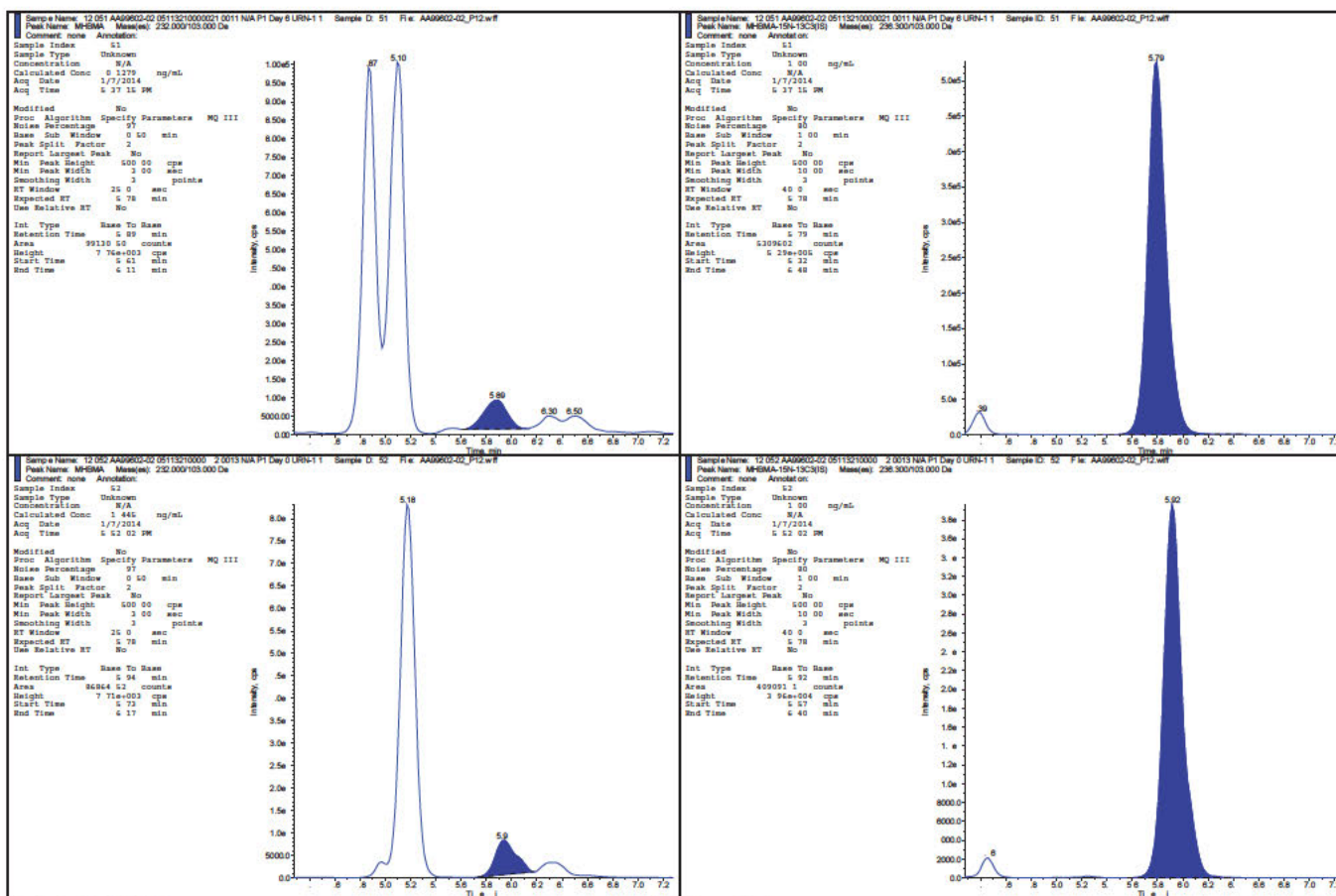


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Page 25 of 45

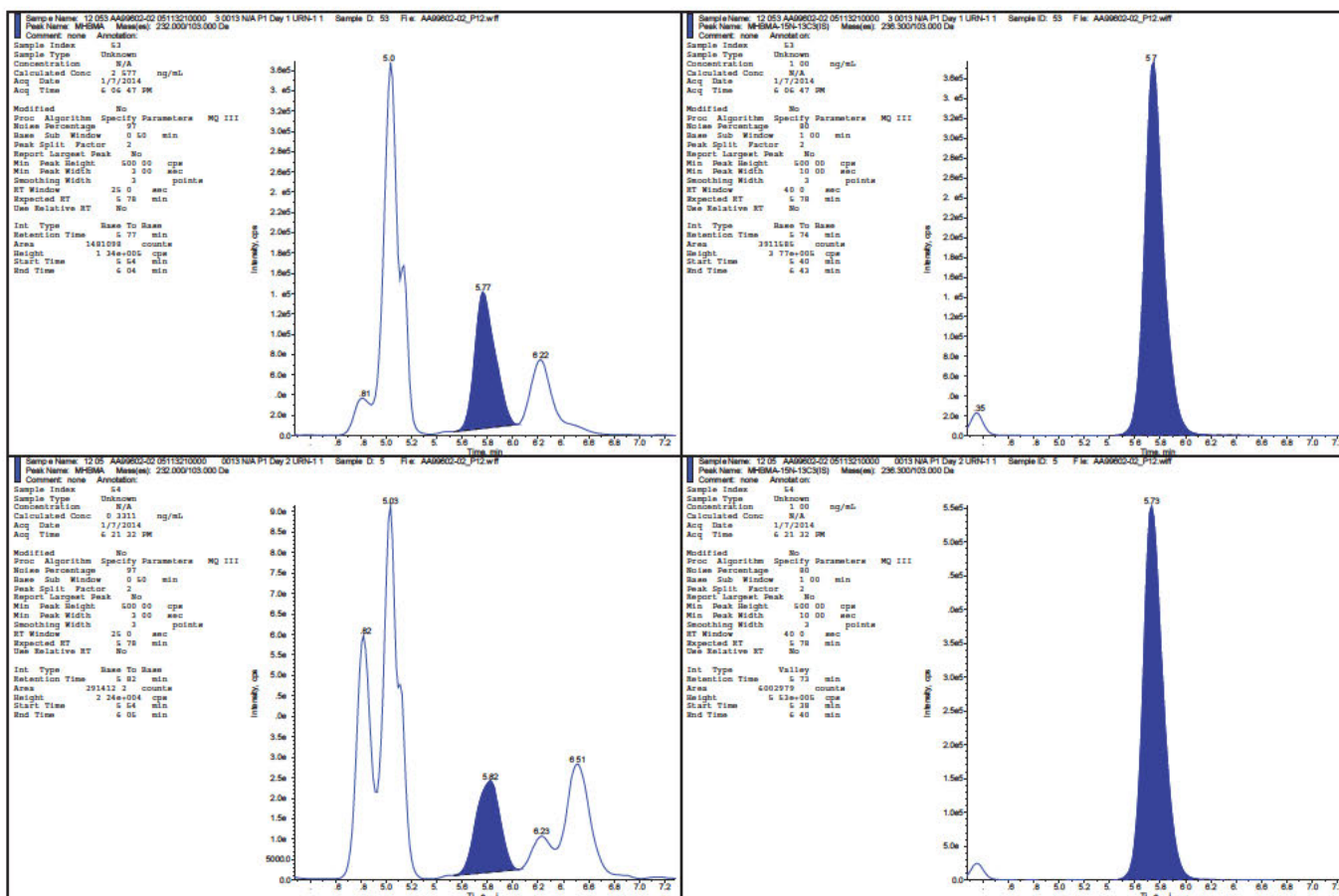




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