



16.1.9.3 BIOANALYTICAL REPORTS

Determination of Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine Samples by LC-MS/MS (Study AA99071-13)



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

Study: AA99071-13

Bioanalytical Final Report

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

Report Date: 13-Mar-2015

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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STATEMENT OF COMPLIANCE

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

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

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

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

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

13-Mar-2015

Date



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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QUALITY ASSURANCE STATEMENT

Phase Audited	Audit Date(s)	Date Reported to Study Director/ Bioanalytical Principal Investigator	Date Audit Report Signed by Management
Bioanalytical Study Plan	18-Jun-2013	18-Jun-2013	24-Jul-2013
Critical Phase Inspection	29, 31-Oct-2013	31-Oct-2013	01-Nov-2013
Database	17-Dec-2013	17-Dec-2013	18-Dec-2013
Bioanalytical Report (Final Draft)	30-May-2014, 02-Jun-2014	02-Jun-2014	04-Sep-2014
Bioanalytical Report (Final)	12-Mar-2015	12-Mar-2015	13-Mar-2015

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

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

13 Mar 2015

Date



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
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1. INTRODUCTION

The purpose of this bioanalytical study (hereafter referred to as study) was to determine the concentration of nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide in human urine samples by a validated LC-MS/MS method. The study samples were collected in the clinical study ZRHR-REXC-03-EU, entitled, "A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement" [3]. Sample analysis was conducted between 14-Nov-2013 and 11-Dec-2013.

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

2. EXPERIMENTAL

2.1. Test Item

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

2.2. Reference Items and Internal Standards

	Analyte	Internal Standard (IS)
ID	Nicotine	d ₄ -Nicotine
Source	(b) (4)	(b) (4)
Lot No.	AC0105001*	AC0105003 ⁺
Purity / Concentration	99.5% (912 µg/mL)*	96.0% (1010 µg/mL) ⁺
Celerion Assigned Correction Factor	1.0000	1.0000
Expiry Date	04-Jan-2014*	30-Jun-2014 ⁺
Storage Conditions	Refrigerated (5 °C), protected from light	Refrigerated (5 °C), protected from light

*Recertified with new expiry date of 30-Jun-2014 with purity/concentration of 99.7% (914 µg/mL)

⁺Current internal standard reference material has been recertified during the study execution



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	Analyte	Internal Standard (IS)
ID	Cotinine	d ₃ -Cotinine
Source	(b) (4)	(b) (4)
Lot No.	AC0105002*	AC0105004*
Purity / Concentration	99.6% (984 µg/mL)*	99.6% (1000 µg/mL) +
Celerion Assigned Correction Factor	1.0000	1.0000
Expiry Date	03-Jan-2014*	01-Jul-2014*
Storage Conditions	Refrigerated (5 °C), protected from light	Refrigerated (5 °C), protected from light

*Recertified with new expiry date of 01-Jul-2014 with purity/concentration of 99.8% (986 µg/mL)

+Current internal standard reference material has been recertified during the study execution

	Analyte	Internal Standard (IS)
ID	<i>trans</i> -3'-Hydroxycotinine	d ₃ - <i>trans</i> -3'-Hydroxycotinine
Source	(b) (4)	(b) (4)
Lot No.	C8-127-040	C8-127-047
Potency	99.7%	99.9%
Celerion Assigned Correction Factor	0.9969	0.9990
Expiry Date	02-Apr-2014	11-Apr-2014
Storage Conditions	Freezer (-20 °C), protected from light, desiccant	Freezer (-20 °C), protected from light, desiccant

	Analyte	Internal Standard (IS)
ID	Nicotine- <i>N</i> -Glucuronide	d ₃ -Nicotine- <i>N</i> -Glucuronide
Source	(b) (4)	(b) (4)
Lot No.	DDT-MDSPSR-S-VI-244A	AC0105011*
Potency / Purity / Concentration	84.0% (potency)	93.0 % (1010 µg/mL) +
Celerion Assigned Correction Factor	0.8400	1.000
Expiry Date	12-Dec-2013	14-Jun-2014*
Storage Conditions	Freezer (-20 °C), protected from light, desiccant	Refrigerated (5 °C), protected from light

+Current internal standard reference material has been recertified during the study execution



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	Analyte	Internal Standard (IS)
ID	Cotinine- <i>N</i> -Glucuronide	d ₃ -Cotinine- <i>N</i> -Glucuronide
Source	(b) (4)	(b) (4)
Lot No.	AC0303173*	AC0105010 ⁺
Purity / Concentration	94.3 % (2470 µg/mL)*	80.9 % (1010 µg/mL) ⁺
Celerion Assigned Correction Factor	1.0000	1.0000
Expiry Date	09-Jan-2014*	13-Jun-2014 ⁺
Storage Conditions	Ambient Temperature, protected from light	Refrigerated (5 °C), protected from light

*Recertified with new expiry date of 08-Jul-2014 with purity/concentration of 68.4% (1790 µg/mL)

+Current internal standard reference material has been recertified during the study execution

	Analyte	Internal Standard (IS)
ID	<i>trans</i> -3'-Hydroxycotinine- <i>O</i> -Glucuronide	d ₃ - <i>trans</i> -3'-Hydroxycotinine- <i>O</i> -Glucuronide
Source	(b) (4)	(b) (4)
Lot No.	AC0105016*	AC0105014 ⁺
Purity / Concentration	90.3 % (2400 µg/mL)*	93.5% (990 µg/mL) ⁺
Celerion Assigned Correction Factor	1.0000	1.0000
Expiry Date	21-Jan-2014*	18-Jun-2014 ⁺
Storage Conditions	Refrigerated (5 °C), protected from light	Refrigerated (5 °C), protected from light

*Recertified with new expiry date of 28-Apr-2014 with purity/concentration of 89.7% (2390 µg/mL)

+Current internal standard reference material has been recertified during the study execution

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

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

2.3. Biological Matrix

Human urine was collected in-house at Celerion in Lincoln, Nebraska. Human urine stored at -20°C may be stored for a period less than 24 months prior to use. Human urine, free of significant interference, was used as a control matrix and to prepare calibration standards and quality control (QC) samples.



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2.4. Test System

2.4.1. Procedure and Instruments

Procedure and Instrumentation	
Extraction Method	Combined liquid-liquid and solid phase extraction
Chromatography system	Perkin Elmer Series 200 Micropump HPLC [^]
MS/MS system	AB SCIEX API 4000 TM [^]
Regression Type	Weighted linear regression curve (1/concentration ²)
Quantitation Method	Peak area ratio
Assay Volume	0.250 mL

[^] = Qualified systems

2.4.2. Computer Application Software

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

[^] = Validated systems

2.5. Calibration Standards, Quality Control Samples

Non-zero calibration standards at the concentration levels of 10.0, 20.0, 50.0, 100, 200, 400, 600, 800, and 1000 ng/mL of nicotine, cotinine, *trans*-3'-hydroxycotinine, and nicotine-*N*-glucuronide, 20.0, 40.0, 100, 200, 400, 800, 1200, 1600, and 2000 ng/mL of cotinine-*N*-glucuronide, and 50.0, 100, 250, 500, 1000, 2000, 3000, 4000, and 5000 ng/mL of *trans*-3'-hydroxycotinine-*O*-glucuronide were prepared in bulk on 29-Oct-2013, aliquoted and stored at -20°C. It should be noted that the standard calibrators were prepared in bulk and stored with appropriate stability established (40 days of long-term storage stability) rather than prepared fresh daily from spiking solutions.

Quality control (QC) samples at the concentration levels of 30.0 ng/mL, 150 ng/mL, and 750 ng/mL of nicotine, cotinine, *trans*-3'-hydroxycotinine, and nicotine-*N*-glucuronide, of 60.0 ng/mL, 300 ng/mL, and 1500 ng/mL of cotinine-*N*-glucuronide, and of 150 ng/mL, 750 ng/mL, 3750 ng/mL of *trans*-3'-hydroxycotinine-*O*-glucuronide were prepared in bulk on 29-Oct-2013, aliquoted and stored at -20°C. QC samples were stored under the same conditions as the study samples were stored. Dilution integrity has been established up to 8,000 ng/mL for



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nicotine, cotinine, *trans*-3'-hydroxycotinine and nicotine-*N*-glucuronide, 16,000 ng/mL for cotinine-*N*-glucuronide, and 40,000 ng/mL for *trans*-3'-hydroxycotinine-*O*-glucuronide. For this study the high concentration QC was used to demonstrate accurate dilution with each analytical run where samples were diluted.

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

2.6. Study Samples

2.6.1. Sample Source and Date of Receipt

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

2.6.2. Sample Identification

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

2.6.3. Sample Storage and Stability

Study samples were stored from sample collection to the end of sample analysis at a nominal temperature of -20°C for a duration not exceeding 154 days.

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

Stability Summary [5]	Nicotine, Cotinine, <i>trans</i> -3'-Hydroxycotinine
Long-term Stability	118 days in polypropylene tubes at -20 C
Short-term Stability	24 hours in polypropylene tubes at ambient temperature under white light
Cumulative Short-term Stability	54 hours in polypropylene tubes at ambient temperature under white light (total of all thaw cycles)
Freeze-thaw Stability	6 freeze (-20 C)-thaw (ambient temperature) cycles in polypropylene tubes under white light
Post-preparative Stability	180 hours in a polypropylene 96 well plate at 5 C
Processed Sample Integrity	107 hours in a polypropylene 96 well plate at 5 C
Sample Shipping Stability	21 days in polypropylene tubes at -80 C



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Stability Summary [5]	Nicotine- <i>N</i> -Glucuronide, Cotinine- <i>N</i> -Glucuronide, <i>trans</i> -3'-Hydroxycotinine- <i>O</i> -Glucuronide
Long-term Stability	118 days in polypropylene tubes at -20 C
Short-term Stability	24 hours in polypropylene tubes at ambient temperature under white light
Cumulative Short-term Stability	54 hours in polypropylene tubes at ambient temperature under white light (total of all thaw cycles)
Freeze-thaw Stability	6 freeze (-20 C)-thaw (ambient temperature) cycles in polypropylene tubes under white light
Post-preparative Stability	181 hours in a polypropylene 96 well plate at 5 C
Processed Sample Integrity	108 hours in a polypropylene 96 well plate at 5 C
Sample Shipping Stability	21 days in polypropylene tubes at -80 C

An extended long-term stability evaluation, which covers the period from sample collection to the end of sample analysis will be performed and reported in an amendment to the Validation Report. A copy of the amendment will be provided to the Sponsor.

2.6.4. Sample Summary

The Sponsor's protocol specifies 40 subjects (SA arm) with 7 sampling times for 24-hour urine collections [3]. In study AA99071, a single subject discontinued from the clinical phase after randomization. The samples from this subject were analyzed and the results reported. Additional information regarding the subject discontinuance is provided in [Section 8.4](#).

	No. of Samples
Specified in protocol/received	280/291
Analysis Not Required (Discontinued from enrollment)	18
Duplicates received	291
Total number of study samples analyzed	273

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



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3. SAMPLE ANALYSIS

3.1. Analytical Method

The determination of nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide in human urine samples was carried out over a calibration range of 10.0 ng/mL to 1000 ng/mL (nicotine, cotinine, *trans*-3'-hydroxycotinine, and nicotine-*N*-glucuronide), 20.0 ng/mL to 2,000 ng/mL (cotinine-*N*-glucuronide), and 50.0 ng/mL to 5000 ng/mL (*trans*-3'-hydroxycotinine-*O*-glucuronide). The analytical procedure was performed at Celerion, Lincoln, Nebraska and is documented in the Method Validation Report for Celerion Study ZZ33881-03 [5]. The analytical method is documented in BAM SOP ZZ33881-03 [6]. See Attachment 7.

An aliquot of human urine containing the analyte and internal standard was extracted using a combined liquid-liquid and solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an AB SCIEX API 4000™ triple quadrupole mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis ($1/\text{concentration}^2$) of peak area ratios of the analyte and internal standard.

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

3.2. Acceptance Criteria

3.2.1. Analytical Run Acceptance Criteria

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

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

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



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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 System Suitability Testing

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

- Sensitivity assessed at the start and end of each analytical run is performed by evaluating the signal-to-noise ratio (SNR) of extracted system suitability samples spiked at the lower limit of quantitation. The SNR must be greater than 5:1 unless otherwise specified in the method.
- System stability (reproducibility of response) is performed by replicate injections at the start (5) and the end (2) of the analytical run with pooled high concentration system suitability samples. The percent coefficient of variation (% CV) of the calculated concentration must be less than or equal to 6%. The mean of the calculated concentration of the last 2 replicates or middle replicates (if applicable) of high concentration system suitability samples must be within 15% difference of the mean of the calculated concentration of the first 5 high concentration system suitability samples.
- The carryover percentage is assessed at the beginning and end of each analytical run. This test is performed by injecting a blank (reconstitution solution) sample immediately after a high concentration system suitability sample. The area counts of the analyte in the blank injection are divided by the analyte area counts in the high concentration system suitability sample and the result is multiplied by 100.

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

Analyte	Carryover criteria (needs to be less than)
All analytes	0.2%

3.2.3. Acceptance Criteria for Sample Dilution

The accuracy of study sample dilution is verified by the DQC samples. At least 50% of the DQC samples must be within $\pm 15.0\%$ of their nominal concentration for the respective dilution factor to be accepted.



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3.2.4. Acceptance Criteria for ISR

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

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

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

4. RESULTS

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

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

4.1. Quality Control and Dilution Quality Control Sample Performance

Between-analytical run precision and accuracy results for QC samples prepared at 30.0, 150, and 750 ng/mL for nicotine, cotinine, *trans*-3'-hydroxycotinine, and nicotine-*N*-glucuronide, 60.0, 300, and 1500 ng/mL for cotinine-*N*-glucuronide, and 150, 750, and 3750 ng/mL for *trans*-3'-hydroxycotinine-*O*-glucuronide are summarized in [Table 2](#), [Table 3](#), [Table 4](#), [Table 5](#), [Table 6](#), and [Table 7](#), respectively. The accuracy of sample dilution was verified by the performance of dilution QC samples. Results for dilution QC samples are summarized in [Table 2](#), [Table 3](#), [Table 4](#), [Table 5](#), [Table 6](#), and [Table 7](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively.

4.2. Calibration Standard Performance

Back-calculated calibration curve standard concentrations are provided in [Table 8](#), [Table 9](#), [Table 10](#), [Table 11](#), [Table 12](#), and [Table 13](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively.



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4.3. Standard Curve Parameters

Standard curve parameters from 9, 9, 9, 9, 9, and 8 successful analytical runs are provided in [Table 14](#), [Table 15](#), [Table 16](#), [Table 17](#), [Table 18](#), and [Table 19](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively. A representative calibration curve is illustrated in [Figure 1](#), [Figure 2](#), [Figure 3](#), [Figure 4](#), [Figure 5](#), and [Figure 6](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively.

4.4. Study Sample Concentrations

Study sample concentrations are provided in [Table 20](#), [Table 21](#), [Table 22](#), [Table 23](#), [Table 24](#), [Table 25](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively. 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 nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, 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 needing re-analysis according to [section 3.2.1](#) for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide are identified in [Table 26](#), [Table 27](#), [Table 28](#), [Table 29](#), [Table 30](#), and [Table 31](#) respectively.

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

After initial analysis, study samples that were identified by the Bioanalytical Principal Investigator for re-assay due to non-analytical reasons were re-assayed if sufficient sample volume remained. These samples are identified in [Table 32](#), [Table 33](#), [Table 34](#), and [Table 35](#) for nicotine, cotinine, nicotine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide, respectively.

4.5.3. Sponsor Selected Reassays

There were no Sponsor selected reassays.



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4.5.4. Incurred Sample Reproducibility

The method for the determination of nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide was considered reproducible, 97.0% out of 33 repeat analyses for nicotine, 97.0% out of 33 repeat analyses for cotinine, 100% out of 33 repeat analyses for *trans*-3'-hydroxycotinine, 97.0% out of 33 repeat analyses for nicotine-*N*-glucuronide, 100% out of 33 repeat analyses for cotinine-*N*-glucuronide, 97.0% out of 33 repeat analyses for *trans*-3'-hydroxycotinine-*O*-glucuronide met acceptance criteria as defined in [section 3.2.4](#). Results are presented in [Table 36](#), [Table 37](#), [Table 38](#), [Table 39](#), [Table 40](#), and [Table 41](#).

5. CHROMATOGRAMS

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

6. DEVIATIONS

There were no protocol and/or significant SOP deviations.

7. EVENTS

7.1. Event Observation EO-LNK-AA99071-13-13-0609 was initiated due to a single sample failed ISR testing for nicotine, cotinine, nicotine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide by more than 66% difference. The sample (Subject 0240, Day 3) was reassayed in triplicate as a value requiring confirmation as specified in Event Resolution ER-LNK-AA99071-13-13-0157. Due to a suspected aliquoting error on Analytical Run 7/8 the ISR result did not confirm the originally measured concentrations for nicotine, cotinine, nicotine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide. The mean concentrations of the VRC results confirmed the ISR results and were reported instead of the original concentrations. There was no further impact from this investigation.

8. ANALYTICAL NOTES

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

Run ID	Analyte	Reason for Non-inclusion
5	Nicotine, Cotinine, and <i>trans</i> -3'-Hydroxycotinine	Analytical Run 5 was reassayed as Analytical Run 14 due to a Sciclone error.
11	Nicotine, Cotinine, and <i>trans</i> -3'-Hydroxycotinine	Analytical Run 11 was reassayed as Analytical Run 12 due to Analytical Run 11 exceeding PSI stability.



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

<u>Run ID</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
4	<i>trans</i> -3'-Hydroxycotinine- <i>O</i> -Glucuronide	Analytical Run 4 was reinjected as Analytical Run 11 due to SST failure – unstable response.

8.3. When a sample was reassayed for only one compound and the reassay result for the other compound was not needed, the unneeded reassay result was deactivated as “Not Used” and was not reported.

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

9. ARCHIVES

At a minimum the following records will be retained:

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

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

Iron Mountain
1601 Leavenworth
Omaha, Nebraska 68102



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10. CONCLUSION

In this bioanalytical study the concentration was determined in a total of 273 samples for nicotine, cotinine, *trans*-3'-hydroxycotinine, nicotine-*N*-glucuronide, cotinine-*N*-glucuronide, and *trans*-3'-hydroxycotinine-*O*-glucuronide in human urine samples collected in the Philip Morris International Research and Development clinical study ZRHR-REXC-03-EU using a validated LC-MS/MS method.

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

11. REFERENCES

- [1] Guidance for Industry – Bioanalytical Method Validation: US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) May 2001
- [2] OECD Principles on Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 1, OECD Publishing, Paris, France (2003).
- [3] Protocol ZRHR-REXC-03-EU: "A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement"
- [4] Study Plan Bioanalysis: Determination of Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine Samples from "A Randomized, Controlled, Open-label, 3-Arm Parallel Group, Single-Center Study to Demonstrate Reductions in Exposure to Selected Smoke Constituents in Smoking, Healthy Subjects Switching to the Tobacco Heating System 2.2 (THS 2.2) or Smoking Abstinence, Compared to Continuing to Use Conventional Cigarettes, for 5 Days in Confinement" by LC-MS/MS, Celerion Study AA99071-06 and AA99071-13
- [5] Validation of an LC-MS/MS Method for the Determination of Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine, Celerion Study ZZ33881-03
- [6] Bioanalytical Method SOP for the Determination of Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine, Celerion Study ZZ33881-03



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RESULT TABLES

Table 1 Summary of Analytical Runs Performed

Analyte Name	Run ID	Regression Status	Extraction Date	Assay Date	Description	Comment
Nicotine	1	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0010-0062 PD 1 AGLYCONES	OK
Nicotine	3	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 AGLYCONES	OK
Nicotine	7	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 AGLYCONES	OK
Nicotine	9	Accepted	26-Nov-2013	27-Nov-2013	SUBS 0306-0325 PD 1 AGLYCONES + REASSAYS	OK
Nicotine	13	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
Nicotine	14	Accepted	26-Nov-2013	26-Nov-2013	RR of BATCH 5 (SUBS 0133-0218 PD 1 AGLYCONES)	OK
Nicotine	15	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS AGLYCONES	OK
Nicotine	17	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS AGLYCONES	OK
Nicotine	19	Accepted	11-Dec-2013	11-Dec-2013	VRCs AGLYCONES	OK
Cotinine	1	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0010-0062 PD 1 AGLYCONES	OK
Cotinine	3	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 AGLYCONES	OK
Cotinine	7	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 AGLYCONES	OK
Cotinine	9	Accepted	26-Nov-2013	27-Nov-2013	SUBS 0306-0325 PD 1 AGLYCONES + REASSAYS	OK
Cotinine	13	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
Cotinine	14	Accepted	26-Nov-2013	26-Nov-2013	RR of BATCH 5 (SUBS 0133-0218 PD 1 AGLYCONES)	OK
Cotinine	15	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS AGLYCONES	OK
Cotinine	17	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS AGLYCONES	OK
Cotinine	19	Accepted	11-Dec-2013	11-Dec-2013	VRCs AGLYCONES	OK
THC	1	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0010-0062 PD 1 AGLYCONES	OK
THC	3	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 AGLYCONES	OK
THC	7	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 AGLYCONES	OK
THC	9	Accepted	26-Nov-2013	27-Nov-2013	SUBS 0306-0325 PD 1 AGLYCONES + REASSAYS	OK
THC	13	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
THC	14	Accepted	26-Nov-2013	26-Nov-2013	RR of BATCH 5 (SUBS 0133-0218 PD 1 AGLYCONES)	OK



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Analyte Name	Run ID	Regression Status	Extraction Date	Assay Date	Description	Comment
THC	15	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS AGLYCONES	OK
THC	17	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS AGLYCONES	OK
THC	19	Accepted	11-Dec-2013	11-Dec-2013	VRCs AGLYCONES	OK
Nicotine Gluc	2	Accepted	14-Nov-2013	16-Nov-2013	SUBS 0010-0062 PD 1 GLUCURONIDES	OK
Nicotine Gluc	4	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 GLUCURONIDES	OK
Nicotine Gluc	6	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0133-0218 PD 1 GLUCURONIDES	OK
Nicotine Gluc	8	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 GLUCURONIDES	OK
Nicotine Gluc	10	Accepted	26-Nov-2013	26-Nov-2013	SUBS 0306-325 PD 1 GLUCURONIDES + REASSAYS	OK
Nicotine Gluc	12	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
Nicotine Gluc	16	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS GLUCURONIDES	OK
Nicotine Gluc	18	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS GLUCURONIDES	OK
Nicotine Gluc	20	Accepted	11-Dec-2013	11-Dec-2013	VRCs GLUCURONIDES	OK
Cotinine Gluc	2	Accepted	14-Nov-2013	16-Nov-2013	SUBS 0010-0062 PD 1 GLUCURONIDES	OK
Cotinine Gluc	4	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 GLUCURONIDES	OK
Cotinine Gluc	6	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0133-0218 PD 1 GLUCURONIDES	OK
Cotinine Gluc	8	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 GLUCURONIDES	OK
Cotinine Gluc	10	Accepted	26-Nov-2013	26-Nov-2013	SUBS 0306-325 PD 1 GLUCURONIDES + REASSAYS	OK
Cotinine Gluc	12	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
Cotinine Gluc	16	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS GLUCURONIDES	OK
Cotinine Gluc	18	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS GLUCURONIDES	OK
Cotinine Gluc	20	Accepted	11-Dec-2013	11-Dec-2013	VRCs GLUCURONIDES	OK
Nicotine Gluc	2	Accepted	14-Nov-2013	16-Nov-2013	SUBS 0010-0062 PD 1 GLUCURONIDES	OK
Nicotine Gluc	4	Accepted	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 GLUCURONIDES	OK
Nicotine Gluc	6	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0133-0218 PD 1 GLUCURONIDES	OK
Nicotine Gluc	8	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 GLUCURONIDES	OK
Nicotine Gluc	10	Accepted	26-Nov-2013	26-Nov-2013	SUBS 0306-325 PD 1 GLUCURONIDES + REASSAYS	OK
Nicotine Gluc	12	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
Nicotine Gluc	16	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS GLUCURONIDES	OK



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Analyte Name	Run ID	Regression Status	Extraction Date	Assay Date	Description	Comment
Nicotine Gluc	18	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS GLUCURONIDES	OK
Nicotine Gluc	20	Accepted	11-Dec-2013	11-Dec-2013	VRCs GLUCURONIDES	OK
THC Gluc	2	Accepted	14-Nov-2013	16-Nov-2013	SUBS 0010-0062 PD 1 GLUCURONIDES	OK
THC Gluc	4	Rejected	14-Nov-2013	17-Nov-2013	SUBS 0063-0128 PD 1 GLUCURONIDES	SST Failure
THC Gluc	6	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0133-0218 PD 1 GLUCURONIDES	OK
THC Gluc	8	Accepted	18-Nov-2013	19-Nov-2013	SUBS 0240-0292 PD 1 GLUCURONIDES	OK
THC Gluc	10	Accepted	26-Nov-2013	26-Nov-2013	SUBS 0306-325 PD 1 GLUCURONIDES + REASSAYS	OK
THC Gluc	12	Accepted	20-Nov-2013	21-Nov-2013	REASSAYS	OK
THC Gluc	16	Accepted	27-Nov-2013	27-Nov-2013	REASSAYS GLUCURONIDES	OK
THC Gluc	18	Accepted	06-Dec-2013	06-Dec-2013	ISRs + REASSAYS GLUCURONIDES	OK
THC Gluc	20	Accepted	11-Dec-2013	11-Dec-2013	VRCs GLUCURONIDES	OK

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



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

Assay Date	Run ID	QC A 30.0 ng/mL	QC B 150 ng/mL	QC C 750 ng/mL	QC C DF10 750 ng/mL	QC C DF2 750 ng/mL	QC C DF5 750 ng/mL
17-Nov-2013	1	29.9	155	772			
		29.2	151	763			
17-Nov-2013	3	30.9	148	749			
		30.1	152	734			
19-Nov-2013	7	29.4	154	727			
		28.7	150	762			
21-Nov-2013	13	27.9	139	767	747		
		29.9	143	756	731		
					769		
26-Nov-2013	14	30.1	150	710			
		29.5	155	740			
27-Nov-2013	9	29.5	148	741	755		
		30.3	153	719	746		
					749		
27-Nov-2013	15	28.6	149	742	727		
		27.7	150	719	695		
					735		
06-Dec-2013	17	31.0	156	746	783	777	756
		28.7	148	781	757	727	728
					777	732	756
11-Dec-2013	19	30.9	152	732			
		31.0	151	750			
Mean		29.6	150	745	748	745	747
S.D.		1.02	4.22	19.6	24.0	27.5	16.2
%CV		3.4	2.8	2.6	3.2	3.7	2.2
%Theoretical		98.7	100.0	99.3	99.7	99.3	99.6
%Bias		-1.3	0.0	-0.7	-0.3	-0.7	-0.4
n		18	18	18	12	3	3



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 3 Quality Control and Dilution Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for Cotinine

Assay Date	Run ID	QC A 30.0 ng/mL	QC B 150 ng/mL	QC C 750 ng/mL	QC C DF10 750 ng/mL	QC C DF2 750 ng/mL	QC C DF5 750 ng/mL
17-Nov-2013	1	30.5	150	748			
		30.0	149	756			
17-Nov-2013	3	28.7	154	747			
		29.0	148	761			
19-Nov-2013	7	31.1	149	775			
		28.1	152	735			
21-Nov-2013	13	30.3	151	732	734		
		30.8	151	715	767		
					719		
26-Nov-2013	14	32.7	155	740			
		29.3	154	794			
27-Nov-2013	9	32.4	154	770	711		
		30.8	147	765	762		
					769		
27-Nov-2013	15	27.8	138	758	727		
		27.6	141	736	646		
					706		
06-Dec-2013	17	30.7	160	761	721	757	787
		30.9	155	721	771	754	745
					751	721	761
11-Dec-2013	19	30.2	149	747			
		30.4	154	730			
Mean		30.1	151	750	732	744	764
S.D.		1.43	5.17	20.1	35.9	20.0	21.2
%CV		4.8	3.4	2.7	4.9	2.7	2.8
%Theoretical		100.3	100.7	100.0	97.6	99.2	101.9
%Bias		0.3	0.7	0.0	-2.4	-0.8	1.9
n		18	18	18	12	3	3



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 4 Quality Control and Dilution Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for *trans*-3'-Hydroxycotinine

Assay Date	Run ID	QC A 30.0 ng/mL	QC B 150 ng/mL	QC C 750 ng/mL	QC C DF10 750 ng/mL	QC C DF2 750 ng/mL	QC C DF5 750 ng/mL
17-Nov-2013	1	29.5	153	715			
		30.8	147	756			
17-Nov-2013	3	30.6	152	752			
		28.5	150	758			
19-Nov-2013	7	29.6	146	720			
		32.3	149	717			
21-Nov-2013	13	27.0	149	778	774		
		27.7	162	750	771		
					720		
26-Nov-2013	14	30.5	155	759			
		29.1	146	719			
27-Nov-2013	9	31.7	161	741	759		
		32.8	149	765	741		
					779		
27-Nov-2013	15	29.6	142	739	747		
		28.8	157	686	751		
					716		
06-Dec-2013	17	29.6	151	747	741	744	720
		29.8	153	760	786	742	781
					728	719	774
11-Dec-2013	19	29.8	154	744			
		29.3	152	740			
Mean		29.8	152	741	751	735	758
S.D.		1.47	5.12	22.5	23.2	13.9	33.4
%CV		4.9	3.4	3.0	3.1	1.9	4.4
%Theoretical		99.3	101.3	98.8	100.1	98.0	101.1
%Bias		-0.7	1.3	-1.2	0.1	-2.0	1.1
n		18	18	18	12	3	3



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 5 Quality Control and Dilution Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for Nicotine-*N*-Glucuronide

Assay Date	Run ID	QC A 30.0 ng/mL	QC B 150 ng/mL	QC C 750 ng/mL	QC C DF10 750 ng/mL	QC C DF2 750 ng/mL	QC C DF5 750 ng/mL
16-Nov-2013	2	32.6	152	716			
		29.9	154	736			
17-Nov-2013	4	33.7	153	717			
		30.4	148	756			
19-Nov-2013	6	31.3	151	713			
		30.0	157	753			
19-Nov-2013	8	29.0	149	751			
		28.5	148	739			
21-Nov-2013	12	31.7	154	743	728		
		26.2	156	712	824		
					707		
26-Nov-2013	10	29.2	162	761	790		
		26.5	156	732	696		
					749		
27-Nov-2013	16	29.0	152	700	711		
		29.6	148	730	739		
					705		
06-Dec-2013	18	30.3	150	741	783	787	759
		32.2	156	779	801	692	821
					742	815	711
11-Dec-2013	20	30.6	152	727			
		30.4	151	741			
Mean		30.1	153	736	748	765	764
S.D.		1.91	3.72	20.0	42.3	64.5	55.1
%CV		6.3	2.4	2.7	5.7	8.4	7.2
%Theoretical		100.3	102.0	98.1	99.7	102.0	101.9
%Bias		0.3	2.0	-1.9	-0.3	2.0	1.9
n		18	18	18	12	3	3



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 6 Quality Control and Dilution Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for Cotinine-*N*-Glucuronide

Assay Date	Run ID	QC A 60.0 ng/mL	QC B 300 ng/mL	QC C 1500 ng/mL	QC C DF10 1500 ng/mL	QC C DF2 1500 ng/mL	QC C DF5 1500 ng/mL
16-Nov-2013	2	58.0	285	1540			
		58.4	288	1420			
17-Nov-2013	4	55.5	300	1480			
		53.5	280	1400			
19-Nov-2013	6	58.3	281	1510			
		55.5	301	1470			
19-Nov-2013	8	59.6	284	1430			
		52.0	272	1480			
21-Nov-2013	12	54.3	302	1510	1290		
		55.0	310	1360	1340		
					1550		
26-Nov-2013	10	66.9	315	1420	1420		
		57.5	290	1350	1500		
					1480		
27-Nov-2013	16	52.0	290	1460	1320		
		60.6	298	1380	1430		
					1410		
06-Dec-2013	18	51.9	314	1400	~1240	1490	~1260
		59.7	266	1530	1400	1380	1350
					1360	1290	1420
11-Dec-2013	20	59.1	304	1450			
		58.6	290	1450			
Mean		57.0	293	1450	1400	1390	1340
S.D.		3.76	13.8	56.4	90.1	100	80.2
%CV		6.6	4.7	3.9	6.4	7.2	6.0
%Theoretical		95.0	97.7	96.7	93.3	92.7	89.3
%Bias		-5.0	-2.3	-3.3	-6.7	-7.3	-10.7
n		18	18	18	12	3	3

~ > 15%Bias



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 7 Quality Control and Dilution Quality Control Sample Data (Between-Analytical Run Precision and Accuracy) for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Assay Date	Run ID	QC A 150 ng/mL	QC B 750 ng/mL	QC C 3750 ng/mL	QC C DF10 3750 ng/mL	QC C DF2 3750 ng/mL	QC C DF5 3750 ng/mL
16-Nov-2013	2	163	714	3570			
		150	745	3520			
19-Nov-2013	6	143	752	3890			
		150	748	3760			
19-Nov-2013	8	145	743	3620			
		146	710	3360			
21-Nov-2013	12	149	730	4010	3740		
		145	651	3620	3610		
					3740		
26-Nov-2013	10	142	758	3850	3580		
		153	787	3680	4090		
					3710		
27-Nov-2013	16	145	737	3680	3560		
		152	802	3740	3620		
					3880		
06-Dec-2013	18	~124	788	3900	3820	~4420	3700
		139	726	4120	3800	3320	3650
					3900	3620	3520
11-Dec-2013	20	166	733	3750			
		141	743	3780			
Mean		147	742	3740	3750	3790	3620
S.D.		9.60	35.3	189	155	569	92.9
%CV		6.5	4.8	5.1	4.1	15.0	2.6
%Theoretical		98.0	98.9	99.7	100.0	101.1	96.5
%Bias		-2.0	-1.1	-0.3	0.0	1.1	-3.5
n		16	16	16	12	3	3

~ > 15%Bias



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 8 Back-calculated Calibration Standard Concentrations for Nicotine

Assay Date	Run ID	STD B 10.0 ng/mL	STD C 20.0 ng/mL	STD D 50.0 ng/mL	STD E 100 ng/mL	STD F 200 ng/mL	STD G 400 ng/mL	STD H 600 ng/mL	STD I 800 ng/mL	STD J 1000 ng/mL
17-Nov-2013	1	9.94	20.0	51.5	101	199	415	576	804	973
17-Nov-2013	3	10.2	19.5	48.3	102	191	415	627	818	960
19-Nov-2013	7	10.1	19.1	52.8	95.6	199	410	601	833	954
21-Nov-2013	13	10.4	18.8	49.4	95.6	190	408	640	844	984
26-Nov-2013	14	9.68	21.1	51.6	101	189	387	612	836	959
27-Nov-2013	9	9.75	21.0	51.1	97.1	189	416	599	785	1020
27-Nov-2013	15	9.79	20.8	50.4	100	201	412	579	807	962
06-Dec-2013	17	10.2	18.9	50.7	100	204	411	620	774	971
11-Dec-2013	19	9.93	20.4	49.3	99.7	200	424	592	792	967
Mean		10.0	20.0	50.6	99.1	196	411	605	810	972
S.D.		0.242	0.915	1.39	2.40	5.93	10.1	21.6	24.3	20.0
%CV		2.4	4.6	2.7	2.4	3.0	2.5	3.6	3.0	2.1
%Bias		0.0	0.0	1.2	-0.9	-2.0	2.8	0.8	1.3	-2.8
n		9	9	9	9	9	9	9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 9 Back-calculated Calibration Standard Concentrations for Cotinine

Assay Date	Run ID	STD B 10.0 ng/mL	STD C 20.0 ng/mL	STD D 50.0 ng/mL	STD E 100 ng/mL	STD F 200 ng/mL	STD G 400 ng/mL	STD H 600 ng/mL	STD I 800 ng/mL	STD J 1000 ng/mL
17-Nov-2013	1	9.94	20.0	50.5	103	202	409	575	793	978
17-Nov-2013	3	9.91	20.4	49.0	103	198	423	616	786	923
19-Nov-2013	7	10.1	19.6	51.1	93.9	207	410	598	818	969
21-Nov-2013	13	10.2	19.6	46.8	104	195	408	593	796	1040
26-Nov-2013	14	9.97	20.2	49.6	101	194	403	585	844	985
27-Nov-2013	9	9.99	20.0	50.4	102	189	406	569	847	1010
27-Nov-2013	15	9.98	20.5	46.4	103	197	411	629	799	961
06-Dec-2013	17	9.94	20.2	50.5	99.6	196	383	615	821	1000
11-Dec-2013	19	9.81	20.7	50.1	102	195	411	589	816	955
Mean		9.98	20.1	49.4	101	197	407	597	813	980
S.D.		0.112	0.377	1.69	3.06	5.10	10.6	20.0	21.9	34.1
%CV		1.1	1.9	3.4	3.0	2.6	2.6	3.4	2.7	3.5
%Bias		-0.2	0.5	-1.2	1.0	-1.5	1.8	-0.5	1.6	-2.0
n		9	9	9	9	9	9	9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 10 Back-calculated Calibration Standard Concentrations for *trans*-3'-Hydroxycotinine

Assay Date	Run ID	STD B 10.0 ng/mL	STD C 20.0 ng/mL	STD D 50.0 ng/mL	STD E 100 ng/mL	STD F 200 ng/mL	STD G 400 ng/mL	STD H 600 ng/mL	STD I 800 ng/mL	STD J 1000 ng/mL
17-Nov-2013	1	9.70	21.3	49.4	100	201	394	585	822	982
17-Nov-2013	3	9.99	20.1	50.1	99.9	199	407	597	797	994
19-Nov-2013	7	9.95	19.9	52.4	98.8	191	408	588	808	1010
21-Nov-2013	13	10.2	19.8	46.8	98.9	202	414	624	801	983
26-Nov-2013	14	9.94	19.8	52.7	101	194	408	603	788	971
27-Nov-2013	9	9.81	20.3	51.9	109	182	402	577	792	1010
27-Nov-2013	15	9.71	20.8	50.9	108	191	403	582	802	961
06-Dec-2013	17	9.96	20.0	50.7	102	203	401	589	778	1000
11-Dec-2013	19	9.93	20.5	48.9	99.5	193	398	603	842	988
Mean		9.91	20.3	50.4	102	195	404	594	803	989
S.D.		0.154	0.509	1.88	3.88	6.81	6.03	14.3	19.1	16.7
%CV		1.6	2.5	3.7	3.8	3.5	1.5	2.4	2.4	1.7
%Bias		-0.9	1.5	0.8	2.0	-2.5	1.0	-1.0	0.4	-1.1
n		9	9	9	9	9	9	9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 11 Back-calculated Calibration Standard Concentrations for Nicotine-*N*-Glucuronide

Assay Date	Run ID	STD B 10.0 ng/mL	STD C 20.0 ng/mL	STD D 50.0 ng/mL	STD E 100 ng/mL	STD F 200 ng/mL	STD G 400 ng/mL	STD H 600 ng/mL	STD I 800 ng/mL	STD J 1000 ng/mL
16-Nov-2013	2	9.68	21.2	51.3	98.4	194	405	595	783	1010
17-Nov-2013	4	9.81	20.7	49.5	106	191	411	595	792	969
19-Nov-2013	6	10.0	19.7	51.5	99.9	201	415	576	781	1010
19-Nov-2013	8	10.1	19.5	51.5	102	195	411	575	800	1000
21-Nov-2013	12	10.2	19.7	47.2	95.7	203	447	606	784	968
26-Nov-2013	10	9.85	20.2	52.7	102	179	420	595	777	1020
27-Nov-2013	16	10.0	19.9	50.2	103	185	396	602	821	1030
06-Dec-2013	18	9.49	21.5	51.5	110	200	388	551	781	980
11-Dec-2013	20	9.71	20.9	51.4	104	197	385	595	793	985
Mean		9.87	20.4	50.8	102	194	409	588	790	997
S.D.		0.225	0.730	1.61	4.20	7.83	18.7	17.3	13.6	22.4
%CV		2.3	3.6	3.2	4.1	4.0	4.6	2.9	1.7	2.2
%Bias		-1.3	2.0	1.6	2.0	-3.0	2.3	-2.0	-1.3	-0.3
n		9	9	9	9	9	9	9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 12 Back-calculated Calibration Standard Concentrations for Cotinine -*N*-Glucuronide

Assay Date	Run ID	STD B 20.0 ng/mL	STD C 40.0 ng/mL	STD D 100 ng/mL	STD E 200 ng/mL	STD F 400 ng/mL	STD G 800 ng/mL	STD H 1200 ng/mL	STD I 1600 ng/mL	STD J 2000 ng/mL
16-Nov-2013	2	19.1	44.2	97.9	197	385	820	1230	1570	1970
17-Nov-2013	4	20.4	38.2	101	197	418	820	1210	1600	1920
19-Nov-2013	6	21.1	35.7	99.4	202	406	821	1200	1610	2000
19-Nov-2013	8	20.2	39.1	100	190	423	798	1260	1620	1890
21-Nov-2013	12	19.8	40.4	102	195	419	822	1220	1630	1790
26-Nov-2013	10	19.2	44.1	94.8	192	407	816	1190	1650	1940
27-Nov-2013	16	20.0	39.9	102	195	395	825	1200	1510	2080
06-Dec-2013	18	19.0	44.0	97.9	208	408	822	1220	1530	1820
11-Dec-2013	20	19.6	42.1	99.1	186	410	839	1190	1590	1970
Mean		19.8	40.9	99.3	196	408	820	1210	1590	1930
S.D.		0.687	2.98	2.30	6.48	12.0	10.6	22.4	46.1	89.5
%CV		3.5	7.3	2.3	3.3	2.9	1.3	1.9	2.9	4.6
%Bias		-1.0	2.3	-0.7	-2.0	2.0	2.5	0.8	-0.6	-3.5
n		9	9	9	9	9	9	9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 13 Back-calculated Calibration Standard Concentrations for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Assay Date	Run ID	STD B 50.0 ng/mL	STD C 100 ng/mL	STD D 250 ng/mL	STD E 500 ng/mL	STD F 1000 ng/mL	STD G 2000 ng/mL	STD H 3000 ng/mL	STD I 4000 ng/mL	STD J 5000 ng/mL
16-Nov-2013	2	48.1	106	253	521	1040	2100	2730	3960	4670
19-Nov-2013	6	49.6	103	240	488	1020	2090	3090	3940	4820
19-Nov-2013	8	49.7	102	247	485	995	2050	3010	3970	5060
21-Nov-2013	12	49.8	101	240	512	1070	2070	3030	4000	4460
26-Nov-2013	10	49.3	104	248	491	929	2110	3120	3960	4940
27-Nov-2013	16	49.1	104	245	484	1080	2030	2960	3830	4940
06-Dec-2013	18	48.9	103	262	482	1030	2030	2690	4150	4990
11-Dec-2013	20	50.9	98.8	230	509	1020	2070	3080	3890	5020
Mean		49.4	103	246	497	1020	2070	2960	3960	4860
S.D.		0.808	2.17	9.55	15.1	47.0	30.4	165	92.5	205
%CV		1.6	2.1	3.9	3.0	4.6	1.5	5.6	2.3	4.2
%Bias		-1.2	3.0	-1.6	-0.6	2.0	3.5	-1.3	-1.0	-2.8
n		8	8	8	8	8	8	8	8	8



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 14 Standard Curve Parameters for Nicotine

Assay Date	Run ID	Slope	Intercept	R-Squared
17-Nov-2013	1	0.0203550319	0.00815787897	0.9992
17-Nov-2013	3	0.0207305971	-0.00281031713	0.9984
19-Nov-2013	7	0.0210018483	0.000547120200	0.9981
21-Nov-2013	13	0.0215029896	-0.00451935803	0.9972
26-Nov-2013	14	0.0212739240	-0.0253022439	0.9978
27-Nov-2013	9	0.0211552099	-0.0108209440	0.9984
27-Nov-2013	15	0.0212039493	0.00687856850	0.9991
06-Dec-2013	17	0.0206242330	0.0230370138	0.9987
11-Dec-2013	19	0.0217143736	-0.0125958232	0.9991
Mean		0.0210624619	-0.00193645609	0.9984
S.D.		0.000432825115	0.0139436092	0.0007
%CV		2.1	-720.1	0.1
n		9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 15 Standard Curve Parameters for Cotinine

Assay Date	Run ID	Slope	Intercept	R-Squared
17-Nov-2013	1	0.0281908006	0.0138708876	0.9993
17-Nov-2013	3	0.0284180315	0.0135240227	0.9980
19-Nov-2013	7	0.0285010043	0.0250979094	0.9987
21-Nov-2013	13	0.0206974475	0.0142036346	0.9985
26-Nov-2013	14	0.0203771931	0.0199062401	0.9992
27-Nov-2013	9	0.0203697787	0.00548516306	0.9984
27-Nov-2013	15	0.0210119506	0.0191630541	0.9981
06-Dec-2013	17	0.0196143928	-0.000215428604	0.9994
11-Dec-2013	19	0.0202528697	0.0122556897	0.9990
Mean		0.0230481632	0.0136990192	0.9987
S.D.		0.00400936368	0.00759767445	0.0005
%CV		17.4	55.5	0.1
n		9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 16 Standard Curve Parameters for *trans*-3'-Hydroxycotinine

Assay Date	Run ID	Slope	Intercept	R-Squared
17-Nov-2013	1	0.00716877100	0.00643553069	0.9988
17-Nov-2013	3	0.00714139267	0.00306584368	0.9999
19-Nov-2013	7	0.00715232500	-0.00530625094	0.9991
21-Nov-2013	13	0.00715902722	0.0204262481	0.9988
26-Nov-2013	14	0.00712242707	0.00325759276	0.9991
27-Nov-2013	9	0.00696618546	0.0101027621	0.9968
27-Nov-2013	15	0.00726252217	0.00985530376	0.9978
06-Dec-2013	17	0.00692901278	0.00894190391	0.9997
11-Dec-2013	19	0.00725483854	0.00722384800	0.9991
Mean		0.00712850021	0.00711142023	0.9988
S.D.		0.000113682082	0.00691916753	0.0010
%CV		1.6	97.3	0.1
n		9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 17 Standard Curve Parameters for Nicotine-*N*-Glucuronide

Assay Date	Run ID	Slope	Intercept	R-Squared
16-Nov-2013	2	0.0744768721	-0.0228553628	0.9988
17-Nov-2013	4	0.0703028629	0.00113999234	0.9986
19-Nov-2013	6	0.0696405942	0.0286785766	0.9992
19-Nov-2013	8	0.0720970233	0.0558661199	0.9992
21-Nov-2013	12	0.0709212492	0.0653450131	0.9966
26-Nov-2013	10	0.0710106661	0.0532396871	0.9970
27-Nov-2013	16	0.0713079012	0.0402192709	0.9986
06-Dec-2013	18	0.119809827	-0.0318766156	0.9955
11-Dec-2013	20	0.0744454331	-0.0204713810	0.9988
Mean		0.0771124921	0.0188094778	0.9980
S.D.		0.0161002111	0.0378156780	0.0013
%CV		20.9	201.0	0.1
n		9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 18 Standard Curve Parameters for Cotinine-*N*-Glucuronide

Assay Date	Run ID	Slope	Intercept	R-Squared
16-Nov-2013	2	0.00270756055	0.00358522654	0.9973
17-Nov-2013	4	0.00271248394	0.00245605528	0.9988
19-Nov-2013	6	0.00270055166	0.00192725703	0.9975
19-Nov-2013	8	0.00271491236	0.0121829346	0.9981
21-Nov-2013	12	0.00275927107	0.0138229277	0.9975
26-Nov-2013	10	0.00273767354	0.0150664242	0.9969
27-Nov-2013	16	0.00280484062	-0.00180776773	0.9990
06-Dec-2013	18	0.00438512557	0.0247708876	0.9958
11-Dec-2013	20	0.00291580591	0.00328225038	0.9981
Mean		0.00293758058	0.00836513284	0.9977
S.D.		0.000547103646	0.00856558358	0.0010
%CV		18.6	102.4	0.1
n		9	9	9



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 19 Standard Curve Parameters for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Assay Date	Run ID	Slope	Intercept	R-Squared
16-Nov-2013	2	0.0150759263	-0.0501300035	0.9963
19-Nov-2013	6	0.0149854834	0.0341824247	0.9987
19-Nov-2013	8	0.0152186749	-0.0421471511	0.9996
21-Nov-2013	12	0.0151741211	0.0202487153	0.9967
26-Nov-2013	10	0.0148990725	-0.00453731035	0.9981
27-Nov-2013	16	0.0149522391	-0.00835697062	0.9980
06-Dec-2013	18	0.00836845836	0.133733986	0.9970
11-Dec-2013	20	0.0147502663	0.116910647	0.9984
Mean		0.0141780302	0.0249880422	0.9979
S.D.		0.00235223957	0.0681552165	0.0011
%CV		16.6	272.8	0.1
n		8	8	8



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 20 Study Sample Concentrations for Nicotine

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	1	0010	-1	0	354	1	OK		Nicotine
05112160000002	1	0010	0	1	296	1	OK		Nicotine
05112160000003	1	0010	1	2	17.3	1	OK		Nicotine
05112160000004	1	0010	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000005	1	0010	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000006	1	0010	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000007	1	0010	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000008	1	0013	-1	0	443	1	OK		Nicotine
05112160000009	9	0013	0	1	1770	1	OK		Nicotine
05112160000010	1	0013	1	2	29.2	1	OK		Nicotine
05112160000011	1	0013	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000012	1	0013	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000013	1	0013	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000014	1	0013	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000015	1	0015	-1	0	783	1	OK		Nicotine
05112160000016	1	0015	0	1	418	1	OK		Nicotine
05112160000017	1	0015	1	2	16.8	1	OK		Nicotine
05112160000018	1	0015	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000019	1	0015	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000020	1	0015	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000021	1	0015	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000022	9	0017	-1	0	1180	1	OK		Nicotine
05112160000023	1	0017	0	1	729	1	OK		Nicotine
05112160000024	1	0017	1	2	58.7	1	OK		Nicotine
05112160000025	1	0017	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	1	0017	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000027	1	0017	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000028	1	0017	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000029	1	0028	-1	0	292	1	OK		Nicotine
05112160000030	1	0028	0	1	701	1	OK		Nicotine
05112160000031	1	0028	1	2	30.2	1	OK		Nicotine
05112160000032	1	0028	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000033	1	0028	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000034	1	0028	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000035	1	0028	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000036	1	0049	-1	0	861	1	OK		Nicotine
05112160000037	1	0049	0	1	380	1	OK		Nicotine
05112160000038	1	0049	1	2	97.4	1	OK		Nicotine
05112160000039	1	0049	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000040	1	0049	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000041	1	0049	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000042	1	0049	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000043	1	0051	-1	0	521	1	OK		Nicotine
05112160000044	1	0051	0	1	558	1	OK		Nicotine
05112160000045	1	0051	1	2	11.8	1	OK		Nicotine
05112160000046	1	0051	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000047	1	0051	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000048	1	0051	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000049	1	0051	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000050	1	0052	-1	0	624	1	OK		Nicotine
05112160000051	9	0052	0	1	1100	1	OK		Nicotine
05112160000052	1	0052	1	2	37.3	1	OK		Nicotine
05112160000053	1	0052	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000054	1	0052	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000055	1	0052	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000056	1	0052	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000057	1	0062	-1	0	449	1	OK		Nicotine
05112160000058	1	0062	0	1	717	1	OK		Nicotine
05112160000059	1	0062	1	2	30.6	1	OK		Nicotine
05112160000060	1	0062	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000061	1	0062	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000062	1	0062	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000063	1	0062	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000064	3	0063	-1	0	614	1	OK		Nicotine
05112160000065	3	0063	0	1	728	1	OK		Nicotine
05112160000066	3	0063	1	2	18.3	1	OK		Nicotine
05112160000067	3	0063	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000068	3	0063	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000069	3	0063	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000070	3	0063	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000071	3	0071	-1	0	768	1	OK		Nicotine
05112160000072	3	0071	0	1	825	1	OK		Nicotine
05112160000073	3	0071	1	2	111	1	OK		Nicotine
05112160000074	3	0071	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000075	3	0071	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000076	3	0071	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000077	3	0071	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000078	3	0076	-1	0	392	1	OK		Nicotine
05112160000079	3	0076	0	1	523	1	OK		Nicotine
05112160000080	3	0076	1	2	45.1	1	OK		Nicotine
05112160000081	3	0076	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000082	3	0076	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000083	3	0076	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000084	3	0076	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000085	3	0086	-1	0	944	1	OK		Nicotine
05112160000086	13	0086	0	1	1080	1	OK		Nicotine
05112160000087	3	0086	1	2	48.7	1	OK		Nicotine
05112160000088	3	0086	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000089	3	0086	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000090	3	0086	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000091	3	0086	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000092	3	0104	-1	0	231	1	OK		Nicotine
05112160000093	3	0104	0	1	426	1	OK		Nicotine
05112160000094	3	0104	1	2	BLQ<(10.0)	1	OK		Nicotine
05112160000095	3	0104	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000096	3	0104	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000097	3	0104	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000098	3	0104	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000099	3	0114	-1	0	241	1	OK		Nicotine
05112160000100	3	0114	0	1	468	1	OK		Nicotine
05112160000101	3	0114	1	2	41.9	1	OK		Nicotine
05112160000102	3	0114	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000103	3	0114	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000104	3	0114	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000105	3	0114	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000106	3	0123	-1	0	178	1	OK		Nicotine
05112160000107	3	0123	0	1	350	1	OK		Nicotine
05112160000108	3	0123	1	2	16.6	1	OK		Nicotine
05112160000109	3	0123	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000110	3	0123	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000111	3	0123	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000112	3	0123	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000113	3	0127	-1	0	660	1	OK		Nicotine
05112160000114	3	0127	0	1	563	1	OK		Nicotine
05112160000115	3	0127	1	2	23.2	1	OK		Nicotine
05112160000116	3	0127	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000117	3	0127	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000118	3	0127	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000119	3	0127	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000120	3	0128	-1	0	215	1	OK		Nicotine
05112160000121	3	0128	0	1	696	1	OK		Nicotine
05112160000122	3	0128	1	2	57.3	1	OK		Nicotine
05112160000123	3	0128	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000124	3	0128	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000125	3	0128	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000126	3	0128	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000127	14	0133	-1	0	784	1	OK		Nicotine
05112160000128	14	0133	0	1	580	1	OK		Nicotine
05112160000129	14	0133	1	2	38.8	1	OK		Nicotine
05112160000130	14	0133	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000131	14	0133	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000132	14	0133	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000133	14	0133	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000134	14	0137	-1	0	488	1	OK		Nicotine
05112160000135	14	0137	0	1	330	1	OK		Nicotine
05112160000136	14	0137	1	2	22.9	1	OK		Nicotine
05112160000137	14	0137	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000138	14	0137	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000139	14	0137	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000140	14	0137	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000141	14	0145	-1	0	265	1	OK		Nicotine
05112160000142	14	0145	0	1	658	1	OK		Nicotine
05112160000143	14	0145	1	2	46.9	1	OK		Nicotine
05112160000144	14	0145	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000145	14	0145	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000146	14	0145	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000147	14	0145	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000148	14	0150	-1	0	901	1	OK		Nicotine
05112160000149	15	0150	0	1	1300	1	OK		Nicotine
05112160000150	14	0150	1	2	152	1	OK		Nicotine
05112160000151	14	0150	2	3	12.3	1	OK		Nicotine
05112160000152	14	0150	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000153	14	0150	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000154	14	0150	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000155	14	0169	-1	0	215	1	OK		Nicotine
05112160000156	14	0169	0	1	294	1	OK		Nicotine
05112160000157	14	0169	1	2	16.4	1	OK		Nicotine
05112160000158	14	0169	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000159	14	0169	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000160	14	0169	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000161	14	0169	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000162	14	0185	-1	0	453	1	OK		Nicotine
05112160000163	14	0185	0	1	325	1	OK		Nicotine
05112160000164	14	0185	1	2	25.0	1	OK		Nicotine
05112160000165	14	0185	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000166	14	0185	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000167	14	0185	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000168	14	0185	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000169	14	0197	-1	0	307	1	OK		Nicotine
05112160000170	15	0197	0	1	2200	1	OK		Nicotine
05112160000171	14	0197	1	2	95.9	1	OK		Nicotine
05112160000172	14	0197	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000173	14	0197	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000174	14	0197	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000175	14	0197	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000176	14	0203	-1	0	394	1	OK		Nicotine
05112160000177	14	0203	0	1	609	1	OK		Nicotine
05112160000178	14	0203	1	2	25.3	1	OK		Nicotine
05112160000179	14	0203	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000180	14	0203	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000181	14	0203	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000182	14	0203	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000183	14	0218	-1	0	358	1	OK		Nicotine
05112160000184	14	0218	0	1	987	1	OK		Nicotine
05112160000185	14	0218	1	2	27.5	1	OK		Nicotine
05112160000186	14	0218	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000187	14	0218	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000188	14	0218	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000189	14	0218	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000190	7	0240	-1	0	362	1	OK		Nicotine
05112160000191	9	0240	0	1	1230	1	OK		Nicotine
05112160000192	7	0240	1	2	BLQ<(10.0)	1	OK		Nicotine
05112160000193	19	0240	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000194	7	0240	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000195	7	0240	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000196	7	0240	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000197	9	0249	-1	0	1300	1	OK		Nicotine
05112160000198	9	0249	0	1	1850	1	OK		Nicotine
05112160000199	7	0249	1	2	68.2	1	OK		Nicotine
05112160000200	7	0249	2	3	11.4	1	OK		Nicotine
05112160000201	7	0249	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000202	7	0249	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000203	7	0249	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000204	7	0251	-1	0	264	1	OK		Nicotine
05112160000205	7	0251	0	1	400	1	OK		Nicotine
05112160000206	7	0251	1	2	BLQ<(10.0)	1	OK		Nicotine
05112160000207	7	0251	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000208	7	0251	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000209	7	0251	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000210	7	0251	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000211	7	0252	-1	0	355	1	OK		Nicotine
05112160000212	7	0252	0	1	646	1	OK		Nicotine
05112160000213	7	0252	1	2	14.8	1	OK		Nicotine
05112160000214	7	0252	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000215	7	0252	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000216	7	0252	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000217	7	0252	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000218	7	0265	-1	0	521	1	OK		Nicotine
05112160000219	7	0265	0	1	917	1	OK		Nicotine
05112160000220	7	0265	1	2	39.8	1	OK		Nicotine
05112160000221	7	0265	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000222	7	0265	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000223	7	0265	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000224	7	0265	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000225	7	0266	-1	0	300	1	OK		Nicotine
05112160000226	7	0266	0	1	437	1	OK		Nicotine
05112160000227	7	0266	1	2	21.2	1	OK		Nicotine
05112160000228	7	0266	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000229	7	0266	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000230	7	0266	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000231	7	0266	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000232	7	0273	-1	0	227	1	OK		Nicotine
05112160000233	7	0273	0	1	706	1	OK		Nicotine
05112160000234	7	0273	1	2	19.9	1	OK		Nicotine
05112160000235	7	0273	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000236	7	0273	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000237	7	0273	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000238	7	0273	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000239	7	0289	-1	0	885	1	OK		Nicotine
05112160000240	7	0289	0	1	716	1	OK		Nicotine
05112160000241	7	0289	1	2	19.6	1	OK		Nicotine
05112160000242	7	0289	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000243	7	0289	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000244	7	0289	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000245	7	0289	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000246	7	0292	-1	0	464	1	OK		Nicotine
05112160000247	7	0292	0	1	439	1	OK		Nicotine
05112160000248	7	0292	1	2	159	1	OK		Nicotine
05112160000249	7	0292	2	3	BLQ<(10.0)	1	OK		Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000250	7	0292	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000251	7	0292	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000252	7	0292	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000253	17	0306	-1	0	1760	1	OK		Nicotine
05112160000254	17	0306	0	1	1350	1	OK		Nicotine
05112160000255	9	0306	1	2	92.3	1	OK		Nicotine
05112160000256	9	0306	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000257	9	0306	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000258	9	0306	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000259	9	0306	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000260	9	0317	-1	0	337	1	OK		Nicotine
05112160000261	9	0317	0	1	581	1	OK		Nicotine
05112160000262	9	0317	1	2	26.0	1	OK		Nicotine
05112160000263	9	0317	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000264	9	0317	3	4	BLQ<(10.0)	1	OK		Nicotine
05112160000265	9	0317	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000266	9	0317	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000267	9	0325	-1	0	525	1	OK		Nicotine
05112160000268	17	0325	0	1	1960	1	OK		Nicotine
05112160000269	9	0325	1	2	133	1	OK		Nicotine
05112160000270	9	0325	2	3	BLQ<(10.0)	1	OK		Nicotine
05112160000271	9	0325	3	4	13.5	1	OK		Nicotine
05112160000272	9	0325	4	5	BLQ<(10.0)	1	OK		Nicotine
05112160000273	9	0325	5	6	BLQ<(10.0)	1	OK		Nicotine
05112160000274		0211	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000275		0211	0	1	.	1	Other	Analysis not required	Nicotine
05112160000554		0211	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000555		0211	0	1	.	2	Other	Analysis not required	Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000561		0242	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000562		0242	0	1	.	2	Other	Analysis not required	Nicotine
05112160000568		0242	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000569		0242	0	1	.	1	Other	Analysis not required	Nicotine
05112160000575		0245	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000576		0245	0	1	.	2	Other	Analysis not required	Nicotine
05112160000582		0245	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000583		0245	0	1	.	1	Other	Analysis not required	Nicotine
05112160000589		0247	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000590		0247	0	1	.	2	Other	Analysis not required	Nicotine
05112160000596		0247	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000597		0247	0	1	.	1	Other	Analysis not required	Nicotine
05112160000603		0288	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000604		0288	0	1	.	2	Other	Analysis not required	Nicotine
05112160000610		0288	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000611		0288	0	1	.	1	Other	Analysis not required	Nicotine
05112160000617		0299	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000618		0299	0	1	.	2	Other	Analysis not required	Nicotine
05112160000624		0299	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000625		0299	0	1	.	1	Other	Analysis not required	Nicotine
05112160000631		0269	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000632		0269	0	1	.	2	Other	Analysis not required	Nicotine
05112160000638		0269	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000639		0269	0	1	.	1	Other	Analysis not required	Nicotine
05112160000645		0309	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000646		0309	0	1	.	2	Other	Analysis not required	Nicotine
05112160000652		0309	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000653		0309	0	1	.	1	Other	Analysis not required	Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000659		0312	-1	0	.	2	Other	Analysis not required	Nicotine
05112160000660		0312	0	1	.	2	Other	Analysis not required	Nicotine
05112160000666		0312	-1	0	.	1	Other	Analysis not required	Nicotine
05112160000667		0312	0	1	.	1	Other	Analysis not required	Nicotine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 21 Study Sample Concentrations for Cotinine

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	9	0010	-1	0	1280	1	OK		Cotinine
05112160000002	1	0010	0	1	480	1	OK		Cotinine
05112160000003	1	0010	1	2	406	1	OK		Cotinine
05112160000004	1	0010	2	3	132	1	OK		Cotinine
05112160000005	1	0010	3	4	45.6	1	OK		Cotinine
05112160000006	1	0010	4	5	20.8	1	OK		Cotinine
05112160000007	1	0010	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000008	9	0013	-1	0	1330	1	OK		Cotinine
05112160000009	1	0013	0	1	966	1	OK		Cotinine
05112160000010	1	0013	1	2	639	1	OK		Cotinine
05112160000011	1	0013	2	3	299	1	OK		Cotinine
05112160000012	1	0013	3	4	111	1	OK		Cotinine
05112160000013	1	0013	4	5	28.8	1	OK		Cotinine
05112160000014	1	0013	5	6	15.6	1	OK		Cotinine
05112160000015	9	0015	-1	0	1050	1	OK		Cotinine
05112160000016	1	0015	0	1	964	1	OK		Cotinine
05112160000017	1	0015	1	2	662	1	OK		Cotinine
05112160000018	1	0015	2	3	234	1	OK		Cotinine
05112160000019	1	0015	3	4	63.6	1	OK		Cotinine
05112160000020	1	0015	4	5	24.3	1	OK		Cotinine
05112160000021	1	0015	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000022	9	0017	-1	0	1130	1	OK		Cotinine
05112160000023	1	0017	0	1	737	1	OK		Cotinine
05112160000024	1	0017	1	2	554	1	OK		Cotinine
05112160000025	1	0017	2	3	205	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	1	0017	3	4	46.6	1	OK		Cotinine
05112160000027	1	0017	4	5	20.1	1	OK		Cotinine
05112160000028	1	0017	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000029	1	0028	-1	0	847	1	OK		Cotinine
05112160000030	1	0028	0	1	833	1	OK		Cotinine
05112160000031	1	0028	1	2	383	1	OK		Cotinine
05112160000032	1	0028	2	3	148	1	OK		Cotinine
05112160000033	1	0028	3	4	48.1	1	OK		Cotinine
05112160000034	1	0028	4	5	17.6	1	OK		Cotinine
05112160000035	1	0028	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000036	9	0049	-1	0	1260	1	OK		Cotinine
05112160000037	1	0049	0	1	707	1	OK		Cotinine
05112160000038	1	0049	1	2	969	1	OK		Cotinine
05112160000039	1	0049	2	3	333	1	OK		Cotinine
05112160000040	1	0049	3	4	136	1	OK		Cotinine
05112160000041	1	0049	4	5	59.3	1	OK		Cotinine
05112160000042	1	0049	5	6	16.3	1	OK		Cotinine
05112160000043	9	0051	-1	0	1070	1	OK		Cotinine
05112160000044	1	0051	0	1	832	1	OK		Cotinine
05112160000045	1	0051	1	2	406	1	OK		Cotinine
05112160000046	1	0051	2	3	112	1	OK		Cotinine
05112160000047	1	0051	3	4	41.7	1	OK		Cotinine
05112160000048	1	0051	4	5	13.4	1	OK		Cotinine
05112160000049	1	0051	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000050	9	0052	-1	0	1510	1	OK		Cotinine
05112160000051	9	0052	0	1	1230	1	OK		Cotinine
05112160000052	1	0052	1	2	741	1	OK		Cotinine
05112160000053	1	0052	2	3	296	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000054	1	0052	3	4	98.9	1	OK		Cotinine
05112160000055	1	0052	4	5	40.9	1	OK		Cotinine
05112160000056	1	0052	5	6	20.3	1	OK		Cotinine
05112160000057	1	0062	-1	0	855	1	OK		Cotinine
05112160000058	1	0062	0	1	750	1	OK		Cotinine
05112160000059	1	0062	1	2	453	1	OK		Cotinine
05112160000060	1	0062	2	3	123	1	OK		Cotinine
05112160000061	1	0062	3	4	40.1	1	OK		Cotinine
05112160000062	1	0062	4	5	17.0	1	OK		Cotinine
05112160000063	1	0062	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000064	13	0063	-1	0	1070	1	OK		Cotinine
05112160000065	3	0063	0	1	937	1	OK		Cotinine
05112160000066	3	0063	1	2	444	1	OK		Cotinine
05112160000067	3	0063	2	3	100	1	OK		Cotinine
05112160000068	3	0063	3	4	45.5	1	OK		Cotinine
05112160000069	3	0063	4	5	12.7	1	OK		Cotinine
05112160000070	3	0063	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000071	13	0071	-1	0	1800	1	OK		Cotinine
05112160000072	13	0071	0	1	1680	1	OK		Cotinine
05112160000073	13	0071	1	2	1180	1	OK		Cotinine
05112160000074	3	0071	2	3	285	1	OK		Cotinine
05112160000075	3	0071	3	4	86.9	1	OK		Cotinine
05112160000076	3	0071	4	5	37.6	1	OK		Cotinine
05112160000077	3	0071	5	6	17.6	1	OK		Cotinine
05112160000078	3	0076	-1	0	619	1	OK		Cotinine
05112160000079	3	0076	0	1	661	1	OK		Cotinine
05112160000080	3	0076	1	2	762	1	OK		Cotinine
05112160000081	3	0076	2	3	247	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000082	3	0076	3	4	131	1	OK		Cotinine
05112160000083	3	0076	4	5	14.1	1	OK		Cotinine
05112160000084	3	0076	5	6	18.3	1	OK		Cotinine
05112160000085	13	0086	-1	0	1720	1	OK		Cotinine
05112160000086	13	0086	0	1	1510	1	OK		Cotinine
05112160000087	3	0086	1	2	927	1	OK		Cotinine
05112160000088	3	0086	2	3	283	1	OK		Cotinine
05112160000089	3	0086	3	4	140	1	OK		Cotinine
05112160000090	3	0086	4	5	62.5	1	OK		Cotinine
05112160000091	3	0086	5	6	31.2	1	OK		Cotinine
05112160000092	3	0104	-1	0	551	1	OK		Cotinine
05112160000093	3	0104	0	1	688	1	OK		Cotinine
05112160000094	3	0104	1	2	299	1	OK		Cotinine
05112160000095	3	0104	2	3	67.1	1	OK		Cotinine
05112160000096	3	0104	3	4	18.3	1	OK		Cotinine
05112160000097	3	0104	4	5	BLQ<(10.0)	1	OK		Cotinine
05112160000098	3	0104	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000099	3	0114	-1	0	649	1	OK		Cotinine
05112160000100	3	0114	0	1	885	1	OK		Cotinine
05112160000101	3	0114	1	2	747	1	OK		Cotinine
05112160000102	3	0114	2	3	238	1	OK		Cotinine
05112160000103	3	0114	3	4	96.1	1	OK		Cotinine
05112160000104	3	0114	4	5	31.6	1	OK		Cotinine
05112160000105	3	0114	5	6	13.0	1	OK		Cotinine
05112160000106	3	0123	-1	0	554	1	OK		Cotinine
05112160000107	3	0123	0	1	771	1	OK		Cotinine
05112160000108	3	0123	1	2	514	1	OK		Cotinine
05112160000109	3	0123	2	3	206	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000110	3	0123	3	4	103	1	OK		Cotinine
05112160000111	3	0123	4	5	31.9	1	OK		Cotinine
05112160000112	3	0123	5	6	12.5	1	OK		Cotinine
05112160000113	13	0127	-1	0	1660	1	OK		Cotinine
05112160000114	3	0127	0	1	510	1	OK		Cotinine
05112160000115	3	0127	1	2	295	1	OK		Cotinine
05112160000116	3	0127	2	3	197	1	OK		Cotinine
05112160000117	3	0127	3	4	97.2	1	OK		Cotinine
05112160000118	3	0127	4	5	45.5	1	OK		Cotinine
05112160000119	3	0127	5	6	22.8	1	OK		Cotinine
05112160000120	13	0128	-1	0	1390	1	OK		Cotinine
05112160000121	13	0128	0	1	1050	1	OK		Cotinine
05112160000122	3	0128	1	2	612	1	OK		Cotinine
05112160000123	3	0128	2	3	242	1	OK		Cotinine
05112160000124	3	0128	3	4	96.9	1	OK		Cotinine
05112160000125	3	0128	4	5	35.1	1	OK		Cotinine
05112160000126	3	0128	5	6	16.7	1	OK		Cotinine
05112160000127	14	0133	-1	0	786	1	OK		Cotinine
05112160000128	15	0133	0	1	1560	1	OK		Cotinine
05112160000129	15	0133	1	2	1010	1	OK		Cotinine
05112160000130	14	0133	2	3	246	1	OK		Cotinine
05112160000131	14	0133	3	4	69.4	1	OK		Cotinine
05112160000132	14	0133	4	5	24.1	1	OK		Cotinine
05112160000133	14	0133	5	6	11.0	1	OK		Cotinine
05112160000134	14	0137	-1	0	658	1	OK		Cotinine
05112160000135	14	0137	0	1	607	1	OK		Cotinine
05112160000136	14	0137	1	2	415	1	OK		Cotinine
05112160000137	14	0137	2	3	98.8	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000138	14	0137	3	4	38.3	1	OK		Cotinine
05112160000139	14	0137	4	5	BLQ<(10.0)	1	OK		Cotinine
05112160000140	14	0137	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000141	14	0145	-1	0	487	1	OK		Cotinine
05112160000142	14	0145	0	1	461	1	OK		Cotinine
05112160000143	14	0145	1	2	303	1	OK		Cotinine
05112160000144	14	0145	2	3	27.2	1	OK		Cotinine
05112160000145	14	0145	3	4	BLQ<(10.0)	1	OK		Cotinine
05112160000146	14	0145	4	5	BLQ<(10.0)	1	OK		Cotinine
05112160000147	14	0145	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000148	15	0150	-1	0	1950	1	OK		Cotinine
05112160000149	15	0150	0	1	1570	1	OK		Cotinine
05112160000150	15	0150	1	2	998	1	OK		Cotinine
05112160000151	14	0150	2	3	521	1	OK		Cotinine
05112160000152	14	0150	3	4	195	1	OK		Cotinine
05112160000153	14	0150	4	5	107	1	OK		Cotinine
05112160000154	14	0150	5	6	52.6	1	OK		Cotinine
05112160000155	14	0169	-1	0	626	1	OK		Cotinine
05112160000156	14	0169	0	1	479	1	OK		Cotinine
05112160000157	14	0169	1	2	423	1	OK		Cotinine
05112160000158	14	0169	2	3	119	1	OK		Cotinine
05112160000159	14	0169	3	4	43.8	1	OK		Cotinine
05112160000160	14	0169	4	5	11.4	1	OK		Cotinine
05112160000161	14	0169	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000162	15	0185	-1	0	1100	1	OK		Cotinine
05112160000163	14	0185	0	1	881	1	OK		Cotinine
05112160000164	14	0185	1	2	508	1	OK		Cotinine
05112160000165	14	0185	2	3	121	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000166	14	0185	3	4	31.8	1	OK		Cotinine
05112160000167	14	0185	4	5	11.4	1	OK		Cotinine
05112160000168	14	0185	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000169	14	0197	-1	0	654	1	OK		Cotinine
05112160000170	15	0197	0	1	1110	1	OK		Cotinine
05112160000171	14	0197	1	2	539	1	OK		Cotinine
05112160000172	14	0197	2	3	121	1	OK		Cotinine
05112160000173	14	0197	3	4	51.3	1	OK		Cotinine
05112160000174	14	0197	4	5	26.3	1	OK		Cotinine
05112160000175	14	0197	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000176	14	0203	-1	0	787	1	OK		Cotinine
05112160000177	14	0203	0	1	803	1	OK		Cotinine
05112160000178	14	0203	1	2	397	1	OK		Cotinine
05112160000179	14	0203	2	3	132	1	OK		Cotinine
05112160000180	14	0203	3	4	43.6	1	OK		Cotinine
05112160000181	14	0203	4	5	14.2	1	OK		Cotinine
05112160000182	14	0203	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000183	15	0218	-1	0	987	1	OK		Cotinine
05112160000184	15	0218	0	1	1280	1	OK		Cotinine
05112160000185	14	0218	1	2	605	1	OK		Cotinine
05112160000186	14	0218	2	3	204	1	OK		Cotinine
05112160000187	14	0218	3	4	82.9	1	OK		Cotinine
05112160000188	14	0218	4	5	22.2	1	OK		Cotinine
05112160000189	14	0218	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000190	9	0240	-1	0	1150	1	OK		Cotinine
05112160000191	9	0240	0	1	1200	1	OK		Cotinine
05112160000192	7	0240	1	2	141	1	OK		Cotinine
05112160000193		0240	2	3	142	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000194	7	0240	3	4	59.4	1	OK		Cotinine
05112160000195	7	0240	4	5	21.1	1	OK		Cotinine
05112160000196	7	0240	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000197	9	0249	-1	0	1610	1	OK		Cotinine
05112160000198	9	0249	0	1	1830	1	OK		Cotinine
05112160000199	9	0249	1	2	1260	1	OK		Cotinine
05112160000200	7	0249	2	3	316	1	OK		Cotinine
05112160000201	7	0249	3	4	122	1	OK		Cotinine
05112160000202	7	0249	4	5	39.0	1	OK		Cotinine
05112160000203	7	0249	5	6	16.5	1	OK		Cotinine
05112160000204	7	0251	-1	0	929	1	OK		Cotinine
05112160000205	9	0251	0	1	1120	1	OK		Cotinine
05112160000206	7	0251	1	2	515	1	OK		Cotinine
05112160000207	7	0251	2	3	112	1	OK		Cotinine
05112160000208	7	0251	3	4	45.6	1	OK		Cotinine
05112160000209	7	0251	4	5	12.5	1	OK		Cotinine
05112160000210	7	0251	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000211	9	0252	-1	0	1070	1	OK		Cotinine
05112160000212	9	0252	0	1	1250	1	OK		Cotinine
05112160000213	7	0252	1	2	612	1	OK		Cotinine
05112160000214	7	0252	2	3	117	1	OK		Cotinine
05112160000215	7	0252	3	4	36.2	1	OK		Cotinine
05112160000216	7	0252	4	5	BLQ<(10.0)	1	OK		Cotinine
05112160000217	7	0252	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000218	7	0265	-1	0	977	1	OK		Cotinine
05112160000219	9	0265	0	1	1300	1	OK		Cotinine
05112160000220	7	0265	1	2	761	1	OK		Cotinine
05112160000221	7	0265	2	3	212	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000222	7	0265	3	4	95.8	1	OK		Cotinine
05112160000223	7	0265	4	5	37.6	1	OK		Cotinine
05112160000224	7	0265	5	6	10.7	1	OK		Cotinine
05112160000225	15	0266	-1	0	1400	1	OK		Cotinine
05112160000226	15	0266	0	1	1430	1	OK		Cotinine
05112160000227	7	0266	1	2	795	1	OK		Cotinine
05112160000228	7	0266	2	3	154	1	OK		Cotinine
05112160000229	7	0266	3	4	51.1	1	OK		Cotinine
05112160000230	7	0266	4	5	18.7	1	OK		Cotinine
05112160000231	7	0266	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000232	15	0273	-1	0	1190	1	OK		Cotinine
05112160000233	15	0273	0	1	1180	1	OK		Cotinine
05112160000234	7	0273	1	2	742	1	OK		Cotinine
05112160000235	7	0273	2	3	254	1	OK		Cotinine
05112160000236	7	0273	3	4	113	1	OK		Cotinine
05112160000237	7	0273	4	5	35.5	1	OK		Cotinine
05112160000238	7	0273	5	6	13.1	1	OK		Cotinine
05112160000239	7	0289	-1	0	970	1	OK		Cotinine
05112160000240	15	0289	0	1	1060	1	OK		Cotinine
05112160000241	7	0289	1	2	696	1	OK		Cotinine
05112160000242	7	0289	2	3	235	1	OK		Cotinine
05112160000243	7	0289	3	4	84.5	1	OK		Cotinine
05112160000244	7	0289	4	5	28.5	1	OK		Cotinine
05112160000245	7	0289	5	6	13.3	1	OK		Cotinine
05112160000246	15	0292	-1	0	1410	1	OK		Cotinine
05112160000247	15	0292	0	1	1250	1	OK		Cotinine
05112160000248	15	0292	1	2	1540	1	OK		Cotinine
05112160000249	7	0292	2	3	423	1	OK		Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000250	7	0292	3	4	207	1	OK		Cotinine
05112160000251	7	0292	4	5	82.9	1	OK		Cotinine
05112160000252	7	0292	5	6	40.7	1	OK		Cotinine
05112160000253	17	0306	-1	0	1710	1	OK		Cotinine
05112160000254	17	0306	0	1	1640	1	OK		Cotinine
05112160000255	17	0306	1	2	1300	1	OK		Cotinine
05112160000256	9	0306	2	3	521	1	OK		Cotinine
05112160000257	9	0306	3	4	298	1	OK		Cotinine
05112160000258	9	0306	4	5	133	1	OK		Cotinine
05112160000259	9	0306	5	6	76.7	1	OK		Cotinine
05112160000260	9	0317	-1	0	609	1	OK		Cotinine
05112160000261	9	0317	0	1	718	1	OK		Cotinine
05112160000262	9	0317	1	2	392	1	OK		Cotinine
05112160000263	9	0317	2	3	135	1	OK		Cotinine
05112160000264	9	0317	3	4	39.7	1	OK		Cotinine
05112160000265	9	0317	4	5	14.6	1	OK		Cotinine
05112160000266	9	0317	5	6	BLQ<(10.0)	1	OK		Cotinine
05112160000267	17	0325	-1	0	2400	1	OK		Cotinine
05112160000268	17	0325	0	1	2360	1	OK		Cotinine
05112160000269	17	0325	1	2	2510	1	OK		Cotinine
05112160000270	9	0325	2	3	772	1	OK		Cotinine
05112160000271	9	0325	3	4	400	1	OK		Cotinine
05112160000272	9	0325	4	5	130	1	OK		Cotinine
05112160000273	9	0325	5	6	66.5	1	OK		Cotinine
05112160000274		0211	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000275		0211	0	1	.	1	Other	Analysis not required	Cotinine
05112160000554		0211	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000555		0211	0	1	.	2	Other	Analysis not required	Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000561		0242	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000562		0242	0	1	.	2	Other	Analysis not required	Cotinine
05112160000568		0242	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000569		0242	0	1	.	1	Other	Analysis not required	Cotinine
05112160000575		0245	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000576		0245	0	1	.	2	Other	Analysis not required	Cotinine
05112160000582		0245	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000583		0245	0	1	.	1	Other	Analysis not required	Cotinine
05112160000589		0247	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000590		0247	0	1	.	2	Other	Analysis not required	Cotinine
05112160000596		0247	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000597		0247	0	1	.	1	Other	Analysis not required	Cotinine
05112160000603		0288	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000604		0288	0	1	.	2	Other	Analysis not required	Cotinine
05112160000610		0288	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000611		0288	0	1	.	1	Other	Analysis not required	Cotinine
05112160000617		0299	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000618		0299	0	1	.	2	Other	Analysis not required	Cotinine
05112160000624		0299	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000625		0299	0	1	.	1	Other	Analysis not required	Cotinine
05112160000631		0269	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000632		0269	0	1	.	2	Other	Analysis not required	Cotinine
05112160000638		0269	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000639		0269	0	1	.	1	Other	Analysis not required	Cotinine
05112160000645		0309	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000646		0309	0	1	.	2	Other	Analysis not required	Cotinine
05112160000652		0309	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000653		0309	0	1	.	1	Other	Analysis not required	Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000659		0312	-1	0	.	2	Other	Analysis not required	Cotinine
05112160000660		0312	0	1	.	2	Other	Analysis not required	Cotinine
05112160000666		0312	-1	0	.	1	Other	Analysis not required	Cotinine
05112160000667		0312	0	1	.	1	Other	Analysis not required	Cotinine



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 22 Study Sample Concentrations for *trans*-3'-Hydroxycotinine

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	9	0010	-1	0	4180	1	OK		THC
05112160000002	9	0010	0	1	1330	1	OK		THC
05112160000003	9	0010	1	2	1820	1	OK		THC
05112160000004	1	0010	2	3	453	1	OK		THC
05112160000005	1	0010	3	4	146	1	OK		THC
05112160000006	1	0010	4	5	82.3	1	OK		THC
05112160000007	1	0010	5	6	28.2	1	OK		THC
05112160000008	9	0013	-1	0	5130	1	OK		THC
05112160000009	9	0013	0	1	3350	1	OK		THC
05112160000010	9	0013	1	2	1560	1	OK		THC
05112160000011	1	0013	2	3	642	1	OK		THC
05112160000012	1	0013	3	4	254	1	OK		THC
05112160000013	1	0013	4	5	78.7	1	OK		THC
05112160000014	1	0013	5	6	47.7	1	OK		THC
05112160000015	9	0015	-1	0	5670	1	OK		THC
05112160000016	9	0015	0	1	3320	1	OK		THC
05112160000017	9	0015	1	2	2360	1	OK		THC
05112160000018	1	0015	2	3	860	1	OK		THC
05112160000019	1	0015	3	4	187	1	OK		THC
05112160000020	1	0015	4	5	116	1	OK		THC
05112160000021	1	0015	5	6	29.6	1	OK		THC
05112160000022	9	0017	-1	0	1850	1	OK		THC
05112160000023	1	0017	0	1	712	1	OK		THC
05112160000024	1	0017	1	2	896	1	OK		THC
05112160000025	1	0017	2	3	427	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	1	0017	3	4	95.7	1	OK		THC
05112160000027	1	0017	4	5	71.3	1	OK		THC
05112160000028	1	0017	5	6	26.2	1	OK		THC
05112160000029	9	0028	-1	0	3590	1	OK		THC
05112160000030	9	0028	0	1	2700	1	OK		THC
05112160000031	9	0028	1	2	1740	1	OK		THC
05112160000032	1	0028	2	3	804	1	OK		THC
05112160000033	1	0028	3	4	160	1	OK		THC
05112160000034	1	0028	4	5	97.8	1	OK		THC
05112160000035	1	0028	5	6	28.2	1	OK		THC
05112160000036	9	0049	-1	0	3130	1	OK		THC
05112160000037	1	0049	0	1	701	1	OK		THC
05112160000038	9	0049	1	2	2160	1	OK		THC
05112160000039	1	0049	2	3	564	1	OK		THC
05112160000040	1	0049	3	4	232	1	OK		THC
05112160000041	1	0049	4	5	148	1	OK		THC
05112160000042	1	0049	5	6	35.9	1	OK		THC
05112160000043	9	0051	-1	0	2460	1	OK		THC
05112160000044	9	0051	0	1	1650	1	OK		THC
05112160000045	1	0051	1	2	800	1	OK		THC
05112160000046	1	0051	2	3	202	1	OK		THC
05112160000047	1	0051	3	4	68.4	1	OK		THC
05112160000048	1	0051	4	5	25.7	1	OK		THC
05112160000049	1	0051	5	6	14.0	1	OK		THC
05112160000050	9	0052	-1	0	5230	1	OK		THC
05112160000051	9	0052	0	1	3870	1	OK		THC
05112160000052	9	0052	1	2	3690	1	OK		THC
05112160000053	9	0052	2	3	1400	1	OK		THC
05112160000054	1	0052	3	4	278	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000055	1	0052	4	5	152	1	OK		THC
05112160000056	1	0052	5	6	62.0	1	OK		THC
05112160000057	9	0062	-1	0	2150	1	OK		THC
05112160000058	9	0062	0	1	1990	1	OK		THC
05112160000059	9	0062	1	2	1190	1	OK		THC
05112160000060	1	0062	2	3	433	1	OK		THC
05112160000061	1	0062	3	4	118	1	OK		THC
05112160000062	1	0062	4	5	72.2	1	OK		THC
05112160000063	1	0062	5	6	18.3	1	OK		THC
05112160000064	13	0063	-1	0	4110	1	OK		THC
05112160000065	13	0063	0	1	3860	1	OK		THC
05112160000066	13	0063	1	2	3340	1	OK		THC
05112160000067	3	0063	2	3	595	1	OK		THC
05112160000068	3	0063	3	4	263	1	OK		THC
05112160000069	3	0063	4	5	76.1	1	OK		THC
05112160000070	3	0063	5	6	30.5	1	OK		THC
05112160000071	13	0071	-1	0	4240	1	OK		THC
05112160000072	13	0071	0	1	2920	1	OK		THC
05112160000073	13	0071	1	2	2370	1	OK		THC
05112160000074	3	0071	2	3	690	1	OK		THC
05112160000075	3	0071	3	4	187	1	OK		THC
05112160000076	3	0071	4	5	72.7	1	OK		THC
05112160000077	3	0071	5	6	33.1	1	OK		THC
05112160000078	13	0076	-1	0	1250	1	OK		THC
05112160000079	3	0076	0	1	831	1	OK		THC
05112160000080	13	0076	1	2	1920	1	OK		THC
05112160000081	3	0076	2	3	703	1	OK		THC
05112160000082	3	0076	3	4	352	1	OK		THC
05112160000083	3	0076	4	5	35.8	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000084	3	0076	5	6	54.1	1	OK		THC
05112160000085	13	0086	-1	0	4570	1	OK		THC
05112160000086	13	0086	0	1	3310	1	OK		THC
05112160000087	13	0086	1	2	2770	1	OK		THC
05112160000088	3	0086	2	3	874	1	OK		THC
05112160000089	3	0086	3	4	402	1	OK		THC
05112160000090	3	0086	4	5	186	1	OK		THC
05112160000091	3	0086	5	6	110	1	OK		THC
05112160000092	13	0104	-1	0	4430	1	OK		THC
05112160000093	13	0104	0	1	2870	1	OK		THC
05112160000094	13	0104	1	2	1330	1	OK		THC
05112160000095	3	0104	2	3	398	1	OK		THC
05112160000096	3	0104	3	4	95.6	1	OK		THC
05112160000097	3	0104	4	5	31.6	1	OK		THC
05112160000098	3	0104	5	6	12.0	1	OK		THC
05112160000099	13	0114	-1	0	1700	1	OK		THC
05112160000100	13	0114	0	1	2440	1	OK		THC
05112160000101	13	0114	1	2	3000	1	OK		THC
05112160000102	3	0114	2	3	916	1	OK		THC
05112160000103	3	0114	3	4	307	1	OK		THC
05112160000104	3	0114	4	5	97.4	1	OK		THC
05112160000105	3	0114	5	6	42.9	1	OK		THC
05112160000106	13	0123	-1	0	1400	1	OK		THC
05112160000107	13	0123	0	1	1720	1	OK		THC
05112160000108	13	0123	1	2	1680	1	OK		THC
05112160000109	3	0123	2	3	634	1	OK		THC
05112160000110	3	0123	3	4	340	1	OK		THC
05112160000111	3	0123	4	5	117	1	OK		THC
05112160000112	3	0123	5	6	47.1	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000113	13	0127	-1	0	7940	1	OK		THC
05112160000114	13	0127	0	1	1520	1	OK		THC
05112160000115	3	0127	1	2	735	1	OK		THC
05112160000116	3	0127	2	3	562	1	OK		THC
05112160000117	3	0127	3	4	265	1	OK		THC
05112160000118	3	0127	4	5	157	1	OK		THC
05112160000119	3	0127	5	6	89.8	1	OK		THC
05112160000120	13	0128	-1	0	3970	1	OK		THC
05112160000121	13	0128	0	1	2470	1	OK		THC
05112160000122	13	0128	1	2	1540	1	OK		THC
05112160000123	3	0128	2	3	457	1	OK		THC
05112160000124	3	0128	3	4	226	1	OK		THC
05112160000125	3	0128	4	5	104	1	OK		THC
05112160000126	3	0128	5	6	50.8	1	OK		THC
05112160000127	15	0133	-1	0	2460	1	OK		THC
05112160000128	15	0133	0	1	4210	1	OK		THC
05112160000129	15	0133	1	2	3590	1	OK		THC
05112160000130	14	0133	2	3	616	1	OK		THC
05112160000131	14	0133	3	4	197	1	OK		THC
05112160000132	14	0133	4	5	95.1	1	OK		THC
05112160000133	14	0133	5	6	50.7	1	OK		THC
05112160000134	15	0137	-1	0	3980	1	OK		THC
05112160000135	15	0137	0	1	2730	1	OK		THC
05112160000136	15	0137	1	2	2080	1	OK		THC
05112160000137	14	0137	2	3	492	1	OK		THC
05112160000138	14	0137	3	4	183	1	OK		THC
05112160000139	14	0137	4	5	67.8	1	OK		THC
05112160000140	14	0137	5	6	21.0	1	OK		THC
05112160000141	15	0145	-1	0	2850	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000142	15	0145	0	1	1870	1	OK		THC
05112160000143	15	0145	1	2	2140	1	OK		THC
05112160000144	14	0145	2	3	349	1	OK		THC
05112160000145	14	0145	3	4	53.8	1	OK		THC
05112160000146	14	0145	4	5	16.6	1	OK		THC
05112160000147	14	0145	5	6	BLQ<(10.0)	1	OK		THC
05112160000148	15	0150	-1	0	4190	1	OK		THC
05112160000149	15	0150	0	1	2210	1	OK		THC
05112160000150	15	0150	1	2	1890	1	OK		THC
05112160000151	14	0150	2	3	830	1	OK		THC
05112160000152	14	0150	3	4	307	1	OK		THC
05112160000153	14	0150	4	5	186	1	OK		THC
05112160000154	14	0150	5	6	105	1	OK		THC
05112160000155	15	0169	-1	0	1590	1	OK		THC
05112160000156	15	0169	0	1	1150	1	OK		THC
05112160000157	15	0169	1	2	1530	1	OK		THC
05112160000158	14	0169	2	3	376	1	OK		THC
05112160000159	14	0169	3	4	147	1	OK		THC
05112160000160	14	0169	4	5	37.8	1	OK		THC
05112160000161	14	0169	5	6	17.3	1	OK		THC
05112160000162	15	0185	-1	0	6810	1	OK		THC
05112160000163	15	0185	0	1	2760	1	OK		THC
05112160000164	15	0185	1	2	2200	1	OK		THC
05112160000165	14	0185	2	3	537	1	OK		THC
05112160000166	14	0185	3	4	171	1	OK		THC
05112160000167	14	0185	4	5	83.9	1	OK		THC
05112160000168	14	0185	5	6	25.9	1	OK		THC
05112160000169	14	0197	-1	0	732	1	OK		THC
05112160000170	15	0197	0	1	1340	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000171	14	0197	1	2	771	1	OK		THC
05112160000172	14	0197	2	3	175	1	OK		THC
05112160000173	14	0197	3	4	59.9	1	OK		THC
05112160000174	14	0197	4	5	42.0	1	OK		THC
05112160000175	14	0197	5	6	13.3	1	OK		THC
05112160000176	15	0203	-1	0	1740	1	OK		THC
05112160000177	15	0203	0	1	1420	1	OK		THC
05112160000178	14	0203	1	2	887	1	OK		THC
05112160000179	14	0203	2	3	402	1	OK		THC
05112160000180	14	0203	3	4	111	1	OK		THC
05112160000181	14	0203	4	5	51.7	1	OK		THC
05112160000182	14	0203	5	6	11.7	1	OK		THC
05112160000183	15	0218	-1	0	3940	1	OK		THC
05112160000184	15	0218	0	1	4860	1	OK		THC
05112160000185	15	0218	1	2	2280	1	OK		THC
05112160000186	15	0218	2	3	1010	1	OK		THC
05112160000187	14	0218	3	4	410	1	OK		THC
05112160000188	14	0218	4	5	119	1	OK		THC
05112160000189	14	0218	5	6	41.8	1	OK		THC
05112160000190	9	0240	-1	0	5130	1	OK		THC
05112160000191	9	0240	0	1	2860	1	OK		THC
05112160000192	7	0240	1	2	529	1	OK		THC
05112160000193	9	0240	2	3	545	1	OK		THC
05112160000194	7	0240	3	4	200	1	OK		THC
05112160000195	7	0240	4	5	80.4	1	OK		THC
05112160000196	7	0240	5	6	24.7	1	OK		THC
05112160000197	9	0249	-1	0	7980	1	OK		THC
05112160000198	9	0249	0	1	6610	1	OK		THC
05112160000199	9	0249	1	2	4320	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000200	9	0249	2	3	1440	1	OK		THC
05112160000201	7	0249	3	4	634	1	OK		THC
05112160000202	7	0249	4	5	215	1	OK		THC
05112160000203	7	0249	5	6	98.5	1	OK		THC
05112160000204	9	0251	-1	0	2900	1	OK		THC
05112160000205	9	0251	0	1	2310	1	OK		THC
05112160000206	9	0251	1	2	2010	1	OK		THC
05112160000207	7	0251	2	3	482	1	OK		THC
05112160000208	7	0251	3	4	178	1	OK		THC
05112160000209	7	0251	4	5	56.0	1	OK		THC
05112160000210	7	0251	5	6	10.9	1	OK		THC
05112160000211	9	0252	-1	0	4270	1	OK		THC
05112160000212	9	0252	0	1	3580	1	OK		THC
05112160000213	9	0252	1	2	2140	1	OK		THC
05112160000214	7	0252	2	3	575	1	OK		THC
05112160000215	7	0252	3	4	125	1	OK		THC
05112160000216	7	0252	4	5	46.8	1	OK		THC
05112160000217	7	0252	5	6	12.1	1	OK		THC
05112160000218	9	0265	-1	0	3620	1	OK		THC
05112160000219	9	0265	0	1	3530	1	OK		THC
05112160000220	15	0265	1	2	2090	1	OK		THC
05112160000221	7	0265	2	3	612	1	OK		THC
05112160000222	7	0265	3	4	239	1	OK		THC
05112160000223	7	0265	4	5	126	1	OK		THC
05112160000224	7	0265	5	6	41.9	1	OK		THC
05112160000225	15	0266	-1	0	4550	1	OK		THC
05112160000226	15	0266	0	1	4190	1	OK		THC
05112160000227	15	0266	1	2	2610	1	OK		THC
05112160000228	7	0266	2	3	579	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000229	7	0266	3	4	176	1	OK		THC
05112160000230	7	0266	4	5	80.4	1	OK		THC
05112160000231	7	0266	5	6	25.1	1	OK		THC
05112160000232	15	0273	-1	0	3640	1	OK		THC
05112160000233	15	0273	0	1	2860	1	OK		THC
05112160000234	15	0273	1	2	2070	1	OK		THC
05112160000235	7	0273	2	3	802	1	OK		THC
05112160000236	7	0273	3	4	358	1	OK		THC
05112160000237	7	0273	4	5	121	1	OK		THC
05112160000238	7	0273	5	6	44.6	1	OK		THC
05112160000239	15	0289	-1	0	2470	1	OK		THC
05112160000240	15	0289	0	1	1580	1	OK		THC
05112160000241	15	0289	1	2	1430	1	OK		THC
05112160000242	7	0289	2	3	488	1	OK		THC
05112160000243	7	0289	3	4	176	1	OK		THC
05112160000244	7	0289	4	5	67.6	1	OK		THC
05112160000245	7	0289	5	6	25.3	1	OK		THC
05112160000246	7	0292	-1	0	929	1	OK		THC
05112160000247	15	0292	0	1	1140	1	OK		THC
05112160000248	15	0292	1	2	1750	1	OK		THC
05112160000249	7	0292	2	3	326	1	OK		THC
05112160000250	7	0292	3	4	231	1	OK		THC
05112160000251	7	0292	4	5	64.0	1	OK		THC
05112160000252	7	0292	5	6	32.3	1	OK		THC
05112160000253	17	0306	-1	0	2430	1	OK		THC
05112160000254	17	0306	0	1	1900	1	OK		THC
05112160000255	17	0306	1	2	1510	1	OK		THC
05112160000256	9	0306	2	3	717	1	OK		THC
05112160000257	9	0306	3	4	386	1	OK		THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000258	9	0306	4	5	186	1	OK		THC
05112160000259	9	0306	5	6	107	1	OK		THC
05112160000260	17	0317	-1	0	3300	1	OK		THC
05112160000261	17	0317	0	1	2080	1	OK		THC
05112160000262	17	0317	1	2	1560	1	OK		THC
05112160000263	9	0317	2	3	549	1	OK		THC
05112160000264	9	0317	3	4	142	1	OK		THC
05112160000265	9	0317	4	5	65.8	1	OK		THC
05112160000266	9	0317	5	6	24.9	1	OK		THC
05112160000267	17	0325	-1	0	8980	1	OK		THC
05112160000268	17	0325	0	1	4540	1	OK		THC
05112160000269	17	0325	1	2	8070	1	OK		THC
05112160000270	17	0325	2	3	2510	1	OK		THC
05112160000271	17	0325	3	4	1160	1	OK		THC
05112160000272	9	0325	4	5	350	1	OK		THC
05112160000273	9	0325	5	6	171	1	OK		THC
05112160000274		0211	-1	0	.	1	Other	Analysis not required	THC
05112160000275		0211	0	1	.	1	Other	Analysis not required	THC
05112160000554		0211	-1	0	.	2	Other	Analysis not required	THC
05112160000555		0211	0	1	.	2	Other	Analysis not required	THC
05112160000561		0242	-1	0	.	2	Other	Analysis not required	THC
05112160000562		0242	0	1	.	2	Other	Analysis not required	THC
05112160000568		0242	-1	0	.	1	Other	Analysis not required	THC
05112160000569		0242	0	1	.	1	Other	Analysis not required	THC
05112160000575		0245	-1	0	.	2	Other	Analysis not required	THC
05112160000576		0245	0	1	.	2	Other	Analysis not required	THC
05112160000582		0245	-1	0	.	1	Other	Analysis not required	THC
05112160000583		0245	0	1	.	1	Other	Analysis not required	THC
05112160000589		0247	-1	0	.	2	Other	Analysis not required	THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000590		0247	0	1	.	2	Other	Analysis not required	THC
05112160000596		0247	-1	0	.	1	Other	Analysis not required	THC
05112160000597		0247	0	1	.	1	Other	Analysis not required	THC
05112160000603		0288	-1	0	.	2	Other	Analysis not required	THC
05112160000604		0288	0	1	.	2	Other	Analysis not required	THC
05112160000610		0288	-1	0	.	1	Other	Analysis not required	THC
05112160000611		0288	0	1	.	1	Other	Analysis not required	THC
05112160000617		0299	-1	0	.	2	Other	Analysis not required	THC
05112160000618		0299	0	1	.	2	Other	Analysis not required	THC
05112160000624		0299	-1	0	.	1	Other	Analysis not required	THC
05112160000625		0299	0	1	.	1	Other	Analysis not required	THC
05112160000631		0269	-1	0	.	2	Other	Analysis not required	THC
05112160000632		0269	0	1	.	2	Other	Analysis not required	THC
05112160000638		0269	-1	0	.	1	Other	Analysis not required	THC
05112160000639		0269	0	1	.	1	Other	Analysis not required	THC
05112160000645		0309	-1	0	.	2	Other	Analysis not required	THC
05112160000646		0309	0	1	.	2	Other	Analysis not required	THC
05112160000652		0309	-1	0	.	1	Other	Analysis not required	THC
05112160000653		0309	0	1	.	1	Other	Analysis not required	THC
05112160000659		0312	-1	0	.	2	Other	Analysis not required	THC
05112160000660		0312	0	1	.	2	Other	Analysis not required	THC
05112160000666		0312	-1	0	.	1	Other	Analysis not required	THC
05112160000667		0312	0	1	.	1	Other	Analysis not required	THC



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 23 Study Sample Concentrations for Nicotine-*N*-Glucuronide

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	2	0010	-1	0	431	1	OK		Nicotine Gluc
05112160000002	2	0010	0	1	119	1	OK		Nicotine Gluc
05112160000003	2	0010	1	2	62.2	1	OK		Nicotine Gluc
05112160000004	2	0010	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000005	2	0010	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000006	2	0010	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000007	2	0010	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000008	2	0013	-1	0	912	1	OK		Nicotine Gluc
05112160000009	10	0013	0	1	1690	1	OK		Nicotine Gluc
05112160000010	2	0013	1	2	234	1	OK		Nicotine Gluc
05112160000011	2	0013	2	3	12.9	1	OK		Nicotine Gluc
05112160000012	2	0013	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000013	2	0013	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000014	2	0013	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000015	2	0015	-1	0	509	1	OK		Nicotine Gluc
05112160000016	2	0015	0	1	535	1	OK		Nicotine Gluc
05112160000017	2	0015	1	2	114	1	OK		Nicotine Gluc
05112160000018	2	0015	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000019	2	0015	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000020	2	0015	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000021	2	0015	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000022	2	0017	-1	0	605	1	OK		Nicotine Gluc
05112160000023	2	0017	0	1	774	1	OK		Nicotine Gluc
05112160000024	2	0017	1	2	238	1	OK		Nicotine Gluc
05112160000025	2	0017	2	3	11.3	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	2	0017	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000027	2	0017	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000028	2	0017	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000029	2	0028	-1	0	244	1	OK		Nicotine Gluc
05112160000030	2	0028	0	1	329	1	OK		Nicotine Gluc
05112160000031	2	0028	1	2	73.2	1	OK		Nicotine Gluc
05112160000032	2	0028	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000033	2	0028	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000034	2	0028	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000035	2	0028	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000036	2	0049	-1	0	569	1	OK		Nicotine Gluc
05112160000037	2	0049	0	1	387	1	OK		Nicotine Gluc
05112160000038	2	0049	1	2	238	1	OK		Nicotine Gluc
05112160000039	2	0049	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000040	2	0049	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000041	2	0049	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000042	2	0049	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000043	2	0051	-1	0	328	1	OK		Nicotine Gluc
05112160000044	2	0051	0	1	342	1	OK		Nicotine Gluc
05112160000045	2	0051	1	2	44.9	1	OK		Nicotine Gluc
05112160000046	2	0051	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000047	2	0051	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000048	2	0051	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000049	2	0051	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000050	2	0052	-1	0	568	1	OK		Nicotine Gluc
05112160000051	2	0052	0	1	800	1	OK		Nicotine Gluc
05112160000052	2	0052	1	2	155	1	OK		Nicotine Gluc
05112160000053	2	0052	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000054	2	0052	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000055	2	0052	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000056	2	0052	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000057	2	0062	-1	0	310	1	OK		Nicotine Gluc
05112160000058	2	0062	0	1	476	1	OK		Nicotine Gluc
05112160000059	2	0062	1	2	85.1	1	OK		Nicotine Gluc
05112160000060	2	0062	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000061	2	0062	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000062	2	0062	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000063	2	0062	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000064	4	0063	-1	0	293	1	OK		Nicotine Gluc
05112160000065	4	0063	0	1	360	1	OK		Nicotine Gluc
05112160000066	4	0063	1	2	61.1	1	OK		Nicotine Gluc
05112160000067	4	0063	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000068	4	0063	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000069	4	0063	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000070	4	0063	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000071	12	0071	-1	0	1140	1	OK		Nicotine Gluc
05112160000072	12	0071	0	1	1230	1	OK		Nicotine Gluc
05112160000073	4	0071	1	2	465	1	OK		Nicotine Gluc
05112160000074	4	0071	2	3	11.4	1	OK		Nicotine Gluc
05112160000075	4	0071	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000076	4	0071	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000077	4	0071	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000078	4	0076	-1	0	417	1	OK		Nicotine Gluc
05112160000079	4	0076	0	1	492	1	OK		Nicotine Gluc
05112160000080	4	0076	1	2	288	1	OK		Nicotine Gluc
05112160000081	4	0076	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000082	4	0076	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000083	4	0076	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000084	4	0076	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000085	12	0086	-1	0	1290	1	OK		Nicotine Gluc
05112160000086	12	0086	0	1	1150	1	OK		Nicotine Gluc
05112160000087	4	0086	1	2	278	1	OK		Nicotine Gluc
05112160000088	4	0086	2	3	17.8	1	OK		Nicotine Gluc
05112160000089	4	0086	3	4	10.4	1	OK		Nicotine Gluc
05112160000090	4	0086	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000091	4	0086	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000092	4	0104	-1	0	196	1	OK		Nicotine Gluc
05112160000093	4	0104	0	1	275	1	OK		Nicotine Gluc
05112160000094	4	0104	1	2	46.3	1	OK		Nicotine Gluc
05112160000095	4	0104	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000096	4	0104	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000097	4	0104	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000098	4	0104	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000099	4	0114	-1	0	303	1	OK		Nicotine Gluc
05112160000100	4	0114	0	1	594	1	OK		Nicotine Gluc
05112160000101	4	0114	1	2	165	1	OK		Nicotine Gluc
05112160000102	4	0114	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000103	4	0114	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000104	4	0114	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000105	4	0114	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000106	4	0123	-1	0	180	1	OK		Nicotine Gluc
05112160000107	4	0123	0	1	377	1	OK		Nicotine Gluc
05112160000108	4	0123	1	2	76.6	1	OK		Nicotine Gluc
05112160000109	4	0123	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000110	4	0123	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000111	4	0123	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000112	4	0123	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000113	4	0127	-1	0	593	1	OK		Nicotine Gluc
05112160000114	4	0127	0	1	335	1	OK		Nicotine Gluc
05112160000115	4	0127	1	2	79.5	1	OK		Nicotine Gluc
05112160000116	4	0127	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000117	4	0127	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000118	4	0127	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000119	4	0127	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000120	12	0128	-1	0	1900	1	OK		Nicotine Gluc
05112160000121	12	0128	0	1	1550	1	OK		Nicotine Gluc
05112160000122	4	0128	1	2	329	1	OK		Nicotine Gluc
05112160000123	4	0128	2	3	12.6	1	OK		Nicotine Gluc
05112160000124	4	0128	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000125	4	0128	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000126	4	0128	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000127	6	0133	-1	0	560	1	OK		Nicotine Gluc
05112160000128	6	0133	0	1	727	1	OK		Nicotine Gluc
05112160000129	6	0133	1	2	187	1	OK		Nicotine Gluc
05112160000130	6	0133	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000131	6	0133	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000132	6	0133	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000133	6	0133	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000134	6	0137	-1	0	240	1	OK		Nicotine Gluc
05112160000135	6	0137	0	1	249	1	OK		Nicotine Gluc
05112160000136	6	0137	1	2	65.4	1	OK		Nicotine Gluc
05112160000137	6	0137	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000138	6	0137	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000139	6	0137	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000140	6	0137	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000141	6	0145	-1	0	158	1	OK		Nicotine Gluc
05112160000142	6	0145	0	1	185	1	OK		Nicotine Gluc
05112160000143	6	0145	1	2	97.3	1	OK		Nicotine Gluc
05112160000144	6	0145	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000145	6	0145	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000146	6	0145	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000147	6	0145	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000148	16	0150	-1	0	1050	1	OK		Nicotine Gluc
05112160000149	6	0150	0	1	971	1	OK		Nicotine Gluc
05112160000150	6	0150	1	2	347	1	OK		Nicotine Gluc
05112160000151	6	0150	2	3	15.5	1	OK		Nicotine Gluc
05112160000152	6	0150	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000153	6	0150	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000154	6	0150	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000155	6	0169	-1	0	293	1	OK		Nicotine Gluc
05112160000156	6	0169	0	1	263	1	OK		Nicotine Gluc
05112160000157	6	0169	1	2	78.3	1	OK		Nicotine Gluc
05112160000158	6	0169	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000159	6	0169	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000160	6	0169	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000161	6	0169	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000162	16	0185	-1	0	1340	1	OK		Nicotine Gluc
05112160000163	6	0185	0	1	908	1	OK		Nicotine Gluc
05112160000164	6	0185	1	2	307	1	OK		Nicotine Gluc
05112160000165	6	0185	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000166	6	0185	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000167	6	0185	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000168	6	0185	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000169	16	0197	-1	0	1220	1	OK		Nicotine Gluc
05112160000170	16	0197	0	1	3050	1	OK		Nicotine Gluc
05112160000171	6	0197	1	2	523	1	OK		Nicotine Gluc
05112160000172	6	0197	2	3	17.7	1	OK		Nicotine Gluc
05112160000173	6	0197	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000174	6	0197	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000175	6	0197	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000176	6	0203	-1	0	315	1	OK		Nicotine Gluc
05112160000177	6	0203	0	1	453	1	OK		Nicotine Gluc
05112160000178	6	0203	1	2	76.2	1	OK		Nicotine Gluc
05112160000179	6	0203	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000180	6	0203	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000181	6	0203	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000182	6	0203	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000183	6	0218	-1	0	279	1	OK		Nicotine Gluc
05112160000184	6	0218	0	1	559	1	OK		Nicotine Gluc
05112160000185	6	0218	1	2	70.3	1	OK		Nicotine Gluc
05112160000186	6	0218	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000187	6	0218	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000188	6	0218	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000189	6	0218	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000190	8	0240	-1	0	946	1	OK		Nicotine Gluc
05112160000191	10	0240	0	1	1180	1	OK		Nicotine Gluc
05112160000192	8	0240	1	2	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000193	20	0240	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000194	8	0240	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000195	8	0240	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000196	8	0240	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000197	8	0249	-1	0	975	1	OK		Nicotine Gluc
05112160000198	8	0249	0	1	953	1	OK		Nicotine Gluc
05112160000199	8	0249	1	2	277	1	OK		Nicotine Gluc
05112160000200	8	0249	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000201	8	0249	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000202	8	0249	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000203	8	0249	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000204	8	0251	-1	0	530	1	OK		Nicotine Gluc
05112160000205	8	0251	0	1	522	1	OK		Nicotine Gluc
05112160000206	8	0251	1	2	120	1	OK		Nicotine Gluc
05112160000207	8	0251	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000208	8	0251	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000209	8	0251	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000210	8	0251	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000211	8	0252	-1	0	227	1	OK		Nicotine Gluc
05112160000212	8	0252	0	1	355	1	OK		Nicotine Gluc
05112160000213	8	0252	1	2	41.5	1	OK		Nicotine Gluc
05112160000214	8	0252	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000215	8	0252	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000216	8	0252	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000217	8	0252	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000218	8	0265	-1	0	318	1	OK		Nicotine Gluc
05112160000219	8	0265	0	1	586	1	OK		Nicotine Gluc
05112160000220	8	0265	1	2	120	1	OK		Nicotine Gluc
05112160000221	8	0265	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000222	8	0265	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000223	8	0265	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000224	8	0265	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000225	8	0266	-1	0	743	1	OK		Nicotine Gluc
05112160000226	8	0266	0	1	711	1	OK		Nicotine Gluc
05112160000227	8	0266	1	2	144	1	OK		Nicotine Gluc
05112160000228	8	0266	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000229	8	0266	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000230	8	0266	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000231	8	0266	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000232	8	0273	-1	0	395	1	OK		Nicotine Gluc
05112160000233	8	0273	0	1	514	1	OK		Nicotine Gluc
05112160000234	8	0273	1	2	94.2	1	OK		Nicotine Gluc
05112160000235	8	0273	2	3	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000236	8	0273	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000237	8	0273	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000238	8	0273	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000239	8	0289	-1	0	800	1	OK		Nicotine Gluc
05112160000240	8	0289	0	1	820	1	OK		Nicotine Gluc
05112160000241	8	0289	1	2	280	1	OK		Nicotine Gluc
05112160000242	8	0289	2	3	12.3	1	OK		Nicotine Gluc
05112160000243	8	0289	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000244	8	0289	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000245	8	0289	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000246	8	0292	-1	0	916	1	OK		Nicotine Gluc
05112160000247	16	0292	0	1	1390	1	OK		Nicotine Gluc
05112160000248	8	0292	1	2	567	1	OK		Nicotine Gluc
05112160000249	8	0292	2	3	13.3	1	OK		Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000250	8	0292	3	4	10.6	1	OK		Nicotine Gluc
05112160000251	8	0292	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000252	8	0292	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000253	18	0306	-1	0	120	1	OK		Nicotine Gluc
05112160000254	18	0306	0	1	133	1	OK		Nicotine Gluc
05112160000255	10	0306	1	2	305	1	OK		Nicotine Gluc
05112160000256	10	0306	2	3	15.8	1	OK		Nicotine Gluc
05112160000257	10	0306	3	4	10.6	1	OK		Nicotine Gluc
05112160000258	10	0306	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000259	10	0306	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000260	10	0317	-1	0	304	1	OK		Nicotine Gluc
05112160000261	10	0317	0	1	440	1	OK		Nicotine Gluc
05112160000262	10	0317	1	2	186	1	OK		Nicotine Gluc
05112160000263	10	0317	2	3	10.5	1	OK		Nicotine Gluc
05112160000264	10	0317	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000265	10	0317	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000266	10	0317	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000267	10	0325	-1	0	736	1	OK		Nicotine Gluc
05112160000268	10	0325	0	1	823	1	OK		Nicotine Gluc
05112160000269	10	0325	1	2	308	1	OK		Nicotine Gluc
05112160000270	10	0325	2	3	12.5	1	OK		Nicotine Gluc
05112160000271	10	0325	3	4	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000272	10	0325	4	5	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000273	10	0325	5	6	BLQ<(10.0)	1	OK		Nicotine Gluc
05112160000274		0211	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000275		0211	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000554		0211	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000555		0211	0	1	.	2	Other	Analysis not required	Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000561		0242	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000562		0242	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000568		0242	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000569		0242	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000575		0245	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000576		0245	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000582		0245	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000583		0245	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000589		0247	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000590		0247	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000596		0247	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000597		0247	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000603		0288	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000604		0288	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000610		0288	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000611		0288	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000617		0299	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000618		0299	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000624		0299	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000625		0299	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000631		0269	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000632		0269	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000638		0269	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000639		0269	0	1	.	1	Other	Analysis not required	Nicotine Gluc
05112160000645		0309	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000646		0309	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000652		0309	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000653		0309	0	1	.	1	Other	Analysis not required	Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000659		0312	-1	0	.	2	Other	Analysis not required	Nicotine Gluc
05112160000660		0312	0	1	.	2	Other	Analysis not required	Nicotine Gluc
05112160000666		0312	-1	0	.	1	Other	Analysis not required	Nicotine Gluc
05112160000667		0312	0	1	.	1	Other	Analysis not required	Nicotine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 24 Study Sample Concentrations for Cotinine-*N*-Glucuronide

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	10	0010	-1	0	4500	1	OK		Cotinine Gluc
05112160000002	2	0010	0	1	1140	1	OK		Cotinine Gluc
05112160000003	10	0010	1	2	1930	1	OK		Cotinine Gluc
05112160000004	2	0010	2	3	606	1	OK		Cotinine Gluc
05112160000005	2	0010	3	4	257	1	OK		Cotinine Gluc
05112160000006	2	0010	4	5	139	1	OK		Cotinine Gluc
05112160000007	2	0010	5	6	47.6	1	OK		Cotinine Gluc
05112160000008	10	0013	-1	0	12300	1	OK		Cotinine Gluc
05112160000009	10	0013	0	1	10700	1	OK		Cotinine Gluc
05112160000010	10	0013	1	2	4930	1	OK		Cotinine Gluc
05112160000011	10	0013	2	3	1980	1	OK		Cotinine Gluc
05112160000012	2	0013	3	4	856	1	OK		Cotinine Gluc
05112160000013	2	0013	4	5	158	1	OK		Cotinine Gluc
05112160000014	2	0013	5	6	98.3	1	OK		Cotinine Gluc
05112160000015	10	0015	-1	0	4140	1	OK		Cotinine Gluc
05112160000016	10	0015	0	1	3270	1	OK		Cotinine Gluc
05112160000017	10	0015	1	2	3190	1	OK		Cotinine Gluc
05112160000018	2	0015	2	3	1270	1	OK		Cotinine Gluc
05112160000019	2	0015	3	4	352	1	OK		Cotinine Gluc
05112160000020	2	0015	4	5	174	1	OK		Cotinine Gluc
05112160000021	2	0015	5	6	45.2	1	OK		Cotinine Gluc
05112160000022	10	0017	-1	0	4140	1	OK		Cotinine Gluc
05112160000023	10	0017	0	1	2560	1	OK		Cotinine Gluc
05112160000024	10	0017	1	2	3970	1	OK		Cotinine Gluc
05112160000025	2	0017	2	3	1570	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	2	0017	3	4	295	1	OK		Cotinine Gluc
05112160000027	2	0017	4	5	187	1	OK		Cotinine Gluc
05112160000028	2	0017	5	6	51.9	1	OK		Cotinine Gluc
05112160000029	10	0028	-1	0	3540	1	OK		Cotinine Gluc
05112160000030	10	0028	0	1	2620	1	OK		Cotinine Gluc
05112160000031	2	0028	1	2	1610	1	OK		Cotinine Gluc
05112160000032	2	0028	2	3	920	1	OK		Cotinine Gluc
05112160000033	2	0028	3	4	237	1	OK		Cotinine Gluc
05112160000034	2	0028	4	5	106	1	OK		Cotinine Gluc
05112160000035	2	0028	5	6	24.8	1	OK		Cotinine Gluc
05112160000036	10	0049	-1	0	4190	1	OK		Cotinine Gluc
05112160000037	2	0049	0	1	1350	1	OK		Cotinine Gluc
05112160000038	10	0049	1	2	4110	1	OK		Cotinine Gluc
05112160000039	2	0049	2	3	1260	1	OK		Cotinine Gluc
05112160000040	2	0049	3	4	853	1	OK		Cotinine Gluc
05112160000041	2	0049	4	5	436	1	OK		Cotinine Gluc
05112160000042	2	0049	5	6	105	1	OK		Cotinine Gluc
05112160000043	10	0051	-1	0	3250	1	OK		Cotinine Gluc
05112160000044	2	0051	0	1	1890	1	OK		Cotinine Gluc
05112160000045	2	0051	1	2	1240	1	OK		Cotinine Gluc
05112160000046	2	0051	2	3	377	1	OK		Cotinine Gluc
05112160000047	2	0051	3	4	136	1	OK		Cotinine Gluc
05112160000048	2	0051	4	5	39.4	1	OK		Cotinine Gluc
05112160000049	2	0051	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000050	10	0052	-1	0	6680	1	OK		Cotinine Gluc
05112160000051	10	0052	0	1	4870	1	OK		Cotinine Gluc
05112160000052	10	0052	1	2	4420	1	OK		Cotinine Gluc
05112160000053	2	0052	2	3	1640	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000054	2	0052	3	4	368	1	OK		Cotinine Gluc
05112160000055	2	0052	4	5	177	1	OK		Cotinine Gluc
05112160000056	2	0052	5	6	81.3	1	OK		Cotinine Gluc
05112160000057	10	0062	-1	0	2080	1	OK		Cotinine Gluc
05112160000058	10	0062	0	1	3290	1	OK		Cotinine Gluc
05112160000059	2	0062	1	2	1640	1	OK		Cotinine Gluc
05112160000060	2	0062	2	3	661	1	OK		Cotinine Gluc
05112160000061	2	0062	3	4	188	1	OK		Cotinine Gluc
05112160000062	2	0062	4	5	97.7	1	OK		Cotinine Gluc
05112160000063	2	0062	5	6	26.6	1	OK		Cotinine Gluc
05112160000064	12	0063	-1	0	3500	1	OK		Cotinine Gluc
05112160000065	12	0063	0	1	3630	1	OK		Cotinine Gluc
05112160000066	12	0063	1	2	2640	1	OK		Cotinine Gluc
05112160000067	4	0063	2	3	405	1	OK		Cotinine Gluc
05112160000068	4	0063	3	4	207	1	OK		Cotinine Gluc
05112160000069	4	0063	4	5	48.6	1	OK		Cotinine Gluc
05112160000070	4	0063	5	6	21.6	1	OK		Cotinine Gluc
05112160000071	12	0071	-1	0	8390	1	OK		Cotinine Gluc
05112160000072	12	0071	0	1	6660	1	OK		Cotinine Gluc
05112160000073	12	0071	1	2	5770	1	OK		Cotinine Gluc
05112160000074	4	0071	2	3	1610	1	OK		Cotinine Gluc
05112160000075	4	0071	3	4	577	1	OK		Cotinine Gluc
05112160000076	4	0071	4	5	198	1	OK		Cotinine Gluc
05112160000077	4	0071	5	6	105	1	OK		Cotinine Gluc
05112160000078	4	0076	-1	0	1550	1	OK		Cotinine Gluc
05112160000079	4	0076	0	1	1500	1	OK		Cotinine Gluc
05112160000080	12	0076	1	2	3500	1	OK		Cotinine Gluc
05112160000081	4	0076	2	3	1100	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000082	4	0076	3	4	730	1	OK		Cotinine Gluc
05112160000083	4	0076	4	5	65.4	1	OK		Cotinine Gluc
05112160000084	4	0076	5	6	92.9	1	OK		Cotinine Gluc
05112160000085	12	0086	-1	0	7970	1	OK		Cotinine Gluc
05112160000086	12	0086	0	1	6630	1	OK		Cotinine Gluc
05112160000087	12	0086	1	2	6390	1	OK		Cotinine Gluc
05112160000088	4	0086	2	3	1930	1	OK		Cotinine Gluc
05112160000089	4	0086	3	4	1040	1	OK		Cotinine Gluc
05112160000090	4	0086	4	5	453	1	OK		Cotinine Gluc
05112160000091	4	0086	5	6	269	1	OK		Cotinine Gluc
05112160000092	4	0104	-1	0	1990	1	OK		Cotinine Gluc
05112160000093	4	0104	0	1	1880	1	OK		Cotinine Gluc
05112160000094	4	0104	1	2	1160	1	OK		Cotinine Gluc
05112160000095	4	0104	2	3	377	1	OK		Cotinine Gluc
05112160000096	4	0104	3	4	94.1	1	OK		Cotinine Gluc
05112160000097	4	0104	4	5	23.3	1	OK		Cotinine Gluc
05112160000098	4	0104	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000099	4	0114	-1	0	1330	1	OK		Cotinine Gluc
05112160000100	12	0114	0	1	2510	1	OK		Cotinine Gluc
05112160000101	12	0114	1	2	3200	1	OK		Cotinine Gluc
05112160000102	4	0114	2	3	1080	1	OK		Cotinine Gluc
05112160000103	4	0114	3	4	436	1	OK		Cotinine Gluc
05112160000104	4	0114	4	5	119	1	OK		Cotinine Gluc
05112160000105	4	0114	5	6	64.2	1	OK		Cotinine Gluc
05112160000106	4	0123	-1	0	1100	1	OK		Cotinine Gluc
05112160000107	4	0123	0	1	1800	1	OK		Cotinine Gluc
05112160000108	4	0123	1	2	1540	1	OK		Cotinine Gluc
05112160000109	4	0123	2	3	532	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000110	4	0123	3	4	361	1	OK		Cotinine Gluc
05112160000111	4	0123	4	5	101	1	OK		Cotinine Gluc
05112160000112	4	0123	5	6	43.6	1	OK		Cotinine Gluc
05112160000113	12	0127	-1	0	5720	1	OK		Cotinine Gluc
05112160000114	12	0127	0	1	2650	1	OK		Cotinine Gluc
05112160000115	4	0127	1	2	1430	1	OK		Cotinine Gluc
05112160000116	4	0127	2	3	1160	1	OK		Cotinine Gluc
05112160000117	4	0127	3	4	603	1	OK		Cotinine Gluc
05112160000118	4	0127	4	5	316	1	OK		Cotinine Gluc
05112160000119	4	0127	5	6	170	1	OK		Cotinine Gluc
05112160000120	12	0128	-1	0	10400	1	OK		Cotinine Gluc
05112160000121	12	0128	0	1	7860	1	OK		Cotinine Gluc
05112160000122	12	0128	1	2	5010	1	OK		Cotinine Gluc
05112160000123	4	0128	2	3	1430	1	OK		Cotinine Gluc
05112160000124	4	0128	3	4	832	1	OK		Cotinine Gluc
05112160000125	4	0128	4	5	290	1	OK		Cotinine Gluc
05112160000126	4	0128	5	6	150	1	OK		Cotinine Gluc
05112160000127	16	0133	-1	0	4560	1	OK		Cotinine Gluc
05112160000128	16	0133	0	1	4380	1	OK		Cotinine Gluc
05112160000129	16	0133	1	2	4350	1	OK		Cotinine Gluc
05112160000130	6	0133	2	3	750	1	OK		Cotinine Gluc
05112160000131	6	0133	3	4	344	1	OK		Cotinine Gluc
05112160000132	6	0133	4	5	133	1	OK		Cotinine Gluc
05112160000133	6	0133	5	6	70.9	1	OK		Cotinine Gluc
05112160000134	16	0137	-1	0	2450	1	OK		Cotinine Gluc
05112160000135	16	0137	0	1	2190	1	OK		Cotinine Gluc
05112160000136	16	0137	1	2	2370	1	OK		Cotinine Gluc
05112160000137	6	0137	2	3	642	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000138	6	0137	3	4	258	1	OK		Cotinine Gluc
05112160000139	6	0137	4	5	68.8	1	OK		Cotinine Gluc
05112160000140	6	0137	5	6	21.0	1	OK		Cotinine Gluc
05112160000141	6	0145	-1	0	1860	1	OK		Cotinine Gluc
05112160000142	6	0145	0	1	1300	1	OK		Cotinine Gluc
05112160000143	16	0145	1	2	1940	1	OK		Cotinine Gluc
05112160000144	6	0145	2	3	404	1	OK		Cotinine Gluc
05112160000145	6	0145	3	4	55.9	1	OK		Cotinine Gluc
05112160000146	6	0145	4	5	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000147	6	0145	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000148	16	0150	-1	0	6660	1	OK		Cotinine Gluc
05112160000149	16	0150	0	1	5030	1	OK		Cotinine Gluc
05112160000150	16	0150	1	2	5380	1	OK		Cotinine Gluc
05112160000151	16	0150	2	3	2470	1	OK		Cotinine Gluc
05112160000152	6	0150	3	4	922	1	OK		Cotinine Gluc
05112160000153	6	0150	4	5	490	1	OK		Cotinine Gluc
05112160000154	6	0150	5	6	274	1	OK		Cotinine Gluc
05112160000155	6	0169	-1	0	1860	1	OK		Cotinine Gluc
05112160000156	6	0169	0	1	1570	1	OK		Cotinine Gluc
05112160000157	16	0169	1	2	2630	1	OK		Cotinine Gluc
05112160000158	6	0169	2	3	586	1	OK		Cotinine Gluc
05112160000159	6	0169	3	4	274	1	OK		Cotinine Gluc
05112160000160	6	0169	4	5	58.3	1	OK		Cotinine Gluc
05112160000161	6	0169	5	6	24.8	1	OK		Cotinine Gluc
05112160000162	16	0185	-1	0	14900	1	OK		Cotinine Gluc
05112160000163	16	0185	0	1	6870	1	OK		Cotinine Gluc
05112160000164	16	0185	1	2	6380	1	OK		Cotinine Gluc
05112160000165	6	0185	2	3	1770	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000166	6	0185	3	4	556	1	OK		Cotinine Gluc
05112160000167	6	0185	4	5	182	1	OK		Cotinine Gluc
05112160000168	6	0185	5	6	49.4	1	OK		Cotinine Gluc
05112160000169	16	0197	-1	0	5580	1	OK		Cotinine Gluc
05112160000170	16	0197	0	1	10700	1	OK		Cotinine Gluc
05112160000171	16	0197	1	2	7300	1	OK		Cotinine Gluc
05112160000172	6	0197	2	3	1890	1	OK		Cotinine Gluc
05112160000173	6	0197	3	4	738	1	OK		Cotinine Gluc
05112160000174	6	0197	4	5	405	1	OK		Cotinine Gluc
05112160000175	6	0197	5	6	144	1	OK		Cotinine Gluc
05112160000176	16	0203	-1	0	2020	1	OK		Cotinine Gluc
05112160000177	16	0203	0	1	1990	1	OK		Cotinine Gluc
05112160000178	6	0203	1	2	1430	1	OK		Cotinine Gluc
05112160000179	6	0203	2	3	612	1	OK		Cotinine Gluc
05112160000180	6	0203	3	4	214	1	OK		Cotinine Gluc
05112160000181	6	0203	4	5	69.6	1	OK		Cotinine Gluc
05112160000182	6	0203	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000183	16	0218	-1	0	2340	1	OK		Cotinine Gluc
05112160000184	16	0218	0	1	3440	1	OK		Cotinine Gluc
05112160000185	6	0218	1	2	1730	1	OK		Cotinine Gluc
05112160000186	6	0218	2	3	966	1	OK		Cotinine Gluc
05112160000187	6	0218	3	4	450	1	OK		Cotinine Gluc
05112160000188	6	0218	4	5	109	1	OK		Cotinine Gluc
05112160000189	6	0218	5	6	37.1	1	OK		Cotinine Gluc
05112160000190	10	0240	-1	0	8450	1	OK		Cotinine Gluc
05112160000191	10	0240	0	1	7010	1	OK		Cotinine Gluc
05112160000192	8	0240	1	2	1410	1	OK		Cotinine Gluc
05112160000193	10	0240	2	3	1360	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000194	8	0240	3	4	506	1	OK		Cotinine Gluc
05112160000195	8	0240	4	5	197	1	OK		Cotinine Gluc
05112160000196	8	0240	5	6	55.9	1	OK		Cotinine Gluc
05112160000197	10	0249	-1	0	7430	1	OK		Cotinine Gluc
05112160000198	10	0249	0	1	5800	1	OK		Cotinine Gluc
05112160000199	10	0249	1	2	5770	1	OK		Cotinine Gluc
05112160000200	8	0249	2	3	1990	1	OK		Cotinine Gluc
05112160000201	8	0249	3	4	1060	1	OK		Cotinine Gluc
05112160000202	8	0249	4	5	256	1	OK		Cotinine Gluc
05112160000203	8	0249	5	6	104	1	OK		Cotinine Gluc
05112160000204	10	0251	-1	0	2560	1	OK		Cotinine Gluc
05112160000205	10	0251	0	1	2690	1	OK		Cotinine Gluc
05112160000206	10	0251	1	2	2530	1	OK		Cotinine Gluc
05112160000207	8	0251	2	3	540	1	OK		Cotinine Gluc
05112160000208	8	0251	3	4	270	1	OK		Cotinine Gluc
05112160000209	8	0251	4	5	58.1	1	OK		Cotinine Gluc
05112160000210	8	0251	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000211	8	0252	-1	0	1700	1	OK		Cotinine Gluc
05112160000212	8	0252	0	1	1640	1	OK		Cotinine Gluc
05112160000213	8	0252	1	2	1170	1	OK		Cotinine Gluc
05112160000214	8	0252	2	3	339	1	OK		Cotinine Gluc
05112160000215	8	0252	3	4	87.0	1	OK		Cotinine Gluc
05112160000216	8	0252	4	5	21.7	1	OK		Cotinine Gluc
05112160000217	8	0252	5	6	BLQ<(20.0)	1	OK		Cotinine Gluc
05112160000218	10	0265	-1	0	3120	1	OK		Cotinine Gluc
05112160000219	10	0265	0	1	4150	1	OK		Cotinine Gluc
05112160000220	16	0265	1	2	3030	1	OK		Cotinine Gluc
05112160000221	8	0265	2	3	960	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000222	8	0265	3	4	534	1	OK		Cotinine Gluc
05112160000223	8	0265	4	5	203	1	OK		Cotinine Gluc
05112160000224	8	0265	5	6	65.5	1	OK		Cotinine Gluc
05112160000225	16	0266	-1	0	4560	1	OK		Cotinine Gluc
05112160000226	16	0266	0	1	4640	1	OK		Cotinine Gluc
05112160000227	16	0266	1	2	3800	1	OK		Cotinine Gluc
05112160000228	8	0266	2	3	827	1	OK		Cotinine Gluc
05112160000229	8	0266	3	4	345	1	OK		Cotinine Gluc
05112160000230	8	0266	4	5	121	1	OK		Cotinine Gluc
05112160000231	8	0266	5	6	37.2	1	OK		Cotinine Gluc
05112160000232	16	0273	-1	0	3120	1	OK		Cotinine Gluc
05112160000233	16	0273	0	1	2610	1	OK		Cotinine Gluc
05112160000234	16	0273	1	2	2130	1	OK		Cotinine Gluc
05112160000235	8	0273	2	3	859	1	OK		Cotinine Gluc
05112160000236	8	0273	3	4	401	1	OK		Cotinine Gluc
05112160000237	8	0273	4	5	106	1	OK		Cotinine Gluc
05112160000238	8	0273	5	6	40.9	1	OK		Cotinine Gluc
05112160000239	16	0289	-1	0	5510	1	OK		Cotinine Gluc
05112160000240	16	0289	0	1	4360	1	OK		Cotinine Gluc
05112160000241	16	0289	1	2	4830	1	OK		Cotinine Gluc
05112160000242	8	0289	2	3	1650	1	OK		Cotinine Gluc
05112160000243	8	0289	3	4	648	1	OK		Cotinine Gluc
05112160000244	8	0289	4	5	181	1	OK		Cotinine Gluc
05112160000245	8	0289	5	6	66.0	1	OK		Cotinine Gluc
05112160000246	16	0292	-1	0	3650	1	OK		Cotinine Gluc
05112160000247	16	0292	0	1	4780	1	OK		Cotinine Gluc
05112160000248	16	0292	1	2	8060	1	OK		Cotinine Gluc
05112160000249	8	0292	2	3	1540	1	OK		Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000250	8	0292	3	4	1130	1	OK		Cotinine Gluc
05112160000251	8	0292	4	5	251	1	OK		Cotinine Gluc
05112160000252	8	0292	5	6	152	1	OK		Cotinine Gluc
05112160000253	18	0306	-1	0	518	1	OK		Cotinine Gluc
05112160000254	18	0306	0	1	461	1	OK		Cotinine Gluc
05112160000255	18	0306	1	2	457	1	OK		Cotinine Gluc
05112160000256	18	0306	2	3	183	1	OK		Cotinine Gluc
05112160000257	10	0306	3	4	1250	1	OK		Cotinine Gluc
05112160000258	10	0306	4	5	457	1	OK		Cotinine Gluc
05112160000259	10	0306	5	6	306	1	OK		Cotinine Gluc
05112160000260	18	0317	-1	0	428	1	OK		Cotinine Gluc
05112160000261	18	0317	0	1	361	1	OK		Cotinine Gluc
05112160000262	18	0317	1	2	364	1	OK		Cotinine Gluc
05112160000263	10	0317	2	3	1300	1	OK		Cotinine Gluc
05112160000264	10	0317	3	4	467	1	OK		Cotinine Gluc
05112160000265	10	0317	4	5	164	1	OK		Cotinine Gluc
05112160000266	10	0317	5	6	56.0	1	OK		Cotinine Gluc
05112160000267	18	0325	-1	0	502	1	OK		Cotinine Gluc
05112160000268	18	0325	0	1	377	1	OK		Cotinine Gluc
05112160000269	18	0325	1	2	639	1	OK		Cotinine Gluc
05112160000270	10	0325	2	3	1910	1	OK		Cotinine Gluc
05112160000271	10	0325	3	4	942	1	OK		Cotinine Gluc
05112160000272	10	0325	4	5	255	1	OK		Cotinine Gluc
05112160000273	10	0325	5	6	162	1	OK		Cotinine Gluc
05112160000274		0211	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000275		0211	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000554		0211	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000555		0211	0	1	.	2	Other	Analysis not required	Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000561		0242	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000562		0242	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000568		0242	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000569		0242	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000575		0245	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000576		0245	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000582		0245	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000583		0245	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000589		0247	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000590		0247	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000596		0247	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000597		0247	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000603		0288	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000604		0288	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000610		0288	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000611		0288	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000617		0299	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000618		0299	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000624		0299	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000625		0299	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000631		0269	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000632		0269	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000638		0269	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000639		0269	0	1	.	1	Other	Analysis not required	Cotinine Gluc
05112160000645		0309	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000646		0309	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000652		0309	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000653		0309	0	1	.	1	Other	Analysis not required	Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000659		0312	-1	0	.	2	Other	Analysis not required	Cotinine Gluc
05112160000660		0312	0	1	.	2	Other	Analysis not required	Cotinine Gluc
05112160000666		0312	-1	0	.	1	Other	Analysis not required	Cotinine Gluc
05112160000667		0312	0	1	.	1	Other	Analysis not required	Cotinine Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 25 Study Sample Concentrations for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000001	2	0010	-1	0	2590	1	OK		THC Gluc
05112160000002	2	0010	0	1	952	1	OK		THC Gluc
05112160000003	2	0010	1	2	1350	1	OK		THC Gluc
05112160000004	2	0010	2	3	313	1	OK		THC Gluc
05112160000005	2	0010	3	4	115	1	OK		THC Gluc
05112160000006	2	0010	4	5	66.7	1	OK		THC Gluc
05112160000007	2	0010	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000008	2	0013	-1	0	3520	1	OK		THC Gluc
05112160000009	2	0013	0	1	2510	1	OK		THC Gluc
05112160000010	2	0013	1	2	991	1	OK		THC Gluc
05112160000011	2	0013	2	3	407	1	OK		THC Gluc
05112160000012	2	0013	3	4	167	1	OK		THC Gluc
05112160000013	2	0013	4	5	57.2	1	OK		THC Gluc
05112160000014	2	0013	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000015	2	0015	-1	0	3140	1	OK		THC Gluc
05112160000016	2	0015	0	1	1680	1	OK		THC Gluc
05112160000017	2	0015	1	2	1390	1	OK		THC Gluc
05112160000018	2	0015	2	3	520	1	OK		THC Gluc
05112160000019	2	0015	3	4	117	1	OK		THC Gluc
05112160000020	2	0015	4	5	85.7	1	OK		THC Gluc
05112160000021	2	0015	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000022	2	0017	-1	0	649	1	OK		THC Gluc
05112160000023	2	0017	0	1	261	1	OK		THC Gluc
05112160000024	2	0017	1	2	363	1	OK		THC Gluc
05112160000025	2	0017	2	3	167	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000026	2	0017	3	4	BLQ<(50.0)	1	OK		THC Gluc
05112160000027	2	0017	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000028	2	0017	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000029	2	0028	-1	0	1210	1	OK		THC Gluc
05112160000030	2	0028	0	1	934	1	OK		THC Gluc
05112160000031	2	0028	1	2	660	1	OK		THC Gluc
05112160000032	2	0028	2	3	334	1	OK		THC Gluc
05112160000033	2	0028	3	4	68.2	1	OK		THC Gluc
05112160000034	2	0028	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000035	2	0028	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000036	2	0049	-1	0	1910	1	OK		THC Gluc
05112160000037	2	0049	0	1	339	1	OK		THC Gluc
05112160000038	2	0049	1	2	1200	1	OK		THC Gluc
05112160000039	2	0049	2	3	296	1	OK		THC Gluc
05112160000040	2	0049	3	4	136	1	OK		THC Gluc
05112160000041	2	0049	4	5	90.4	1	OK		THC Gluc
05112160000042	2	0049	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000043	2	0051	-1	0	1350	1	OK		THC Gluc
05112160000044	2	0051	0	1	774	1	OK		THC Gluc
05112160000045	2	0051	1	2	430	1	OK		THC Gluc
05112160000046	2	0051	2	3	112	1	OK		THC Gluc
05112160000047	2	0051	3	4	BLQ<(50.0)	1	OK		THC Gluc
05112160000048	2	0051	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000049	2	0051	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000050	2	0052	-1	0	1980	1	OK		THC Gluc
05112160000051	2	0052	0	1	1480	1	OK		THC Gluc
05112160000052	2	0052	1	2	1430	1	OK		THC Gluc
05112160000053	2	0052	2	3	526	1	OK		THC Gluc
05112160000054	2	0052	3	4	96.6	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000055	2	0052	4	5	52.7	1	OK		THC Gluc
05112160000056	2	0052	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000057	2	0062	-1	0	1130	1	OK		THC Gluc
05112160000058	2	0062	0	1	873	1	OK		THC Gluc
05112160000059	2	0062	1	2	603	1	OK		THC Gluc
05112160000060	2	0062	2	3	239	1	OK		THC Gluc
05112160000061	2	0062	3	4	68.6	1	OK		THC Gluc
05112160000062	2	0062	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000063	2	0062	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000064	12	0063	-1	0	2520	1	OK		THC Gluc
05112160000065	12	0063	0	1	2460	1	OK		THC Gluc
05112160000066	12	0063	1	2	2530	1	OK		THC Gluc
05112160000067	12	0063	2	3	417	1	OK		THC Gluc
05112160000068	12	0063	3	4	196	1	OK		THC Gluc
05112160000069	12	0063	4	5	51.9	1	OK		THC Gluc
05112160000070	12	0063	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000071	12	0071	-1	0	2190	1	OK		THC Gluc
05112160000072	12	0071	0	1	1350	1	OK		THC Gluc
05112160000073	12	0071	1	2	1050	1	OK		THC Gluc
05112160000074	12	0071	2	3	336	1	OK		THC Gluc
05112160000075	12	0071	3	4	80.3	1	OK		THC Gluc
05112160000076	12	0071	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000077	12	0071	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000078	12	0076	-1	0	924	1	OK		THC Gluc
05112160000079	12	0076	0	1	650	1	OK		THC Gluc
05112160000080	12	0076	1	2	1460	1	OK		THC Gluc
05112160000081	12	0076	2	3	519	1	OK		THC Gluc
05112160000082	12	0076	3	4	259	1	OK		THC Gluc
05112160000083	12	0076	4	5	BLQ<(50.0)	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000084	12	0076	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000085	12	0086	-1	0	1680	1	OK		THC Gluc
05112160000086	12	0086	0	1	1040	1	OK		THC Gluc
05112160000087	12	0086	1	2	904	1	OK		THC Gluc
05112160000088	12	0086	2	3	323	1	OK		THC Gluc
05112160000089	12	0086	3	4	143	1	OK		THC Gluc
05112160000090	12	0086	4	5	66.6	1	OK		THC Gluc
05112160000091	12	0086	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000092	12	0104	-1	0	1990	1	OK		THC Gluc
05112160000093	12	0104	0	1	1440	1	OK		THC Gluc
05112160000094	12	0104	1	2	583	1	OK		THC Gluc
05112160000095	12	0104	2	3	181	1	OK		THC Gluc
05112160000096	12	0104	3	4	BLQ<(50.0)	1	OK		THC Gluc
05112160000097	12	0104	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000098	12	0104	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000099	12	0114	-1	0	744	1	OK		THC Gluc
05112160000100	12	0114	0	1	1160	1	OK		THC Gluc
05112160000101	12	0114	1	2	1570	1	OK		THC Gluc
05112160000102	12	0114	2	3	462	1	OK		THC Gluc
05112160000103	12	0114	3	4	170	1	OK		THC Gluc
05112160000104	12	0114	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000105	12	0114	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000106	12	0123	-1	0	691	1	OK		THC Gluc
05112160000107	12	0123	0	1	874	1	OK		THC Gluc
05112160000108	12	0123	1	2	835	1	OK		THC Gluc
05112160000109	12	0123	2	3	298	1	OK		THC Gluc
05112160000110	12	0123	3	4	179	1	OK		THC Gluc
05112160000111	12	0123	4	5	62.7	1	OK		THC Gluc
05112160000112	12	0123	5	6	BLQ<(50.0)	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000113	12	0127	-1	0	4230	1	OK		THC Gluc
05112160000114	12	0127	0	1	1880	1	OK		THC Gluc
05112160000115	12	0127	1	2	1000	1	OK		THC Gluc
05112160000116	12	0127	2	3	748	1	OK		THC Gluc
05112160000117	12	0127	3	4	304	1	OK		THC Gluc
05112160000118	12	0127	4	5	206	1	OK		THC Gluc
05112160000119	12	0127	5	6	114	1	OK		THC Gluc
05112160000120	12	0128	-1	0	1660	1	OK		THC Gluc
05112160000121	12	0128	0	1	1020	1	OK		THC Gluc
05112160000122	12	0128	1	2	640	1	OK		THC Gluc
05112160000123	12	0128	2	3	192	1	OK		THC Gluc
05112160000124	12	0128	3	4	91.3	1	OK		THC Gluc
05112160000125	12	0128	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000126	12	0128	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000127	6	0133	-1	0	3040	1	OK		THC Gluc
05112160000128	6	0133	0	1	2010	1	OK		THC Gluc
05112160000129	6	0133	1	2	1710	1	OK		THC Gluc
05112160000130	6	0133	2	3	288	1	OK		THC Gluc
05112160000131	6	0133	3	4	114	1	OK		THC Gluc
05112160000132	6	0133	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000133	6	0133	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000134	6	0137	-1	0	1860	1	OK		THC Gluc
05112160000135	6	0137	0	1	1260	1	OK		THC Gluc
05112160000136	6	0137	1	2	986	1	OK		THC Gluc
05112160000137	6	0137	2	3	230	1	OK		THC Gluc
05112160000138	6	0137	3	4	93.1	1	OK		THC Gluc
05112160000139	6	0137	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000140	6	0137	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000141	6	0145	-1	0	2110	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000142	6	0145	0	1	1180	1	OK		THC Gluc
05112160000143	6	0145	1	2	1510	1	OK		THC Gluc
05112160000144	6	0145	2	3	288	1	OK		THC Gluc
05112160000145	6	0145	3	4	BLQ<(50.0)	1	OK		THC Gluc
05112160000146	6	0145	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000147	6	0145	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000148	6	0150	-1	0	2560	1	OK		THC Gluc
05112160000149	6	0150	0	1	1450	1	OK		THC Gluc
05112160000150	6	0150	1	2	1260	1	OK		THC Gluc
05112160000151	6	0150	2	3	518	1	OK		THC Gluc
05112160000152	6	0150	3	4	177	1	OK		THC Gluc
05112160000153	6	0150	4	5	134	1	OK		THC Gluc
05112160000154	6	0150	5	6	66.1	1	OK		THC Gluc
05112160000155	6	0169	-1	0	899	1	OK		THC Gluc
05112160000156	6	0169	0	1	738	1	OK		THC Gluc
05112160000157	6	0169	1	2	1070	1	OK		THC Gluc
05112160000158	6	0169	2	3	218	1	OK		THC Gluc
05112160000159	6	0169	3	4	93.3	1	OK		THC Gluc
05112160000160	6	0169	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000161	6	0169	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000162	6	0185	-1	0	4420	1	OK		THC Gluc
05112160000163	6	0185	0	1	1660	1	OK		THC Gluc
05112160000164	6	0185	1	2	1390	1	OK		THC Gluc
05112160000165	6	0185	2	3	321	1	OK		THC Gluc
05112160000166	6	0185	3	4	101	1	OK		THC Gluc
05112160000167	6	0185	4	5	50.2	1	OK		THC Gluc
05112160000168	6	0185	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000169	6	0197	-1	0	872	1	OK		THC Gluc
05112160000170	6	0197	0	1	1570	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000171	6	0197	1	2	870	1	OK		THC Gluc
05112160000172	6	0197	2	3	191	1	OK		THC Gluc
05112160000173	6	0197	3	4	55.8	1	OK		THC Gluc
05112160000174	6	0197	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000175	6	0197	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000176	6	0203	-1	0	1370	1	OK		THC Gluc
05112160000177	6	0203	0	1	1190	1	OK		THC Gluc
05112160000178	6	0203	1	2	678	1	OK		THC Gluc
05112160000179	6	0203	2	3	305	1	OK		THC Gluc
05112160000180	6	0203	3	4	90.7	1	OK		THC Gluc
05112160000181	6	0203	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000182	6	0203	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000183	6	0218	-1	0	2040	1	OK		THC Gluc
05112160000184	6	0218	0	1	3000	1	OK		THC Gluc
05112160000185	6	0218	1	2	1380	1	OK		THC Gluc
05112160000186	6	0218	2	3	724	1	OK		THC Gluc
05112160000187	6	0218	3	4	274	1	OK		THC Gluc
05112160000188	6	0218	4	5	70.4	1	OK		THC Gluc
05112160000189	6	0218	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000190	8	0240	-1	0	1600	1	OK		THC Gluc
05112160000191	8	0240	0	1	888	1	OK		THC Gluc
05112160000192	8	0240	1	2	184	1	OK		THC Gluc
05112160000193		0240	2	3	168	1	OK		THC Gluc
05112160000194	8	0240	3	4	69.9	1	OK		THC Gluc
05112160000195	8	0240	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000196	8	0240	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000197	8	0249	-1	0	4750	1	OK		THC Gluc
05112160000198	8	0249	0	1	2910	1	OK		THC Gluc
05112160000199	8	0249	1	2	1840	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000200	8	0249	2	3	720	1	OK		THC Gluc
05112160000201	8	0249	3	4	292	1	OK		THC Gluc
05112160000202	8	0249	4	5	99.6	1	OK		THC Gluc
05112160000203	8	0249	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000204	8	0251	-1	0	707	1	OK		THC Gluc
05112160000205	8	0251	0	1	608	1	OK		THC Gluc
05112160000206	8	0251	1	2	562	1	OK		THC Gluc
05112160000207	8	0251	2	3	147	1	OK		THC Gluc
05112160000208	8	0251	3	4	63.3	1	OK		THC Gluc
05112160000209	8	0251	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000210	8	0251	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000211	8	0252	-1	0	2130	1	OK		THC Gluc
05112160000212	8	0252	0	1	1610	1	OK		THC Gluc
05112160000213	8	0252	1	2	848	1	OK		THC Gluc
05112160000214	8	0252	2	3	269	1	OK		THC Gluc
05112160000215	8	0252	3	4	58.7	1	OK		THC Gluc
05112160000216	8	0252	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000217	8	0252	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000218	8	0265	-1	0	2410	1	OK		THC Gluc
05112160000219	8	0265	0	1	2100	1	OK		THC Gluc
05112160000220	8	0265	1	2	1200	1	OK		THC Gluc
05112160000221	8	0265	2	3	410	1	OK		THC Gluc
05112160000222	8	0265	3	4	154	1	OK		THC Gluc
05112160000223	8	0265	4	5	76.7	1	OK		THC Gluc
05112160000224	8	0265	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000225	8	0266	-1	0	1960	1	OK		THC Gluc
05112160000226	8	0266	0	1	1520	1	OK		THC Gluc
05112160000227	8	0266	1	2	1070	1	OK		THC Gluc
05112160000228	8	0266	2	3	254	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000229	8	0266	3	4	81.6	1	OK		THC Gluc
05112160000230	8	0266	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000231	8	0266	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000232	8	0273	-1	0	2190	1	OK		THC Gluc
05112160000233	8	0273	0	1	1520	1	OK		THC Gluc
05112160000234	8	0273	1	2	1230	1	OK		THC Gluc
05112160000235	8	0273	2	3	548	1	OK		THC Gluc
05112160000236	8	0273	3	4	235	1	OK		THC Gluc
05112160000237	8	0273	4	5	76.5	1	OK		THC Gluc
05112160000238	8	0273	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000239	8	0289	-1	0	974	1	OK		THC Gluc
05112160000240	8	0289	0	1	572	1	OK		THC Gluc
05112160000241	8	0289	1	2	559	1	OK		THC Gluc
05112160000242	8	0289	2	3	183	1	OK		THC Gluc
05112160000243	8	0289	3	4	67.9	1	OK		THC Gluc
05112160000244	8	0289	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000245	8	0289	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000246	8	0292	-1	0	422	1	OK		THC Gluc
05112160000247	8	0292	0	1	501	1	OK		THC Gluc
05112160000248	8	0292	1	2	823	1	OK		THC Gluc
05112160000249	8	0292	2	3	163	1	OK		THC Gluc
05112160000250	8	0292	3	4	124	1	OK		THC Gluc
05112160000251	8	0292	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000252	8	0292	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000253	10	0306	-1	0	1170	1	OK		THC Gluc
05112160000254	10	0306	0	1	698	1	OK		THC Gluc
05112160000255	10	0306	1	2	598	1	OK		THC Gluc
05112160000256	10	0306	2	3	292	1	OK		THC Gluc
05112160000257	10	0306	3	4	151	1	OK		THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000258	10	0306	4	5	86.0	1	OK		THC Gluc
05112160000259	10	0306	5	6	50.4	1	OK		THC Gluc
05112160000260	10	0317	-1	0	2020	1	OK		THC Gluc
05112160000261	10	0317	0	1	1320	1	OK		THC Gluc
05112160000262	10	0317	1	2	784	1	OK		THC Gluc
05112160000263	10	0317	2	3	292	1	OK		THC Gluc
05112160000264	10	0317	3	4	66.2	1	OK		THC Gluc
05112160000265	10	0317	4	5	BLQ<(50.0)	1	OK		THC Gluc
05112160000266	10	0317	5	6	BLQ<(50.0)	1	OK		THC Gluc
05112160000267	10	0325	-1	0	3950	1	OK		THC Gluc
05112160000268	10	0325	0	1	2180	1	OK		THC Gluc
05112160000269	10	0325	1	2	3690	1	OK		THC Gluc
05112160000270	10	0325	2	3	1360	1	OK		THC Gluc
05112160000271	10	0325	3	4	601	1	OK		THC Gluc
05112160000272	10	0325	4	5	173	1	OK		THC Gluc
05112160000273	10	0325	5	6	95.7	1	OK		THC Gluc
05112160000274		0211	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000275		0211	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000554		0211	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000555		0211	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000561		0242	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000562		0242	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000568		0242	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000569		0242	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000575		0245	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000576		0245	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000582		0245	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000583		0245	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000589		0247	-1	0	.	2	Other	Analysis not required	THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Custom ID	Run ID	Subject	Start Day Nominal	Day Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05112160000590		0247	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000596		0247	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000597		0247	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000603		0288	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000604		0288	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000610		0288	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000611		0288	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000617		0299	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000618		0299	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000624		0299	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000625		0299	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000631		0269	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000632		0269	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000638		0269	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000639		0269	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000645		0309	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000646		0309	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000652		0309	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000653		0309	0	1	.	1	Other	Analysis not required	THC Gluc
05112160000659		0312	-1	0	.	2	Other	Analysis not required	THC Gluc
05112160000660		0312	0	1	.	2	Other	Analysis not required	THC Gluc
05112160000666		0312	-1	0	.	1	Other	Analysis not required	THC Gluc
05112160000667		0312	0	1	.	1	Other	Analysis not required	THC Gluc



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 26 Summary of Reassay for Analytical Reasons for Nicotine

Run ID	Reason	Sample Name
1	AAR	AA99071-13 05112160000009 0013 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000022 0017 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000051 0052 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000191 0240 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000197 0249 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000198 0249 SA P1 Day 1 URN-1
9	AAR	AA99071-13 05112160000253 0306 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000254 0306 SA P1 Day 1 URN-1
9	AAR	AA99071-13 05112160000268 0325 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000149 0150 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000170 0197 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 27 Summary of Reassay for Analytical Reasons for Cotinine

Run ID	Reason	Sample Name
1	AAR	AA99071-13 05112160000001 0010 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000008 0013 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000015 0015 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000022 0017 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000036 0049 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000043 0051 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000050 0052 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000051 0052 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000064 0063 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000071 0071 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000072 0071 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000073 0071 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000085 0086 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000113 0127 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000120 0128 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000121 0128 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000190 0240 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000191 0240 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000197 0249 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000198 0249 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000199 0249 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000205 0251 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000211 0252 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000212 0252 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000219 0265 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000225 0266 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000226 0266 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000232 0273 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000233 0273 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000240 0289 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000246 0292 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000247 0292 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000248 0292 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000253 0306 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000254 0306 SA P1 Day 1 URN-1
9	AAR	AA99071-13 05112160000255 0306 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000267 0325 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000268 0325 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
9	AAR	AA99071-13 05112160000269 0325 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000128 0133 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000129 0133 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000148 0150 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000149 0150 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000150 0150 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000162 0185 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000170 0197 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000183 0218 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000184 0218 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 28 Summary of Reassay for Analytical Reasons for *trans*-3'-Hydroxycotinine

Run ID	Reason	Sample Name
1	AAR	AA99071-13 05112160000001 0010 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000002 0010 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000003 0010 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000008 0013 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000009 0013 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000010 0013 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000015 0015 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000016 0015 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000017 0015 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000022 0017 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000029 0028 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000030 0028 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000031 0028 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000036 0049 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000038 0049 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000043 0051 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000044 0051 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000050 0052 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000051 0052 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000052 0052 SA P1 Day 2 URN-1
1	AAR	AA99071-13 05112160000053 0052 SA P1 Day 3 URN-1
1	AAR	AA99071-13 05112160000057 0062 SA P1 Day 0 URN-1
1	AAR	AA99071-13 05112160000058 0062 SA P1 Day 1 URN-1
1	AAR	AA99071-13 05112160000059 0062 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000064 0063 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000065 0063 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000066 0063 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000071 0071 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000072 0071 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000073 0071 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000078 0076 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000080 0076 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000085 0086 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000087 0086 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000092 0104 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000093 0104 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000094 0104 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000099 0114 SA P1 Day 0 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
3	AAR	AA99071-13 05112160000100 0114 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000101 0114 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000106 0123 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000107 0123 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000108 0123 SA P1 Day 2 URN-1
3	AAR	AA99071-13 05112160000113 0127 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000114 0127 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000120 0128 SA P1 Day 0 URN-1
3	AAR	AA99071-13 05112160000121 0128 SA P1 Day 1 URN-1
3	AAR	AA99071-13 05112160000122 0128 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000190 0240 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000191 0240 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000193 0240 SA P1 Day 3 URN-1
7	AAR	AA99071-13 05112160000197 0249 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000198 0249 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000199 0249 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000200 0249 SA P1 Day 3 URN-1
7	AAR	AA99071-13 05112160000204 0251 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000205 0251 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000206 0251 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000211 0252 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000212 0252 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000213 0252 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000218 0265 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000219 0265 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000220 0265 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000225 0266 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000226 0266 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000227 0266 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000232 0273 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000233 0273 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000234 0273 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000239 0289 SA P1 Day 0 URN-1
7	AAR	AA99071-13 05112160000240 0289 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000241 0289 SA P1 Day 2 URN-1
7	AAR	AA99071-13 05112160000247 0292 SA P1 Day 1 URN-1
7	AAR	AA99071-13 05112160000248 0292 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000253 0306 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000254 0306 SA P1 Day 1 URN-1
9	AAR	AA99071-13 05112160000255 0306 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000260 0317 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000261 0317 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
9	AAR	AA99071-13 05112160000262 0317 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000267 0325 SA P1 Day 0 URN-1
9	AAR	AA99071-13 05112160000268 0325 SA P1 Day 1 URN-1
9	AAR	AA99071-13 05112160000269 0325 SA P1 Day 2 URN-1
9	AAR	AA99071-13 05112160000270 0325 SA P1 Day 3 URN-1
9	AAR	AA99071-13 05112160000271 0325 SA P1 Day 4 URN-1
14	AAR	AA99071-13 05112160000127 0133 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000128 0133 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000129 0133 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000134 0137 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000135 0137 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000136 0137 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000141 0145 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000142 0145 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000143 0145 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000148 0150 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000149 0150 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000150 0150 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000155 0169 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000156 0169 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000157 0169 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000162 0185 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000163 0185 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000164 0185 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000170 0197 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000176 0203 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000177 0203 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000183 0218 SA P1 Day 0 URN-1
14	AAR	AA99071-13 05112160000184 0218 SA P1 Day 1 URN-1
14	AAR	AA99071-13 05112160000185 0218 SA P1 Day 2 URN-1
14	AAR	AA99071-13 05112160000186 0218 SA P1 Day 3 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 29 Summary of Reassay for Analytical Reasons for Nicotine-*N*-Glucuronide

Run ID	Reason	Sample Name
2	AAR	AA99071-13 05112160000009 0013 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000071 0071 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000072 0071 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000085 0086 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000120 0128 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000121 0128 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000148 0150 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000162 0185 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000169 0197 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000170 0197 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000191 0240 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000247 0292 SA P1 Day 1 URN-1
10	AAR	AA99071-13 05112160000253 0306 SA P1 Day 0 URN-1
10	AAR	AA99071-13 05112160000254 0306 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 30 Summary of Reassay for Analytical Reasons for Cotinine-*N*-Glucuronide

Run ID	Reason	Sample Name
2	AAR	AA99071-13 05112160000001 0010 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000003 0010 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000008 0013 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000009 0013 SA P1 Day 1 URN-1
2	AAR	AA99071-13 05112160000010 0013 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000011 0013 SA P1 Day 3 URN-1
2	AAR	AA99071-13 05112160000015 0015 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000016 0015 SA P1 Day 1 URN-1
2	AAR	AA99071-13 05112160000017 0015 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000022 0017 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000023 0017 SA P1 Day 1 URN-1
2	AAR	AA99071-13 05112160000024 0017 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000029 0028 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000030 0028 SA P1 Day 1 URN-1
2	AAR	AA99071-13 05112160000036 0049 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000038 0049 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000043 0051 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000050 0052 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000051 0052 SA P1 Day 1 URN-1
2	AAR	AA99071-13 05112160000052 0052 SA P1 Day 2 URN-1
2	AAR	AA99071-13 05112160000057 0062 SA P1 Day 0 URN-1
2	AAR	AA99071-13 05112160000058 0062 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000064 0063 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000065 0063 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000066 0063 SA P1 Day 2 URN-1
4	AAR	AA99071-13 05112160000071 0071 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000072 0071 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000073 0071 SA P1 Day 2 URN-1
4	AAR	AA99071-13 05112160000080 0076 SA P1 Day 2 URN-1
4	AAR	AA99071-13 05112160000085 0086 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000087 0086 SA P1 Day 2 URN-1
4	AAR	AA99071-13 05112160000100 0114 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000101 0114 SA P1 Day 2 URN-1
4	AAR	AA99071-13 05112160000113 0127 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000114 0127 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000120 0128 SA P1 Day 0 URN-1
4	AAR	AA99071-13 05112160000121 0128 SA P1 Day 1 URN-1
4	AAR	AA99071-13 05112160000122 0128 SA P1 Day 2 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
6	AAR	AA99071-13 05112160000127 0133 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000128 0133 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000129 0133 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000134 0137 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000135 0137 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000136 0137 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000143 0145 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000148 0150 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000149 0150 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000150 0150 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000151 0150 SA P1 Day 3 URN-1
6	AAR	AA99071-13 05112160000157 0169 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000162 0185 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000163 0185 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000164 0185 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000169 0197 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000170 0197 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000171 0197 SA P1 Day 2 URN-1
6	AAR	AA99071-13 05112160000176 0203 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000177 0203 SA P1 Day 1 URN-1
6	AAR	AA99071-13 05112160000183 0218 SA P1 Day 0 URN-1
6	AAR	AA99071-13 05112160000184 0218 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000190 0240 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000191 0240 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000193 0240 SA P1 Day 3 URN-1
8	AAR	AA99071-13 05112160000197 0249 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000198 0249 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000199 0249 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000204 0251 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000205 0251 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000206 0251 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000218 0265 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000219 0265 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000220 0265 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000225 0266 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000226 0266 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000227 0266 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000232 0273 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000233 0273 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000234 0273 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000239 0289 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000240 0289 SA P1 Day 1 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
8	AAR	AA99071-13 05112160000241 0289 SA P1 Day 2 URN-1
8	AAR	AA99071-13 05112160000246 0292 SA P1 Day 0 URN-1
8	AAR	AA99071-13 05112160000247 0292 SA P1 Day 1 URN-1
8	AAR	AA99071-13 05112160000248 0292 SA P1 Day 2 URN-1
10	AAR	AA99071-13 05112160000253 0306 SA P1 Day 0 URN-1
10	AAR	AA99071-13 05112160000254 0306 SA P1 Day 1 URN-1
10	AAR	AA99071-13 05112160000255 0306 SA P1 Day 2 URN-1
10	AAR	AA99071-13 05112160000256 0306 SA P1 Day 3 URN-1
10	AAR	AA99071-13 05112160000260 0317 SA P1 Day 0 URN-1
10	AAR	AA99071-13 05112160000261 0317 SA P1 Day 1 URN-1
10	AAR	AA99071-13 05112160000262 0317 SA P1 Day 2 URN-1
10	AAR	AA99071-13 05112160000267 0325 SA P1 Day 0 URN-1
10	AAR	AA99071-13 05112160000268 0325 SA P1 Day 1 URN-1
10	AAR	AA99071-13 05112160000269 0325 SA P1 Day 2 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 31 Summary of Reassay for Analytical Reasons for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Run ID	Reason	Sample Name
4	Fail	AA99071-13 05112160000064 0063 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000065 0063 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000066 0063 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000067 0063 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000068 0063 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000069 0063 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000070 0063 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000071 0071 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000072 0071 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000073 0071 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000074 0071 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000075 0071 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000076 0071 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000077 0071 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000078 0076 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000079 0076 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000080 0076 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000081 0076 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000082 0076 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000083 0076 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000084 0076 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000085 0086 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000086 0086 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000087 0086 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000088 0086 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000089 0086 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000090 0086 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000091 0086 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000092 0104 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000093 0104 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000094 0104 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000095 0104 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000096 0104 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000097 0104 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000098 0104 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000099 0114 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000100 0114 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000101 0114 SA P1 Day 2 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Run ID	Reason	Sample Name
4	Fail	AA99071-13 05112160000102 0114 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000103 0114 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000104 0114 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000105 0114 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000106 0123 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000107 0123 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000108 0123 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000109 0123 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000110 0123 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000111 0123 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000112 0123 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000113 0127 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000114 0127 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000115 0127 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000116 0127 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000117 0127 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000118 0127 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000119 0127 SA P1 Day 6 URN-1
4	Fail	AA99071-13 05112160000120 0128 SA P1 Day 0 URN-1
4	Fail	AA99071-13 05112160000121 0128 SA P1 Day 1 URN-1
4	Fail	AA99071-13 05112160000122 0128 SA P1 Day 2 URN-1
4	Fail	AA99071-13 05112160000123 0128 SA P1 Day 3 URN-1
4	Fail	AA99071-13 05112160000124 0128 SA P1 Day 4 URN-1
4	Fail	AA99071-13 05112160000125 0128 SA P1 Day 5 URN-1
4	Fail	AA99071-13 05112160000126 0128 SA P1 Day 6 URN-1



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 32. Summary of Reassays for Sample Investigation for Nicotine

Subject	Period	Timepoint	Analyte	Reasons for Reassay	Original Units	Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat Reassays	CV% of Reassays	% Difference and 2	% Difference and 3	% Difference and 3	% Difference from Original	Confirms Original	Reported Concentration
240	1	Day 3	Nicotine	VRC	ng/mL	38 700	10 000	10 000	10 000	10 000	0 000	0 000	0 000	0 000	74 160	No	10 000



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 33. Summary of Reassays for Sample Investigation for Cotinine

Subject	Period	Timepoint	Analyte	Reasons for Reassay	Original Units	Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat Reassays	CV% of Reassays	% Difference and 2	% Difference and 3	% Difference and 3	% Difference from Original	Confirms Original	Reported Concentration
240	1	Day 3	Cotinine	VRC	ng/mL	541 000	141 000	144 000	140 000	141 667	1 469	2 105	2 817	0 712	73 814	No	142 000



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 34. Summary of Reassays for Sample Investigation for Nicotine-*N*-Glucuronide

Subject	Period	Timepoint	Analyte	Reassay	Units	Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat Reassays	CV% of Reassays	CV% of Reassay 1 and 2	CV% of Reassay 2 and 3	CV% of Reassay 1 and 3	Difference from Original	Confirms Original	Reported Concentration
240	1	Day 3	Nicotine Gluc	VRC	ng/mL	277 000	10 000	10 000	10 000	10 000	0 000	0 000	0 000	0 000	96 390	No	10 000



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 35. Summary of Reassays for Sample Investigation for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Subject	Period	Timepoint	Analyte	Reassay	Units	Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat Reassays	CV% of Reassays	Reasons for Difference				Confirms Original	Reported Concentration
												% Difference and 2	% Difference and 3	% Difference and 3	% Difference from Original		
240	1	Day 3	THC Gluc	VRC	ng/mL	531 000	168 000	184 000	153 000	168 333	9 210	9 091	18 398	9 346	68 299	No	168 000



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13

Table 36. Incurred Sample Reproducibility Assessment for Nicotine

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	Nicotine	ng/mL	296	292	294	1.36	Pass	No	97.0
0013	1	Day 0	Nicotine	ng/mL	443	447	445	0.90	Pass	No	
0015	1	Day 0	Nicotine	ng/mL	783	757	770	3.38	Pass	No	
0017	1	Day 1	Nicotine	ng/mL	729	736	733	0.95	Pass	No	
0028	1	Day 0	Nicotine	ng/mL	292	303	298	3.69	Pass	No	
0049	1	Day 1	Nicotine	ng/mL	380	357	369	6.23	Pass	No	
0051	1	Day 0	Nicotine	ng/mL	521	514	518	1.35	Pass	No	
0052	1	Day 1	Nicotine	ng/mL	1100	1150	1,130	4.42	Pass	No	
0062	1	Day 2	Nicotine	ng/mL	30.6	31.0	30.8	1.30	Pass	No	
0063	1	Day 0	Nicotine	ng/mL	614	609	612	0.82	Pass	No	
0071	1	Day 1	Nicotine	ng/mL	825	812	819	1.59	Pass	No	
0076	1	Day 0	Nicotine	ng/mL	392	385	389	1.80	Pass	No	
0086	1	Day 2	Nicotine	ng/mL	48.7	44.6	46.7	8.78	Pass	No	
0104	1	Day 0	Nicotine	ng/mL	231	236	234	2.14	Pass	No	
0114	1	Day 0	Nicotine	ng/mL	241	269	255	10.98	Pass	No	
0123	1	Day 0	Nicotine	ng/mL	178	170	174	4.60	Pass	No	
0127	1	Day 0	Nicotine	ng/mL	660	741	701	11.55	Pass	No	
0128	1	Day 0	Nicotine	ng/mL	215	229	222	6.31	Pass	No	
0133	1	Day 1	Nicotine	ng/mL	580	565	573	2.62	Pass	No	
0137	1	Day 0	Nicotine	ng/mL	488	534	511	9.00	Pass	No	
0145	1	Day 0	Nicotine	ng/mL	265	277	271	4.43	Pass	No	
0150	1	Day 1	Nicotine	ng/mL	1300	1170	1,240	10.48	Pass	No	
0169	1	Day 1	Nicotine	ng/mL	294	305	300	3.67	Pass	No	
0185	1	Day 0	Nicotine	ng/mL	453	425	439	6.38	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	Nicotine	ng/mL	307	336	322	9.01	Pass	No	
0203	1	Day 0	Nicotine	ng/mL	394	399	397	1.26	Pass	No	
0240	1	Day 3	Nicotine	ng/mL	38.7	10.0	24.4	117.62	Fail	Event	
0249	1	Day 1	Nicotine	ng/mL	1850	1710	1,780	7.87	Pass	No	
0252	1	Day 1	Nicotine	ng/mL	646	681	664	5.27	Pass	No	
0265	1	Day 2	Nicotine	ng/mL	39.8	43.3	41.6	8.41	Pass	No	
0273	1	Day 0	Nicotine	ng/mL	227	225	226	0.88	Pass	No	
0289	1	Day 0	Nicotine	ng/mL	885	931	908	5.07	Pass	No	
0292	1	Day 0	Nicotine	ng/mL	464	464	464	0.00	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 37 Incurred Sample Reproducibility Assessment for Cotinine

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	Cotinine	ng/mL	480	483	482	0.62	Pass	No	97.0
0013	1	Day 0	Cotinine	ng/mL	1330	1330	1,330	0.00	Pass	No	
0015	1	Day 0	Cotinine	ng/mL	1050	1070	1,060	1.89	Pass	No	
0017	1	Day 1	Cotinine	ng/mL	737	763	750	3.47	Pass	No	
0028	1	Day 0	Cotinine	ng/mL	847	893	870	5.29	Pass	No	
0049	1	Day 1	Cotinine	ng/mL	707	729	718	3.06	Pass	No	
0051	1	Day 0	Cotinine	ng/mL	1070	1100	1,090	2.75	Pass	No	
0052	1	Day 1	Cotinine	ng/mL	1230	1230	1,230	0.00	Pass	No	
0062	1	Day 2	Cotinine	ng/mL	453	412	433	9.47	Pass	No	
0063	1	Day 0	Cotinine	ng/mL	1070	1090	1,080	1.85	Pass	No	
0071	1	Day 1	Cotinine	ng/mL	1680	1690	1,690	0.59	Pass	No	
0076	1	Day 0	Cotinine	ng/mL	619	638	629	3.02	Pass	No	
0086	1	Day 2	Cotinine	ng/mL	927	981	954	5.66	Pass	No	
0104	1	Day 0	Cotinine	ng/mL	551	541	546	1.83	Pass	No	
0114	1	Day 0	Cotinine	ng/mL	649	695	672	6.85	Pass	No	
0123	1	Day 0	Cotinine	ng/mL	554	568	561	2.50	Pass	No	
0127	1	Day 0	Cotinine	ng/mL	1660	1710	1,690	2.96	Pass	No	
0128	1	Day 0	Cotinine	ng/mL	1390	1270	1,330	9.02	Pass	No	
0133	1	Day 1	Cotinine	ng/mL	1560	1600	1,580	2.53	Pass	No	
0137	1	Day 0	Cotinine	ng/mL	658	658	658	0.00	Pass	No	
0145	1	Day 0	Cotinine	ng/mL	487	489	488	0.41	Pass	No	
0150	1	Day 1	Cotinine	ng/mL	1570	1620	1,600	3.13	Pass	No	
0169	1	Day 1	Cotinine	ng/mL	479	513	496	6.85	Pass	No	
0185	1	Day 0	Cotinine	ng/mL	1100	1170	1,140	6.14	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	Cotinine	ng/mL	654	674	664	3.01	Pass	No	
0203	1	Day 0	Cotinine	ng/mL	787	781	784	0.77	Pass	No	
0240	1	Day 3	Cotinine	ng/mL	541	146	344	114.83	Fail	Event	
0249	1	Day 1	Cotinine	ng/mL	1830	1700	1,770	7.34	Pass	No	
0252	1	Day 1	Cotinine	ng/mL	1250	1150	1,200	8.33	Pass	No	
0265	1	Day 2	Cotinine	ng/mL	761	750	756	1.46	Pass	No	
0273	1	Day 0	Cotinine	ng/mL	1190	1120	1,160	6.03	Pass	No	
0289	1	Day 0	Cotinine	ng/mL	970	1010	990	4.04	Pass	No	
0292	1	Day 0	Cotinine	ng/mL	1410	1220	1,320	14.39	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 38 Incurred Sample Reproducibility Assessment for *trans*-3'-Hydroxycotinine

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	THC	ng/mL	1330	1310	1,320	1.52	Pass	No	100.0
0013	1	Day 0	THC	ng/mL	5130	4870	5,000	5.20	Pass	No	
0015	1	Day 0	THC	ng/mL	5670	5800	5,740	2.26	Pass	No	
0017	1	Day 1	THC	ng/mL	712	716	714	0.56	Pass	No	
0028	1	Day 0	THC	ng/mL	3590	3440	3,520	4.26	Pass	No	
0049	1	Day 1	THC	ng/mL	701	677	689	3.48	Pass	No	
0051	1	Day 0	THC	ng/mL	2460	2480	2,470	0.81	Pass	No	
0052	1	Day 1	THC	ng/mL	3870	3660	3,770	5.57	Pass	No	
0062	1	Day 2	THC	ng/mL	1190	1050	1,120	12.50	Pass	No	
0063	1	Day 0	THC	ng/mL	4110	3790	3,950	8.10	Pass	No	
0071	1	Day 1	THC	ng/mL	2920	2820	2,870	3.48	Pass	No	
0076	1	Day 0	THC	ng/mL	1250	1270	1,260	1.59	Pass	No	
0086	1	Day 2	THC	ng/mL	2770	2710	2,740	2.19	Pass	No	
0104	1	Day 0	THC	ng/mL	4430	4190	4,310	5.57	Pass	No	
0114	1	Day 0	THC	ng/mL	1700	1690	1,700	0.59	Pass	No	
0123	1	Day 0	THC	ng/mL	1400	1450	1,430	3.50	Pass	No	
0127	1	Day 0	THC	ng/mL	7940	7870	7,910	0.88	Pass	No	
0128	1	Day 0	THC	ng/mL	3970	3610	3,790	9.50	Pass	No	
0133	1	Day 1	THC	ng/mL	4210	3960	4,090	6.11	Pass	No	
0137	1	Day 0	THC	ng/mL	3980	4220	4,100	5.85	Pass	No	
0145	1	Day 0	THC	ng/mL	2850	3070	2,960	7.43	Pass	No	
0150	1	Day 1	THC	ng/mL	2210	2280	2,250	3.11	Pass	No	
0169	1	Day 1	THC	ng/mL	1150	1160	1,160	0.86	Pass	No	
0185	1	Day 0	THC	ng/mL	6810	6770	6,790	0.59	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	THC	ng/mL	732	758	745	3.49	Pass	No	
0203	1	Day 0	THC	ng/mL	1740	1850	1,800	6.11	Pass	No	
0240	1	Day 3	THC	ng/mL	545	529	537	2.98	Pass	No	
0249	1	Day 1	THC	ng/mL	6610	5750	6,180	13.92	Pass	No	
0252	1	Day 1	THC	ng/mL	3580	3360	3,470	6.34	Pass	No	
0265	1	Day 2	THC	ng/mL	2090	1900	2,000	9.50	Pass	No	
0273	1	Day 0	THC	ng/mL	3640	3600	3,620	1.10	Pass	No	
0289	1	Day 0	THC	ng/mL	2470	2470	2,470	0.00	Pass	No	
0292	1	Day 0	THC	ng/mL	929	943	936	1.50	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 39 Incurred Sample Reproducibility Assessment for Nicotine-*N*-Glucuronide

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	Nicotine Gluc	ng/mL	119	119	119	0.00	Pass	No	97.0
0013	1	Day 0	Nicotine Gluc	ng/mL	912	928	920	1.74	Pass	No	
0015	1	Day 0	Nicotine Gluc	ng/mL	509	524	517	2.90	Pass	No	
0017	1	Day 1	Nicotine Gluc	ng/mL	774	914	844	16.59	Pass	No	
0028	1	Day 0	Nicotine Gluc	ng/mL	244	273	259	11.20	Pass	No	
0049	1	Day 1	Nicotine Gluc	ng/mL	387	403	395	4.05	Pass	No	
0051	1	Day 0	Nicotine Gluc	ng/mL	328	348	338	5.92	Pass	No	
0052	1	Day 1	Nicotine Gluc	ng/mL	800	877	839	9.18	Pass	No	
0062	1	Day 2	Nicotine Gluc	ng/mL	85.1	83.7	84.4	1.66	Pass	No	
0063	1	Day 0	Nicotine Gluc	ng/mL	293	295	294	0.68	Pass	No	
0071	1	Day 1	Nicotine Gluc	ng/mL	1230	1320	1,280	7.03	Pass	No	
0076	1	Day 0	Nicotine Gluc	ng/mL	417	417	417	0.00	Pass	No	
0086	1	Day 2	Nicotine Gluc	ng/mL	278	278	278	0.00	Pass	No	
0104	1	Day 0	Nicotine Gluc	ng/mL	196	175	186	11.29	Pass	No	
0114	1	Day 0	Nicotine Gluc	ng/mL	303	315	309	3.88	Pass	No	
0123	1	Day 0	Nicotine Gluc	ng/mL	180	177	179	1.68	Pass	No	
0127	1	Day 0	Nicotine Gluc	ng/mL	593	653	623	9.63	Pass	No	
0128	1	Day 0	Nicotine Gluc	ng/mL	1900	1690	1,800	11.67	Pass	No	
0133	1	Day 1	Nicotine Gluc	ng/mL	727	713	720	1.94	Pass	No	
0137	1	Day 0	Nicotine Gluc	ng/mL	240	232	236	3.39	Pass	No	
0145	1	Day 0	Nicotine Gluc	ng/mL	158	153	156	3.21	Pass	No	
0150	1	Day 1	Nicotine Gluc	ng/mL	971	1040	1,010	6.83	Pass	No	
0169	1	Day 1	Nicotine Gluc	ng/mL	263	256	260	2.69	Pass	No	
0185	1	Day 0	Nicotine Gluc	ng/mL	1340	1380	1,360	2.94	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	Nicotine Gluc	ng/mL	1220	1380	1,300	12.31	Pass	No	
0203	1	Day 0	Nicotine Gluc	ng/mL	315	307	311	2.57	Pass	No	
0240	1	Day 3	Nicotine Gluc	ng/mL	277	10.0	144	185.42	Fail	Event	
0249	1	Day 1	Nicotine Gluc	ng/mL	953	955	954	0.21	Pass	No	
0252	1	Day 1	Nicotine Gluc	ng/mL	355	362	359	1.95	Pass	No	
0265	1	Day 2	Nicotine Gluc	ng/mL	120	122	121	1.65	Pass	No	
0273	1	Day 0	Nicotine Gluc	ng/mL	395	416	406	5.17	Pass	No	
0289	1	Day 0	Nicotine Gluc	ng/mL	800	818	809	2.22	Pass	No	
0292	1	Day 0	Nicotine Gluc	ng/mL	916	985	951	7.26	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 40 Incurred Sample Reproducibility Assessment for Cotinine-*N*-Glucuronide

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	Cotinine Gluc	ng/mL	1140	1150	1,150	0.87	Pass	No	100.0
0013	1	Day 0	Cotinine Gluc	ng/mL	12300	11000	11,700	11.11	Pass	No	
0015	1	Day 0	Cotinine Gluc	ng/mL	4140	4030	4,090	2.69	Pass	No	
0017	1	Day 1	Cotinine Gluc	ng/mL	2560	2870	2,720	11.40	Pass	No	
0028	1	Day 0	Cotinine Gluc	ng/mL	3540	3130	3,340	12.28	Pass	No	
0049	1	Day 1	Cotinine Gluc	ng/mL	1350	1240	1,300	8.46	Pass	No	
0051	1	Day 0	Cotinine Gluc	ng/mL	3250	3240	3,250	0.31	Pass	No	
0052	1	Day 1	Cotinine Gluc	ng/mL	4870	4600	4,740	5.70	Pass	No	
0062	1	Day 2	Cotinine Gluc	ng/mL	1640	1720	1,680	4.76	Pass	No	
0063	1	Day 0	Cotinine Gluc	ng/mL	3500	3400	3,450	2.90	Pass	No	
0071	1	Day 1	Cotinine Gluc	ng/mL	6660	5610	6,140	17.10	Pass	No	
0076	1	Day 0	Cotinine Gluc	ng/mL	1550	1620	1,590	4.40	Pass	No	
0086	1	Day 2	Cotinine Gluc	ng/mL	6390	6030	6,210	5.80	Pass	No	
0104	1	Day 0	Cotinine Gluc	ng/mL	1990	2030	2,010	1.99	Pass	No	
0114	1	Day 0	Cotinine Gluc	ng/mL	1330	1290	1,310	3.05	Pass	No	
0123	1	Day 0	Cotinine Gluc	ng/mL	1100	1060	1,080	3.70	Pass	No	
0127	1	Day 0	Cotinine Gluc	ng/mL	5720	5820	5,770	1.73	Pass	No	
0128	1	Day 0	Cotinine Gluc	ng/mL	10400	8880	9,640	15.77	Pass	No	
0133	1	Day 1	Cotinine Gluc	ng/mL	4380	4310	4,350	1.61	Pass	No	
0137	1	Day 0	Cotinine Gluc	ng/mL	2450	2290	2,370	6.75	Pass	No	
0145	1	Day 0	Cotinine Gluc	ng/mL	1860	1710	1,790	8.38	Pass	No	
0150	1	Day 1	Cotinine Gluc	ng/mL	5030	4800	4,920	4.67	Pass	No	
0169	1	Day 1	Cotinine Gluc	ng/mL	1570	1570	1,570	0.00	Pass	No	
0185	1	Day 0	Cotinine Gluc	ng/mL	14900	14000	14,500	6.21	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	Cotinine Gluc	ng/mL	5580	5410	5,500	3.09	Pass	No	
0203	1	Day 0	Cotinine Gluc	ng/mL	2020	2040	2,030	0.99	Pass	No	
0240	1	Day 3	Cotinine Gluc	ng/mL	1360	1400	1,380	2.90	Pass	No	
0249	1	Day 1	Cotinine Gluc	ng/mL	5800	5970	5,890	2.89	Pass	No	
0252	1	Day 1	Cotinine Gluc	ng/mL	1640	1590	1,620	3.09	Pass	No	
0265	1	Day 2	Cotinine Gluc	ng/mL	3030	2700	2,870	11.50	Pass	No	
0273	1	Day 0	Cotinine Gluc	ng/mL	3120	2700	2,910	14.43	Pass	No	
0289	1	Day 0	Cotinine Gluc	ng/mL	5510	5350	5,430	2.95	Pass	No	
0292	1	Day 0	Cotinine Gluc	ng/mL	3650	3440	3,550	5.92	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Table 41 Incurred Sample Reproducibility Assessment for *trans*-3'-Hydroxycotinine-*O*-Glucuronide

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0010	1	Day 1	THC Gluc	ng/mL	952	945	949	0.74	Pass	No	97.0
0013	1	Day 0	THC Gluc	ng/mL	3520	4170	3,850	16.88	Pass	No	
0015	1	Day 0	THC Gluc	ng/mL	3140	3090	3,120	1.60	Pass	No	
0017	1	Day 1	THC Gluc	ng/mL	261	272	267	4.12	Pass	No	
0028	1	Day 0	THC Gluc	ng/mL	1210	1220	1,220	0.82	Pass	No	
0049	1	Day 1	THC Gluc	ng/mL	339	301	320	11.88	Pass	No	
0051	1	Day 0	THC Gluc	ng/mL	1350	1470	1,410	8.51	Pass	No	
0052	1	Day 1	THC Gluc	ng/mL	1480	1580	1,530	6.54	Pass	No	
0062	1	Day 2	THC Gluc	ng/mL	603	652	628	7.80	Pass	No	
0063	1	Day 0	THC Gluc	ng/mL	2520	2660	2,590	5.41	Pass	No	
0071	1	Day 1	THC Gluc	ng/mL	1350	1290	1,320	4.55	Pass	No	
0076	1	Day 0	THC Gluc	ng/mL	924	1010	967	8.89	Pass	No	
0086	1	Day 2	THC Gluc	ng/mL	904	995	950	9.58	Pass	No	
0104	1	Day 0	THC Gluc	ng/mL	1990	1990	1,990	0.00	Pass	No	
0114	1	Day 0	THC Gluc	ng/mL	744	783	764	5.10	Pass	No	
0123	1	Day 0	THC Gluc	ng/mL	691	646	669	6.73	Pass	No	
0127	1	Day 0	THC Gluc	ng/mL	4230	4180	4,210	1.19	Pass	No	
0128	1	Day 0	THC Gluc	ng/mL	1660	1610	1,640	3.05	Pass	No	
0133	1	Day 1	THC Gluc	ng/mL	2010	1890	1,950	6.15	Pass	No	
0137	1	Day 0	THC Gluc	ng/mL	1860	2090	1,980	11.62	Pass	No	
0145	1	Day 0	THC Gluc	ng/mL	2110	1840	1,980	13.64	Pass	No	
0150	1	Day 1	THC Gluc	ng/mL	1450	1470	1,460	1.37	Pass	No	
0169	1	Day 1	THC Gluc	ng/mL	738	711	725	3.72	Pass	No	
0185	1	Day 0	THC Gluc	ng/mL	4420	4610	4,520	4.20	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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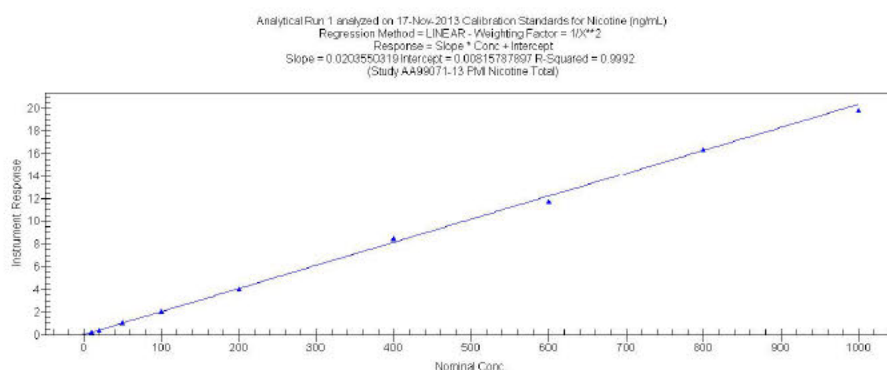
Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0197	1	Day 0	THC Gluc	ng/mL	872	797	835	8.98	Pass	No	
0203	1	Day 0	THC Gluc	ng/mL	1370	1430	1,400	4.29	Pass	No	
0240	1	Day 3	THC Gluc	ng/mL	531	166	349	104.58	Fail	Event	
0249	1	Day 1	THC Gluc	ng/mL	2910	3170	3,040	8.55	Pass	No	
0252	1	Day 1	THC Gluc	ng/mL	1610	1430	1,520	11.84	Pass	No	
0265	1	Day 2	THC Gluc	ng/mL	1200	1450	1,330	18.80	Pass	No	
0273	1	Day 0	THC Gluc	ng/mL	2190	2360	2,280	7.46	Pass	No	
0289	1	Day 0	THC Gluc	ng/mL	974	911	943	6.68	Pass	No	
0292	1	Day 0	THC Gluc	ng/mL	422	381	402	10.20	Pass	No	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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FIGURES

Figure 1 Calibration Curve for Nicotine in Control Matrix, Watson Run ID 1¹

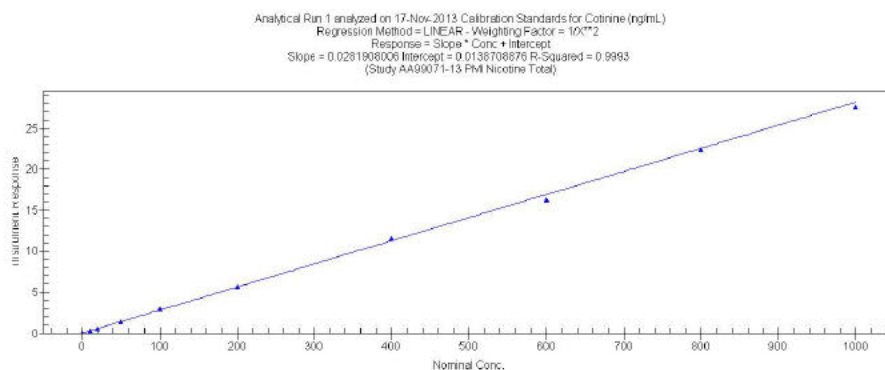


¹ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Figure 2 Calibration Curve for Cotinine in Control Matrix, Watson Run ID 1²

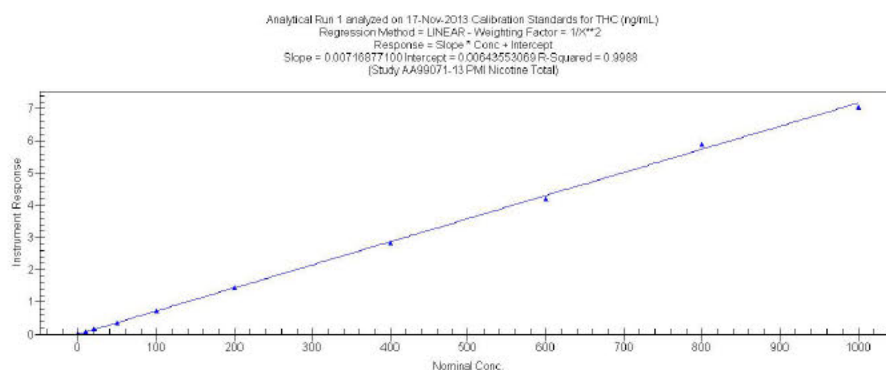


² Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Figure 3 Calibration Curve for *trans*-3'-Hydroxycotinine in Control Matrix, Watson Run ID 1³

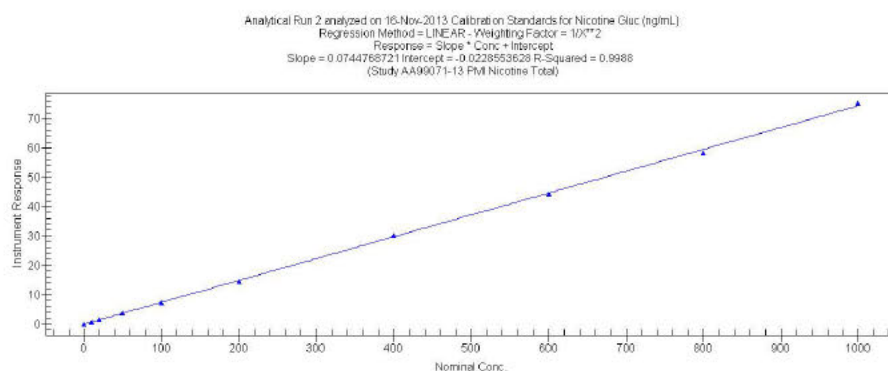


³ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Figure 4 Calibration Curve for Nicotine-*N*-Glucuronide in Control Matrix, Watson Run ID 2⁴

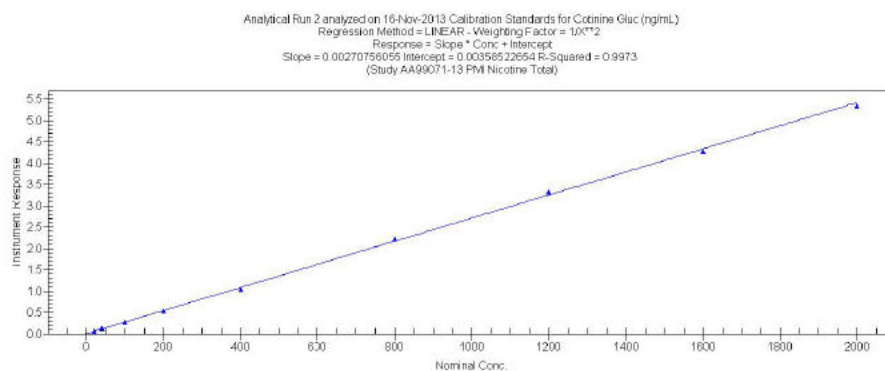


⁴ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Figure 5 Calibration Curve for Cotinine-*N*-Glucuronide in Control Matrix, Watson Run ID 2⁵

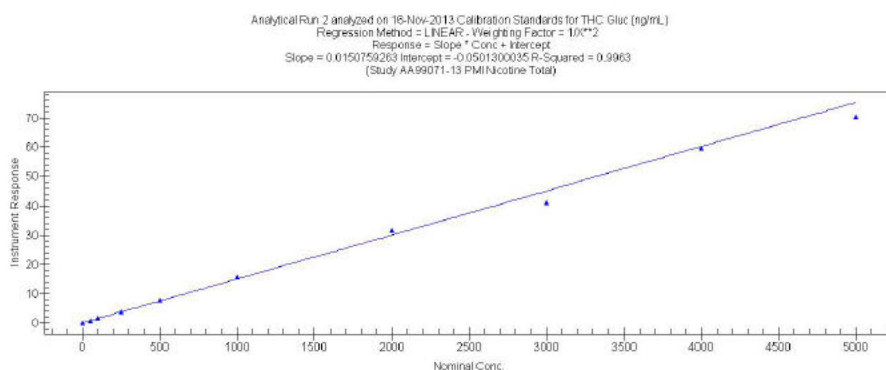


⁵ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Figure 6 Calibration Curve for *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Control Matrix, Watson Run ID 2⁶



⁶ Note: Though included on the figure above, the Standard 0 (blank sample extracted with internal standard) was not used as a standard to calculate the calibration curve parameters.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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ATTACHMENTS

Attachment 1 General List of Abbreviations used at Celerion

Abbreviations are used in this document as applicable.

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



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Abbreviation	Description
HSR	High standard removed
ID	Identifier
INC	Incongruous
INS	Instrumentation
IS	Internal standard
ISA	Insufficient volume for full analysis
ISP	Incomplete sample processing
ISR	Incurred sample reproducibility
ISV	Insufficient volume
IVR	Insufficient volume to reassay
L	Litre, liter
LLOQ	Lower limit of quantitation
LNK	Celerion, Lincoln site
M	Molar
mg	Milligram
mL	Millilitre, milliliter
mol	Mole
MS	Mass spectrometry
MW	Molecular weight
n	Number of data points
N/AP	Not applicable
N/AV	Not available
NFV	Not full volume
ng	Nanogram
No	Number
NU	Not used
OECD	Organization for Economic Cooperation and Development
PD	Period
pg	Picogram
QC	Quality control
QCs	Quality control samples
R E	Relative error



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Abbreviation	Description
REF	Reference
RI	Reinjection
RIA	Rarioimmunoassay
RT	Room temperature
RR	Reanalysis
RVL	Remaining volume low
S A	Smoking Abstinence
S D	Standard deviation
SOP	Standard operating procedure
SPE	Solid-phase extraction
SST	System suitability test
STD	Standard
Sub	Subject
SVD	Sample volume depleted
TBD	To be determined
Temp	Temperature
THS	Tobacco Heating System
UCR	Unacceptable chromatography
UISR	Unacceptable internal standard response
ULOQ	Upper limit of quantitation
U S FDA	United States Food and Drug Administration
USP	US pharmacopeia
\bar{x}	Mean



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Attachment 2 Temperature Definitions at Celerion

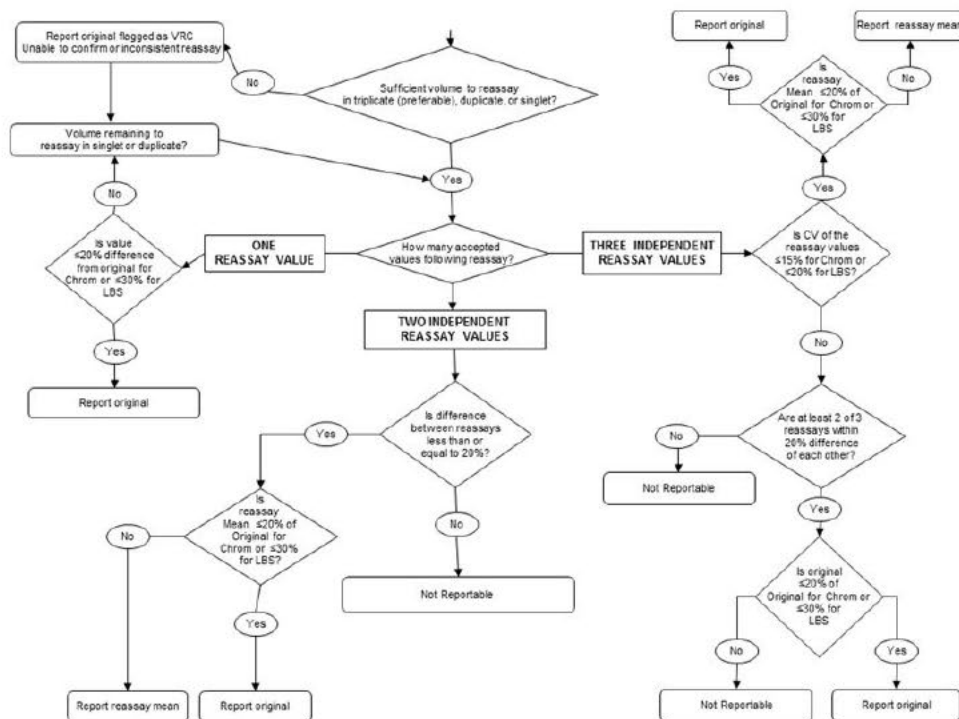
Values for temperatures are nominal temperatures representing the following temperature ranges:

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



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Attachment 3 Procedure for VRC and SSR Reassays and Reporting of Reassay Results



To compare reassays:

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

To compare to original:

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

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

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



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Attachment 4 General List of Calculation Formulae

Mean:	Error! Objects cannot be created from editing field codes.
Standard Deviation (SD):	Error! Objects cannot be created from editing field codes.
Precision (RSD, CV):	Error! Objects cannot be created from editing field codes.
Accuracy (% Theoretical):	Error! Objects cannot be created from editing field codes.
	Error! Objects cannot be created from editing field codes.
Inaccuracy (% Bias, % RE):	Error! Objects cannot be created from editing field codes.
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x = value (e.g. analyte concentration, OD value, cpm value, peak signal)

n = number of values

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Error! Objects cannot be created from editing field codes.