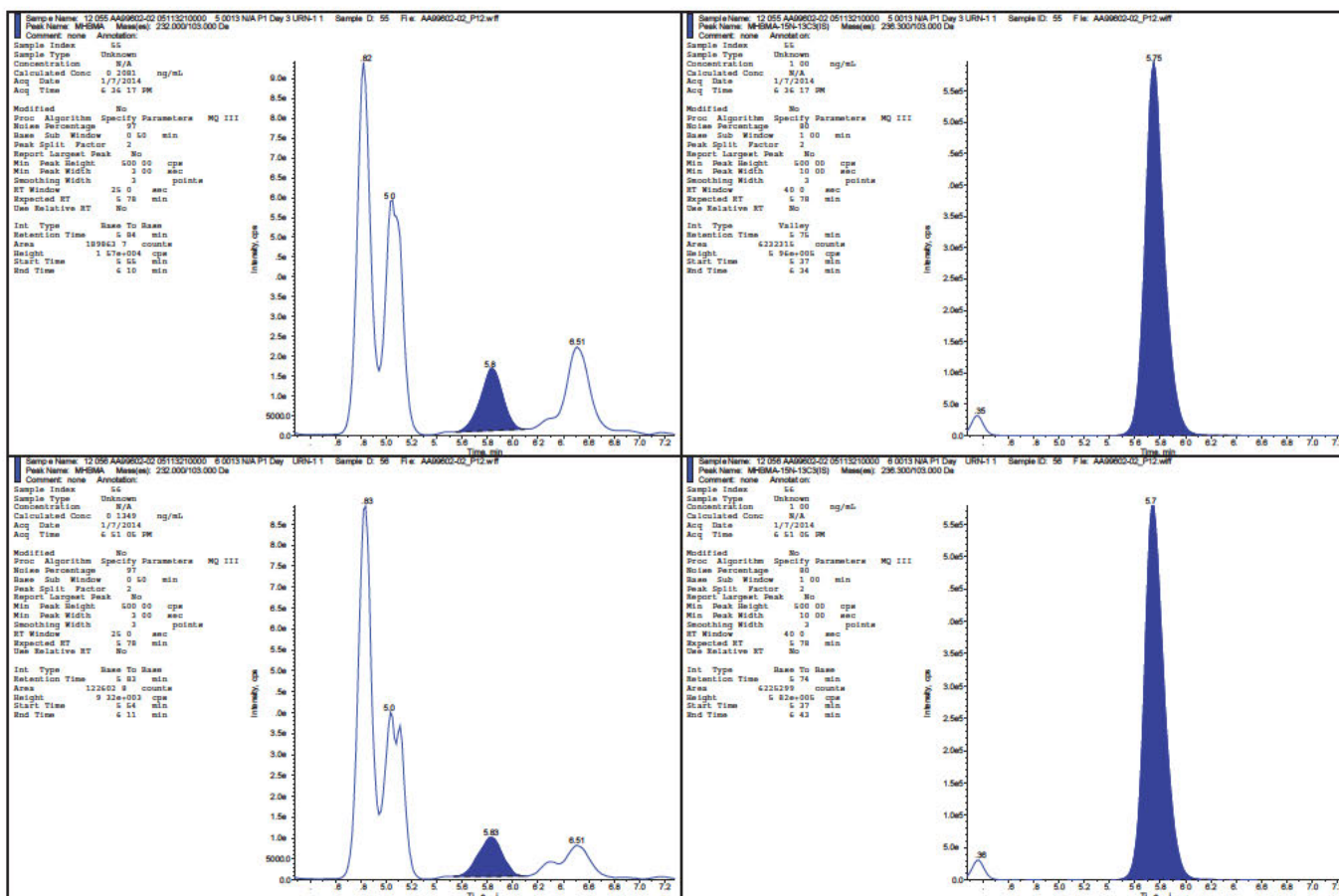
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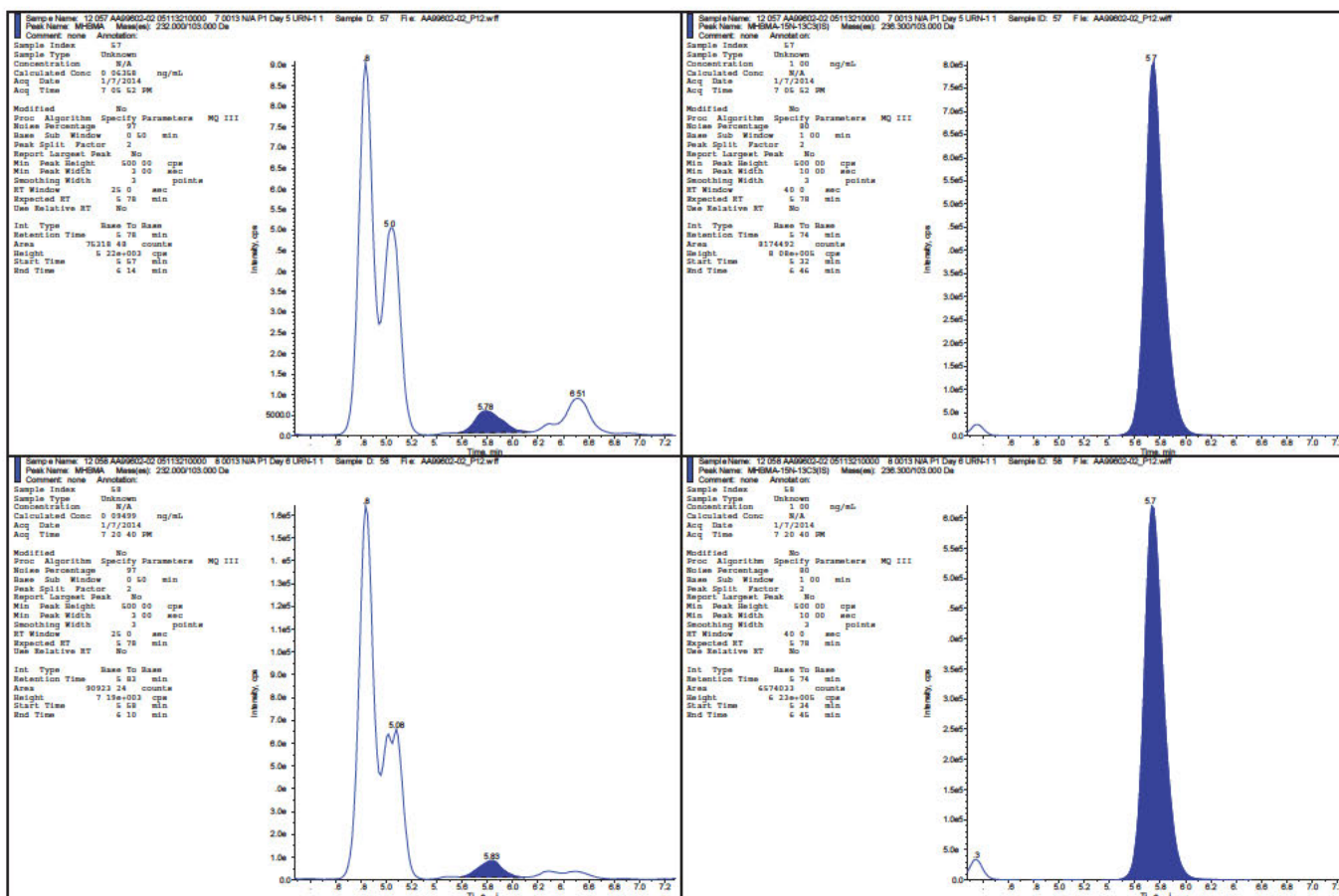
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Page 28 of 45