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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Attachment 5 Reassay Descriptions

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



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
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Attachment 6 Certificates of Analysis



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

(b) (4)

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

(b) (4)

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Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13

Attachment 7 Bioanalytical Method Summary



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 -- CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: Nicotine		Matrix: Urine	
MVR/SOP no. & date: ZZ33881-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln	
LLOQ: 10.0 ng/mL		ULOQ: 1000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.			
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in any of the 10 human urine lots that were fortified at the concentration of the LLOQ (10.0 ng/mL) and in any of the 10 human urine lots that were fortified at the concentration of the high QC (750 ng/mL) samples		
Accuracy:	Intra-batch: -7.0 to 2.0% R.E. Inter-batch: -3.0 to 0.1% R.E.		
Precision:	Intra-batch: 1.8 to 9.3% CV Inter-batch: 2.5 to 5.9% CV		
Recovery:	90% recovery at 30.0 ng/mL in human urine 101% recovery at 150 ng/mL in human urine 97% recovery at 750 ng/mL in human urine		
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light		
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light		
Long-term stability:	118 days in polypropylene tubes at -20°C		
Stock solution stability:	40 days at 100 µg/mL in boxed water in polypropylene tubes at -20°C		
Post-preparative stability:	180 hours in a polypropylene 96 well plate 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"		



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FDR_QM000496 - CR204A2

Version N°: 2.0

Page 2 of 2

BMS completed by:		
Name:	Date:	Signature:
Erica Nach.	14-MAY-2013	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 – CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: Cotinine		Matrix: Urine	
MVR/SOP no. & date: ZZ33861-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln	
LLOQ: 10.0 ng/mL		ULOQ: 1000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.			
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in any of the 10 human urine lots that were fortified at the concentration of the LLOQ (10.0 ng/mL) and in any of the 10 human urine lots that were fortified at the concentration of the high QC (750 ng/mL) samples		
Accuracy:	Intra-batch: -10.6 to 5.3% R.E. Inter-batch: -4.3 to 2.0% R.E.		
Precision:	Intra-batch: 1.4 to 8.6% CV Inter-batch: 2.2 to 7.2% CV		
Recovery:	91% recovery at 30.0 ng/mL in human urine 100% recovery at 150 ng/mL in human urine 97% recovery at 750 ng/mL in human urine		
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light		
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light		
Long-term stability:	118 days in polypropylene tubes at -20°C		
Stock solution stability:	40 days at 100 µg/mL in boxed water in polypropylene tubes at -20°C		
Post-preparative stability:	180 hours in a polypropylene 96 well plate 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"		



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 - CR204A2

Version N°: 2.0

Page 2 of 2

BMS completed by:		
Name:	Date:	Signature:
Erica Nachi	14-MAY-2013	Eva J. Nachi



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 – CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: <i>trans</i> -3'-hydroxycotinine		Matrix: Urine
MVR/SOP no. & date: ZZ33881-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln
LLOQ: 10.0 ng/mL		ULOQ: 1000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.		
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in any of the 10 human urine lots that were fortified at the concentration of the LLOQ (10.0 ng/mL) or in any of the 10 human urine lots that were fortified at the concentration of the high QC (750 ng/mL) samples	
Accuracy:	Intra-batch: -9.5 to 0.3% R.E. Inter-batch: -3.9 to -0.7% R.E.	
Precision:	Intra-batch: 1.1 to 11.5% CV Inter-batch: 1.9 to 8.1% CV	
Recovery:	49% recovery at 30.0 ng/mL in human urine 52% recovery at 150 ng/mL in human urine 51% recovery at 750 ng/mL in human urine	
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light	
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light	
Long-term stability:	118 days in polypropylene tubes at -20°C	
Stock solution stability:	41 days at approximately 1000 µg/mL in boxed water in polypropylene tubes at -20°C	
Post-preparative stability:	180 hours in a polypropylene 96 well plate 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"	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 - CR204A2

Version N°: 2.0

Page 2 of 2

BMS completed by:

Name:	Date:	Signature:
Erica Nachi	14-MAY-2013	Erica J Nachi



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 -- CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: Nicotine- <i>N</i> -glucuronide		Matrix: Urine
MVR/SOP no. & date: ZZ33881-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln
LLOQ: 10.0 ng/mL		ULOQ: 1000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.		
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in any of the 10 human urine lots that were fortified at the concentration of the LLOQ (10.0 ng/mL) or in any of the 10 human urine lots that were fortified at the concentration of the high QC (750 ng/mL) samples	
Accuracy:	Intra-batch: -11.3 to 2.7% R.E. Inter-batch: -5.0 to 0.0% R.E.	
Precision:	Intra-batch: 1.5 to 9.2% CV Inter-batch: 3.7 to 8.3% CV	
Recovery:	47% recovery at 30.0 ng/mL in human urine 52% recovery at 150 ng/mL in human urine 54% recovery at 750 ng/mL in human urine	
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light	
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light	
Long-term stability:	118 days in polypropylene tubes at -20°C	
Stock solution stability:	71 days at approximately 1000 µg/mL in boxed water in polypropylene tubes at -20°C	
Post-preparative stability:	181 hours in a polypropylene 96 well plate 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"	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOP_QM000496 – CR204A2

Version N°: 2.0

Page 2 of 2

BMS completed by:		
Name:	Date:	Signature:
Erica Nachi	14. MAY. 2013	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 - CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: Cotinine- <i>N</i> -glucuronide		Matrix: Urine
MVR/SOP no. & date: ZZ33881-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln
LLOQ: 20.0 ng/mL		ULOQ: 2000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.		
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in 9 of the 10 human urine lots that were fortified at the concentration of the LLOQ (20.0 ng/mL) or in any of the 10 human urine lots that were fortified at the concentration of the high QC (1500 ng/mL) samples	
Accuracy:	Intra-batch: -9.5 to 10.2% R.E. Inter-batch: -3.5 to 4.2% R.E.	
Precision:	Intra-batch: 3.9 to 11.3% CV Inter-batch: 6.3 to 11.5% CV	
Recovery:	46% recovery at 60.0 ng/mL in human urine 48% recovery at 300 ng/mL in human urine 51% recovery at 1500 ng/mL in human urine	
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light	
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light	
Long-term stability:	118 days in polypropylene tubes at -20°C	
Stock solution stability:	120 days at approximately 1000 µg/mL in boxed water in polypropylene tubes at -20°C	
Post-preparative stability:	181 hours in a polypropylene 96 well plate 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"	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000496 - CR204A2

Version N°: 2.0

Page 2 of 2

BMS completed by:		
Name:	Date:	Signature:
Erica Nachi	14 MAY 2013	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
Celerion Study AA99071-13



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000498 - CR204A2

Version N°: 2.0

Page 1 of 2

Biomarker: <i>Trans</i> -3'-hydroxycotinine- <i>O</i> -glucuronide		Matrix: Urine
MVR/SOP no. & date: ZZ33881-03 / 16-Oct-2012		CRO/Laboratory: Celerion-Lincoln
LLOQ: 50.0 ng/mL		ULOQ: 5000 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 combined liquid-liquid and solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 4000 TM mass spectrometer using an ESI source. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration ²) of peak area ratios of the analyte and internal standard.		
Selectivity/Sensitivity/Matrix effect:	No significant matrix effect was observed in 9 of the 10 human urine lots that were fortified at the concentration of the LLOQ (50.0 ng/mL) or in any of the 10 human urine lots that were fortified at the concentration of the high QC (3750 ng/mL) samples	
Accuracy:	Intra-batch: -7.8 to 0.0% R.E. Inter-batch: -6.0 to -3.3% R.E.	
Precision:	Intra-batch: 1.6 to 8.9% CV Inter-batch: 3.5 to 7.4% CV	
Recovery:	42% recovery at 150 ng/mL in human urine 49% recovery at 750 ng/mL in human urine 49% recovery at 3750 ng/mL in human urine	
Freeze and thaw stability:	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light	
Short-term temperature stability:	54 hours in polypropylene tubes at ambient temperature under white light	
Long-term stability:	118 days in polypropylene tubes at -20°C	
Stock solution stability:	120 days at approximately 1000 µg/mL in boxed water in polypropylene tubes at -20°C	
Post-preparative stability:	181 hours in a polypropylene 96 well plate 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"	



Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide
in Human Urine
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BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR_QM000486 – CR204A2

Version N°: 2.0

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BMS completed by:		
Name:	Date:	Signature:
Erica Nachi	14-MAY 2013	



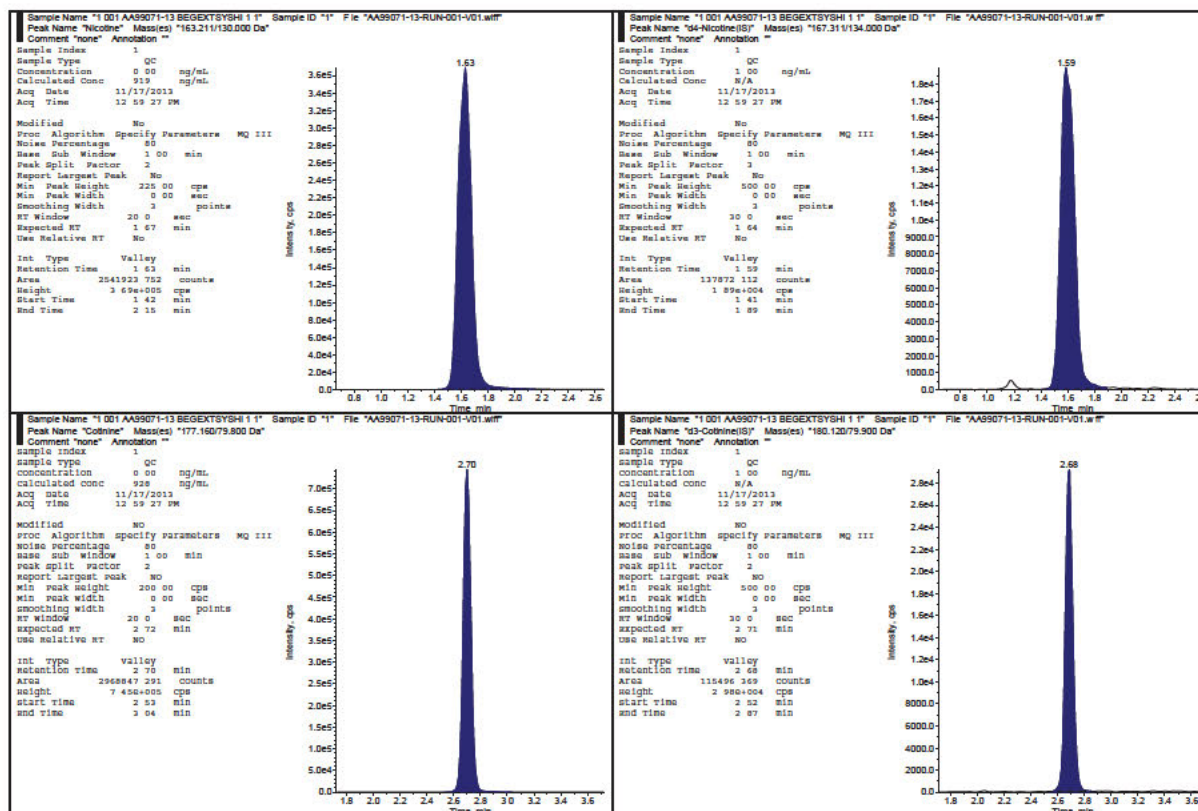
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Attachment 8 Chromatograms

Total number of pages including this page: 281

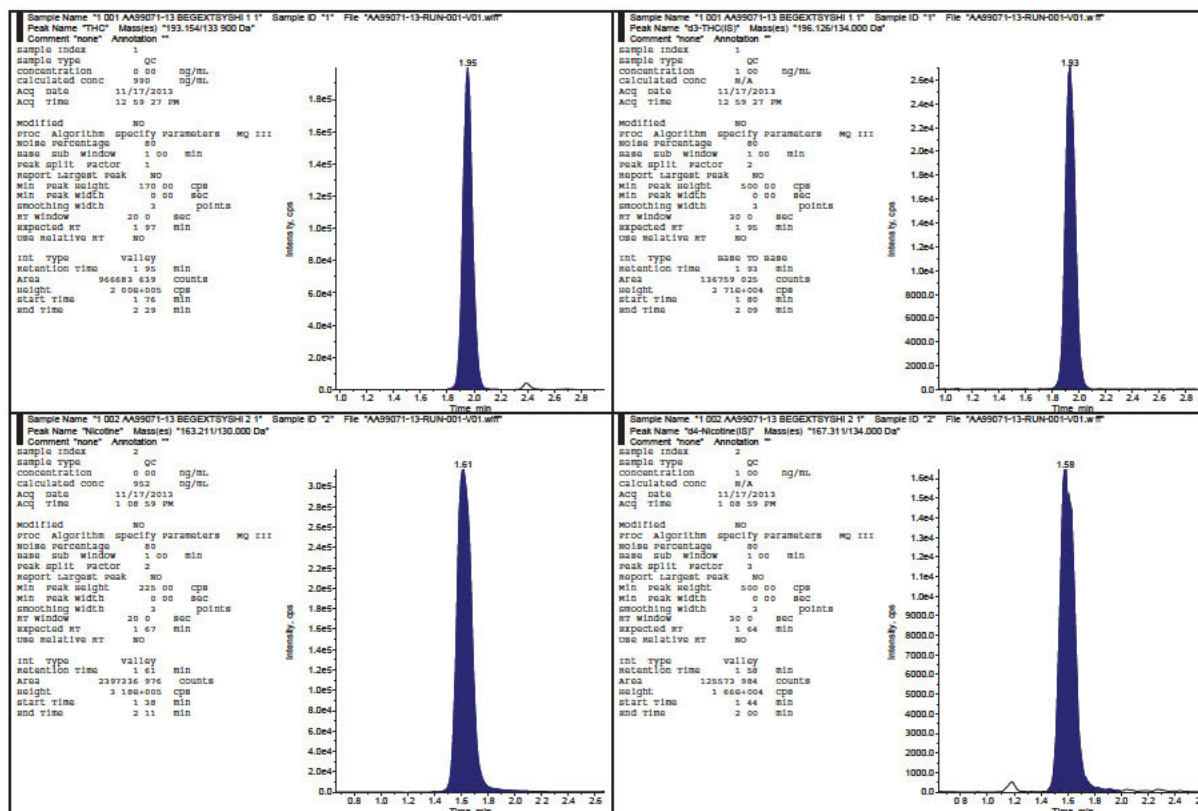


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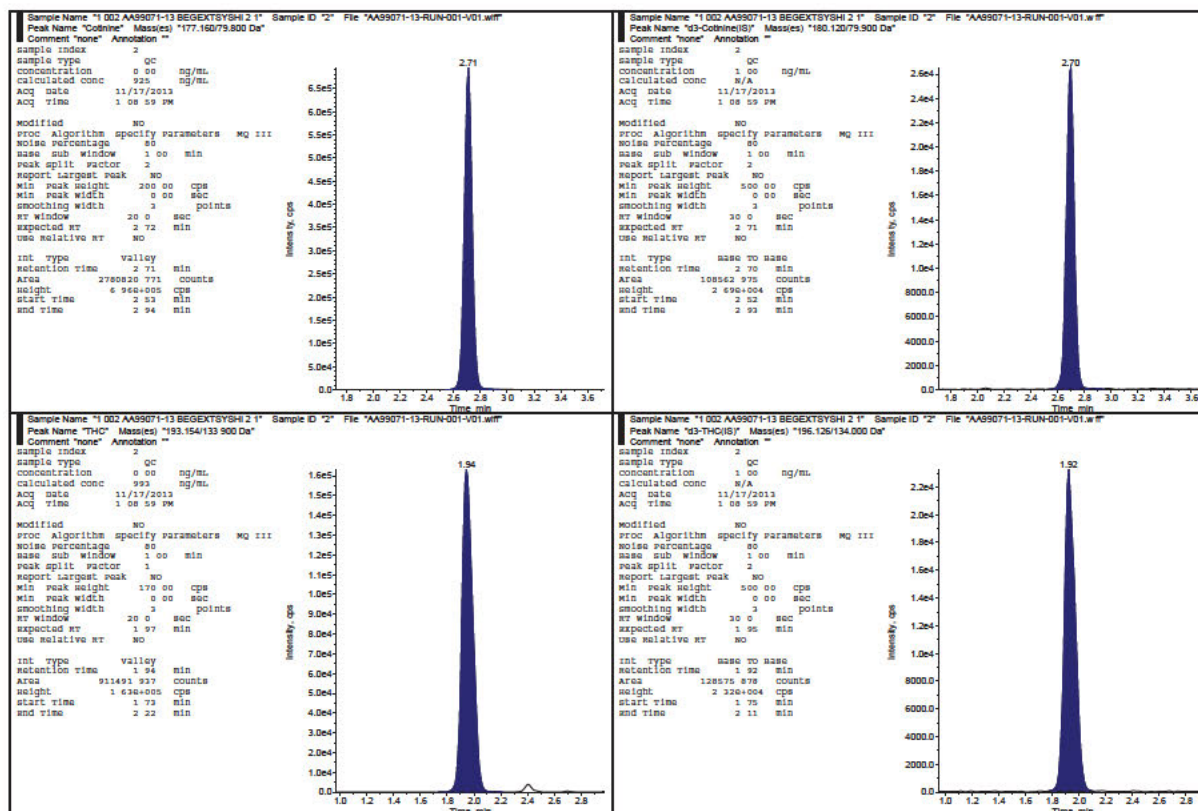


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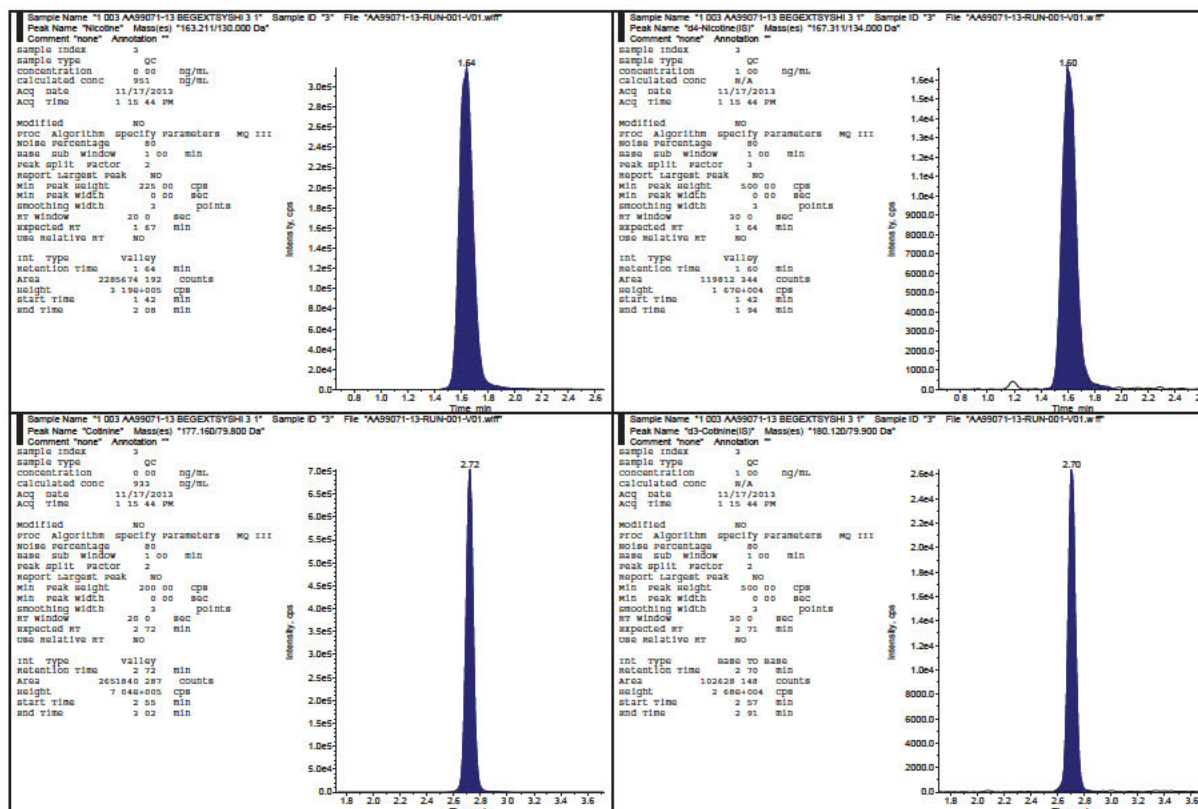


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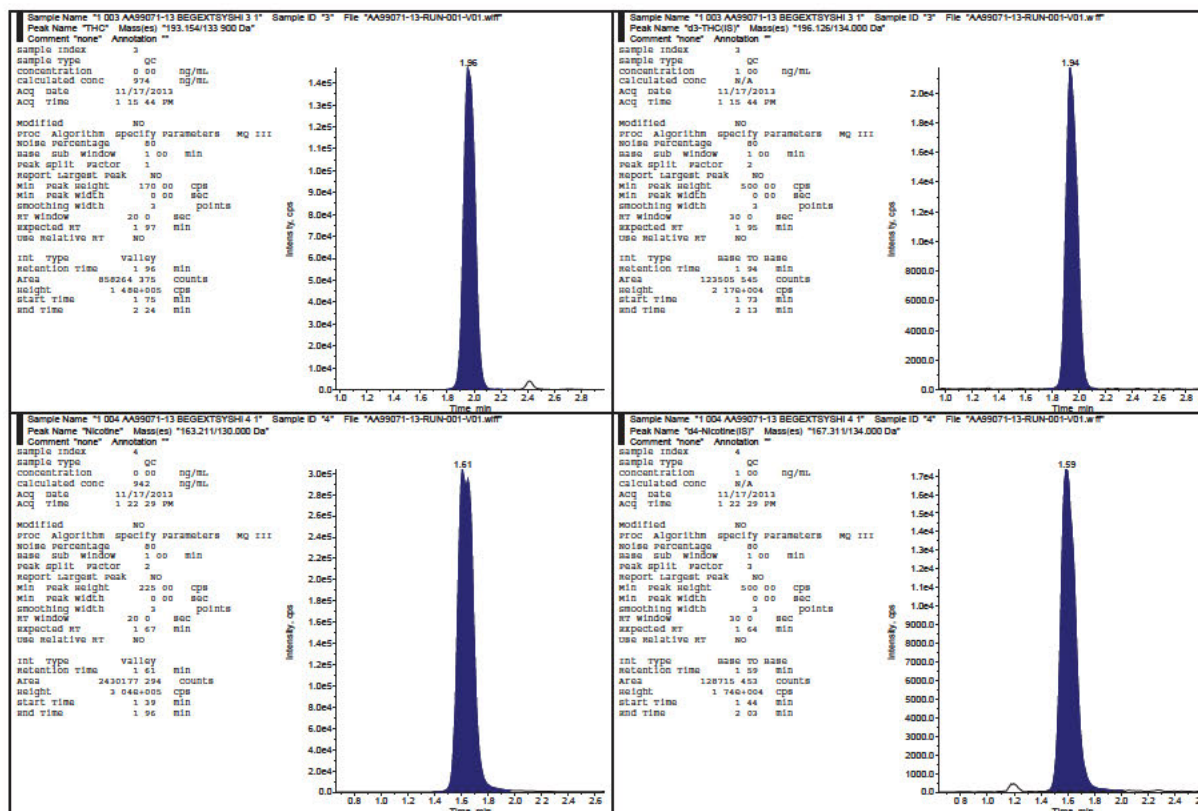


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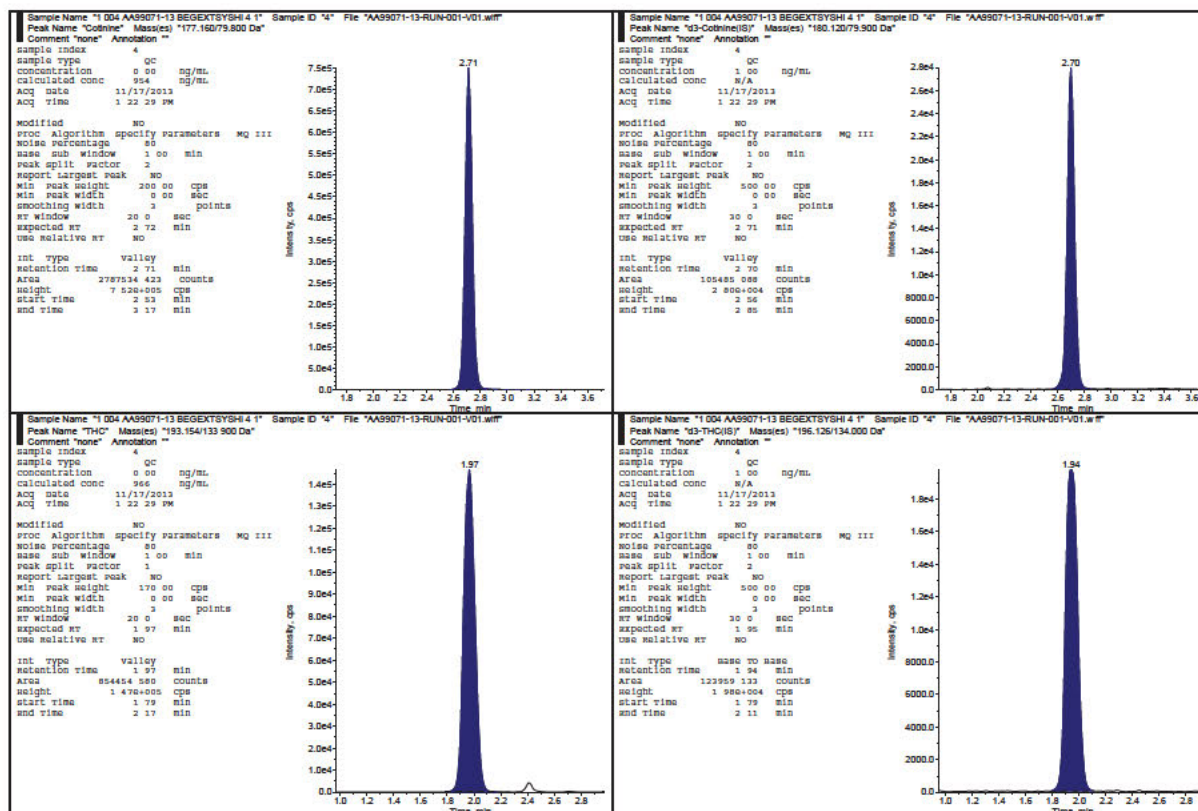


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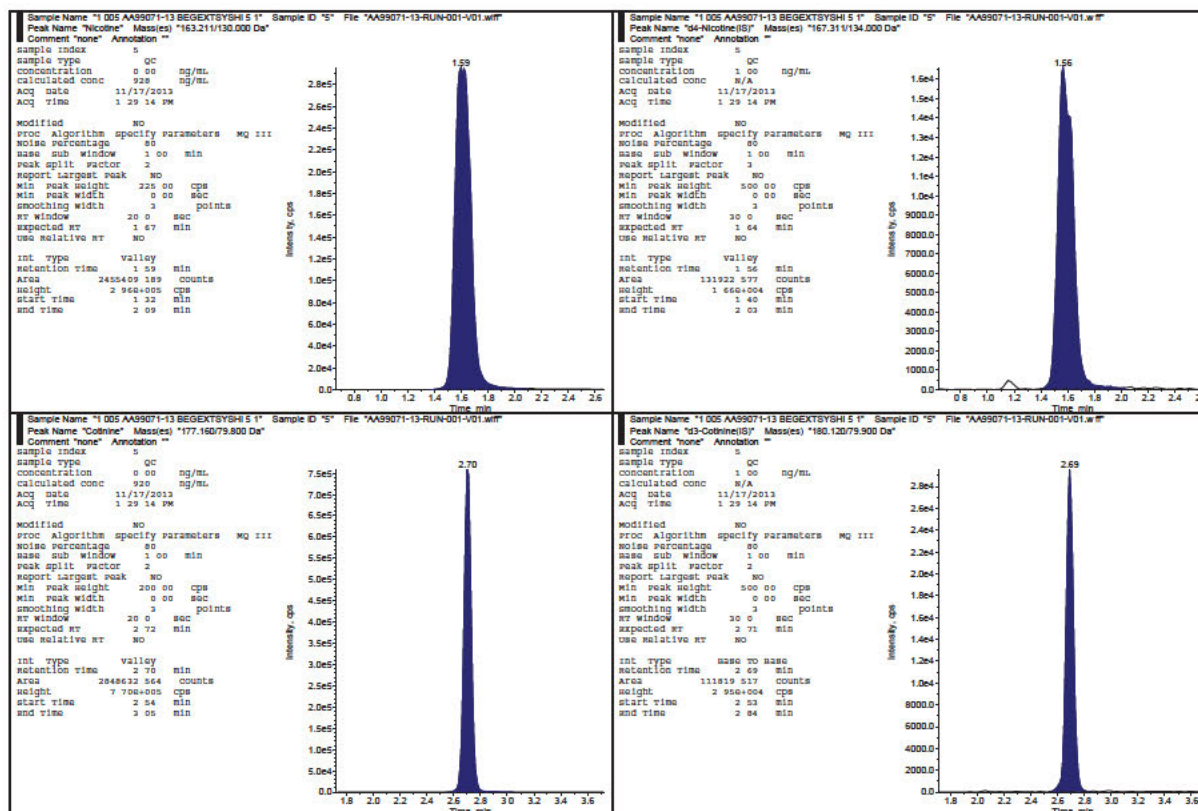


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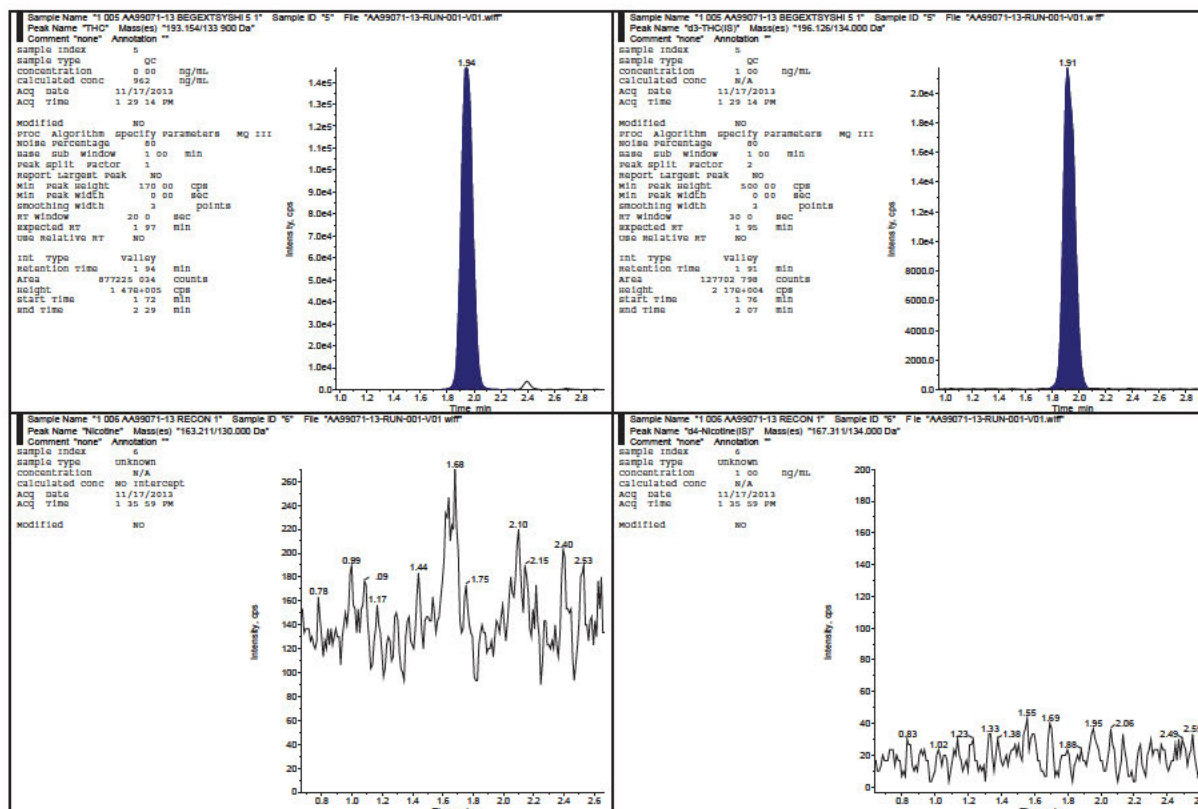


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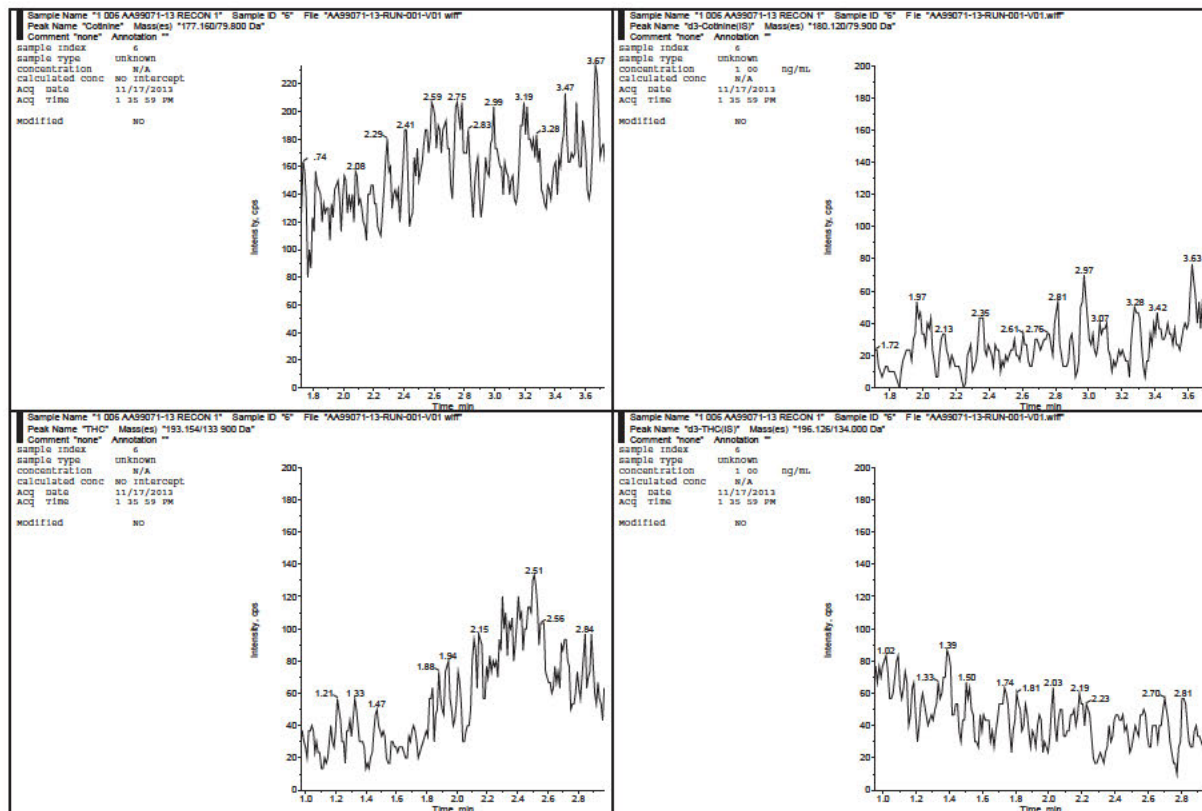


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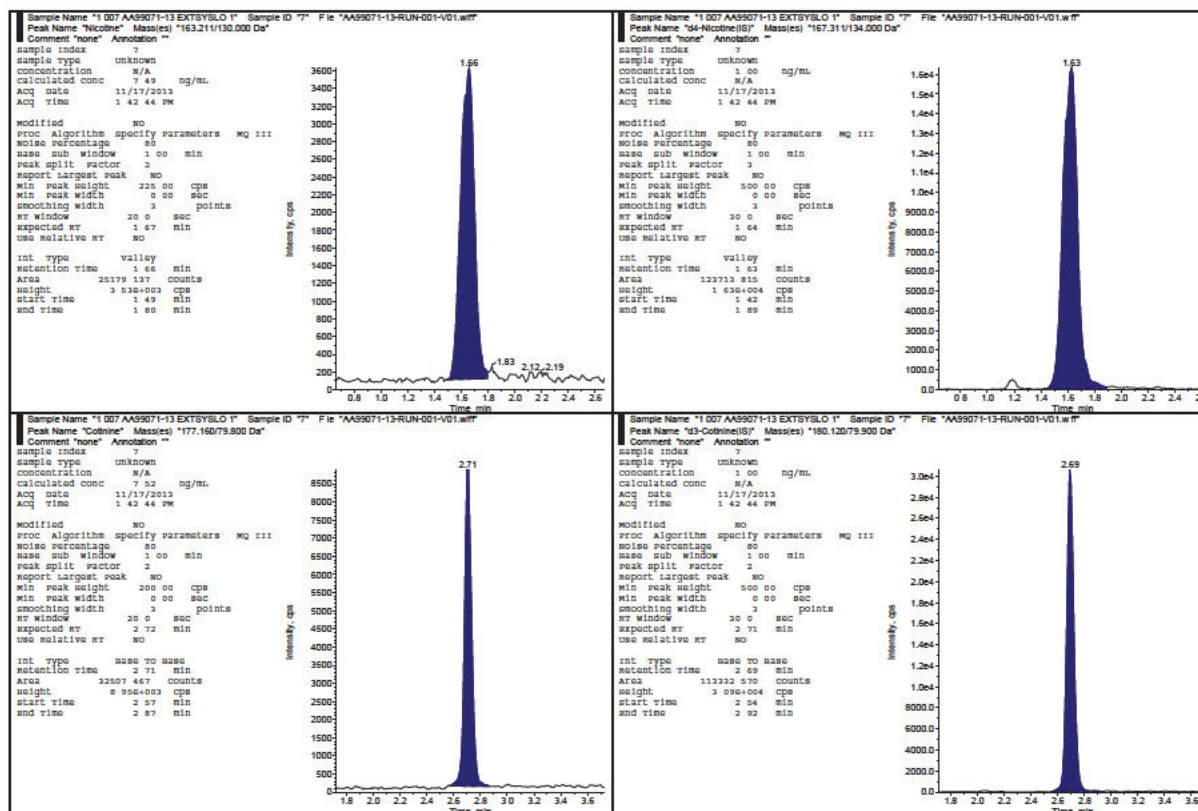


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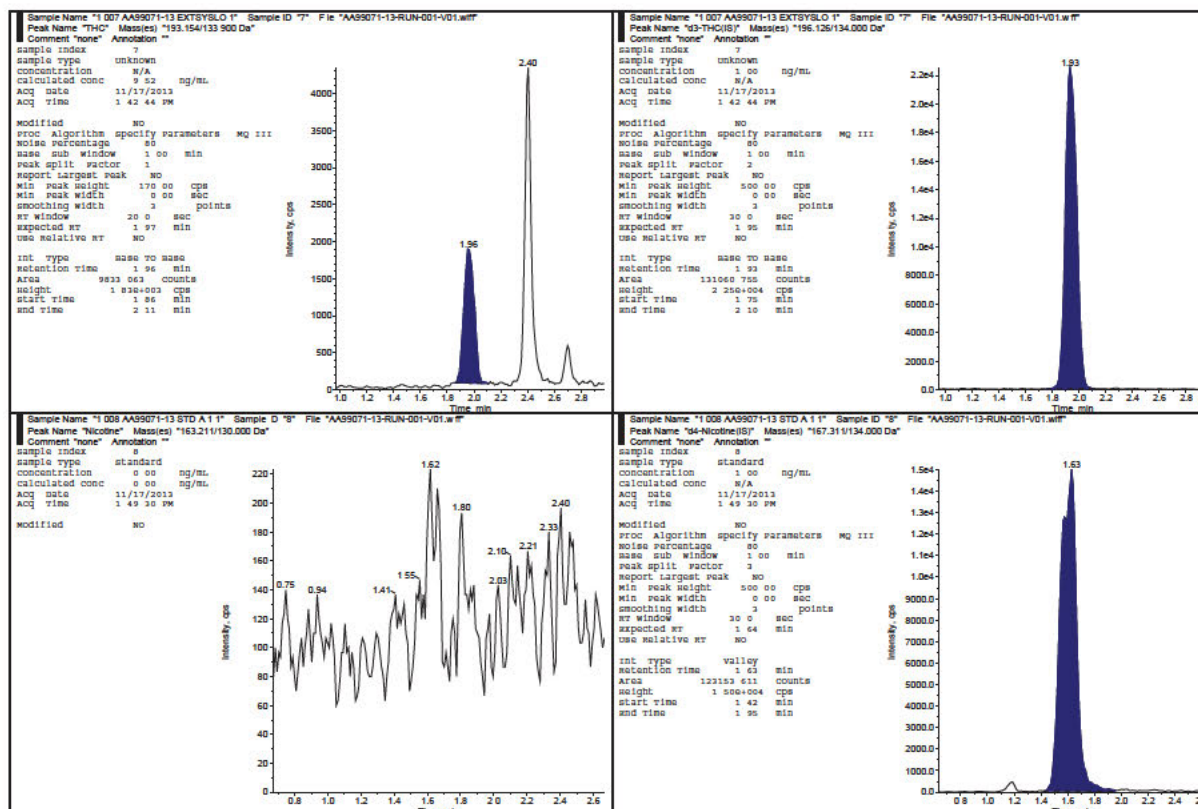


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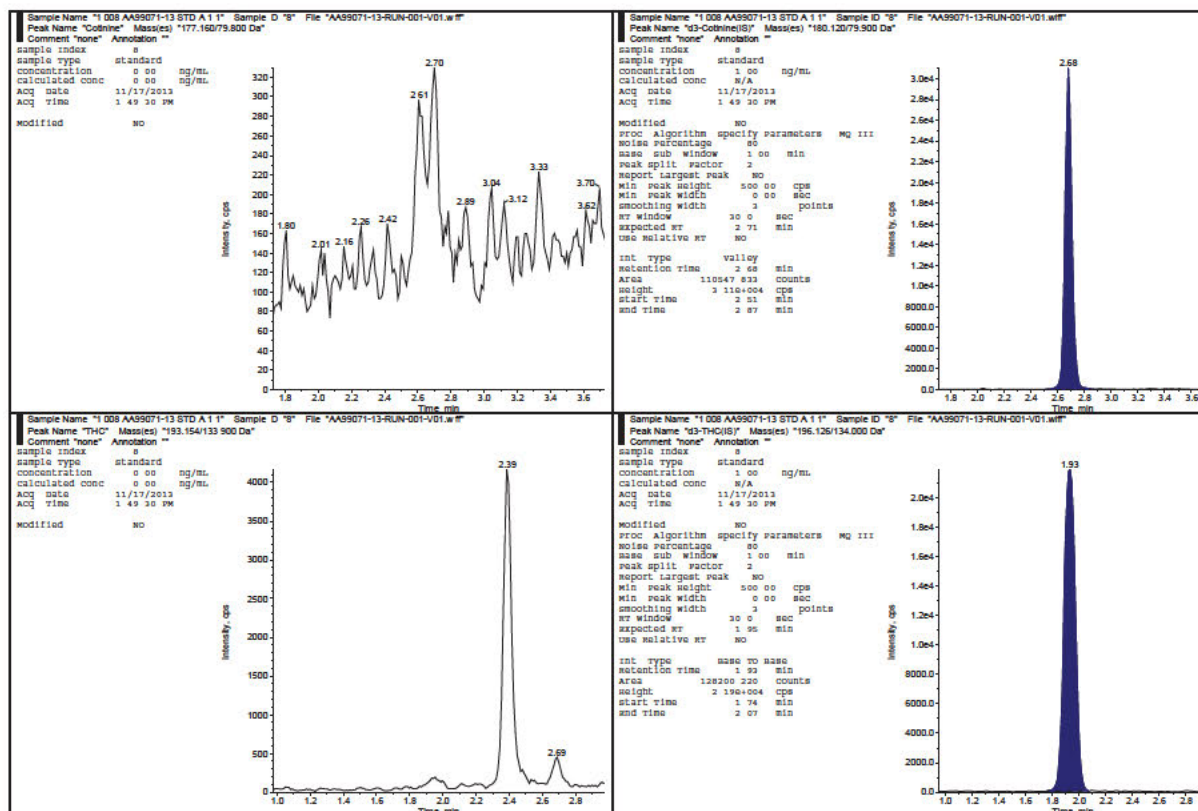


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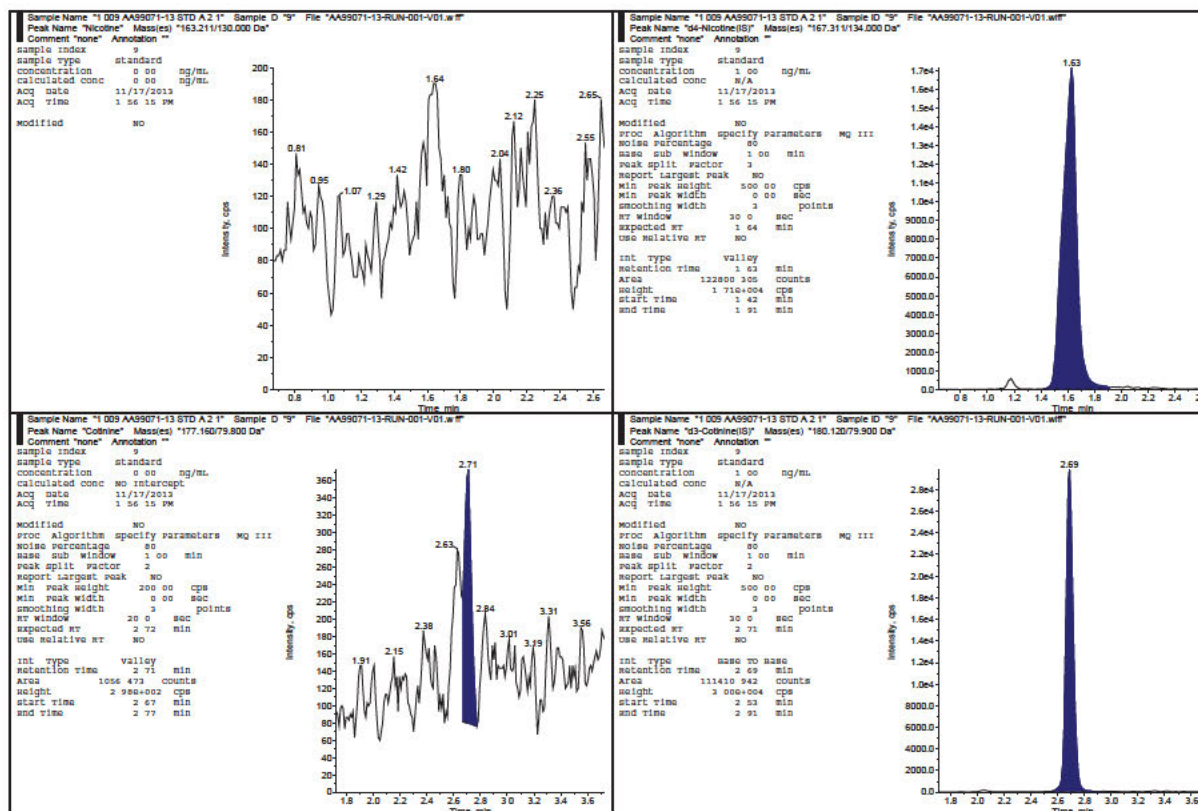


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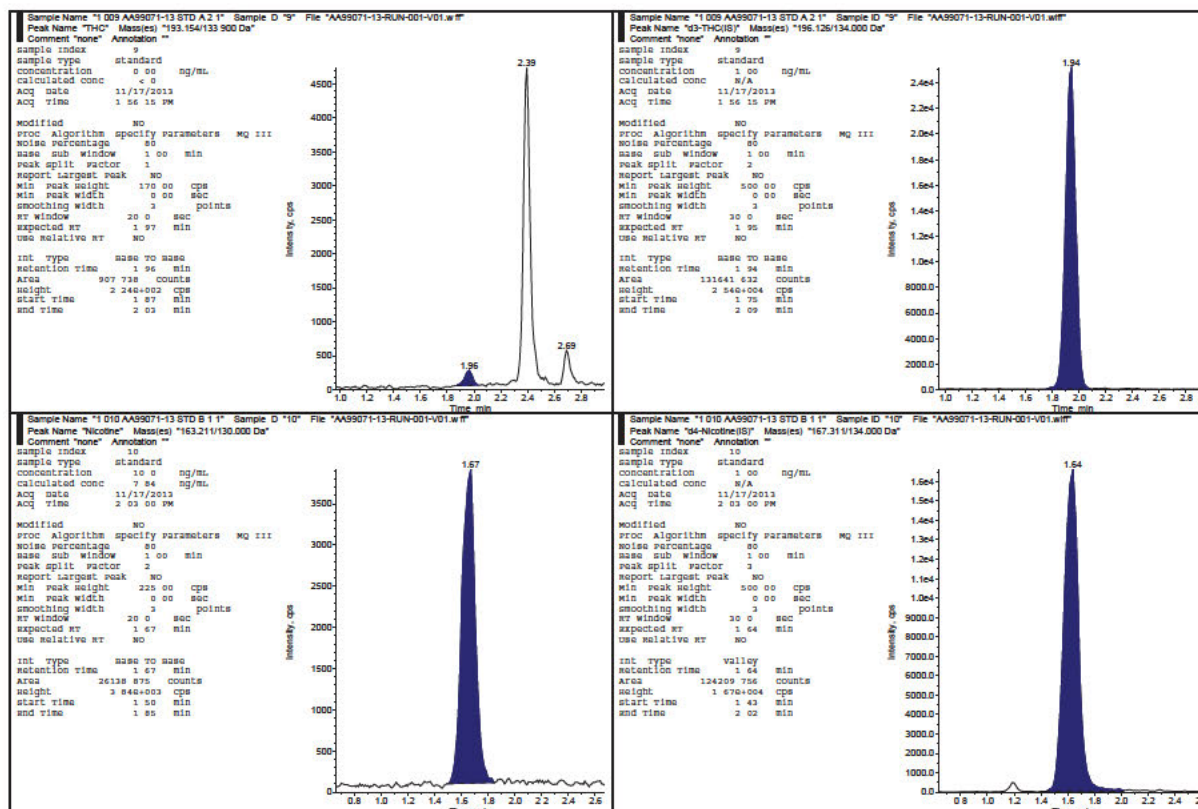


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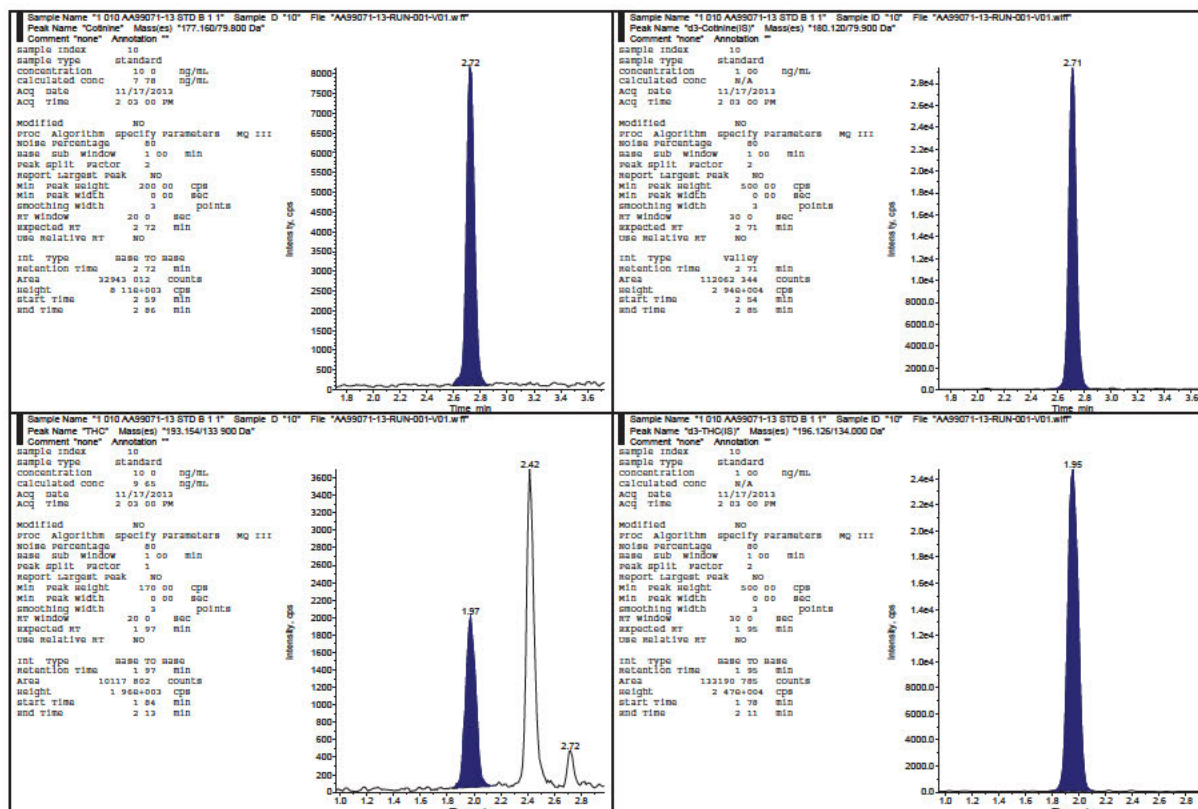


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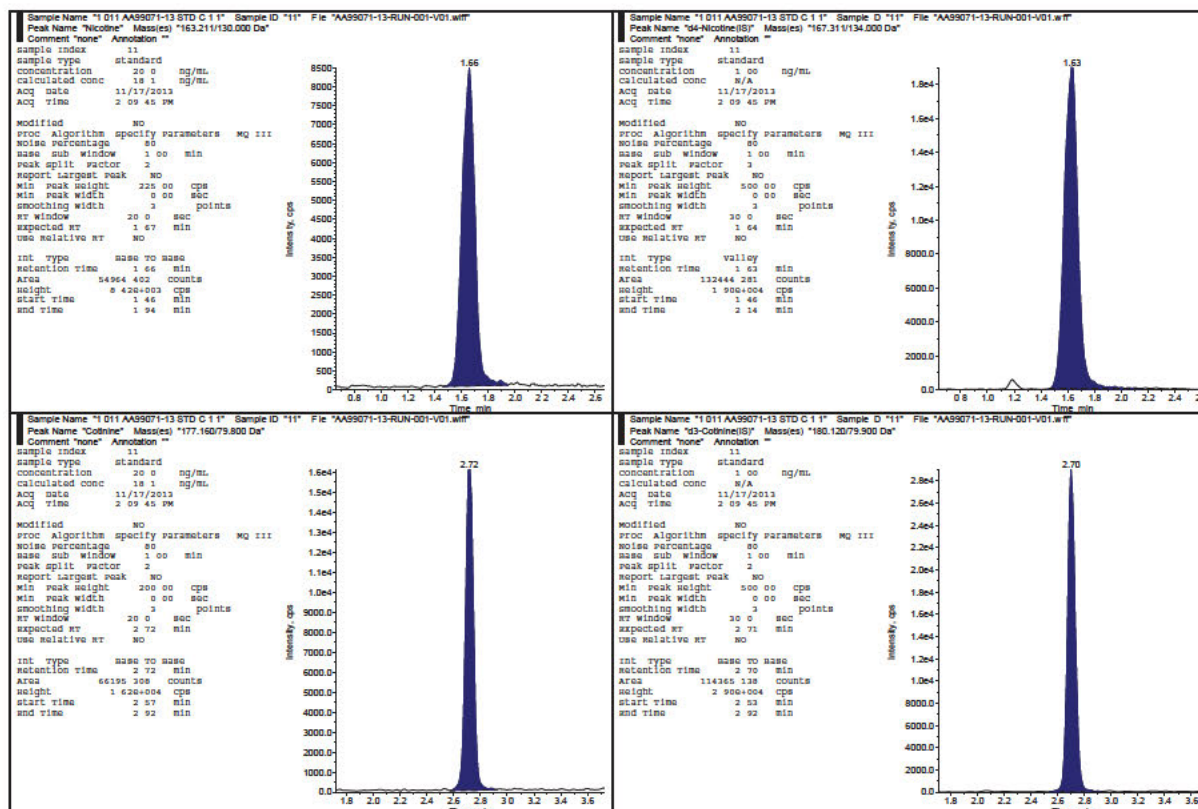


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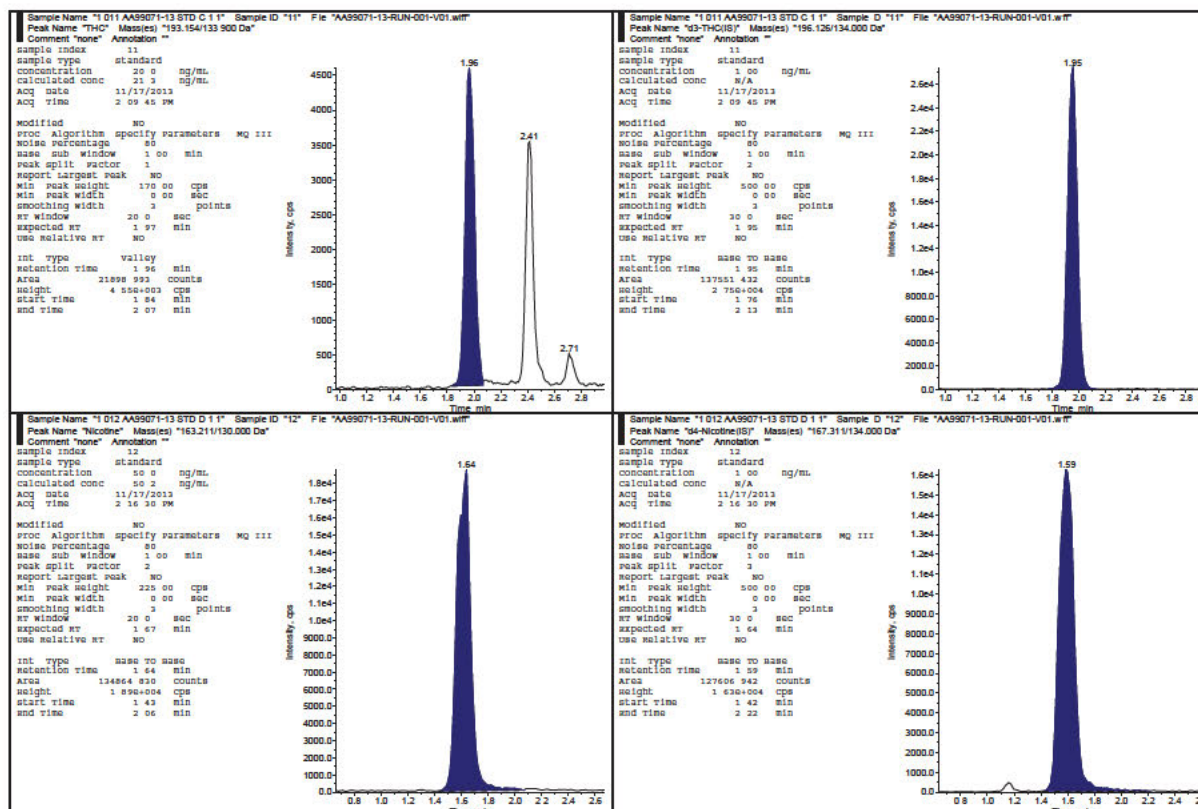


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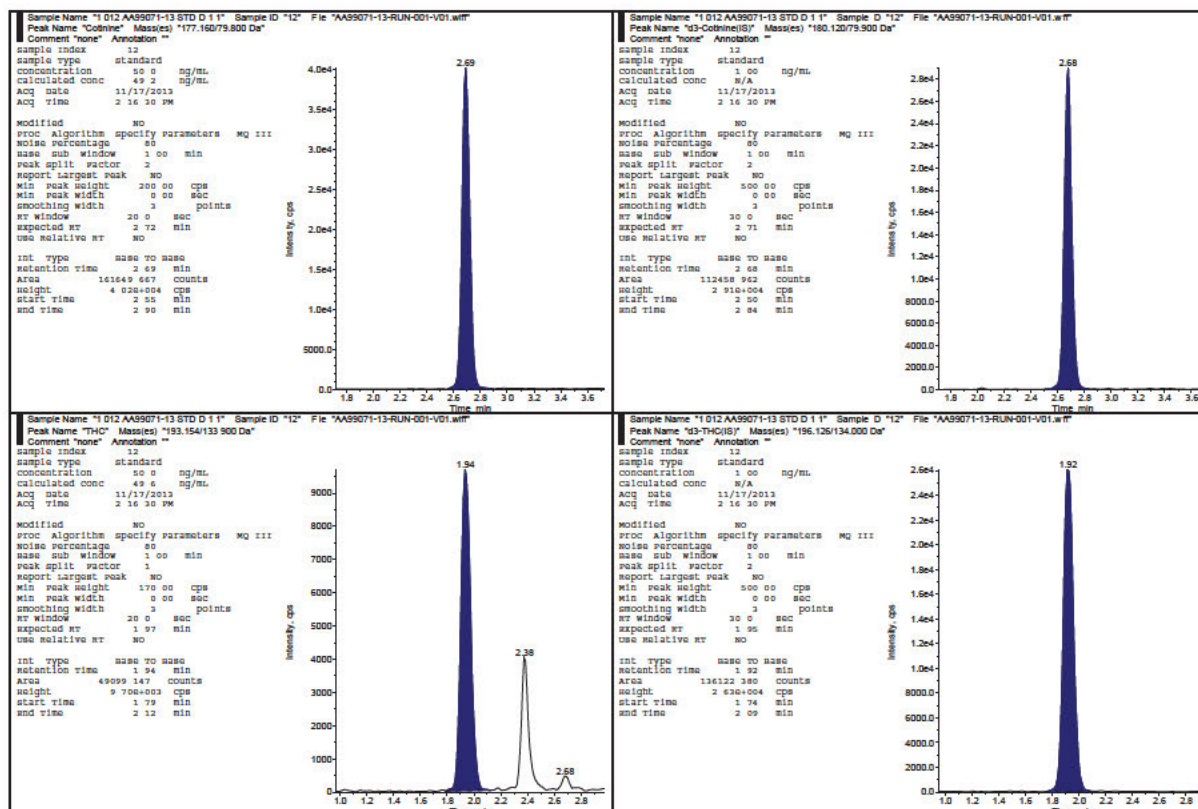


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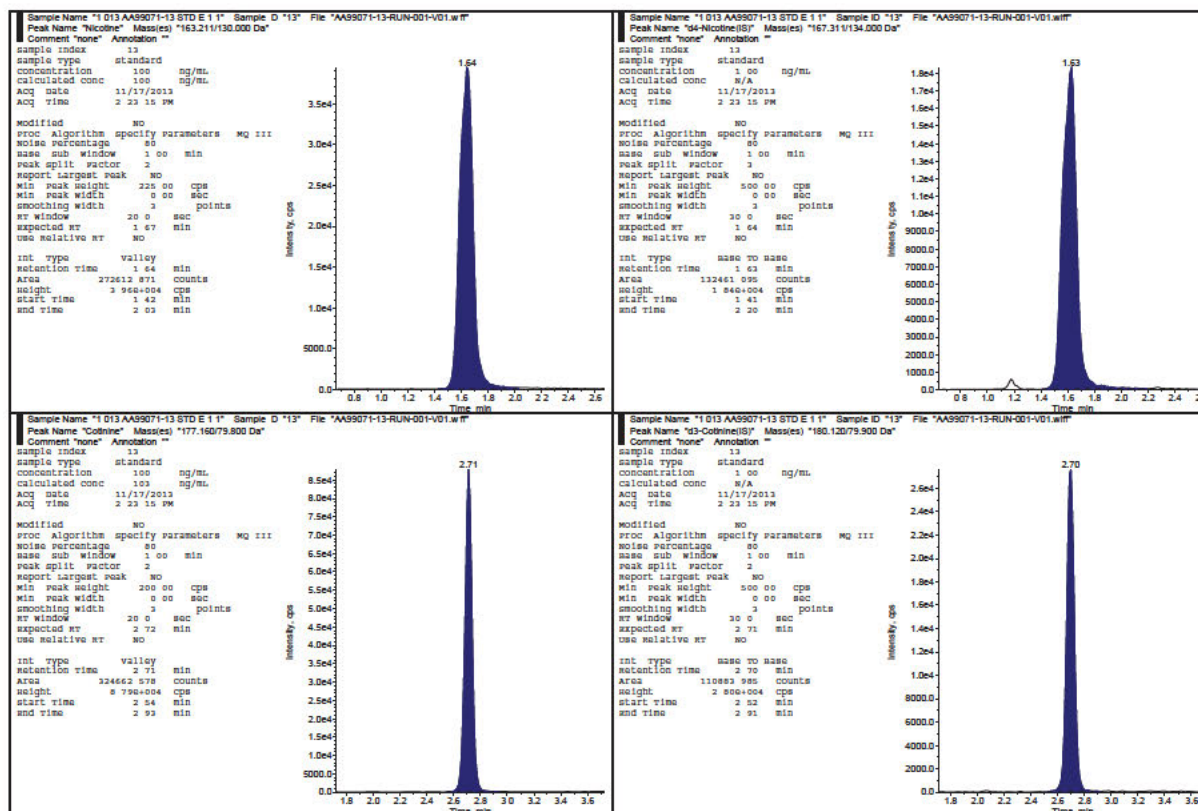


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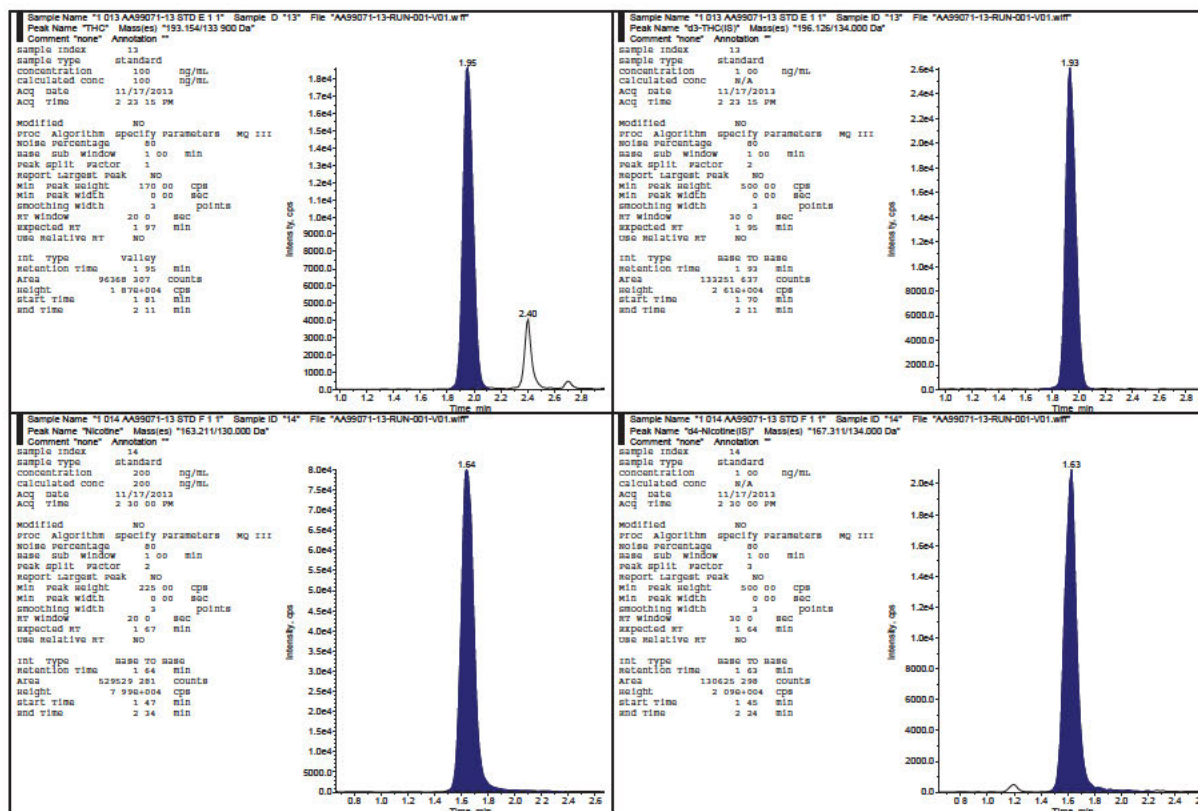


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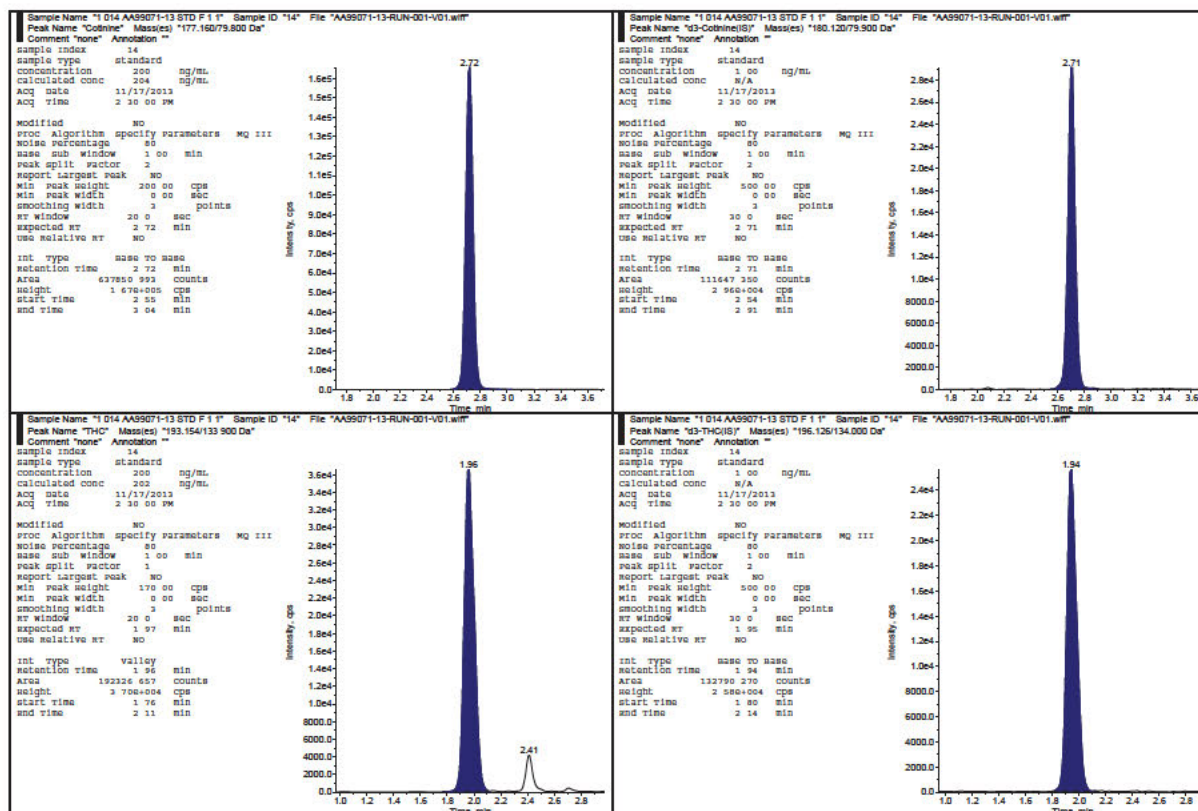


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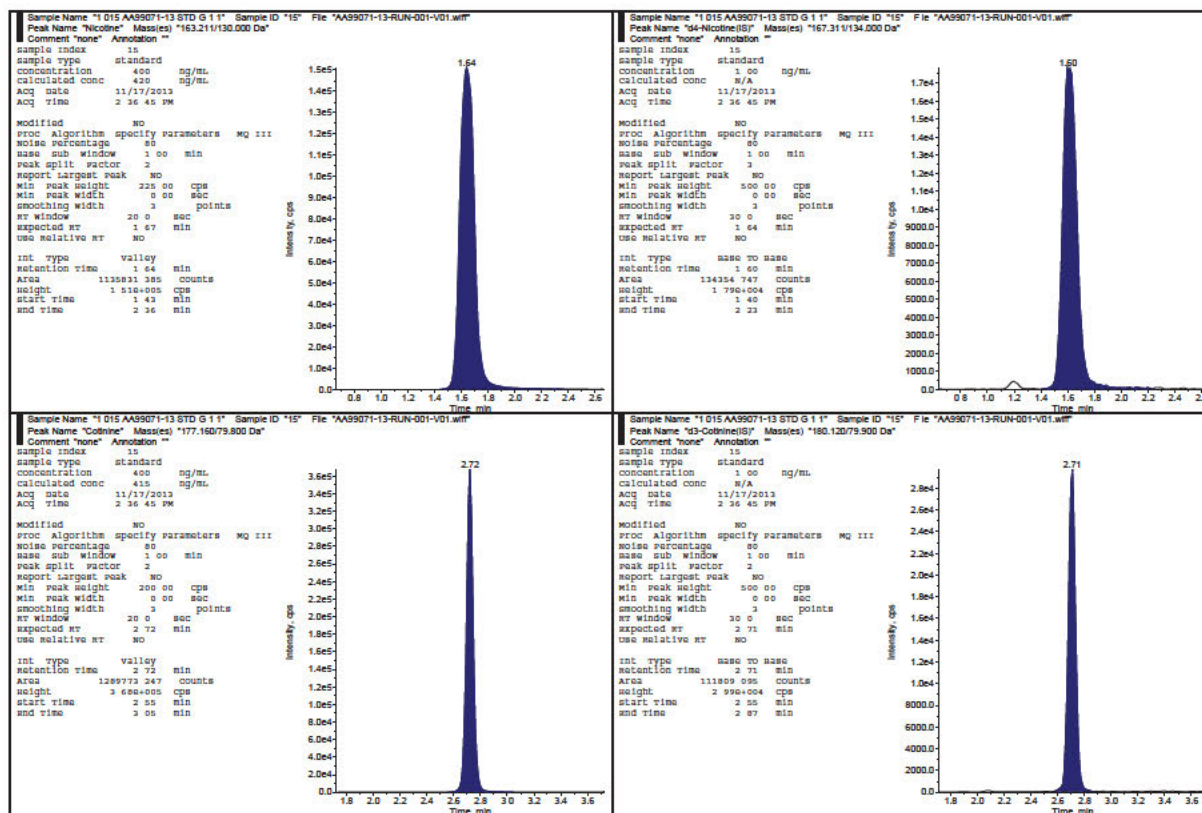


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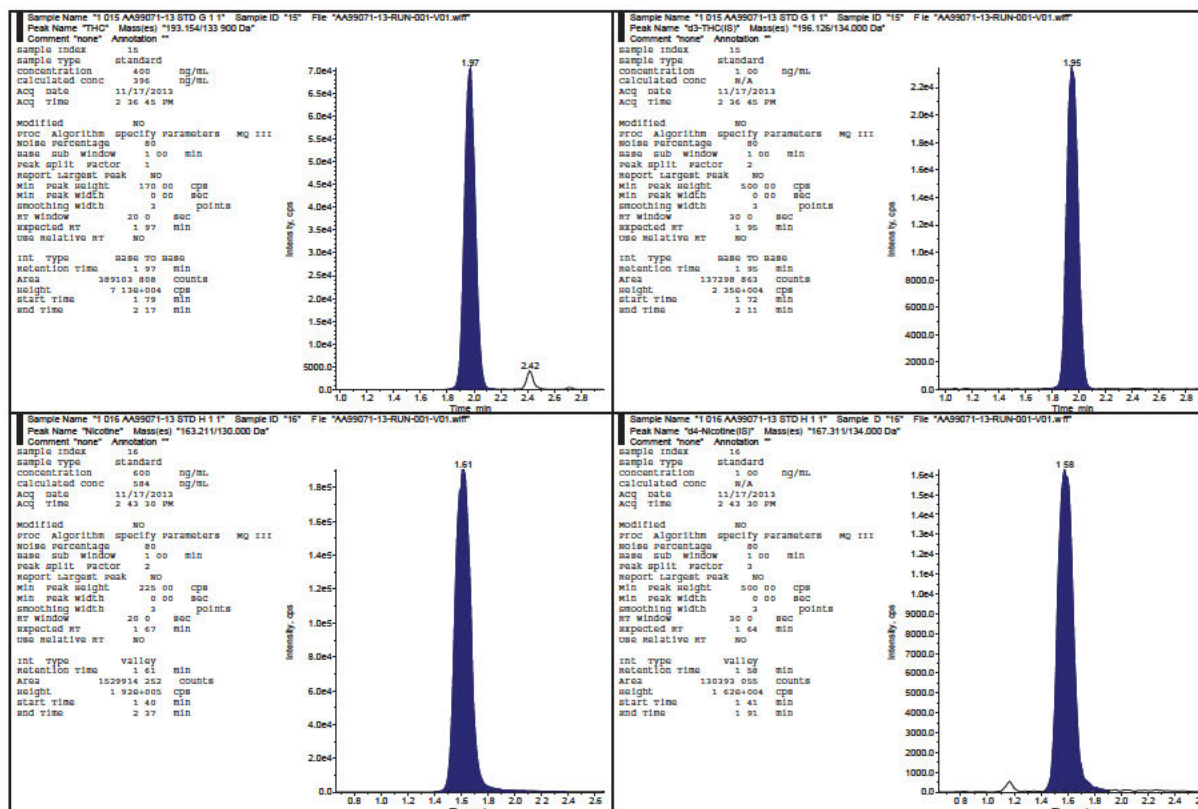


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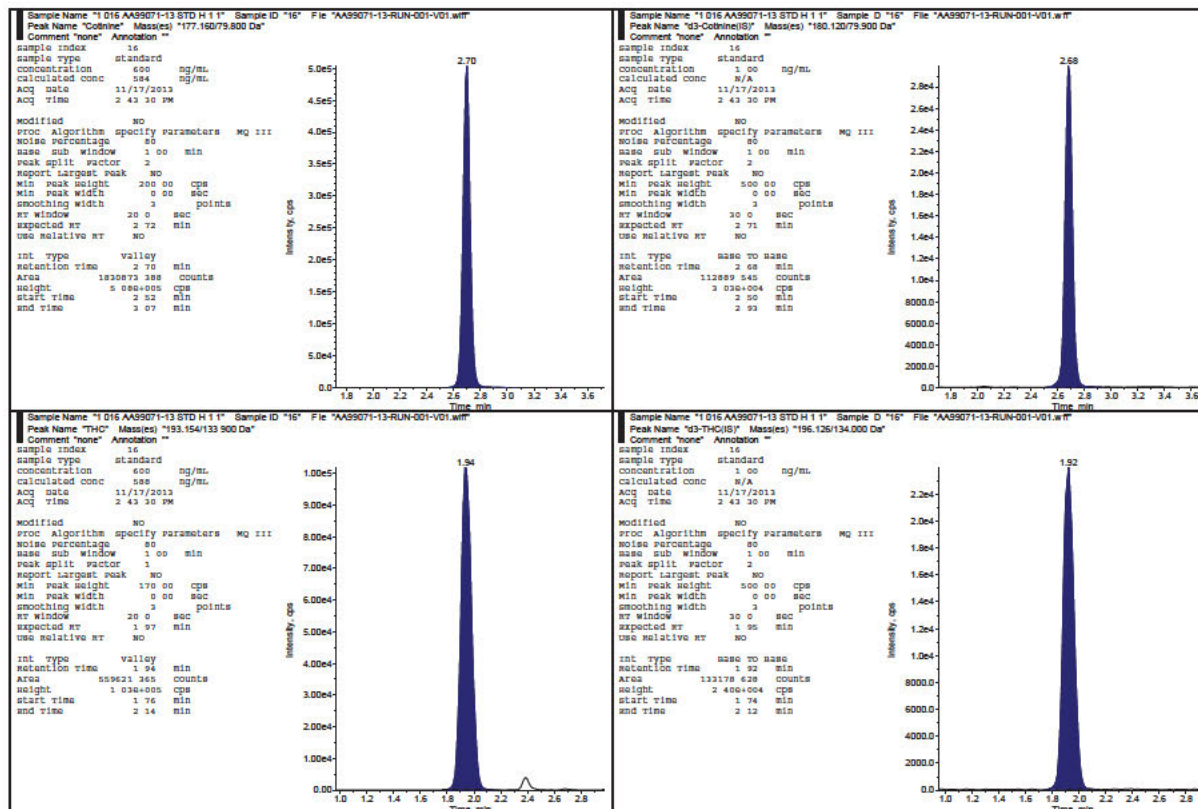


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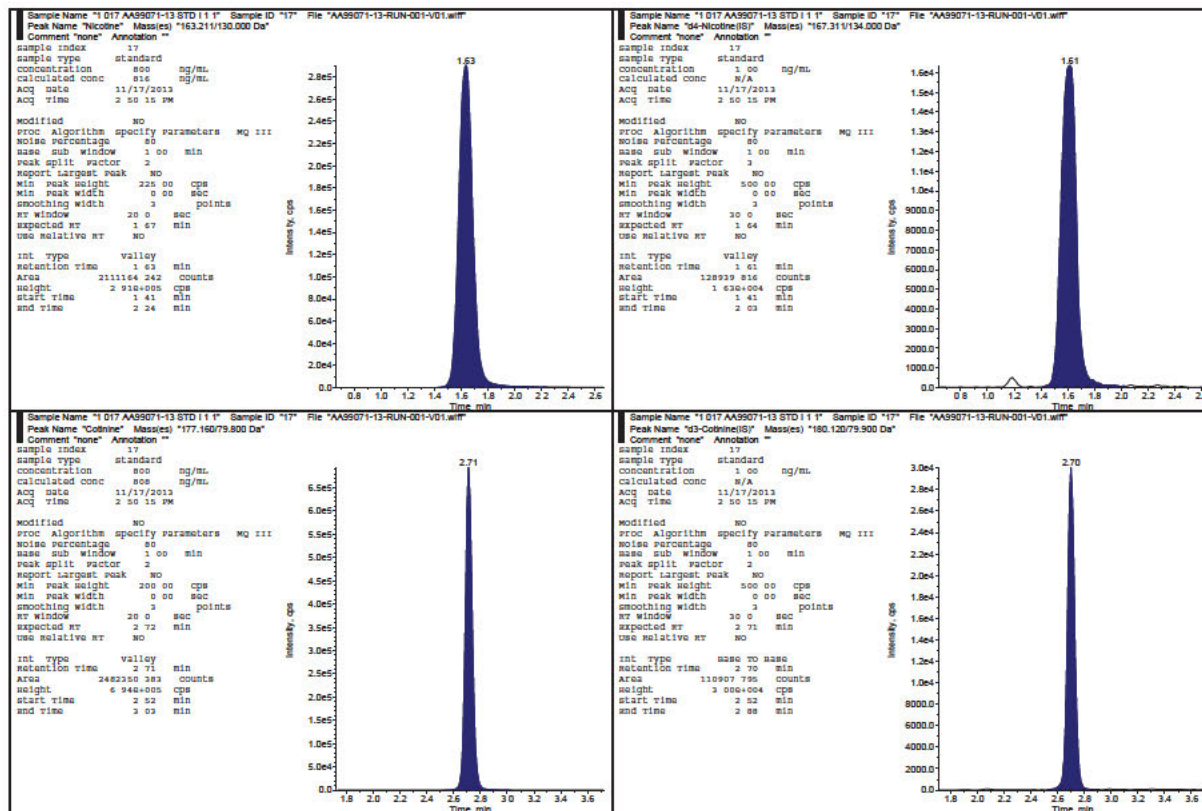


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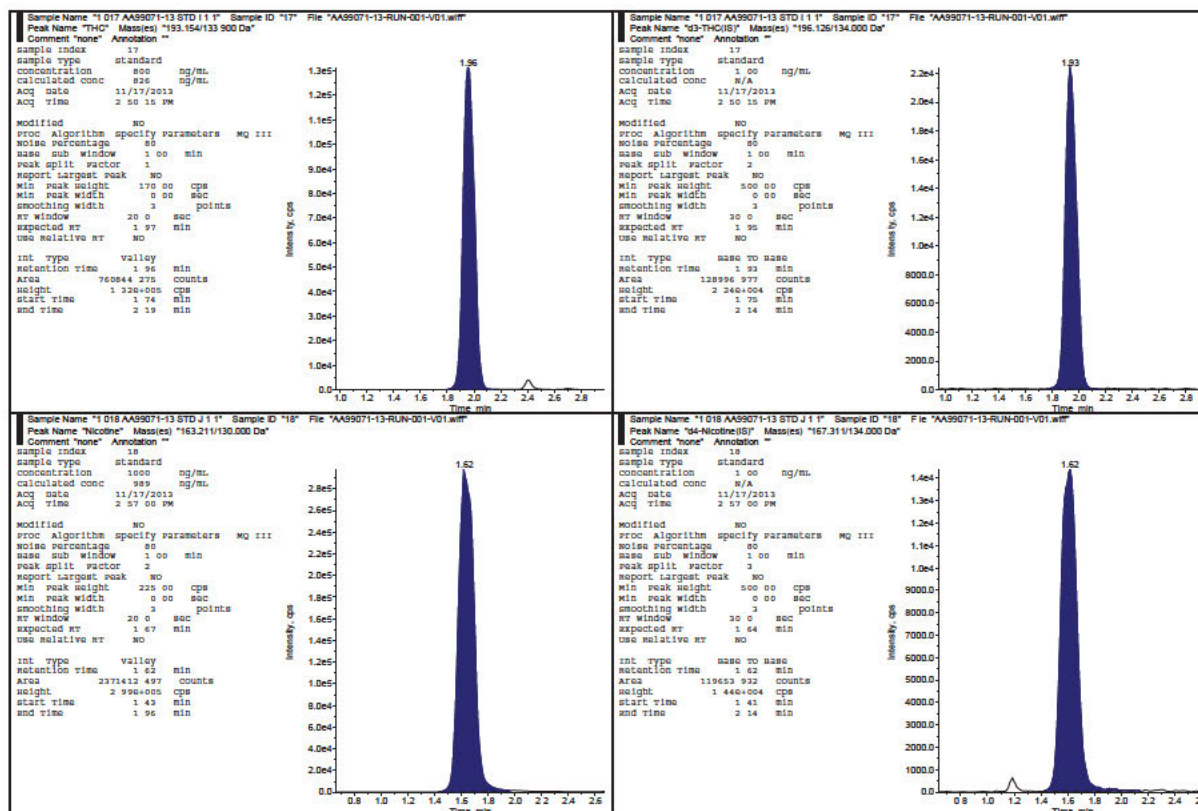


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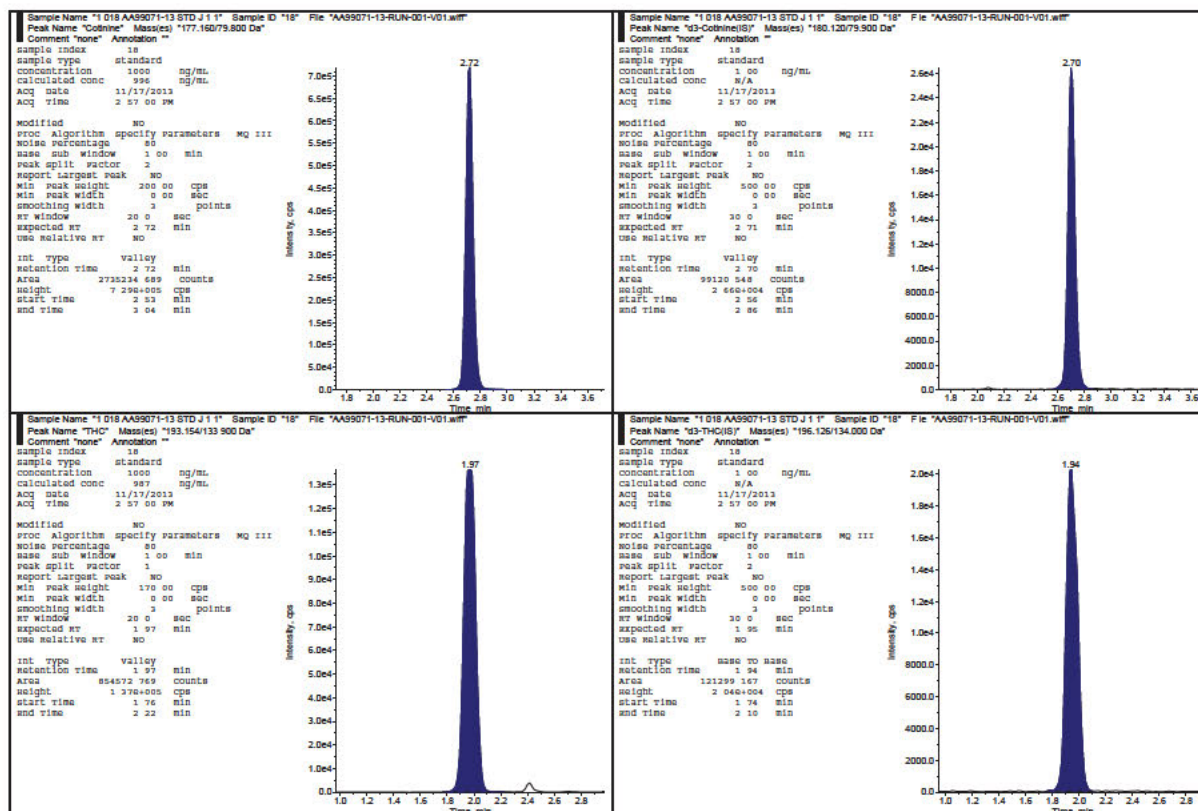


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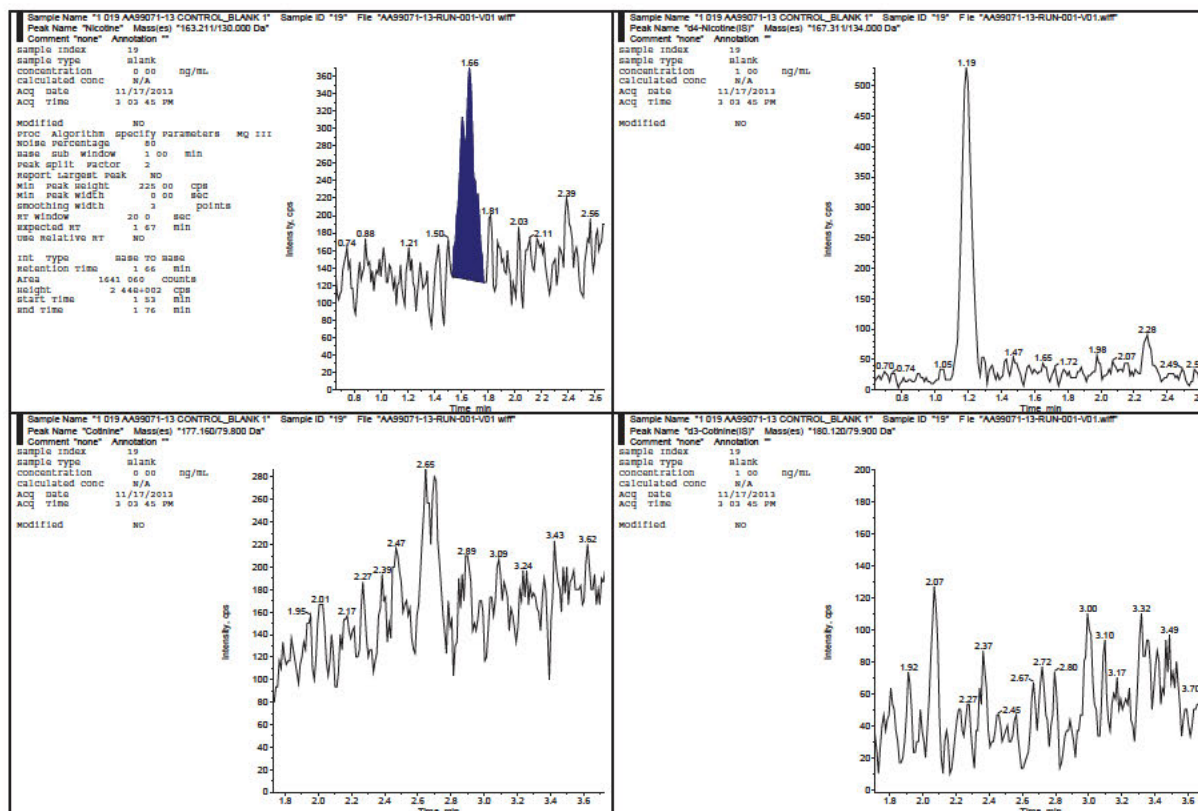


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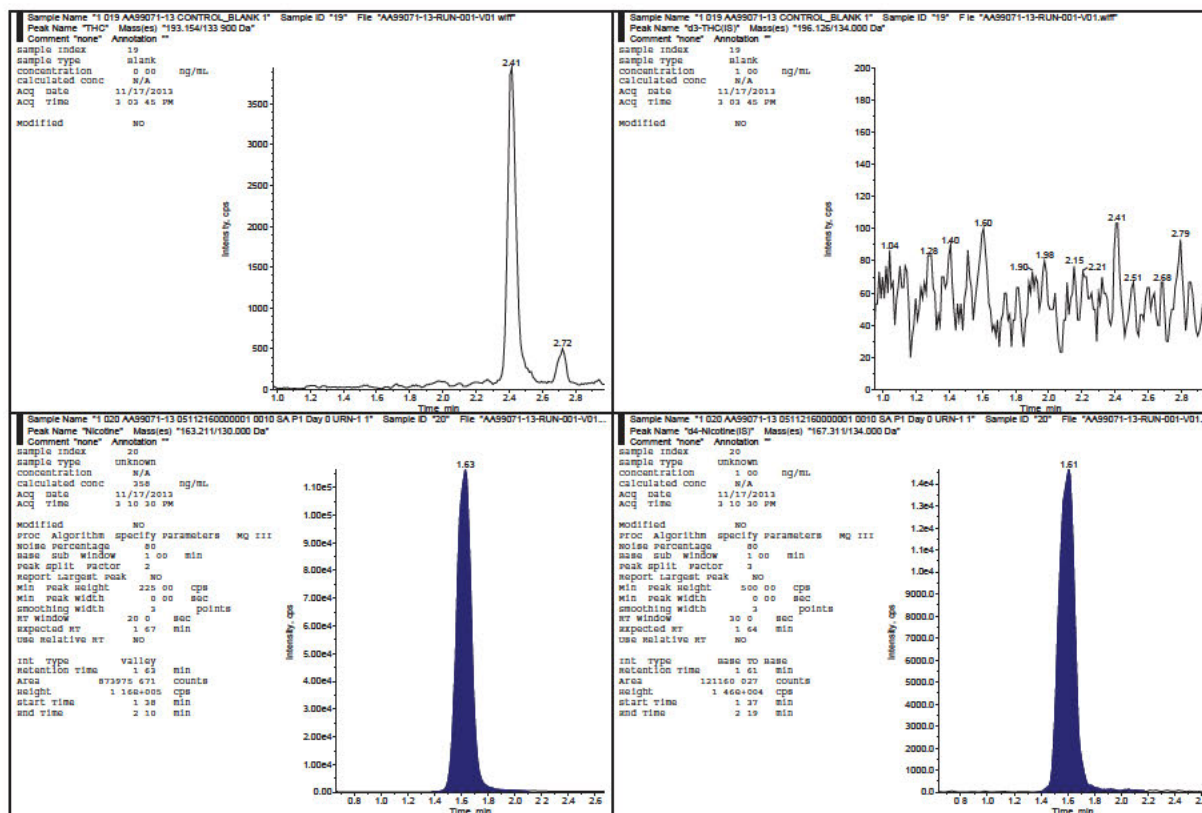


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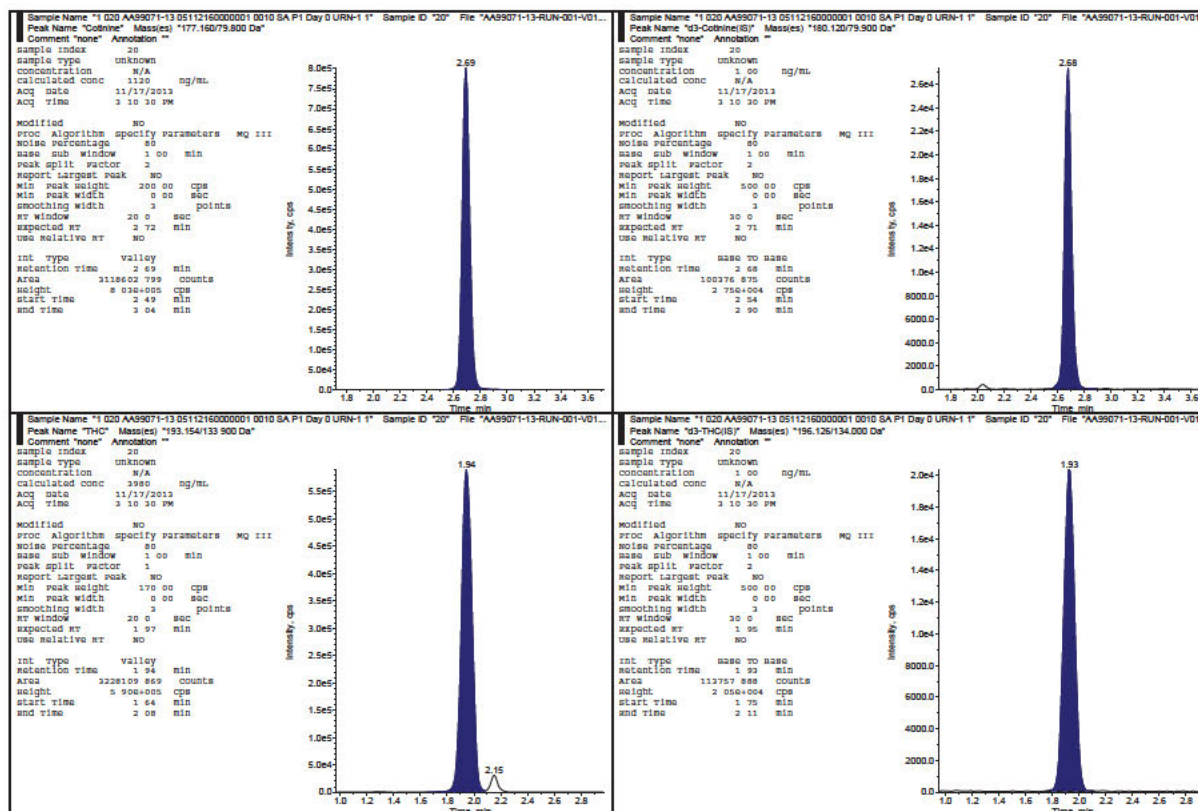


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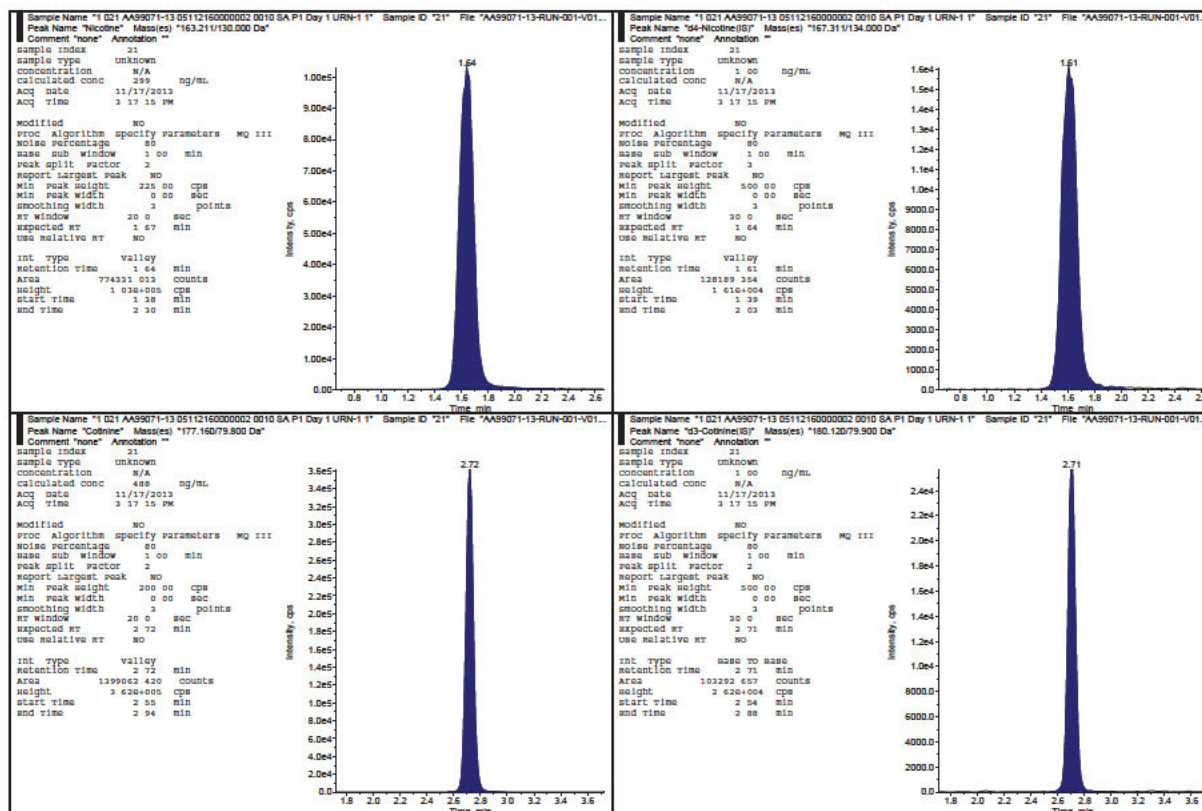


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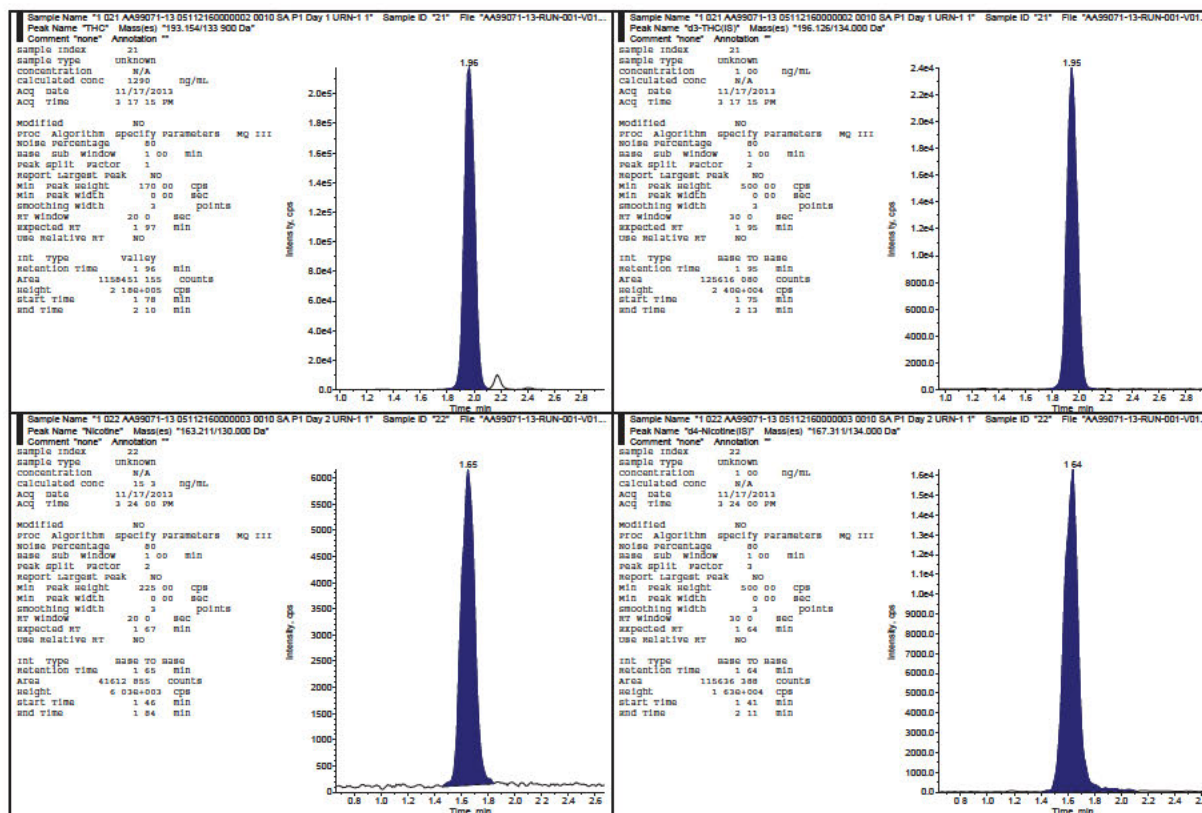


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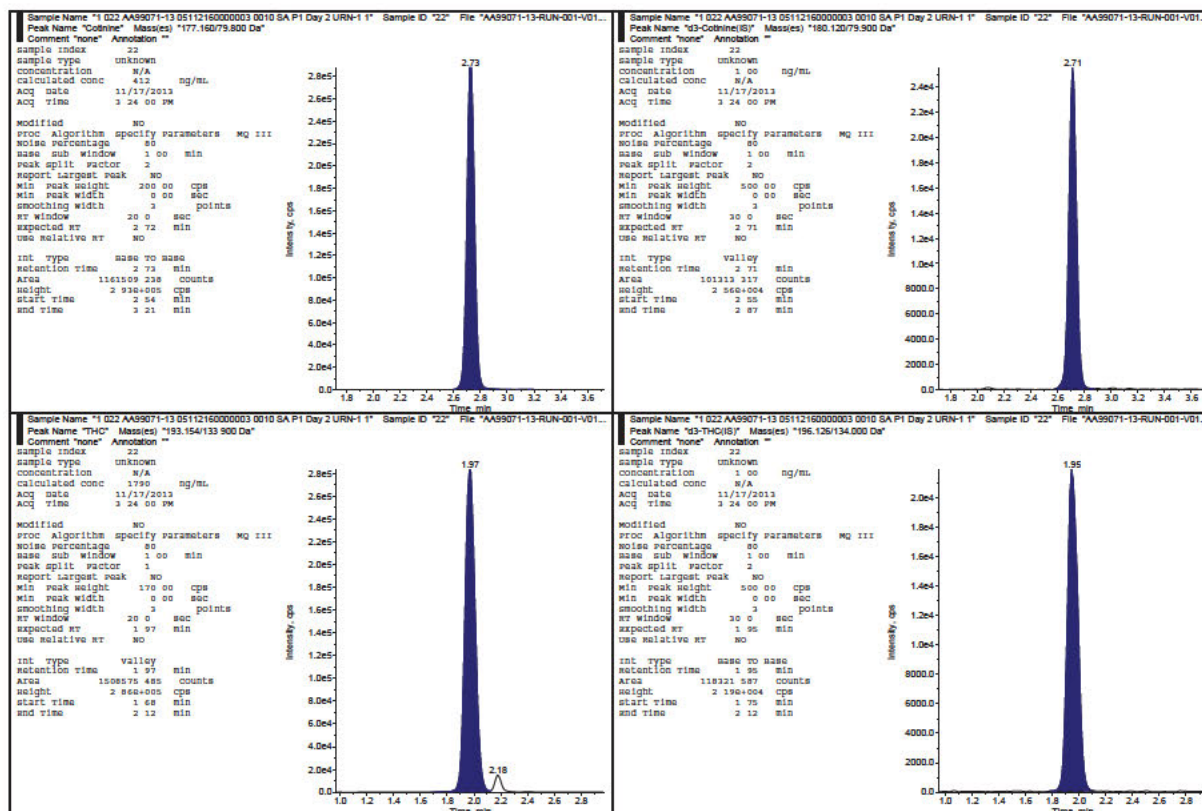


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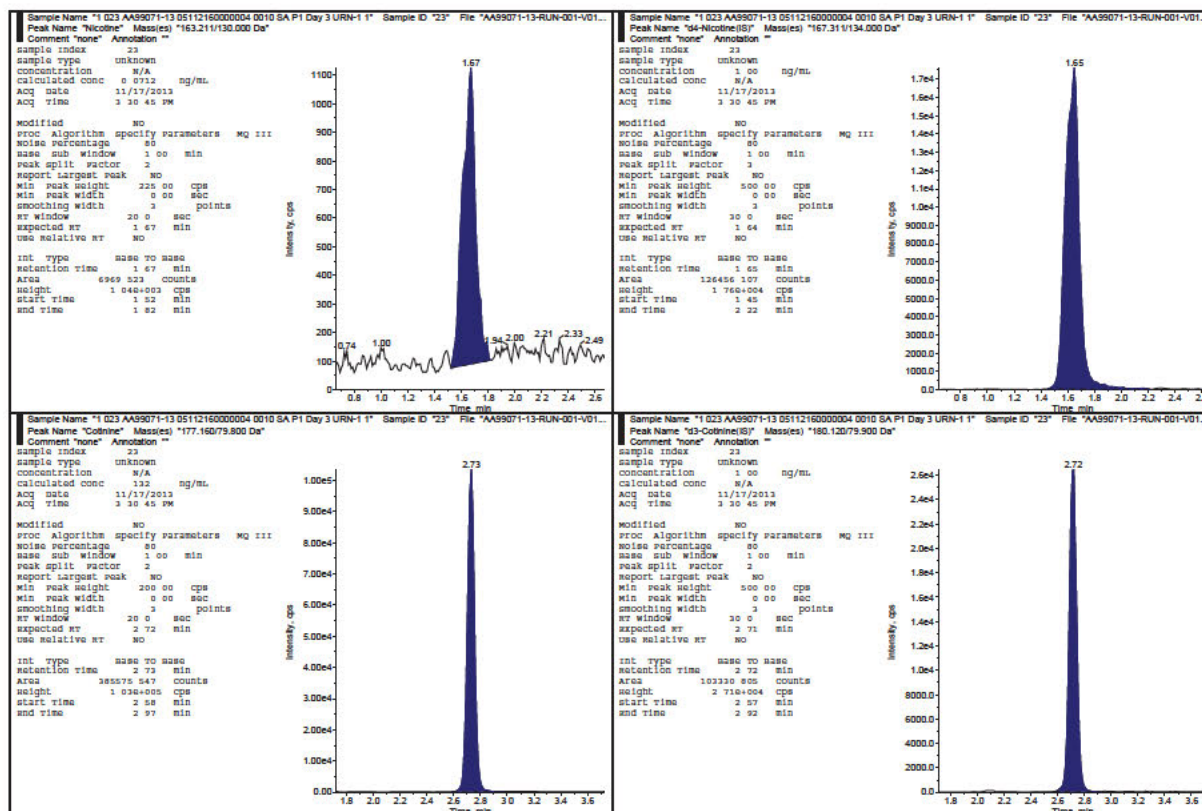


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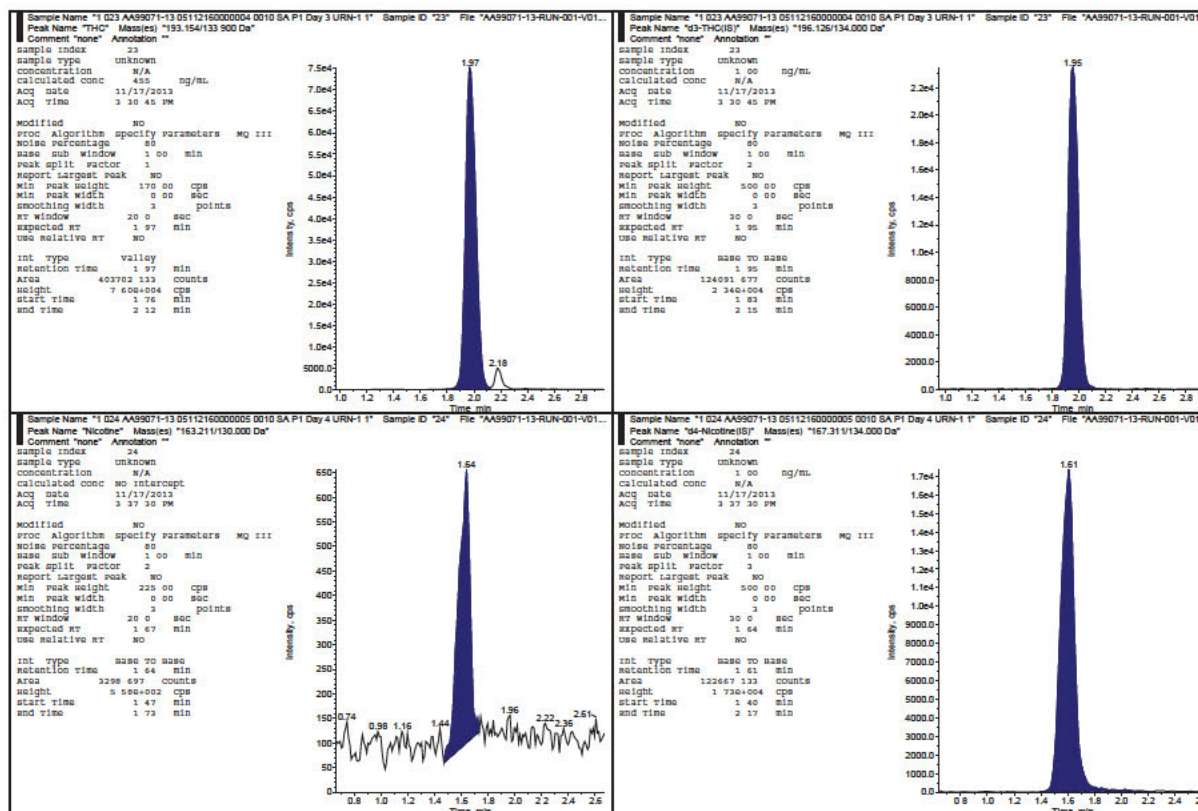


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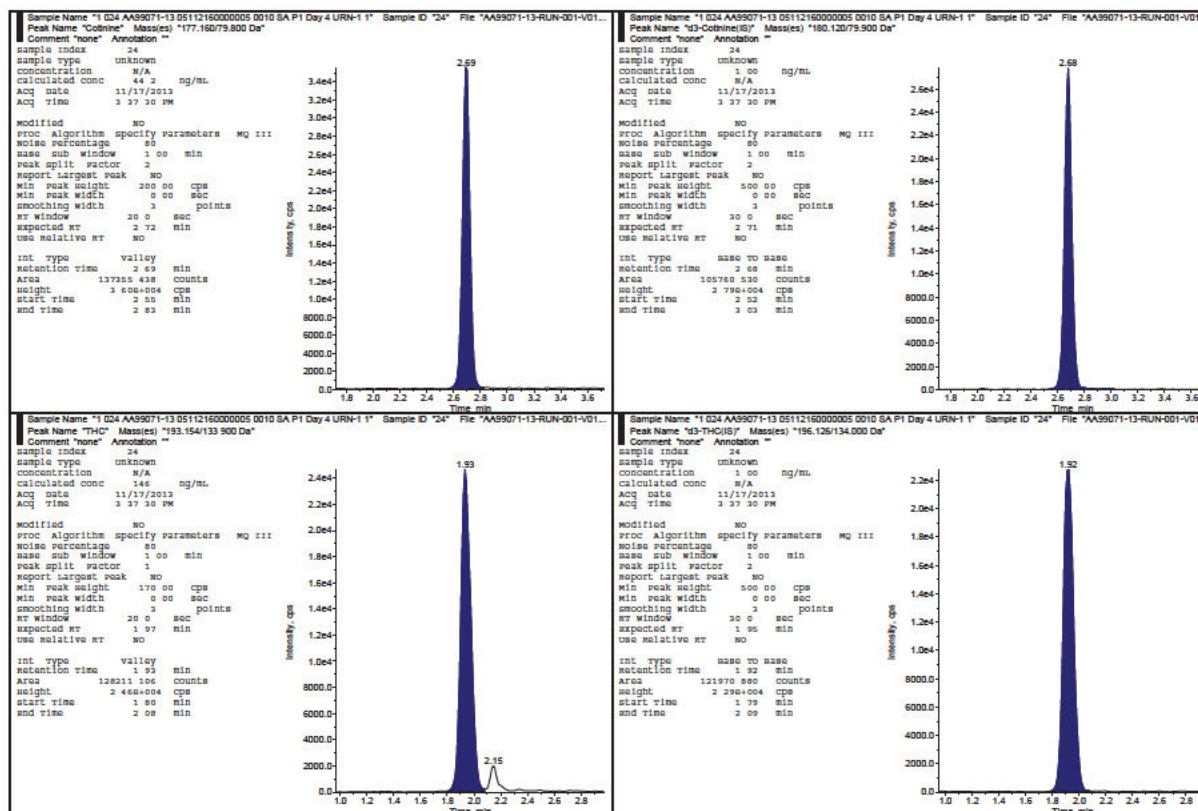


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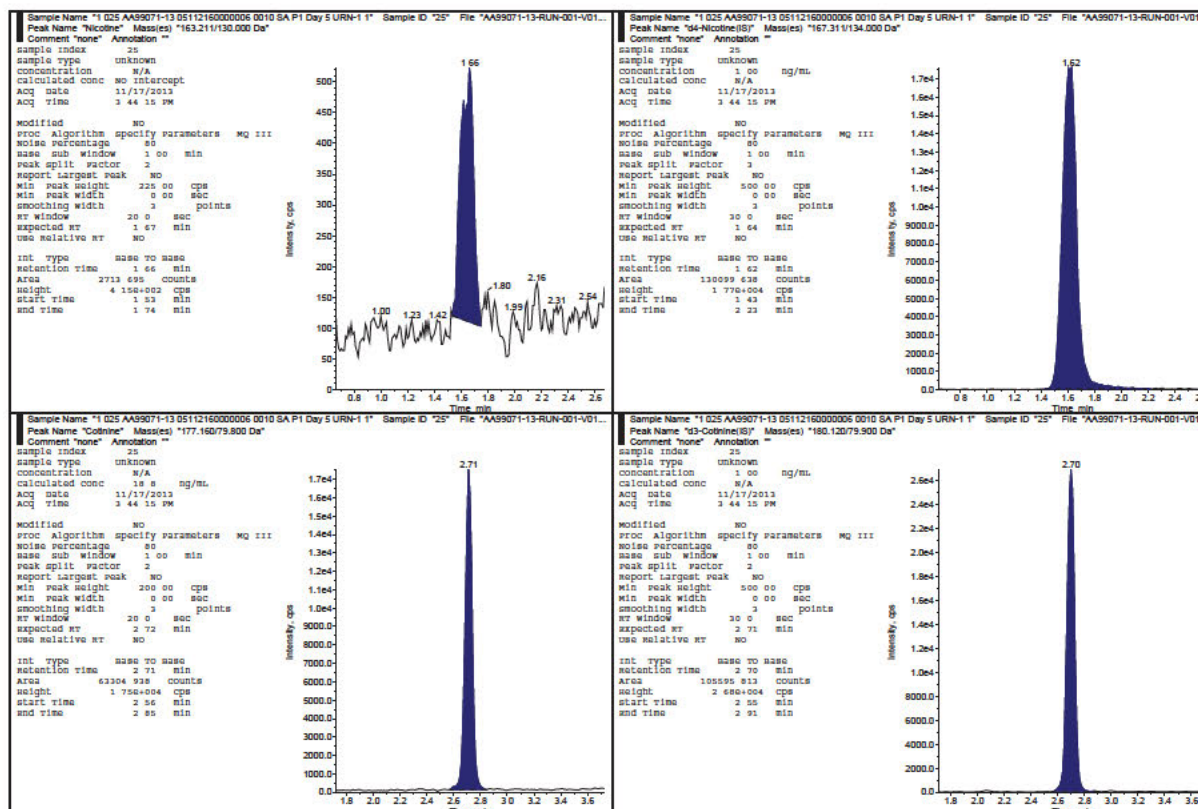