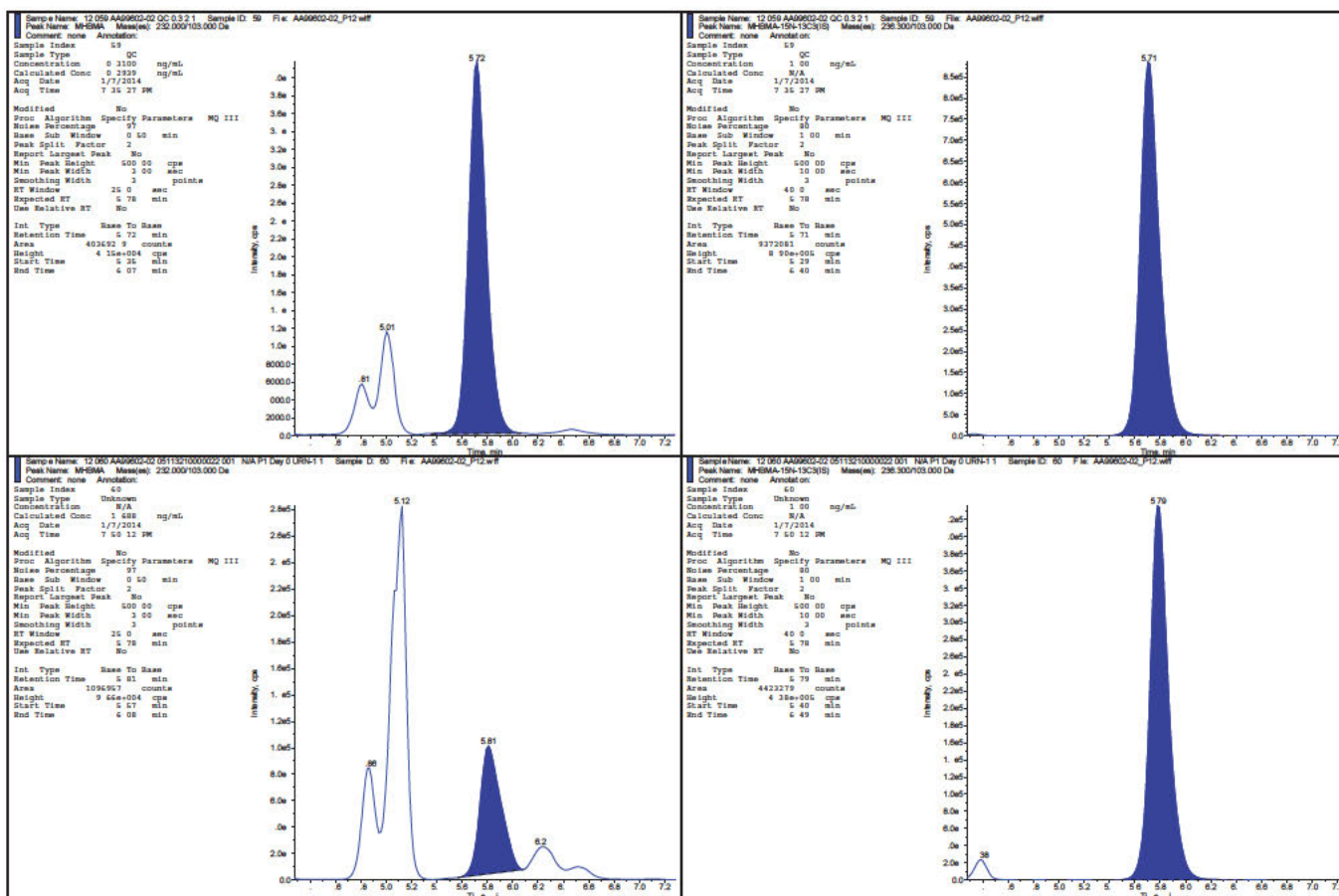


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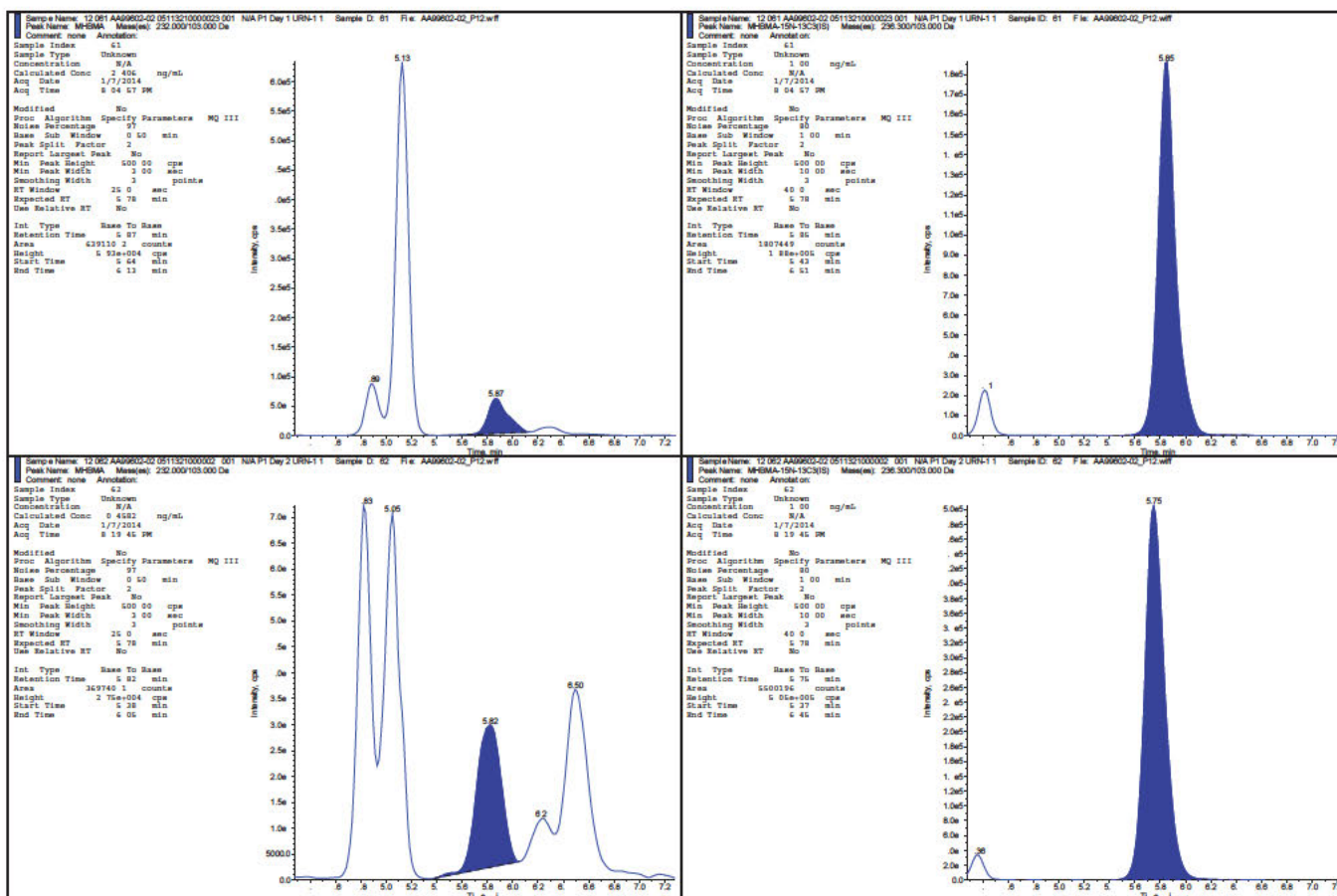




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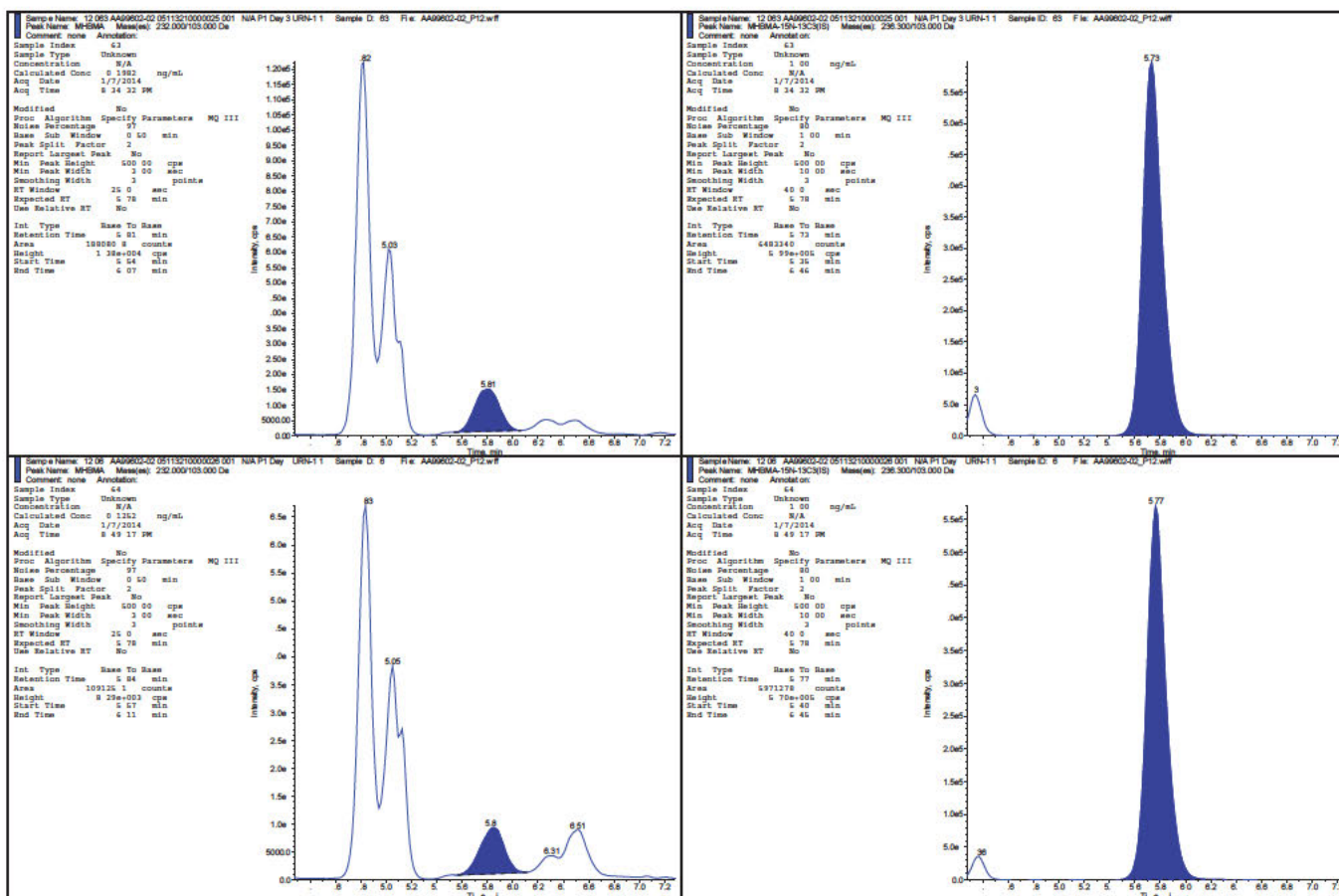
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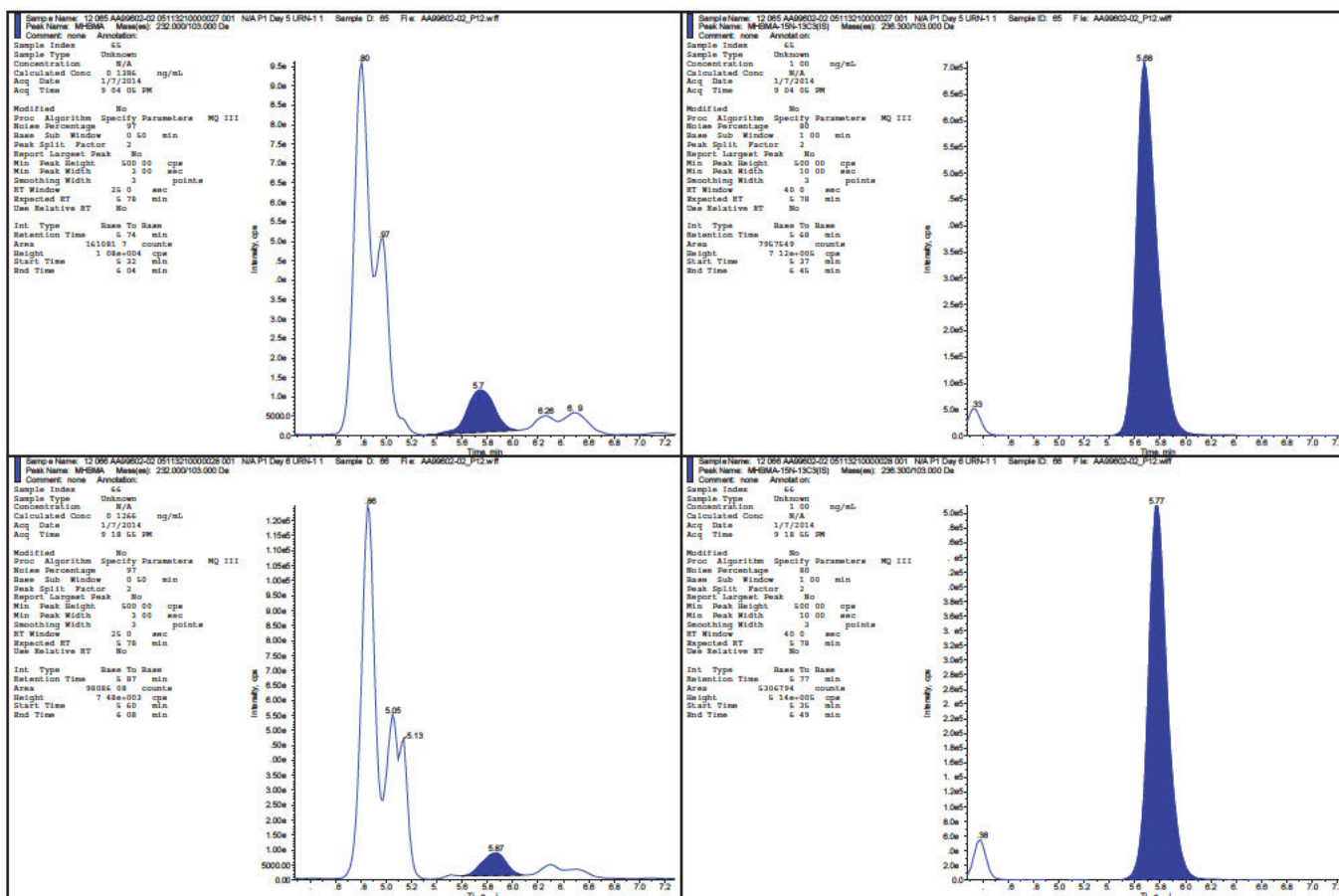
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Page 32 of 45

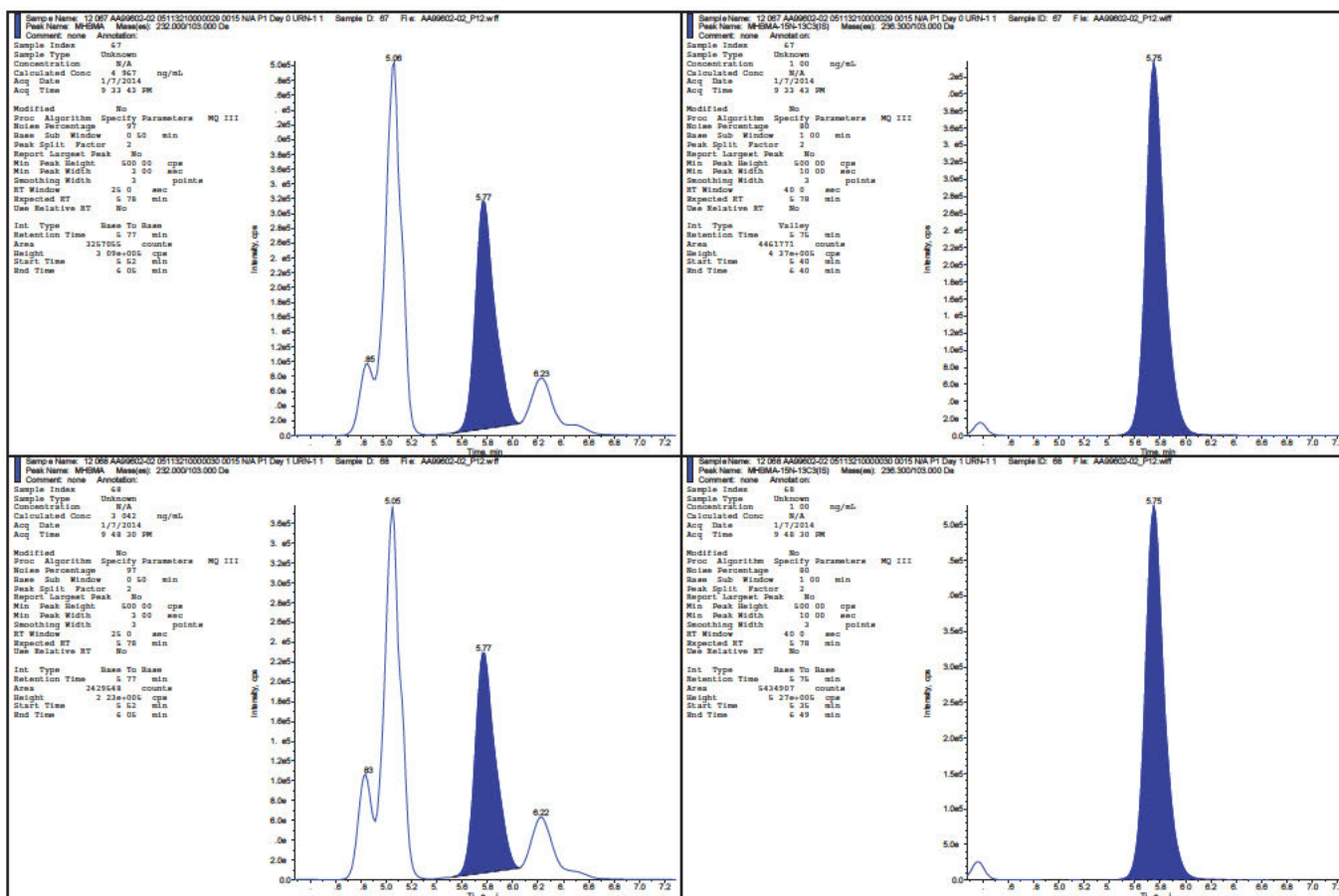


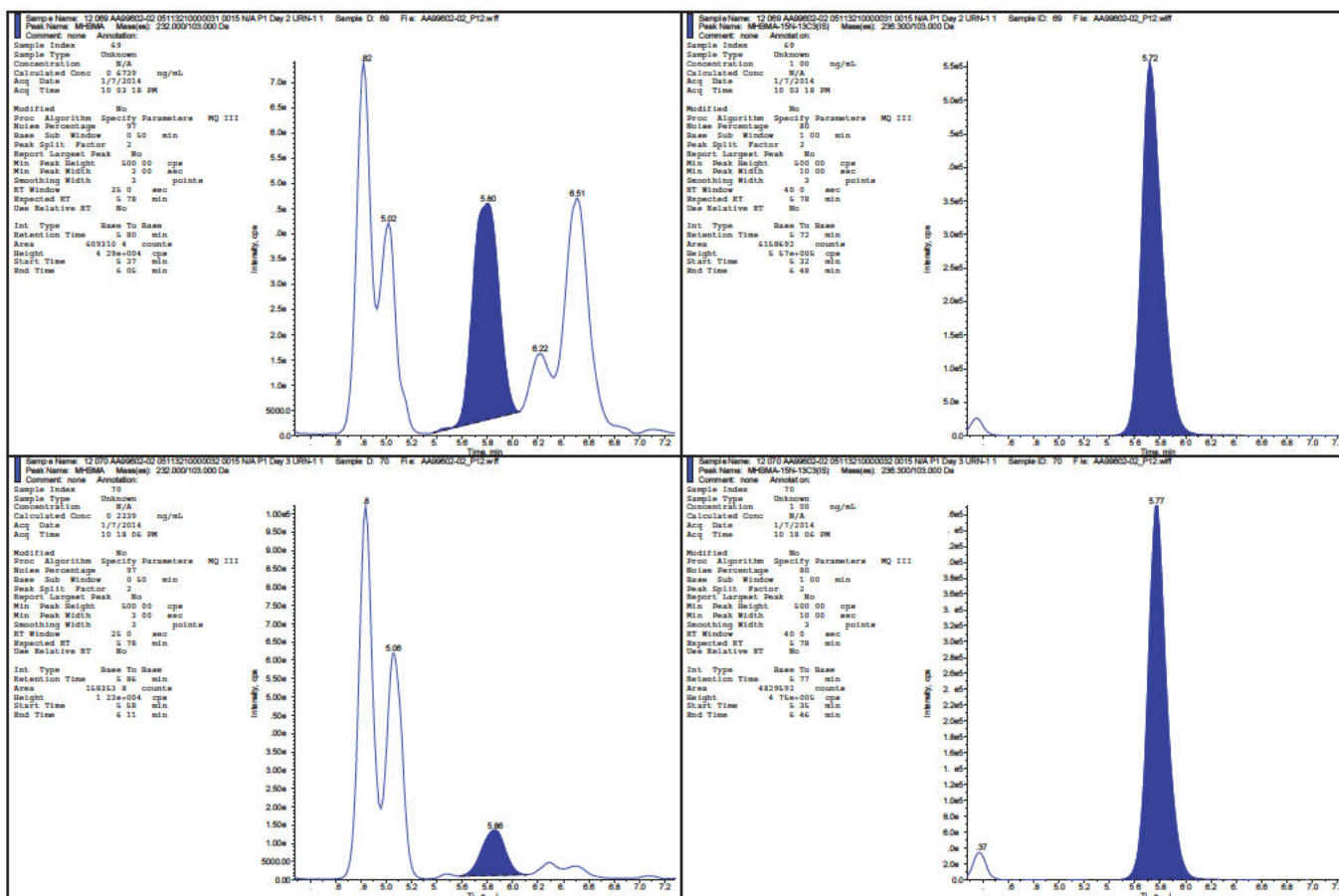
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Page 33 of 45