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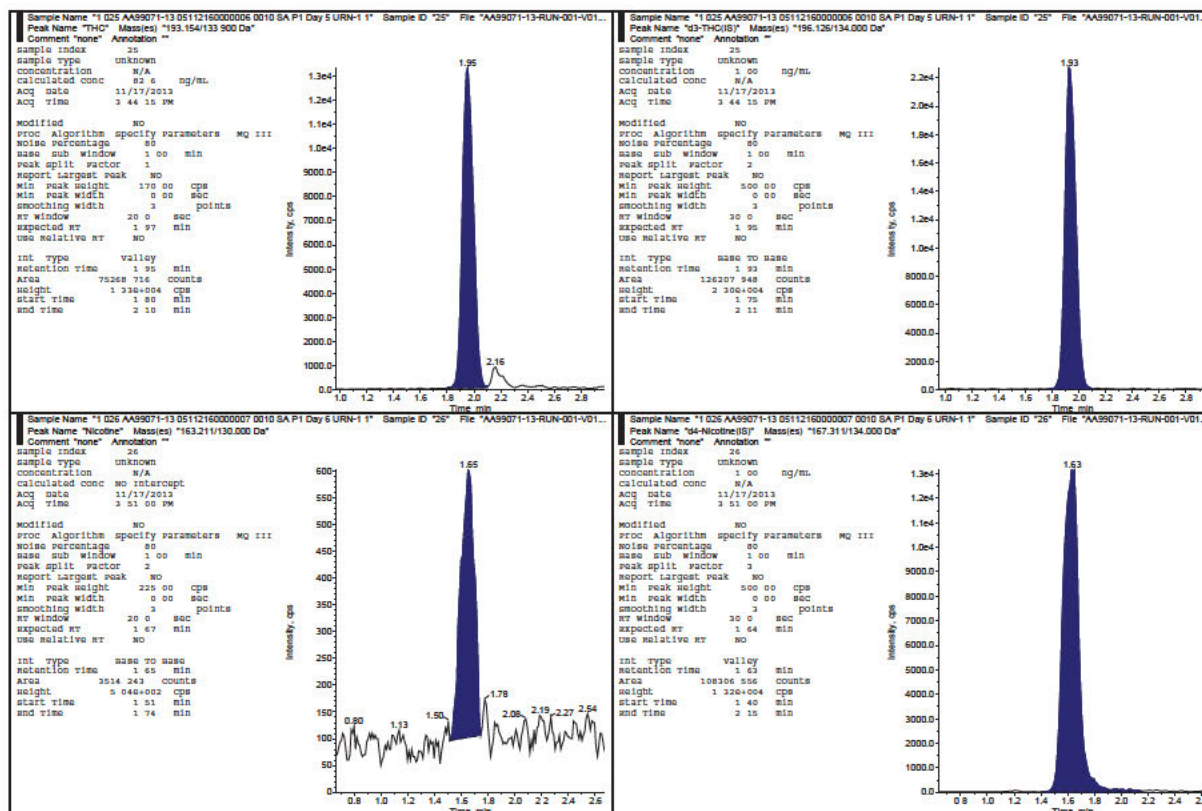


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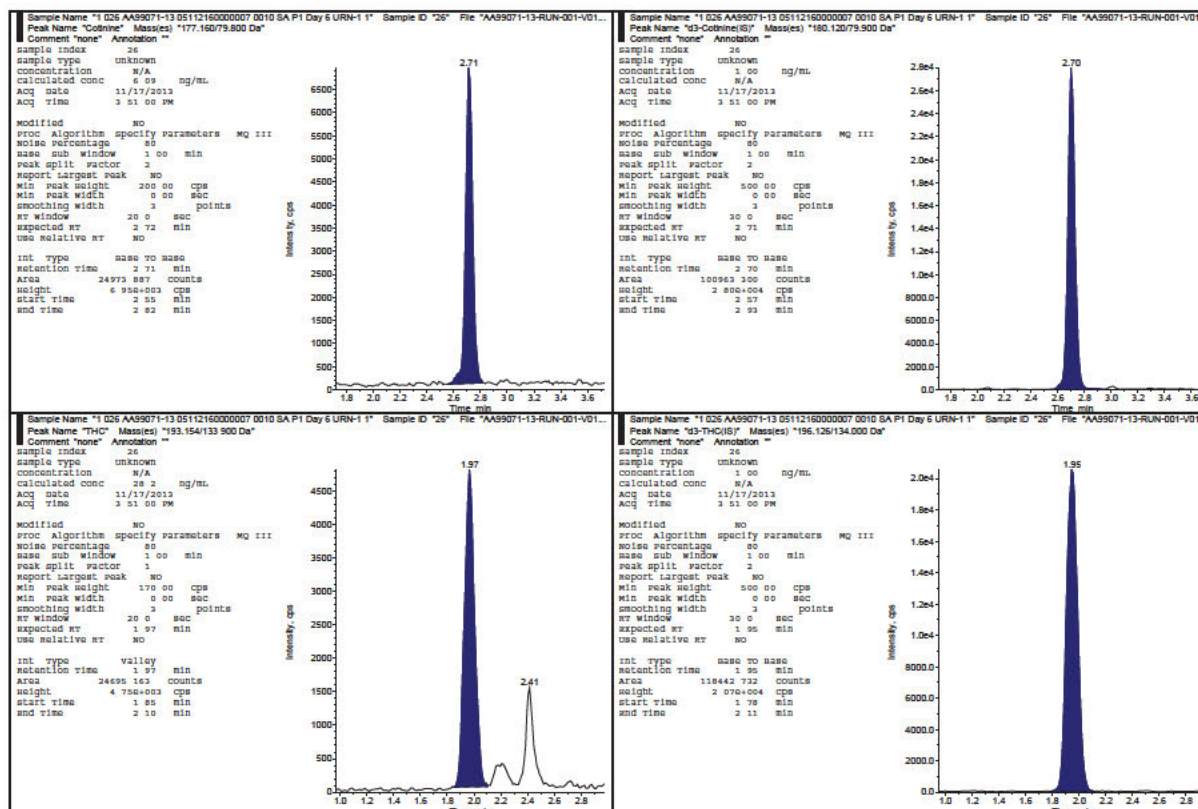


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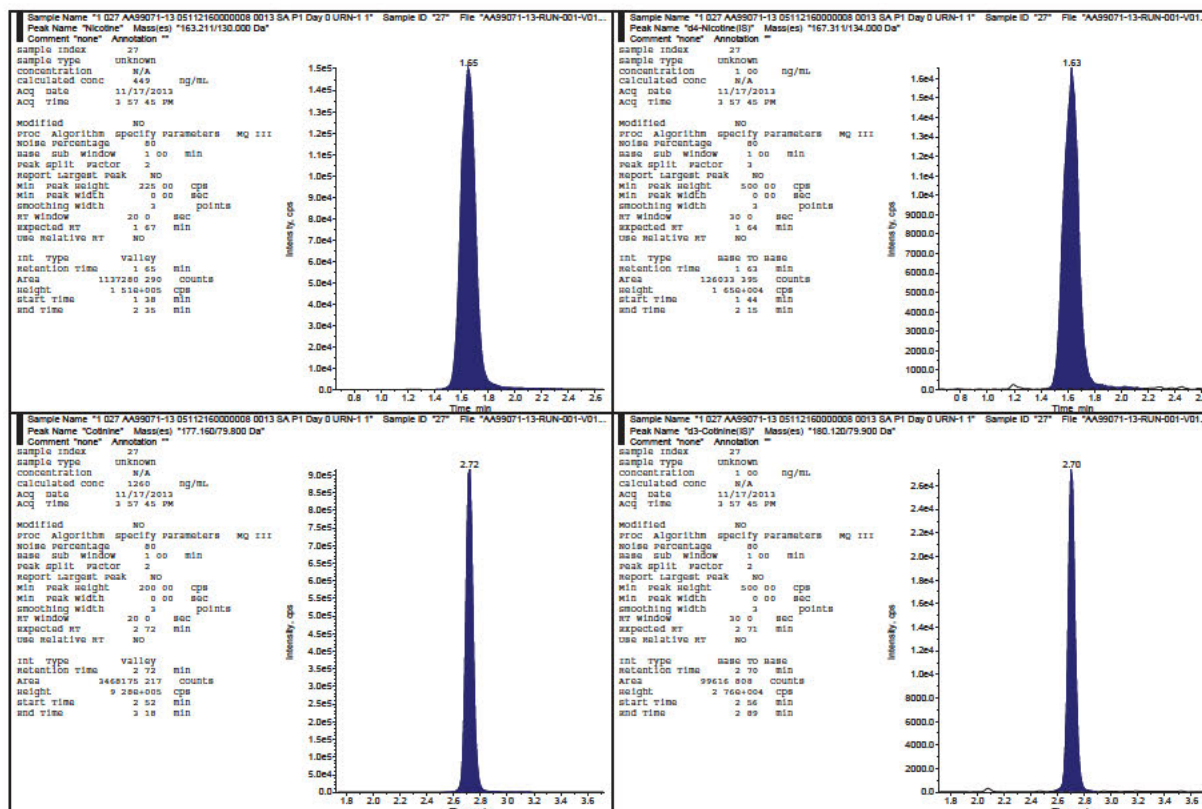


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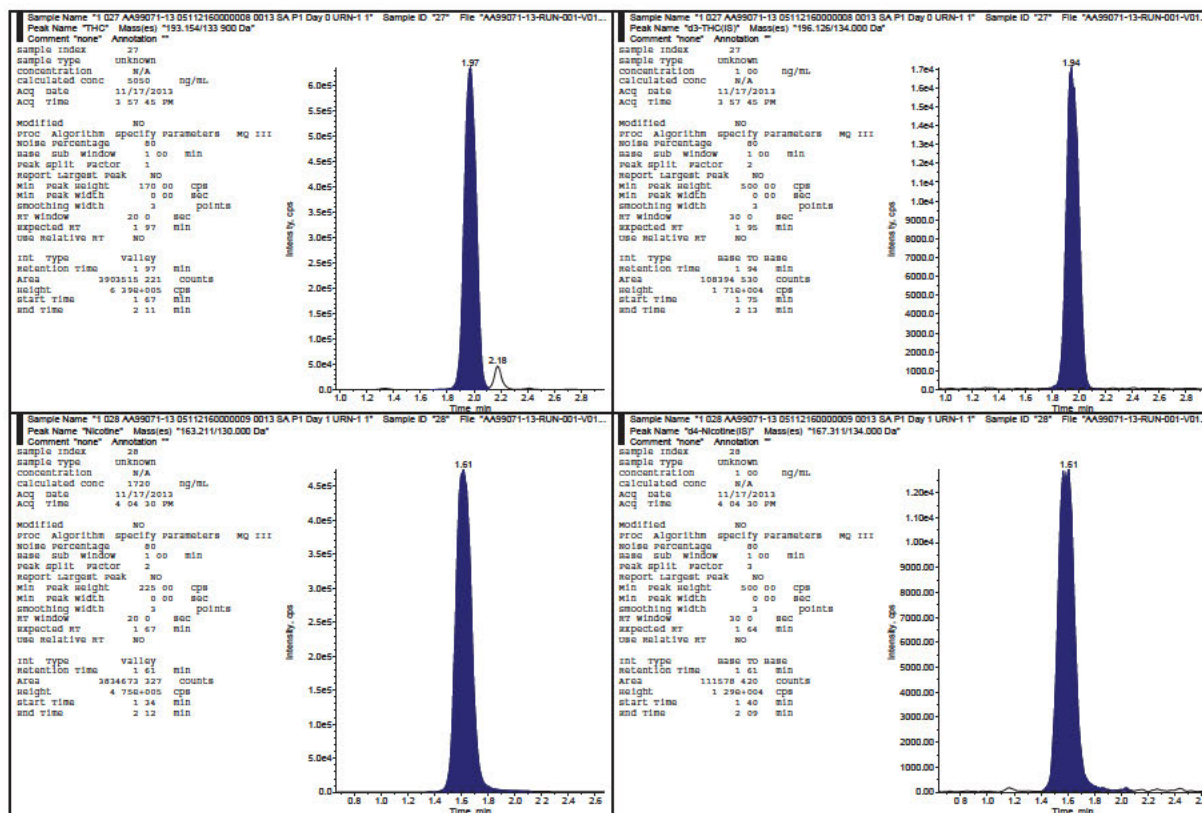


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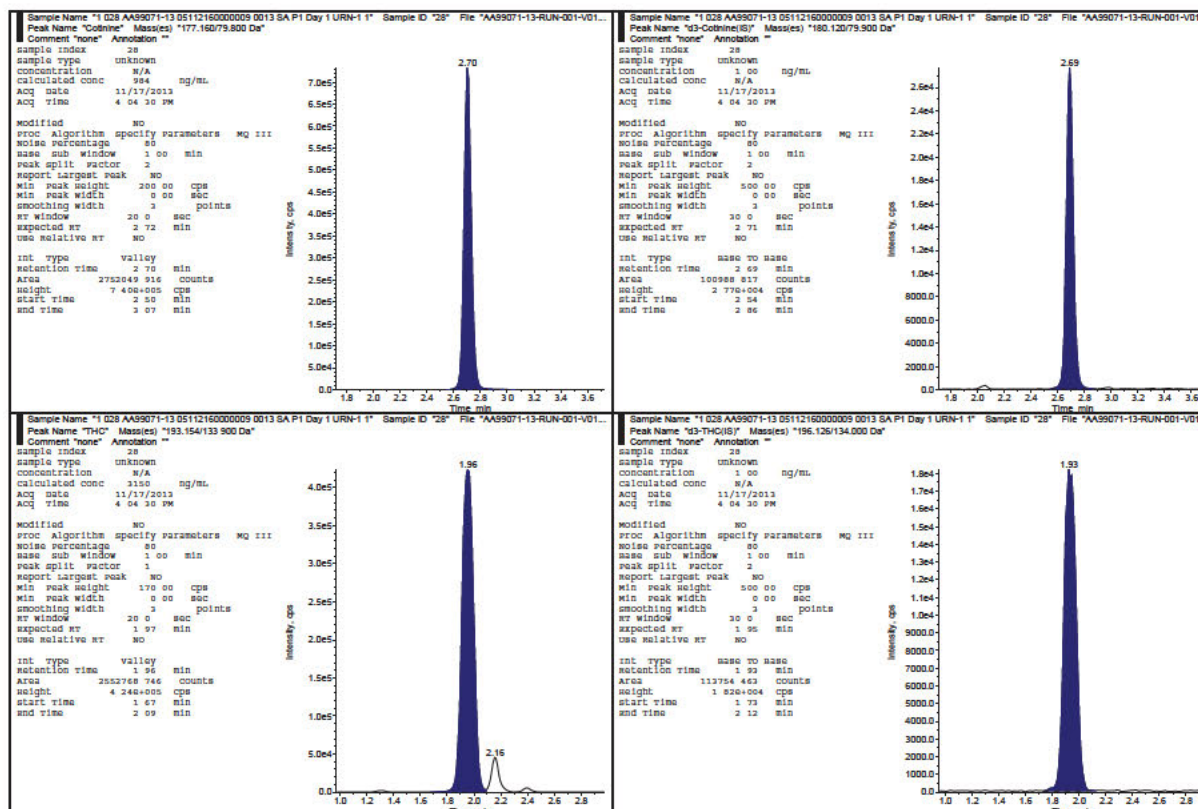


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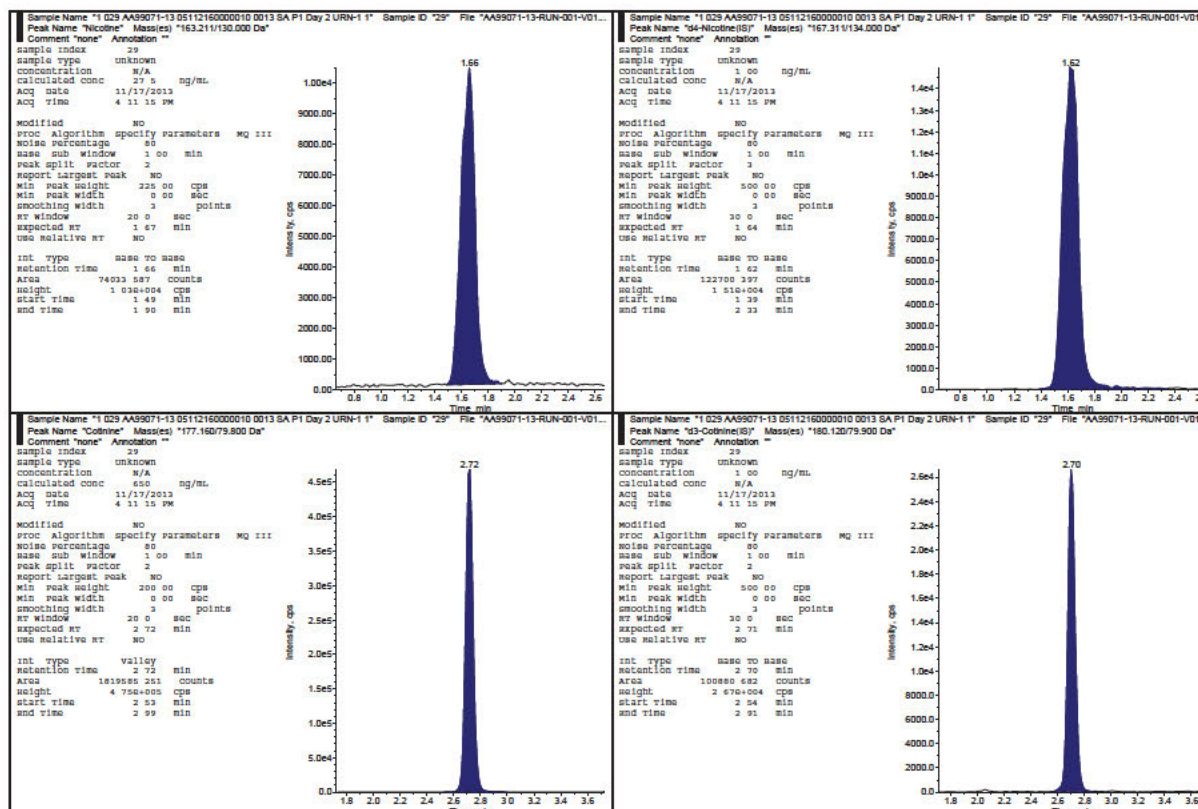


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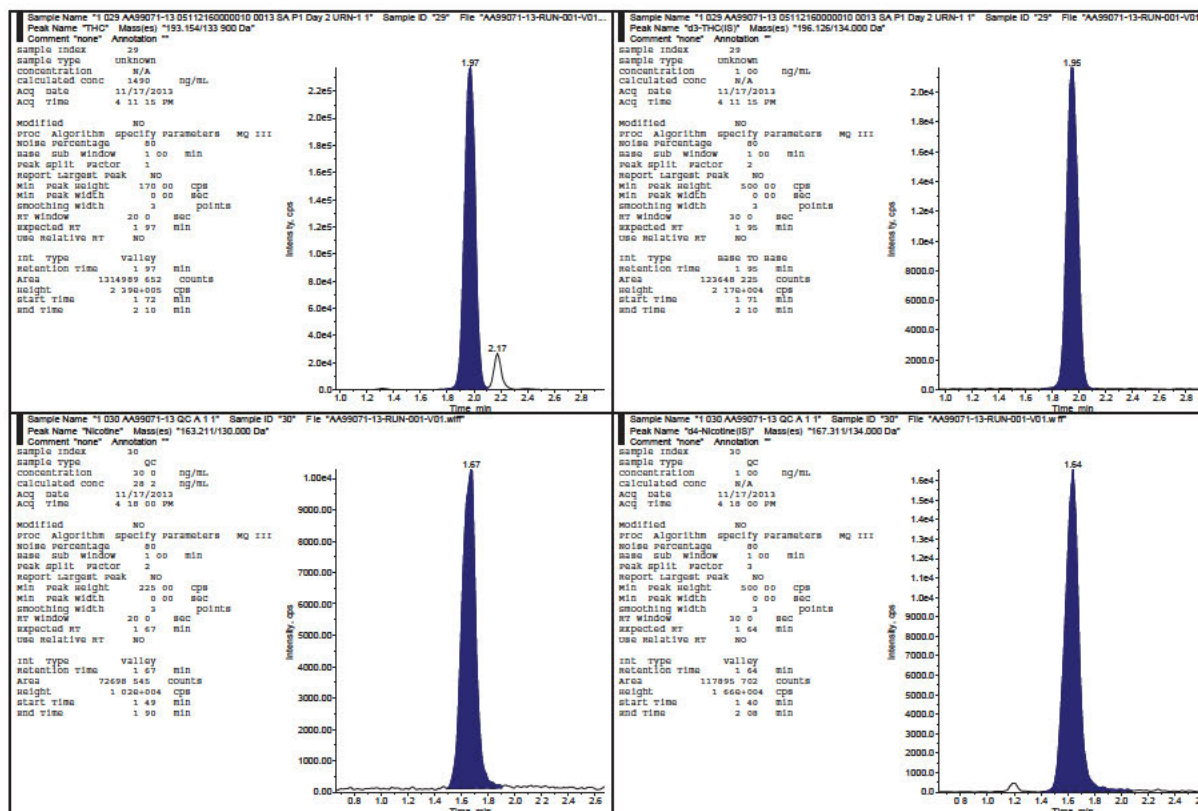


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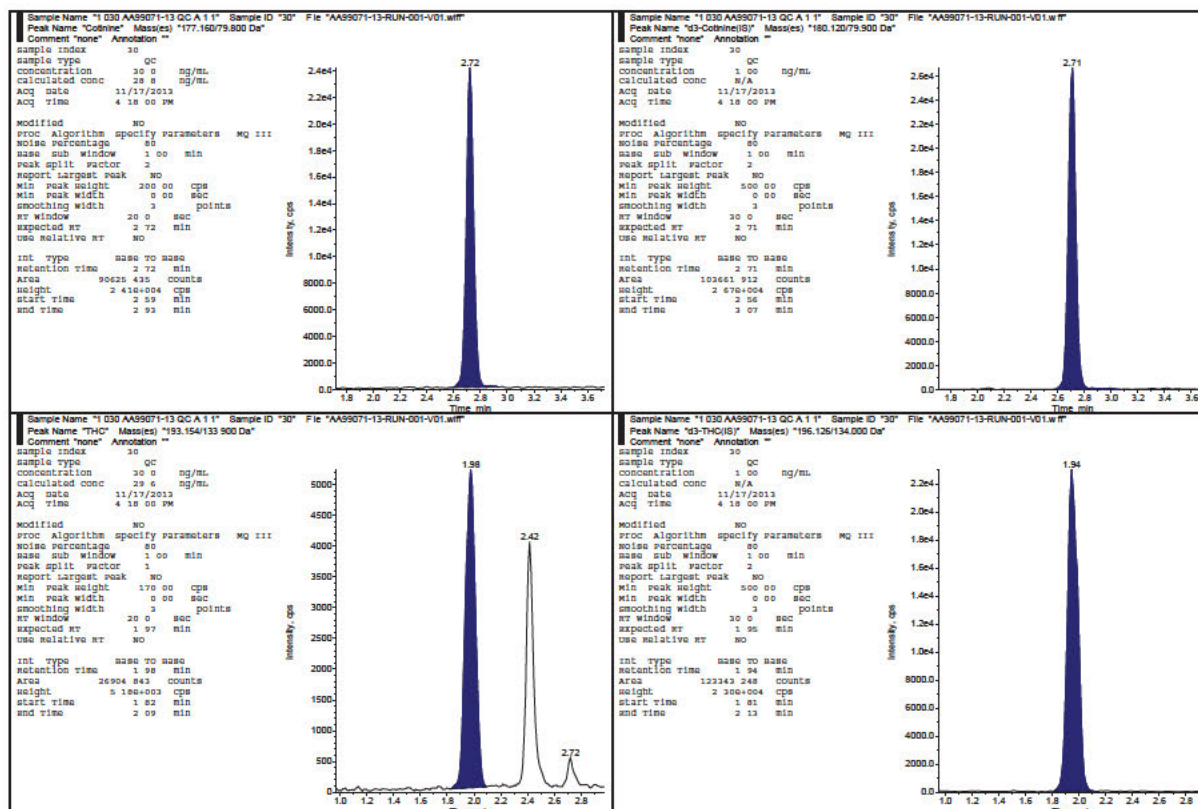


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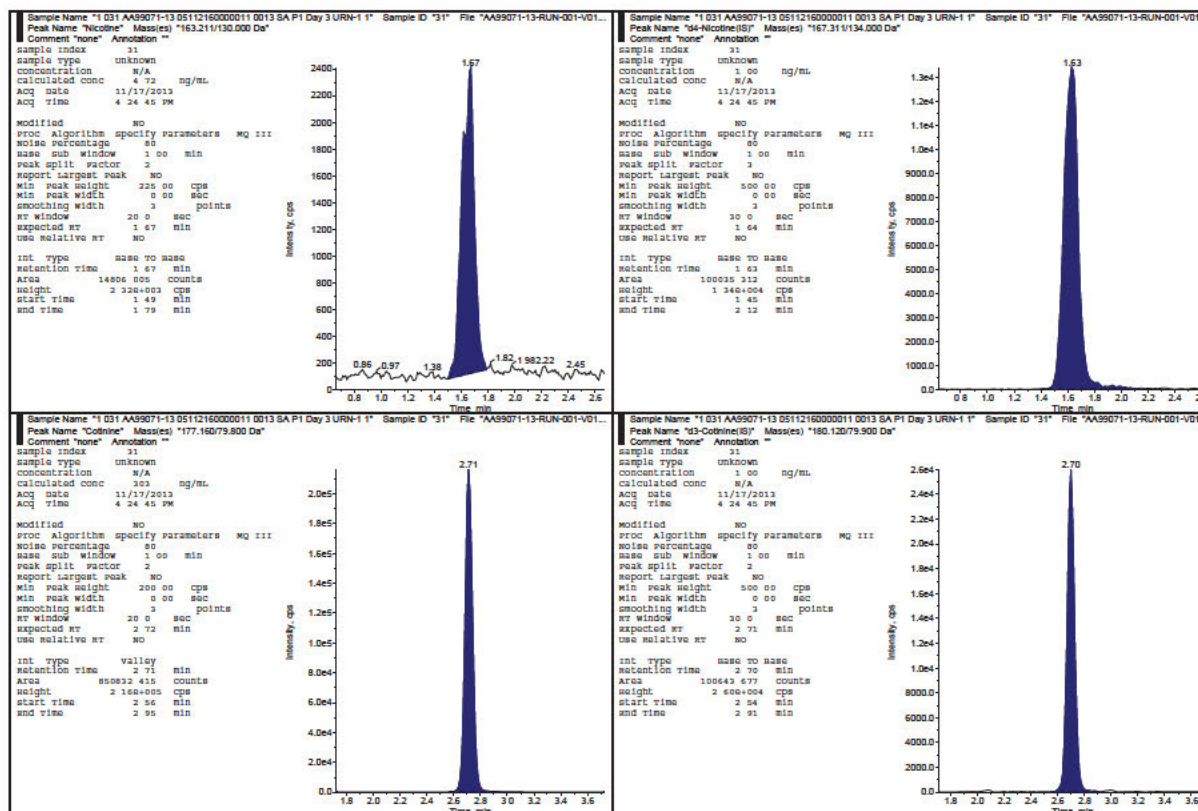


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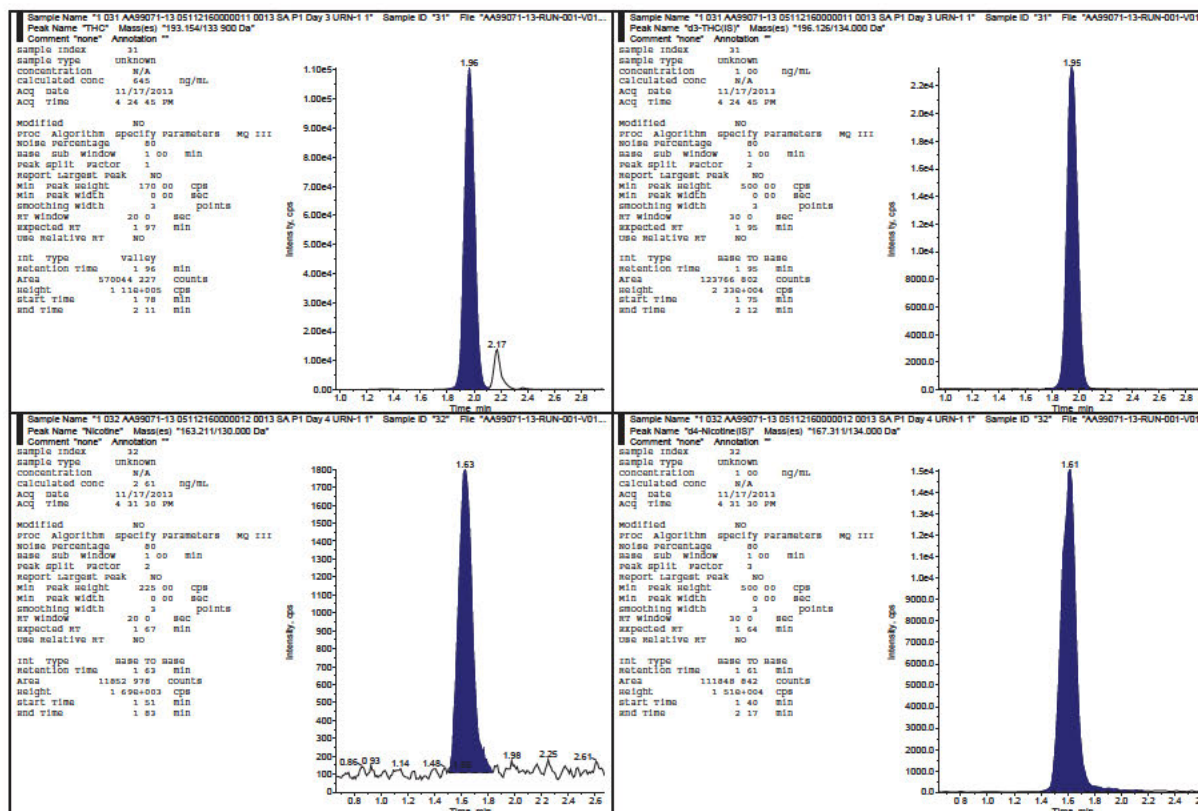


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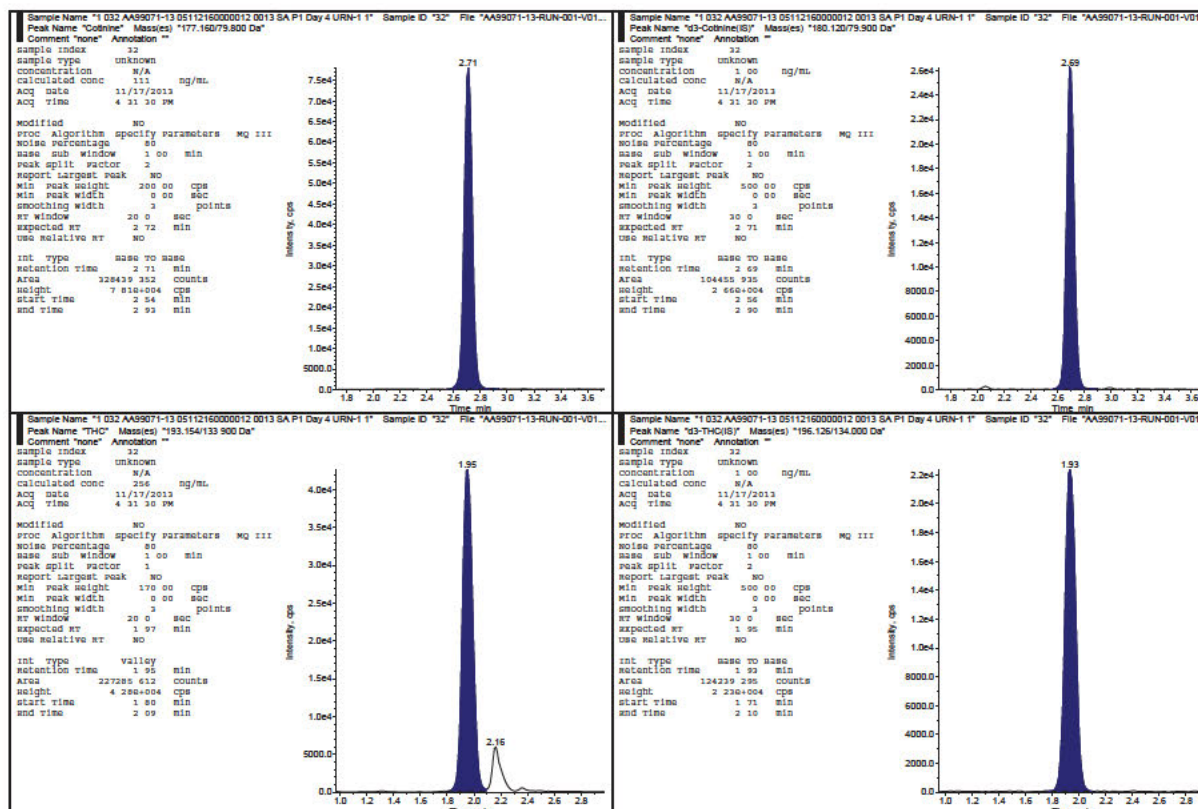


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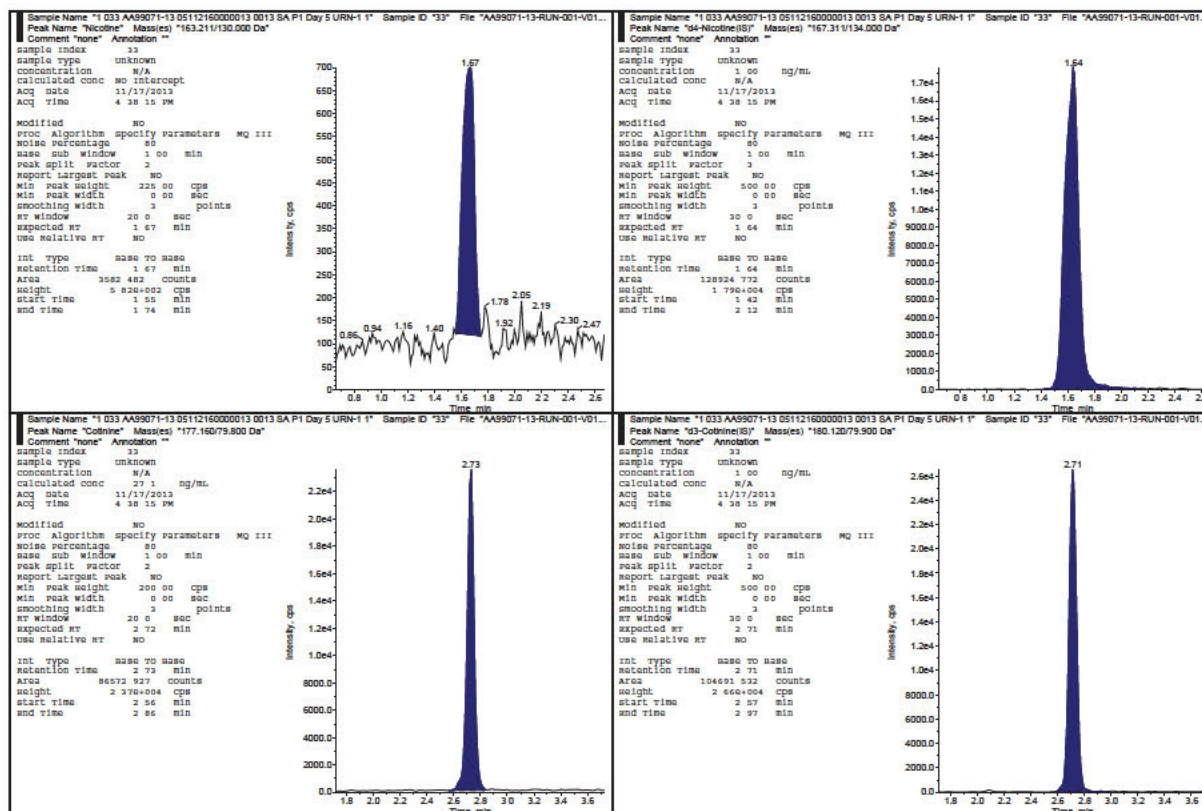


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Celerion Study AA99071-13



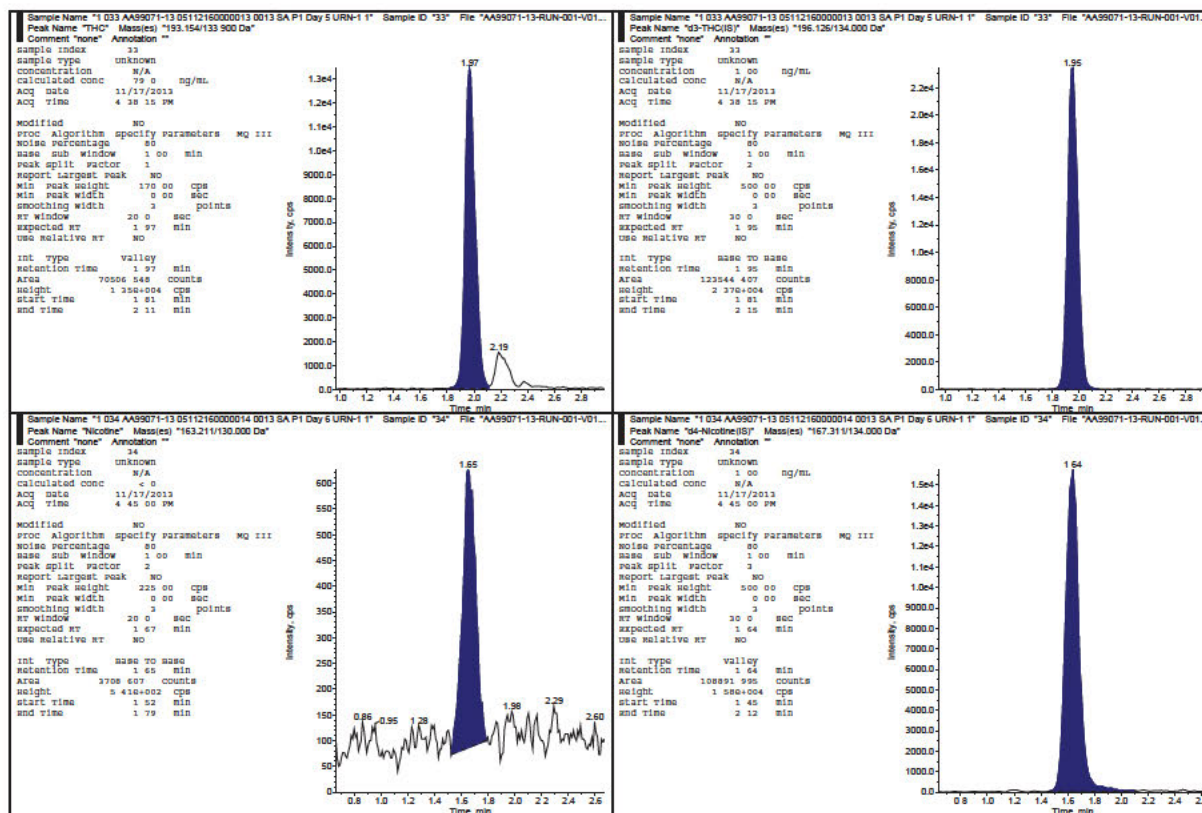


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Celerion Study AA99071-13



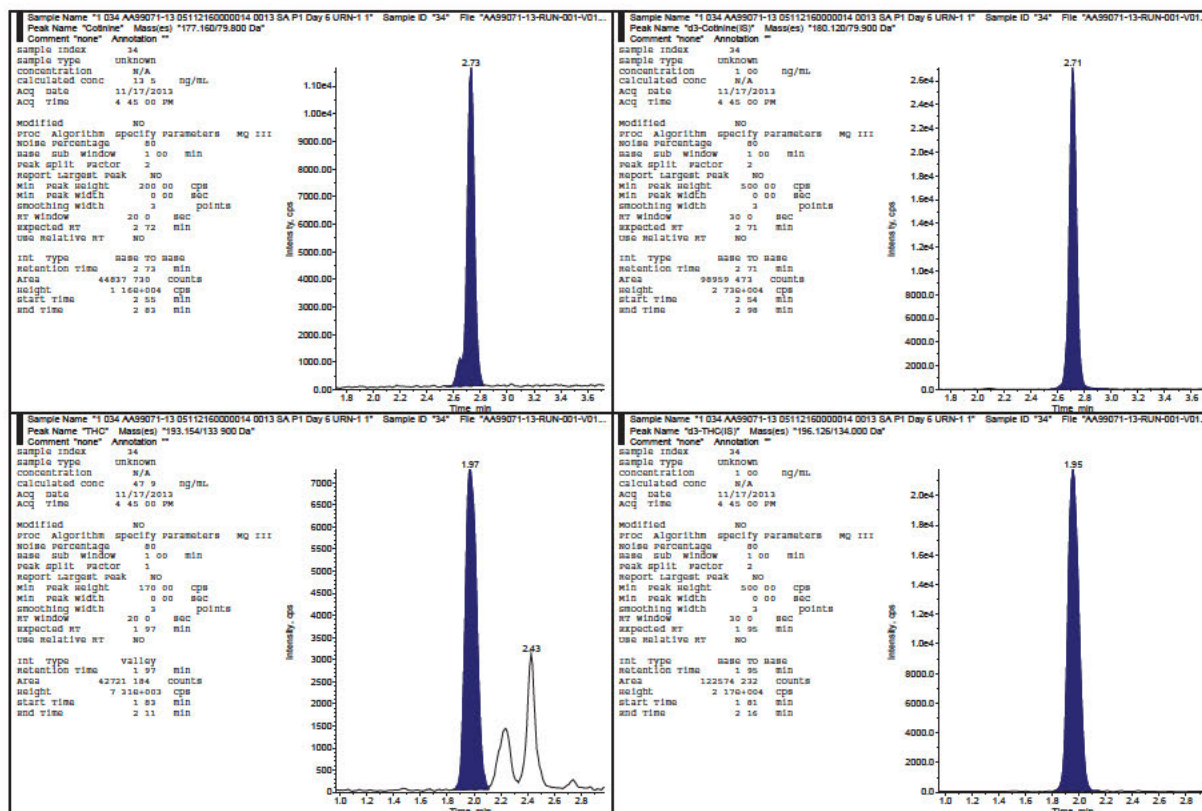


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Celerion Study AA99071-13



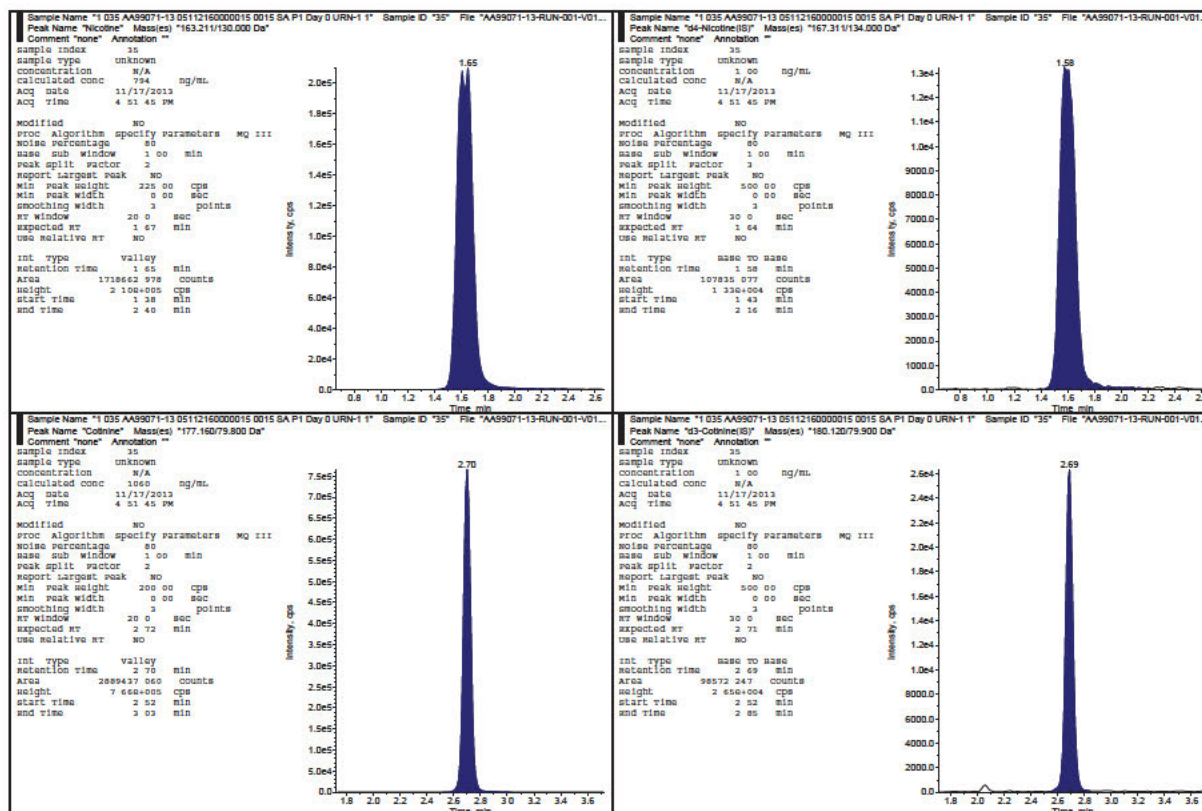


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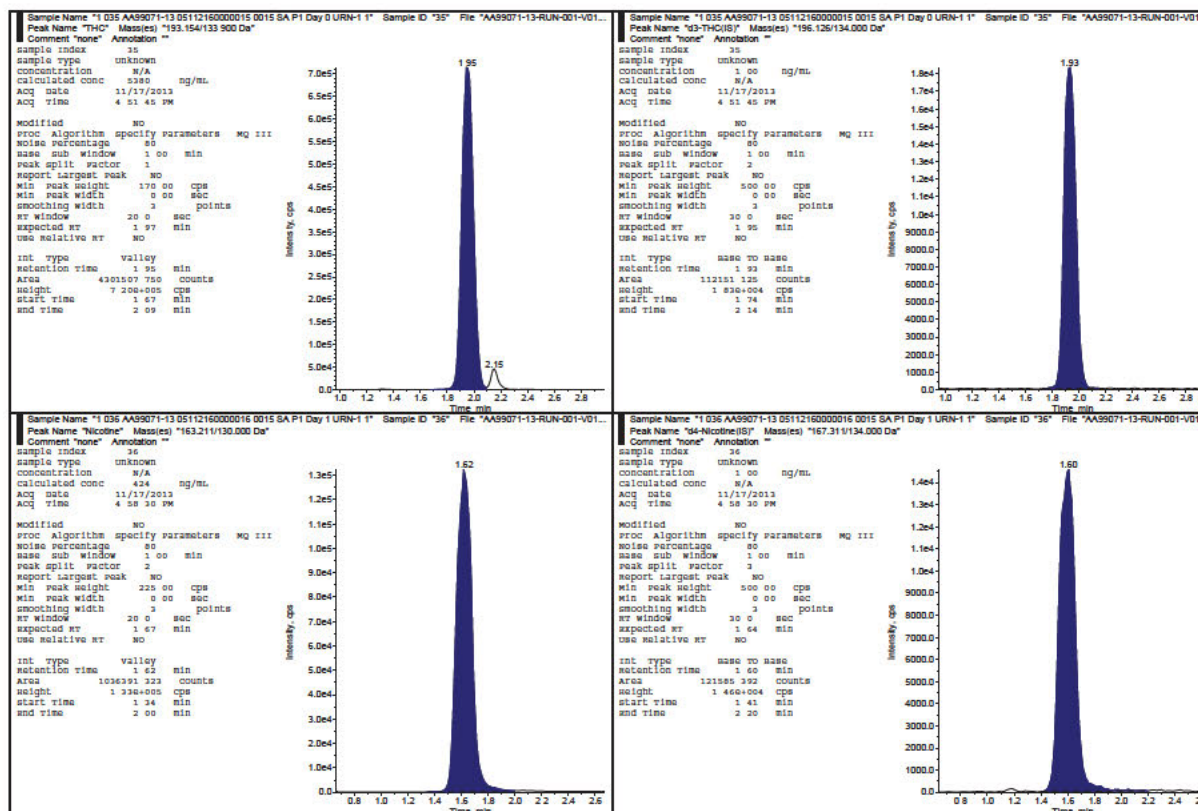


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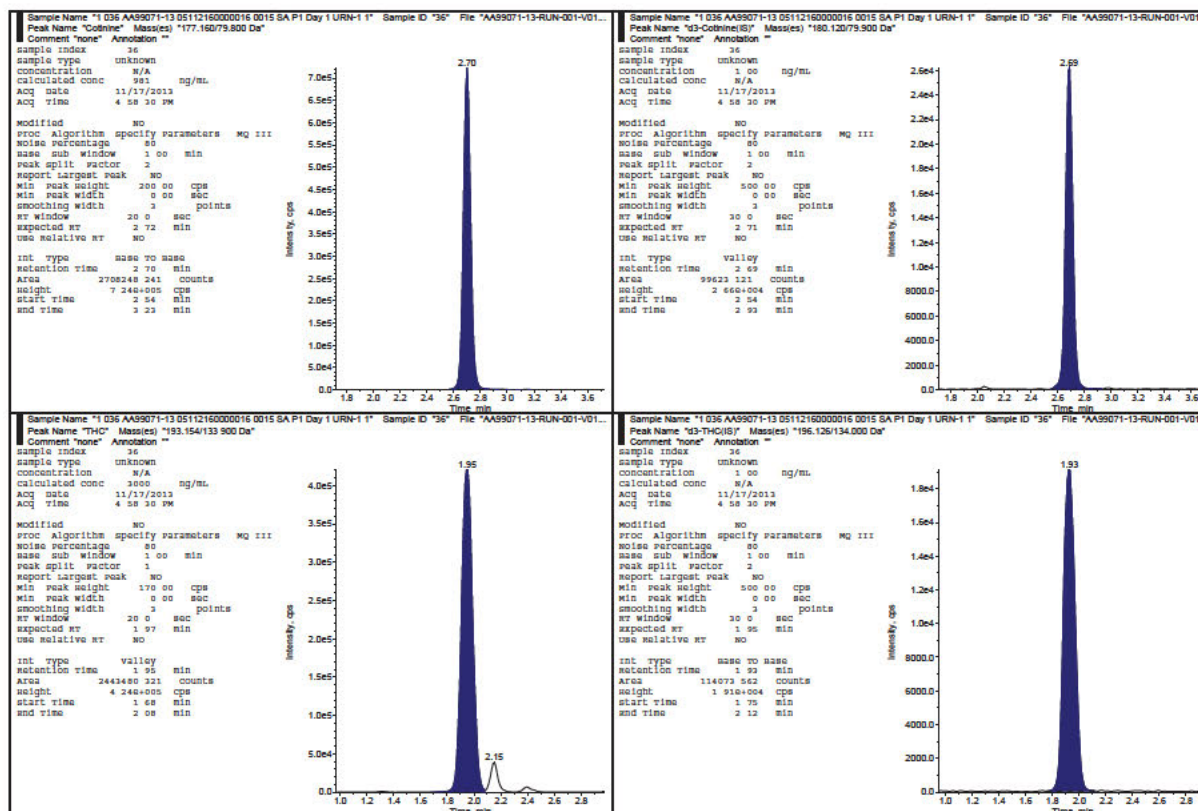


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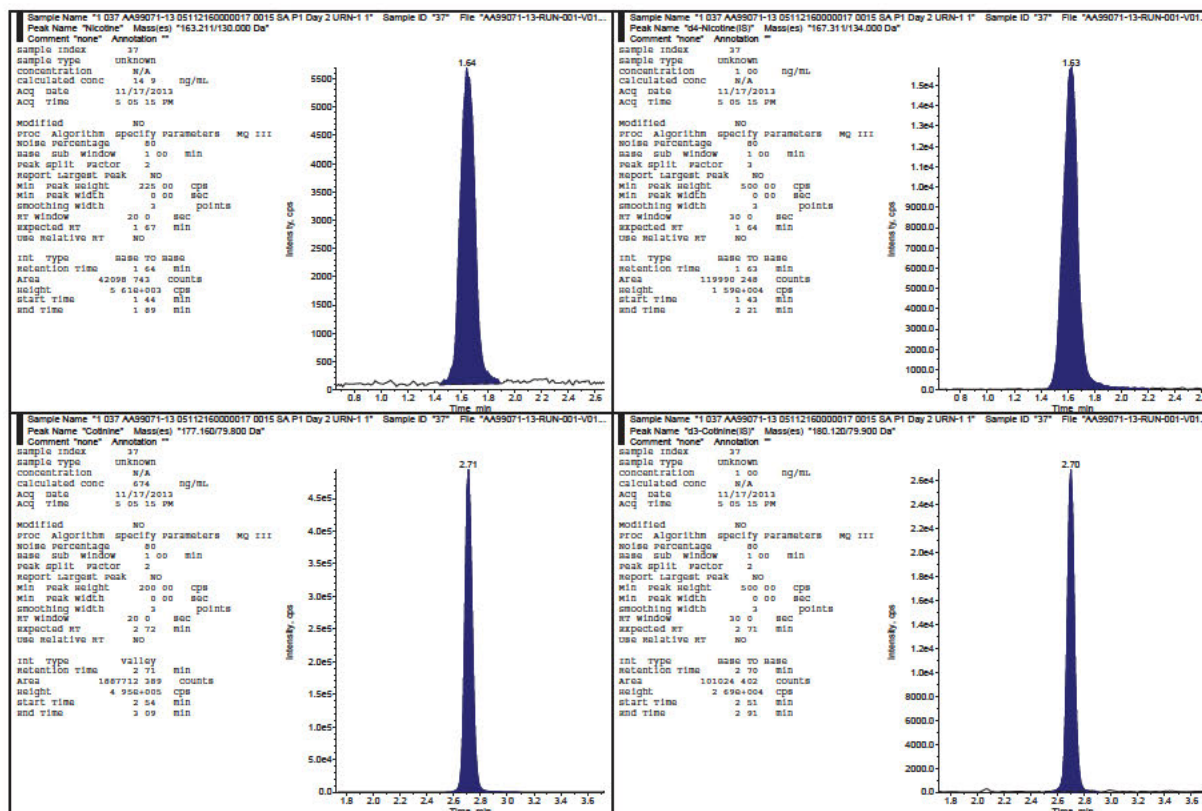


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Celerion Study AA99071-13



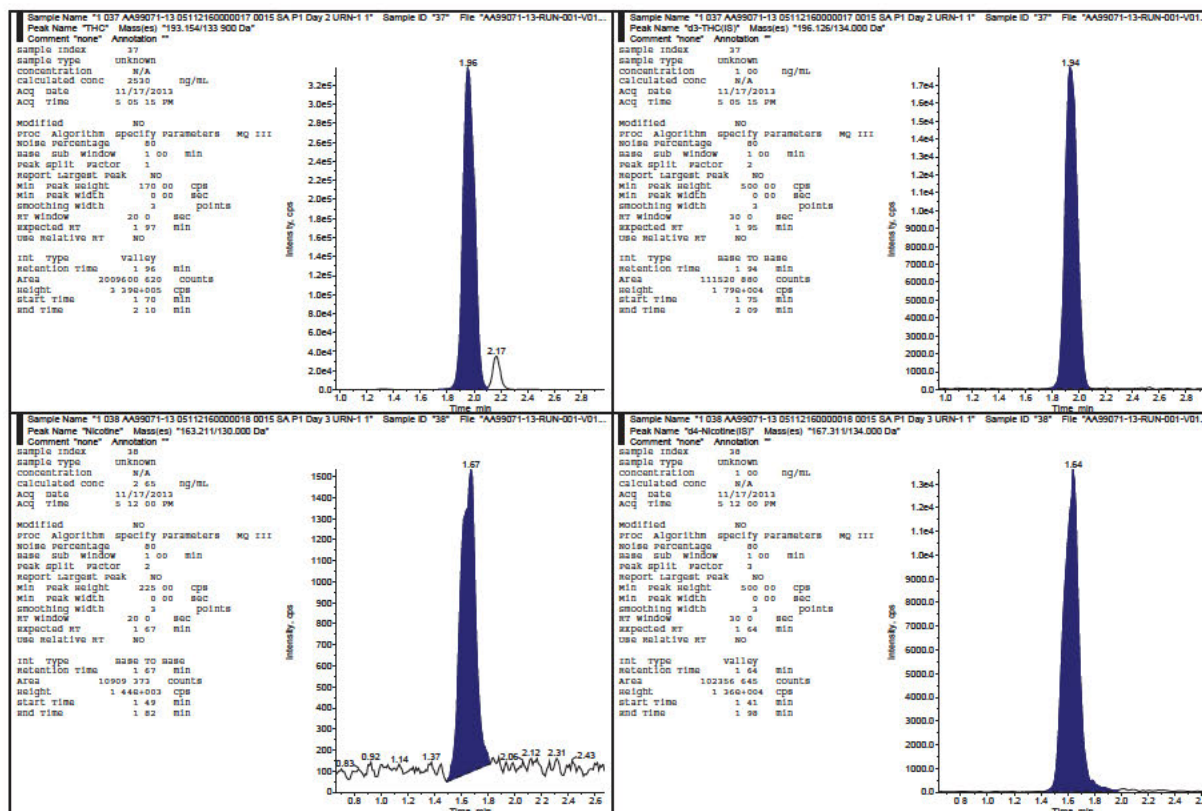


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Celerion Study AA99071-13



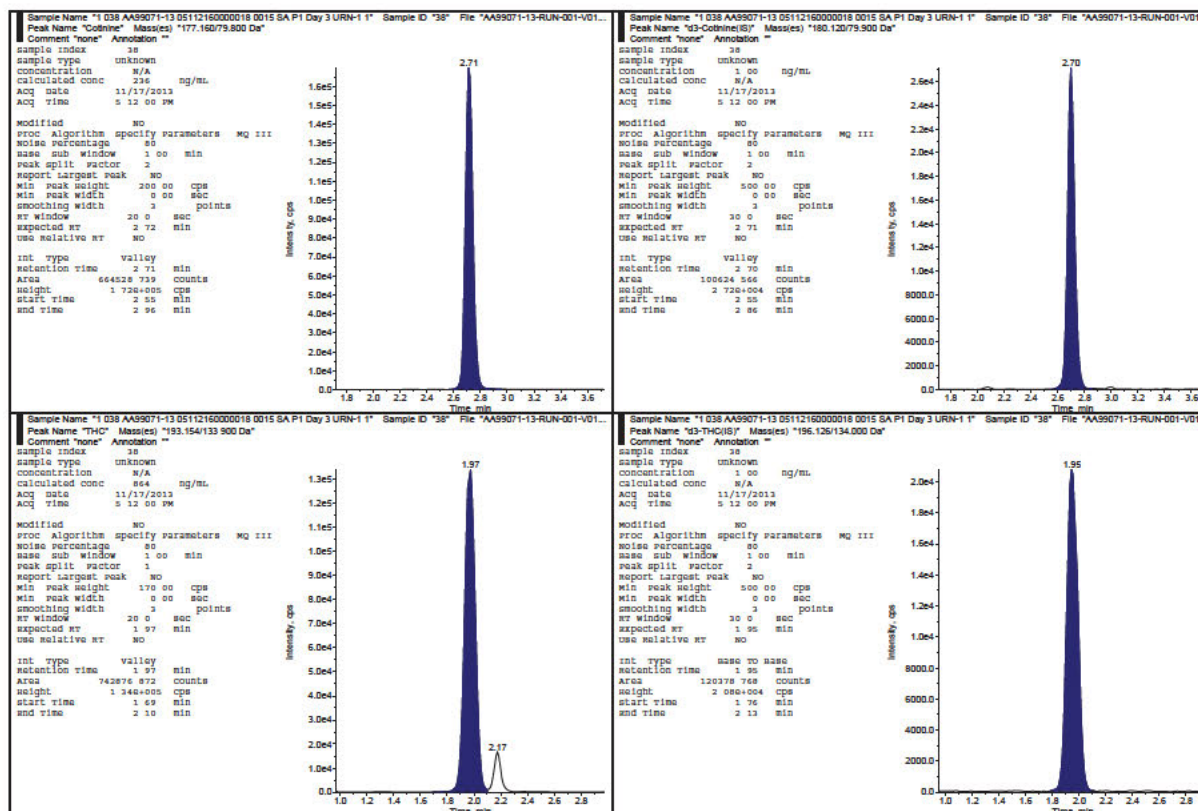


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Celerion Study AA99071-13



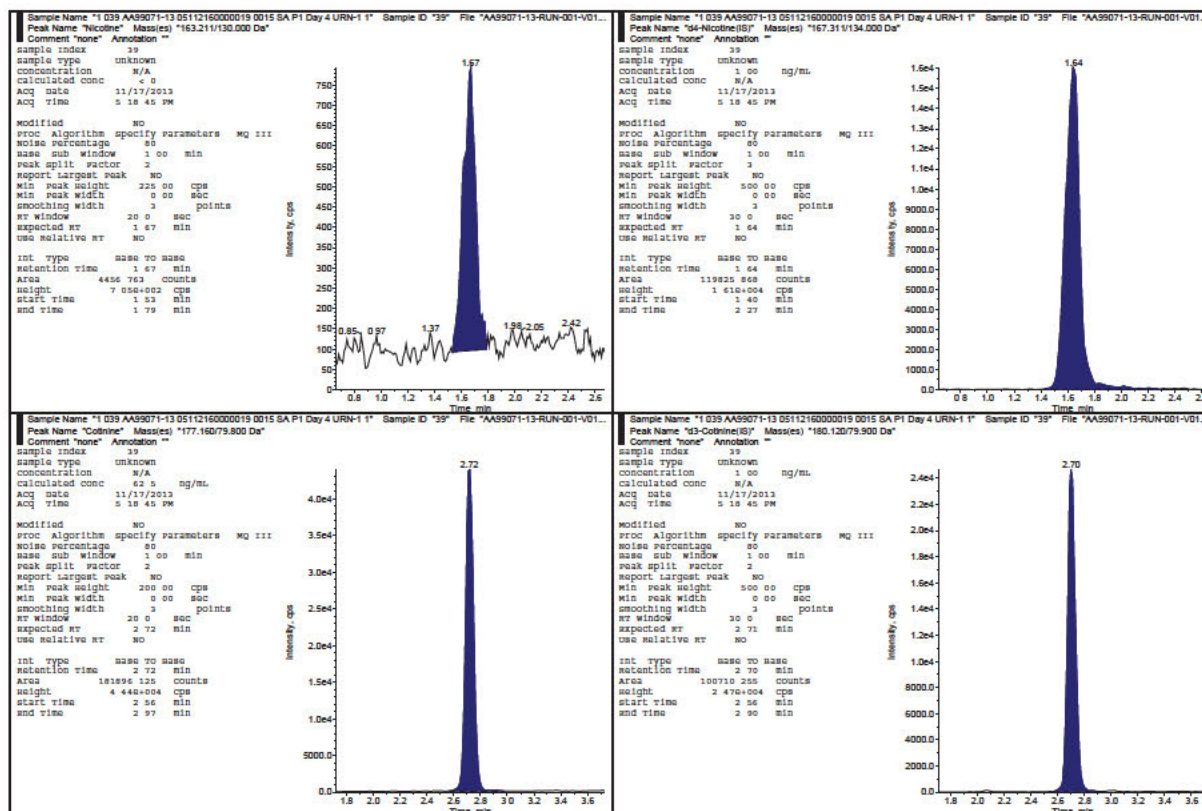


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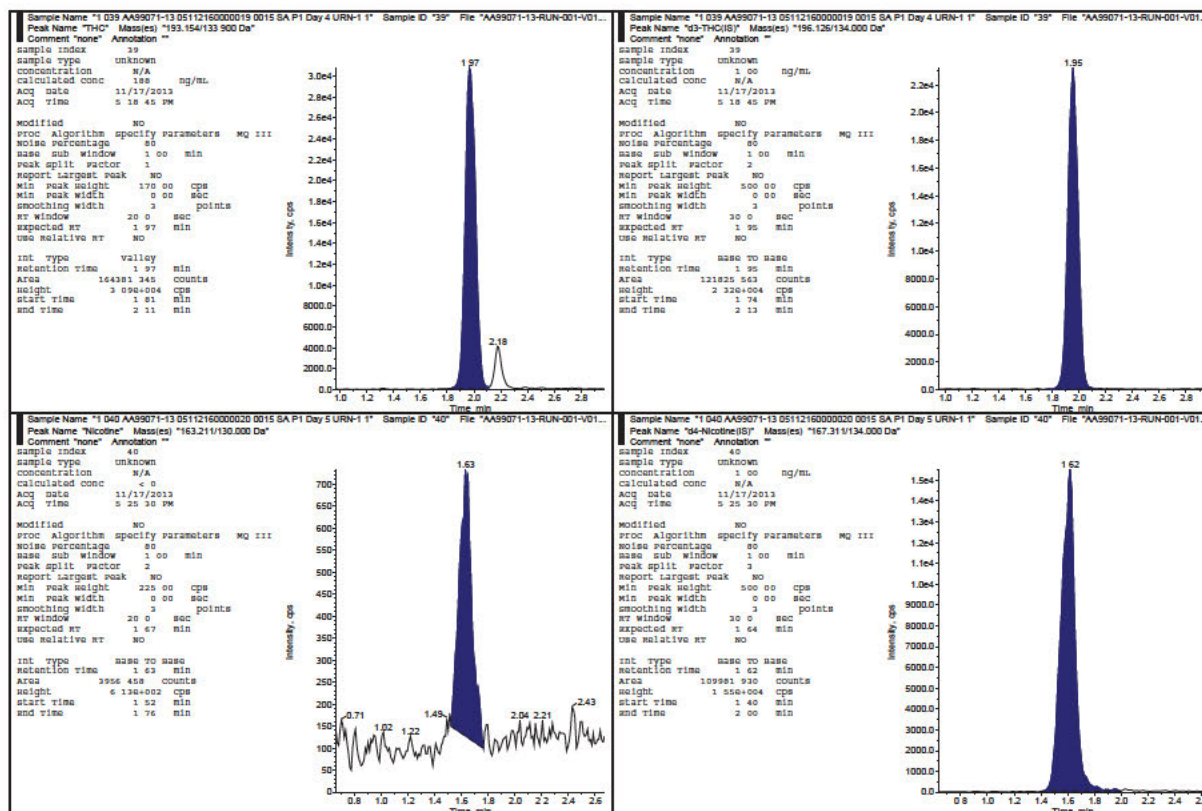


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Celerion Study AA99071-13



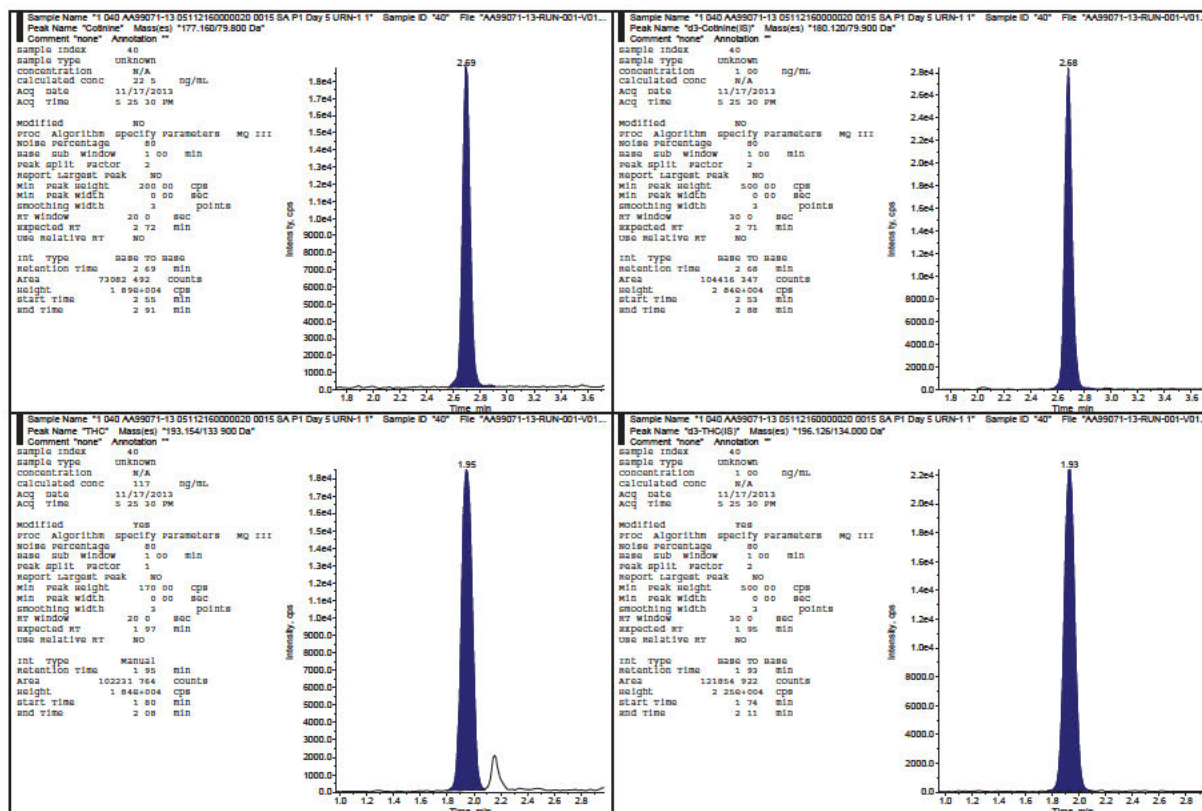


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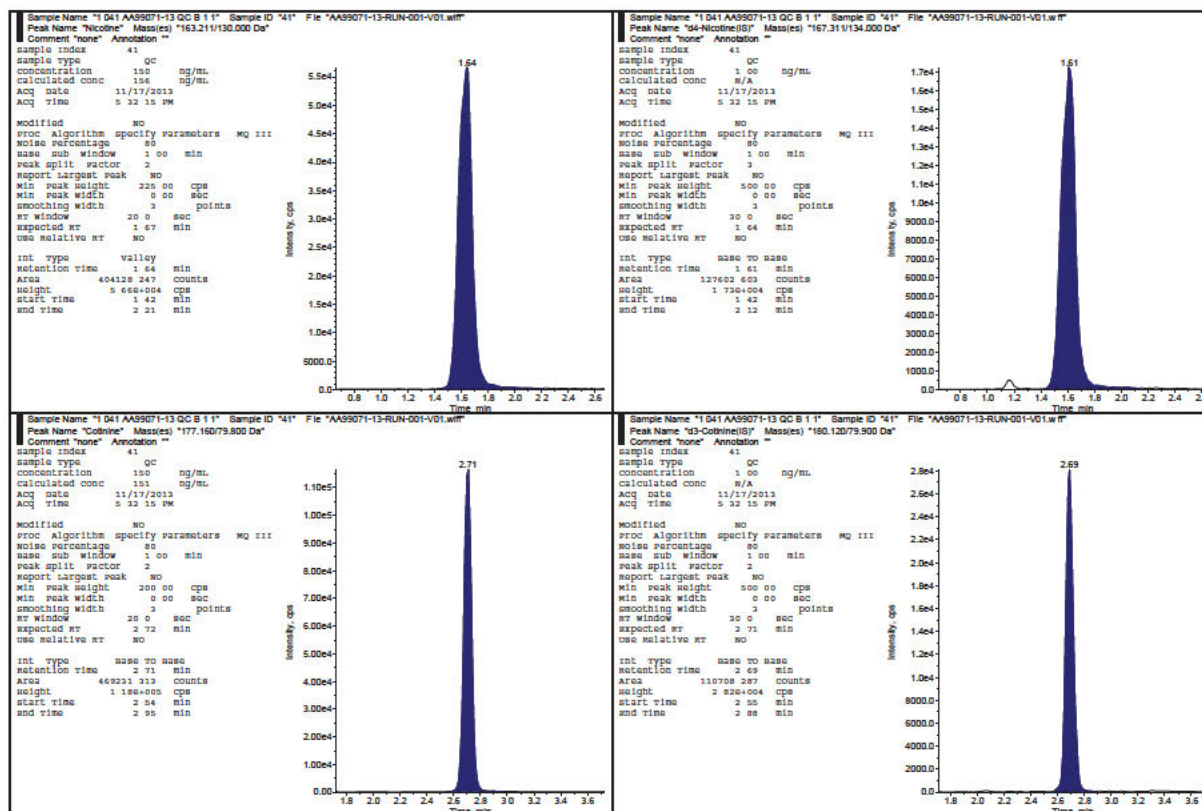


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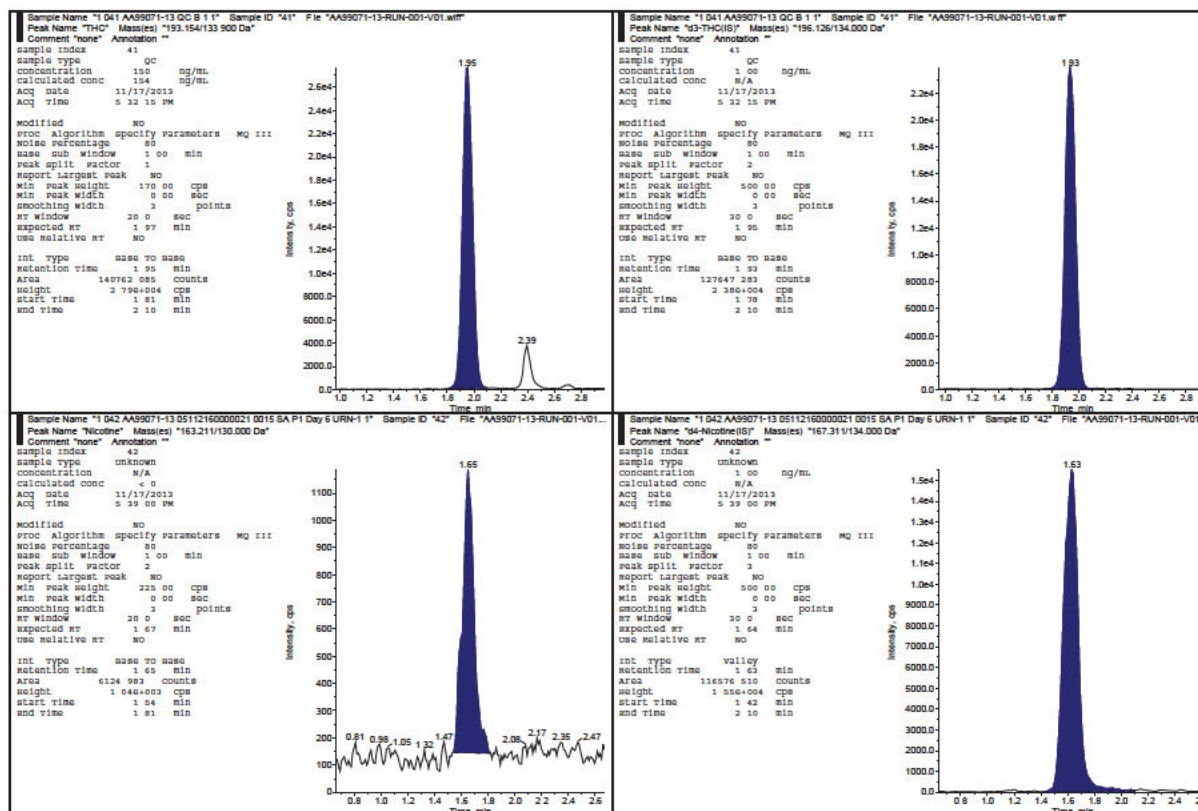


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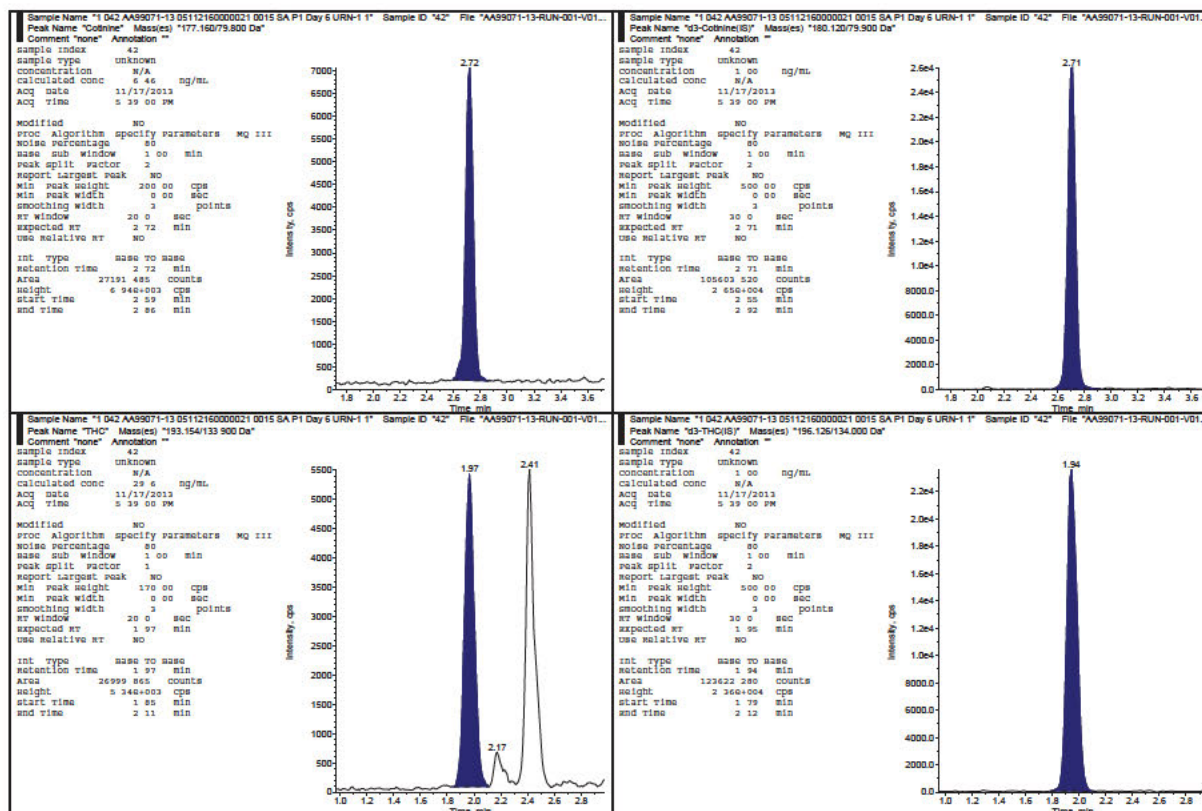


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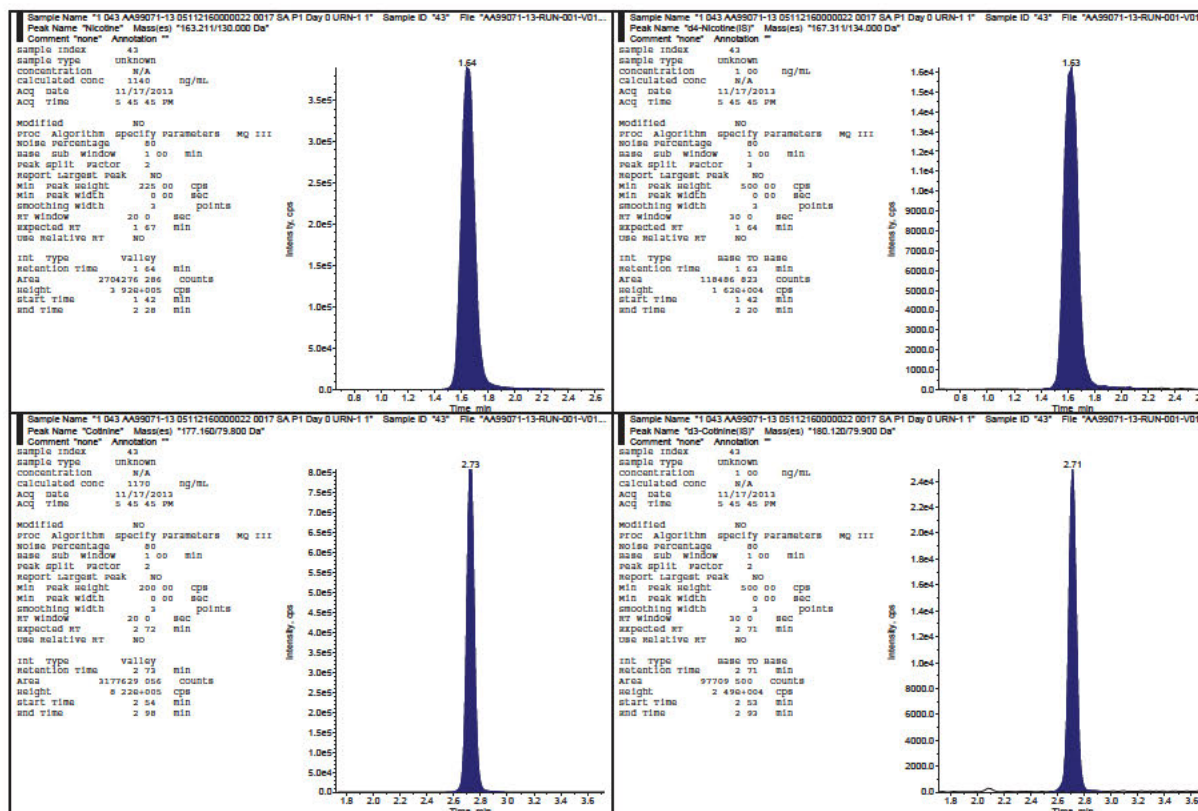


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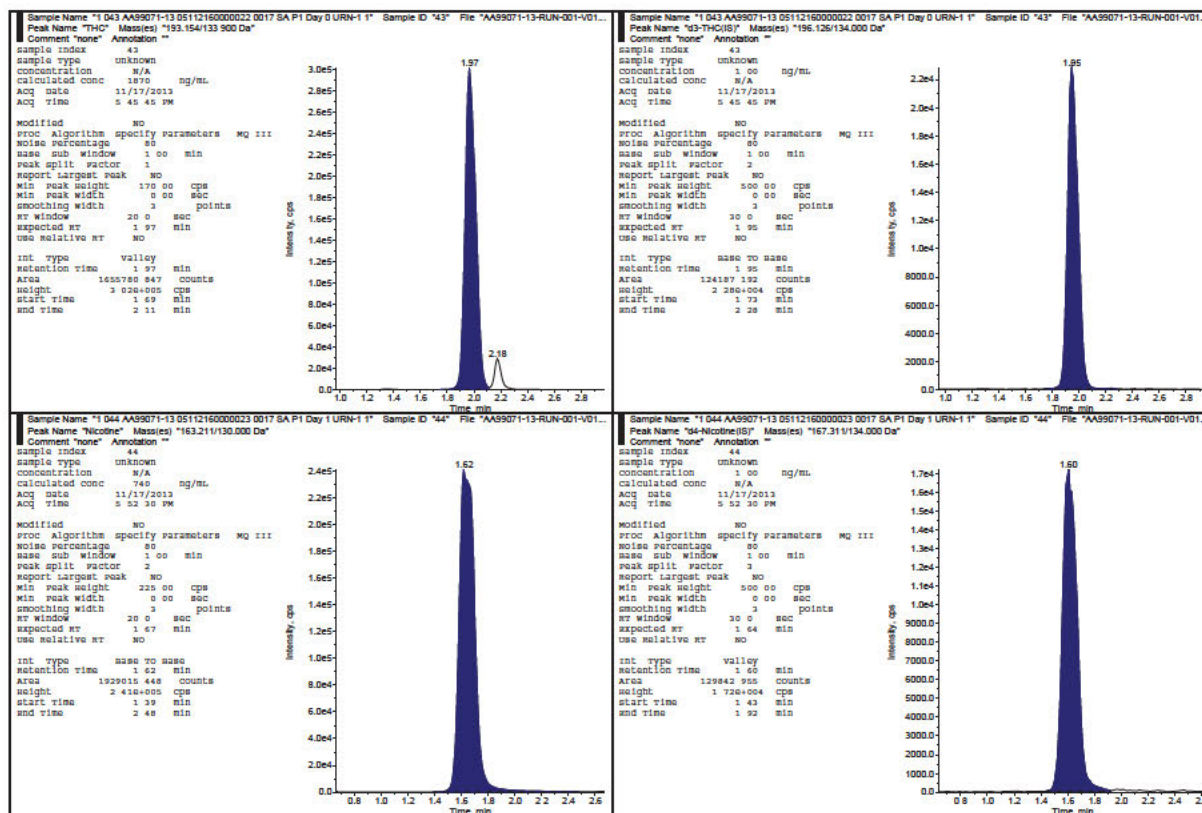


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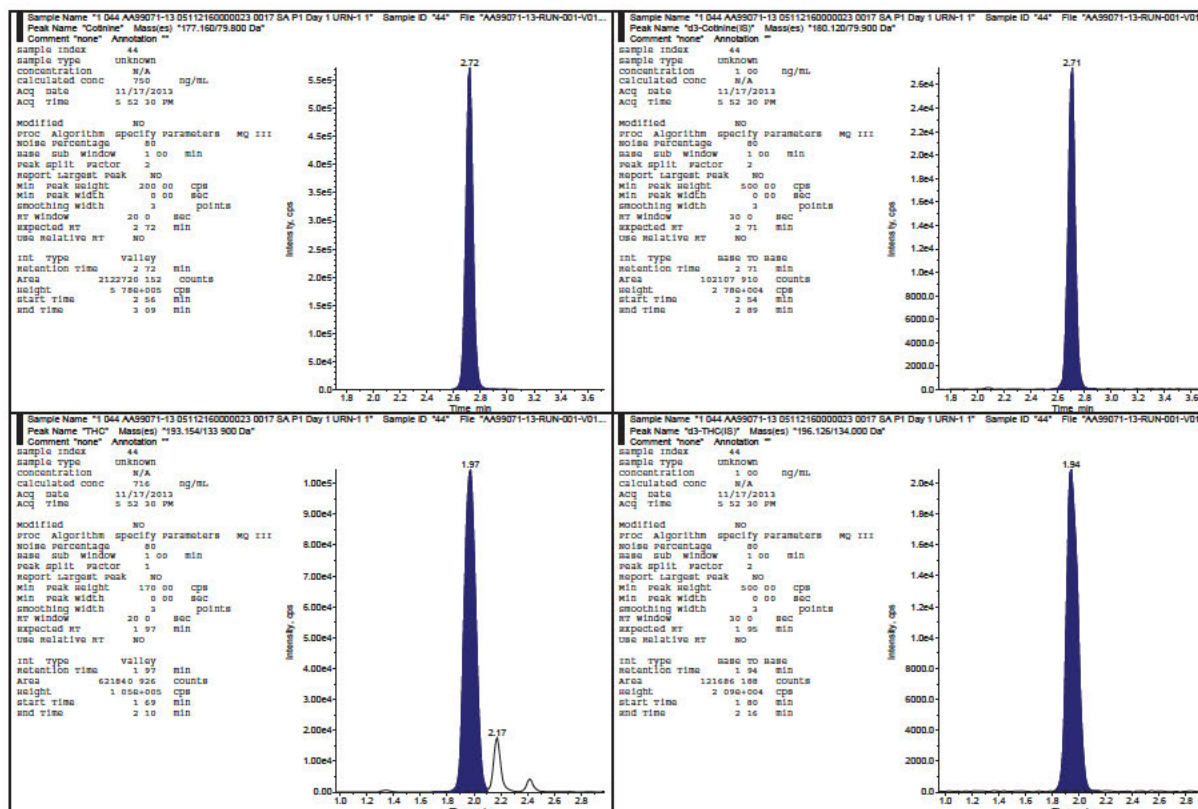


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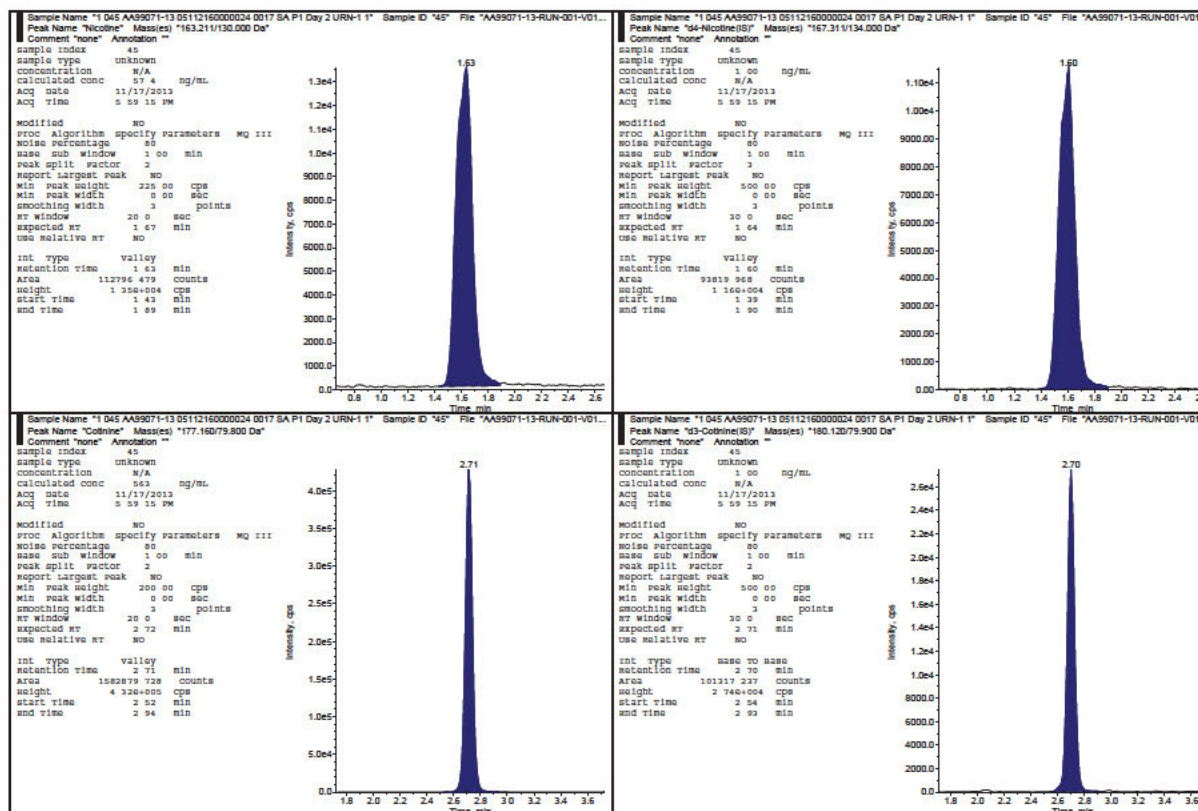


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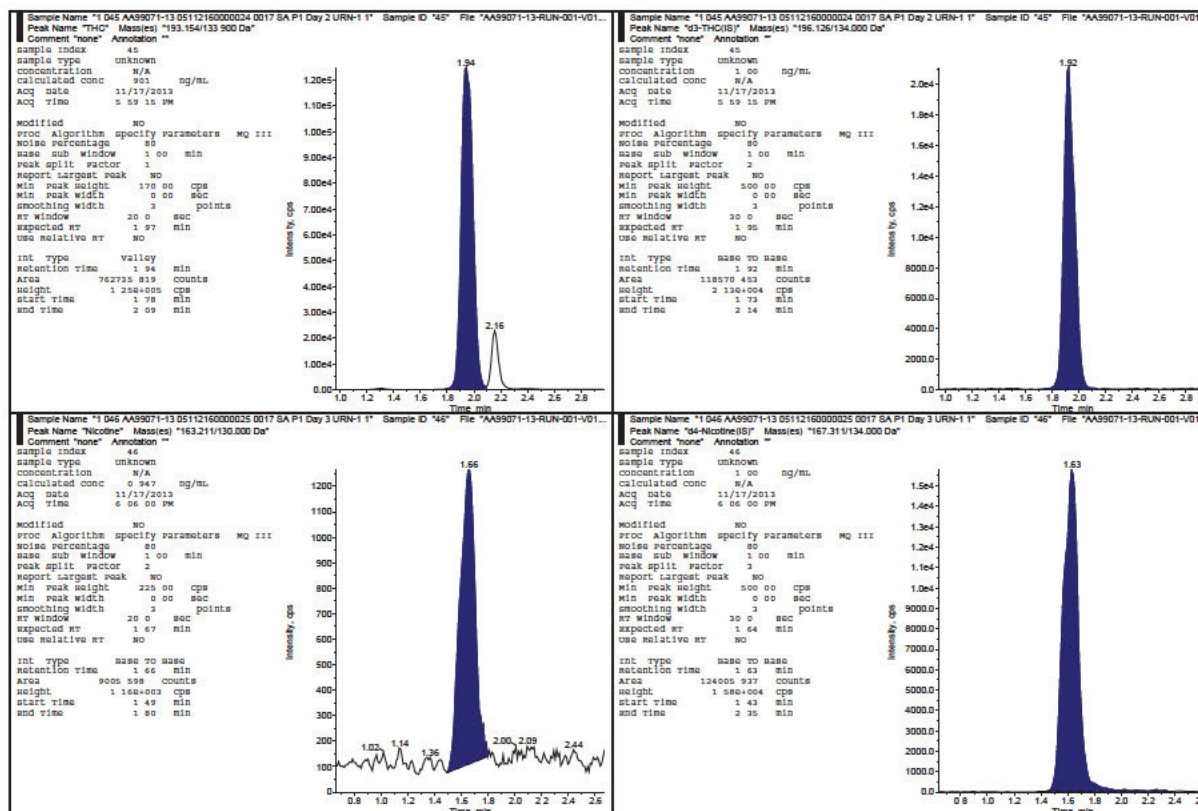


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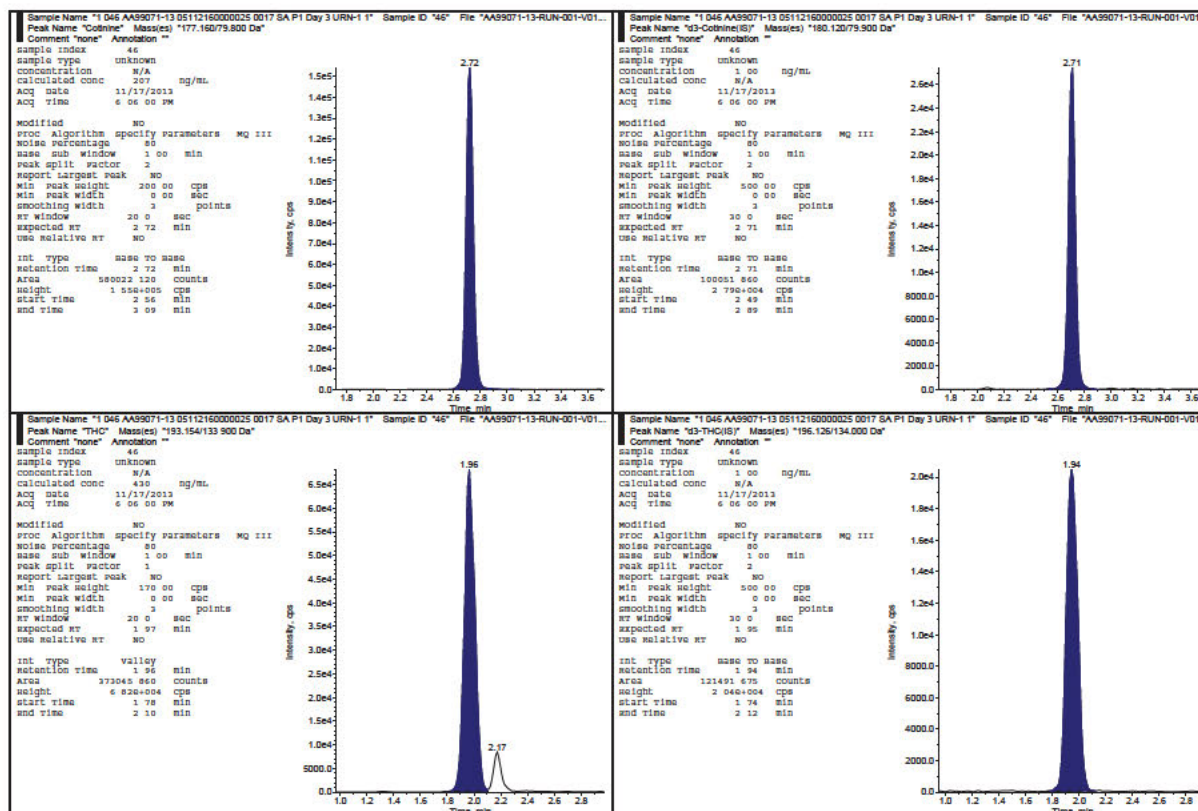


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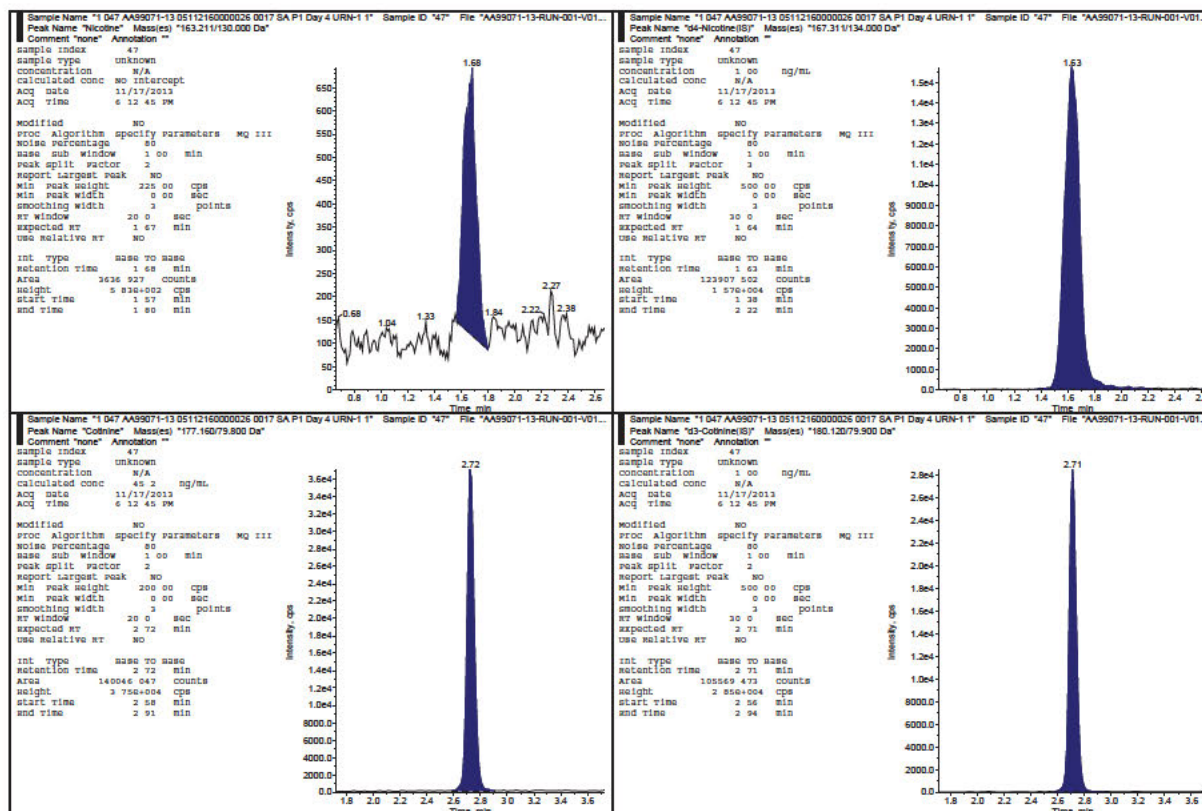


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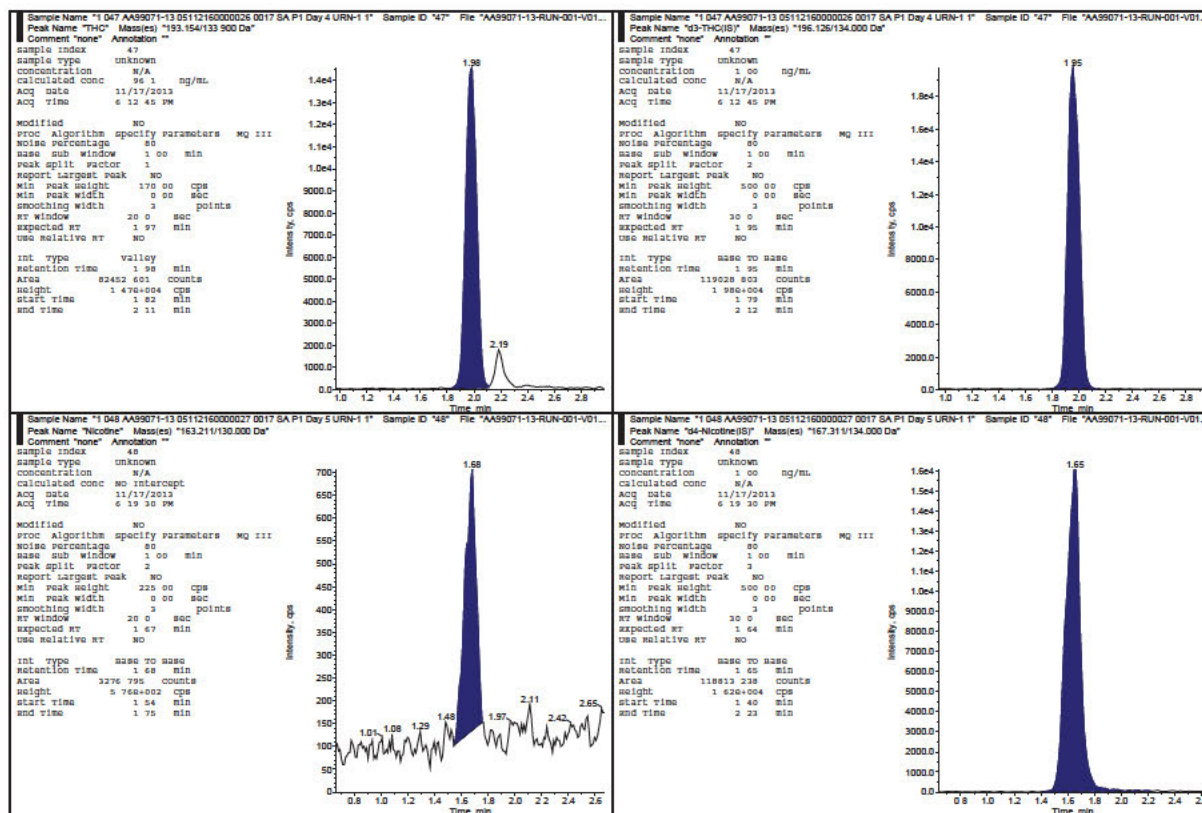


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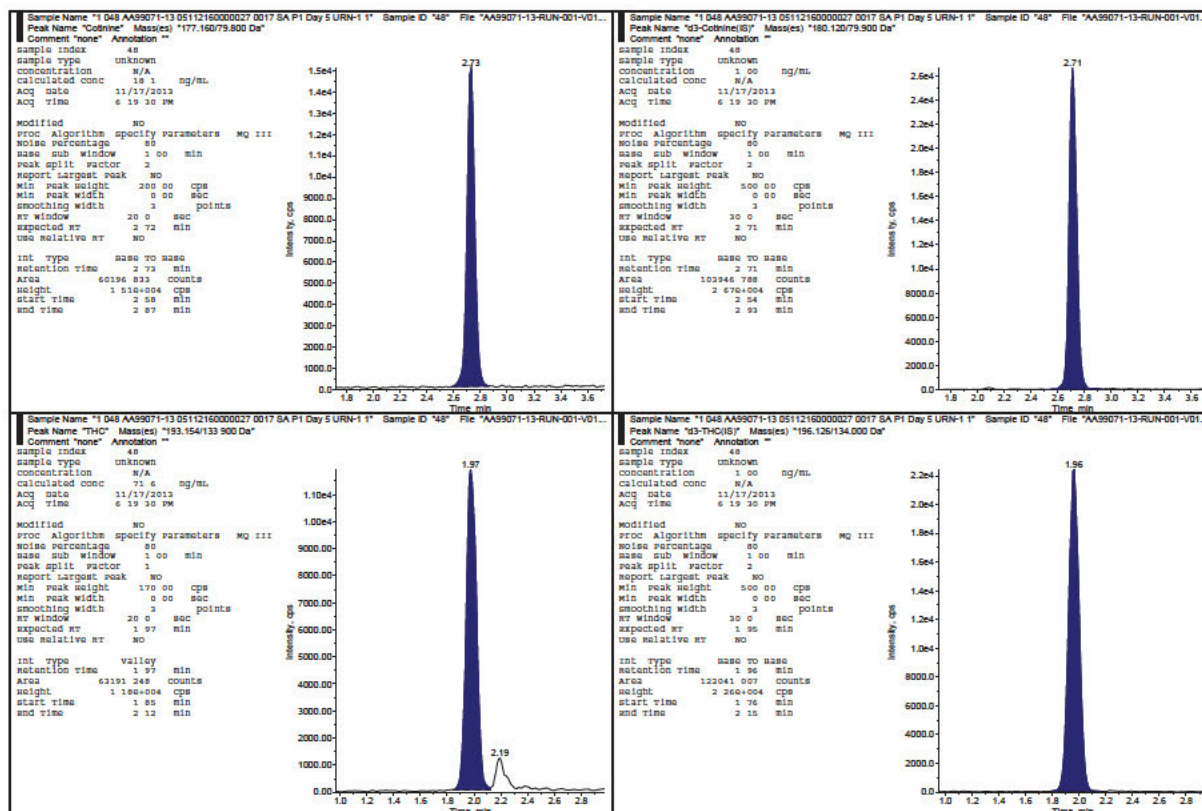


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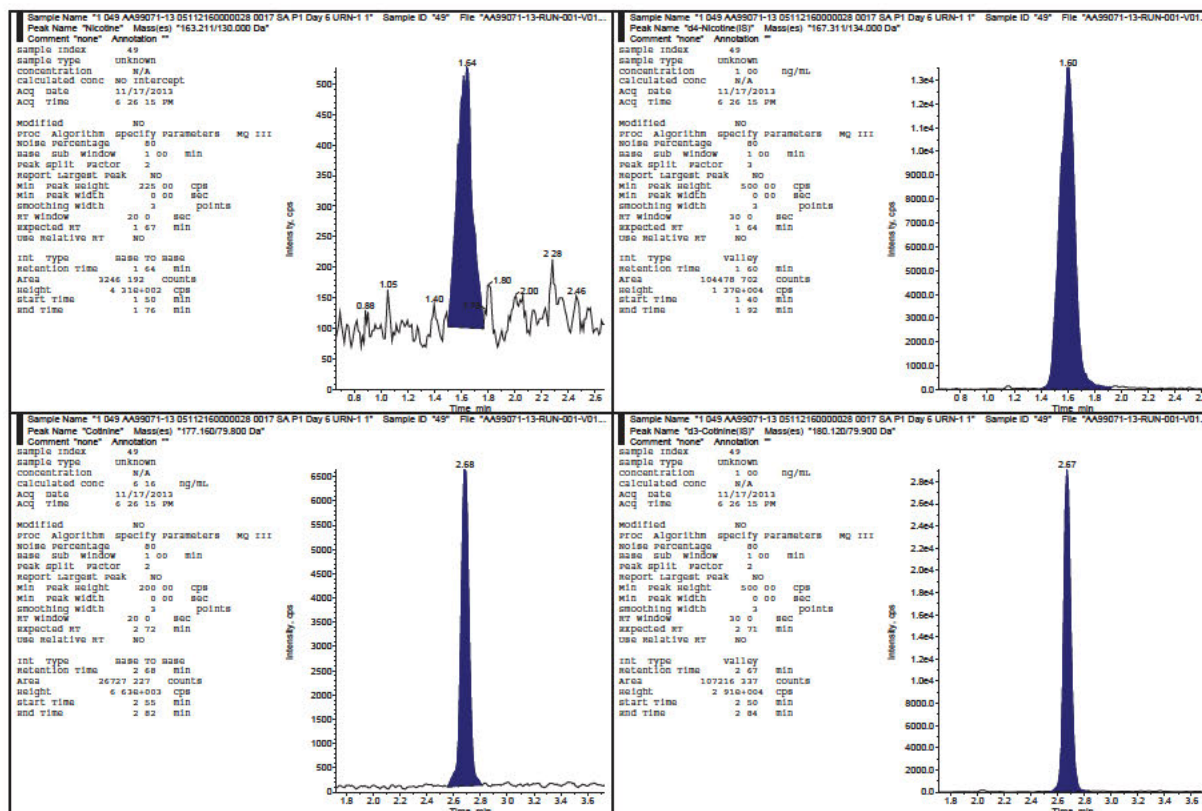