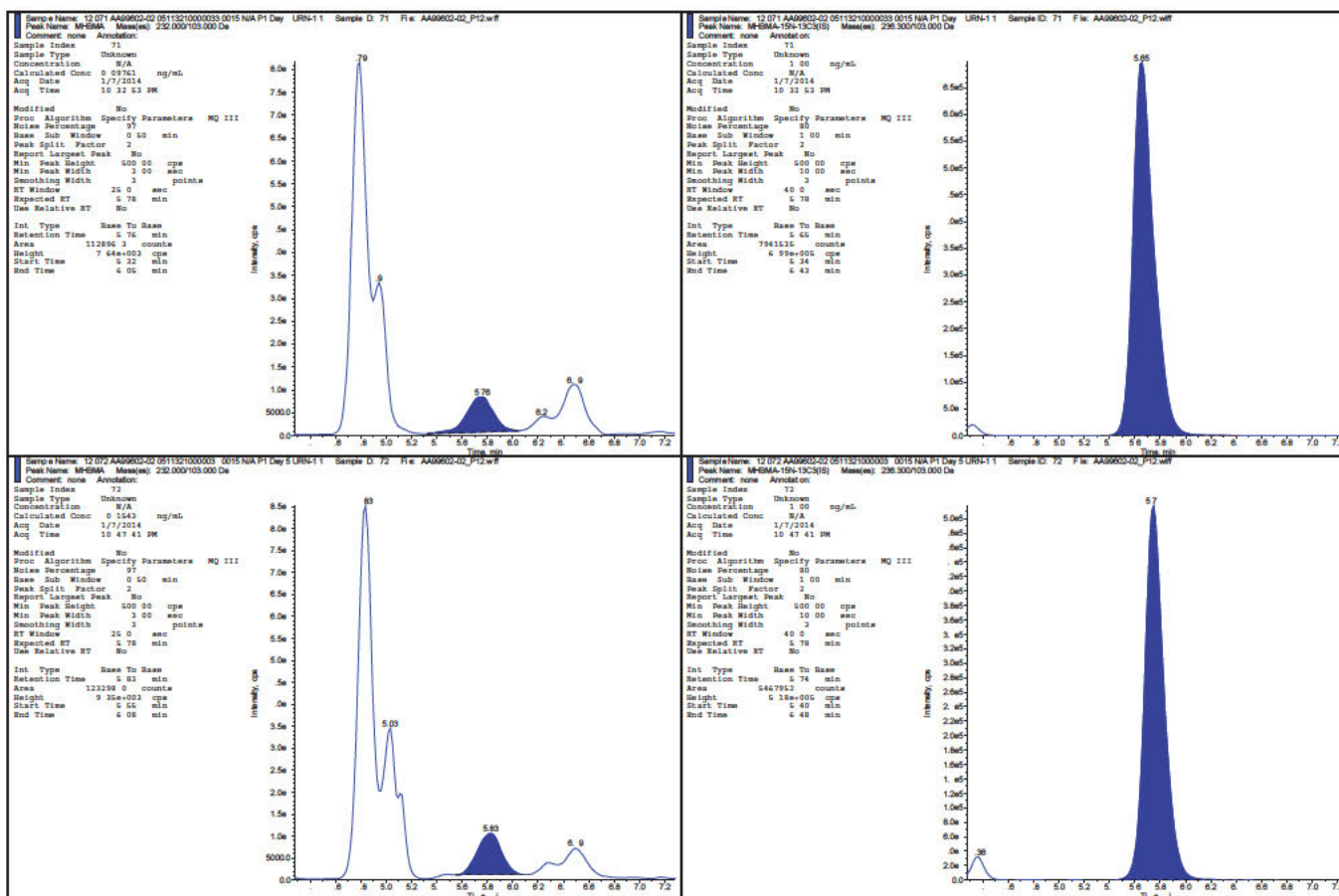




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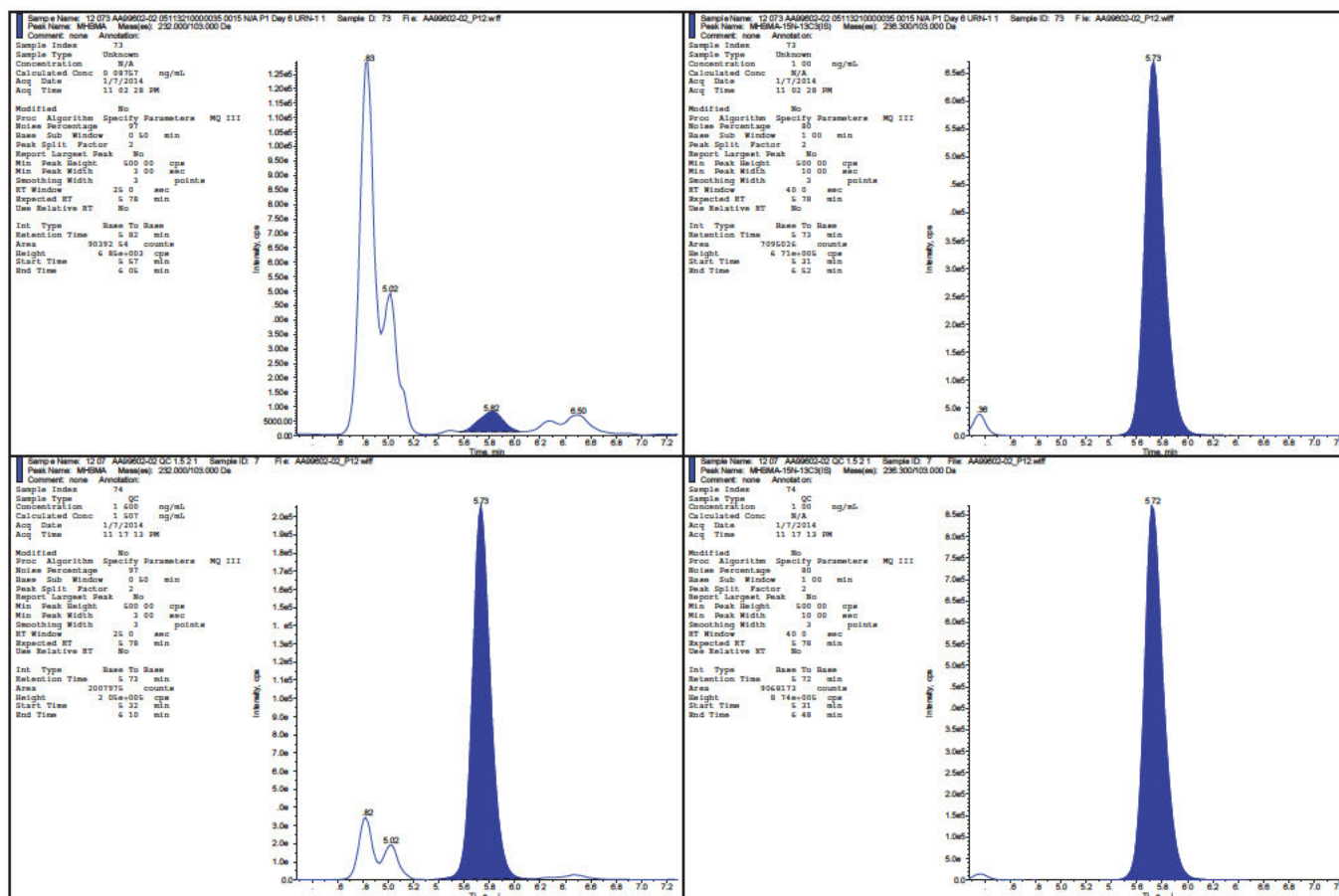
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Page 36 of 45