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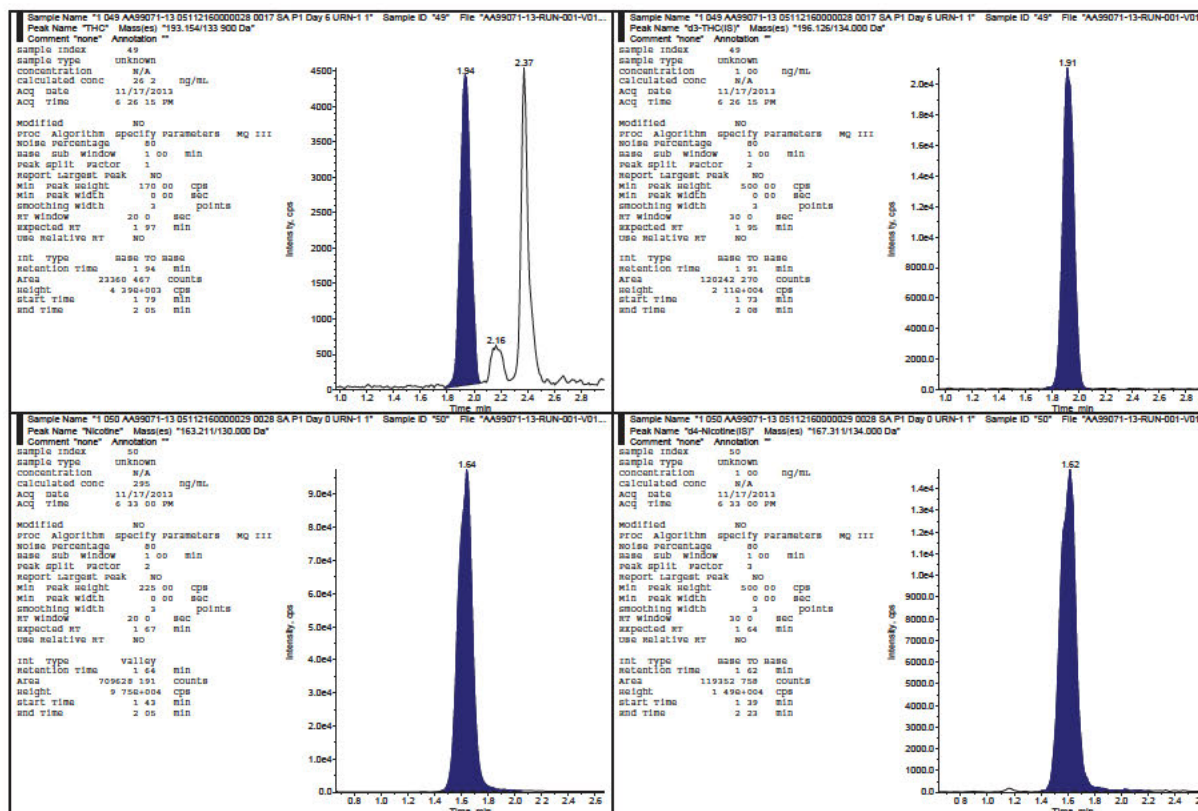


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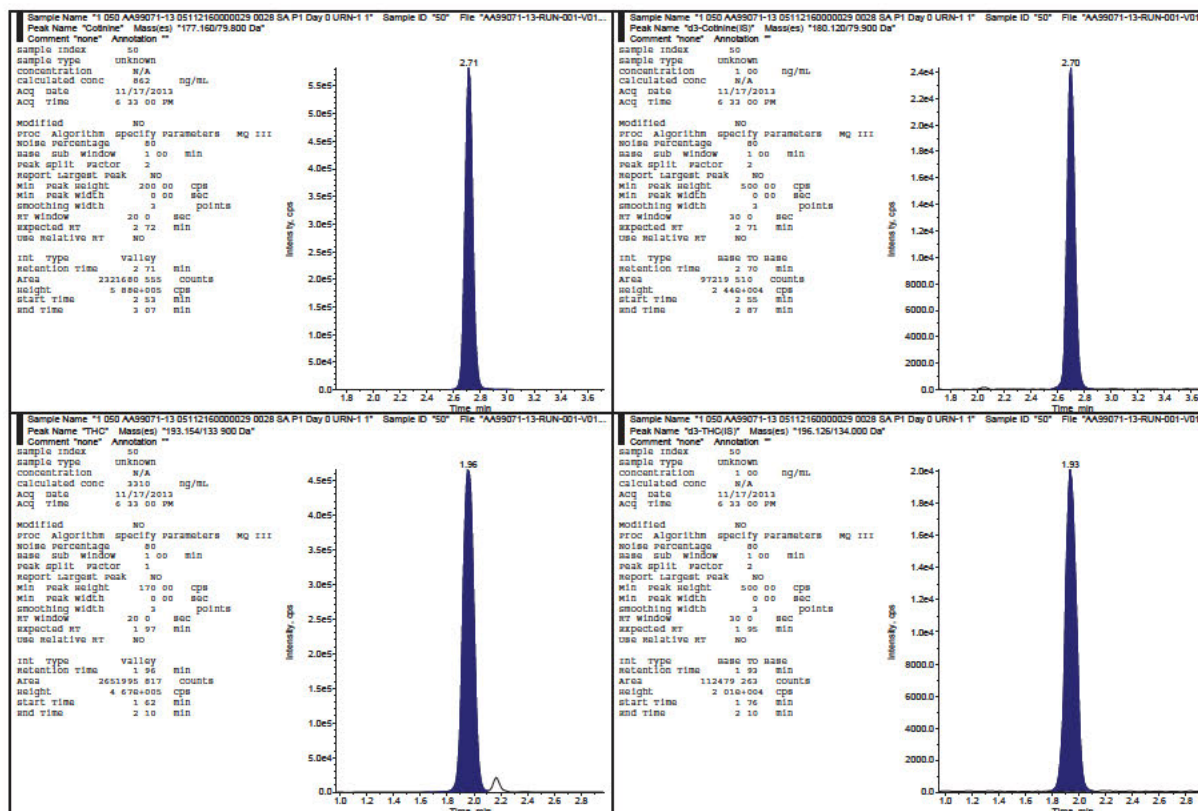


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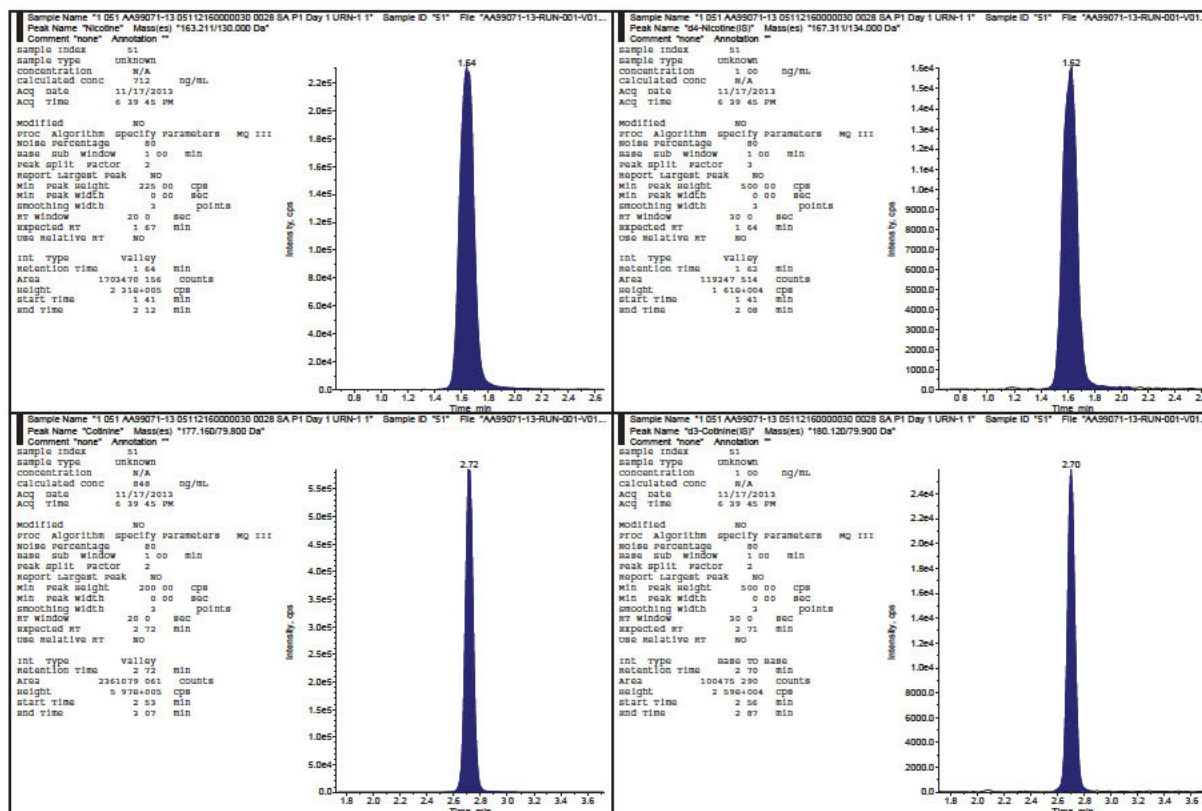


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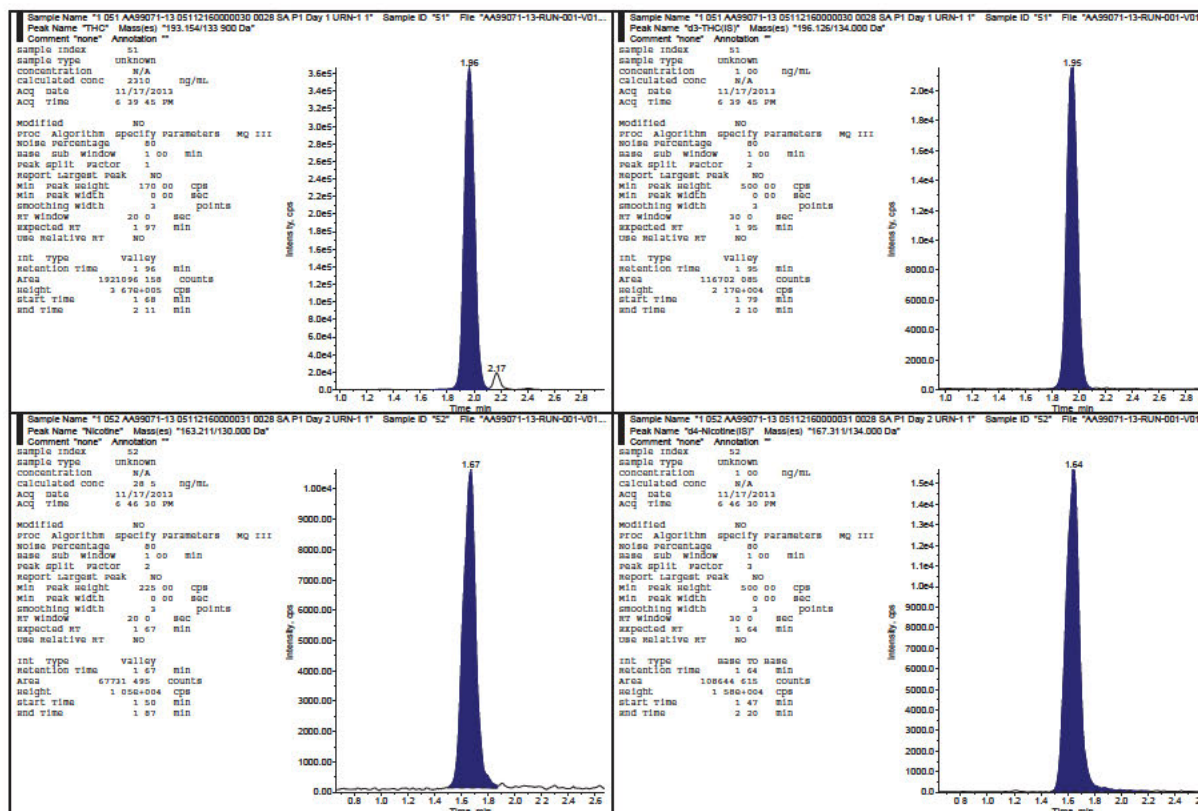


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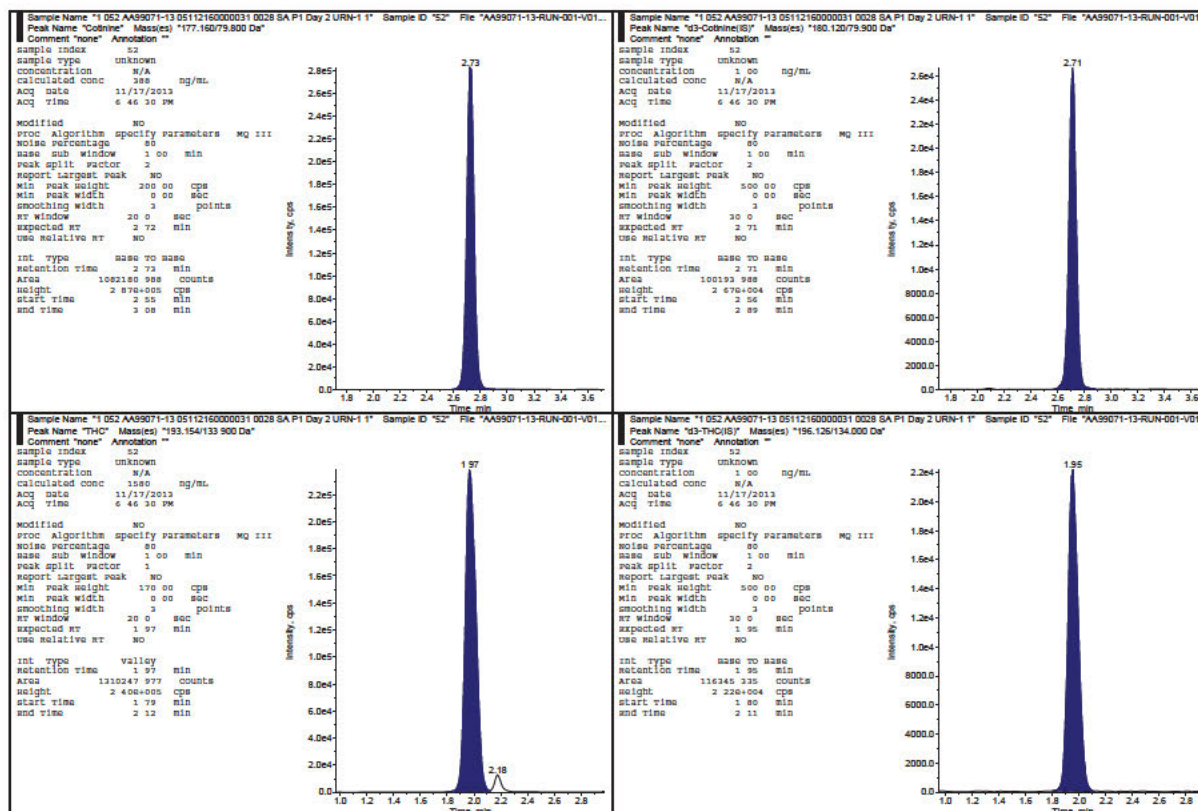


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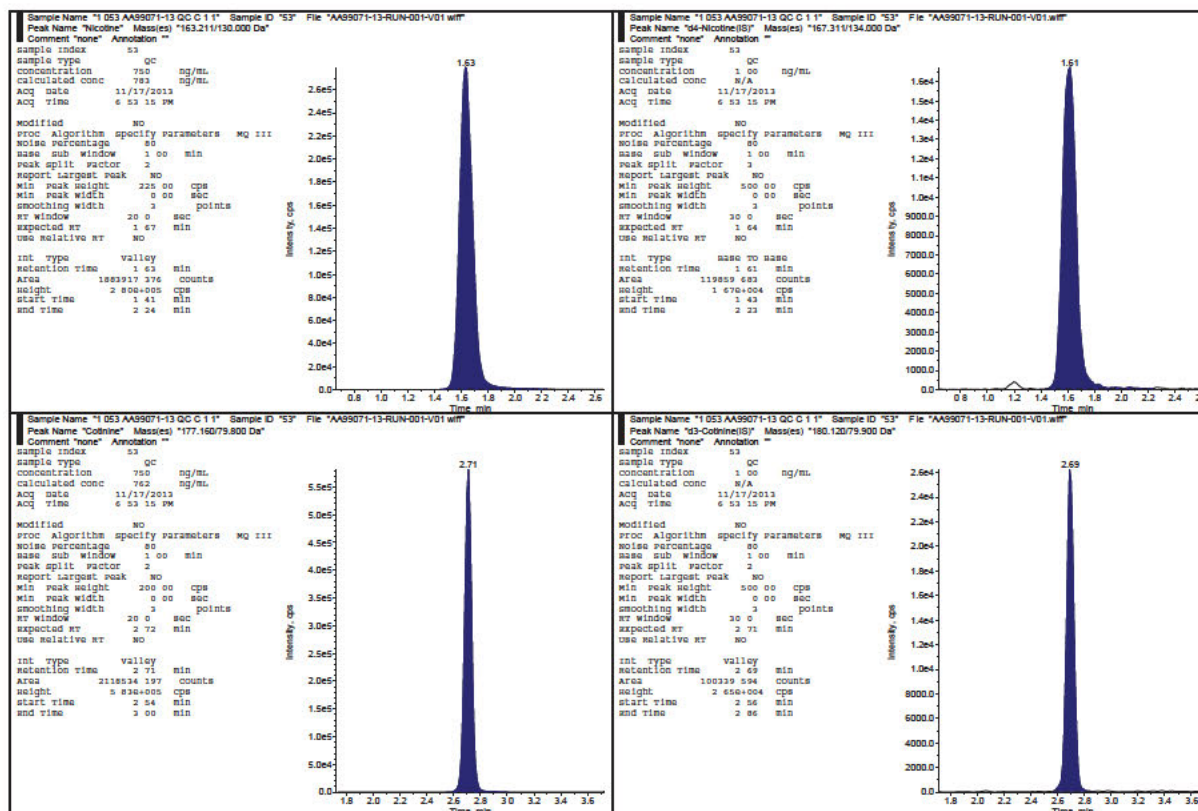


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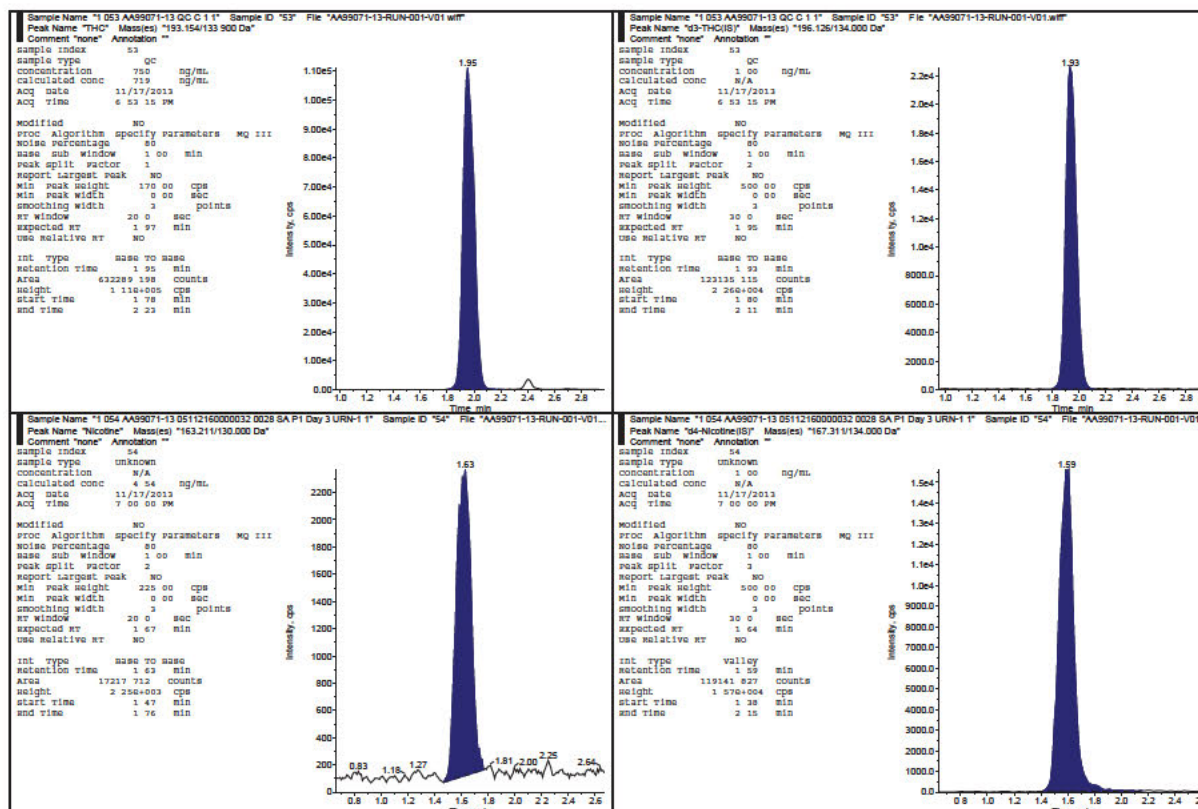


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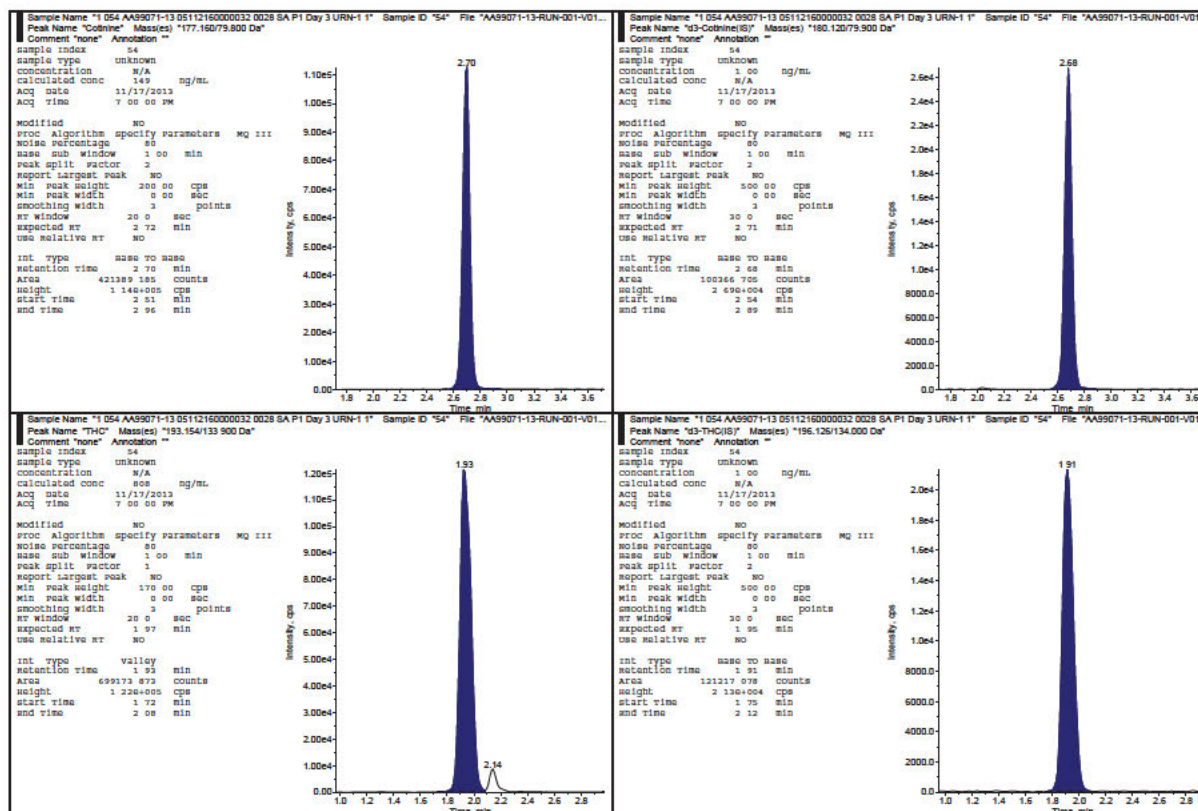


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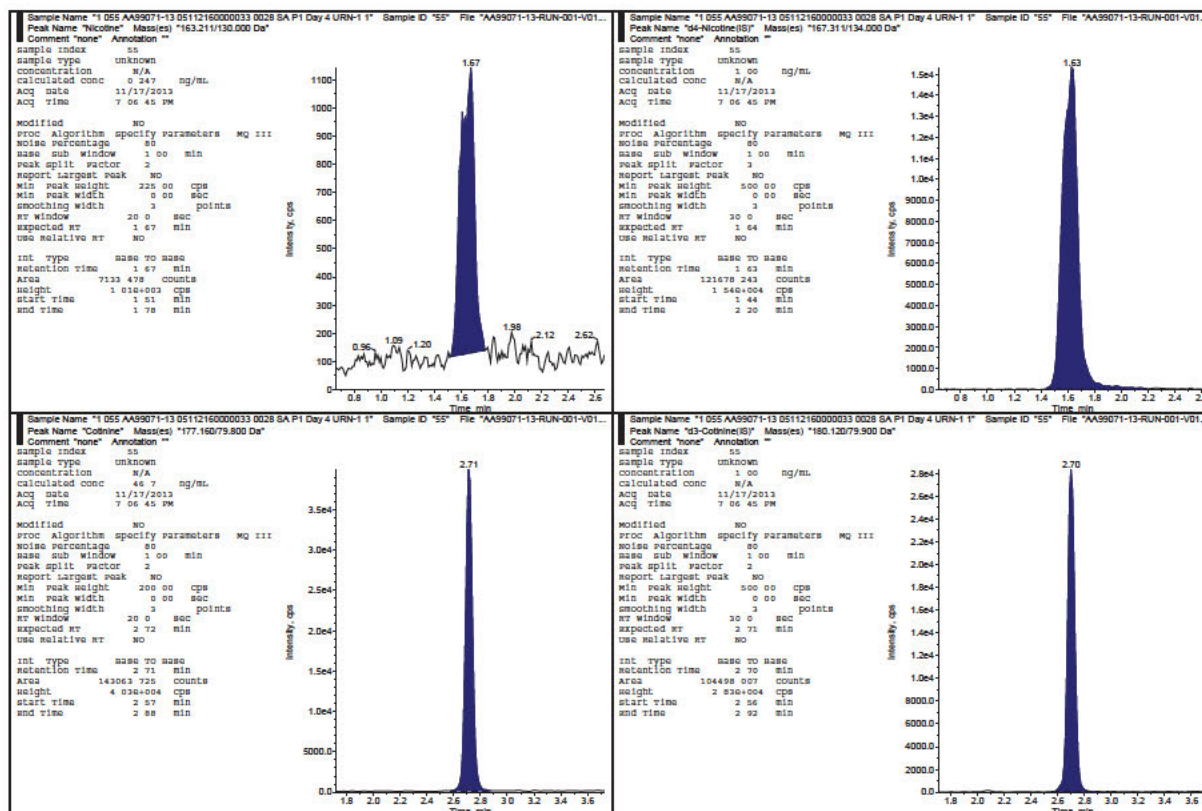


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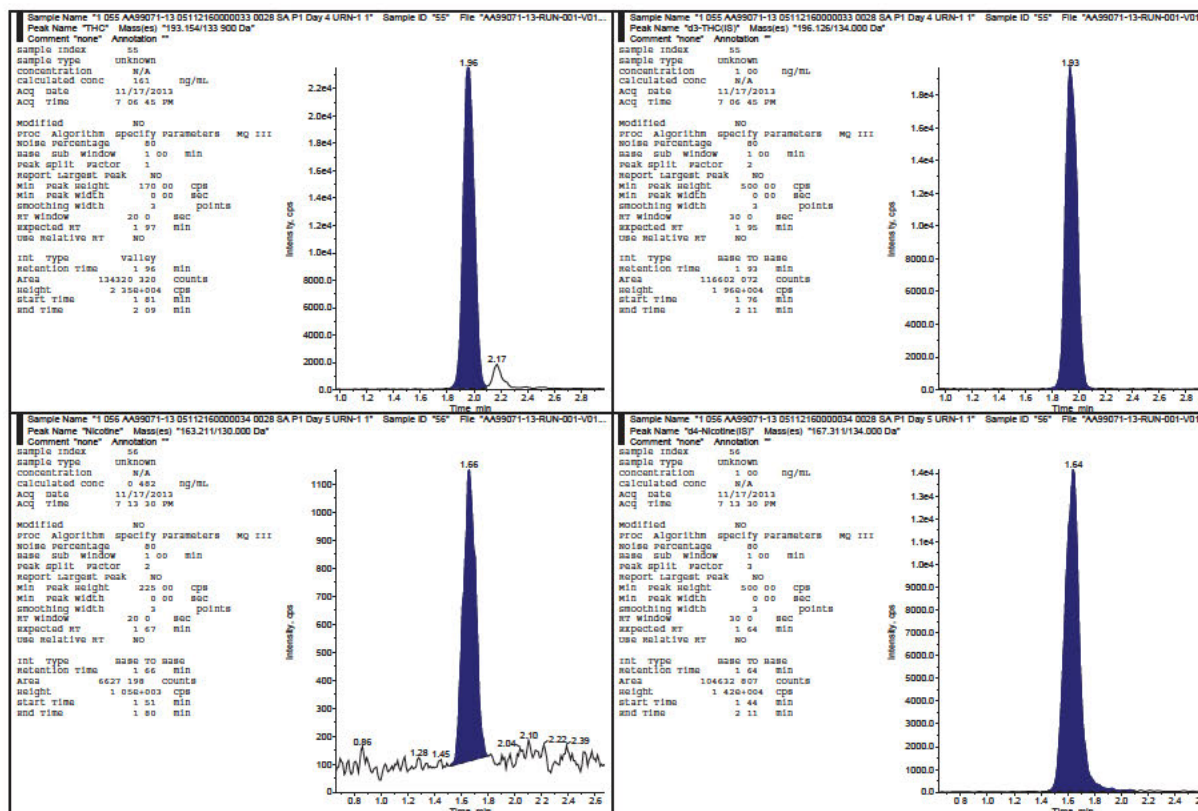


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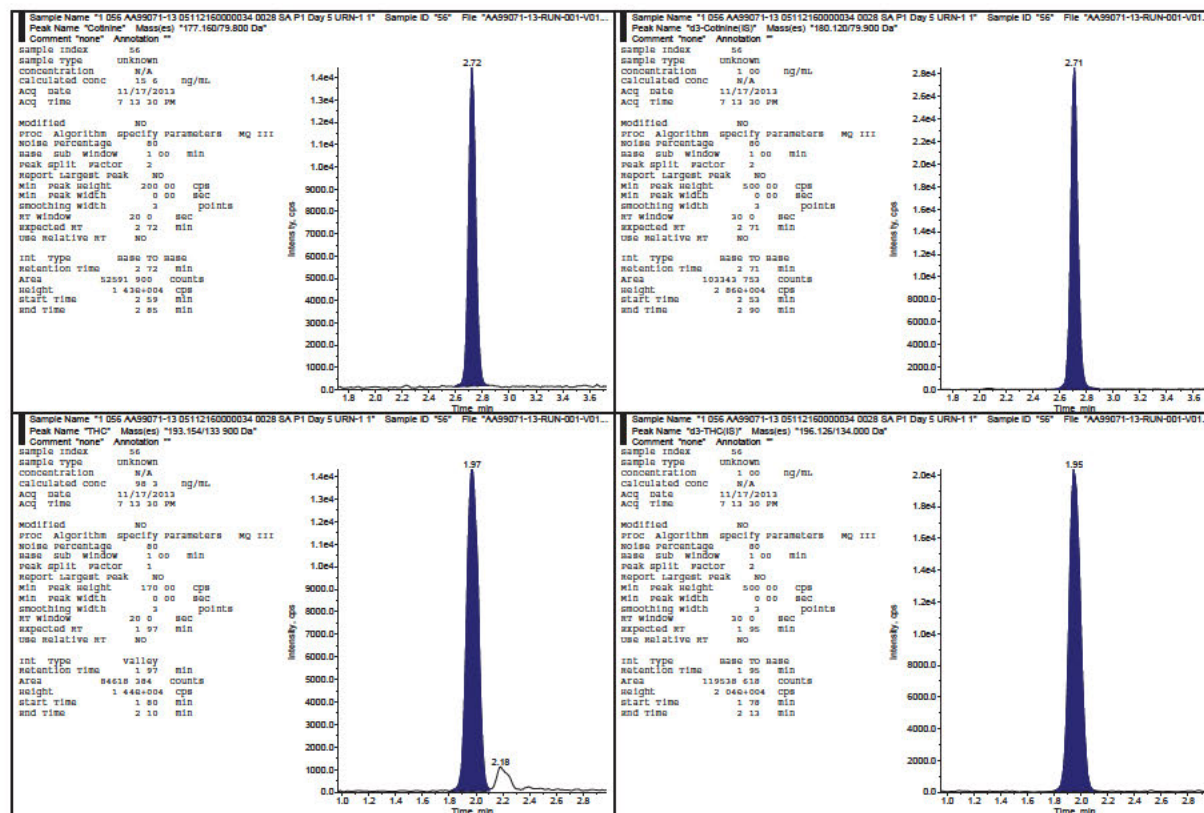


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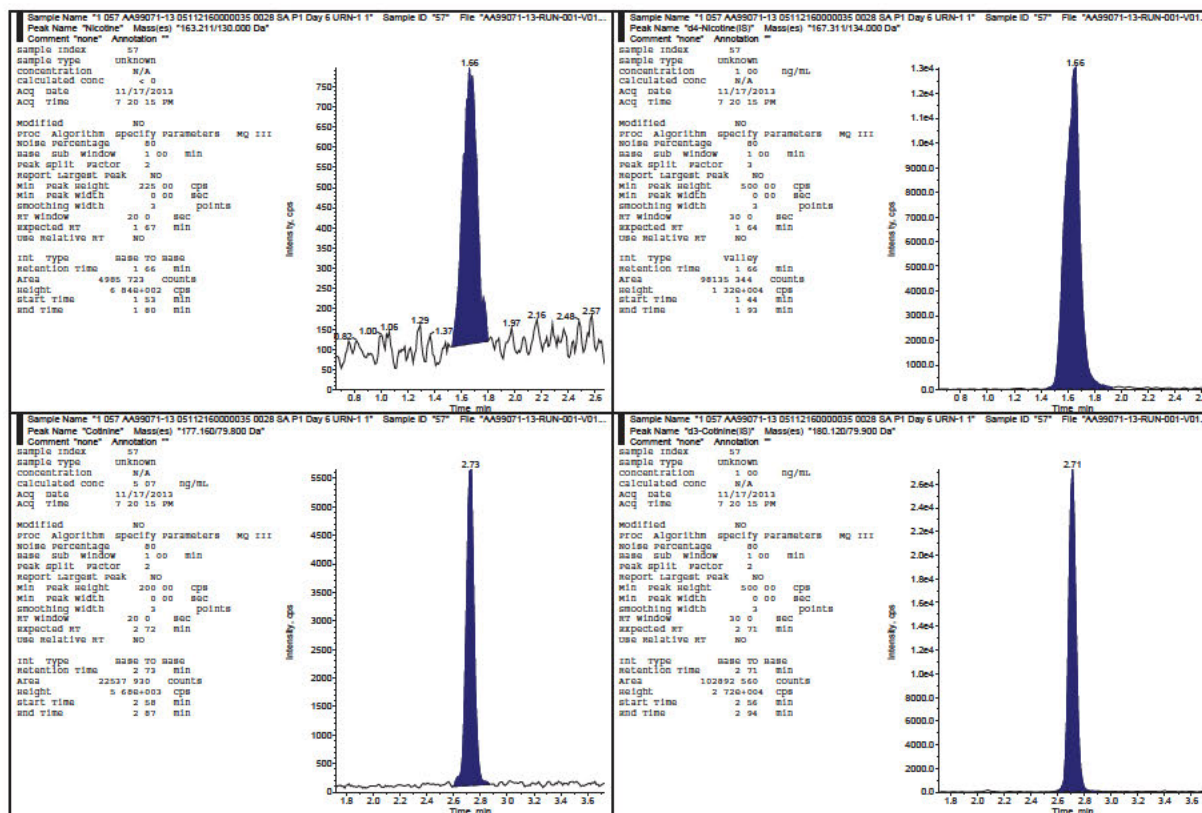


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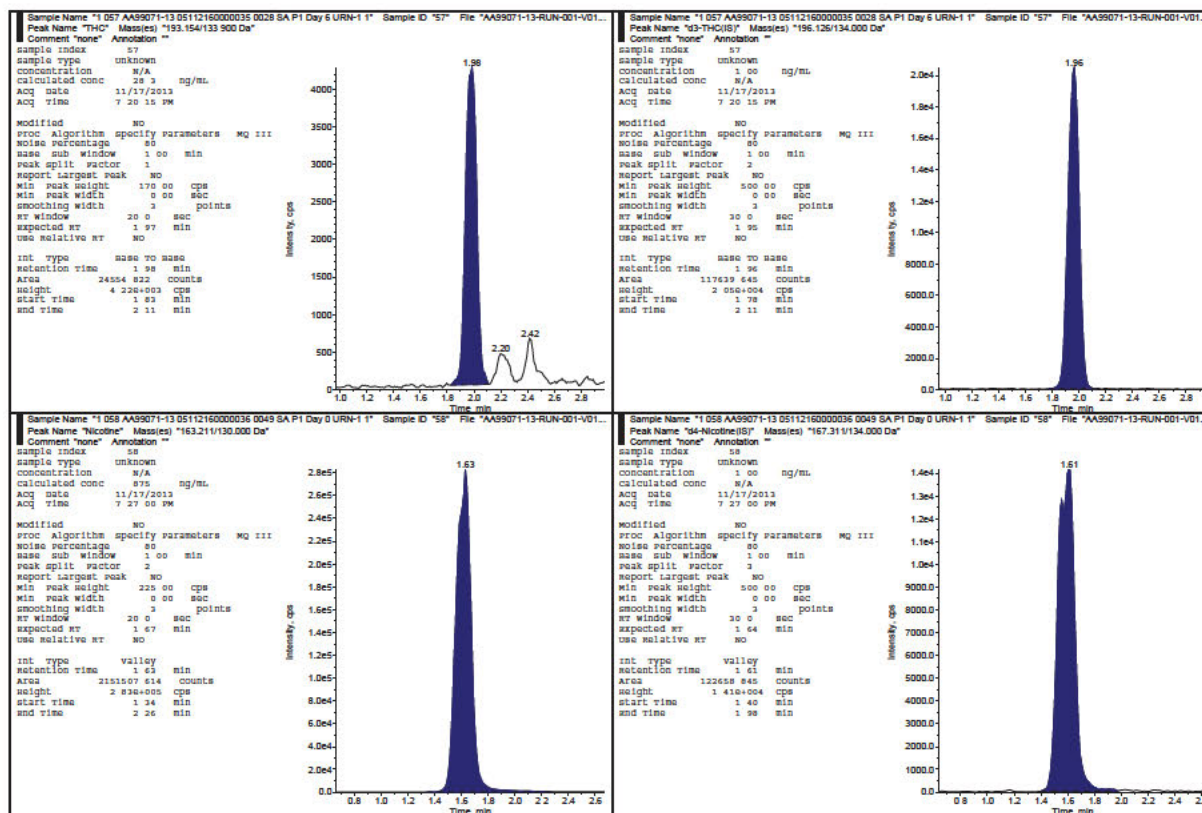


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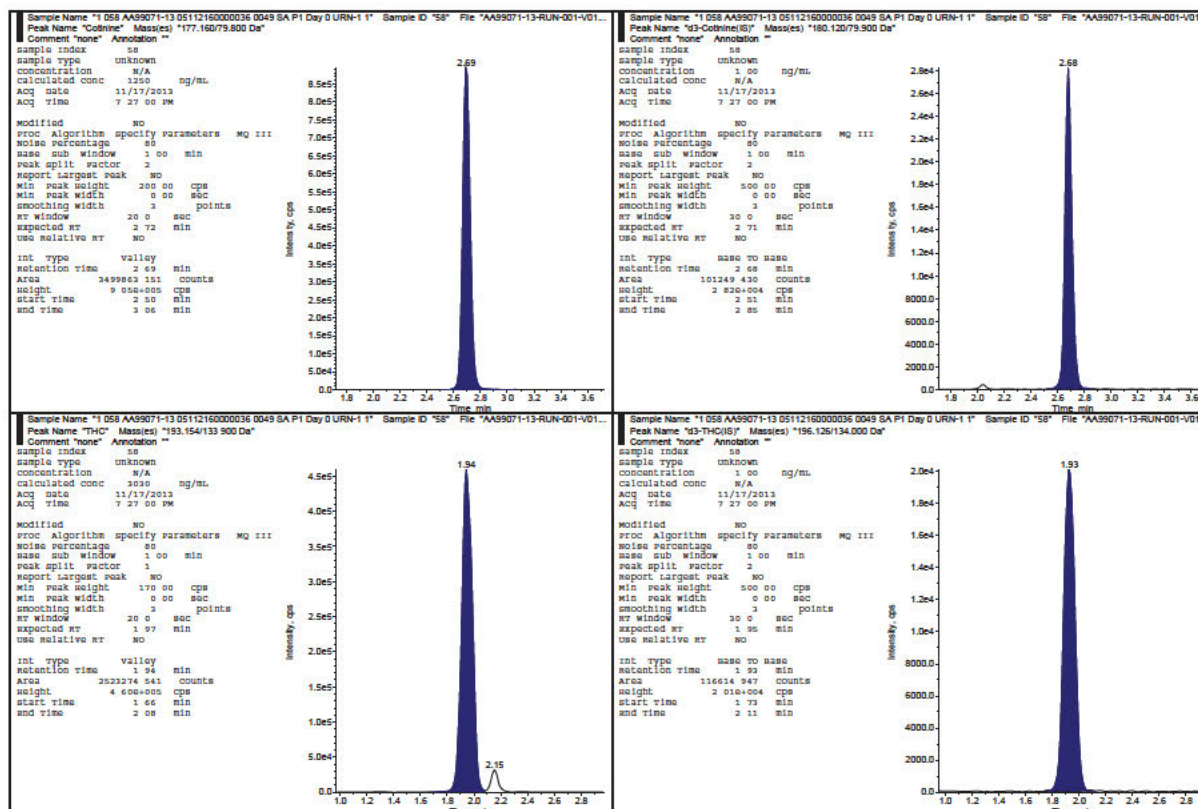


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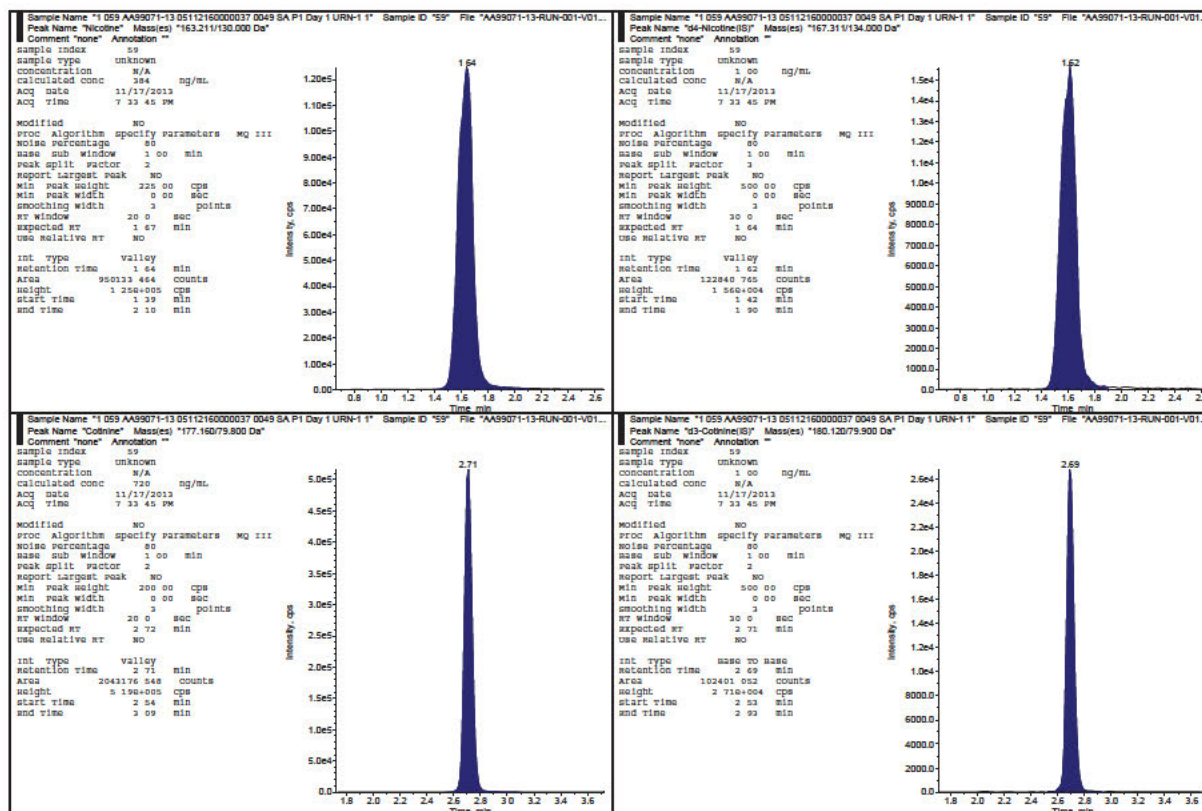


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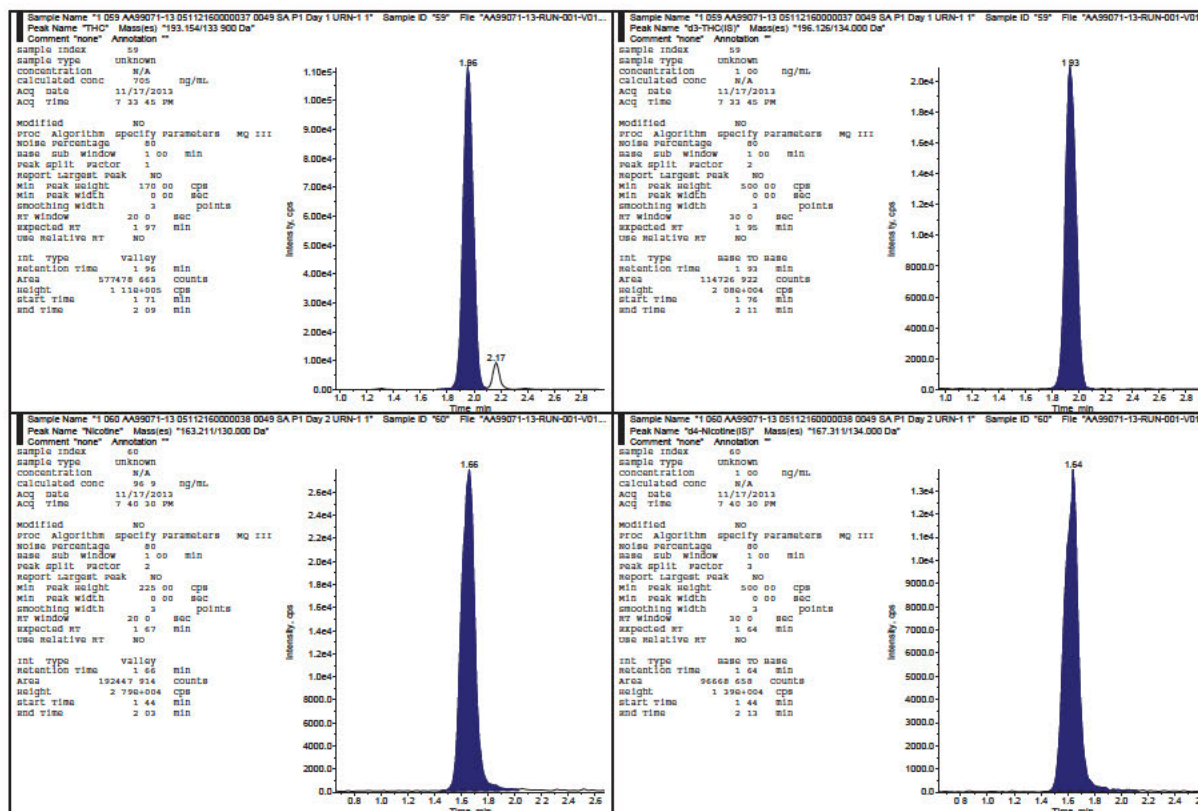


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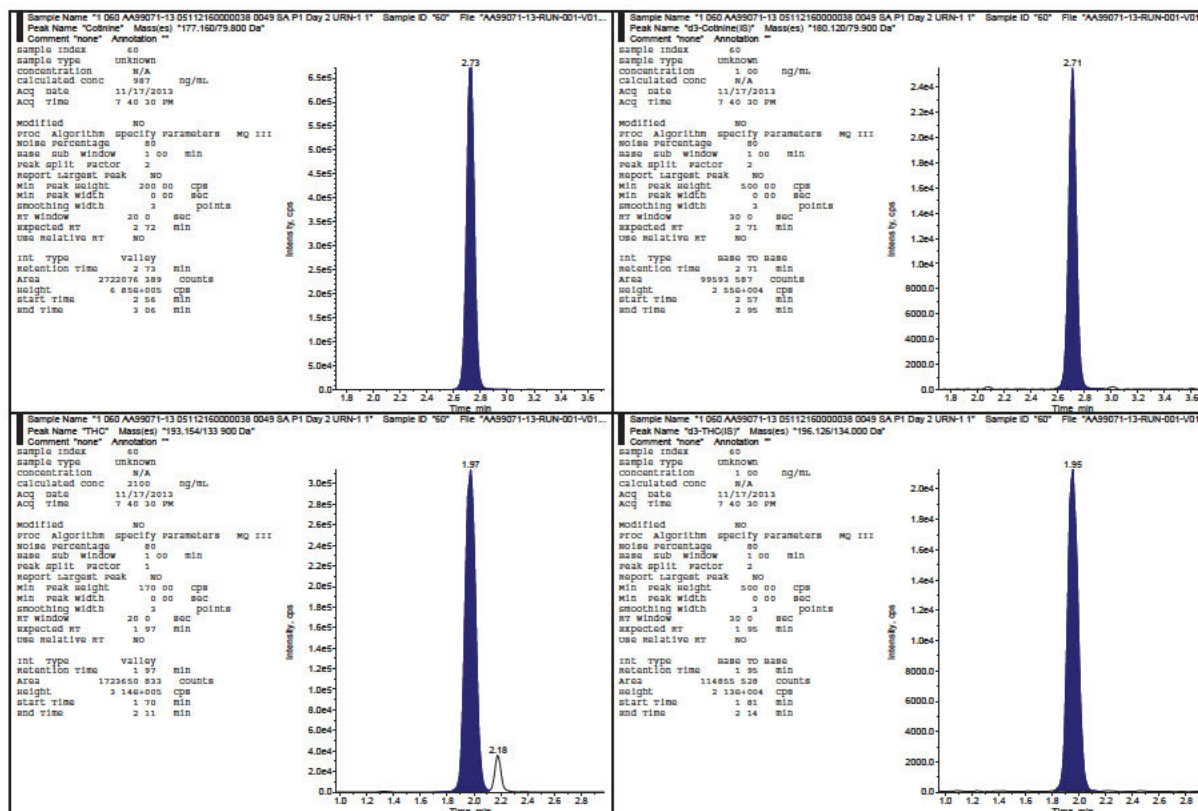


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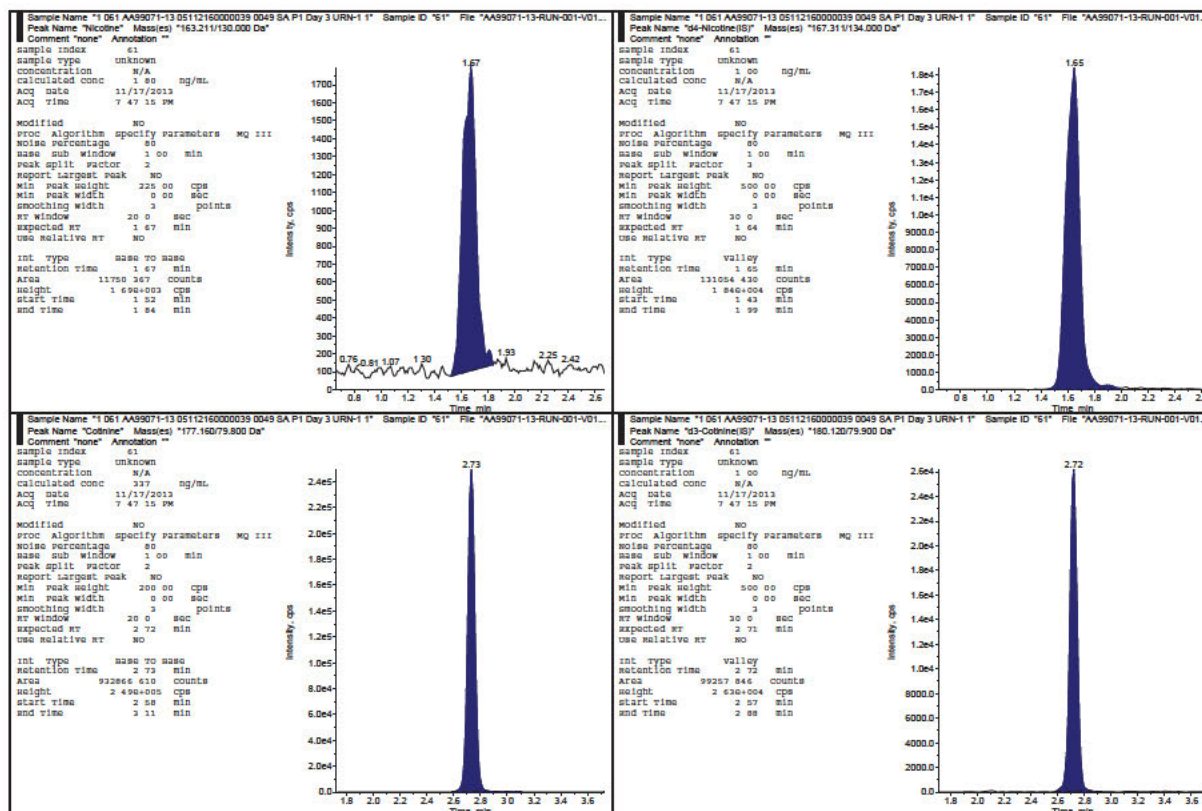


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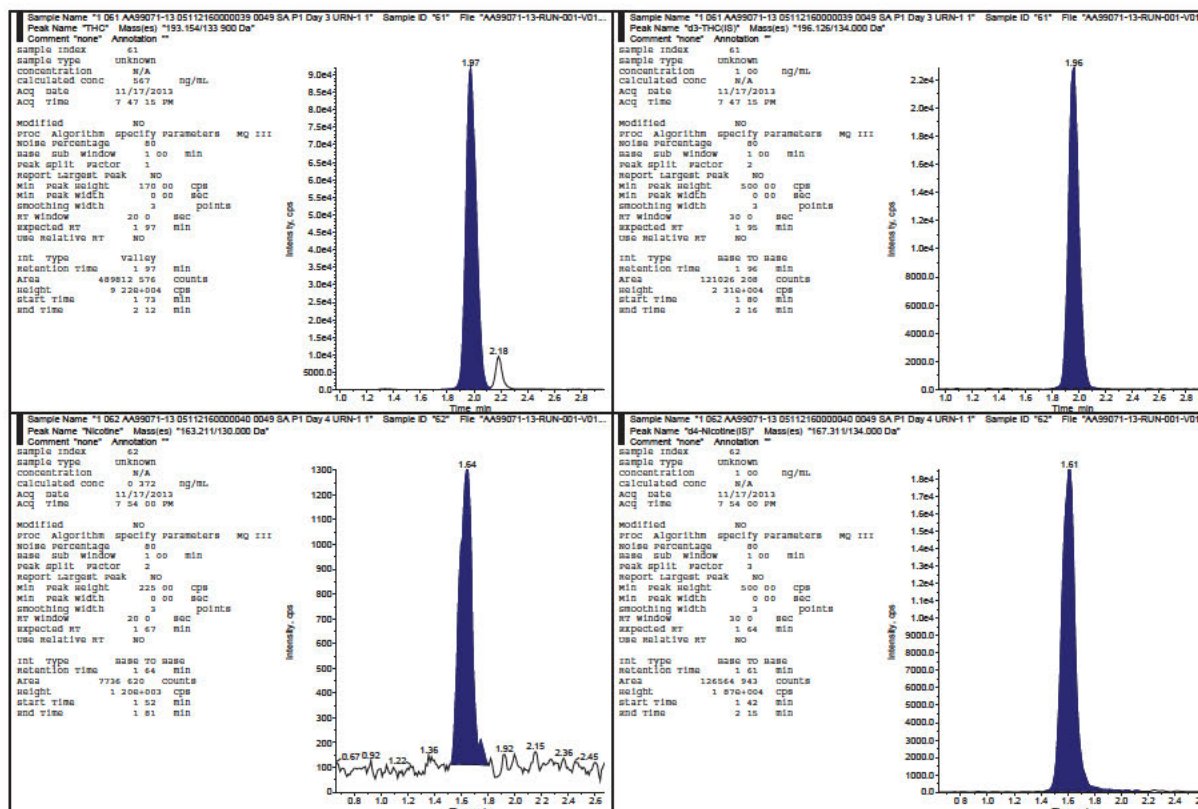


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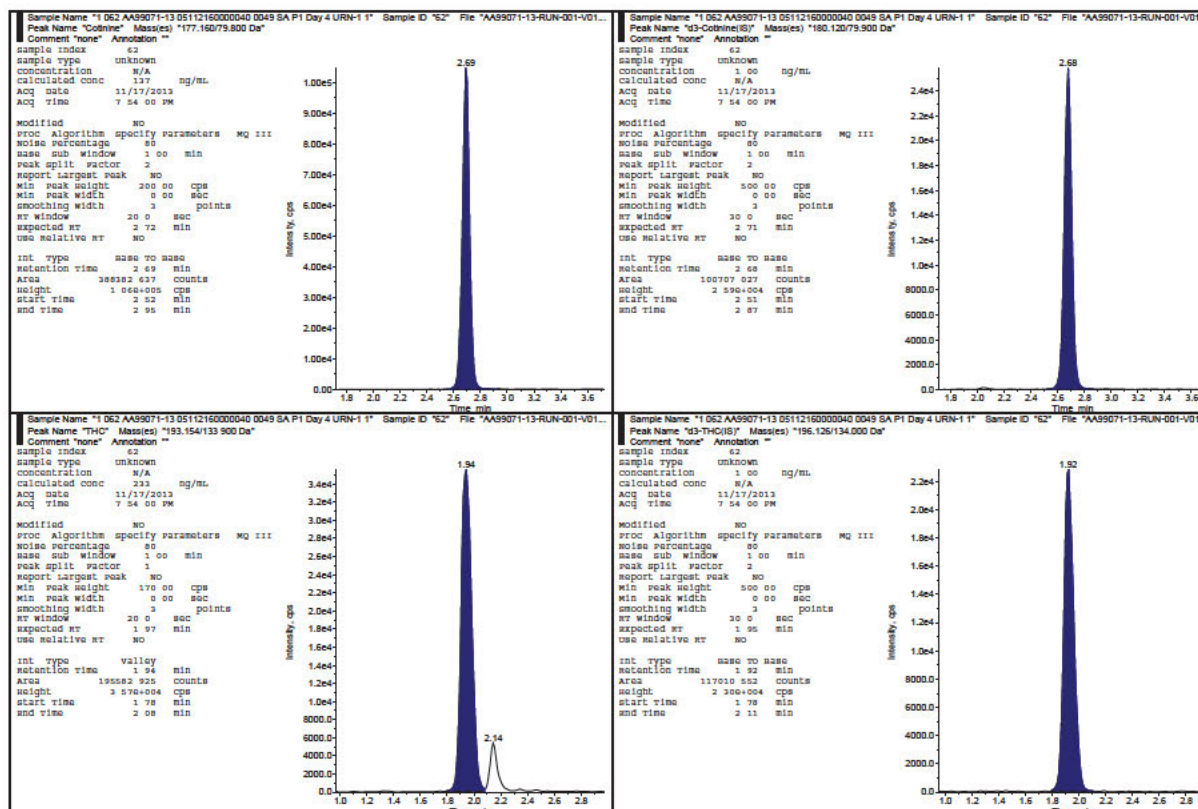


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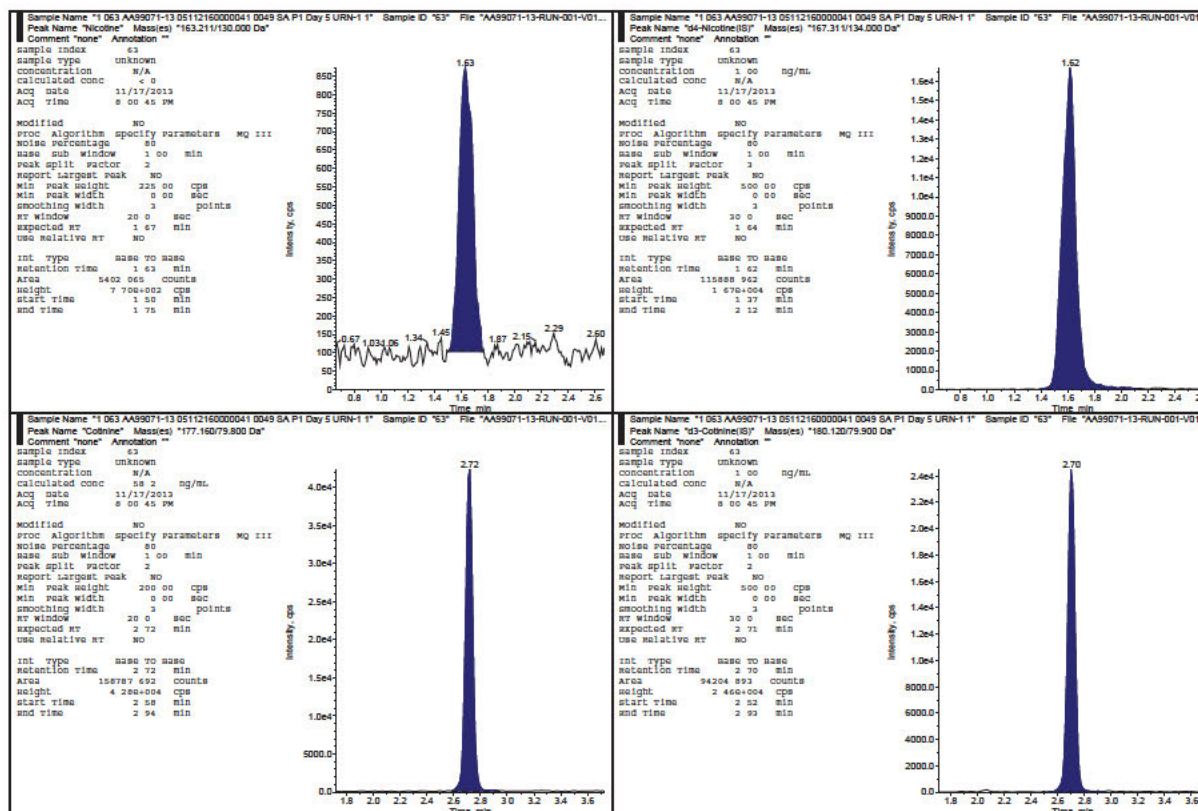


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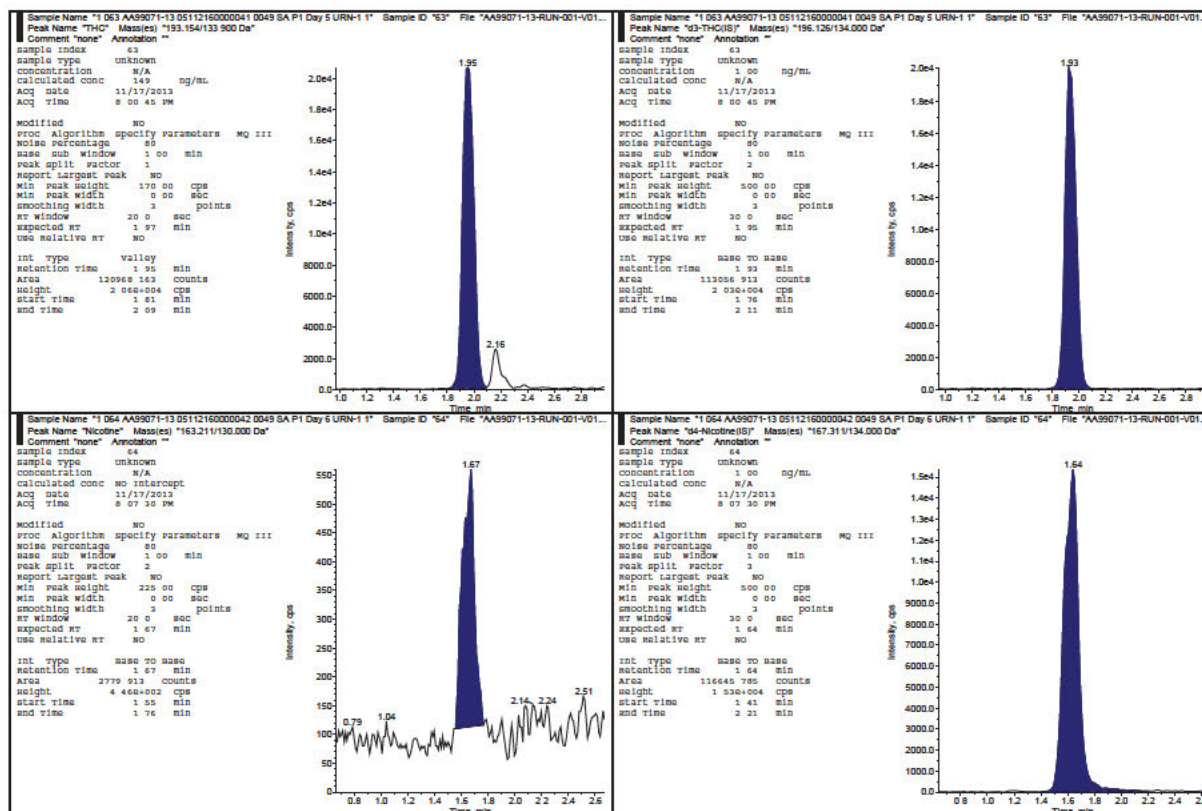


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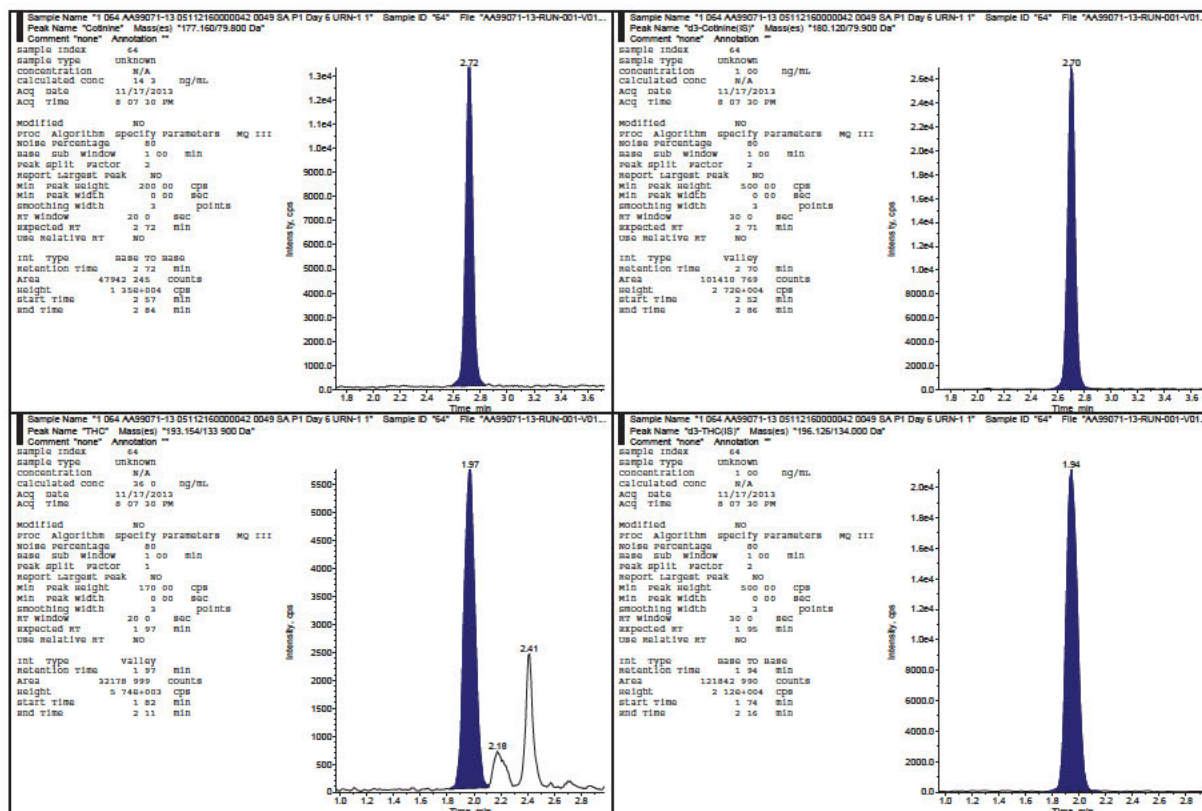


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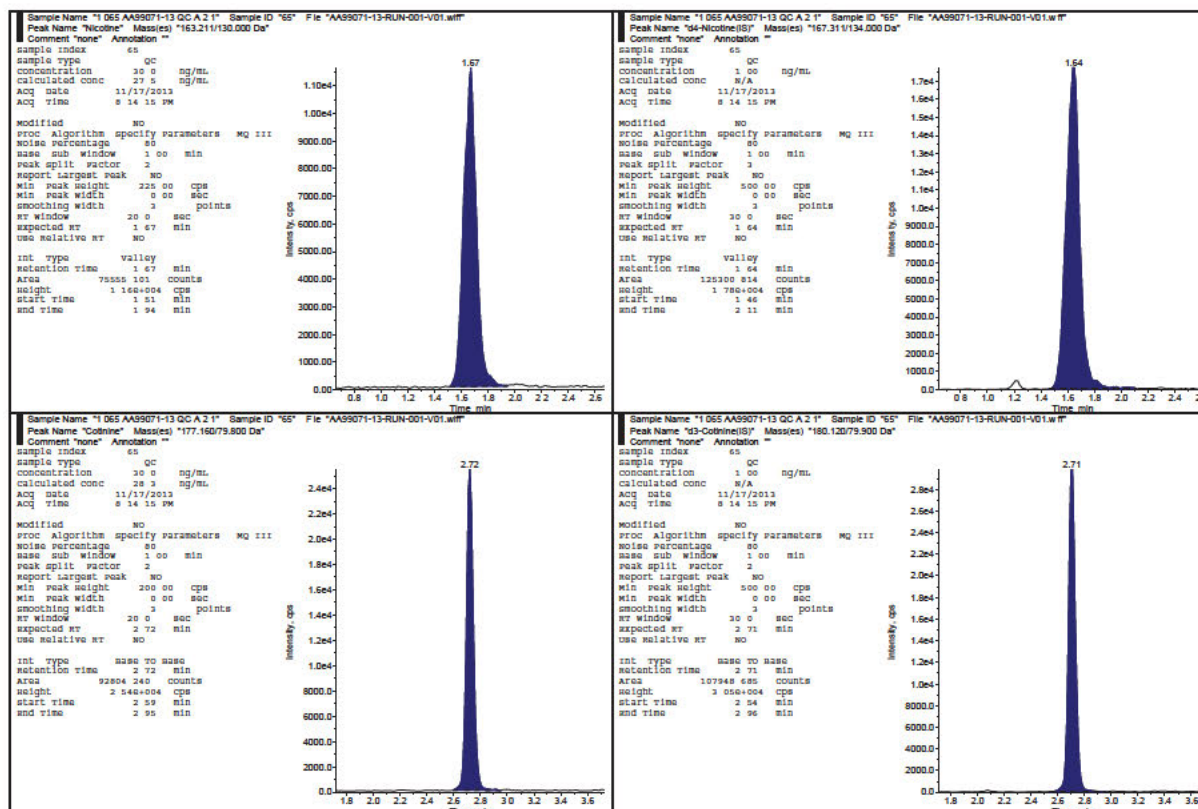


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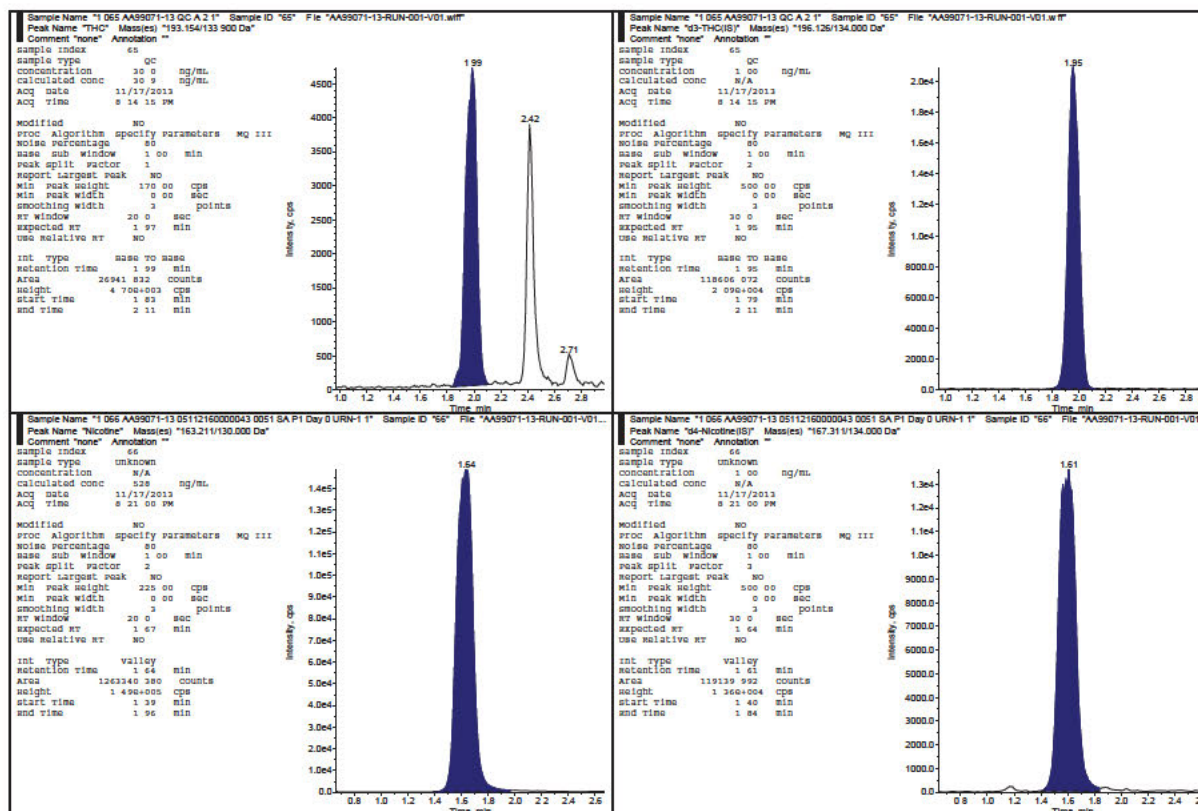


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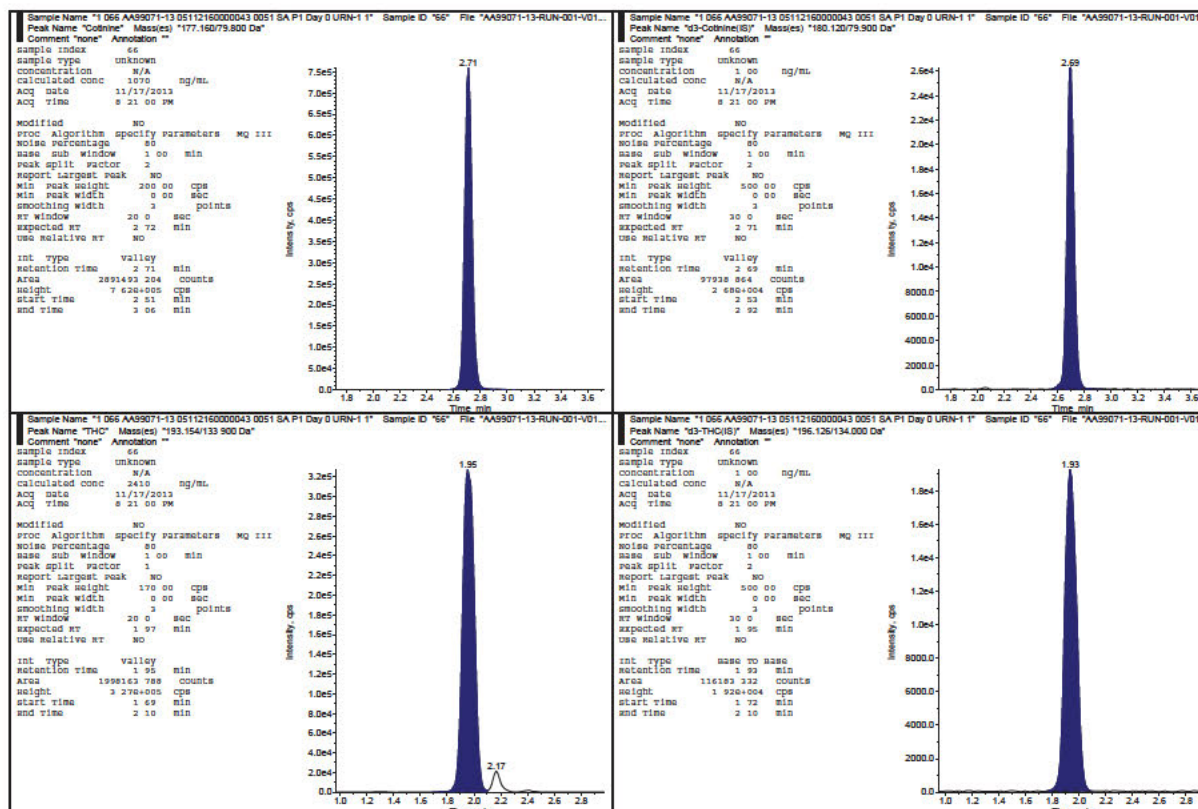


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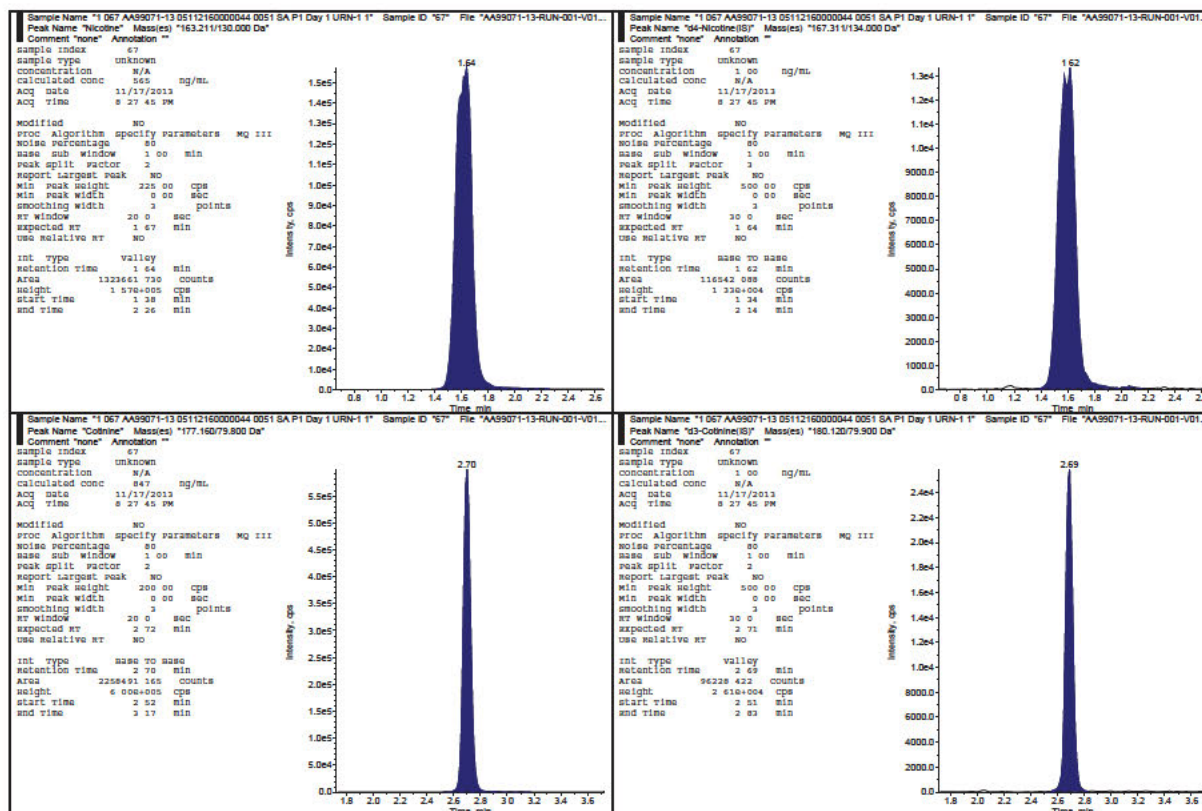


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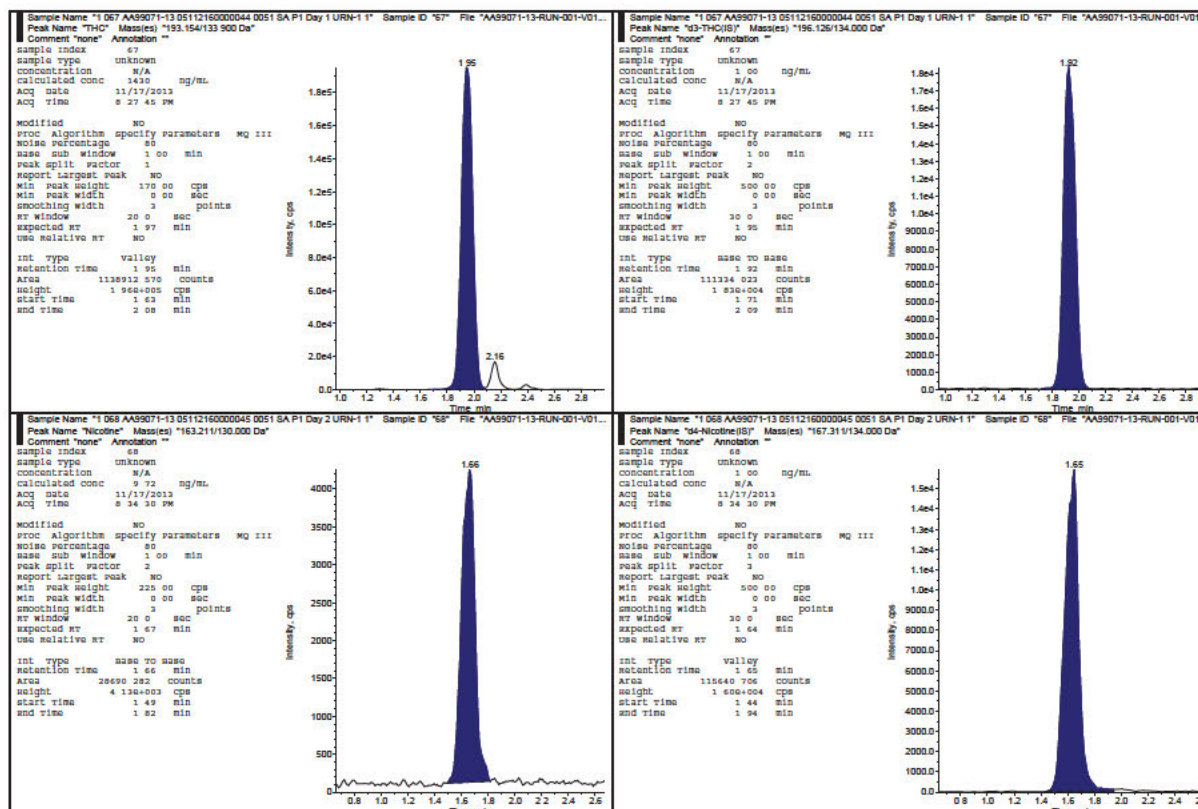


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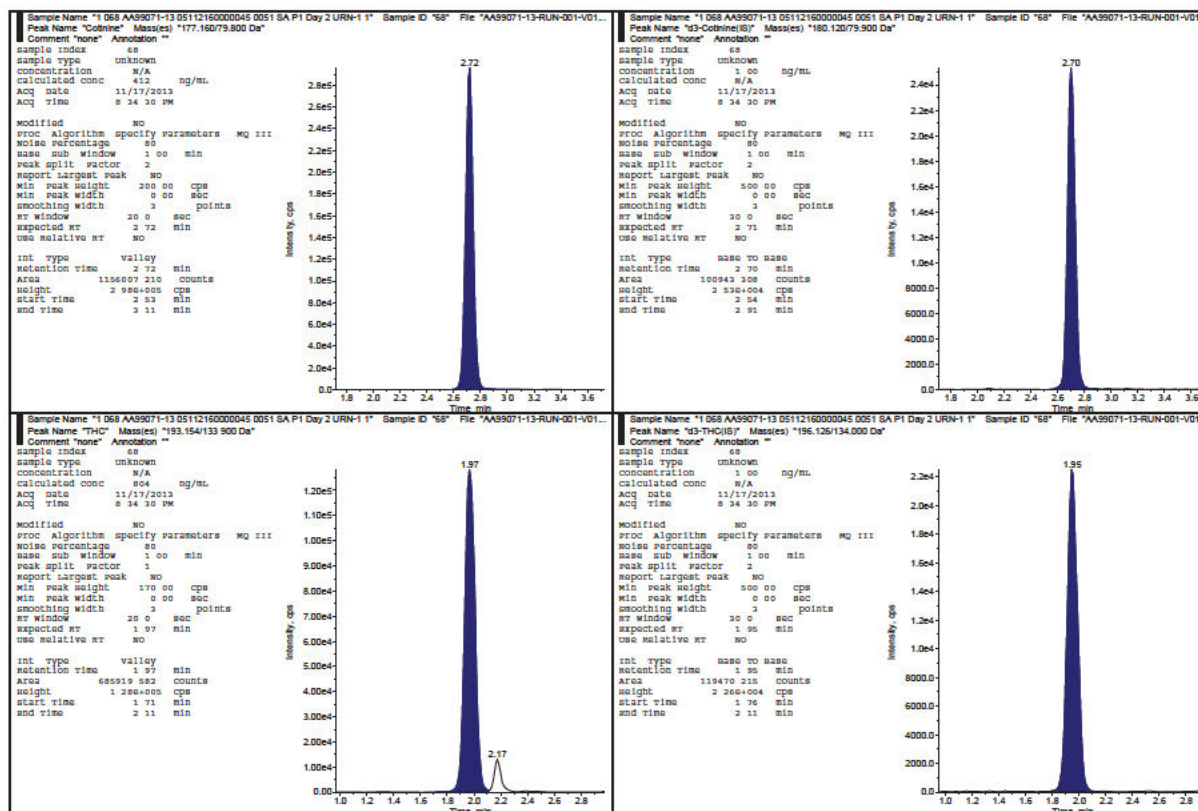


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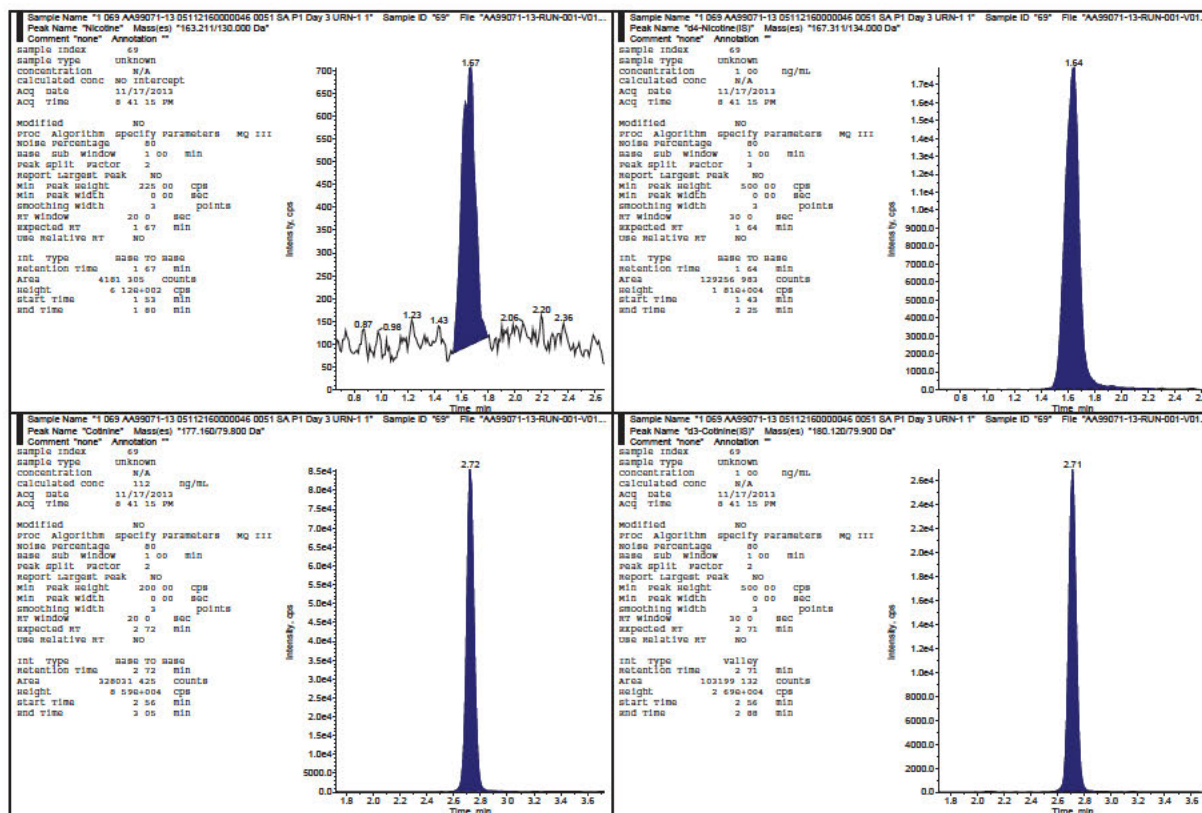


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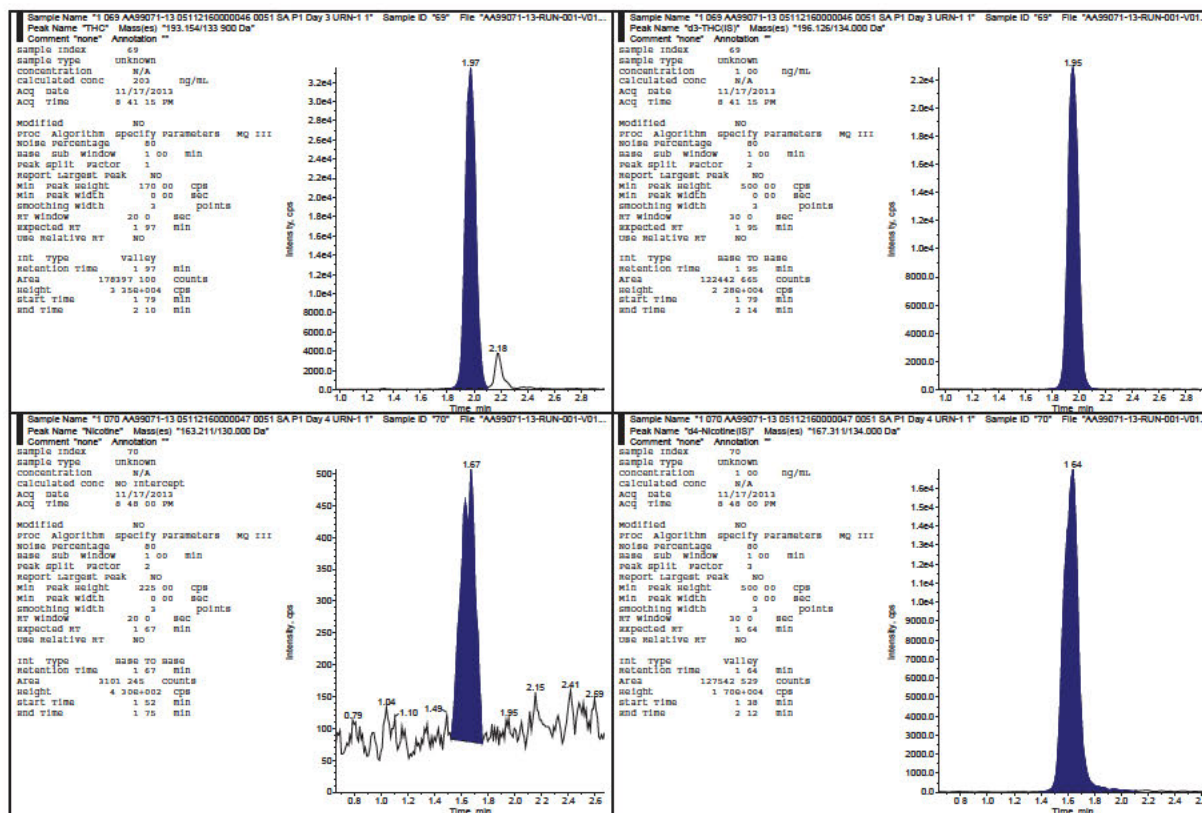


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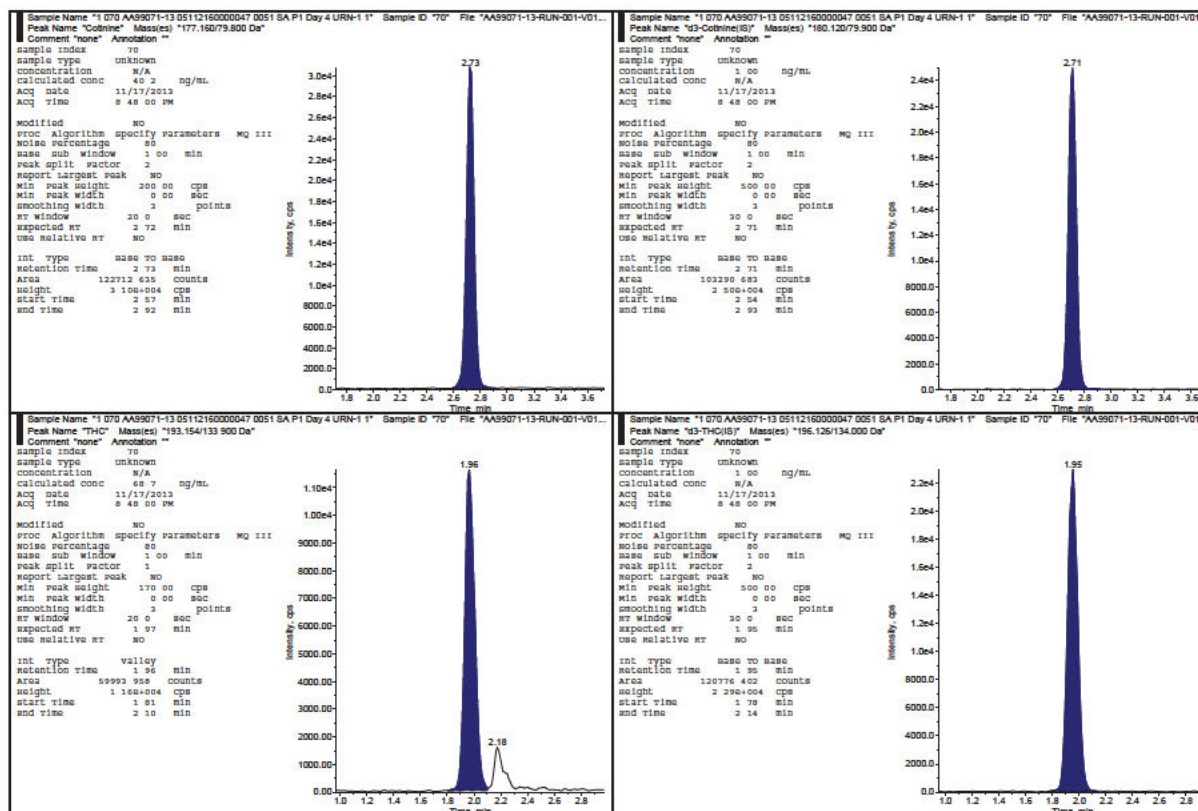


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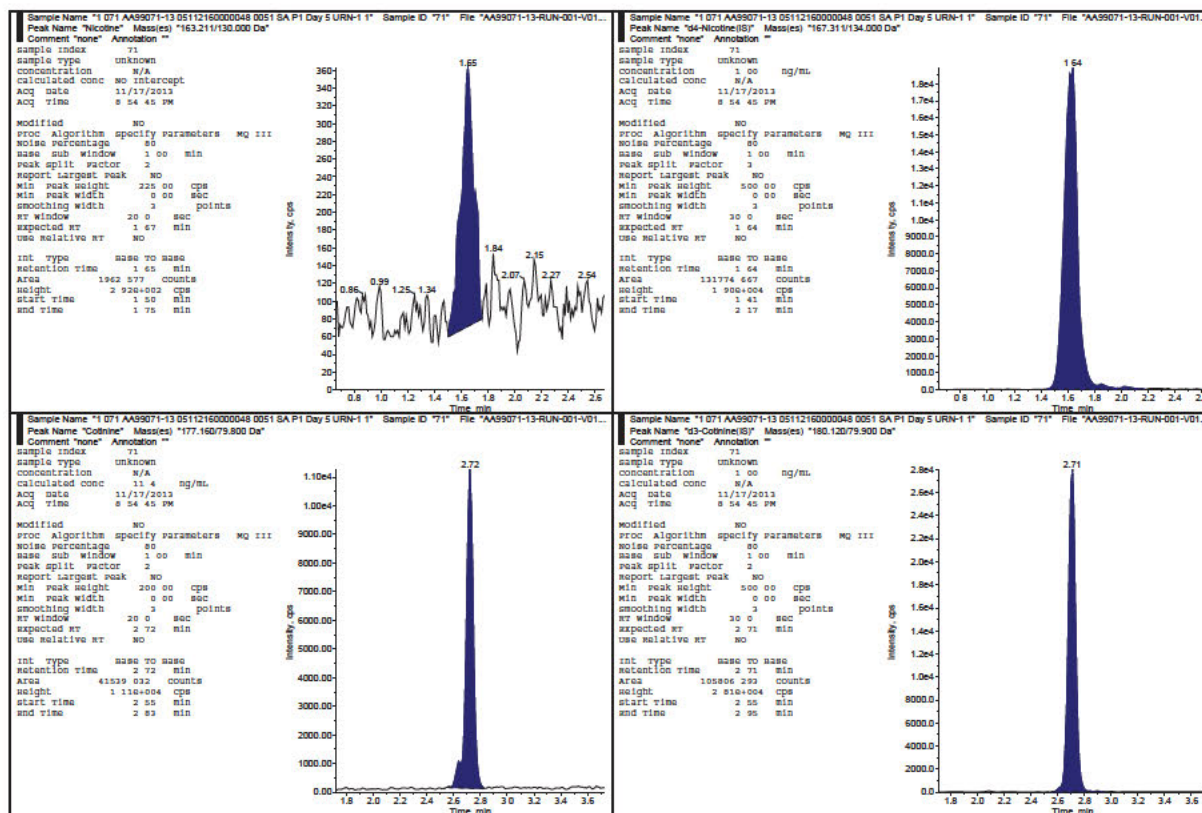


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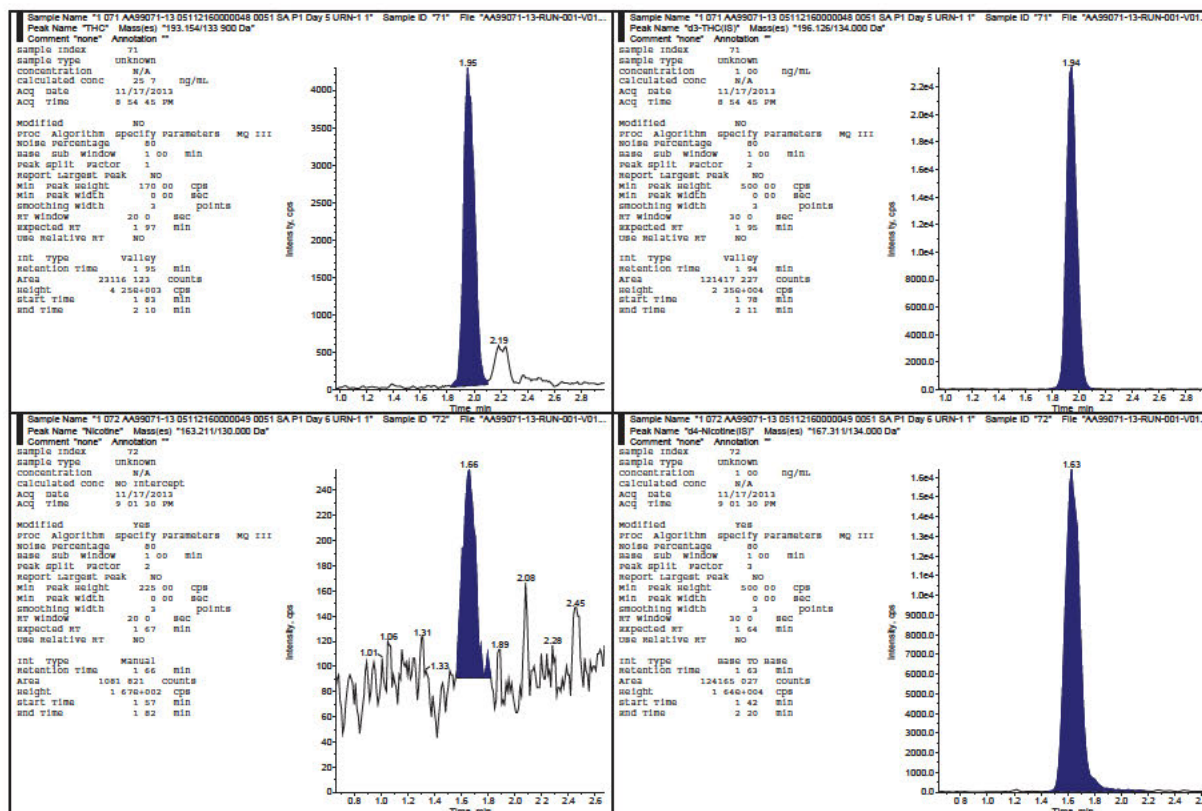


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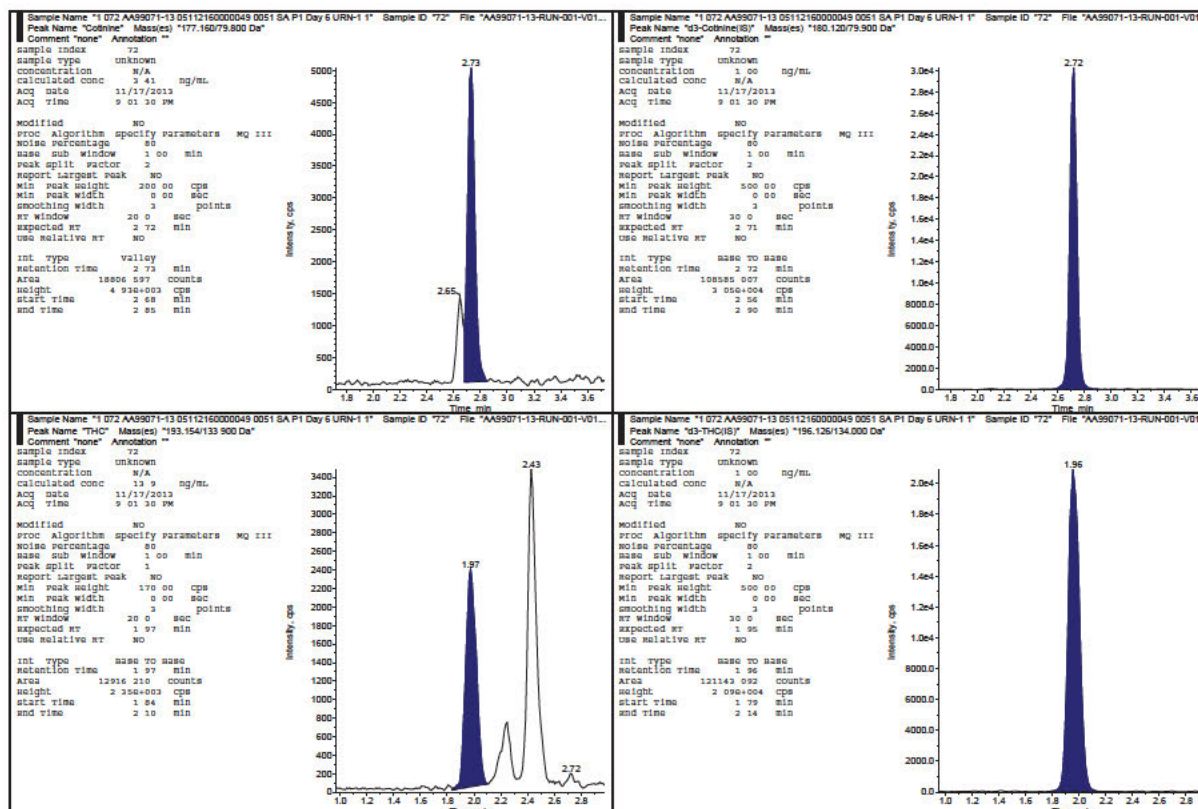


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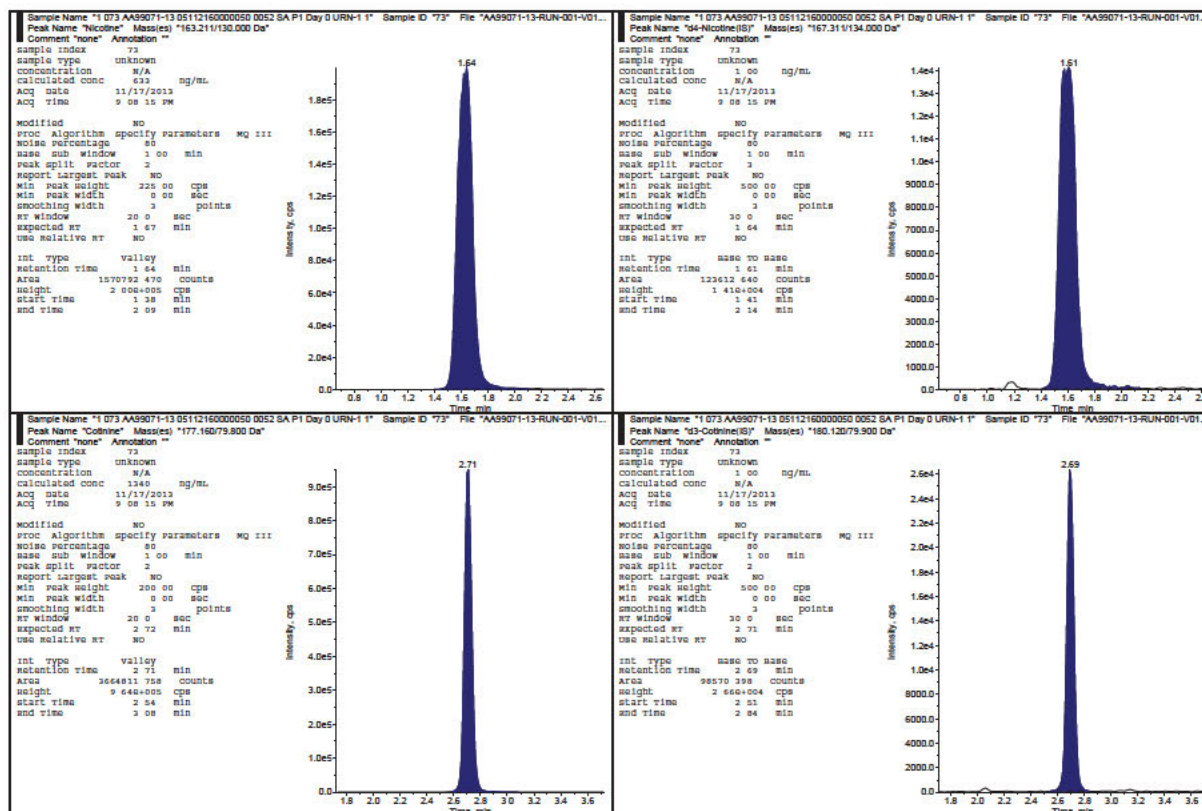


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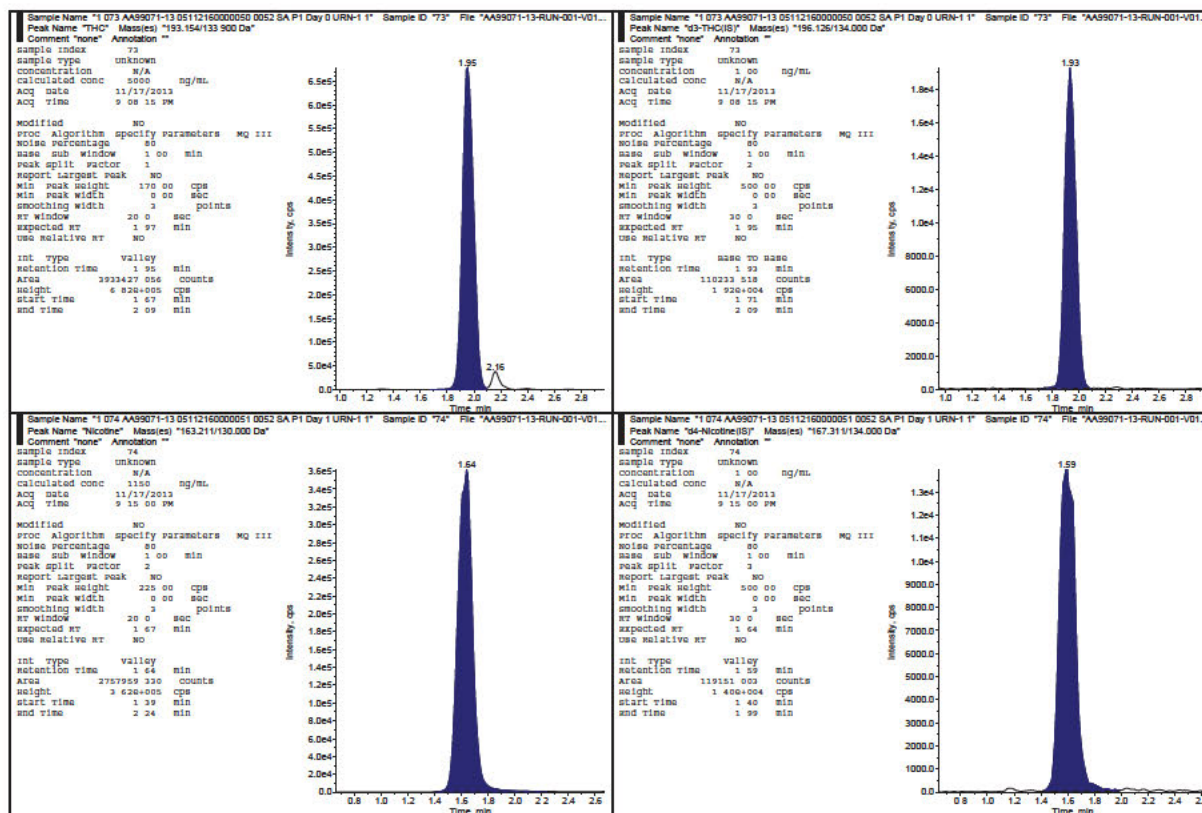


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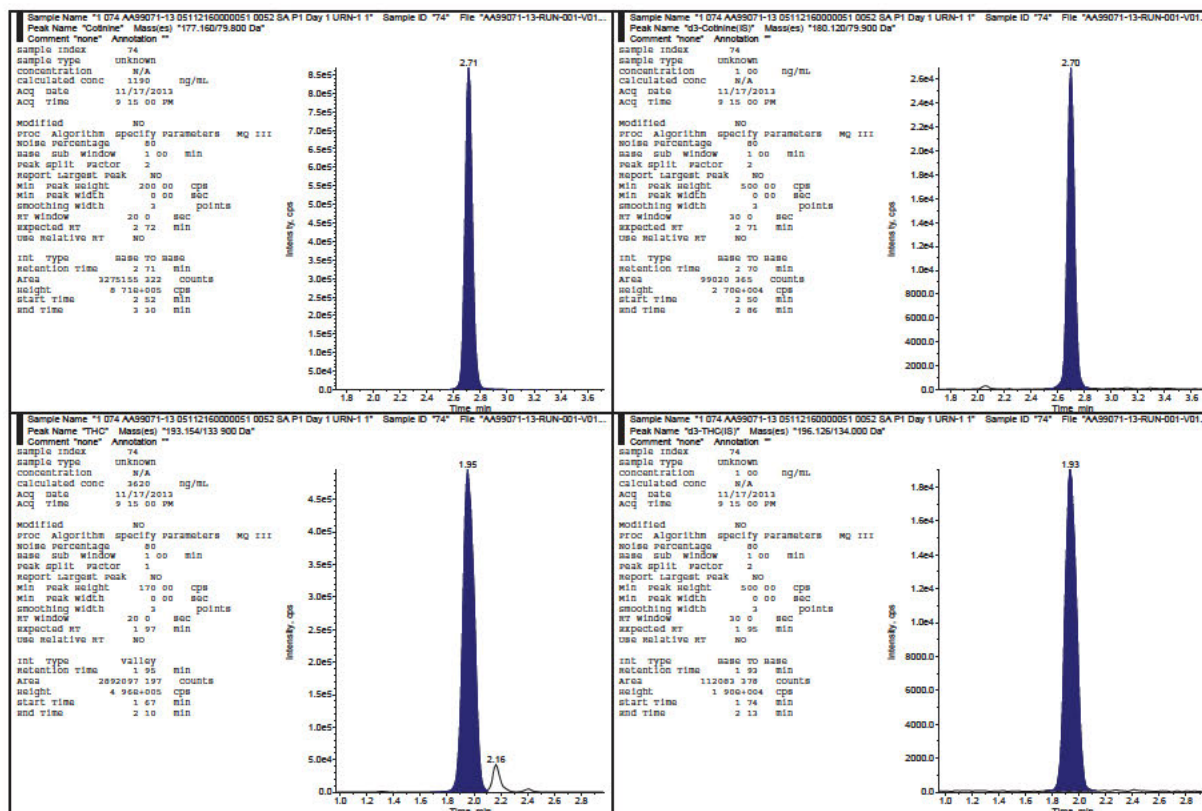


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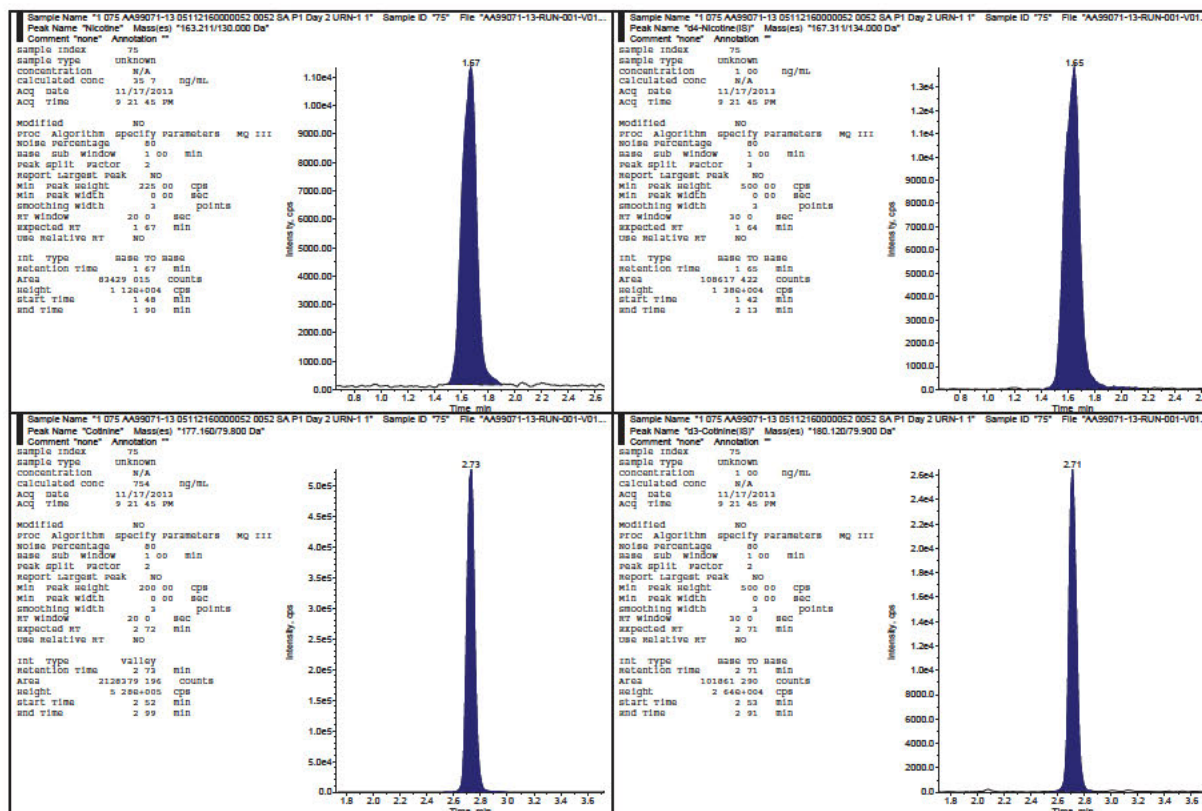


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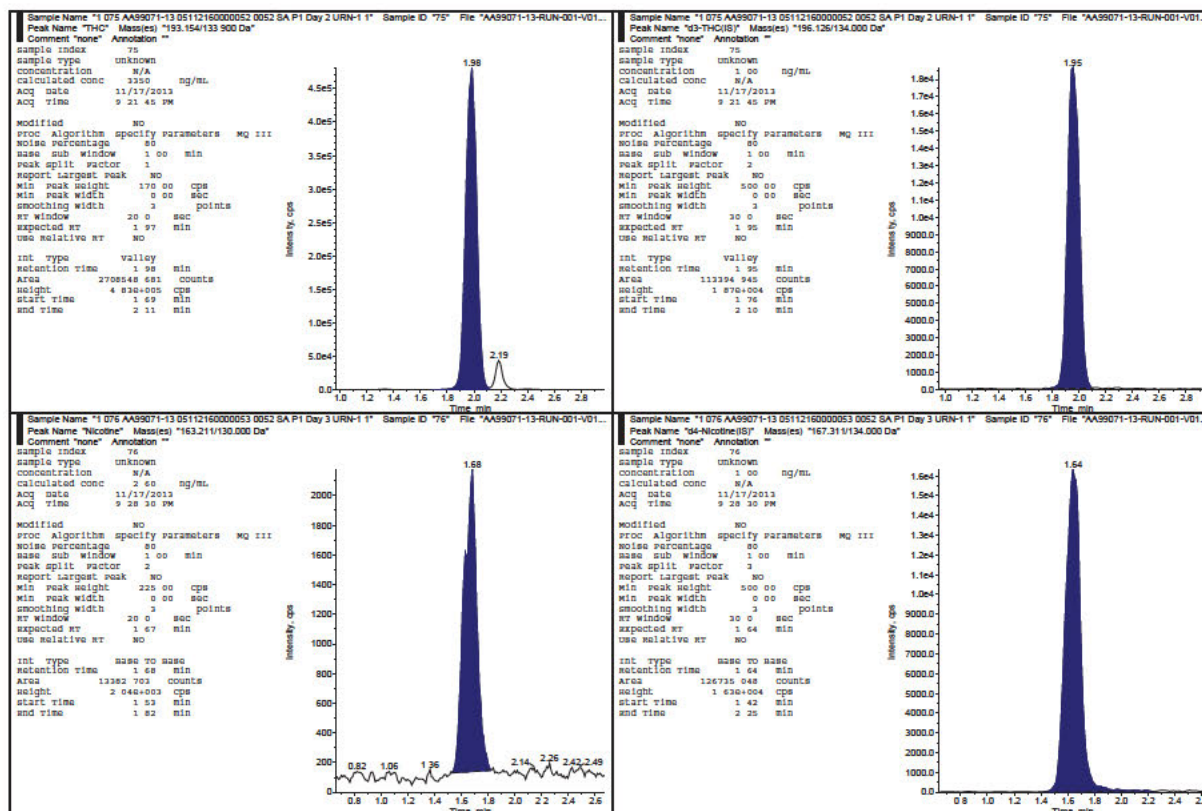


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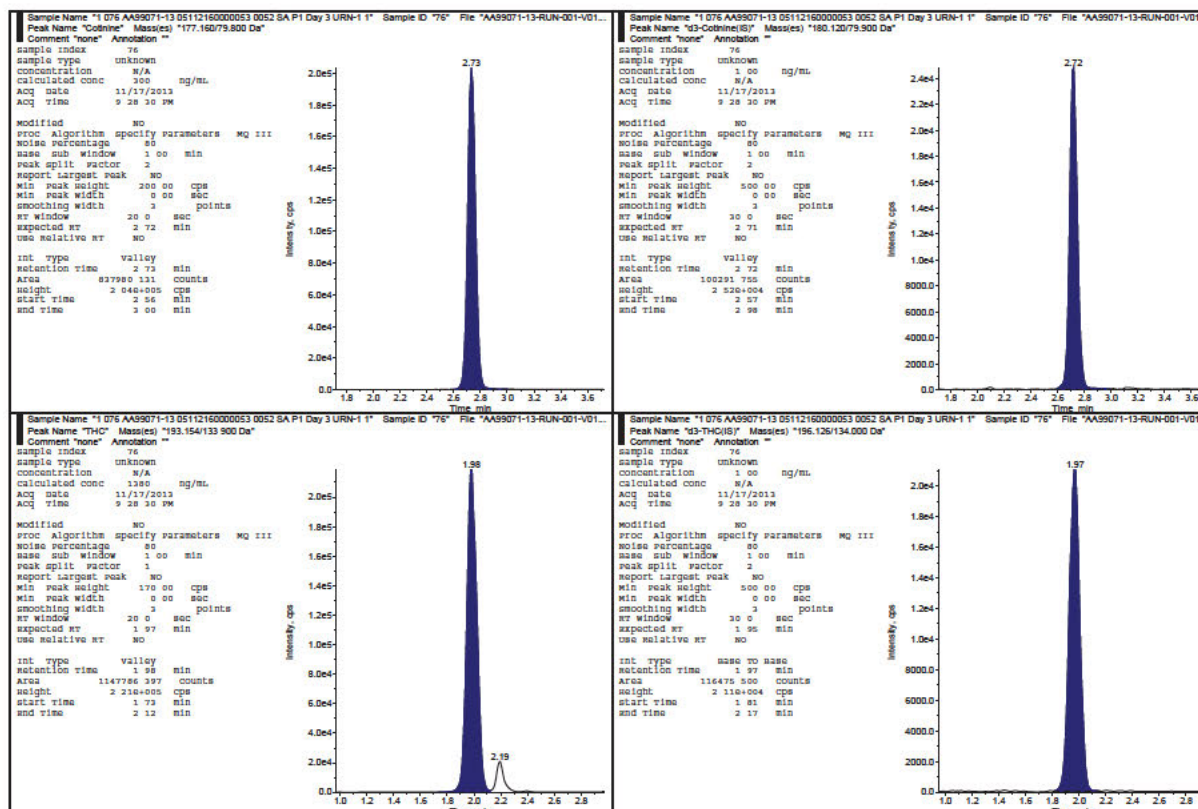


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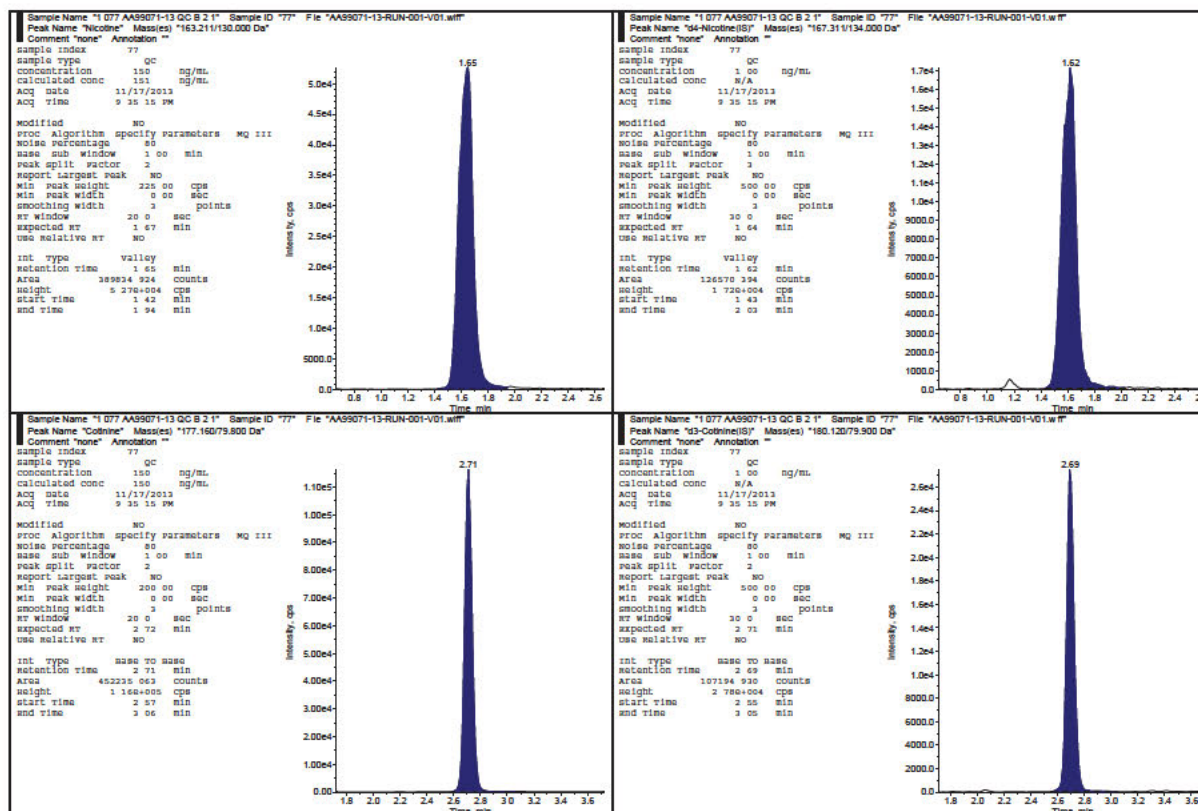


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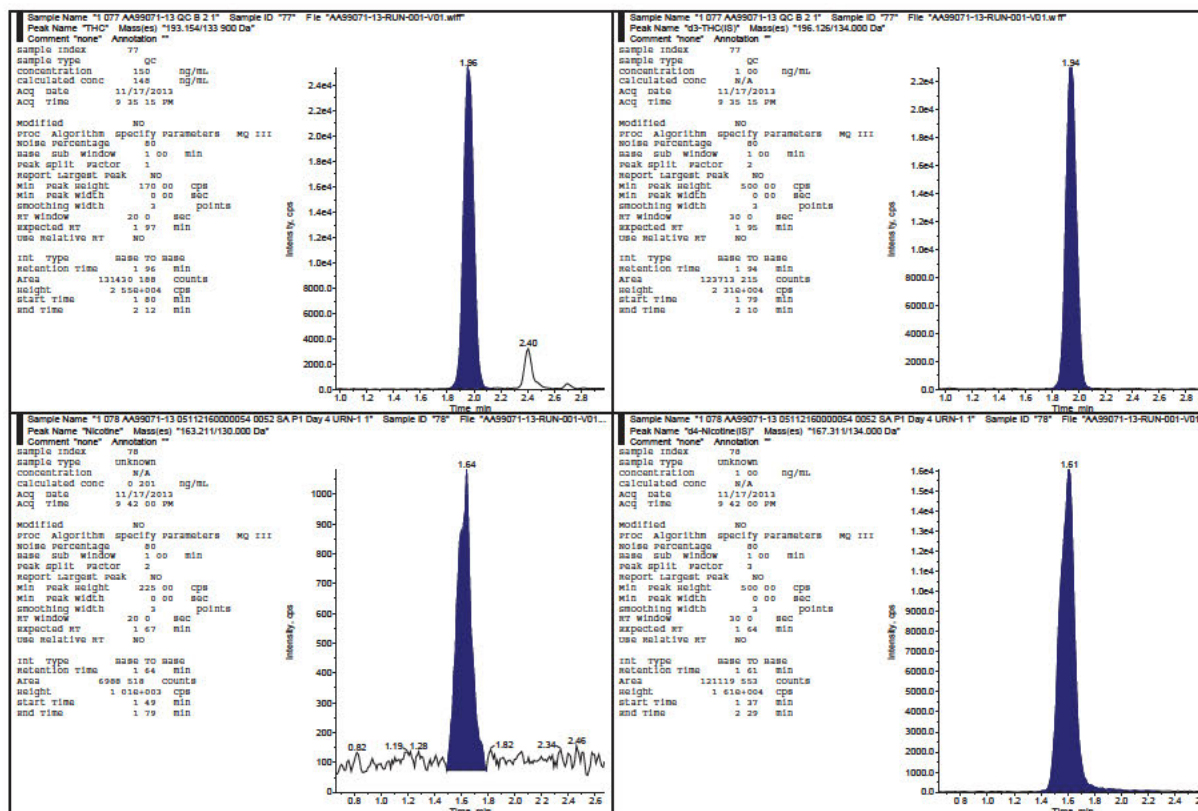


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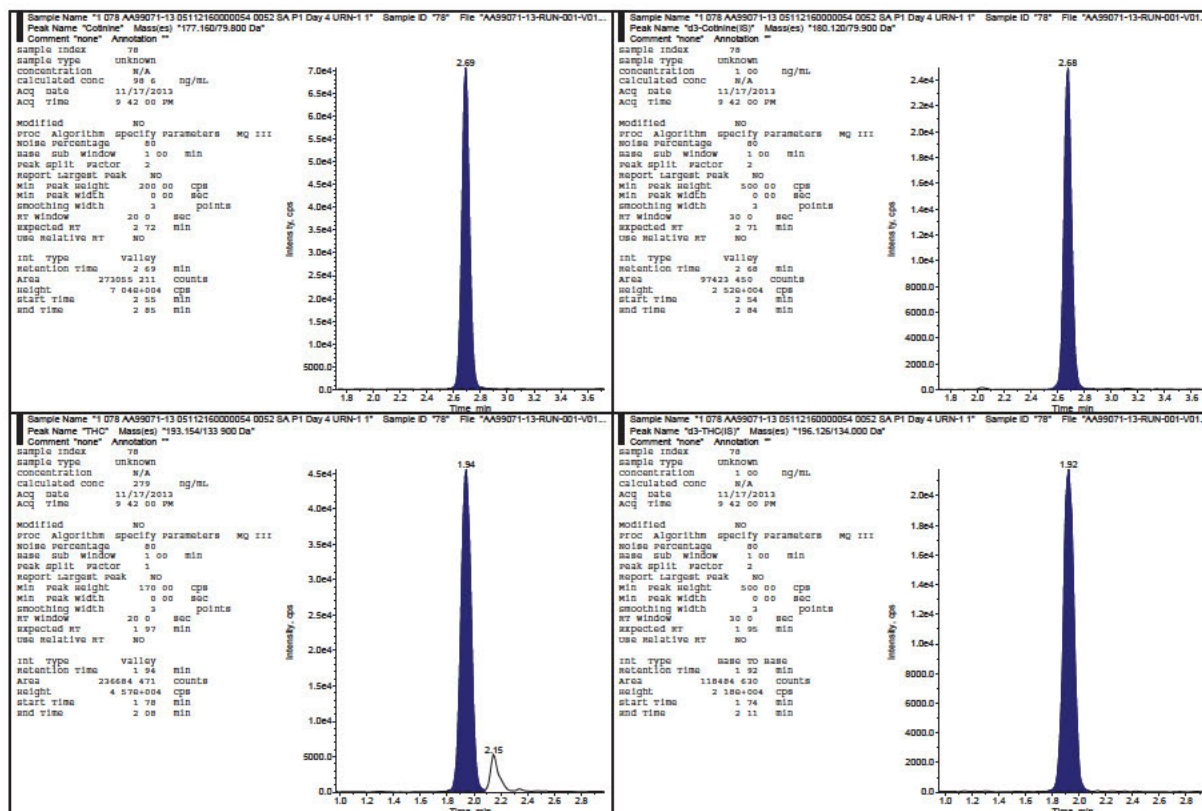


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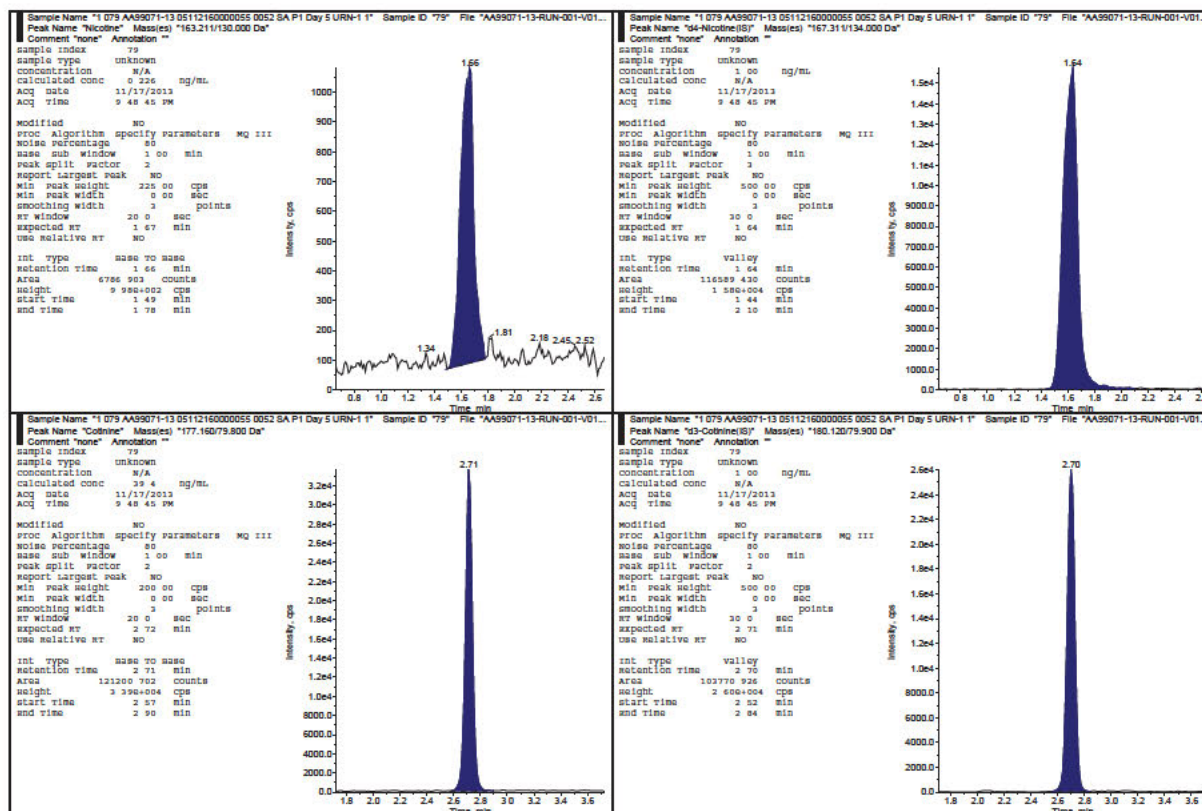


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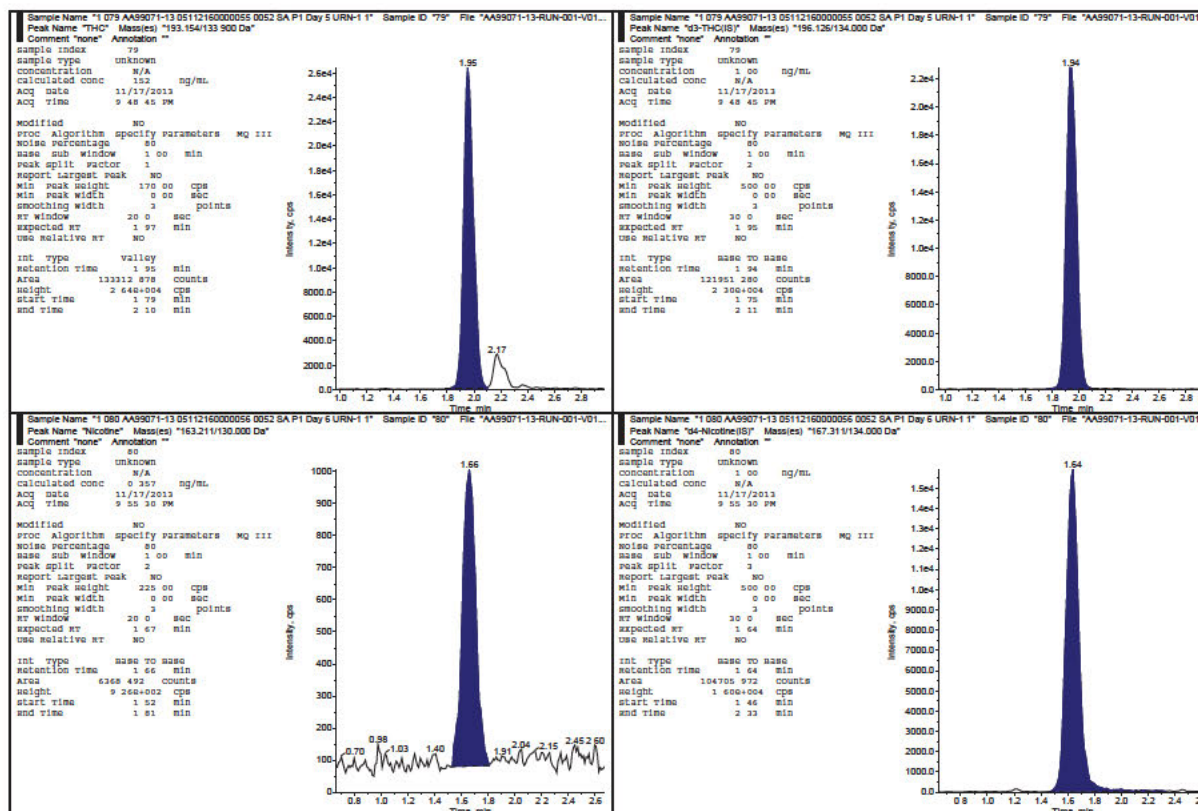


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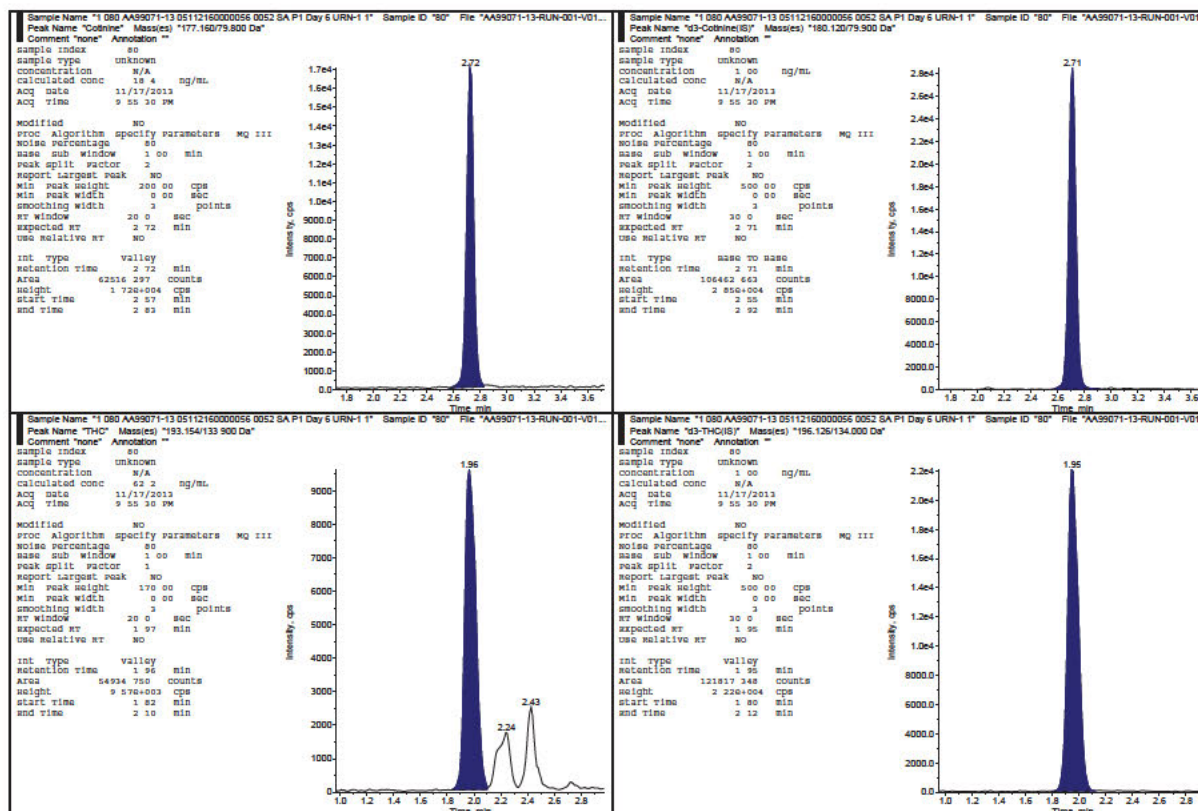


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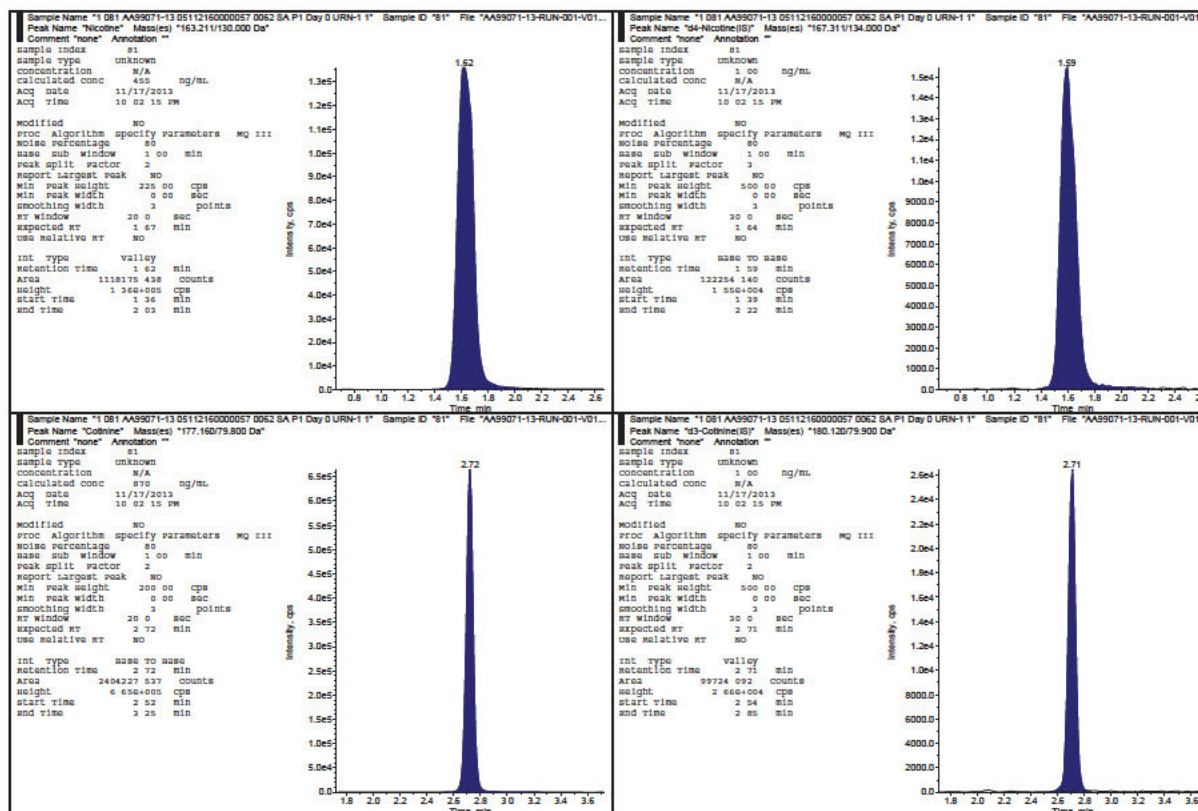


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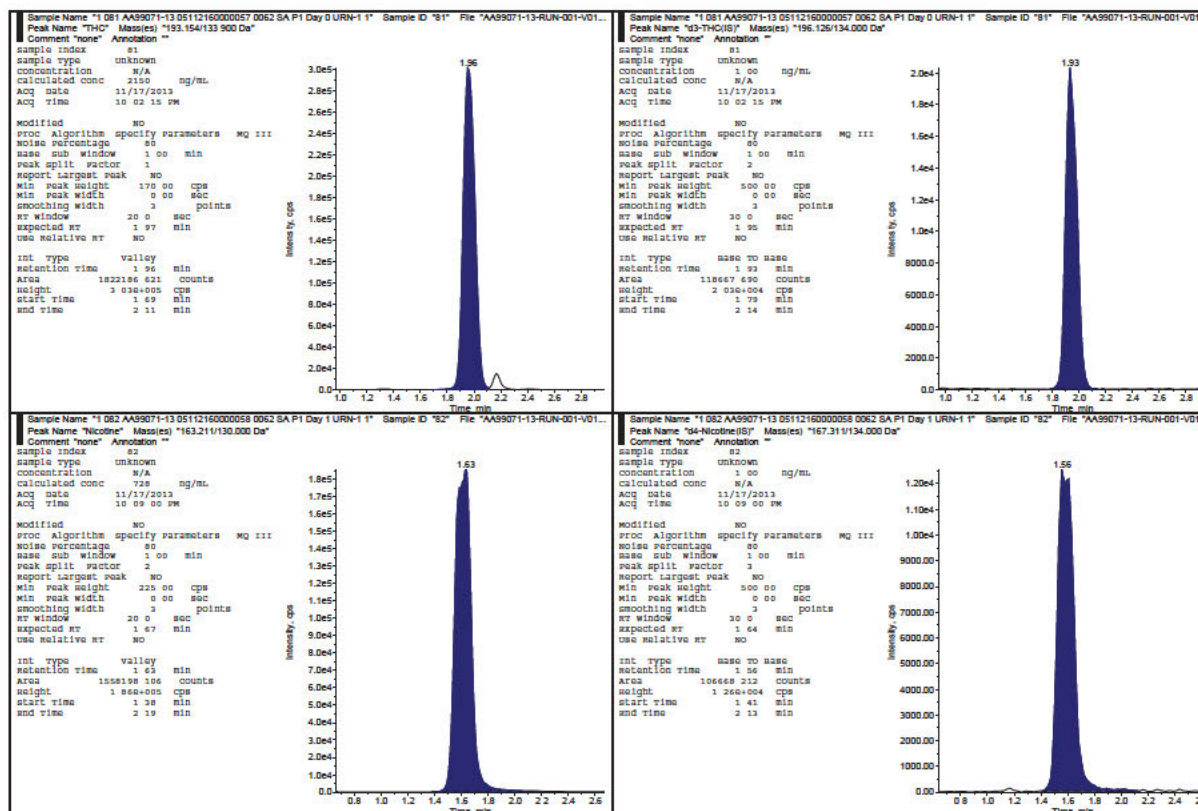


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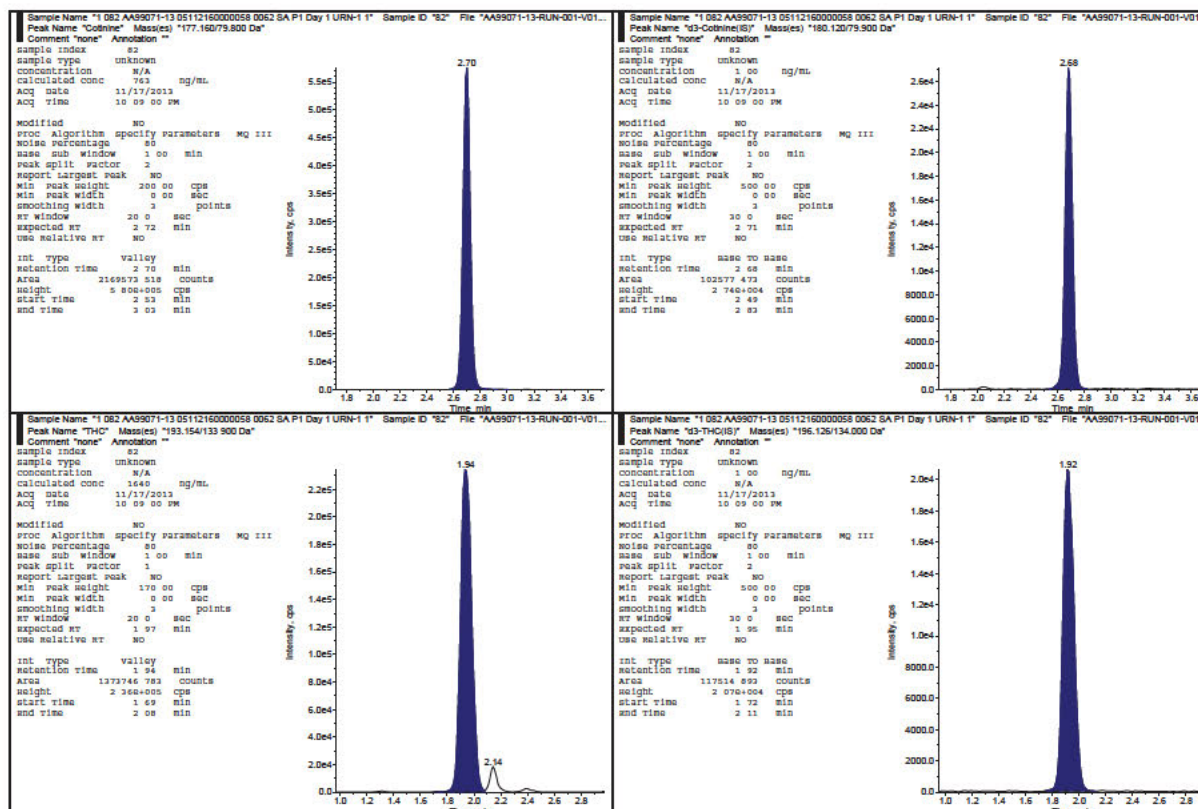


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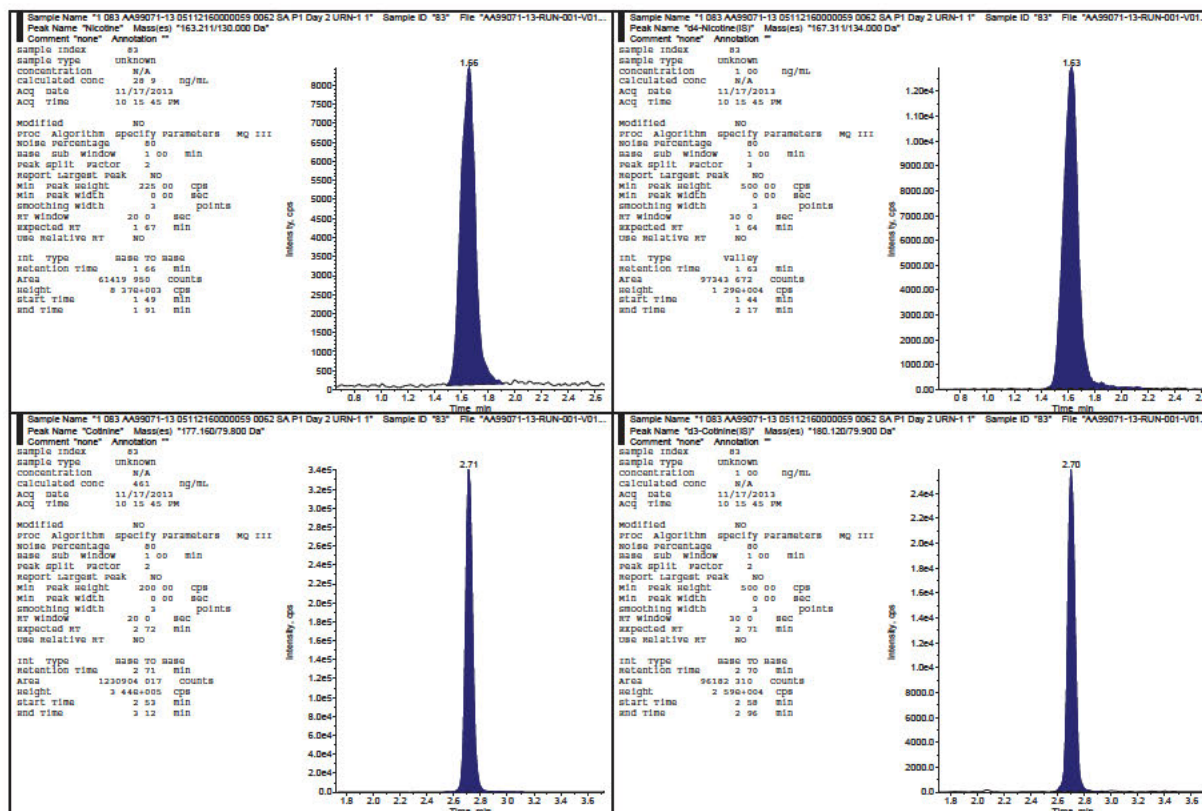


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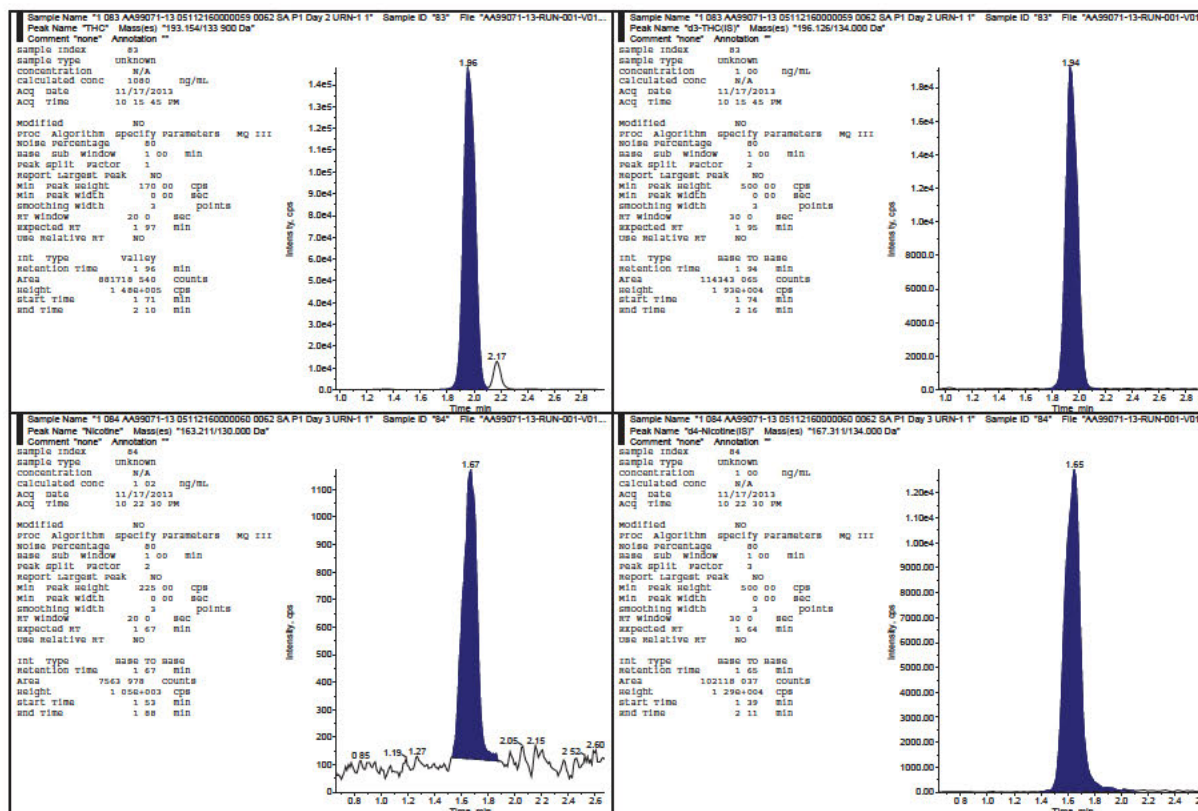


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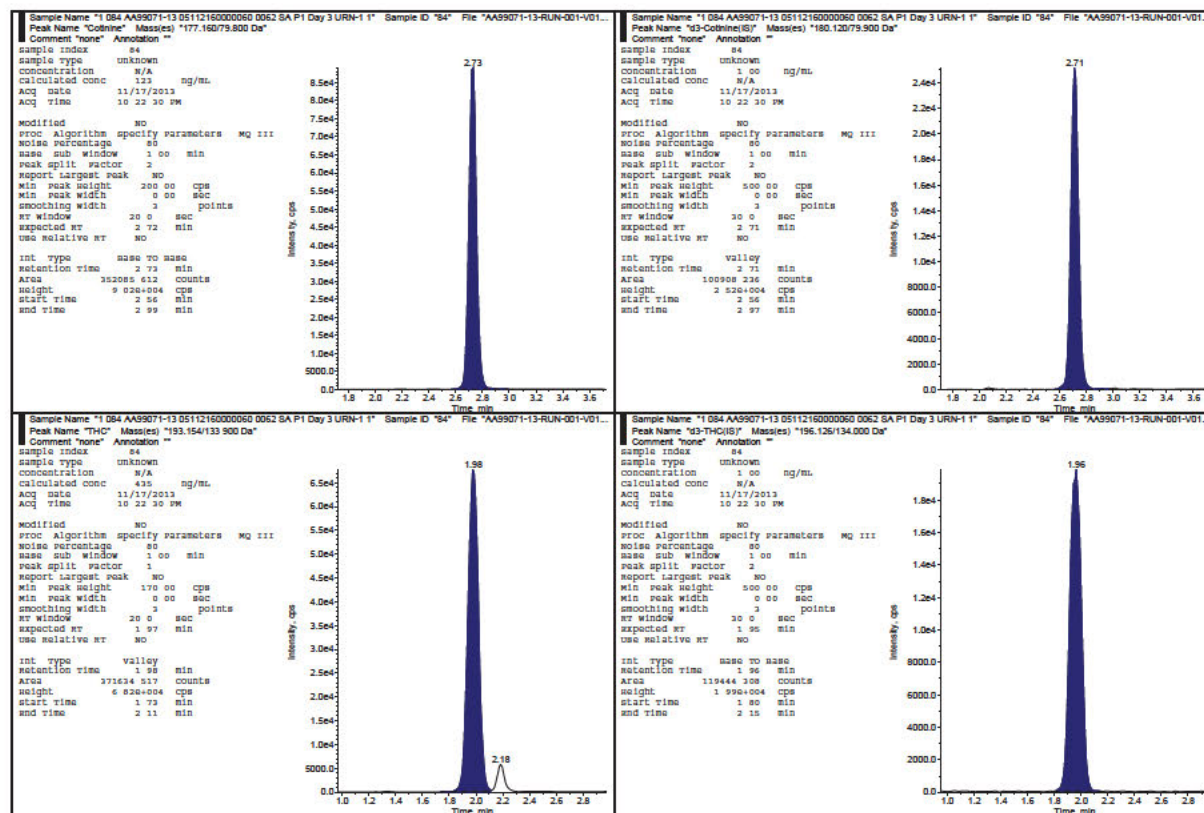


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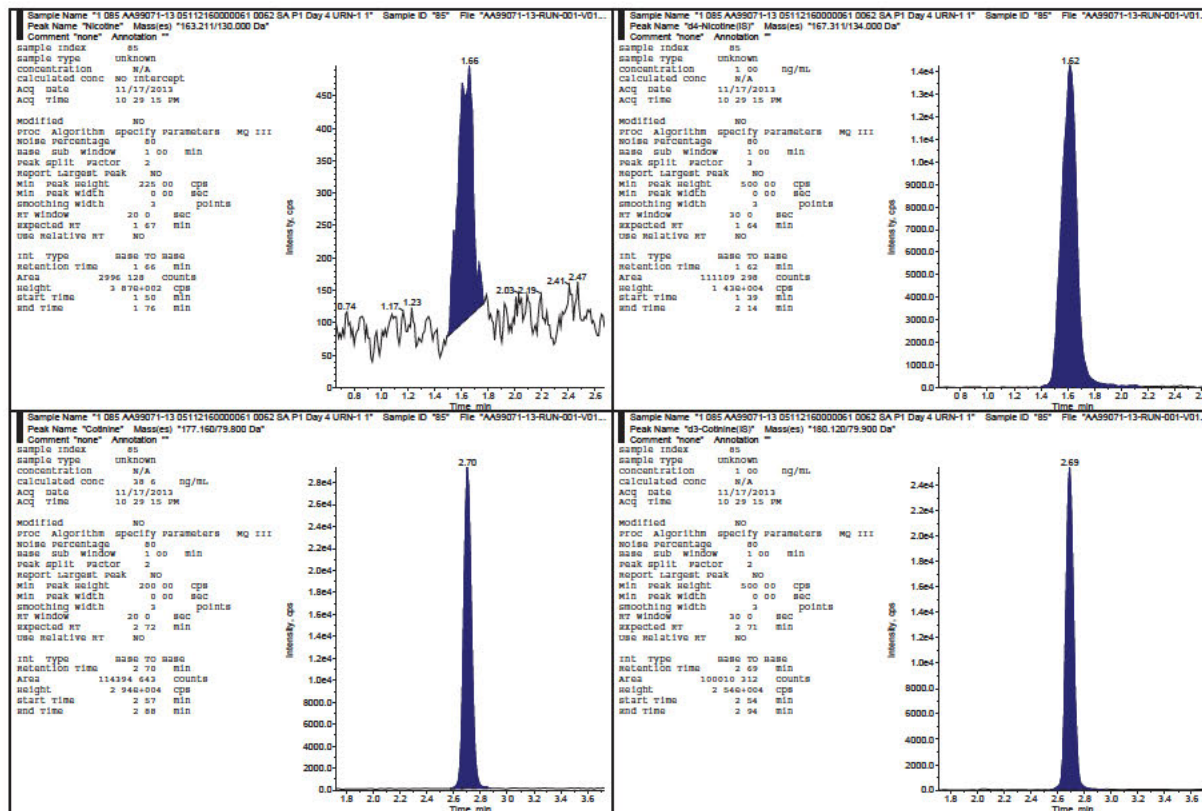


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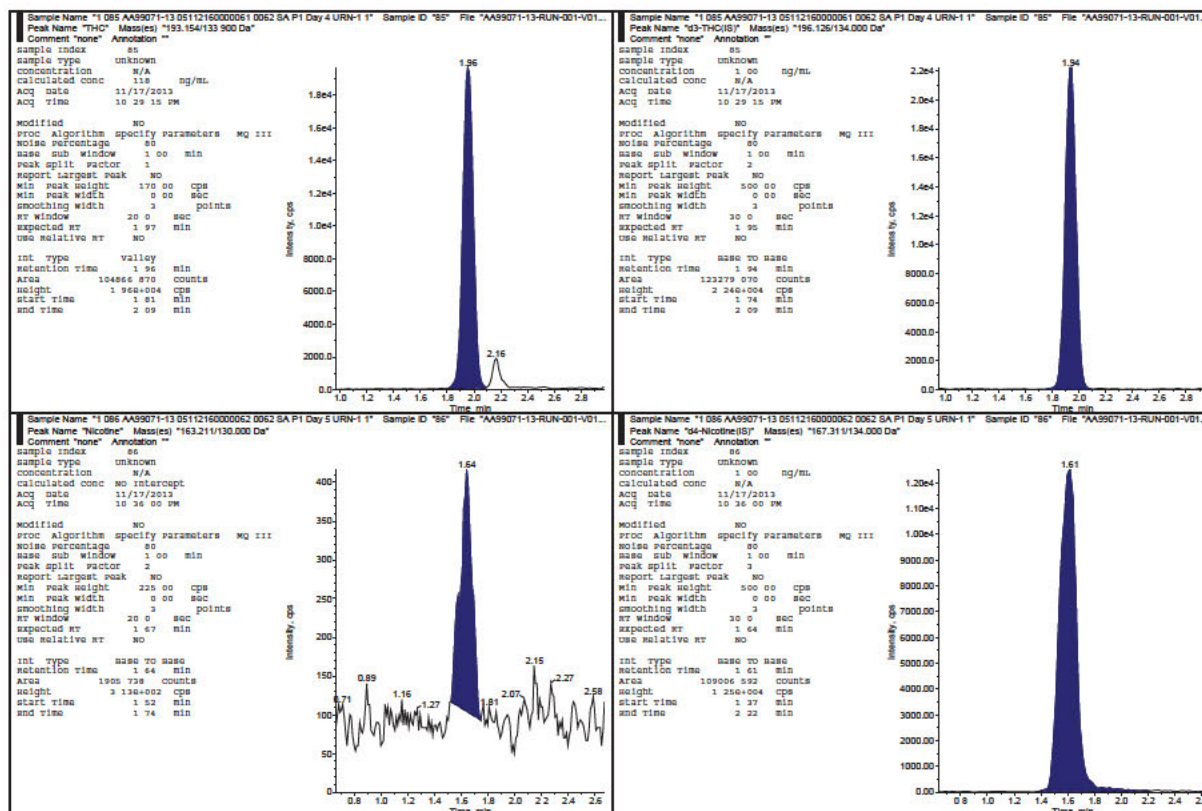


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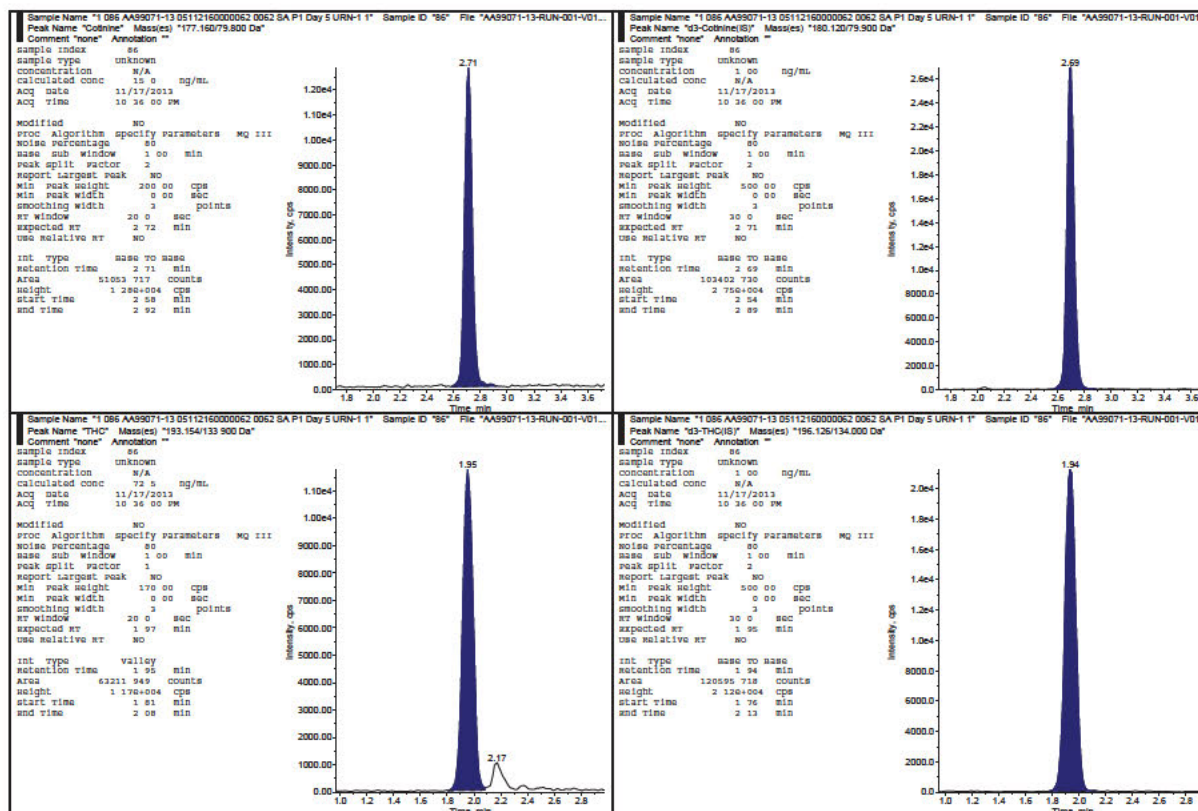


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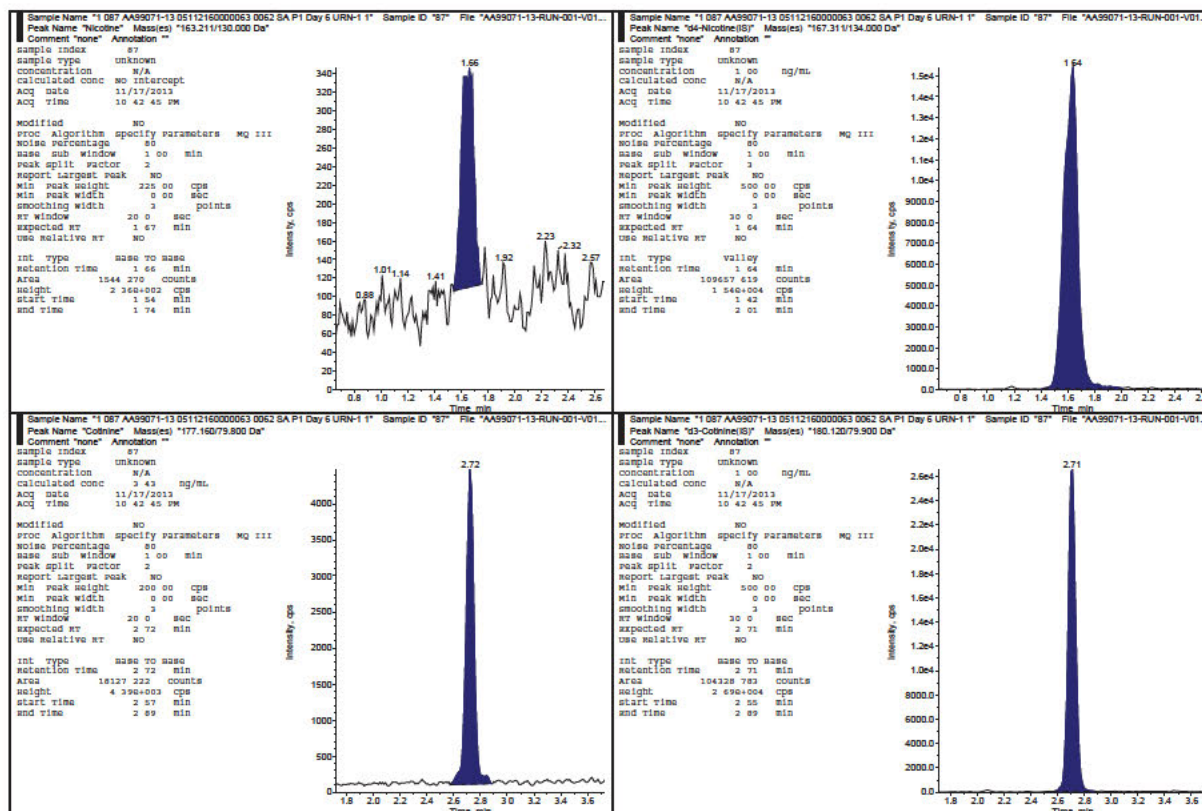


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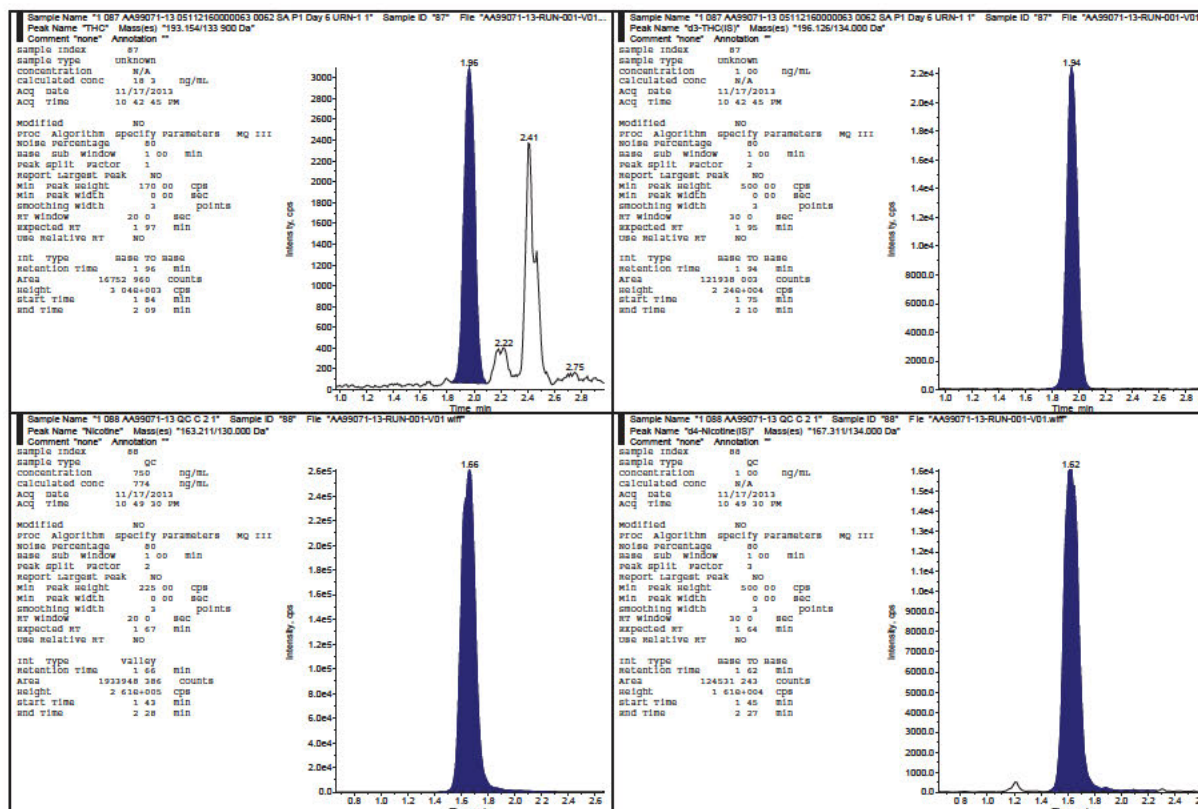


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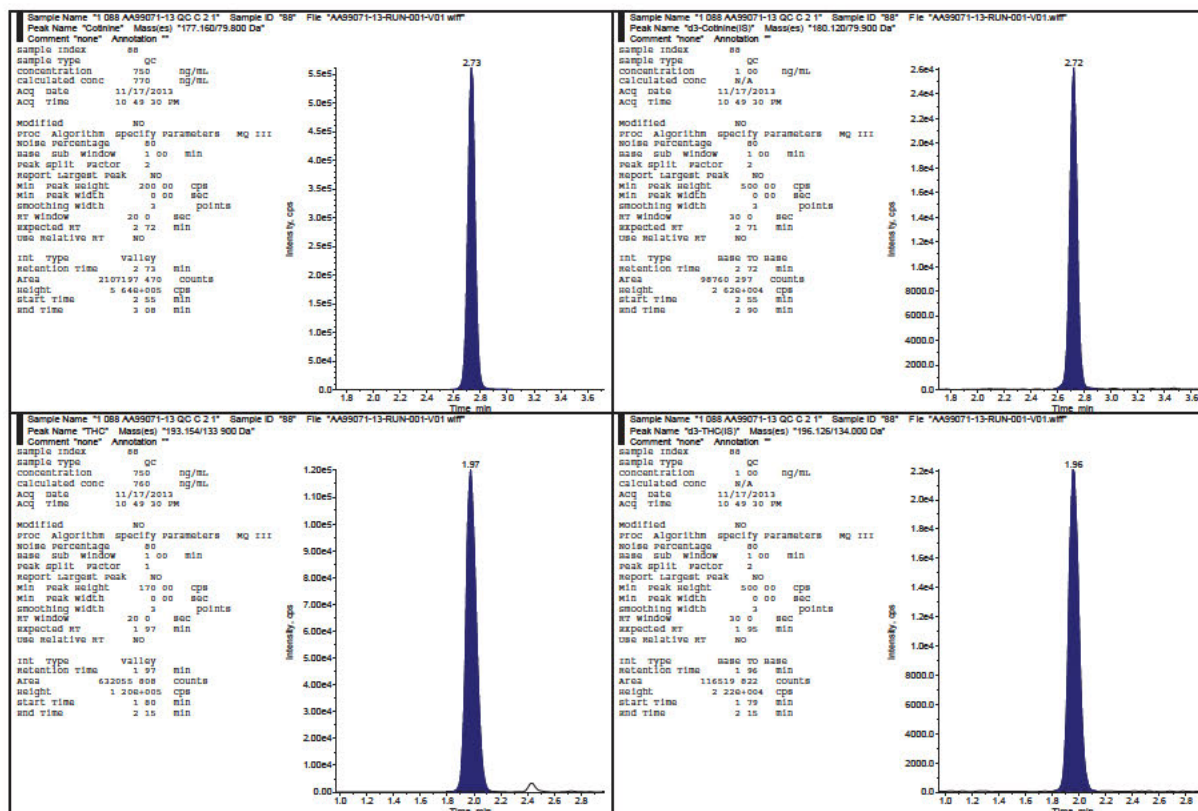


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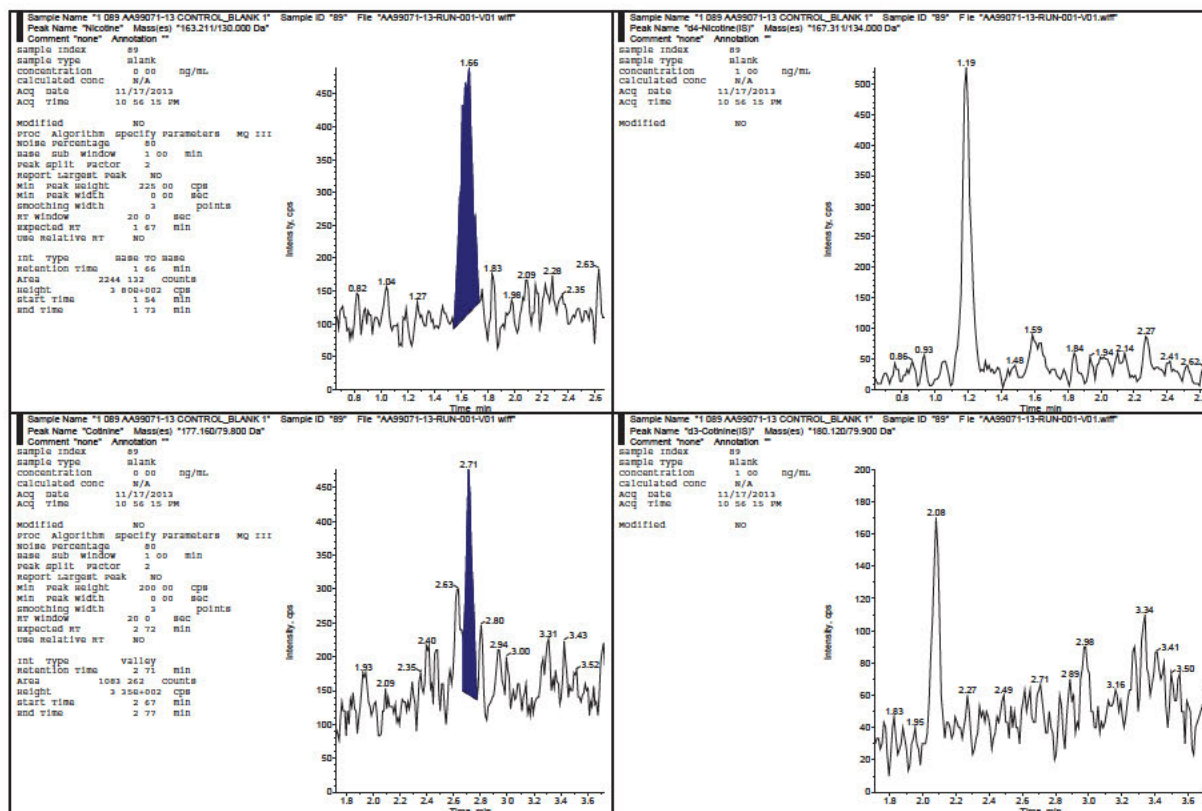


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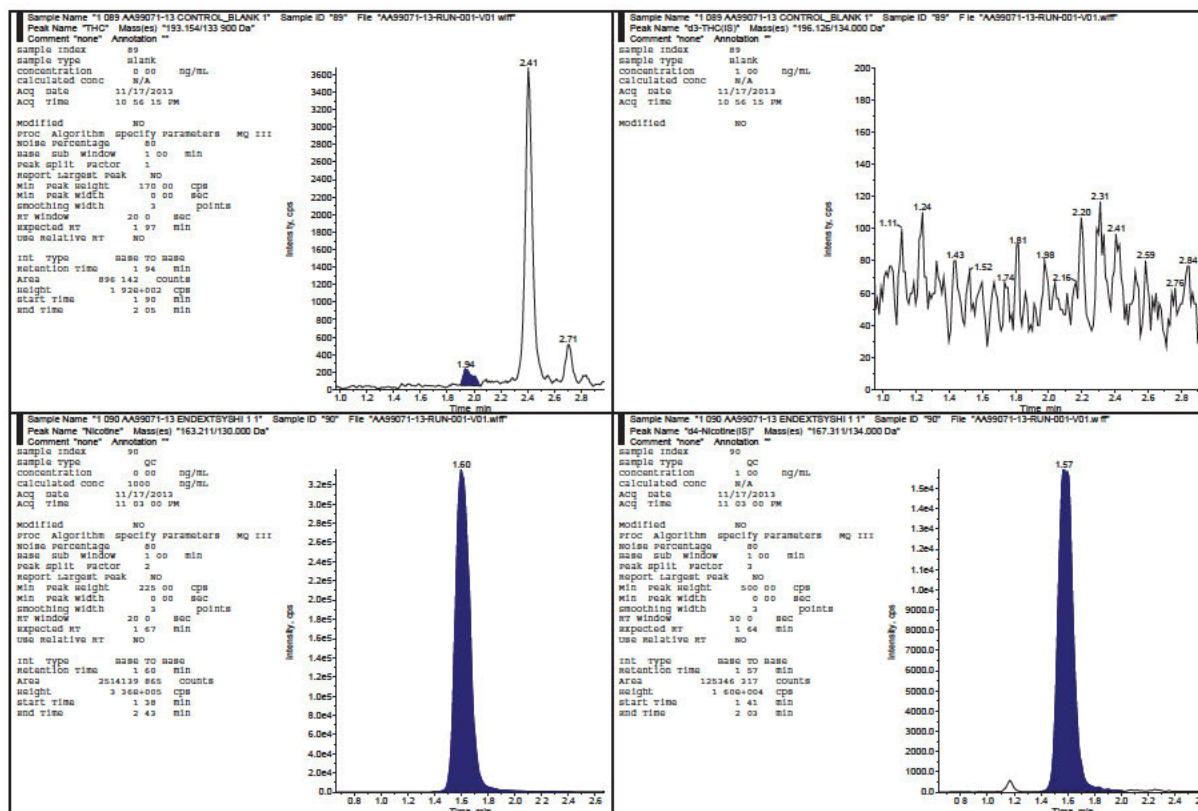


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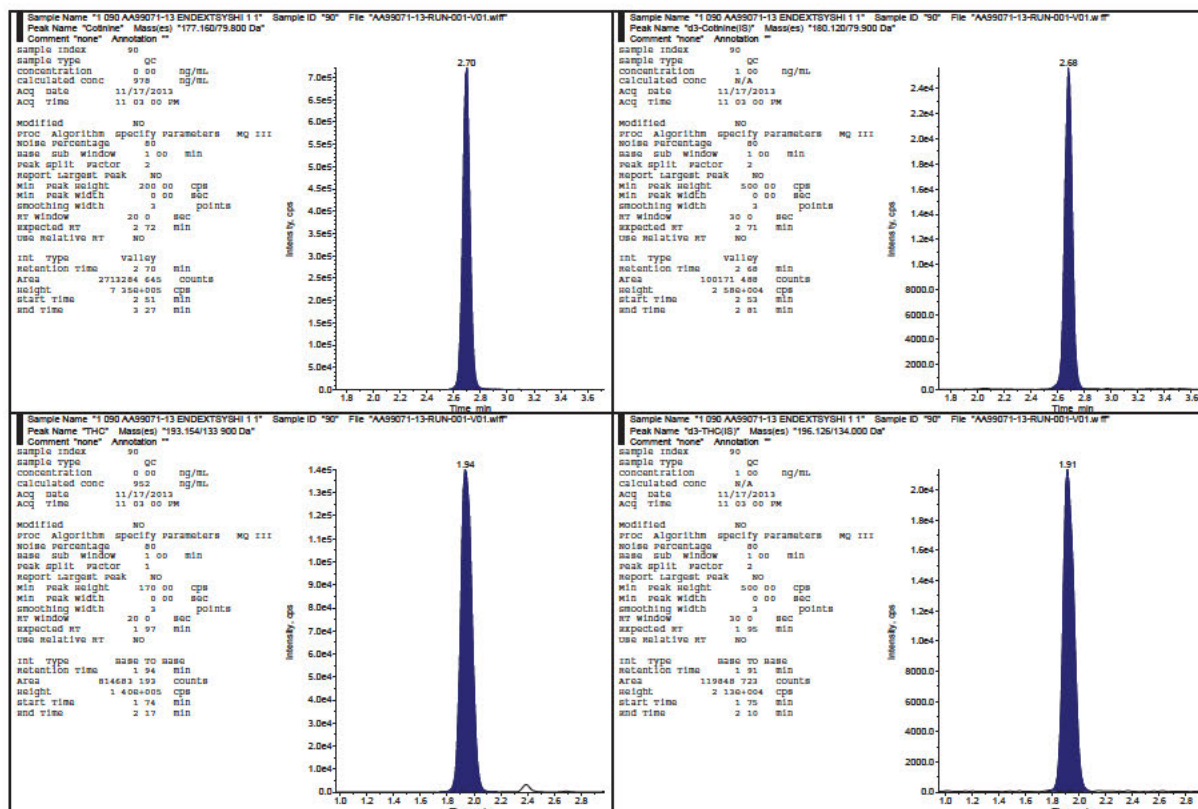


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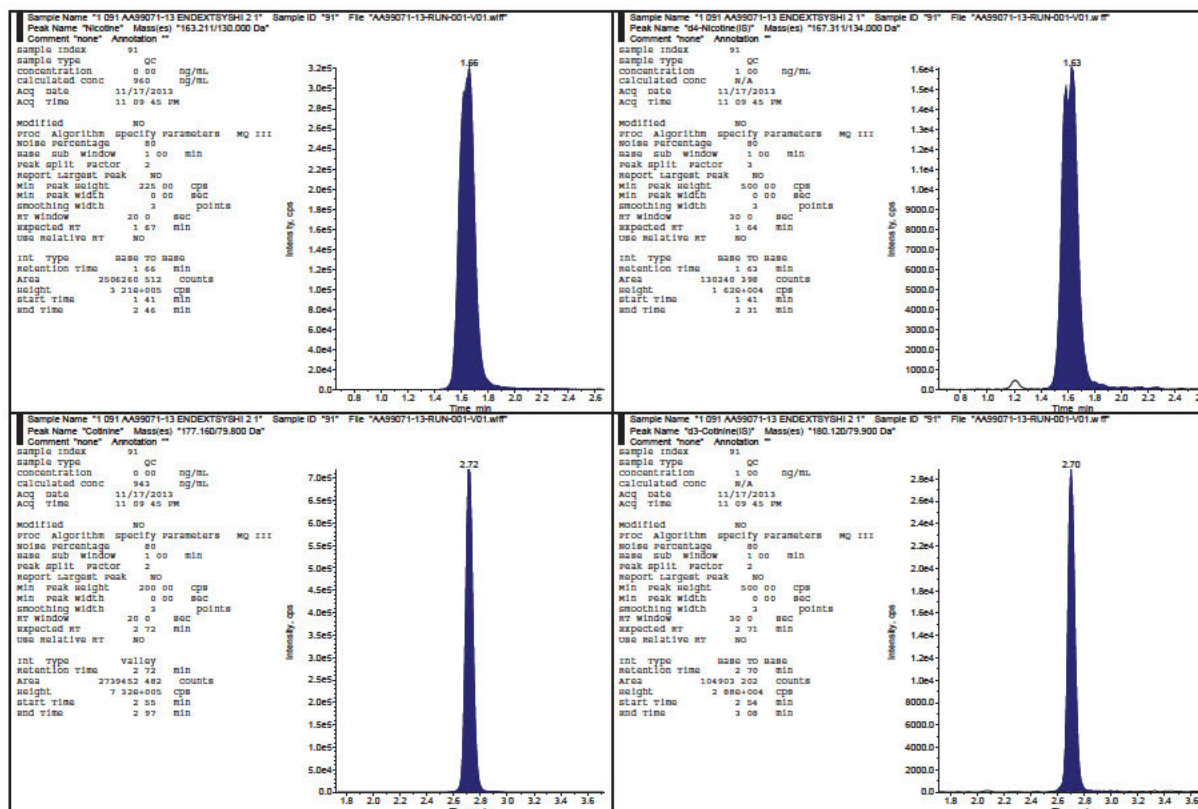


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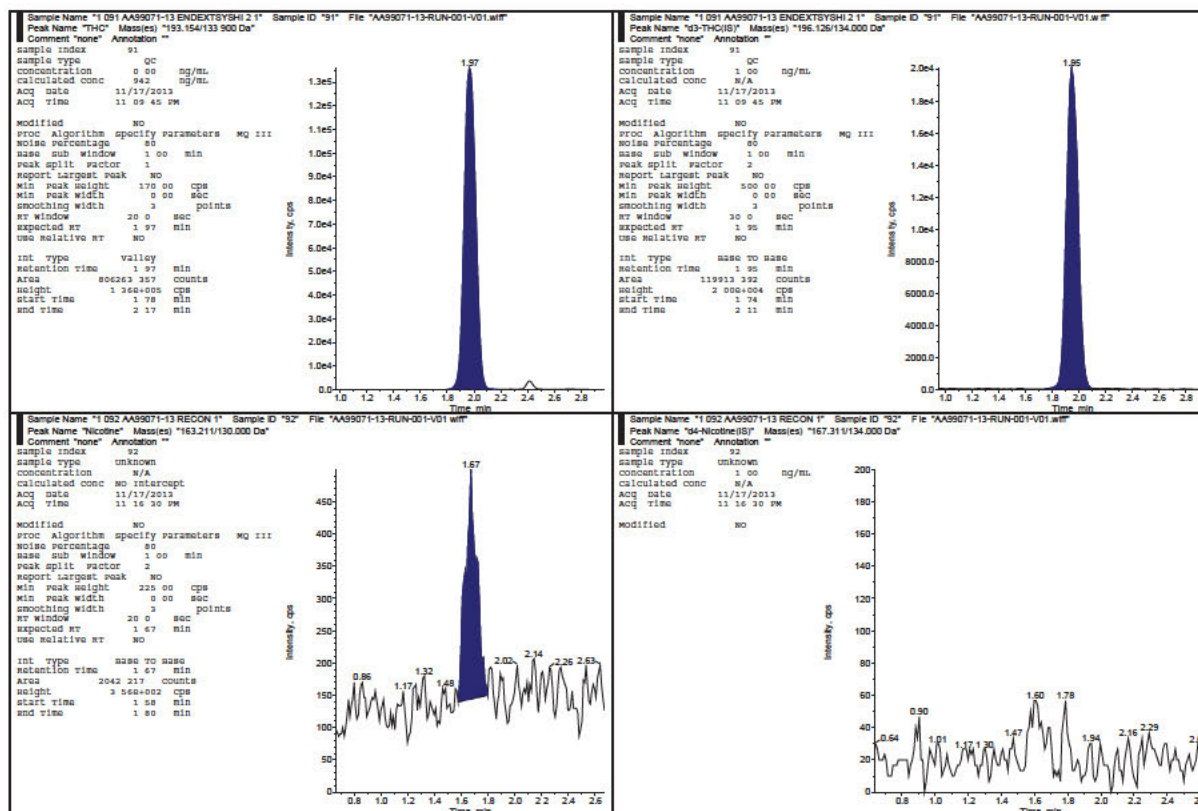


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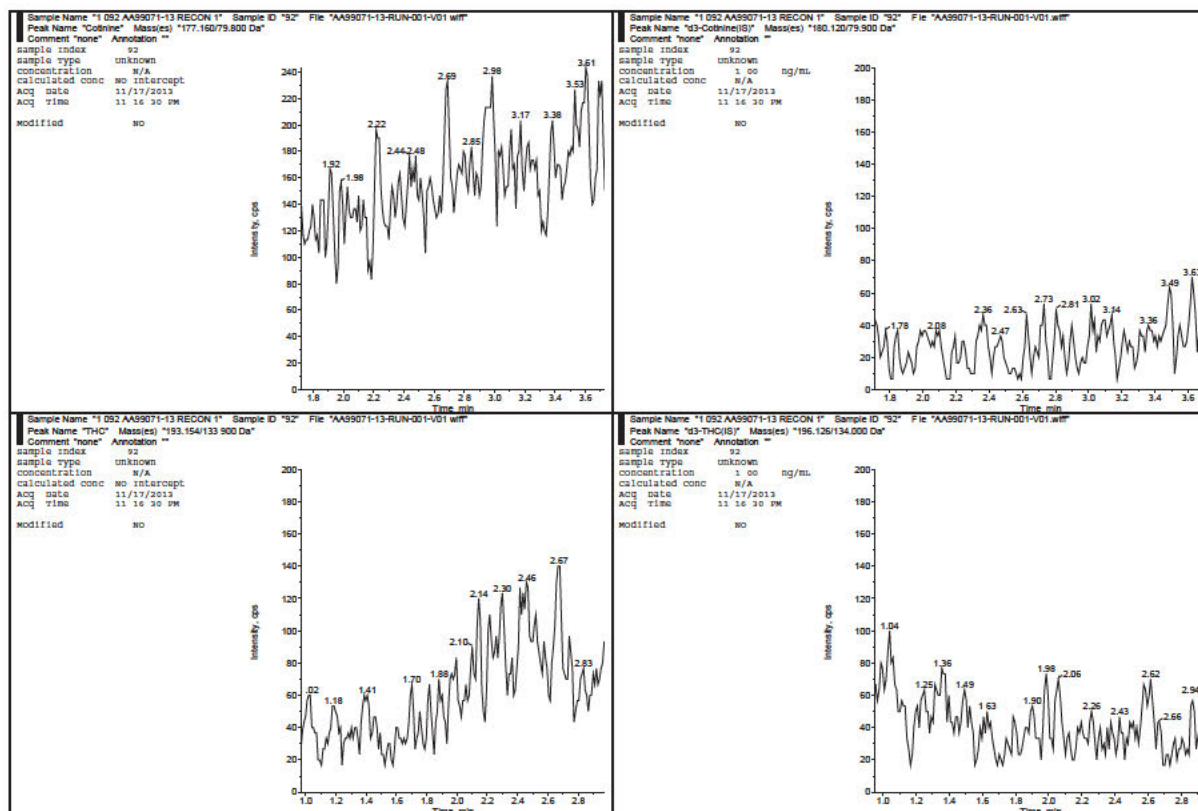


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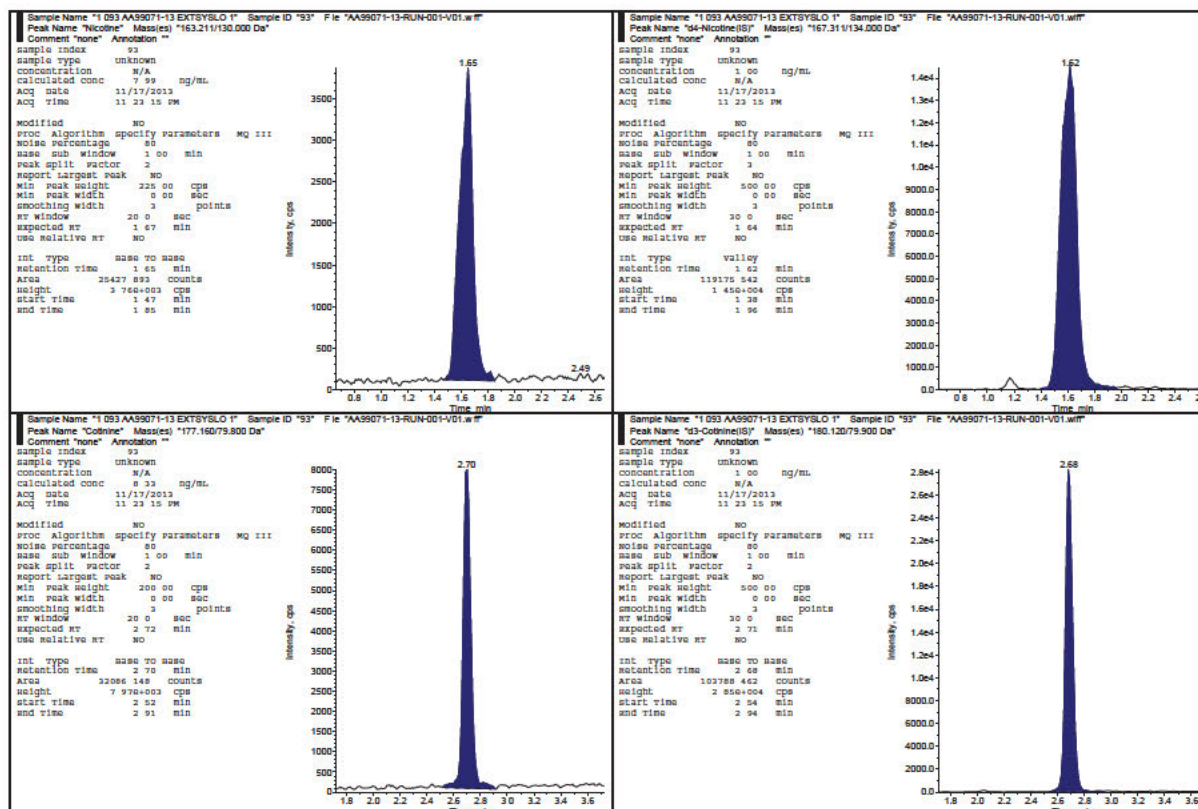


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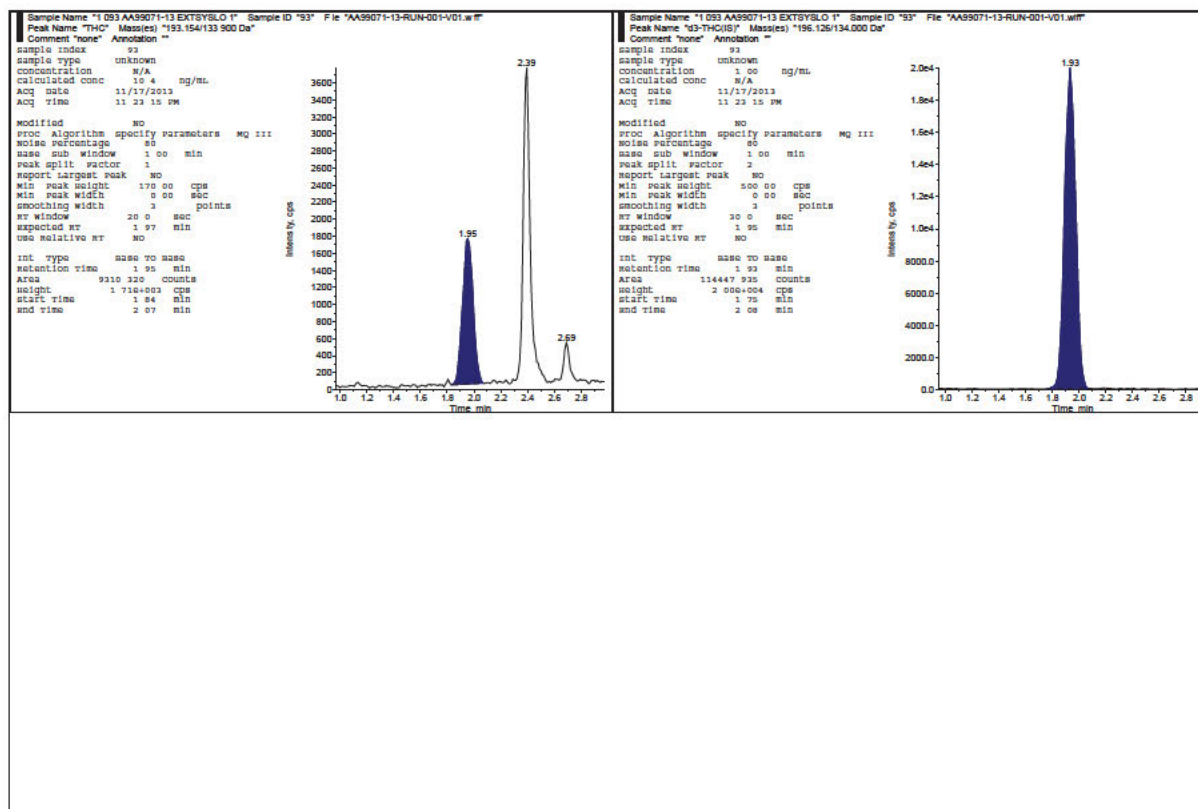


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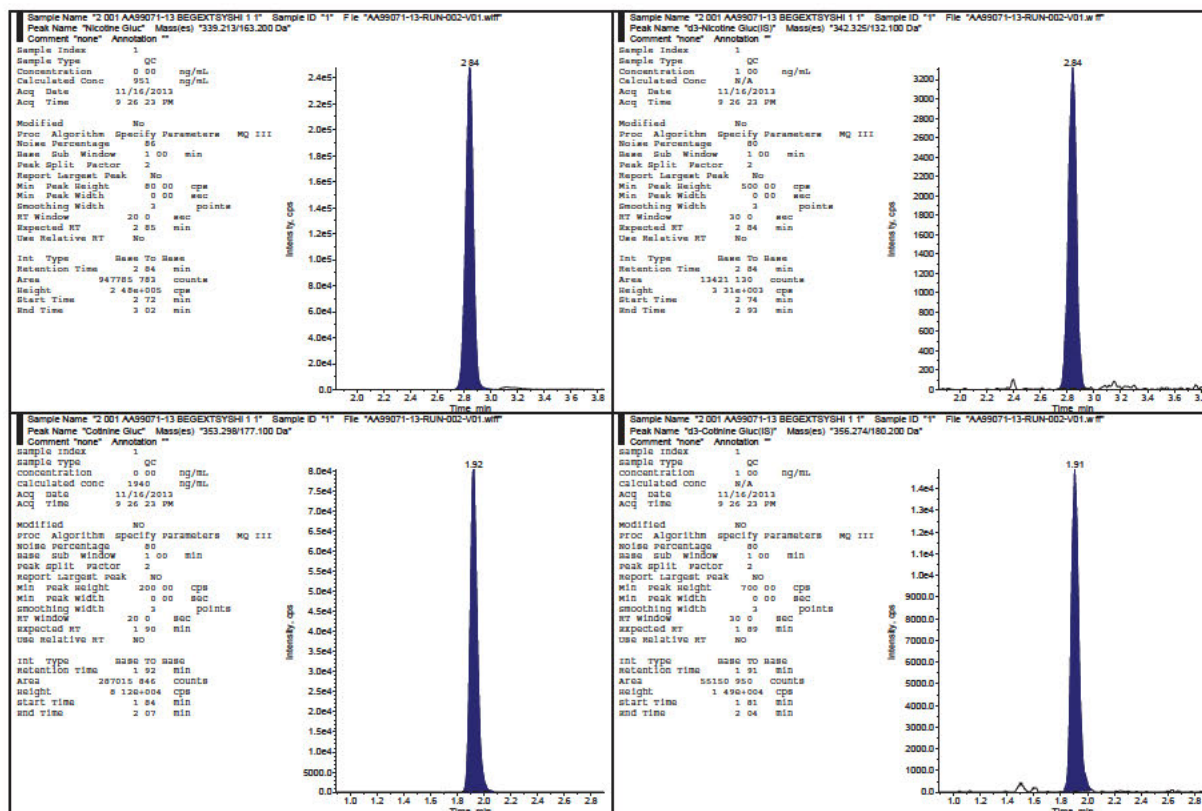


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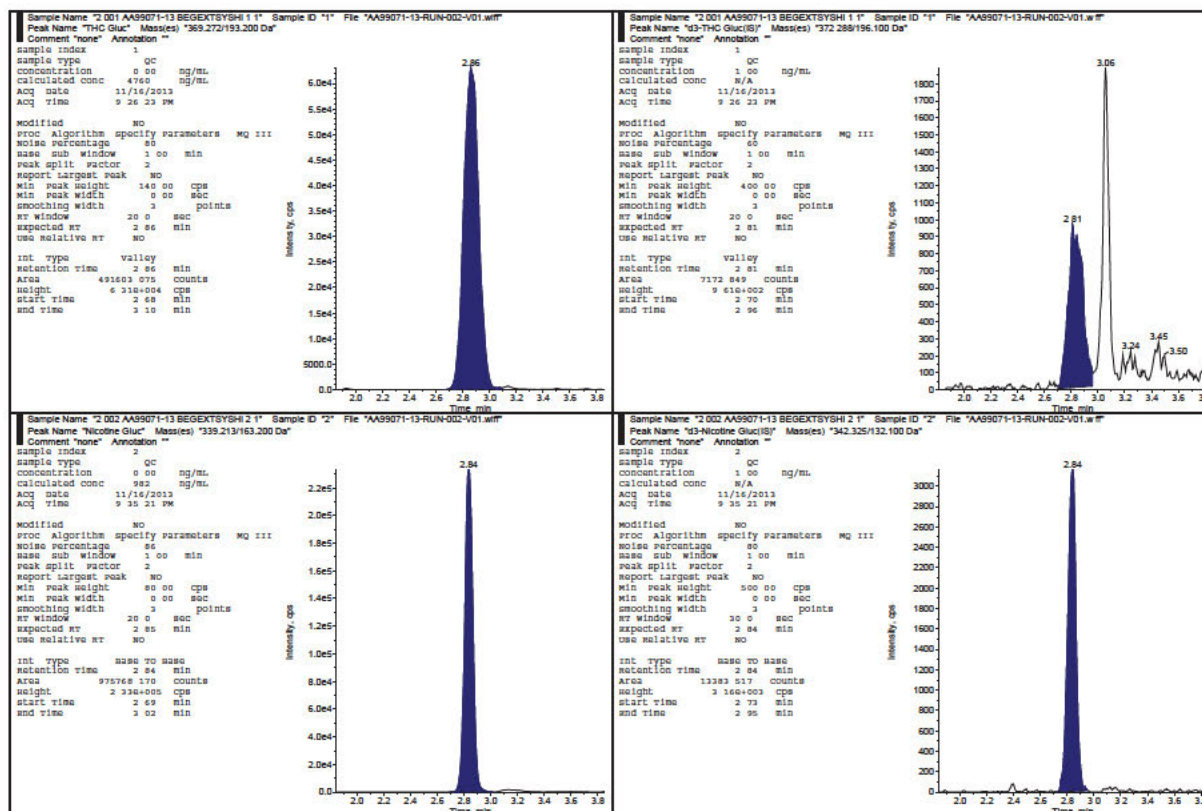


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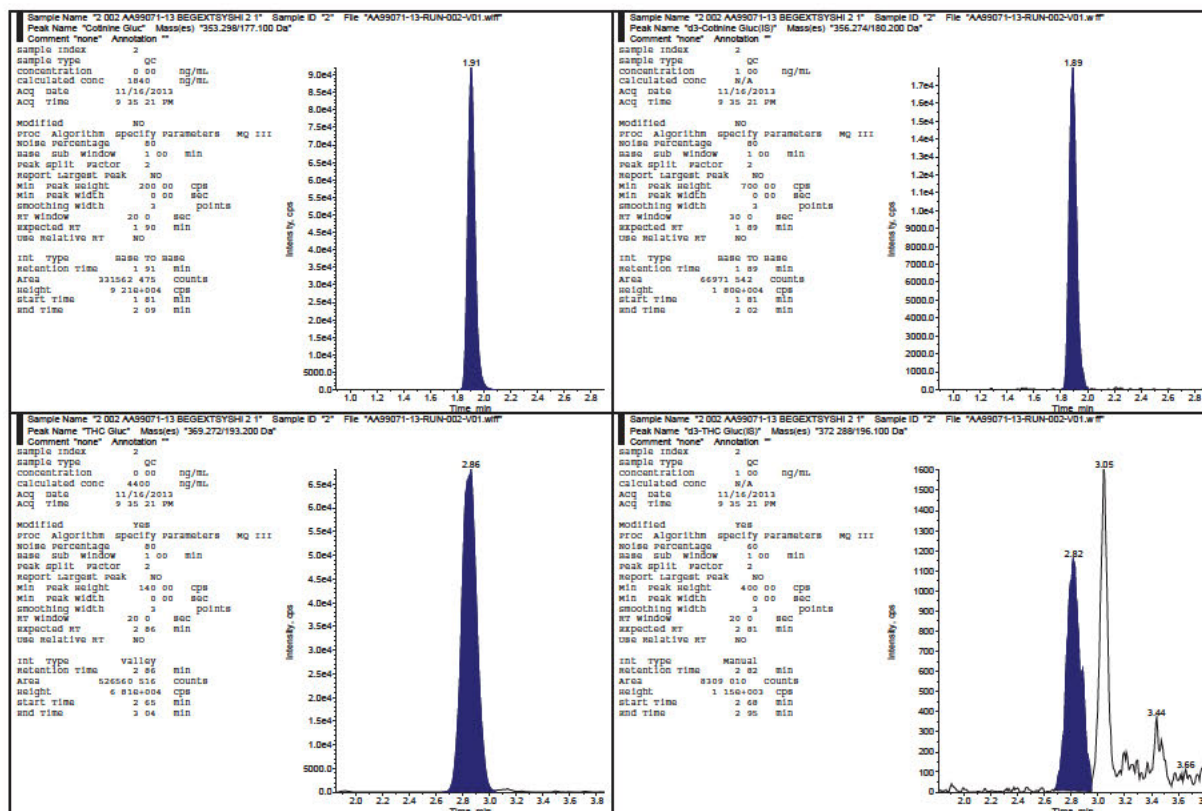


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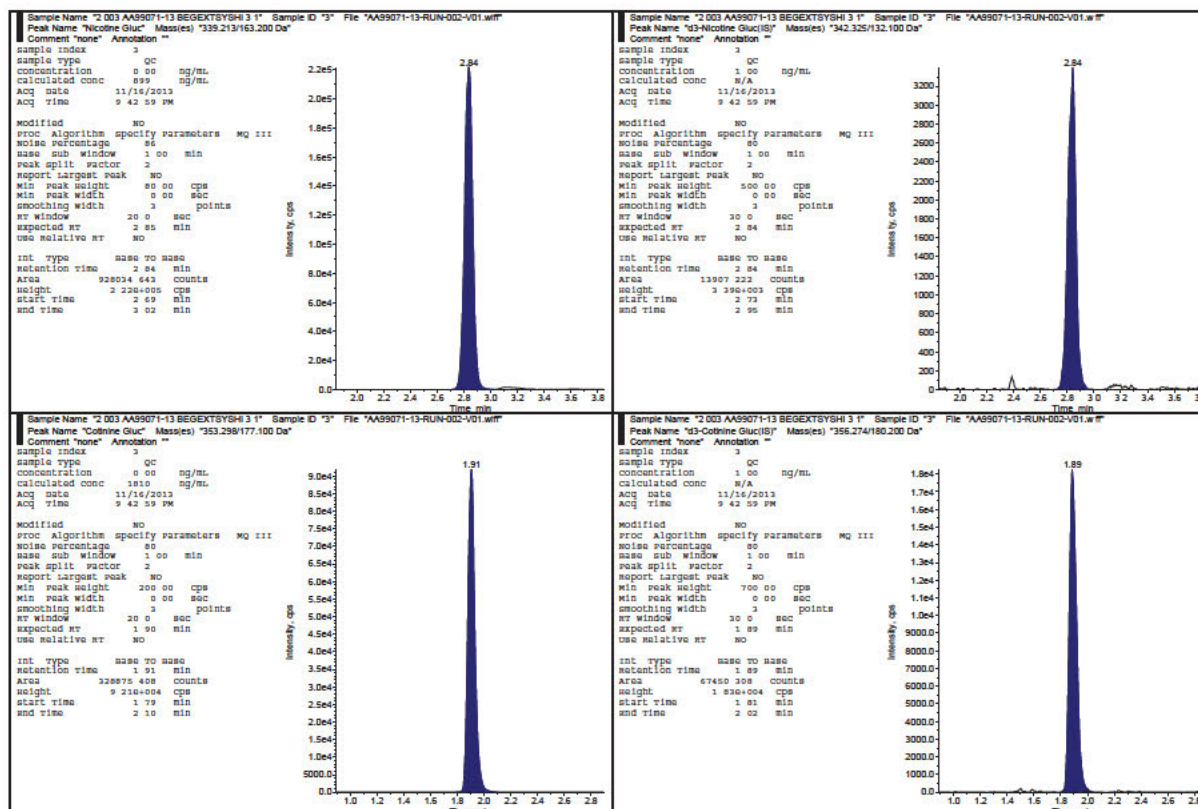


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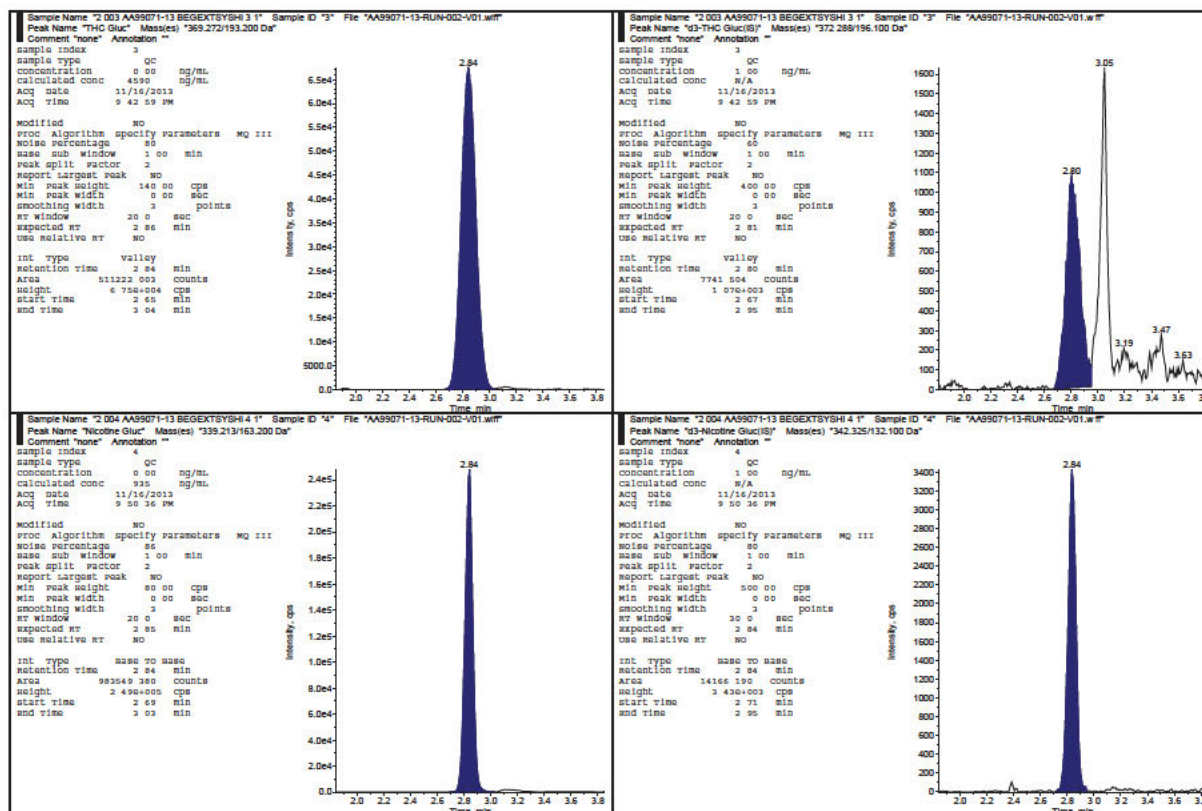