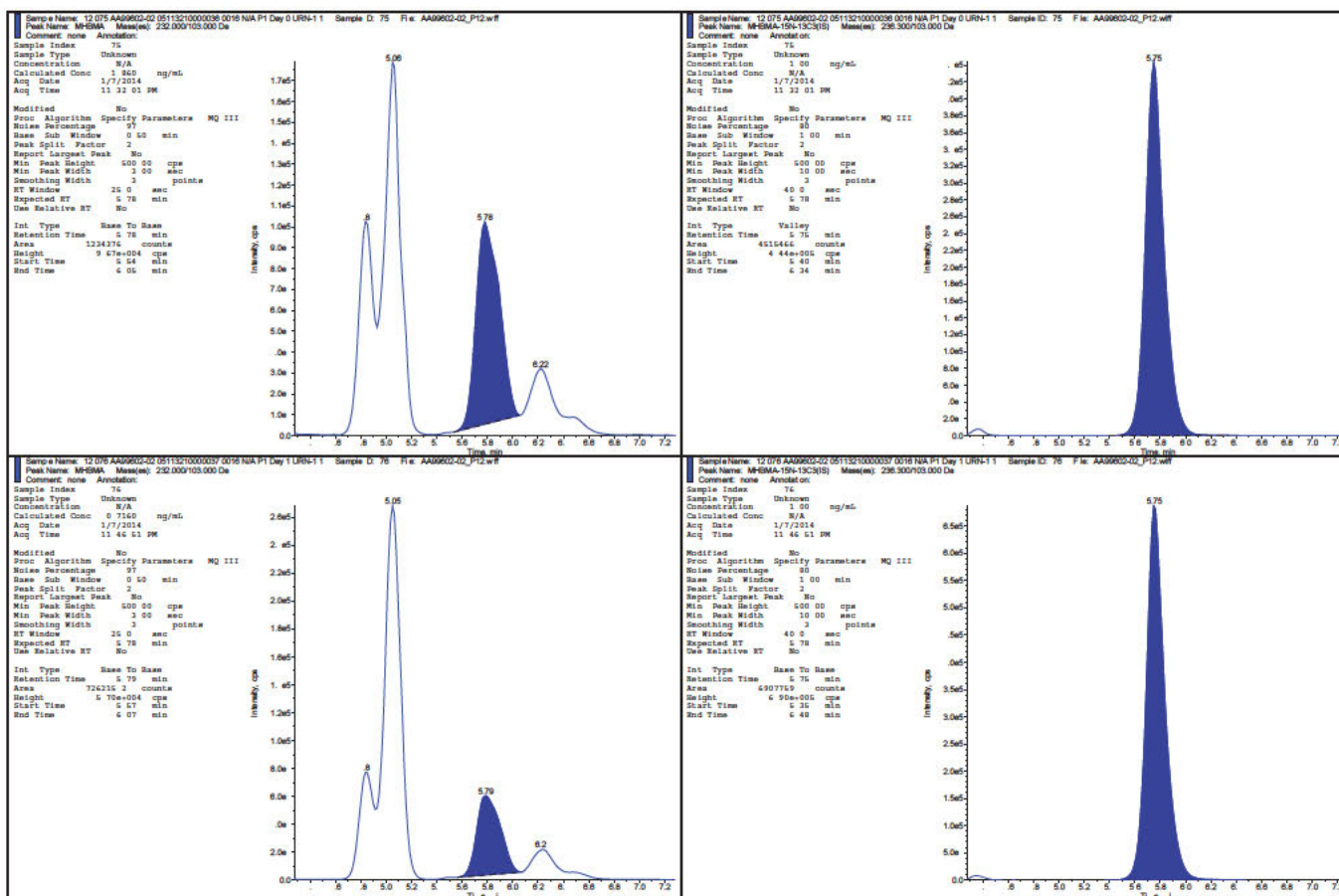


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Page 37 of 45

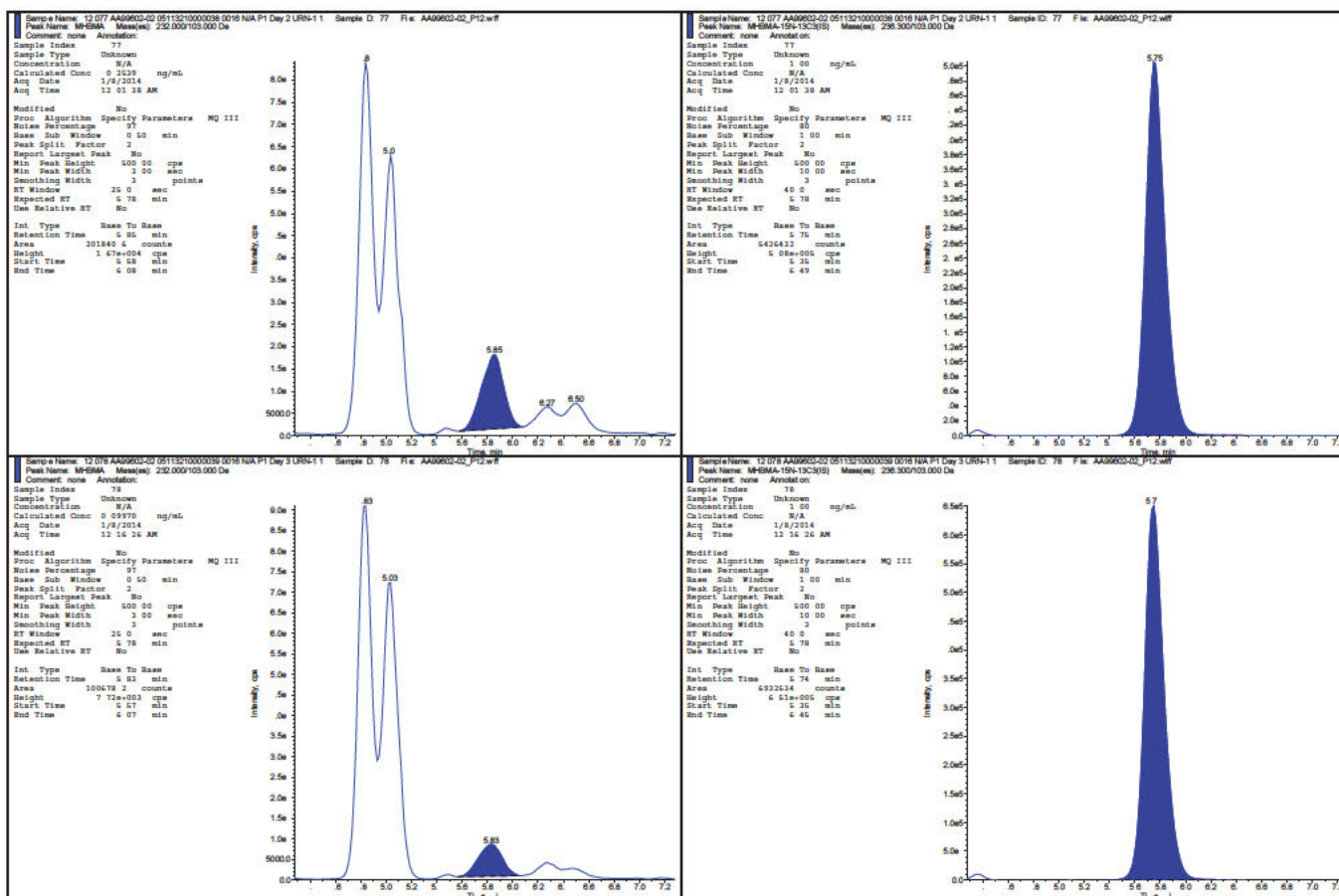


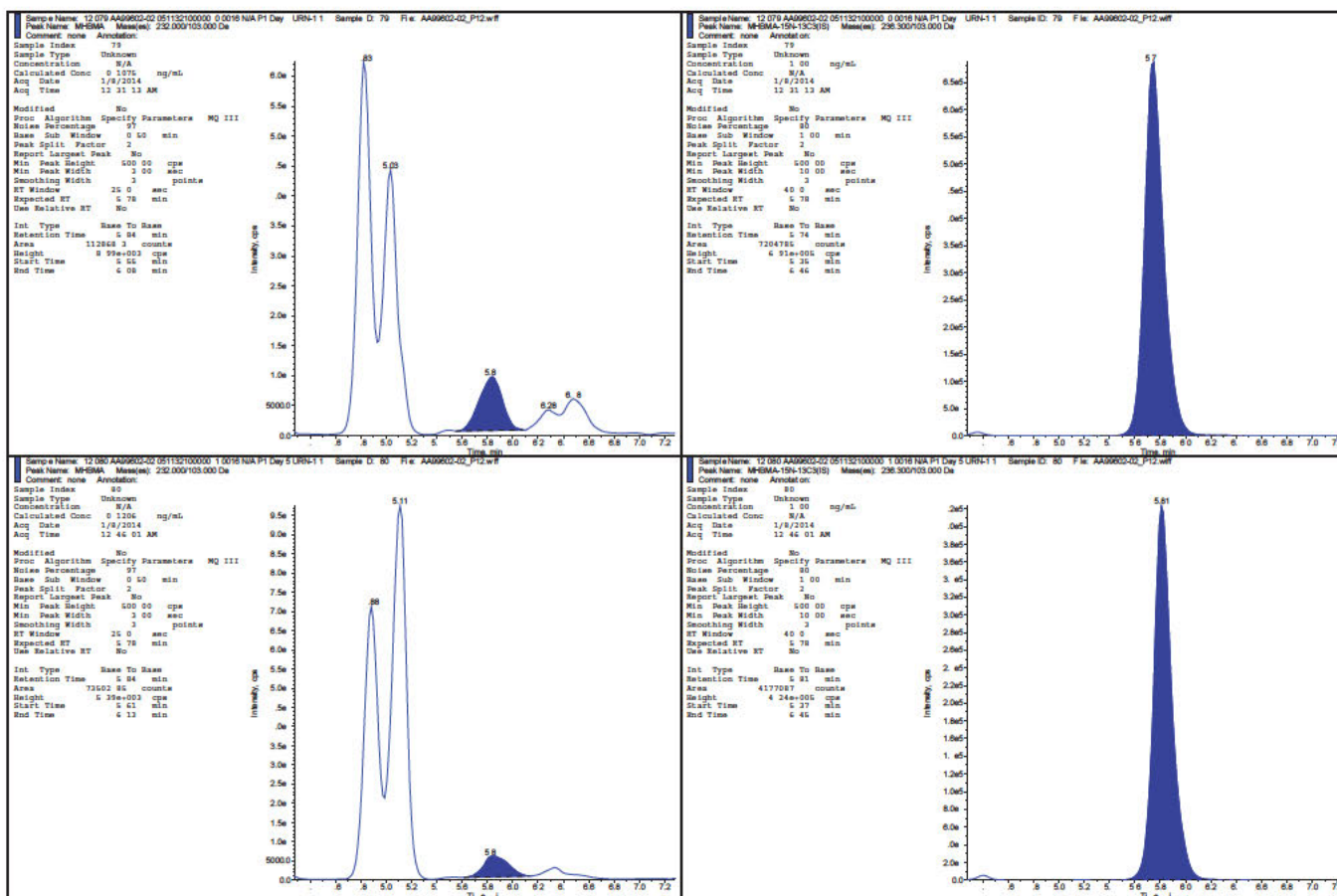


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Page 38 of 45

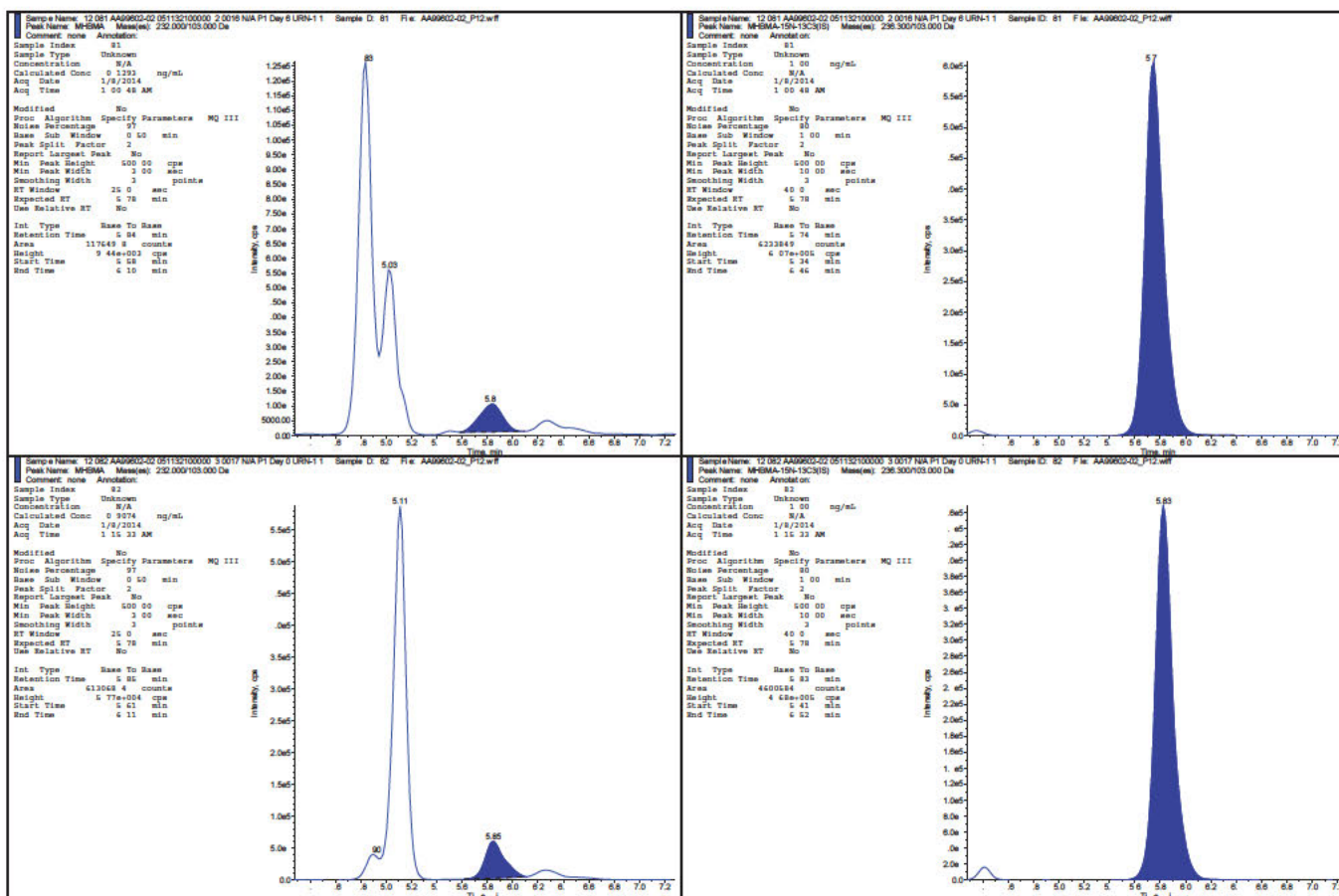




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Results Name: AA99602-02\_P12-01.rdb

Analyst Version: 1.5.2

Page 40 of 45

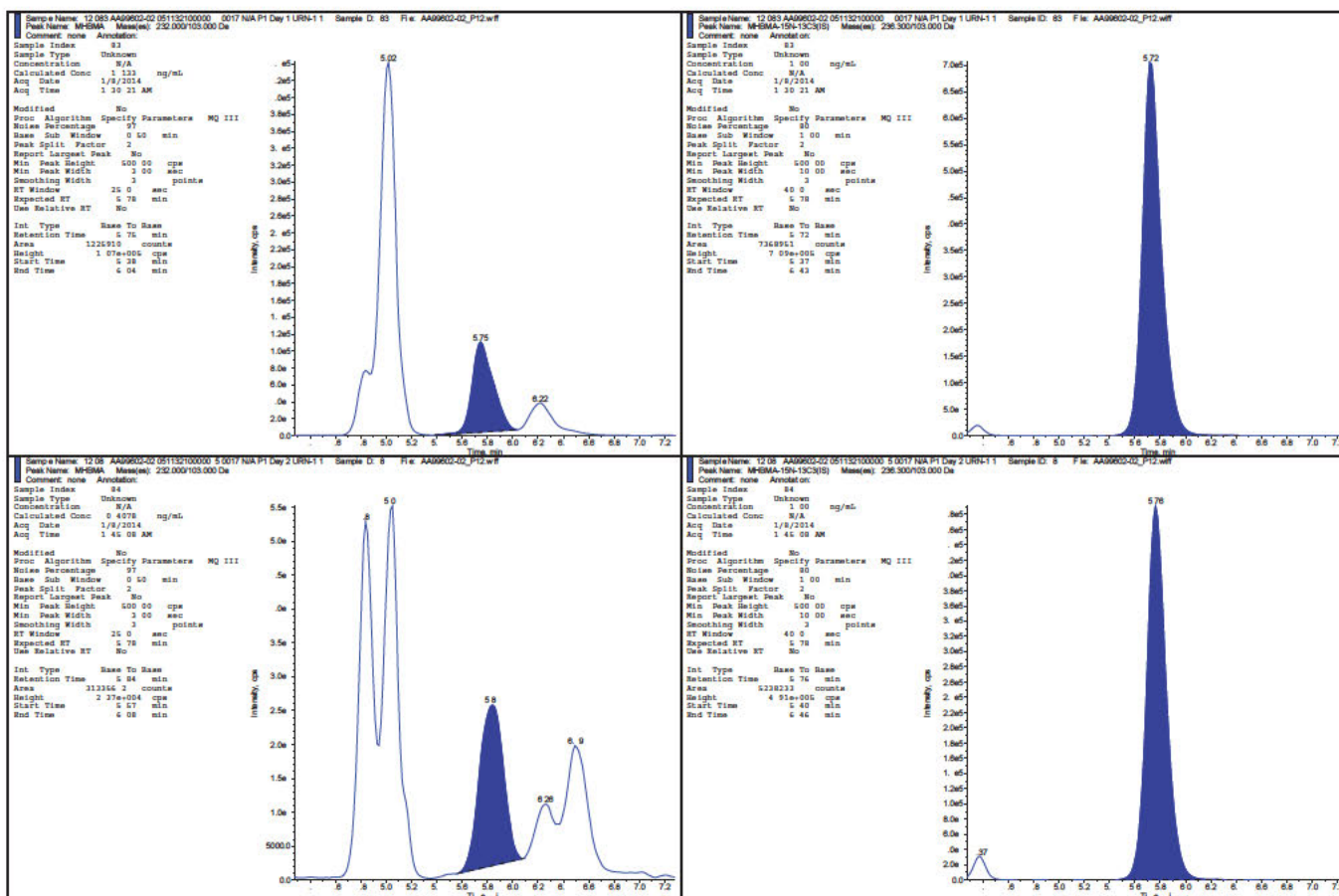


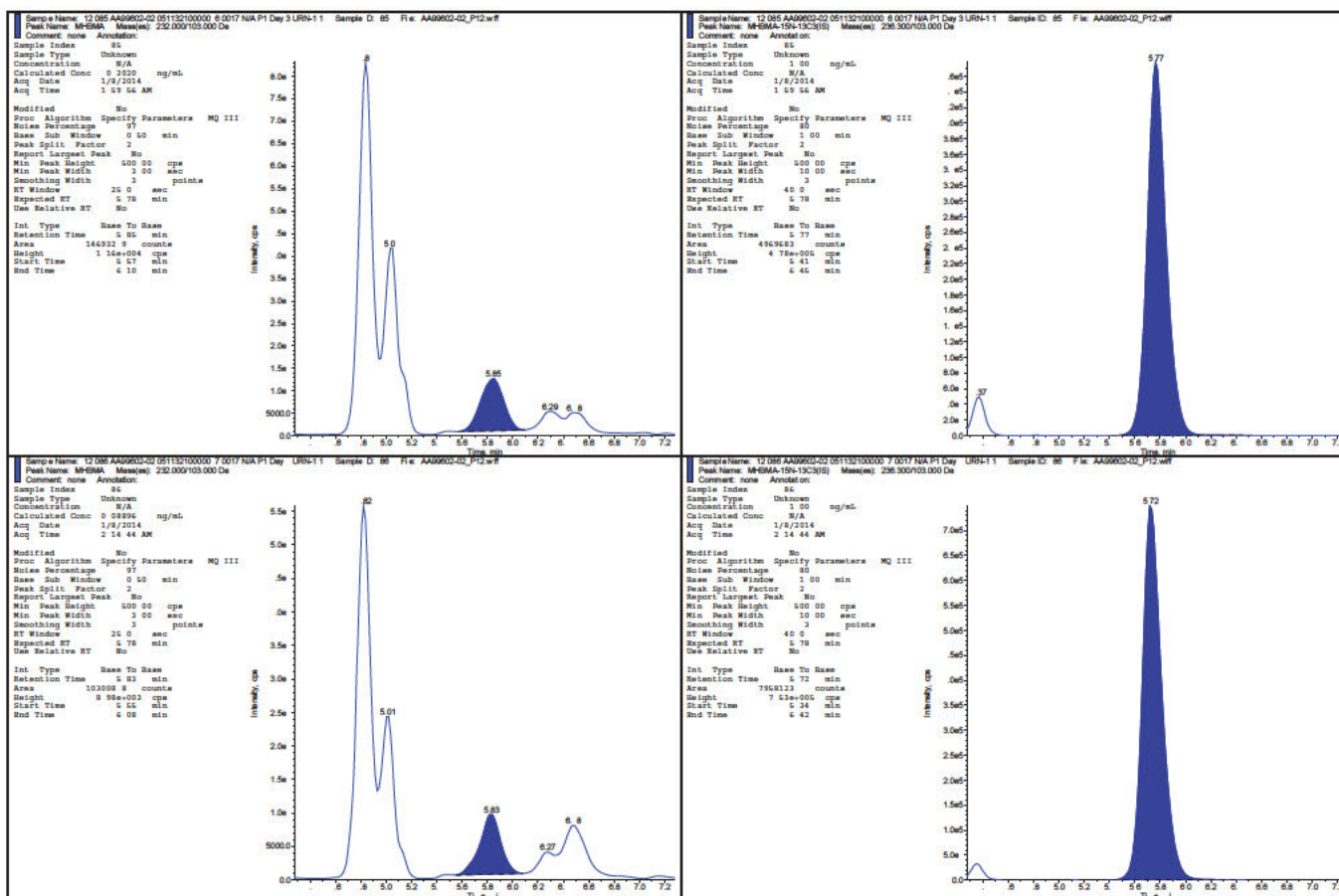
Project: AA99602-02  
Results Name: AA99602-02\_P12-01.rdb