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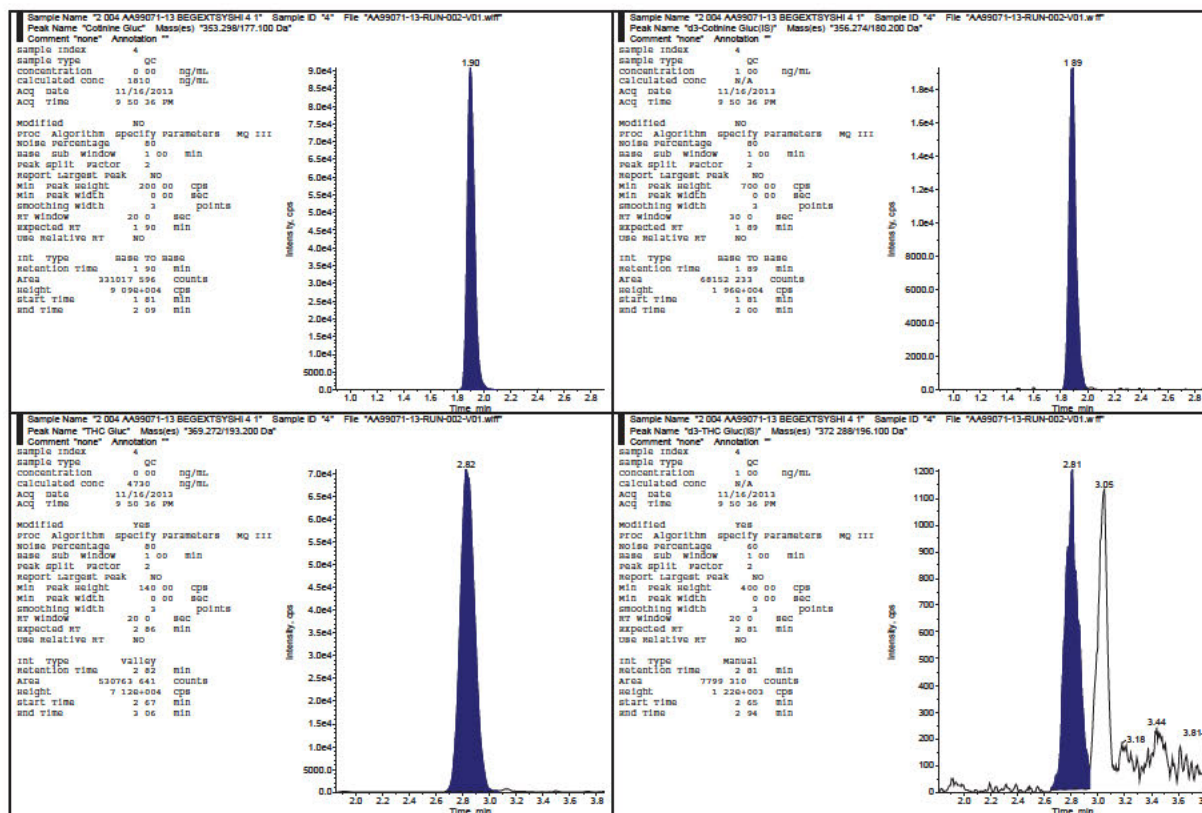


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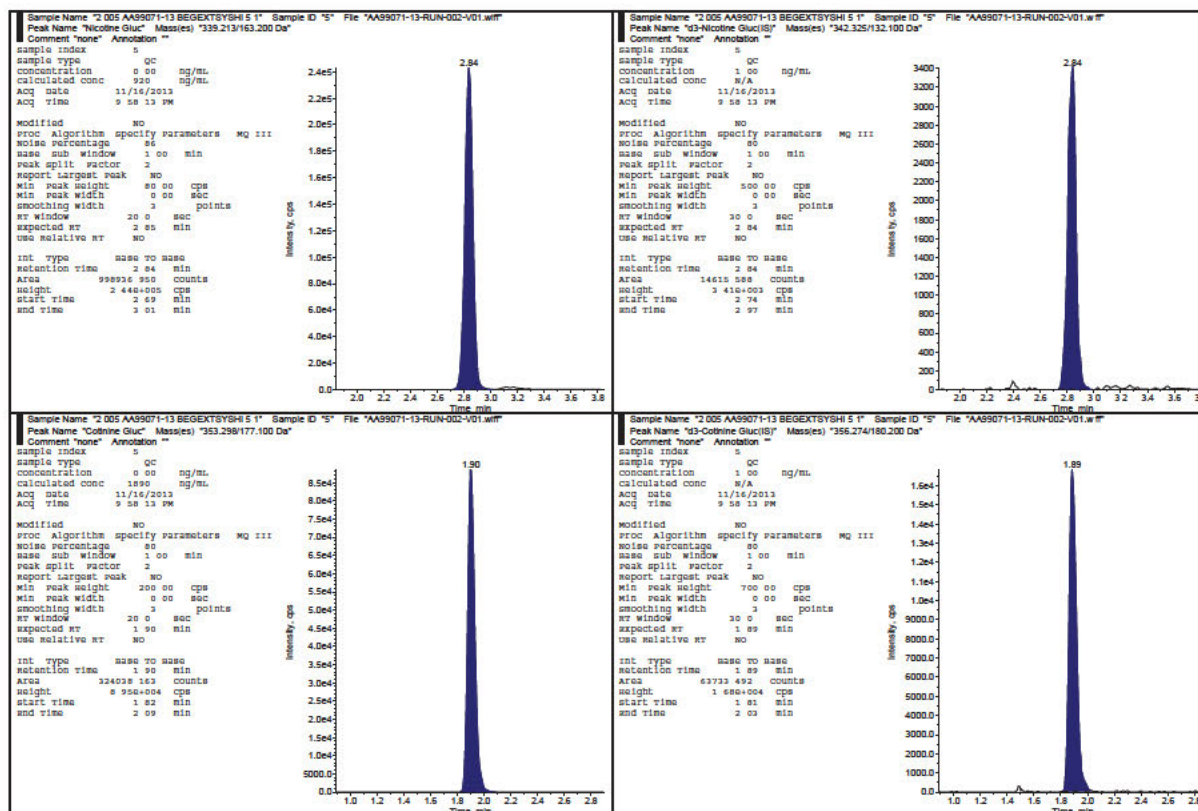


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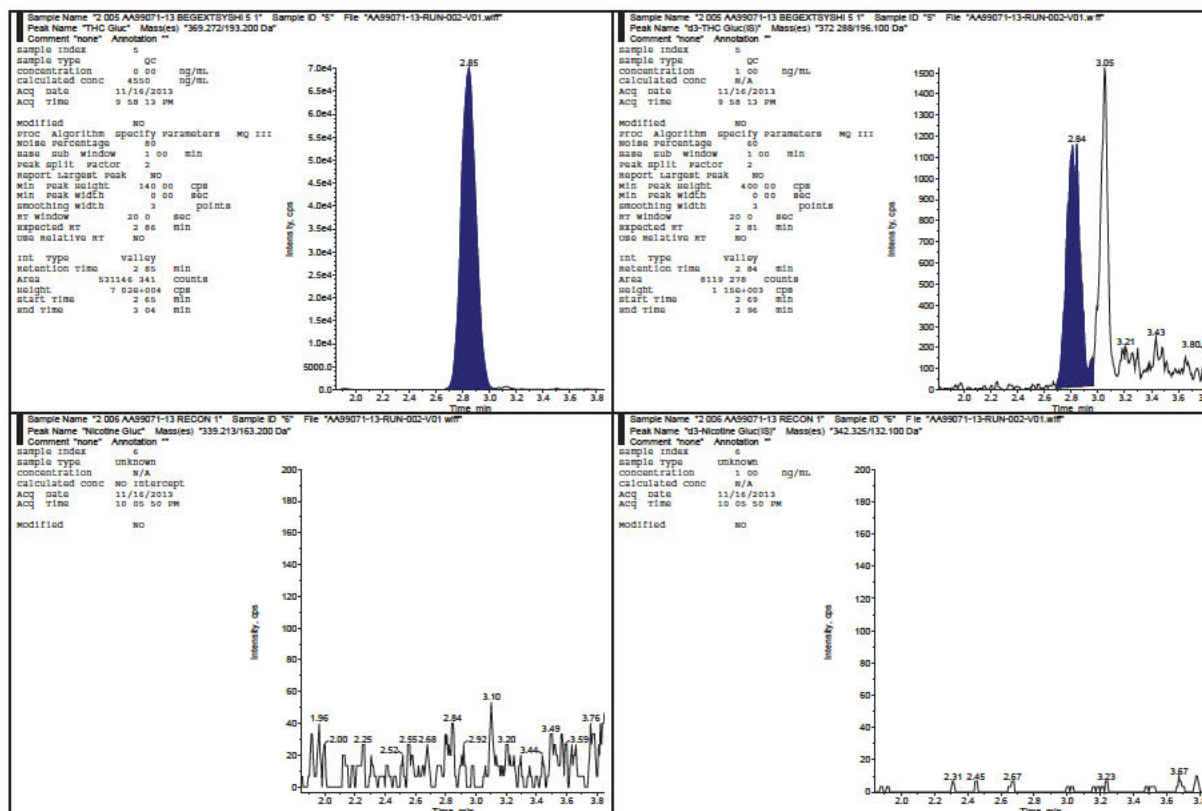


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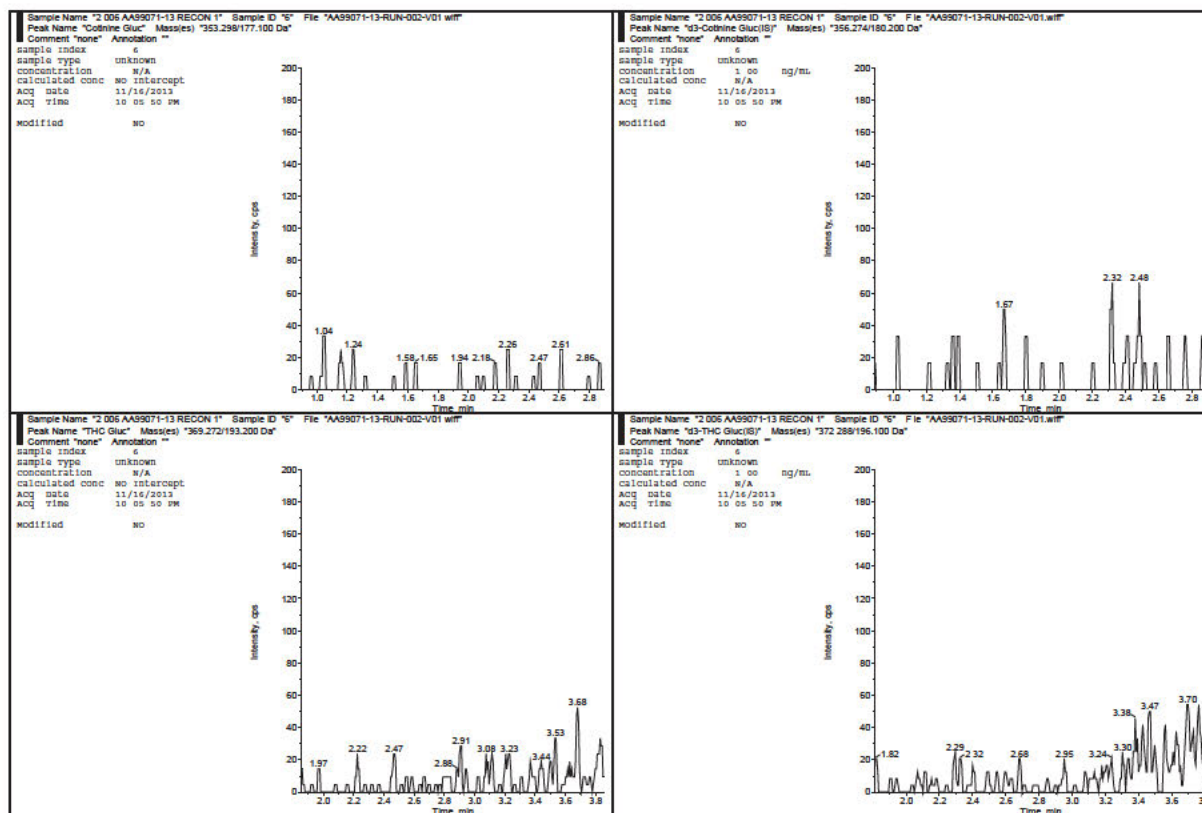


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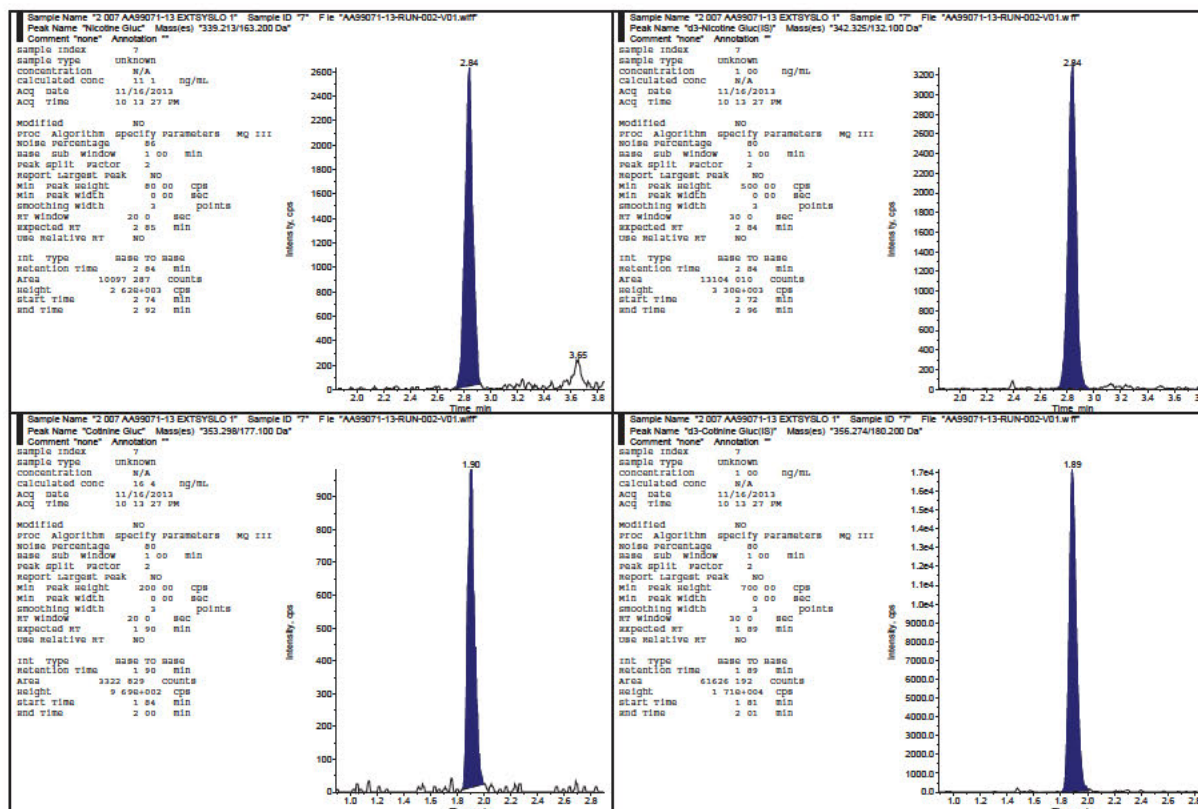


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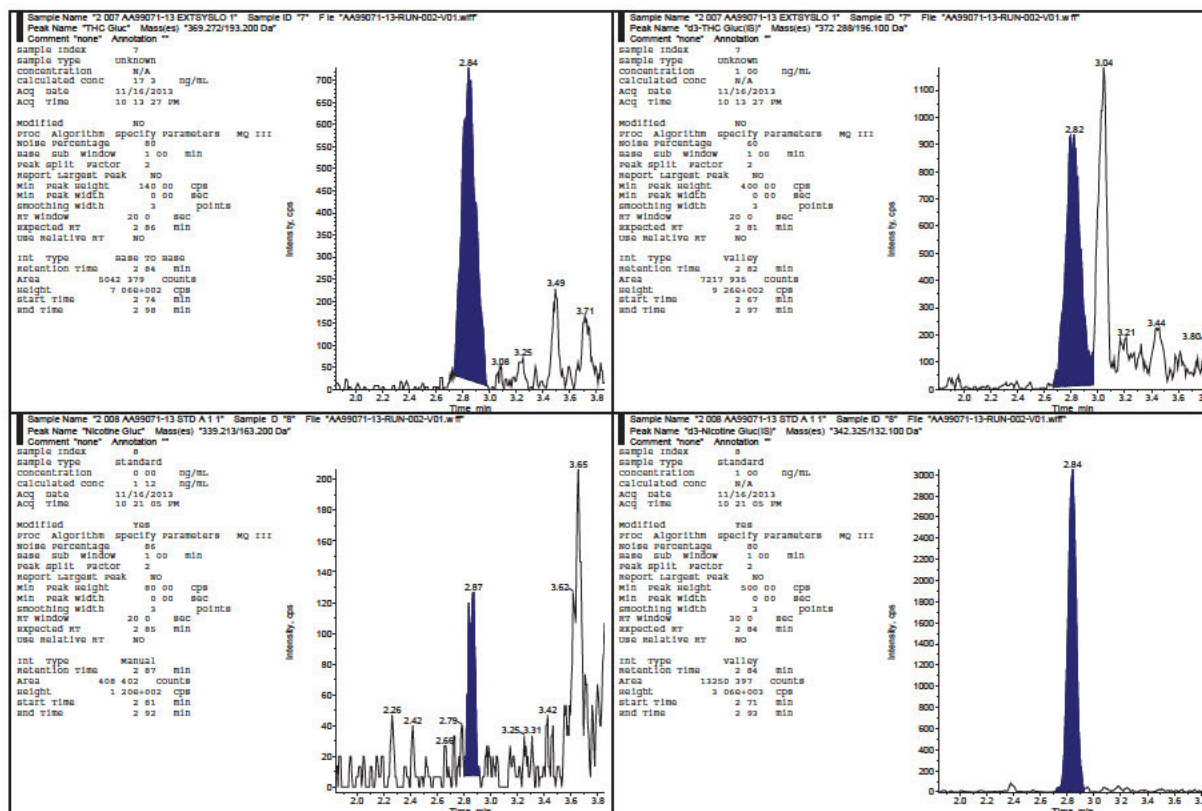


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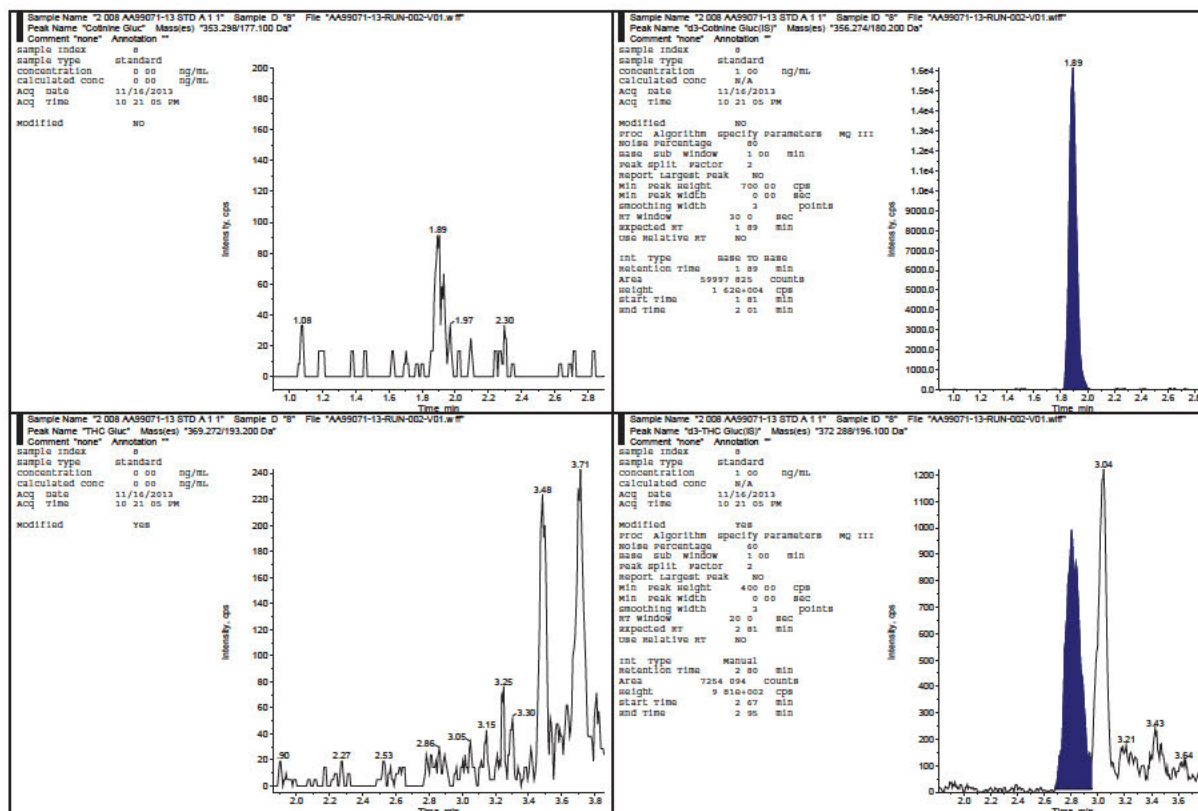


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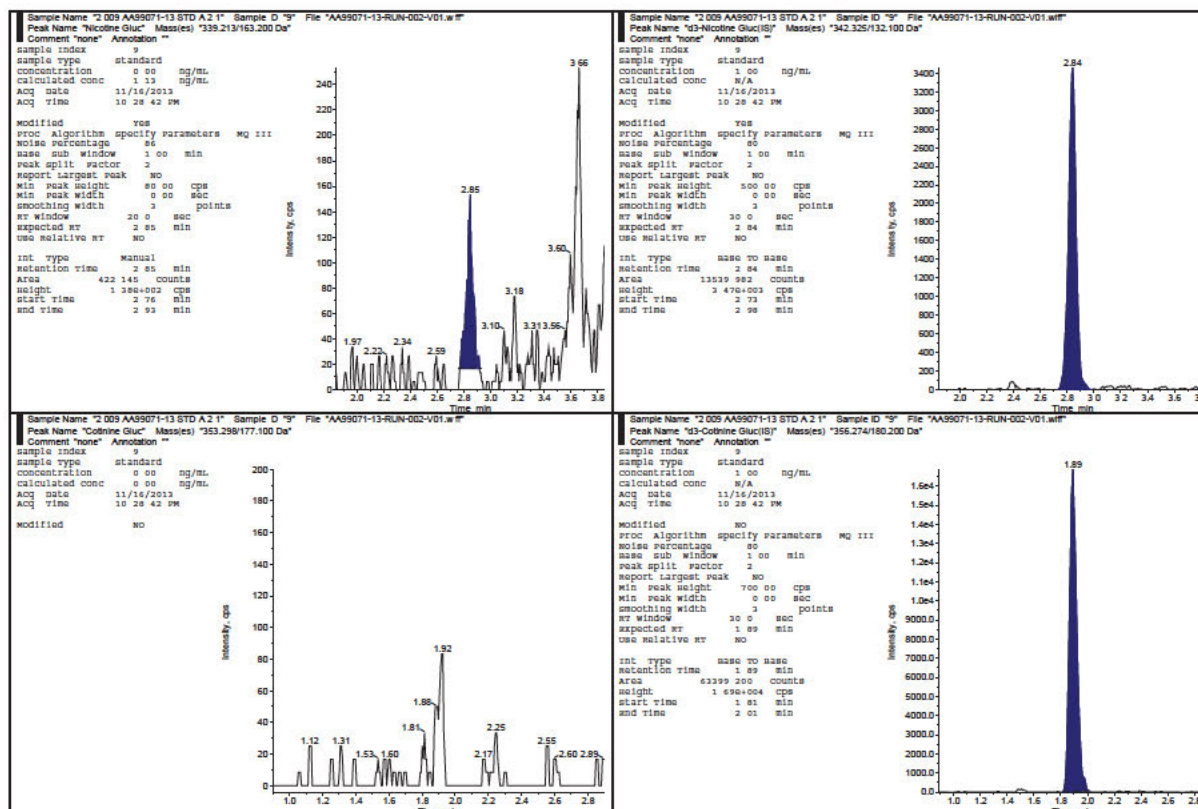


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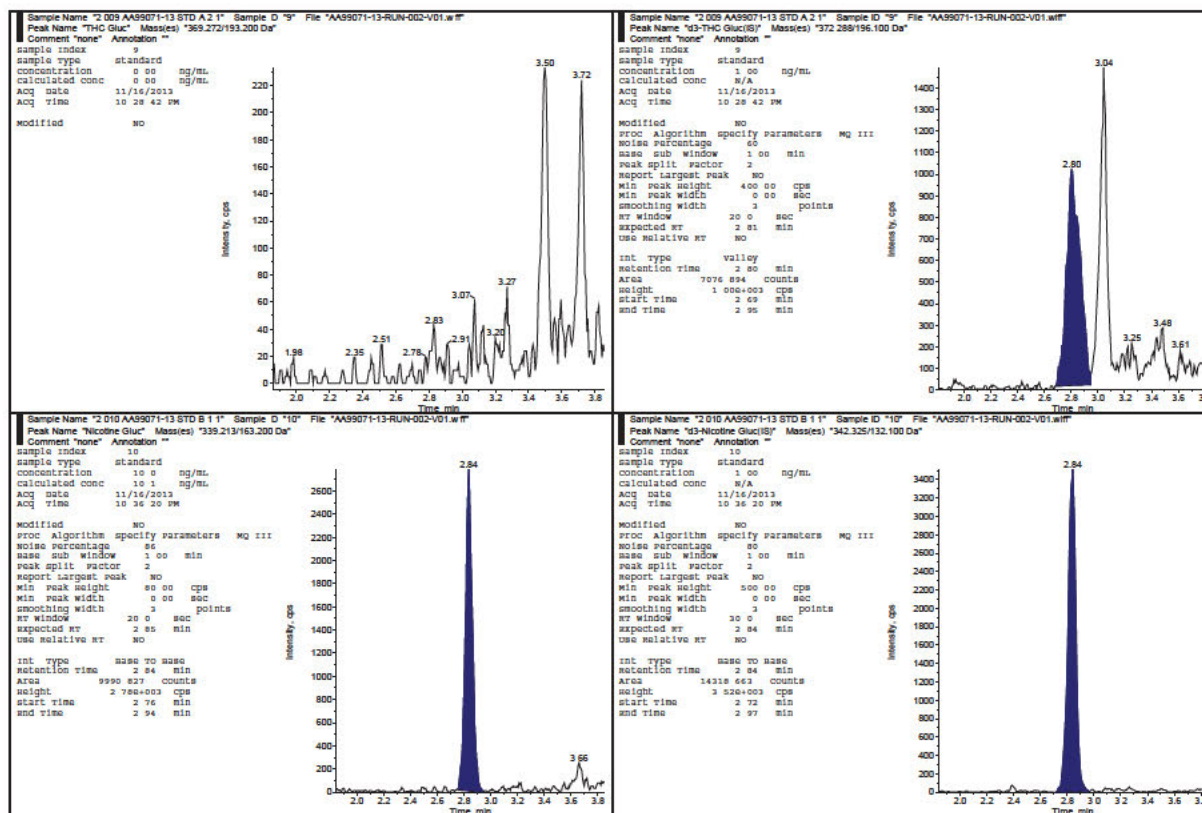


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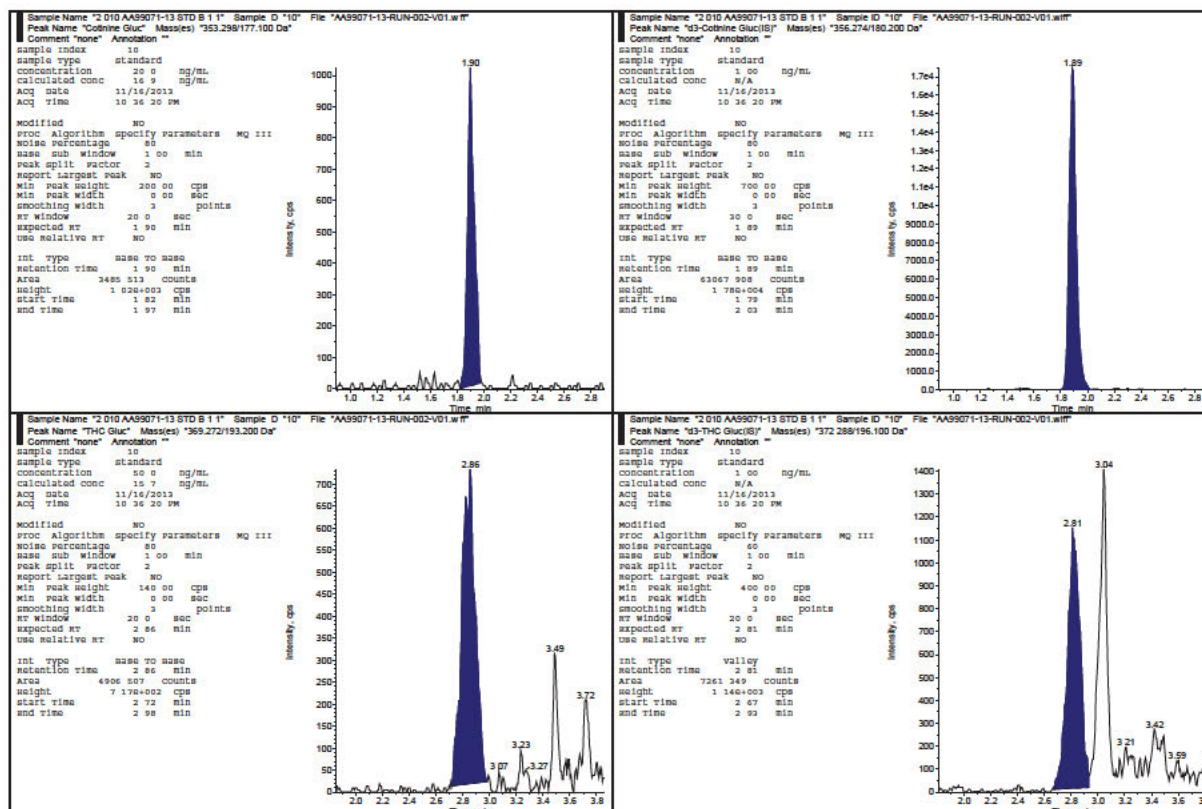


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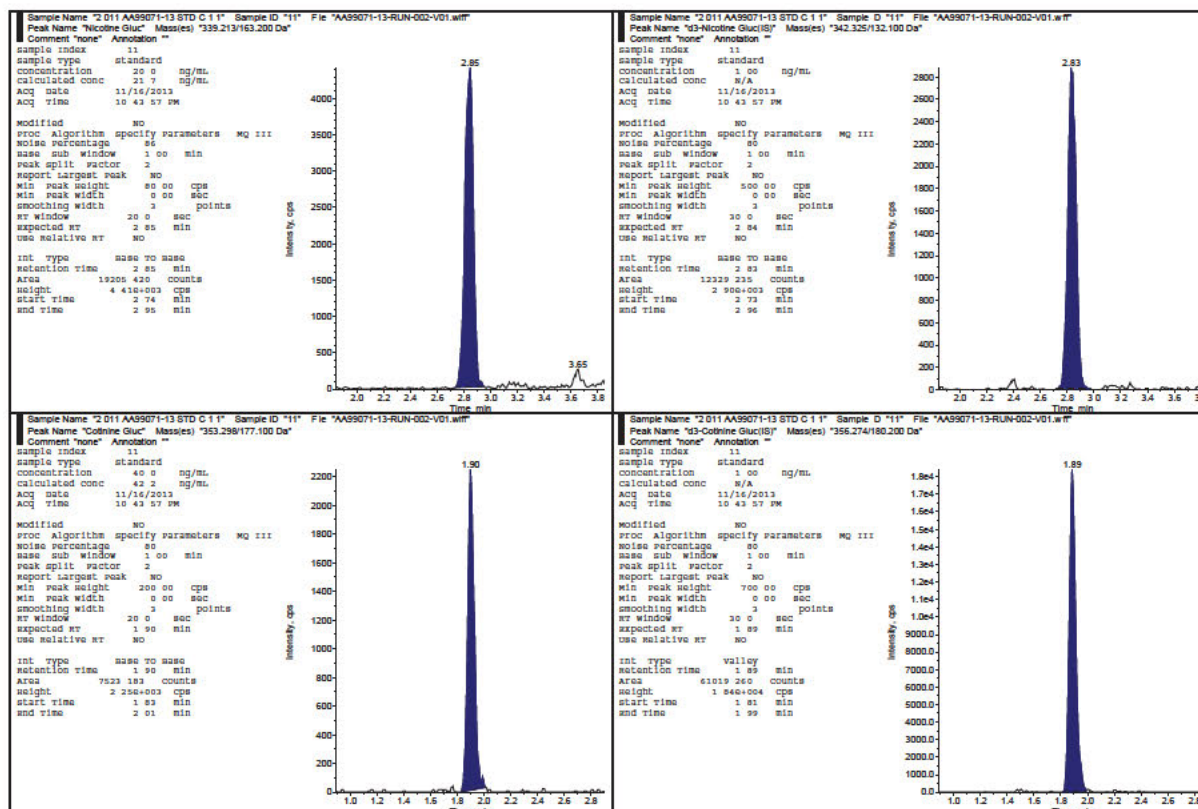


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Celerion Study AA99071-13



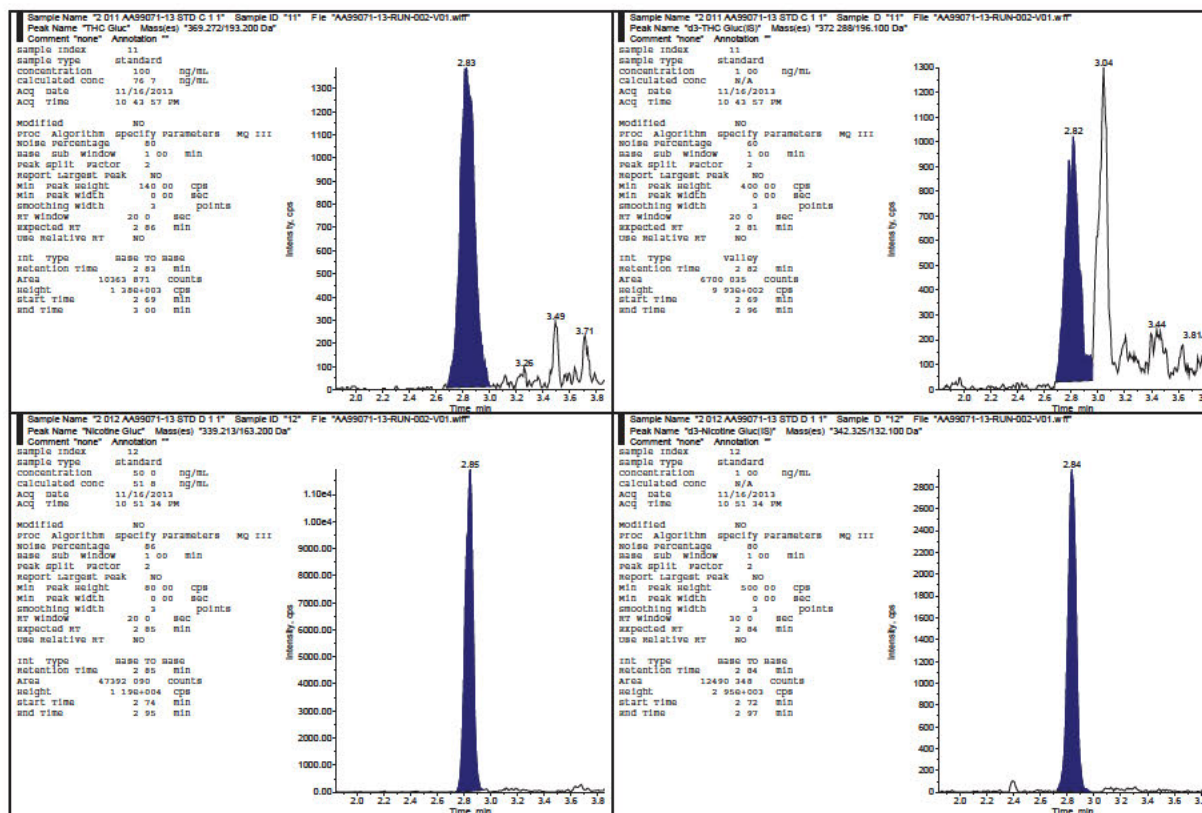


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Celerion Study AA99071-13



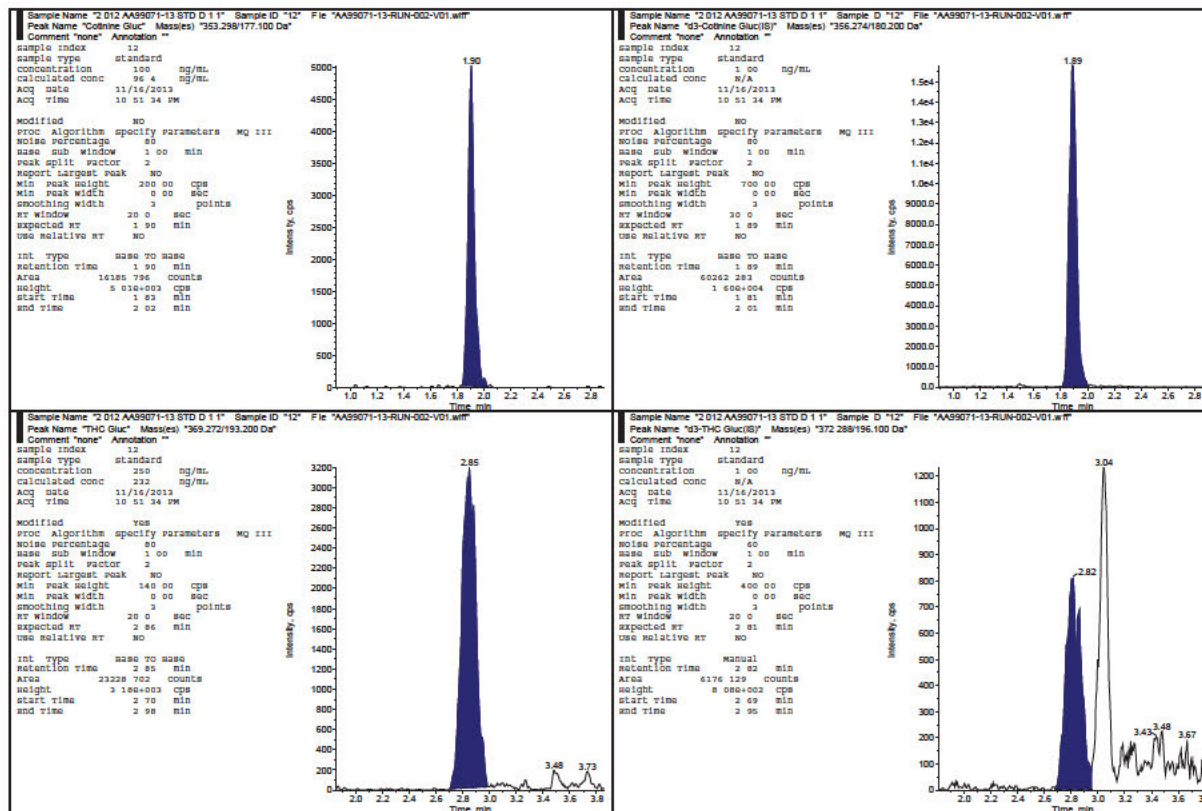


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Celerion Study AA99071-13



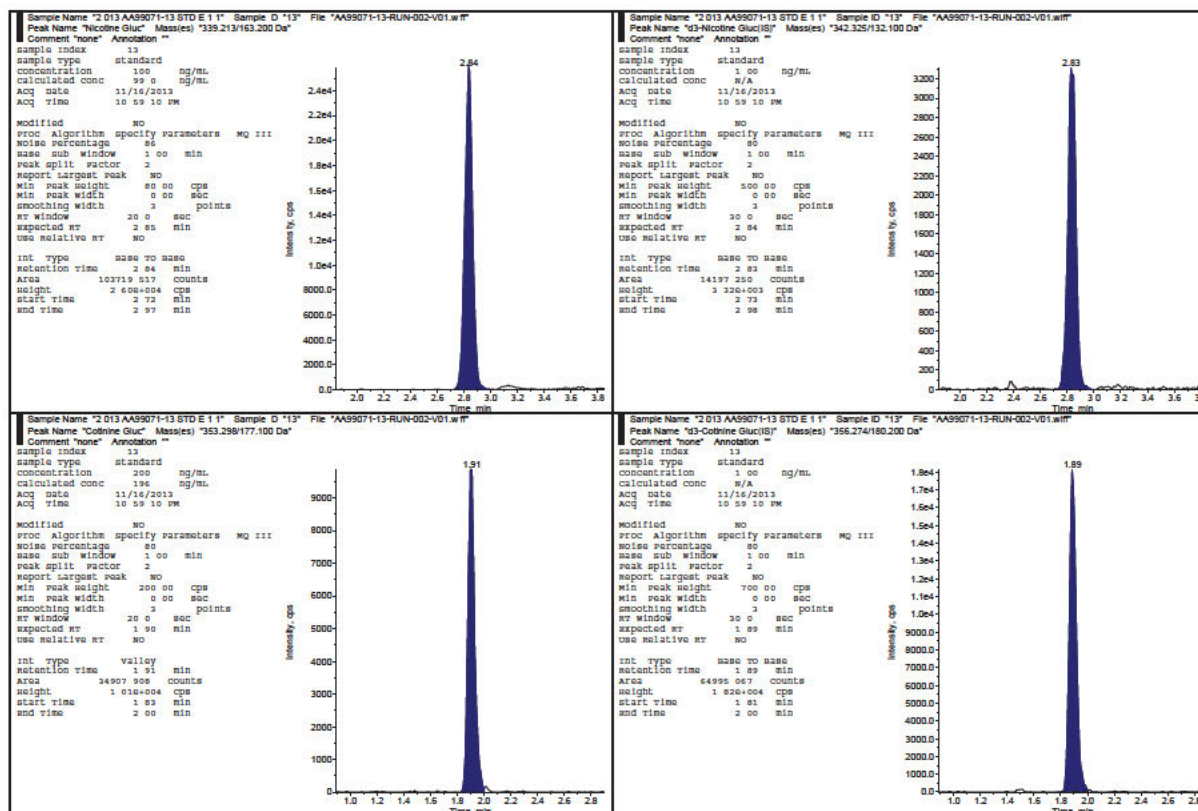


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Celerion Study AA99071-13



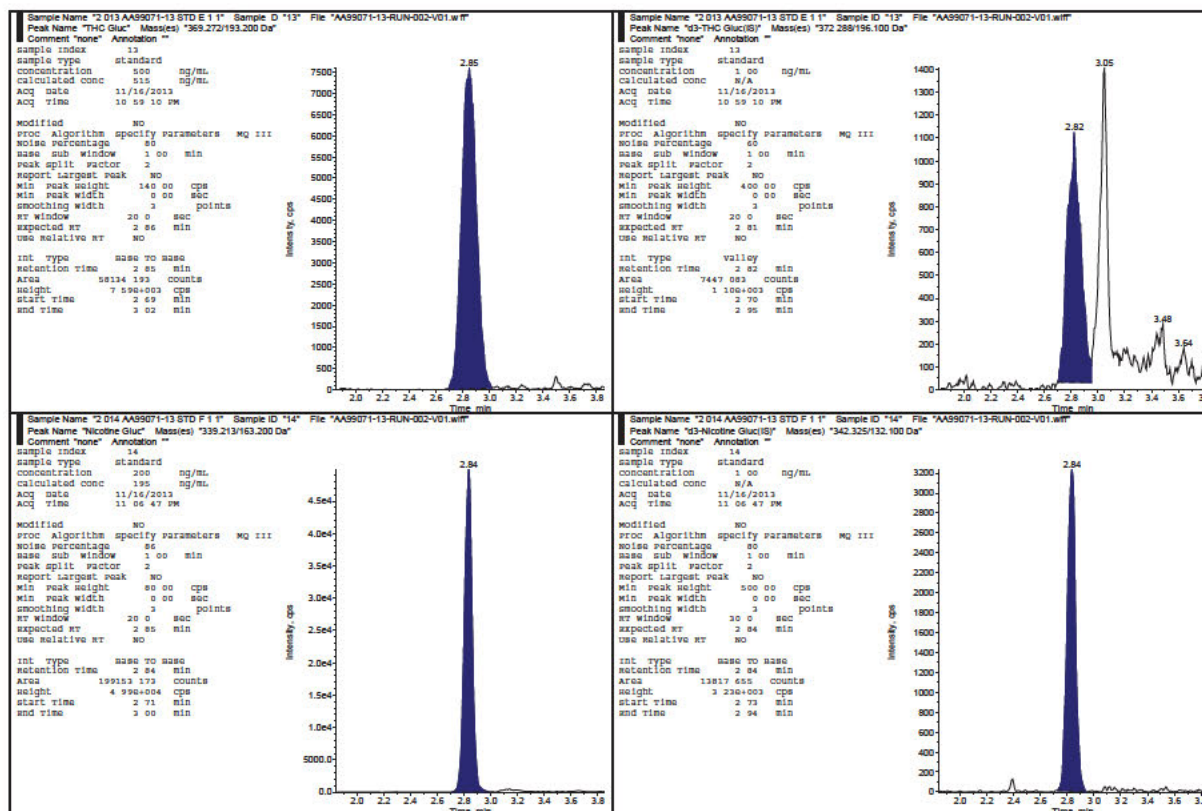


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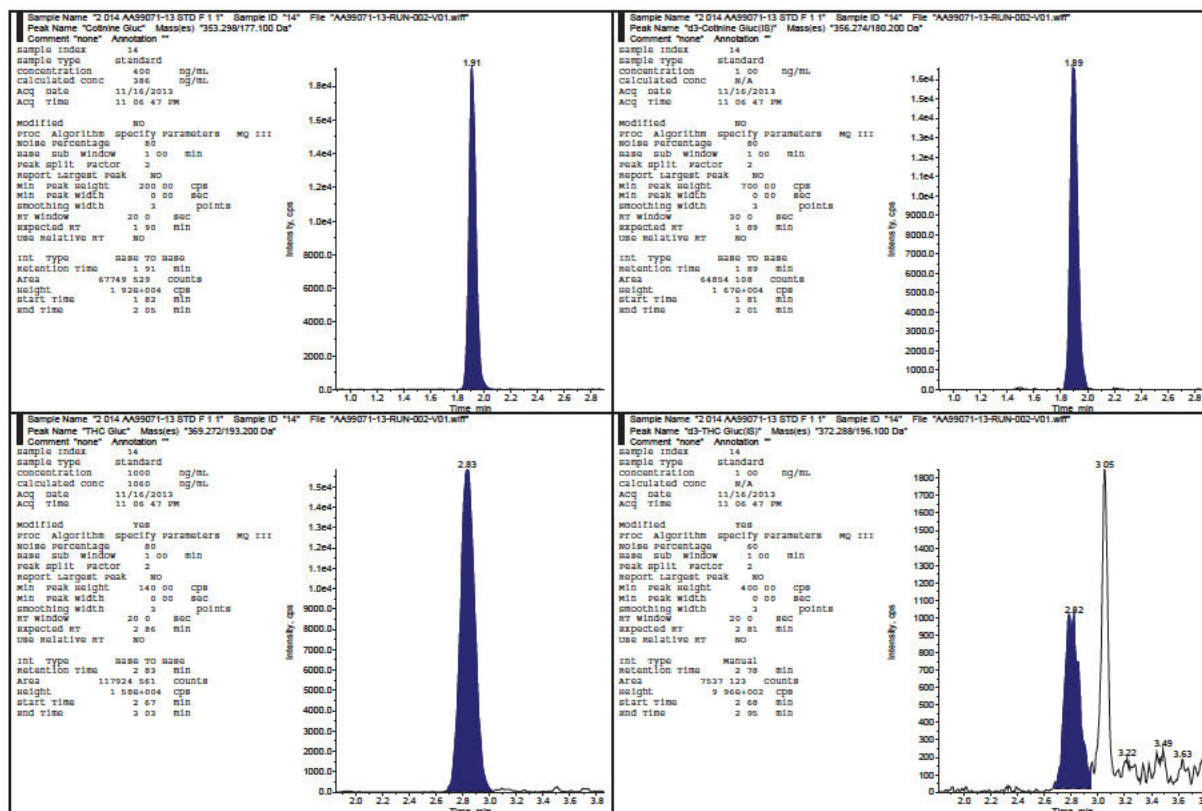


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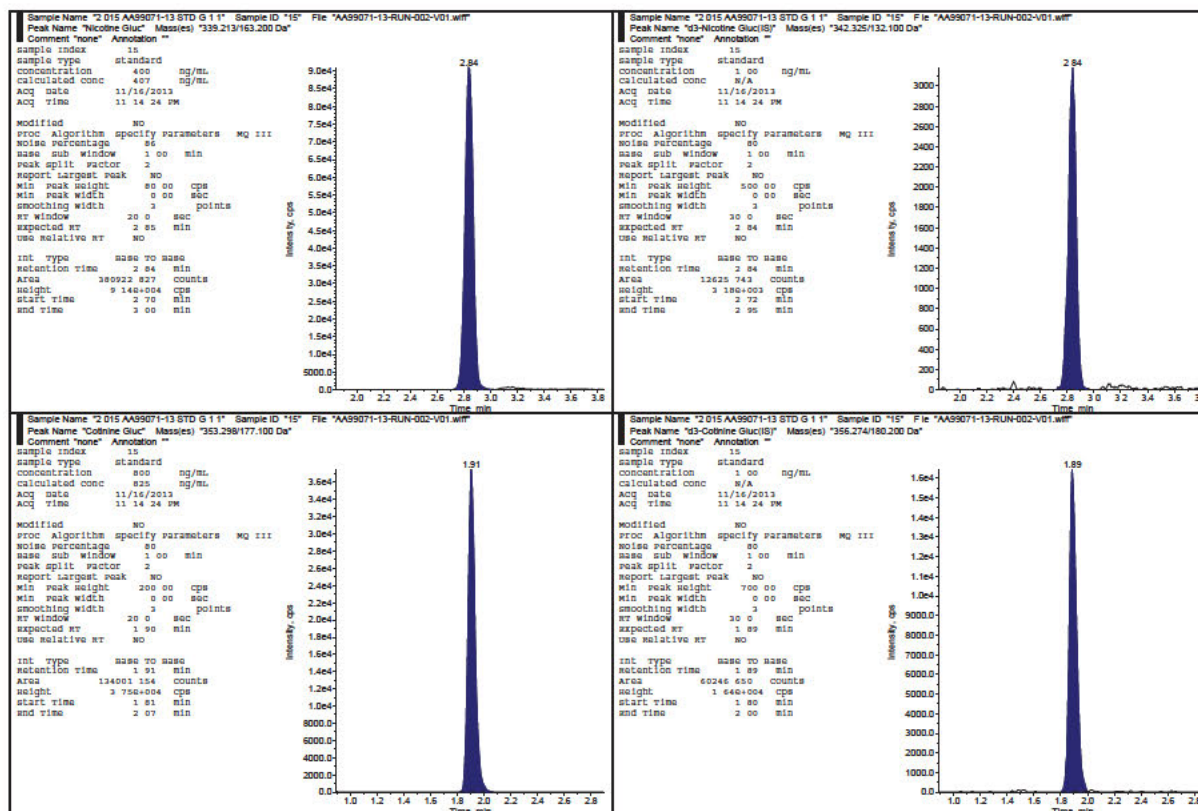


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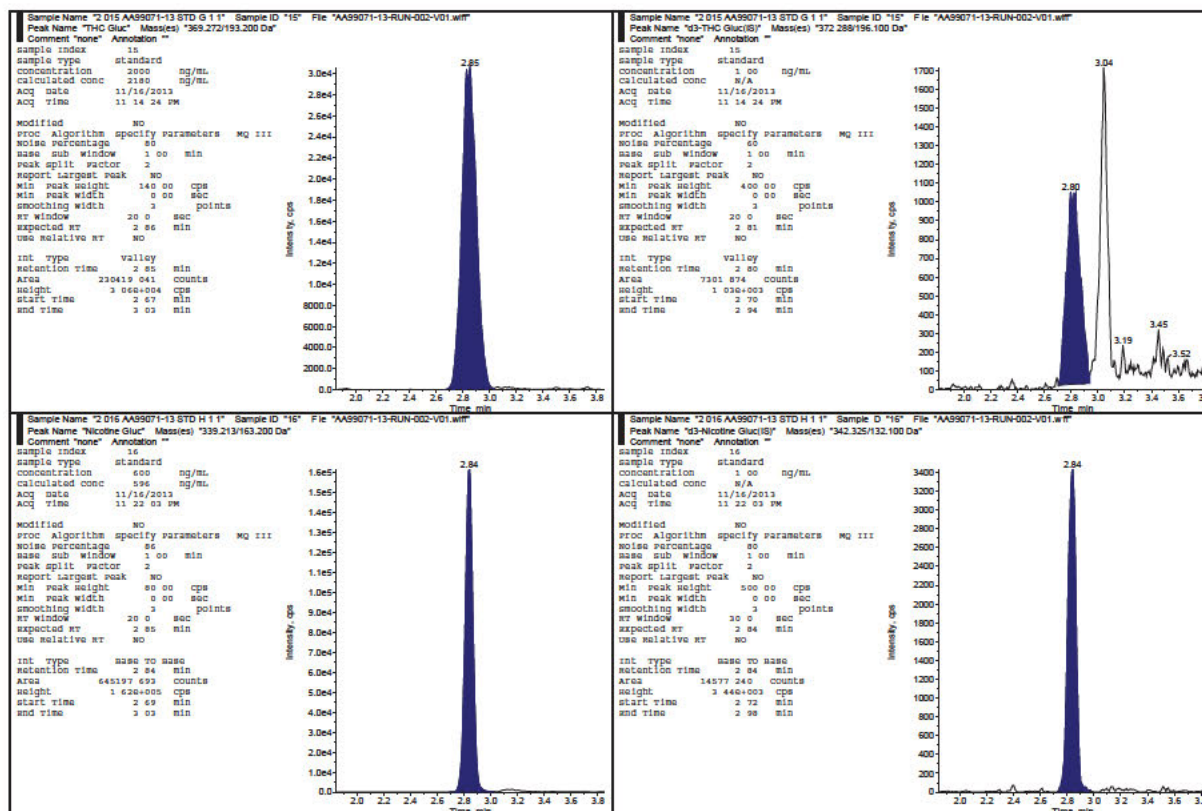


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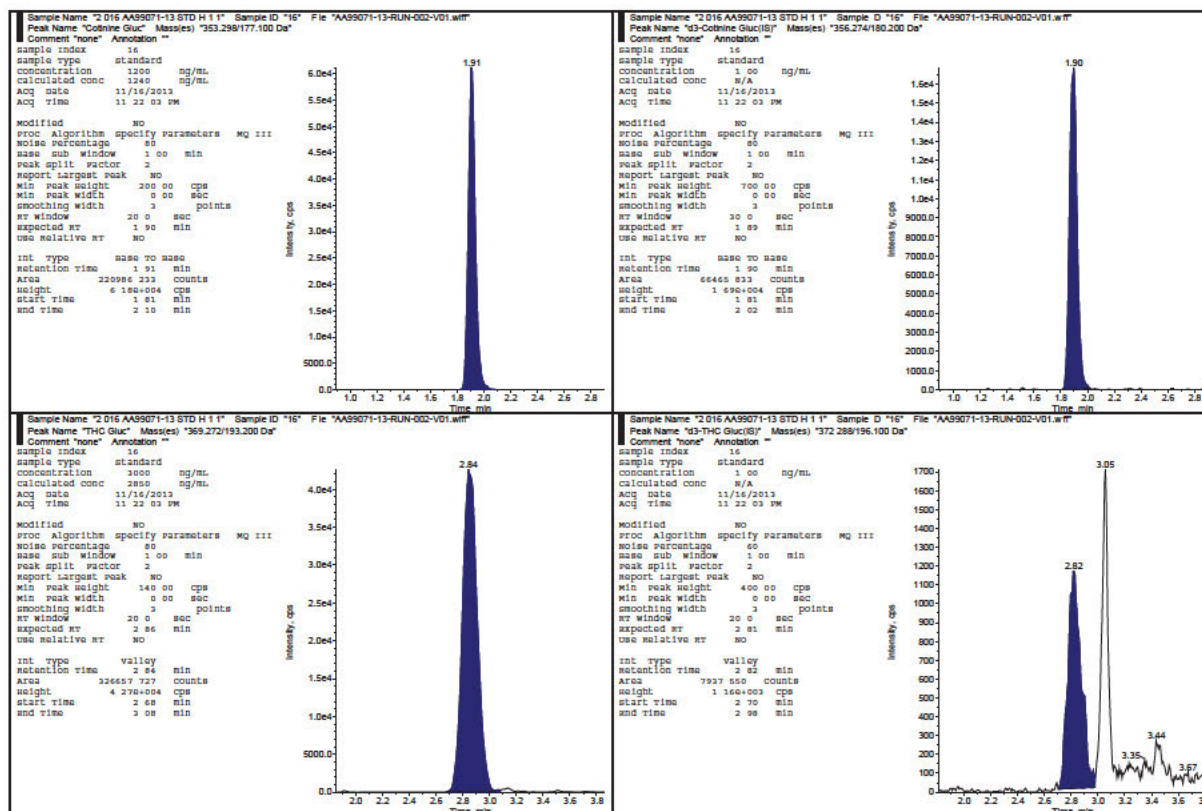


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Celerion Study AA99071-13



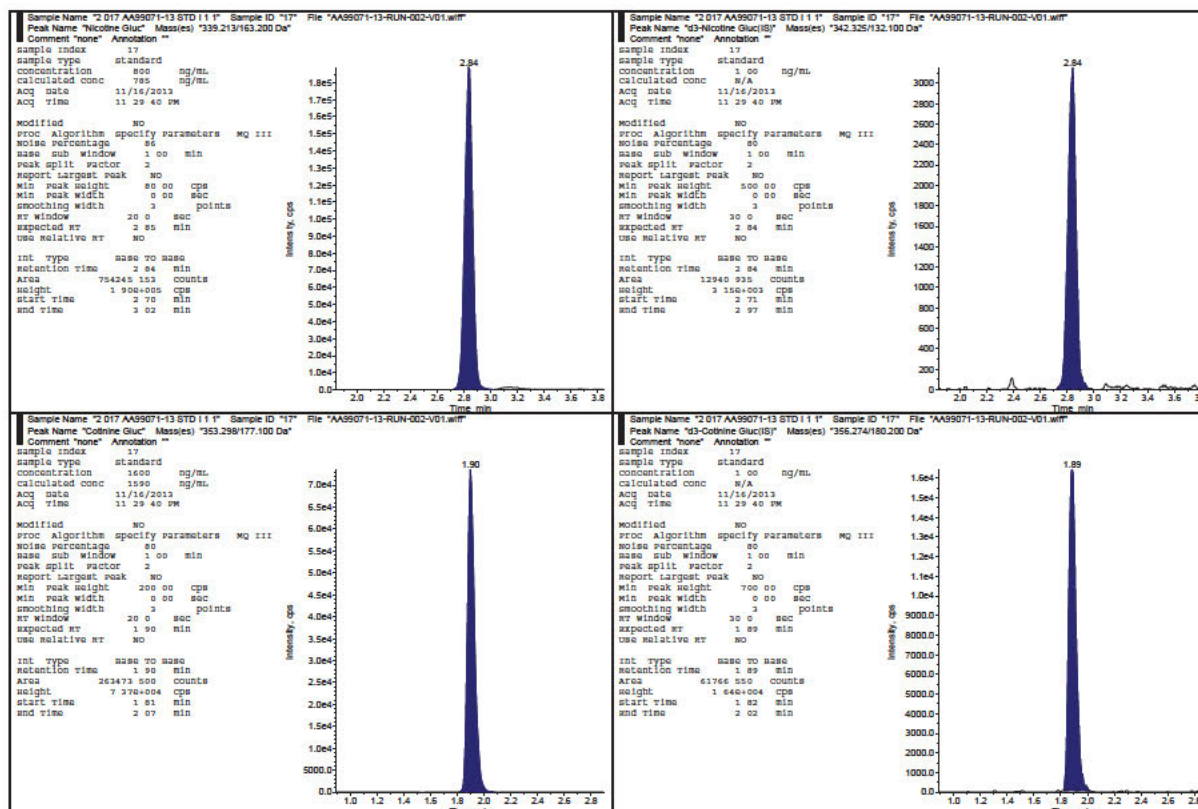


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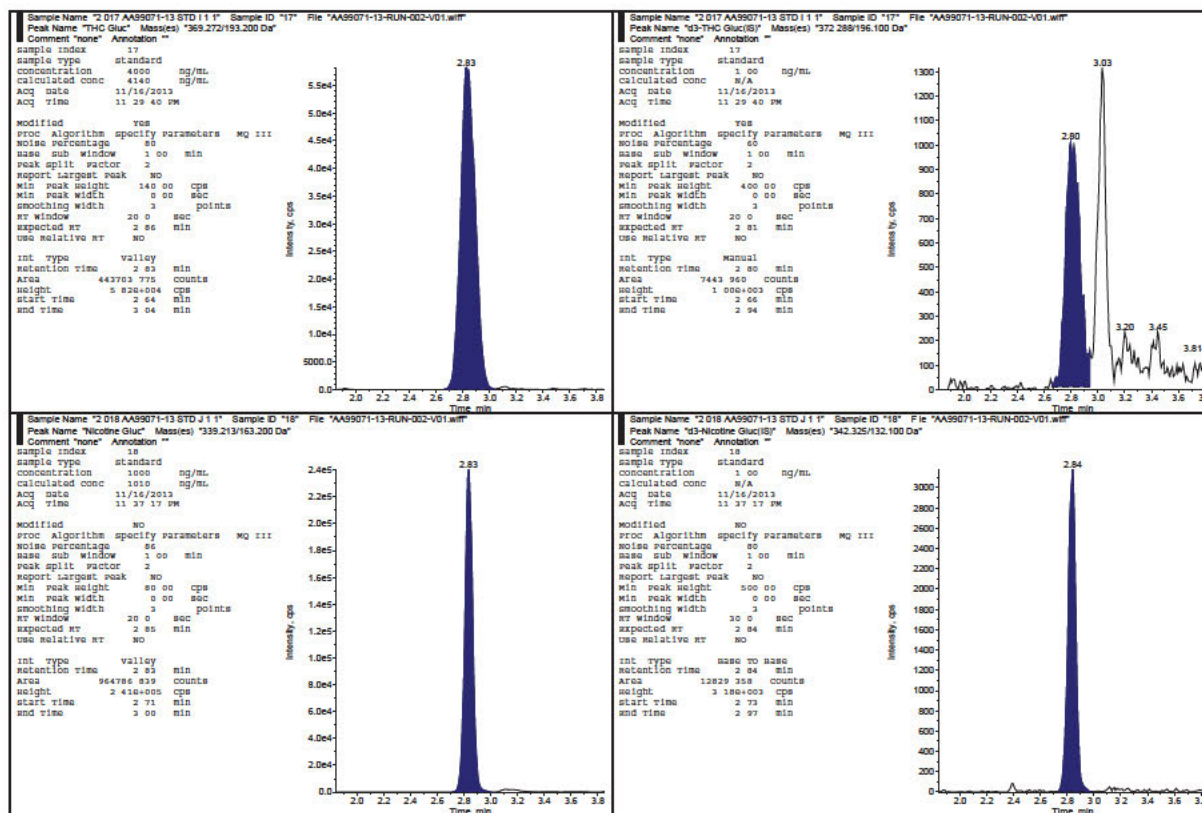


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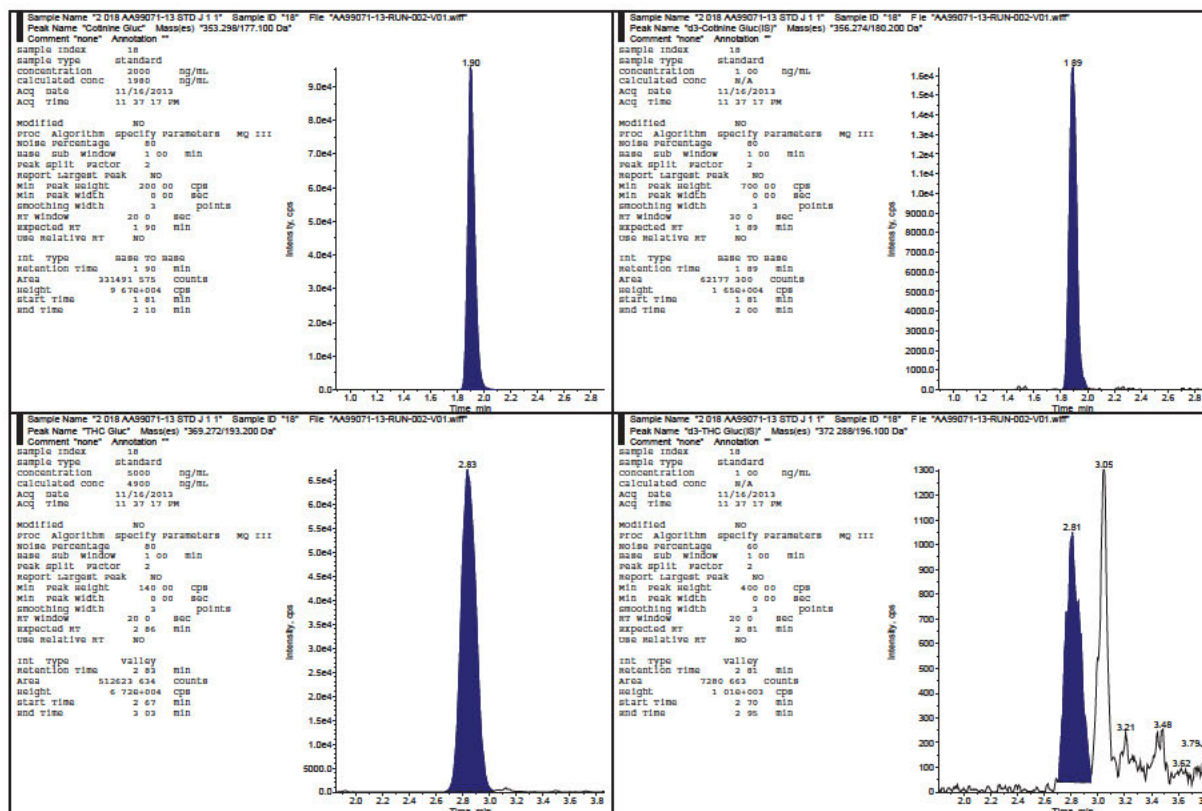


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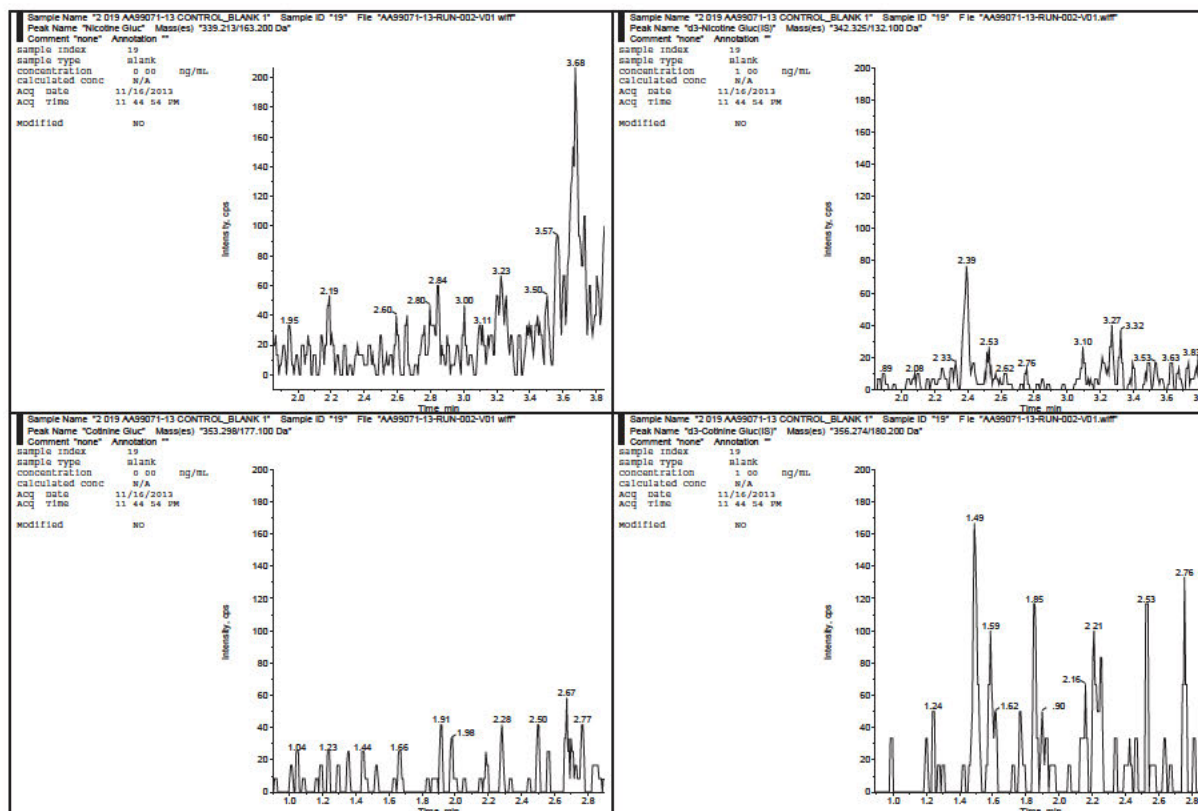


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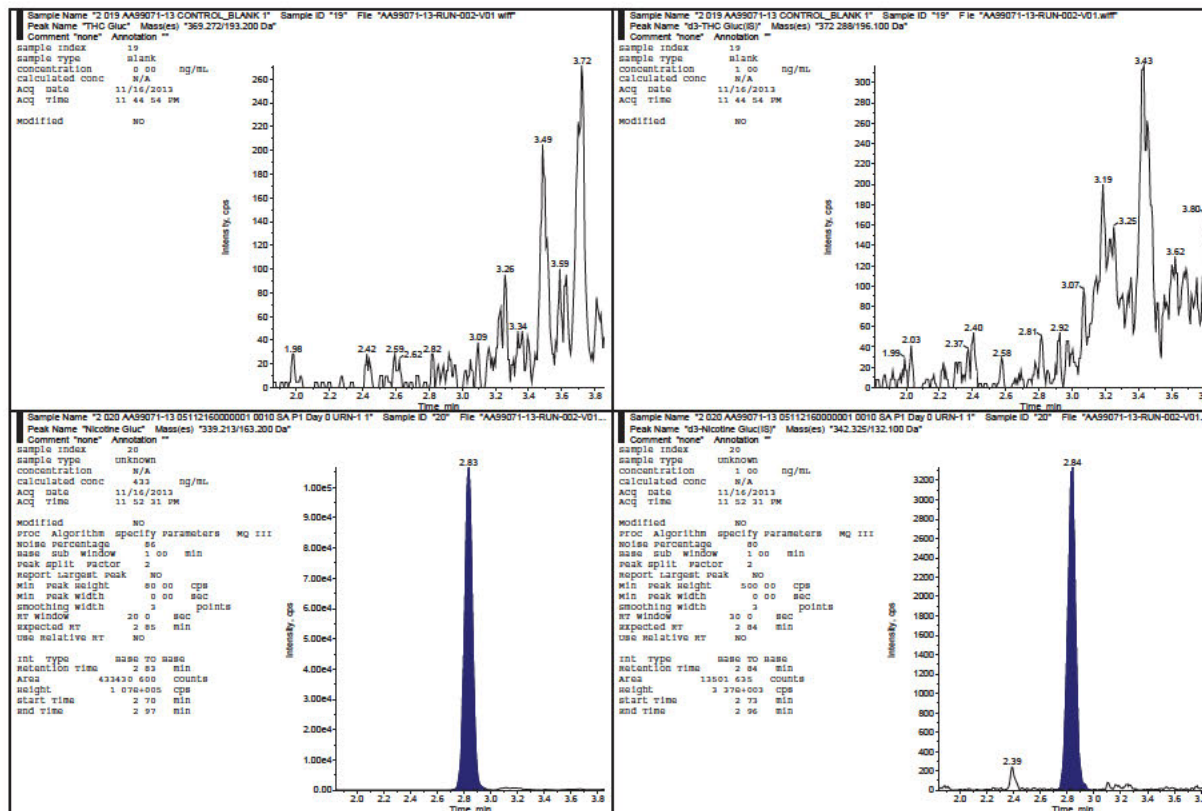


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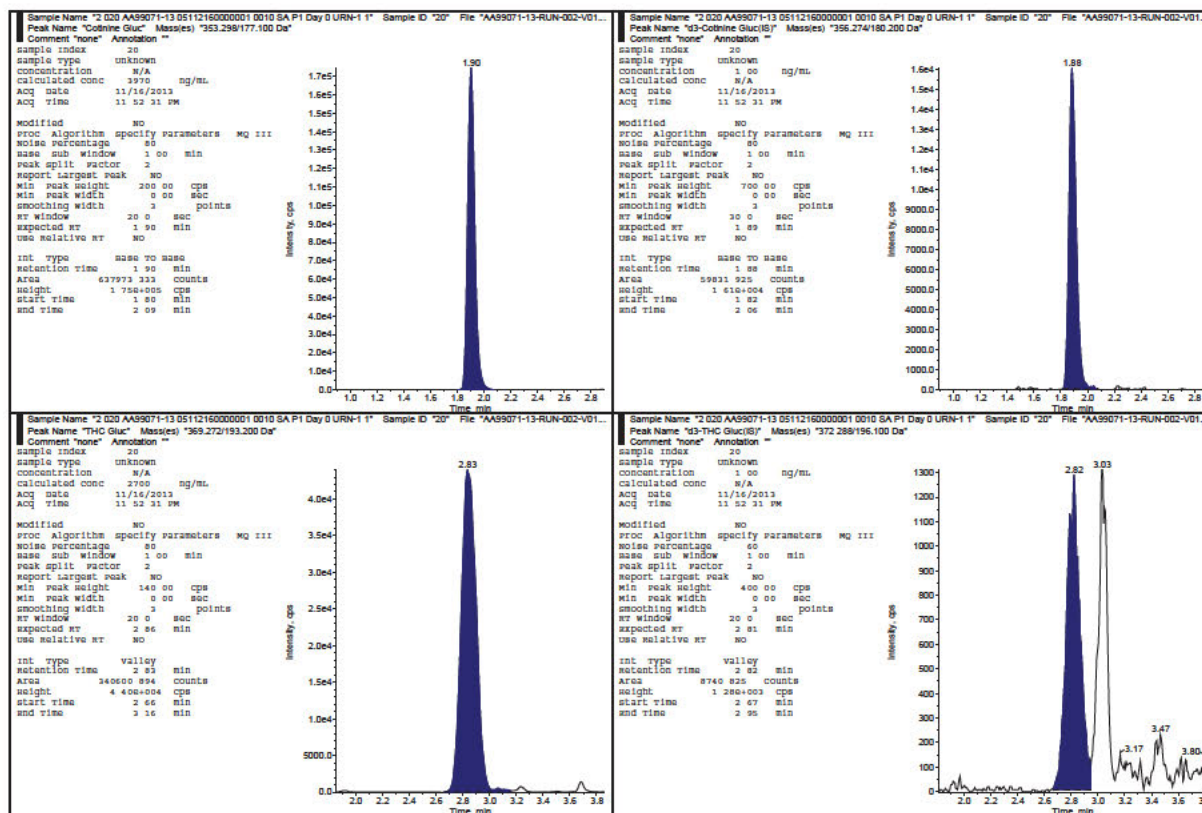


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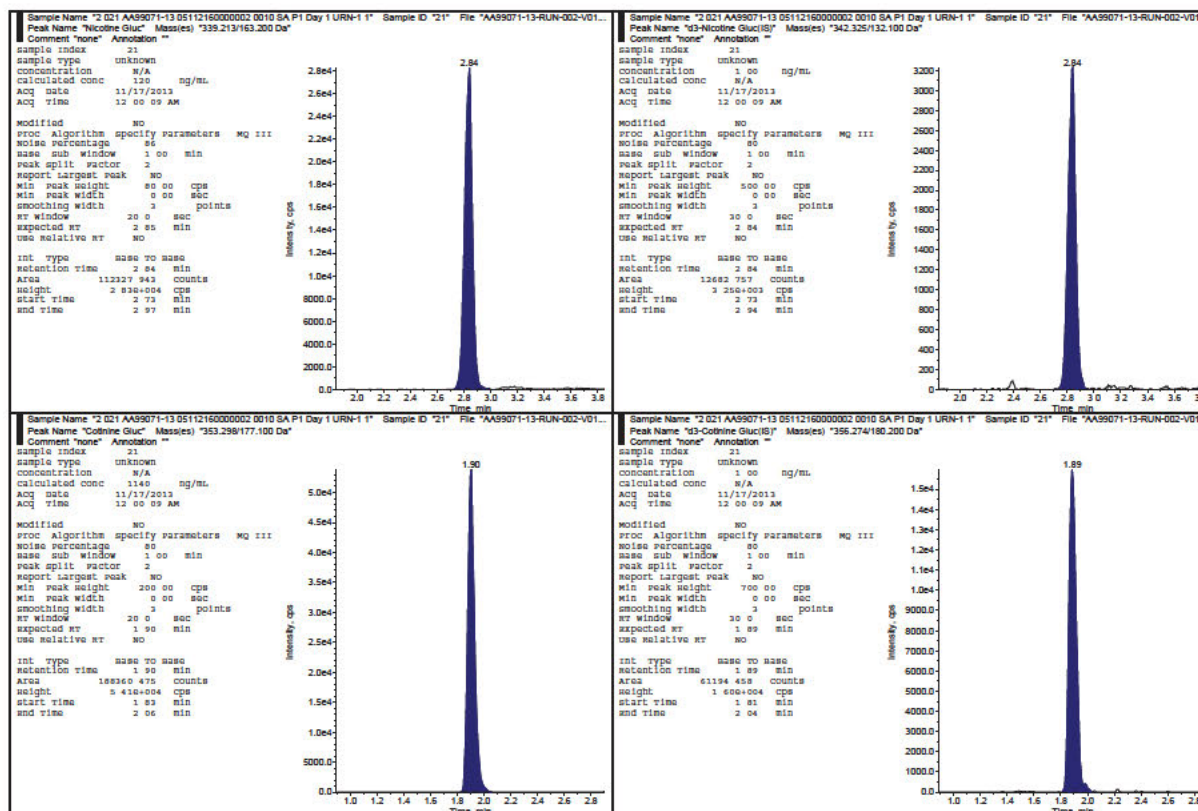


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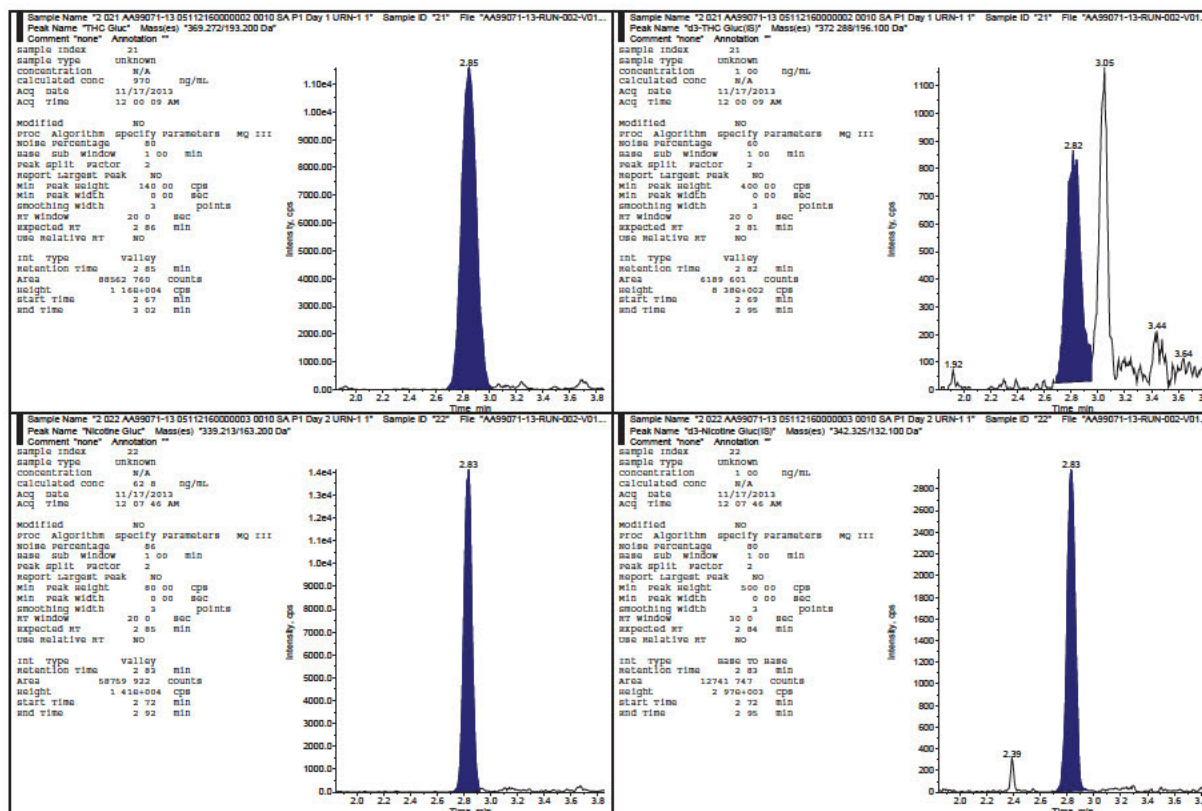


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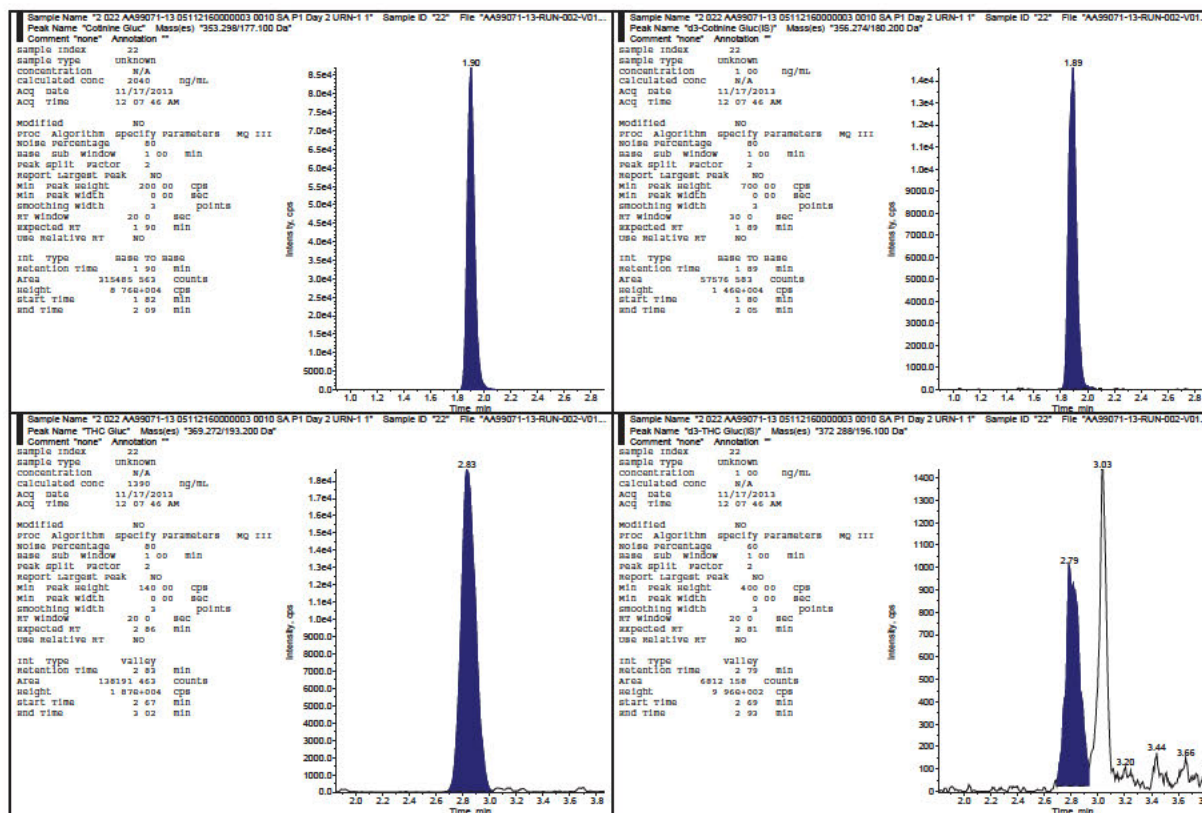


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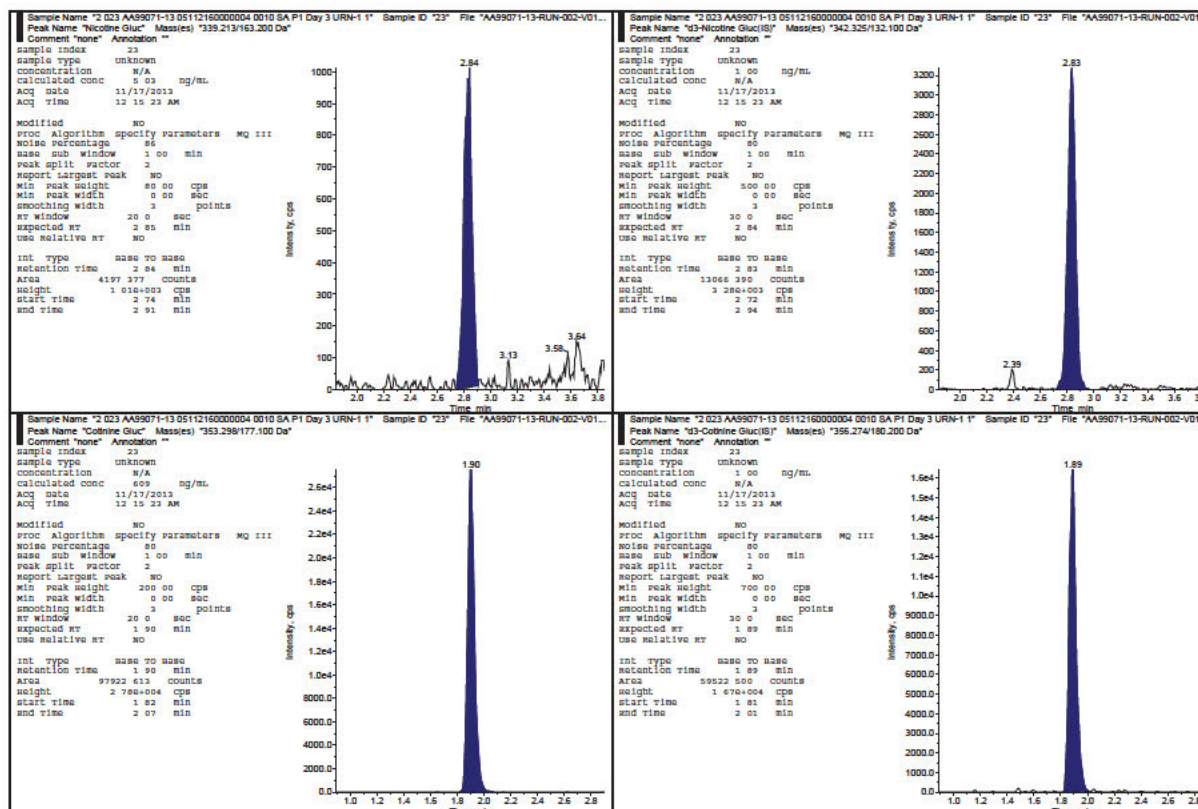


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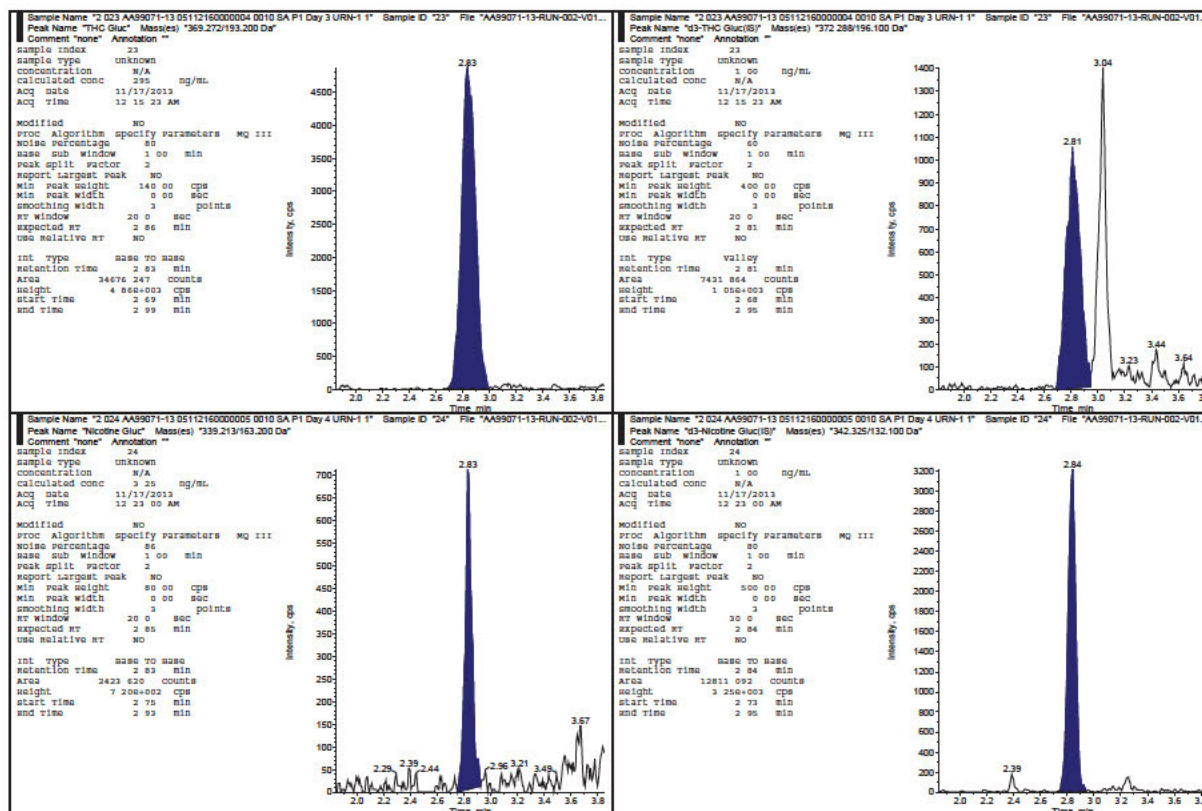


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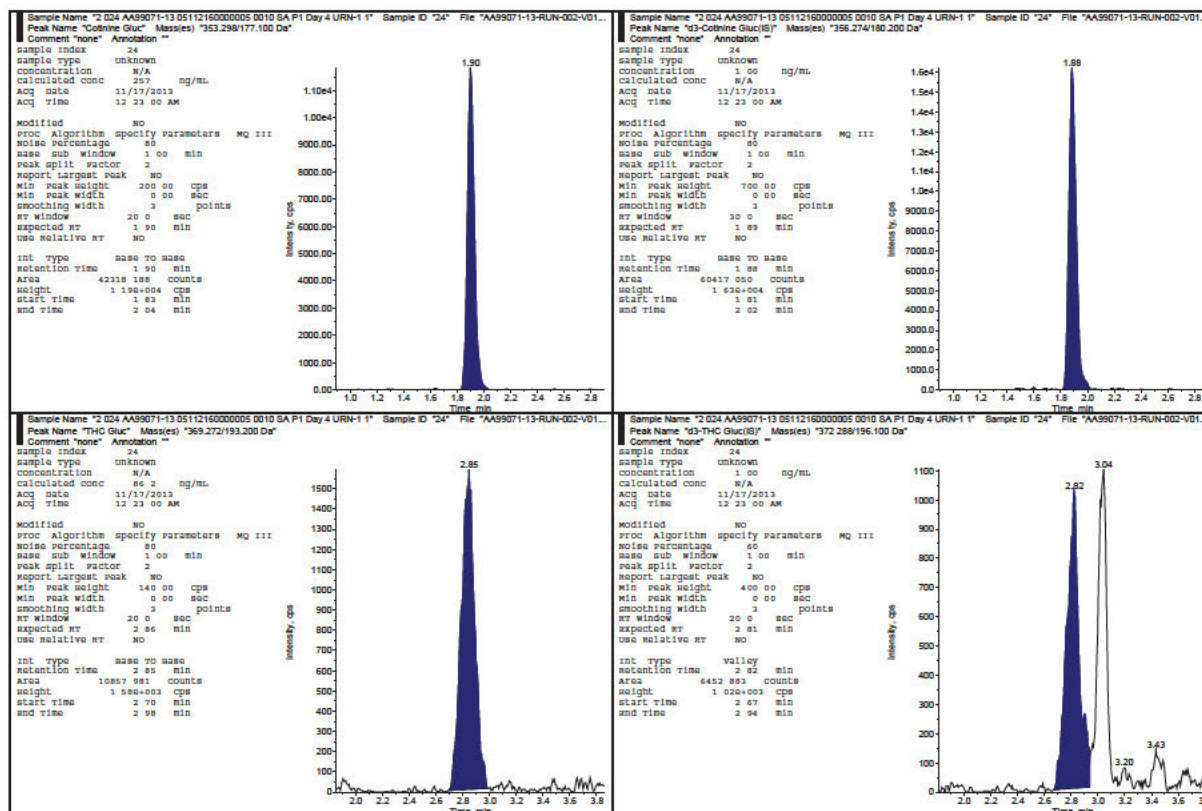


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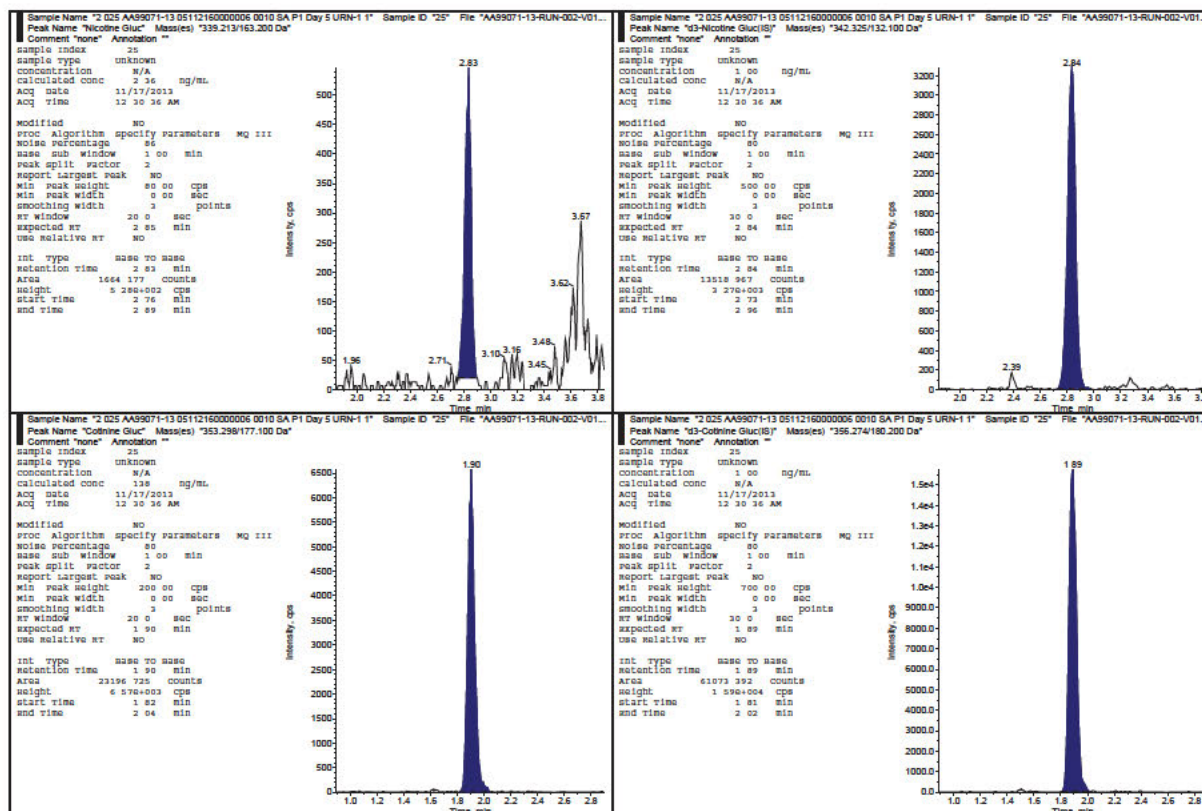


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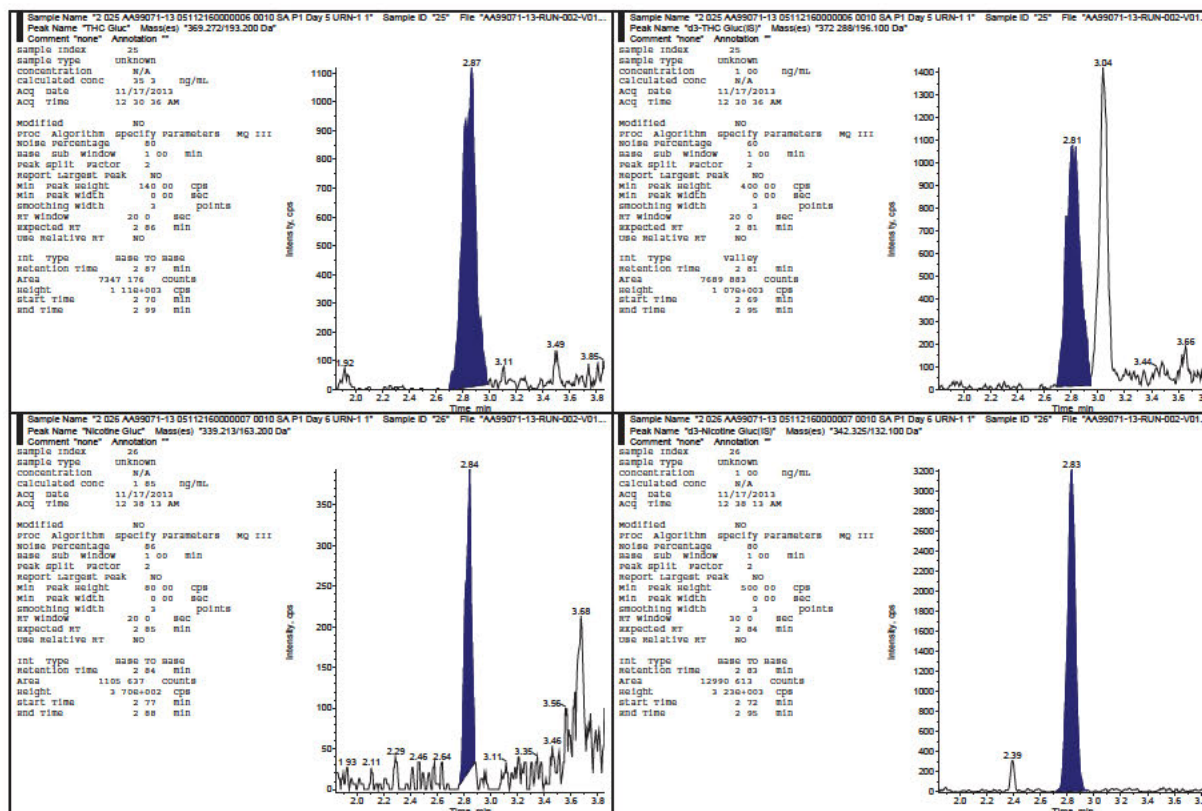


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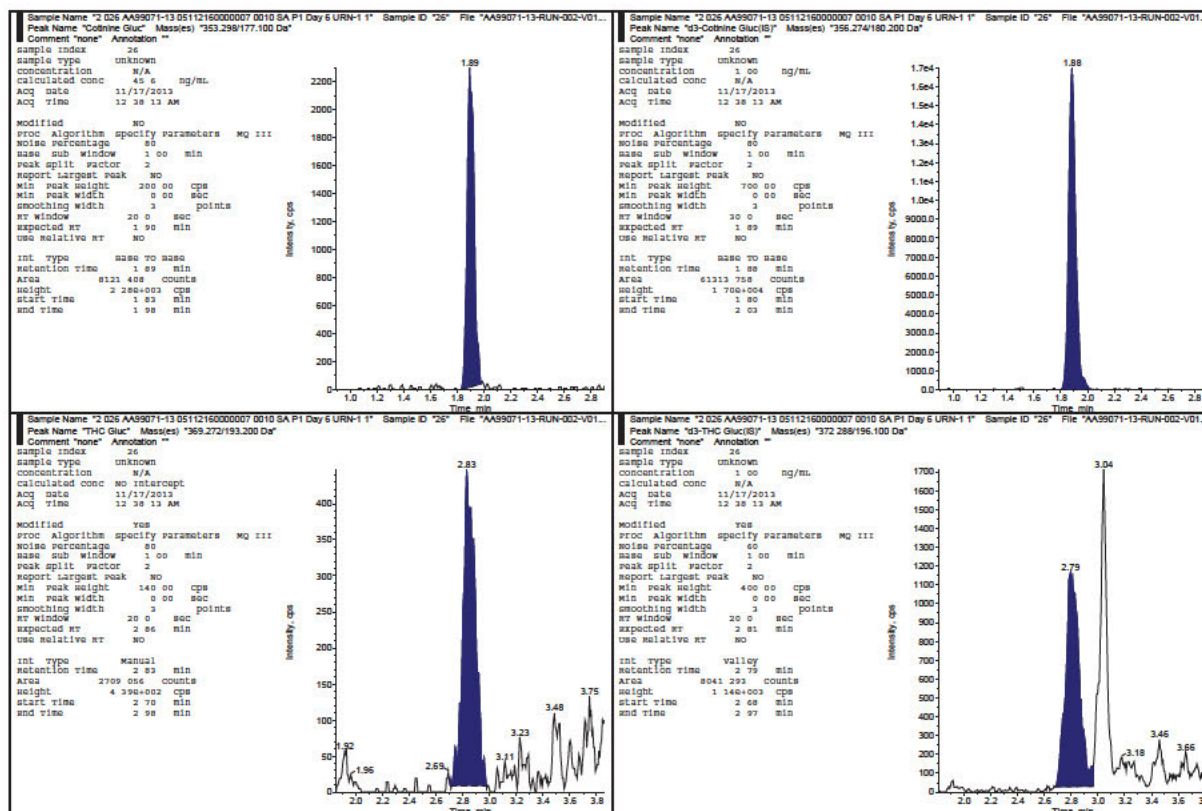


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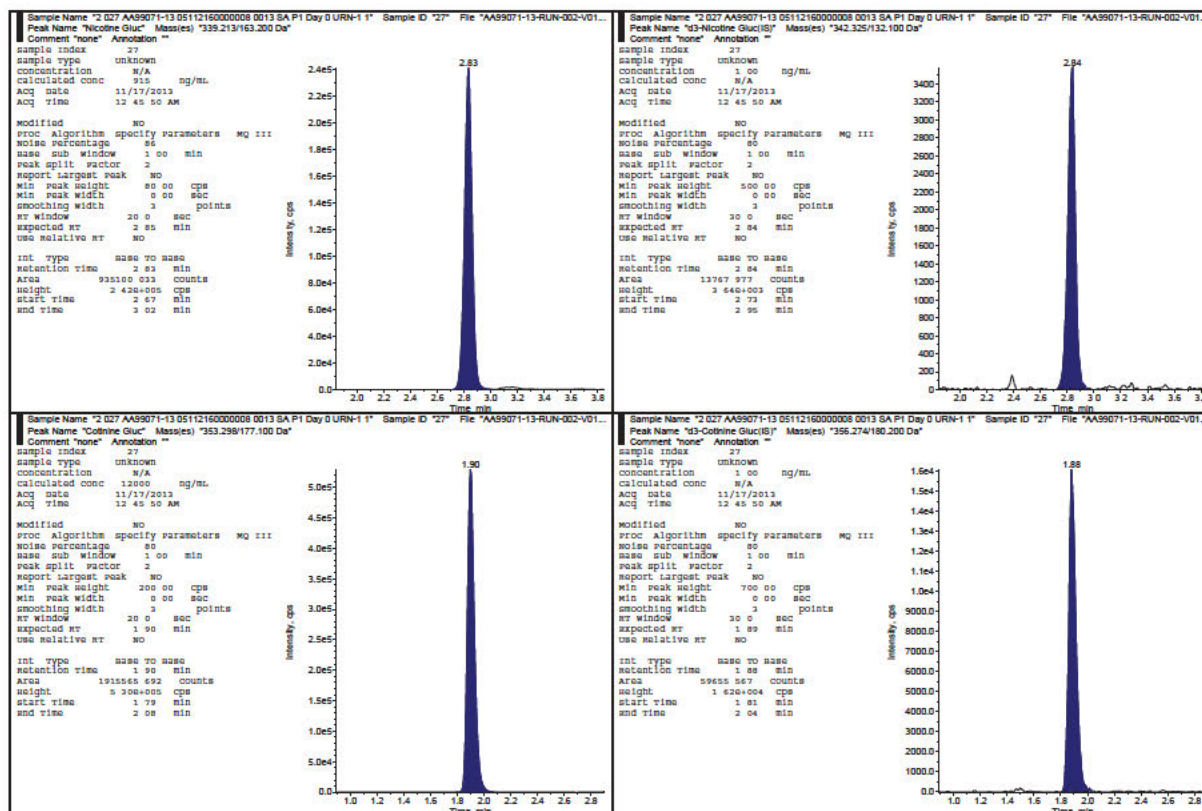