Analyst Version: 1.5.2

Page 41 of 45



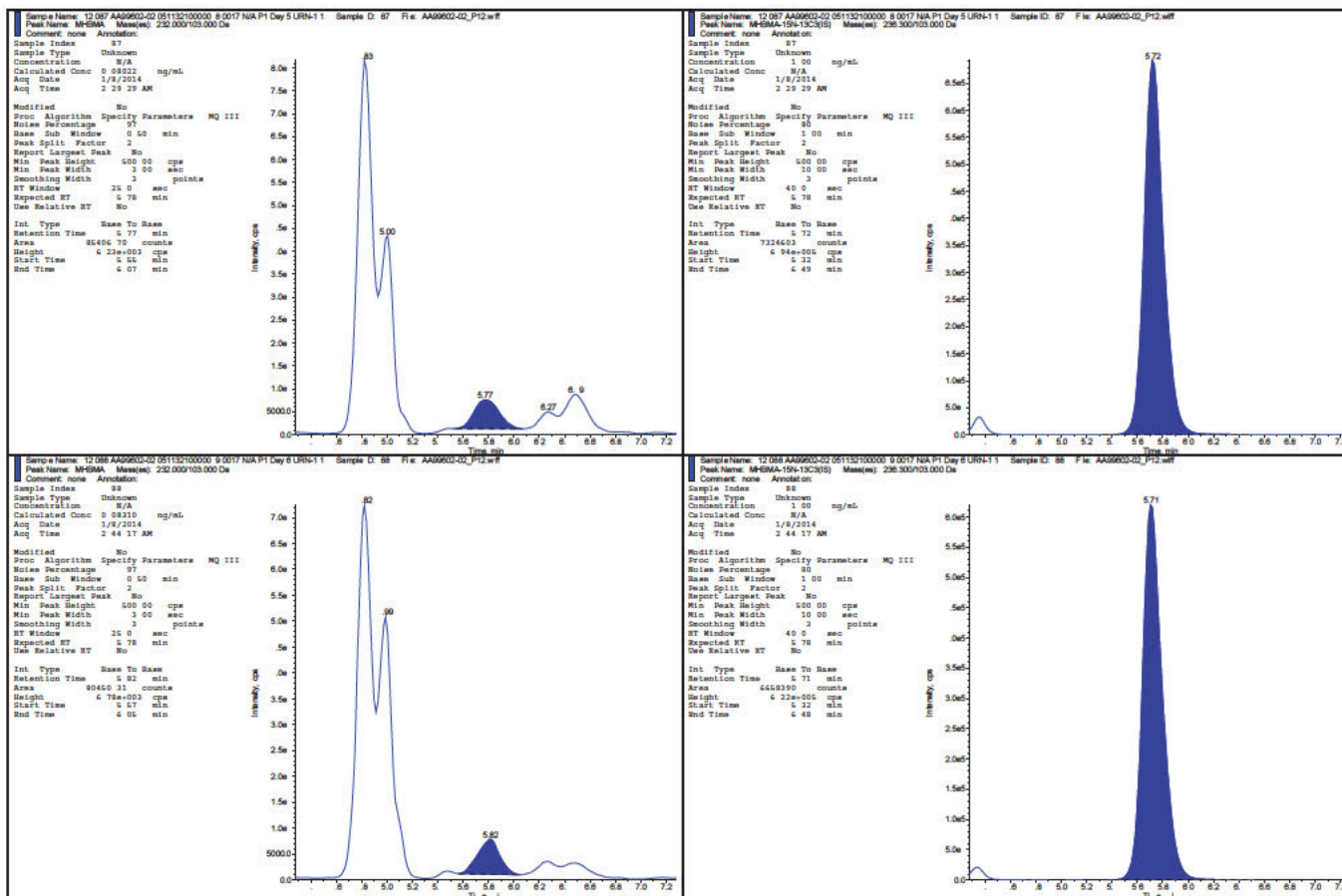




Project: AA99602-02  
Results Name: AA99602-02\_P12-01.rdb

Analyst Version: 1.5.2

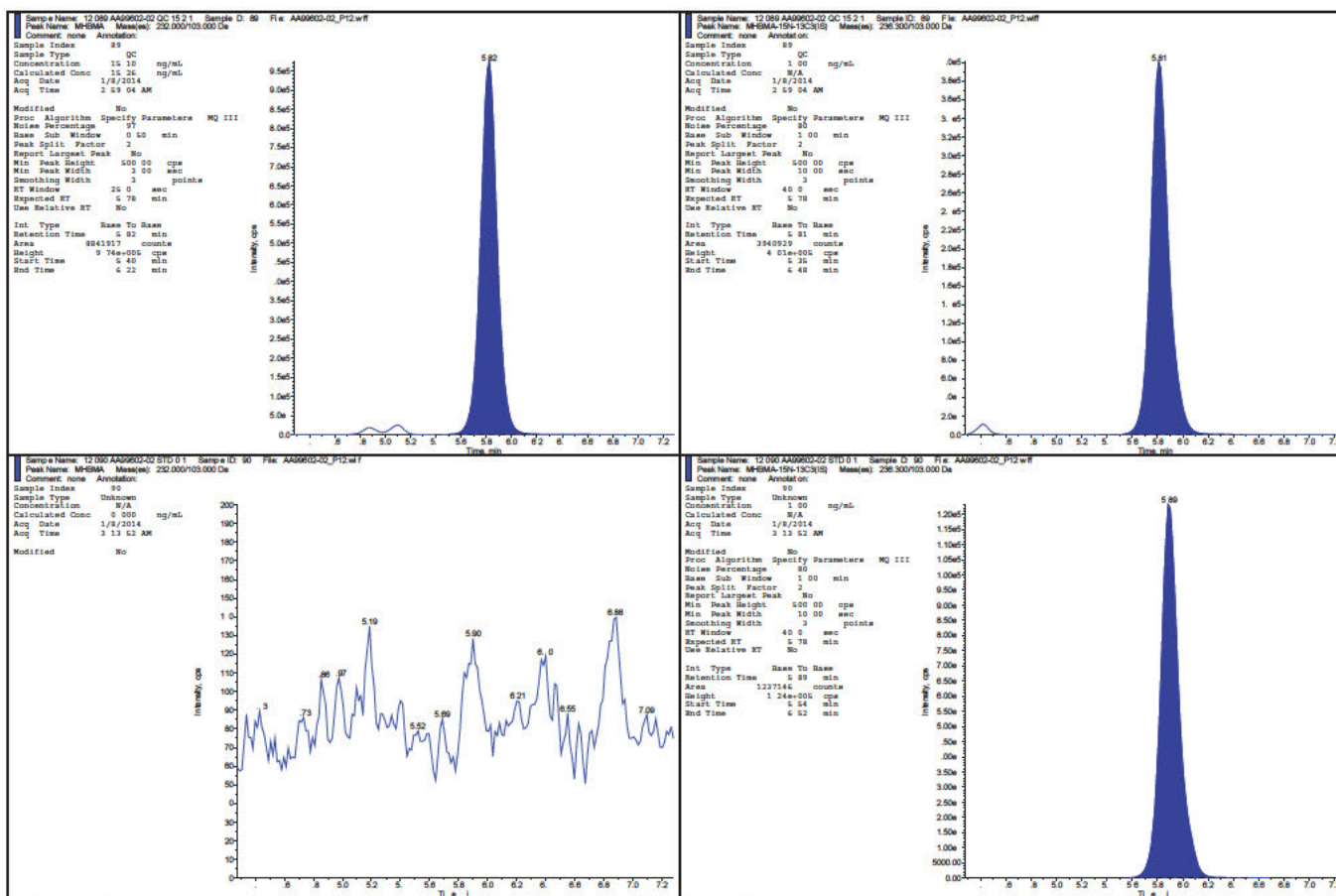
Page 43 of 45



Project: AA99602-02  
Results Name: AA99602-02\_P12-01.rdb

Analyst Version: 1.5.2

Page 44 of 45



Project: AA99602-02  
Results Name: AA99602-02\_P12-01.rdb

Analyst Version: 1.5.2

Page 45 of 45