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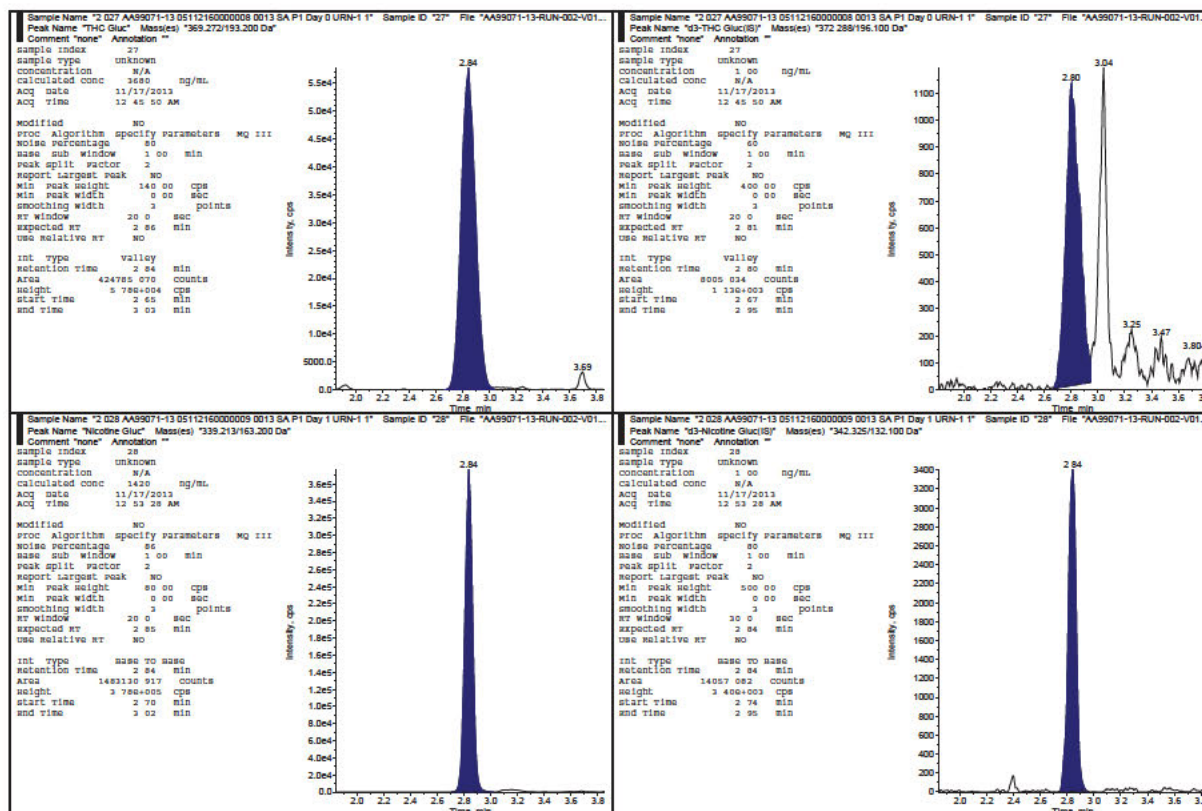


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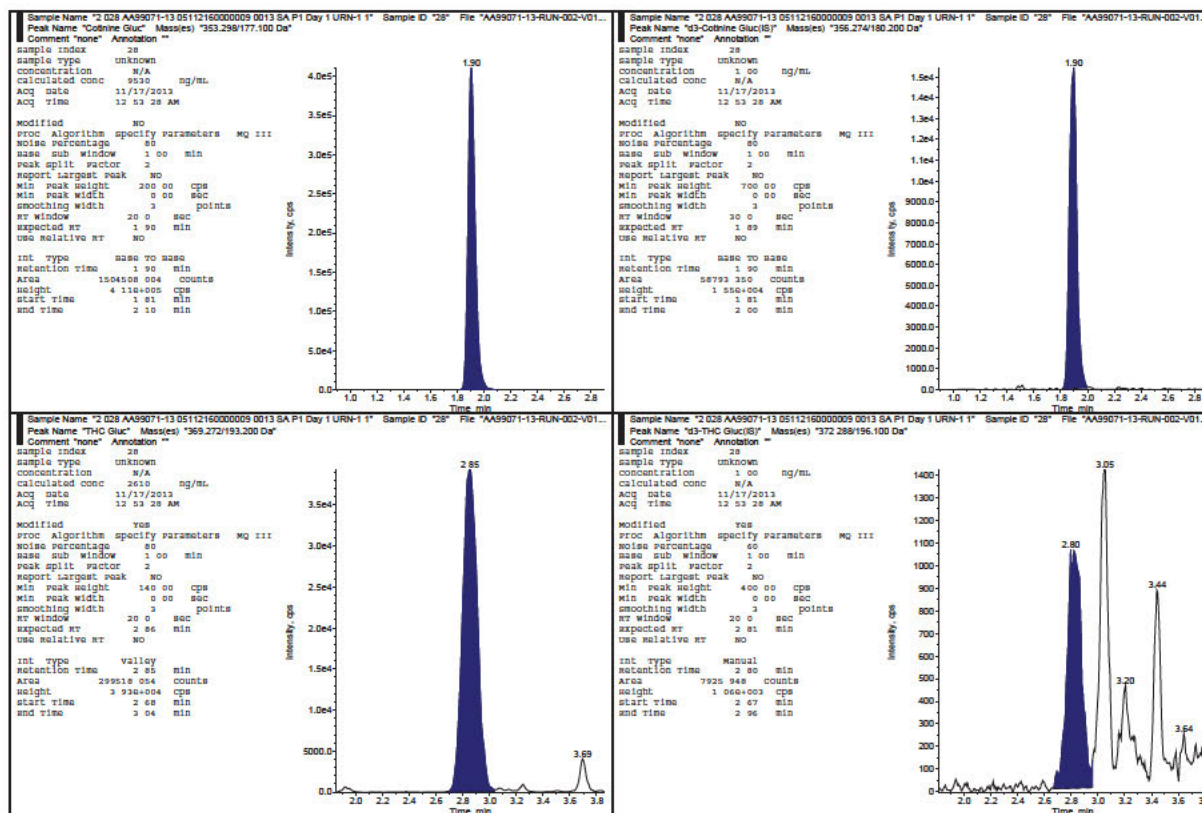


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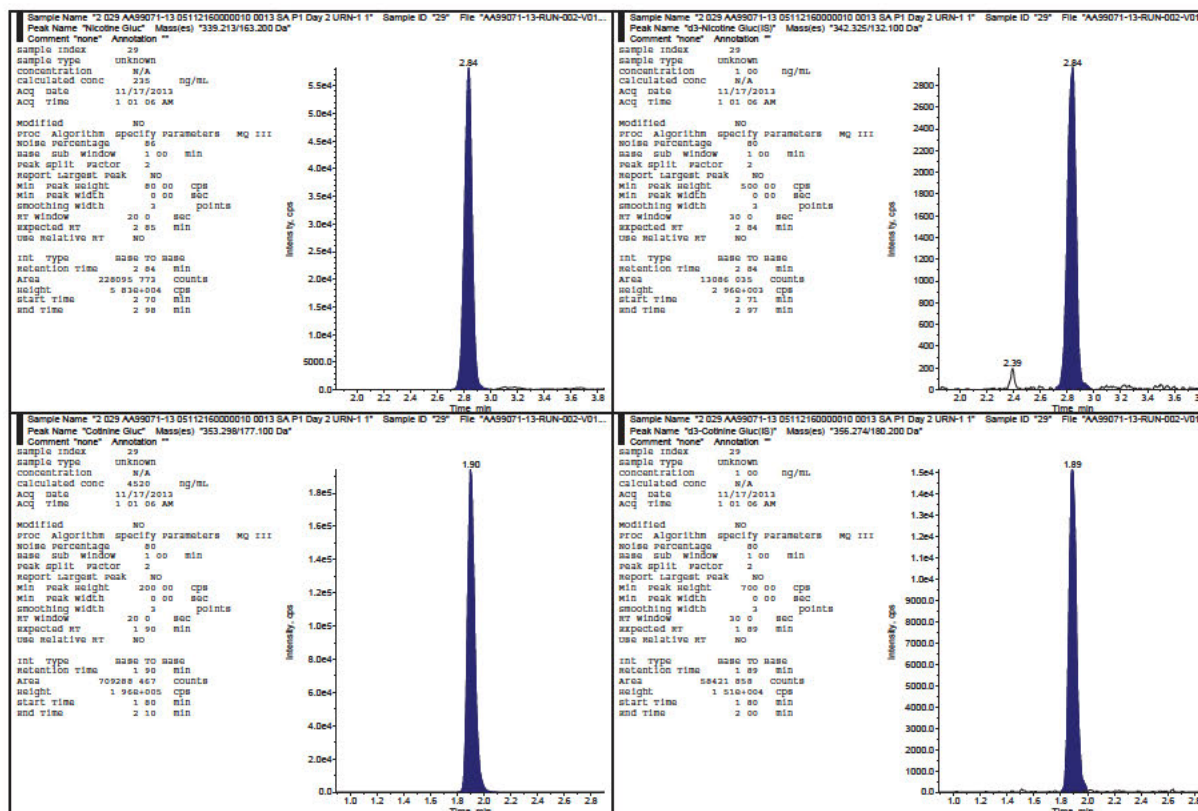


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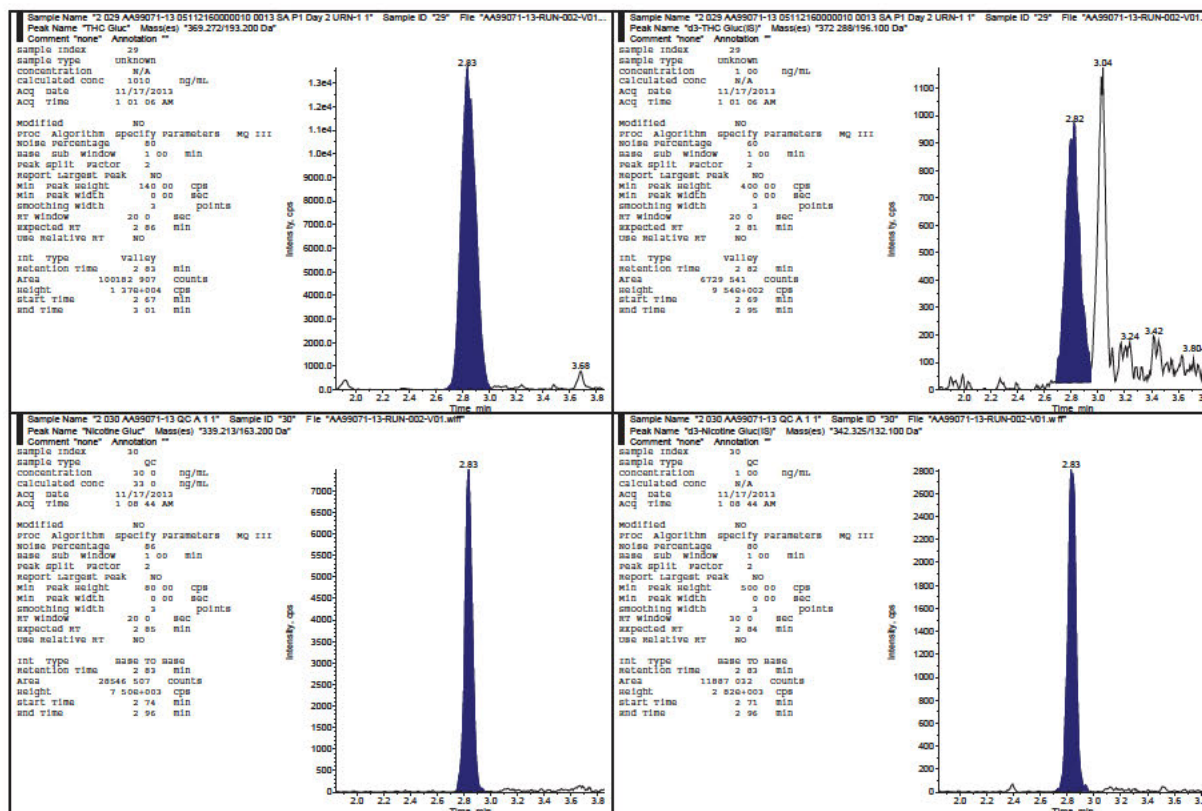


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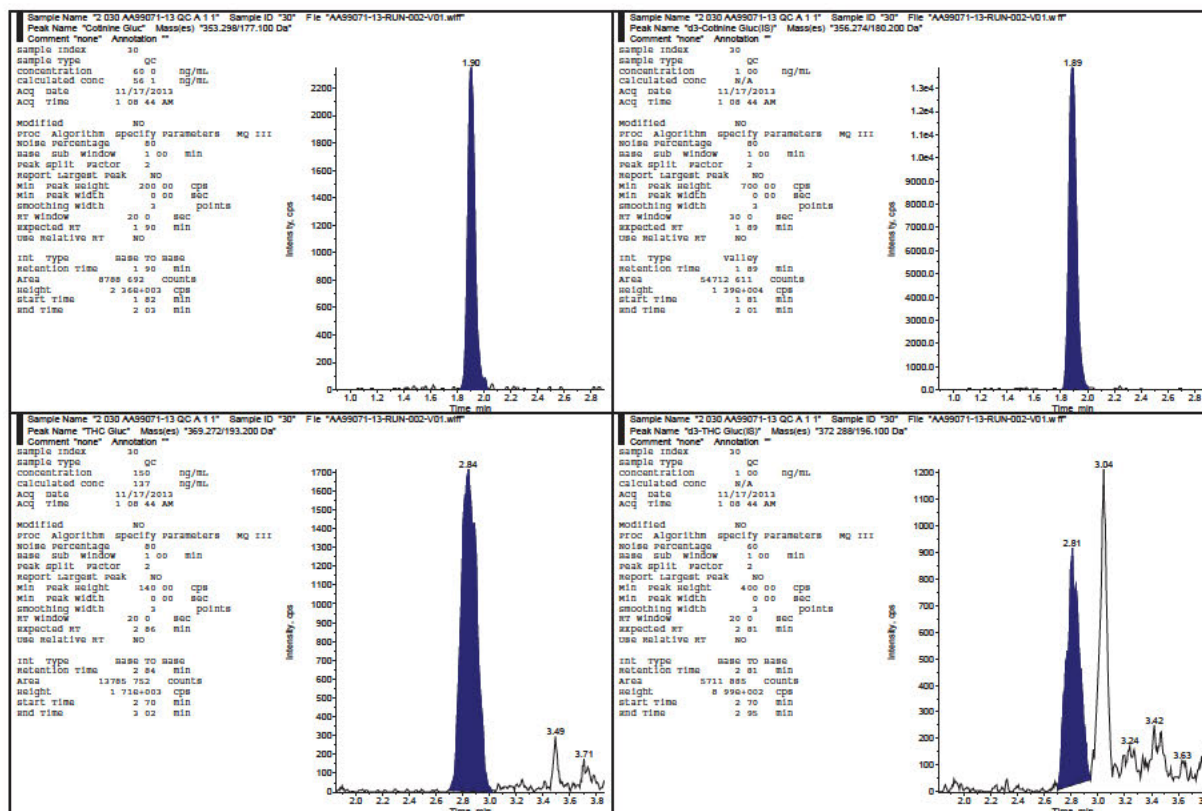


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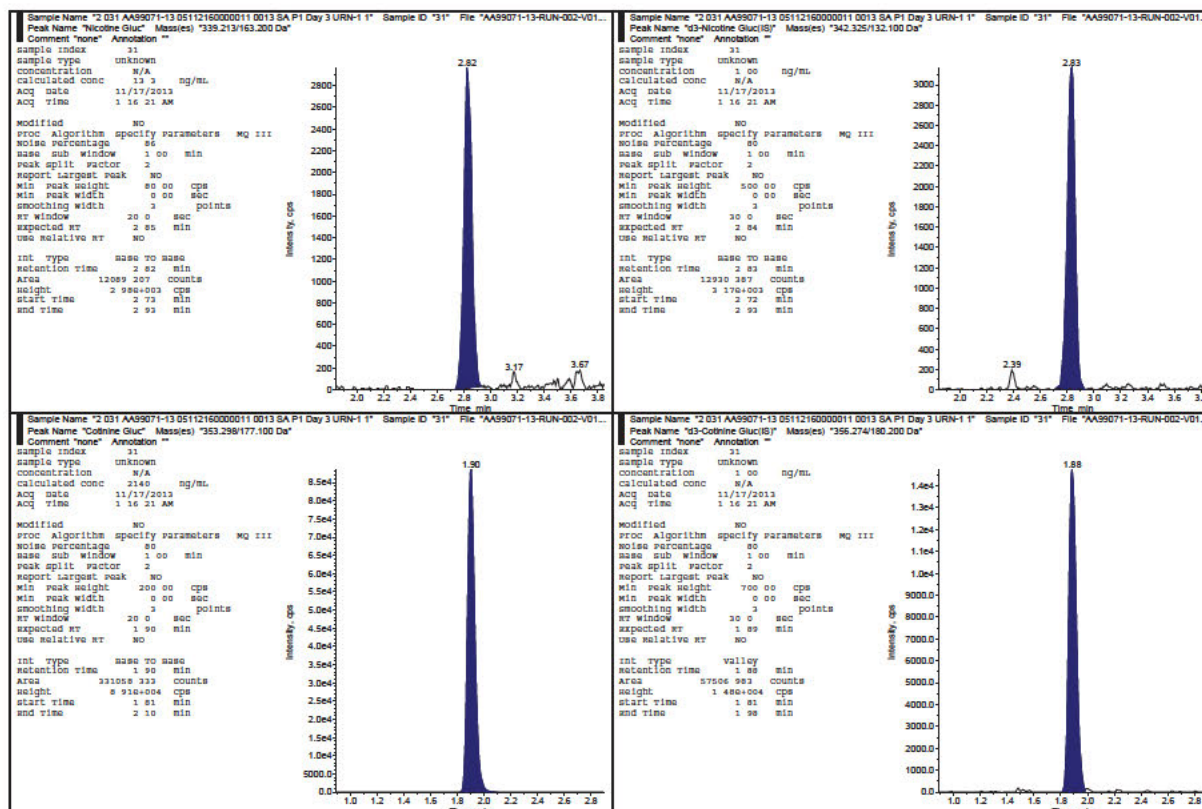


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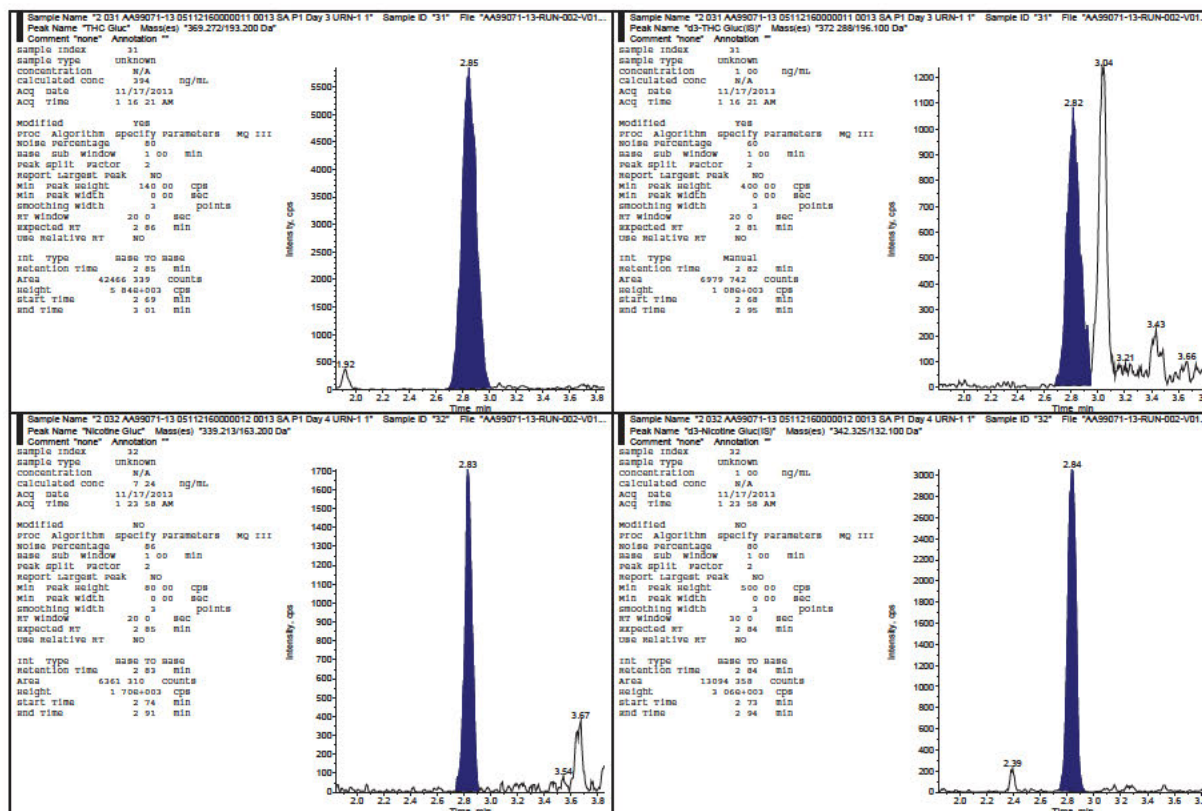


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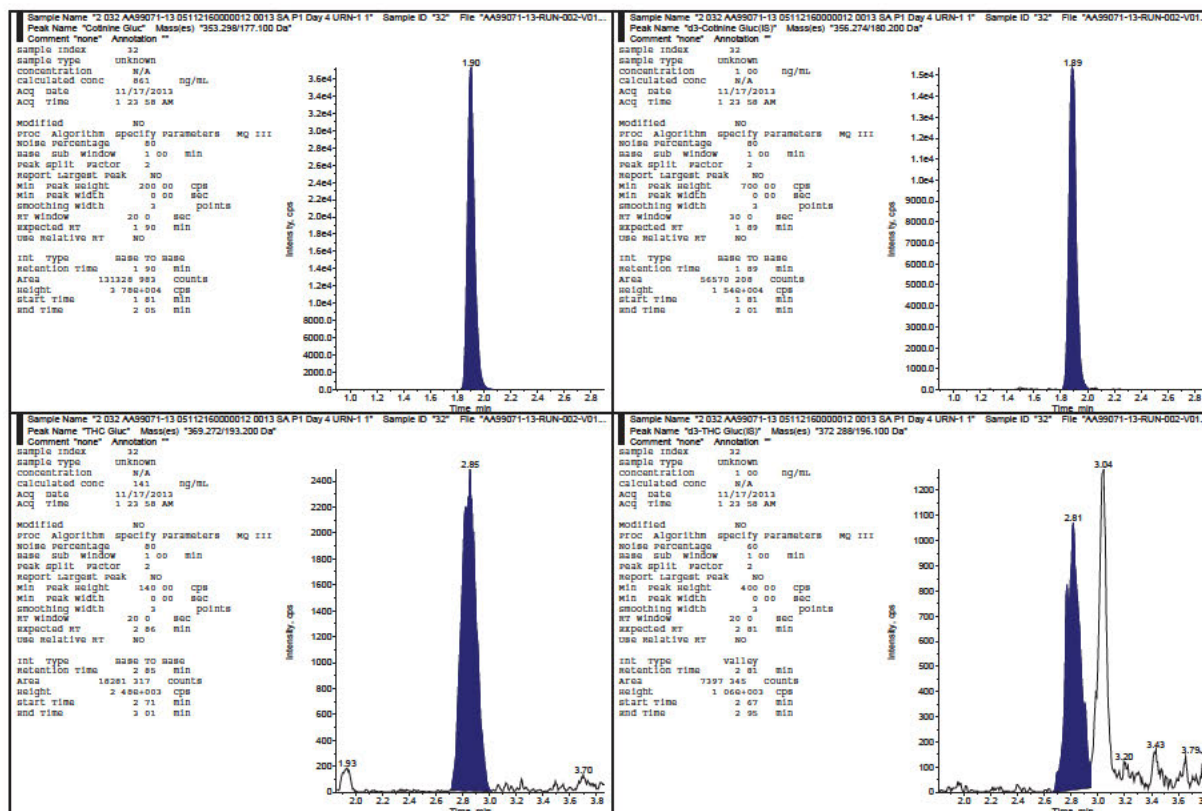


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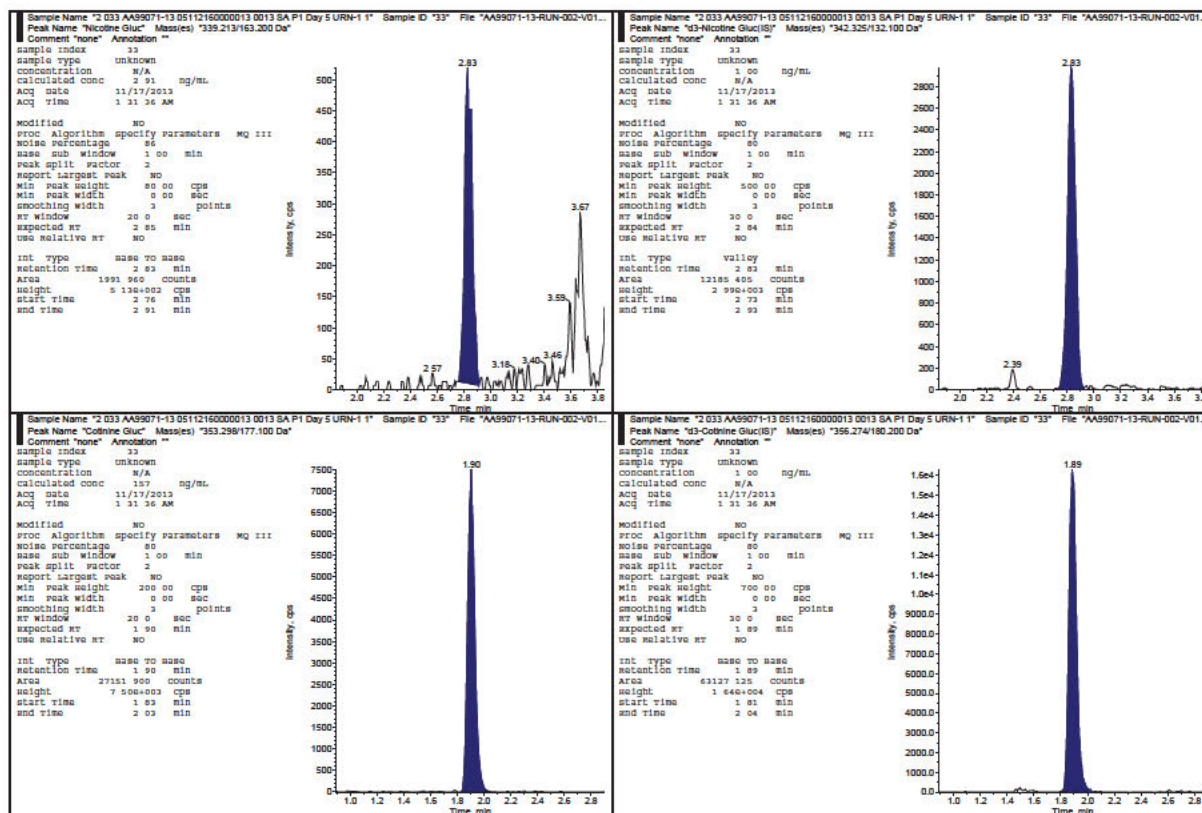


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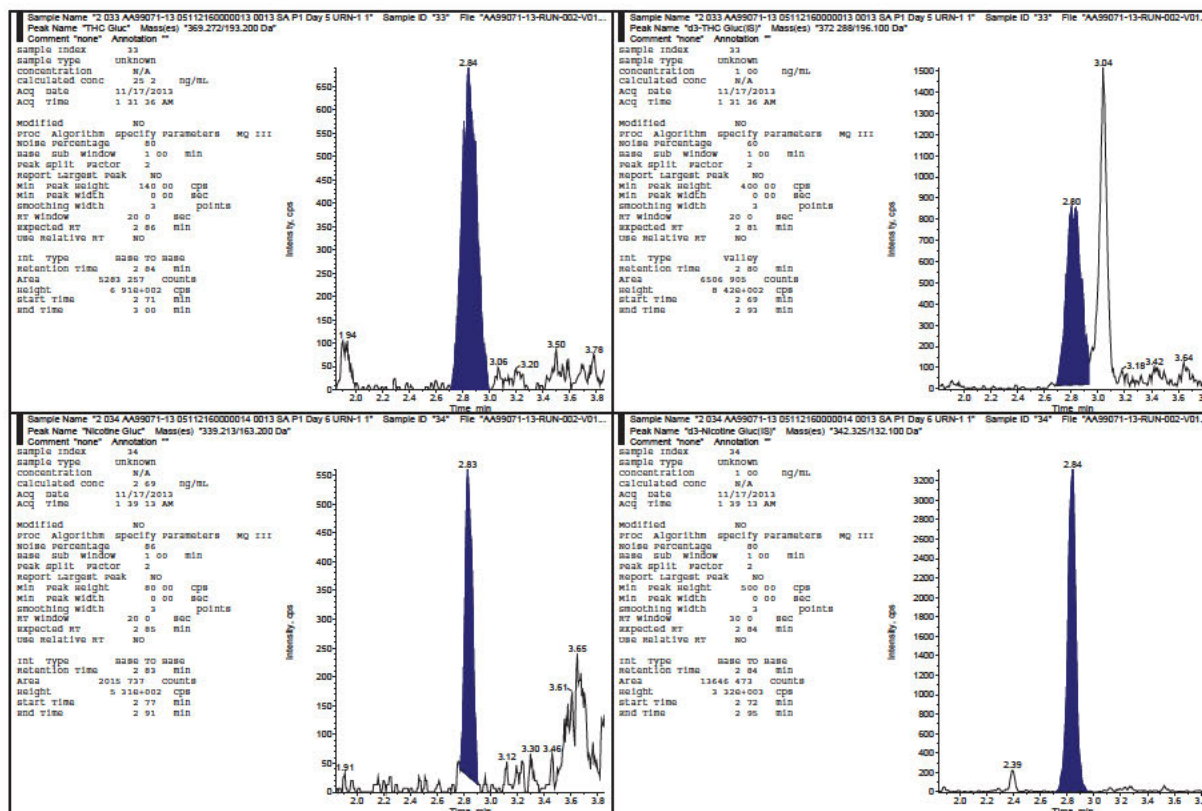


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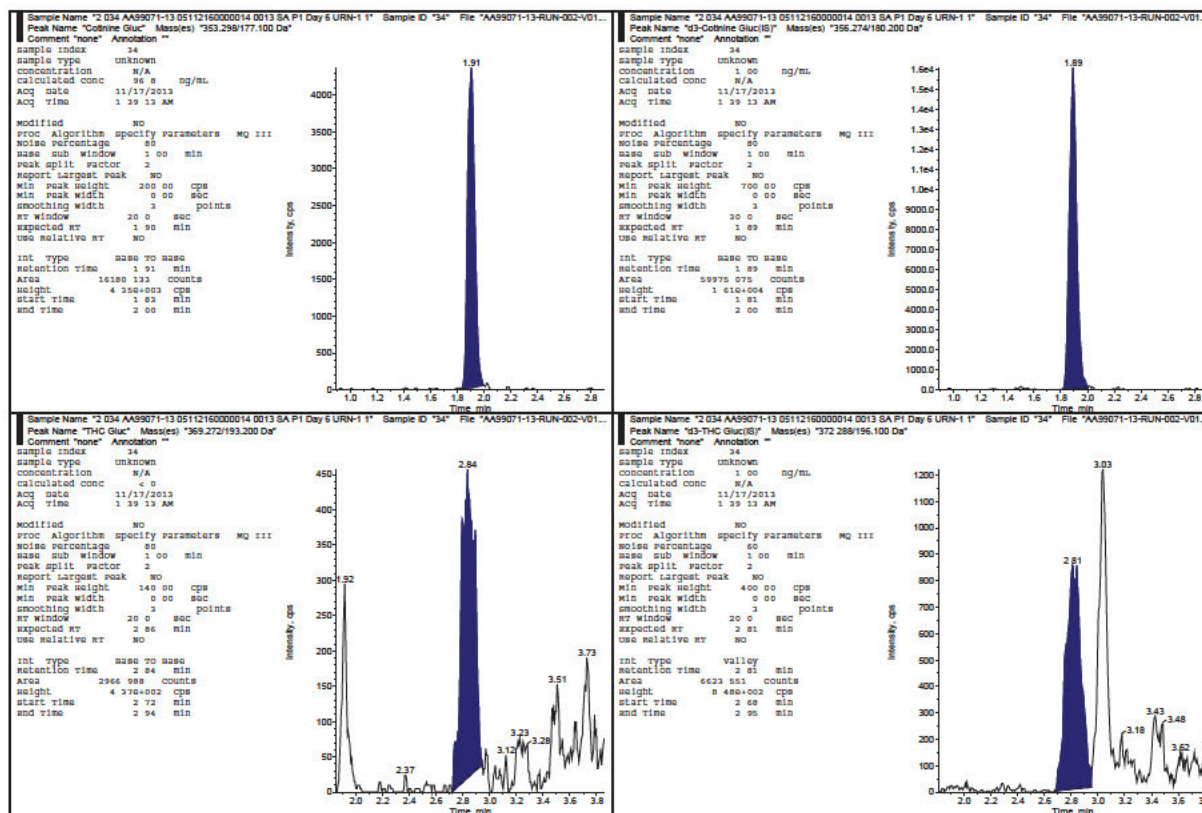


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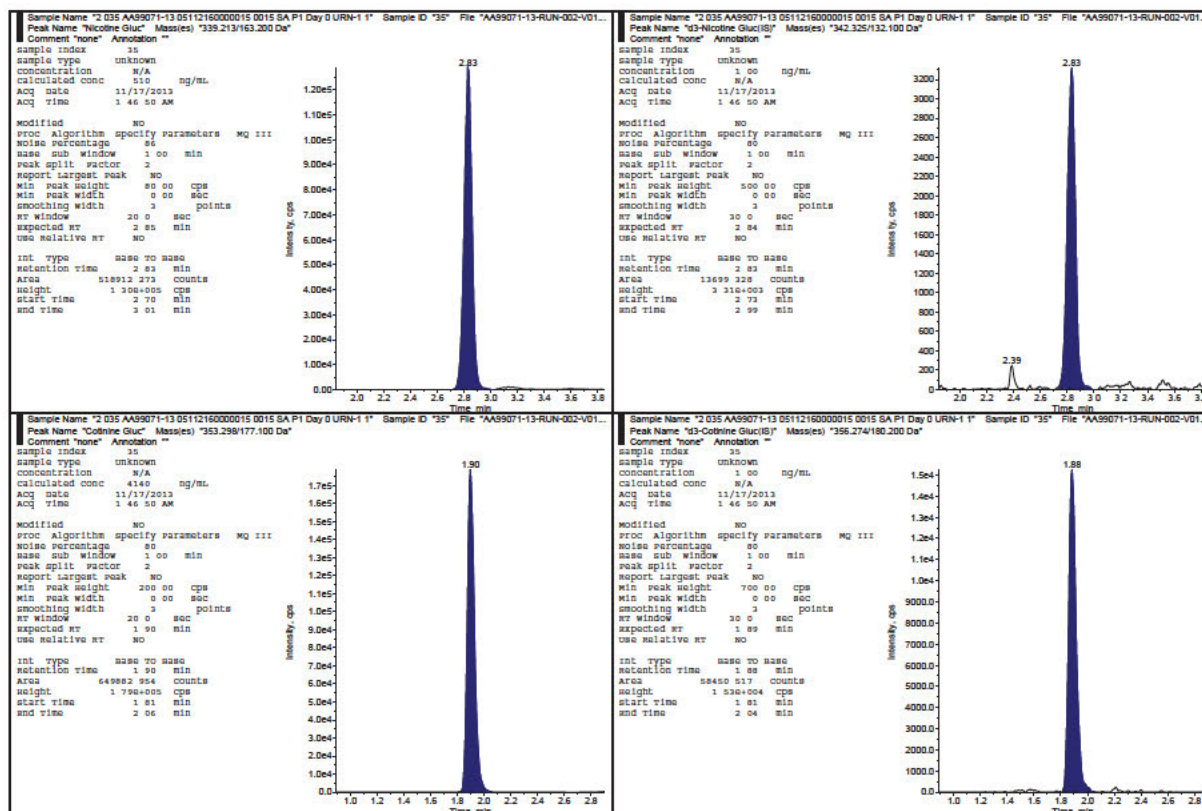


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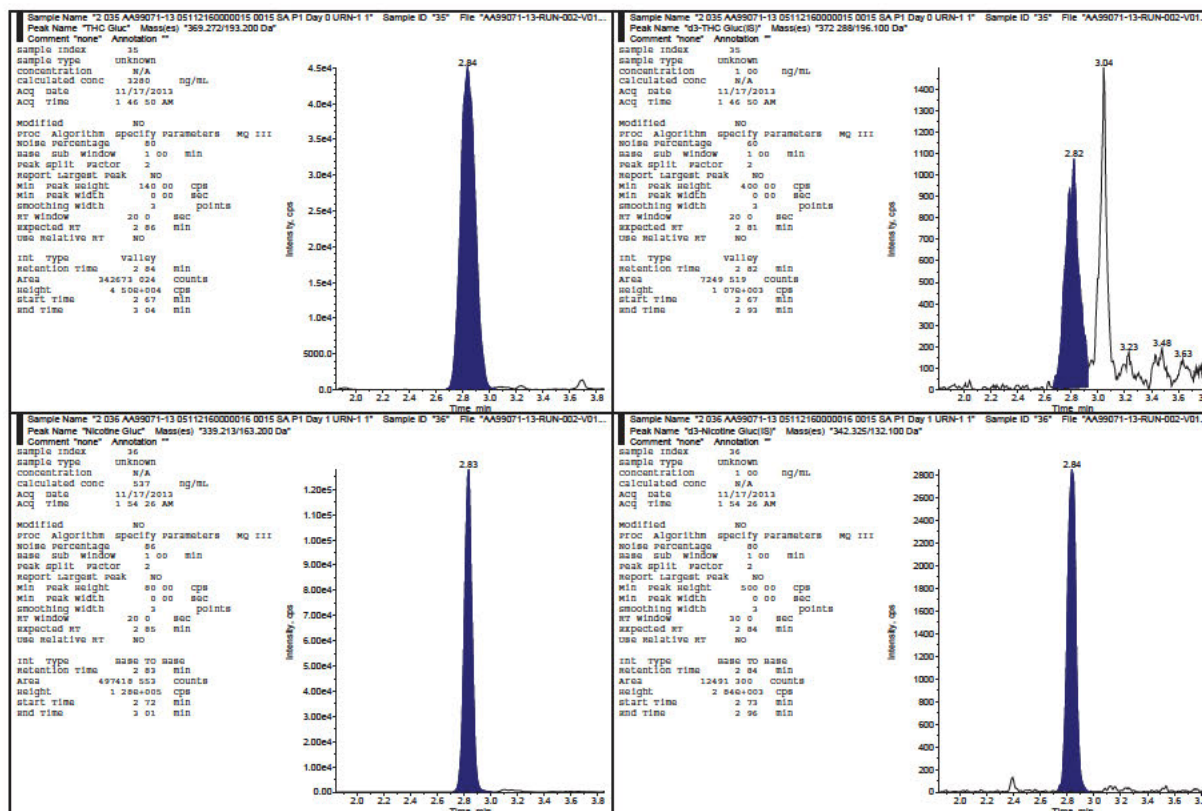


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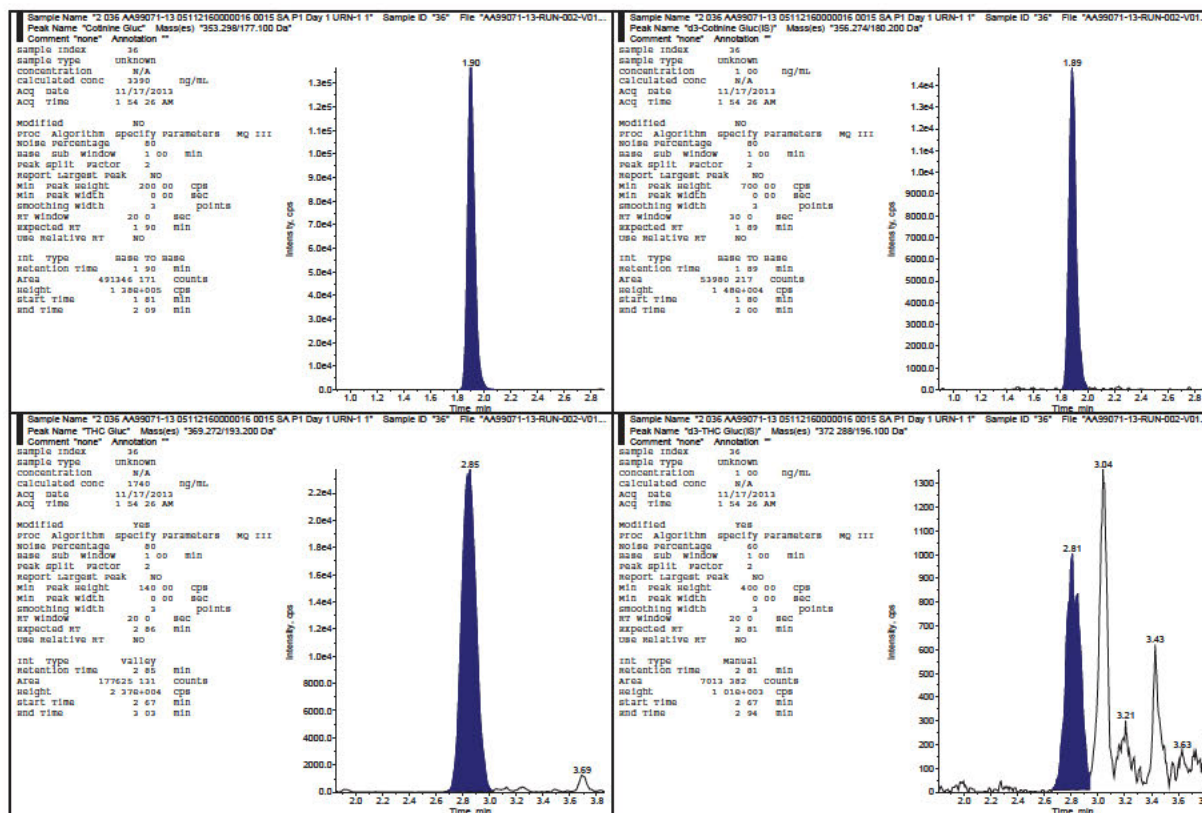


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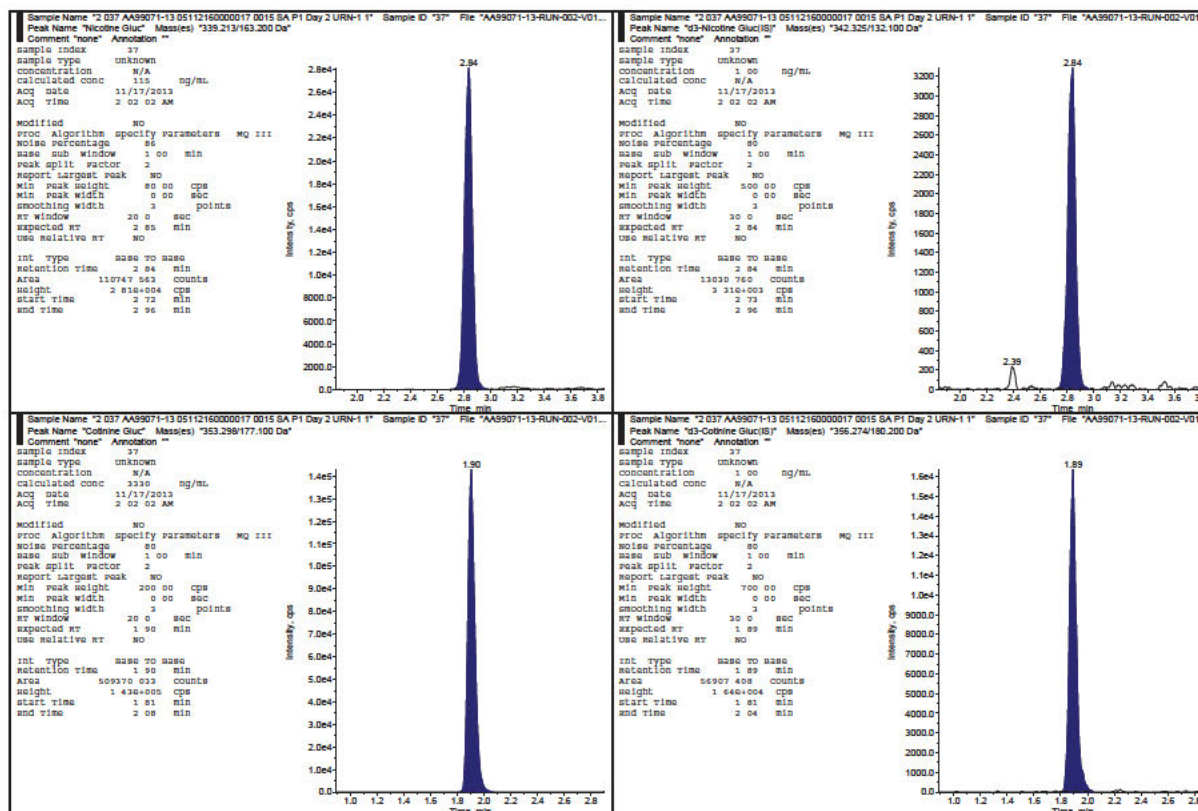


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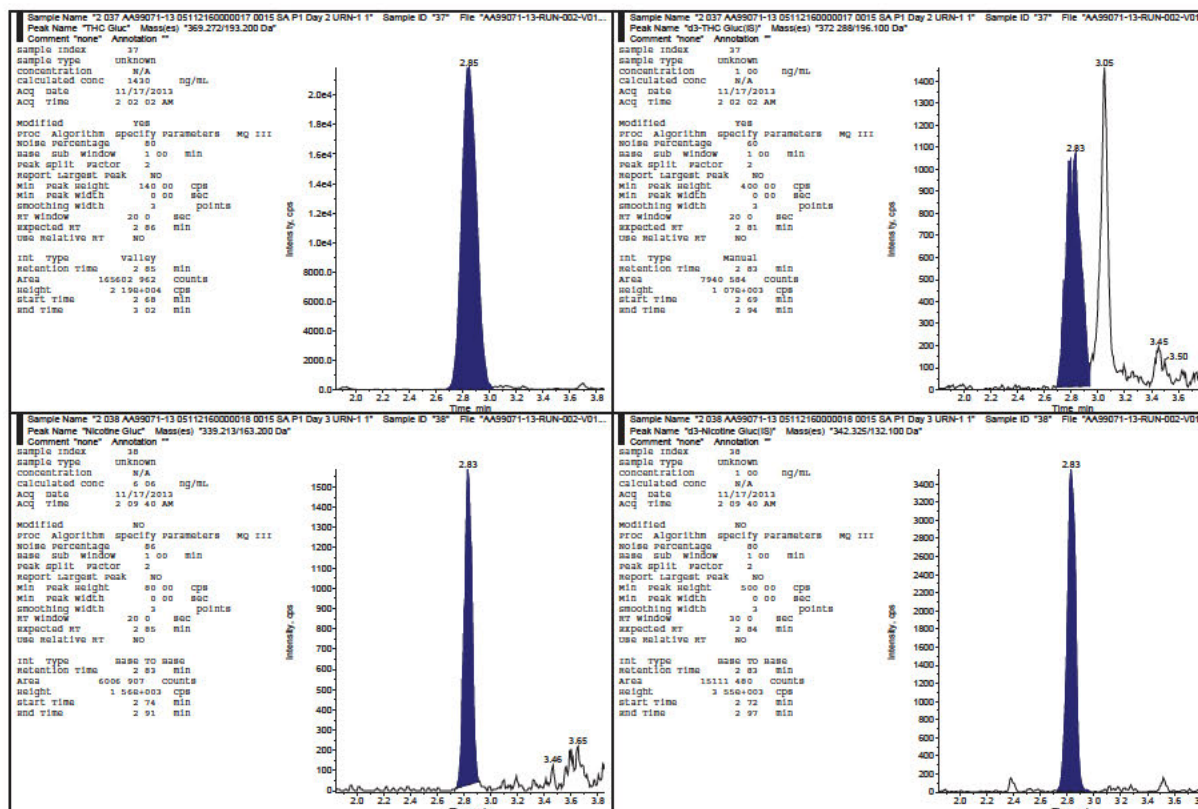


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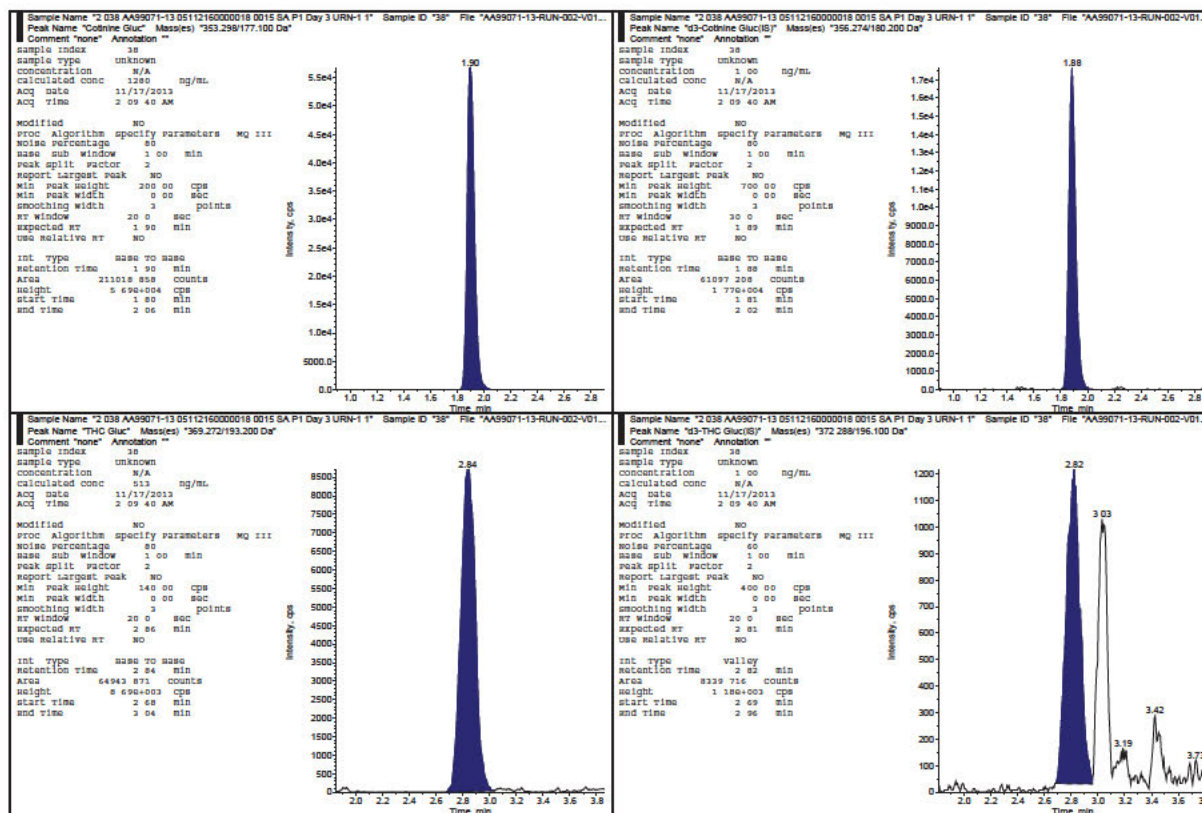


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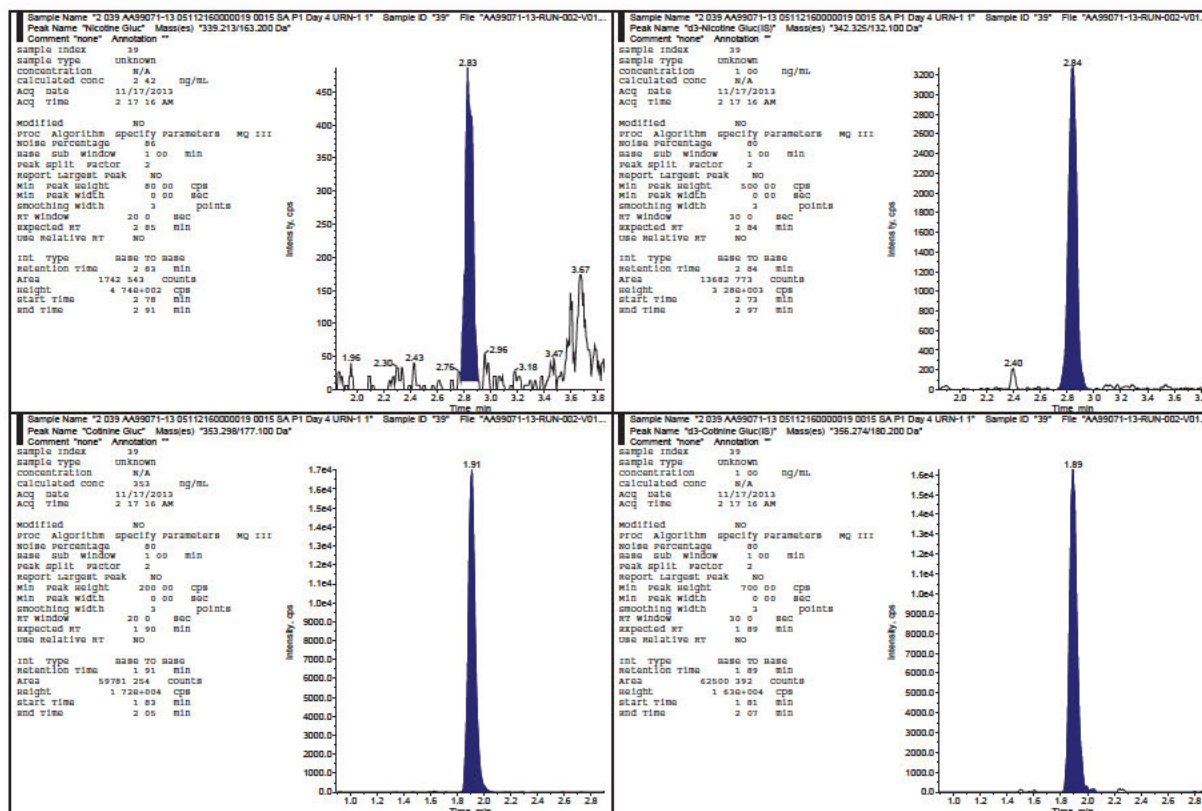


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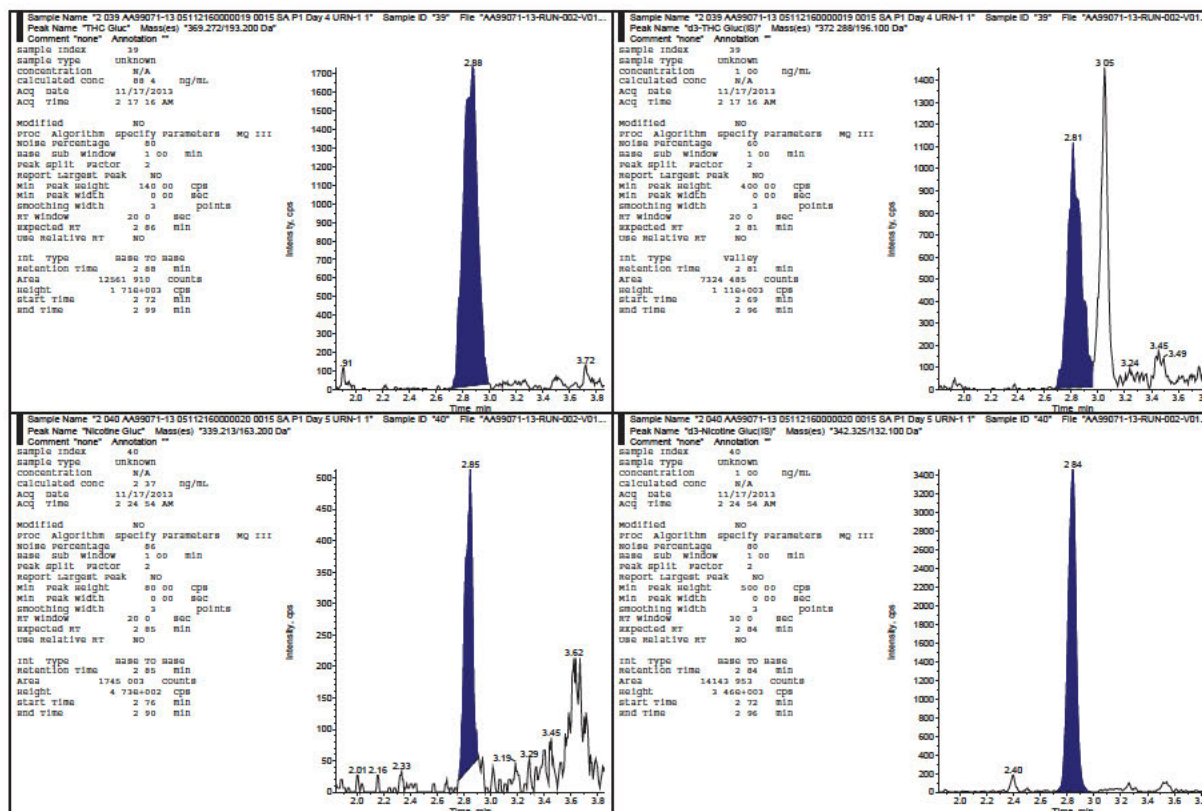


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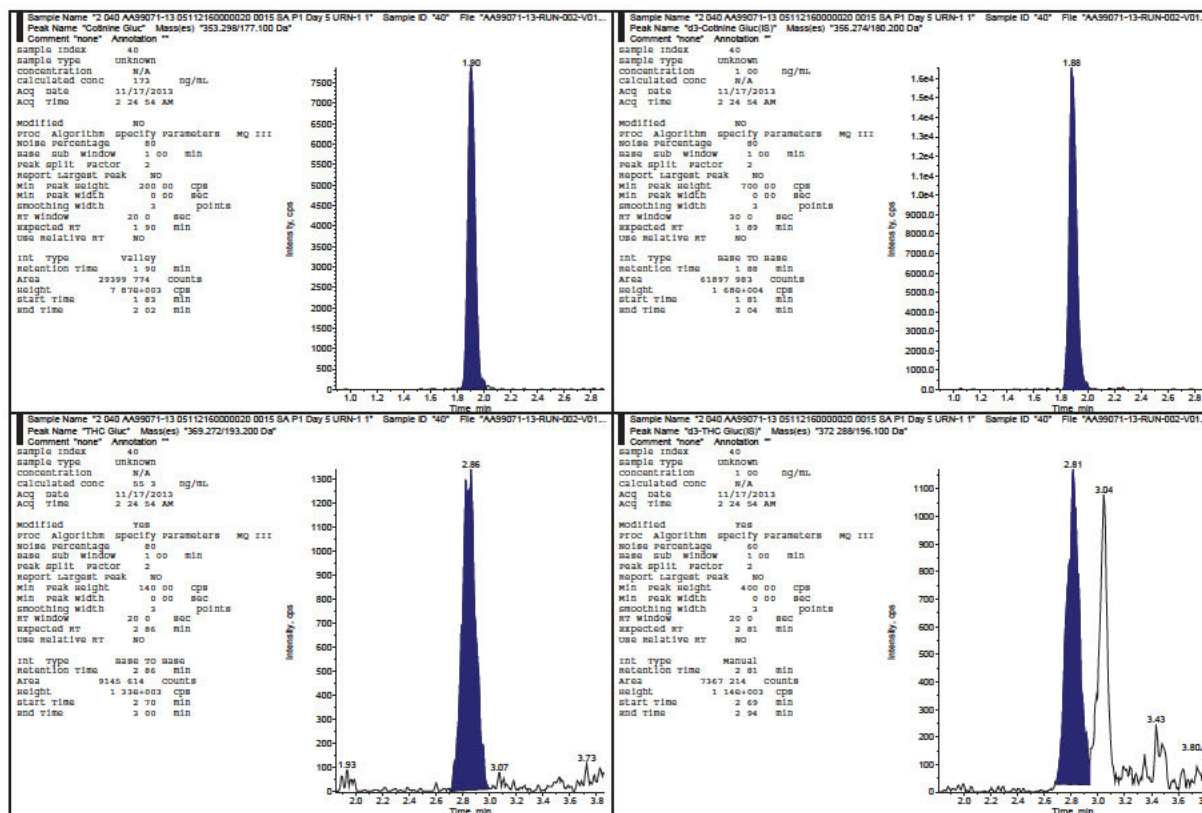


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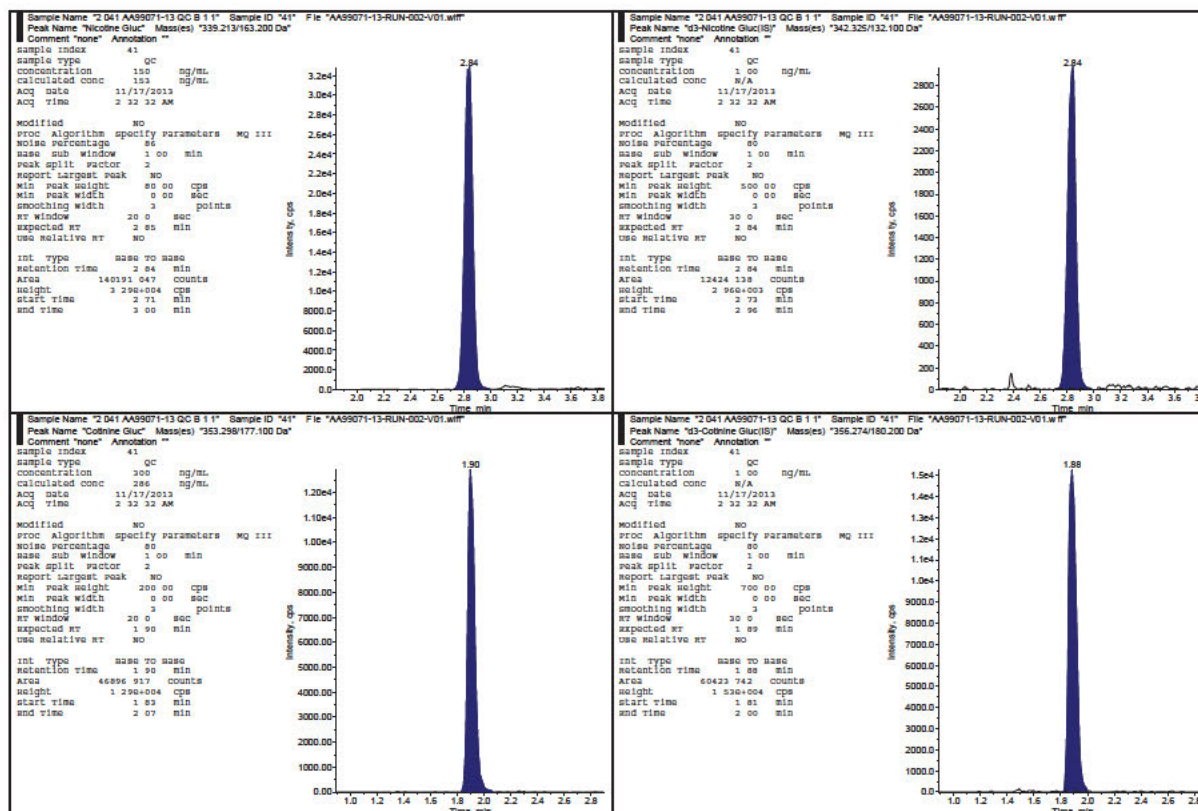


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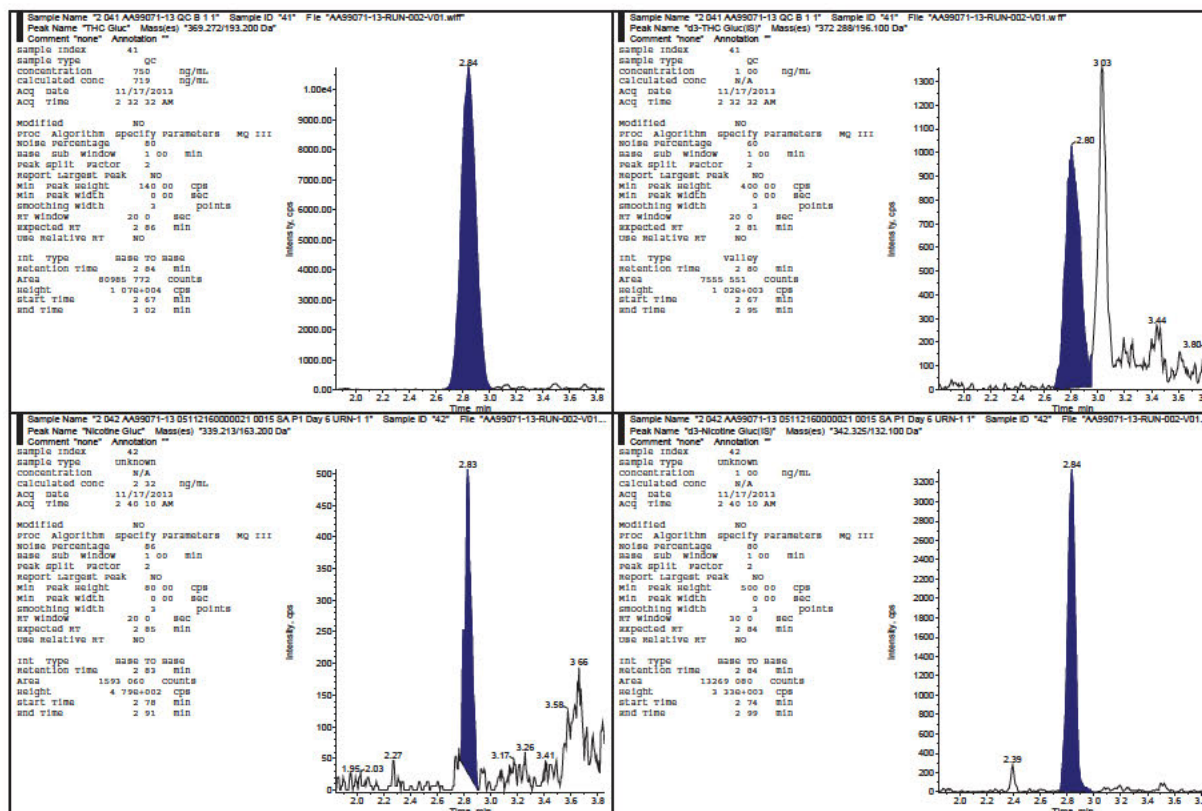


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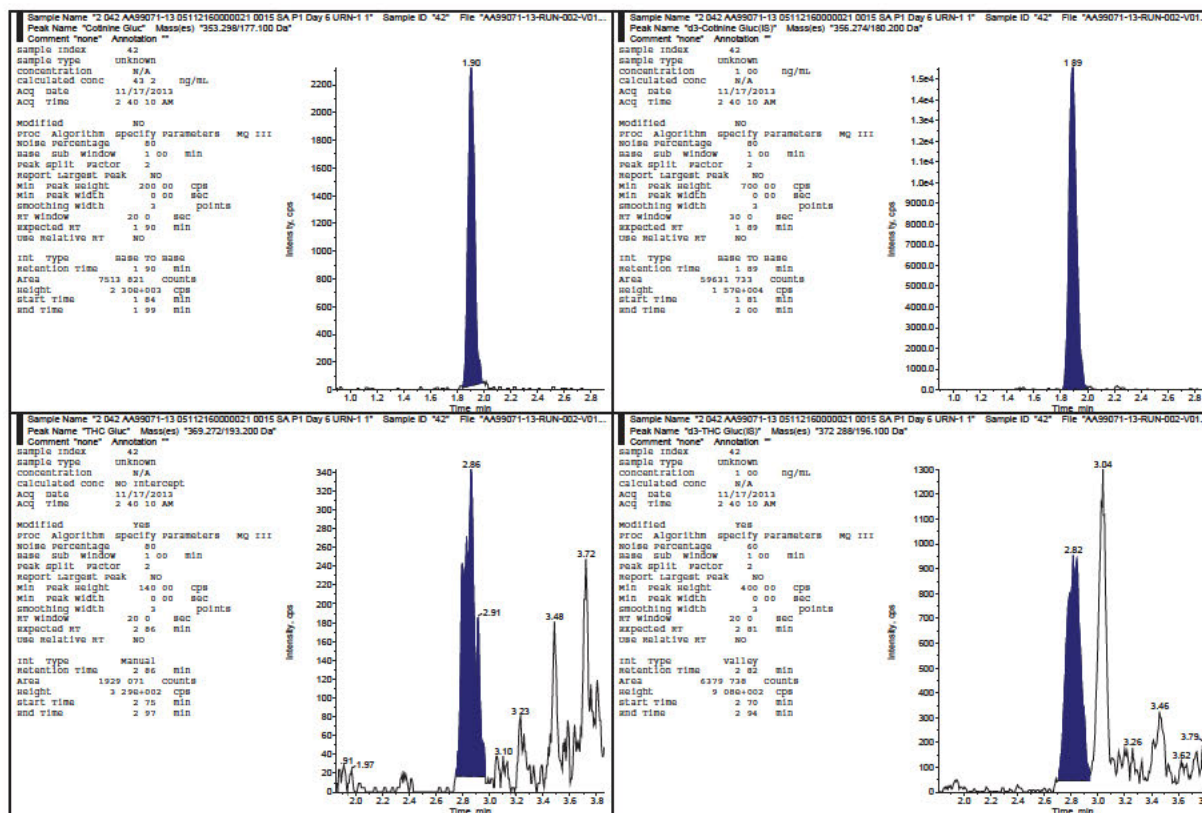


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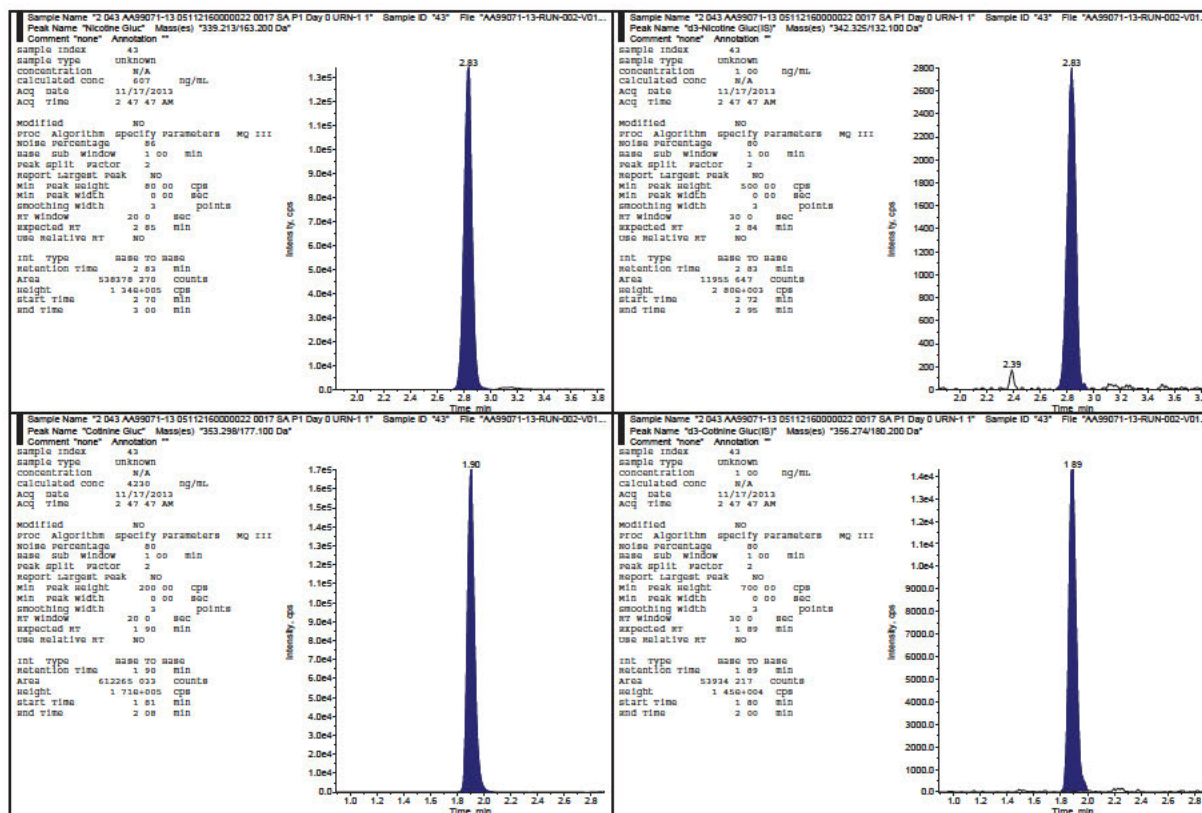


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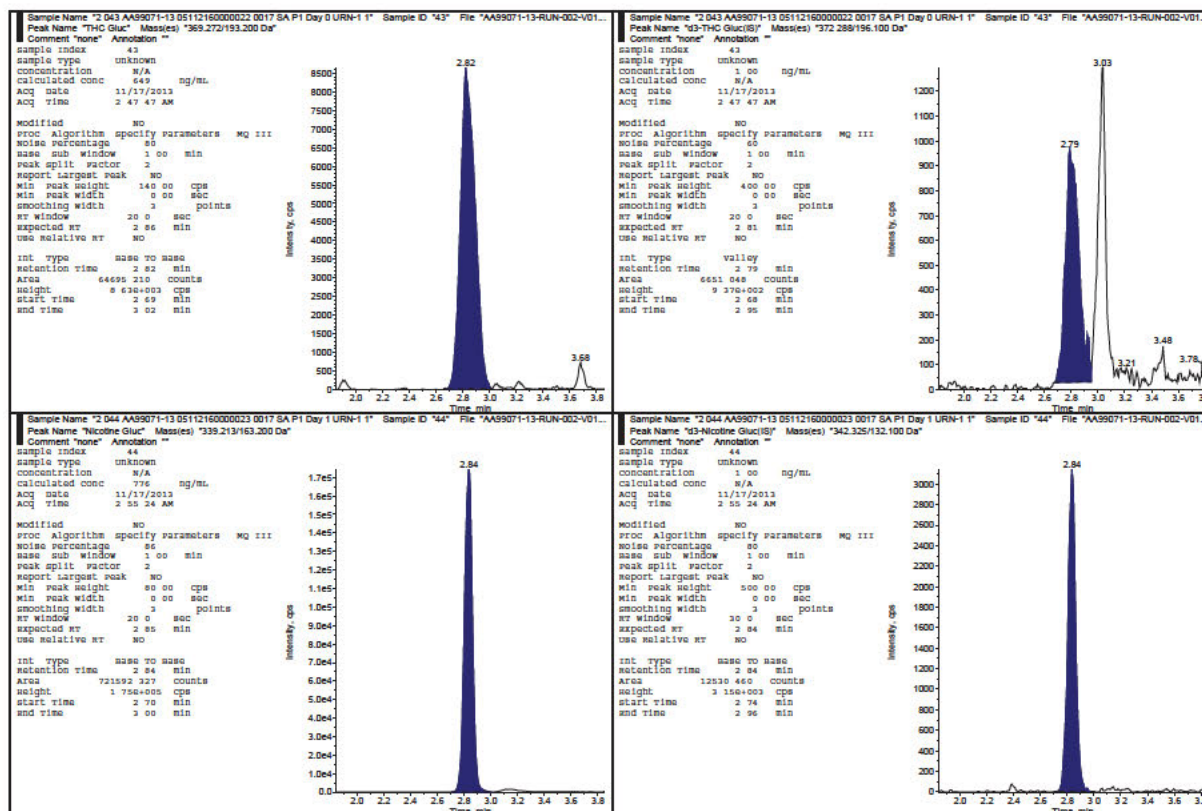


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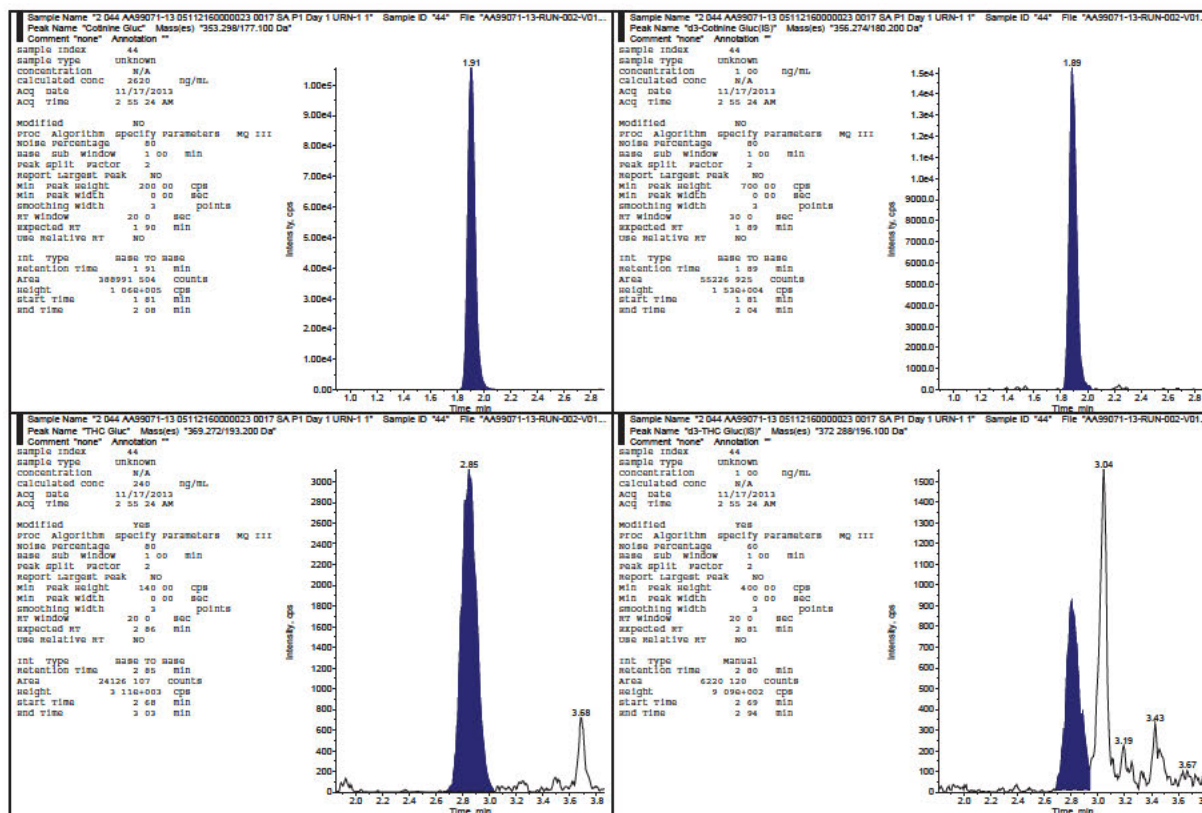


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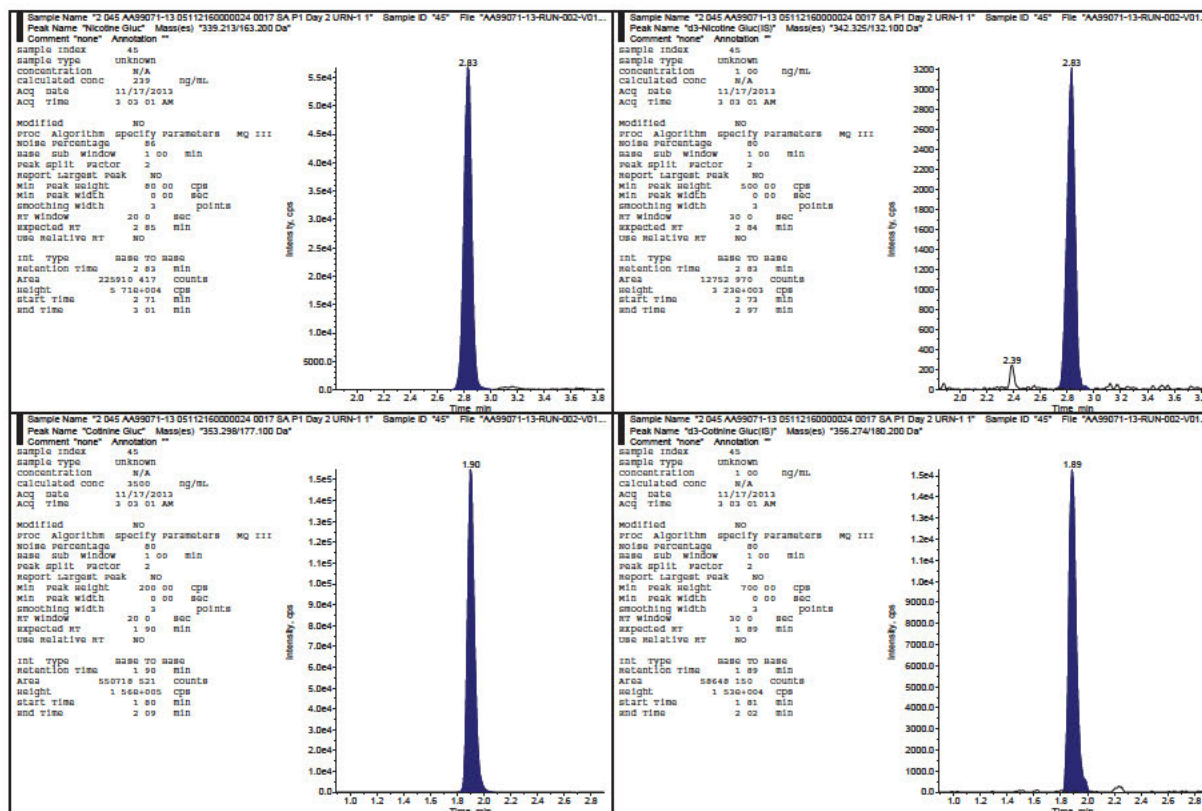


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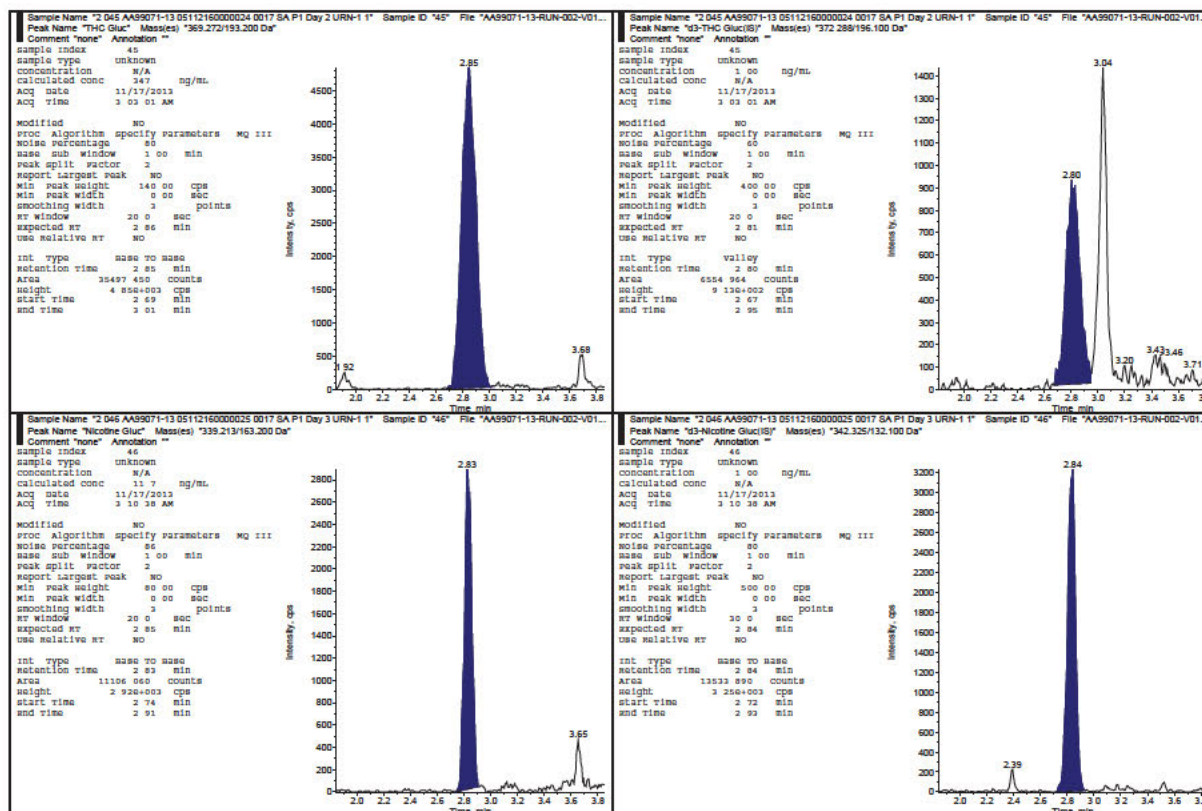


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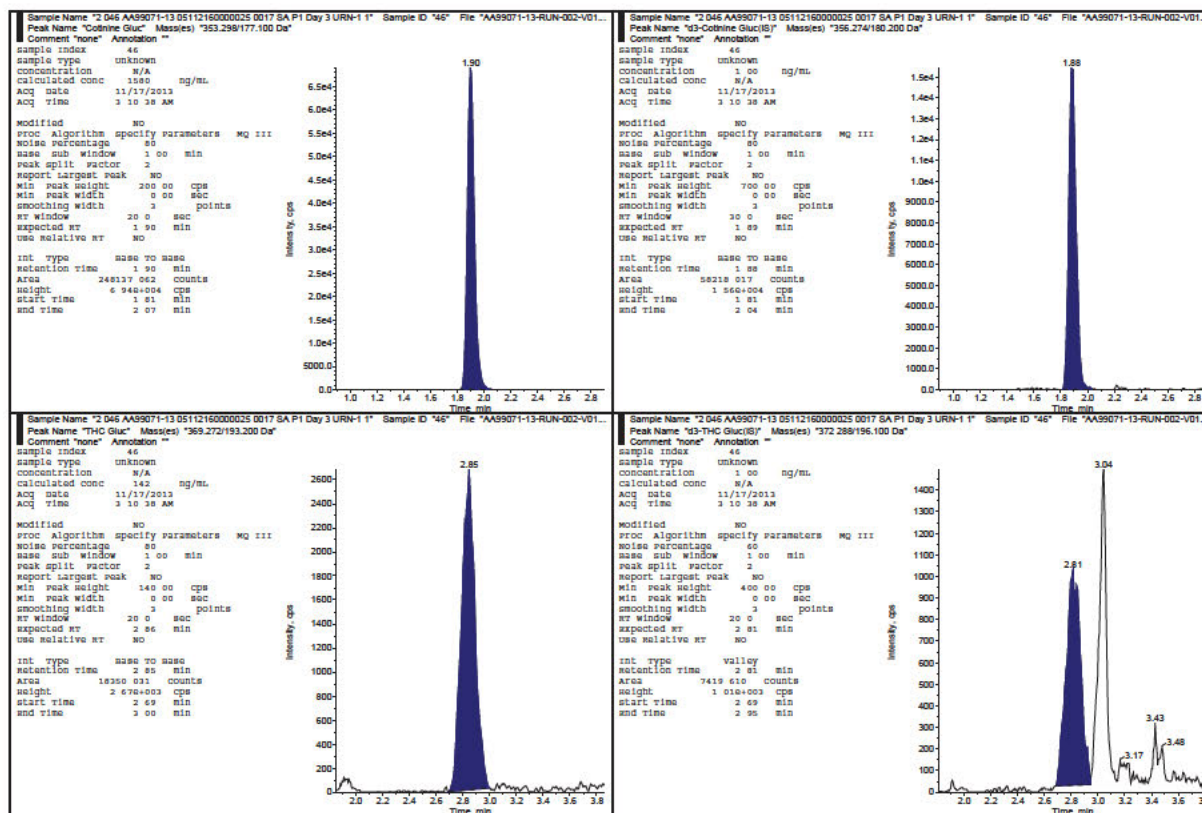


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Celerion Study AA99071-13



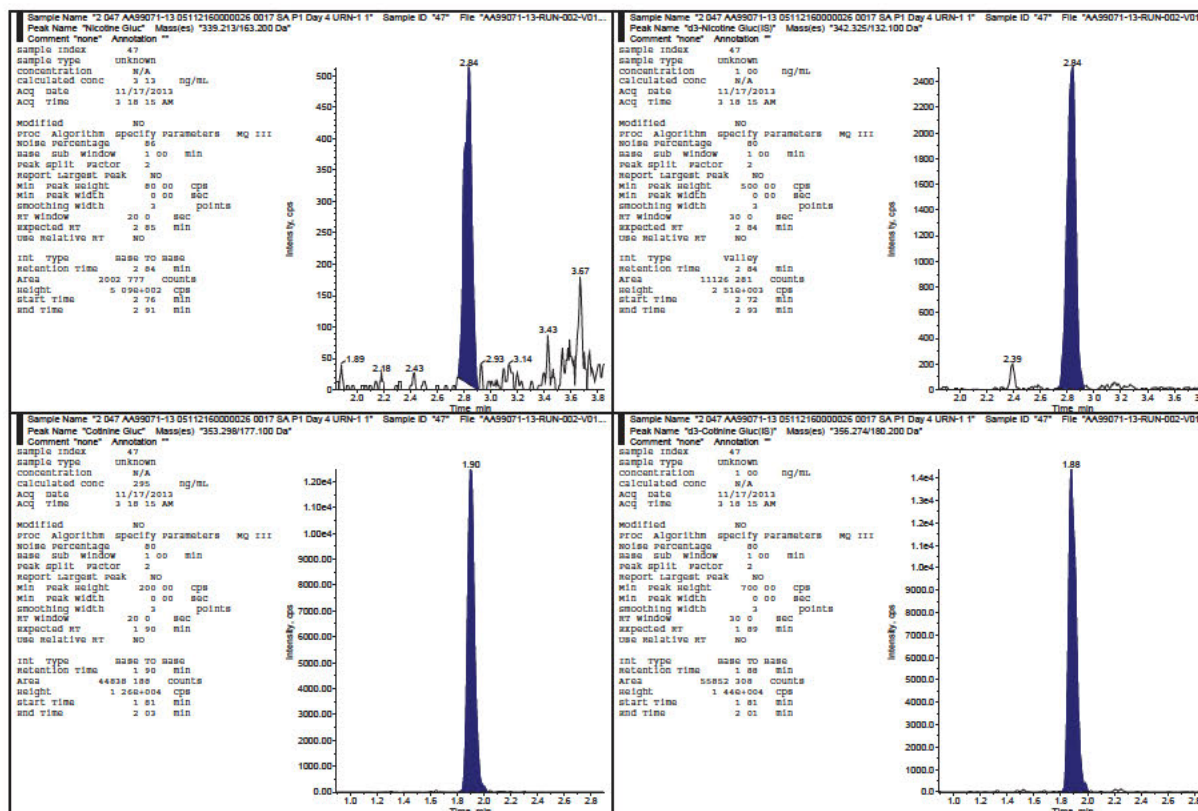


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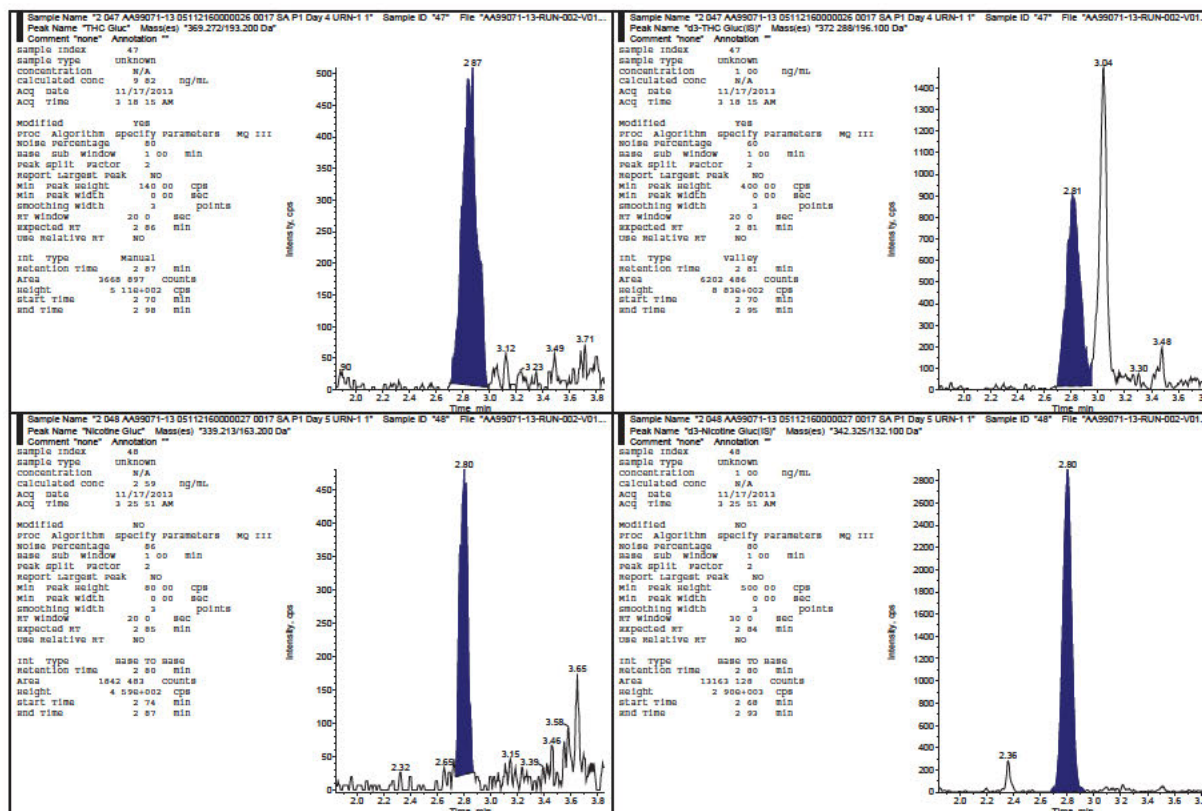


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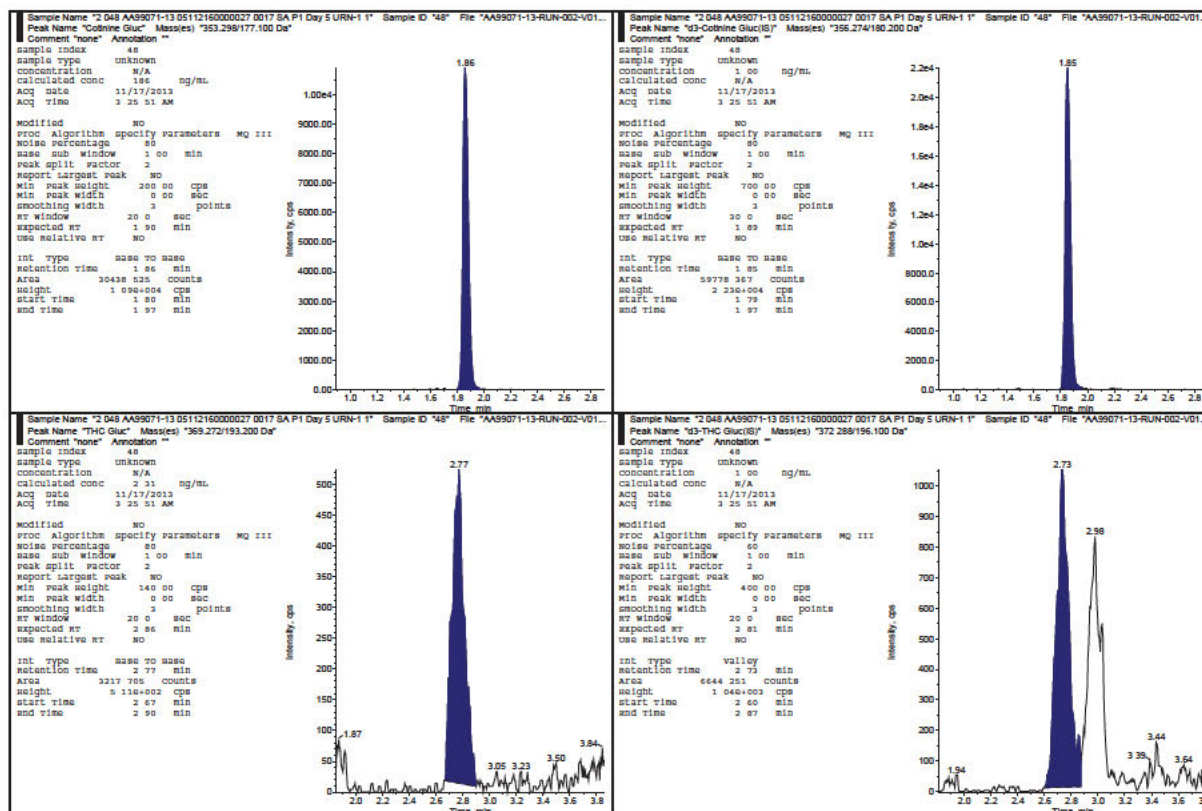


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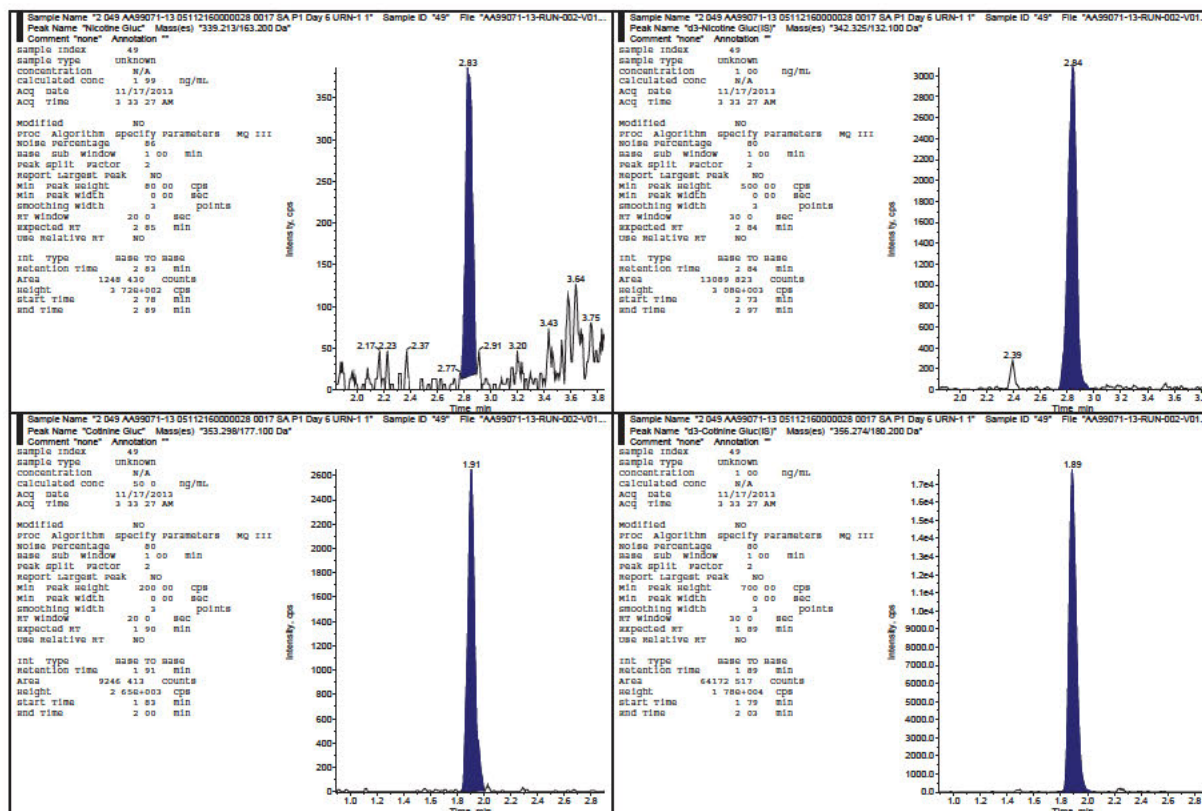


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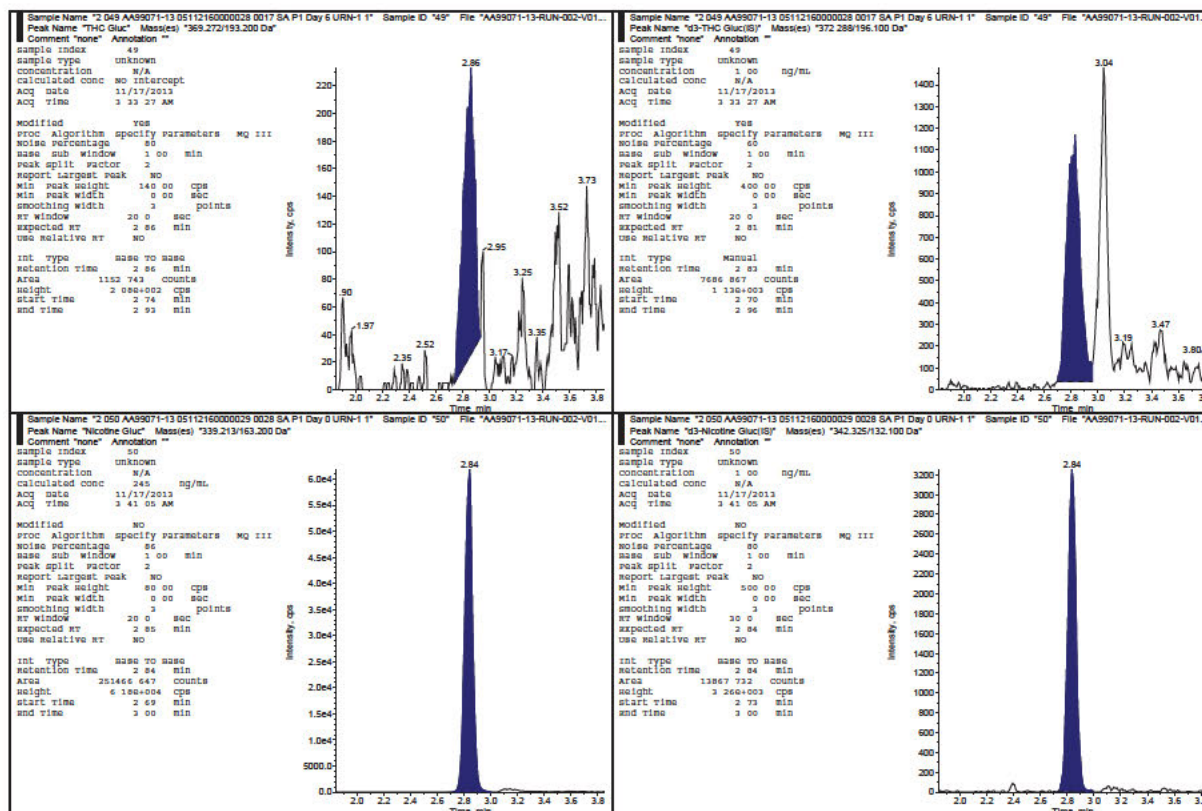


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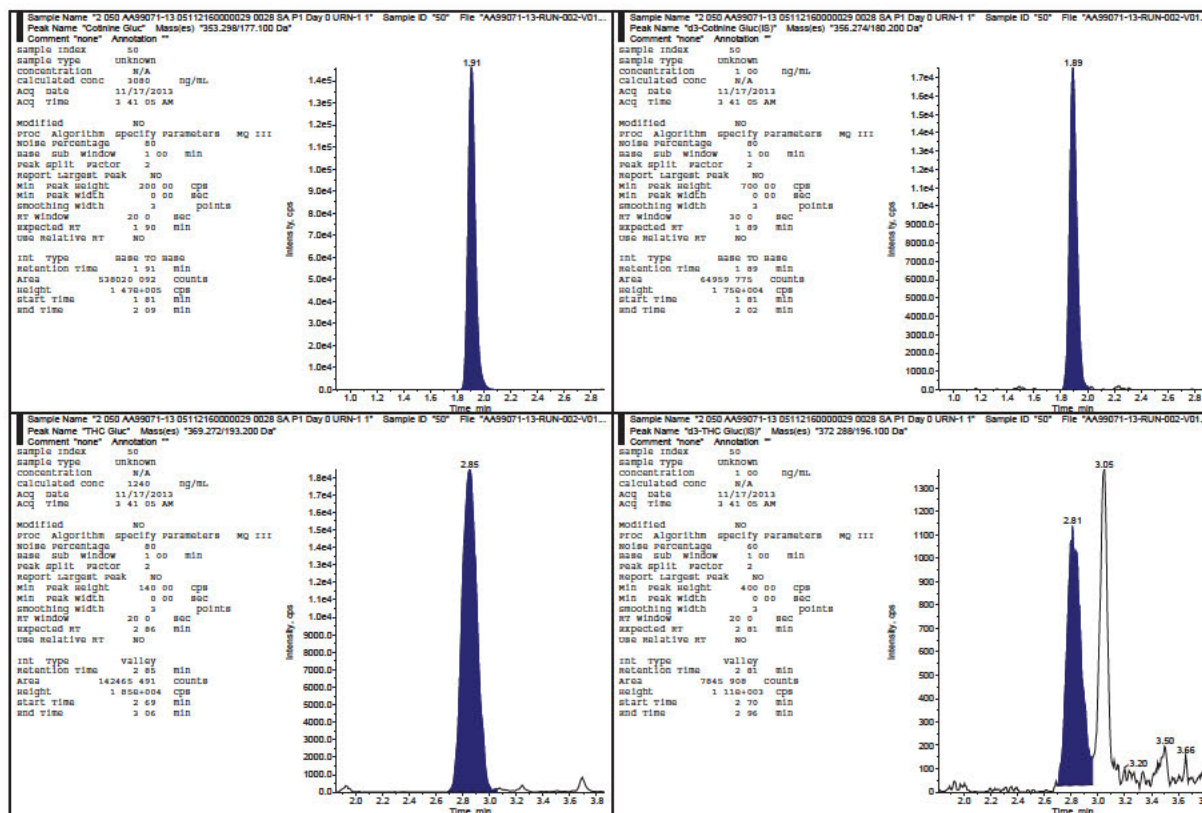


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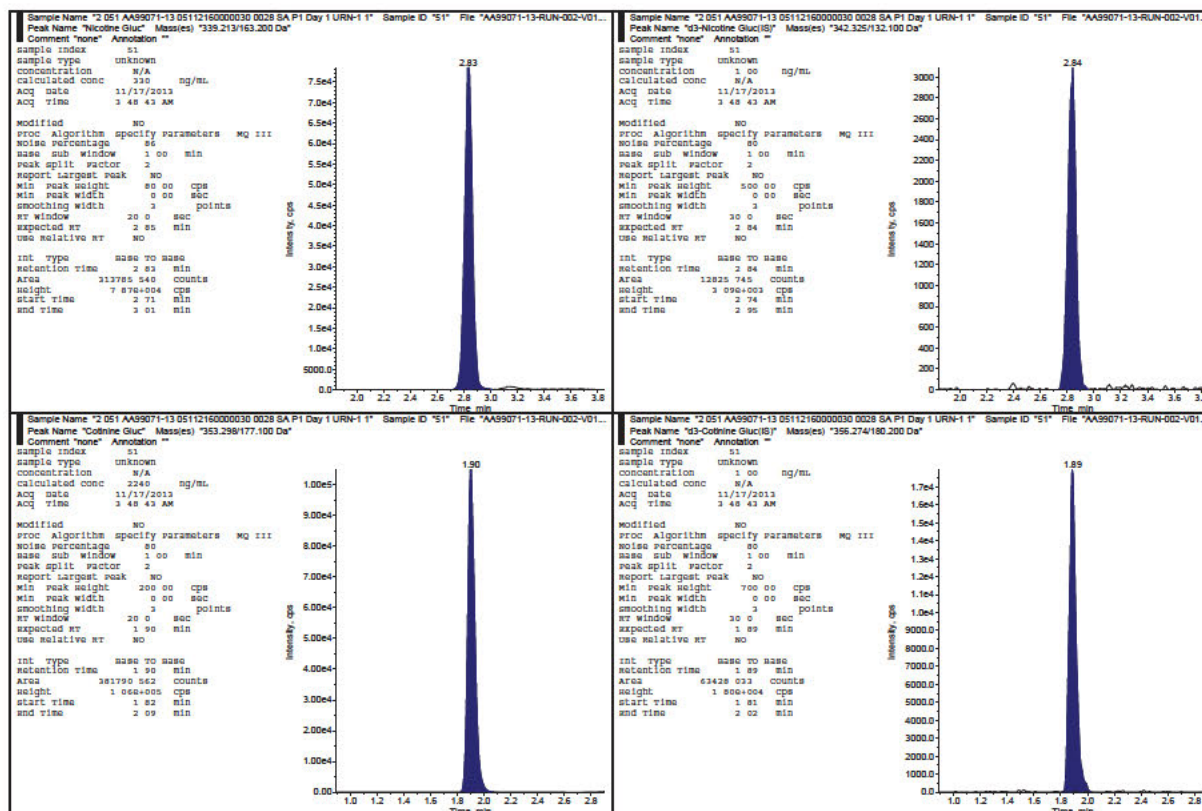


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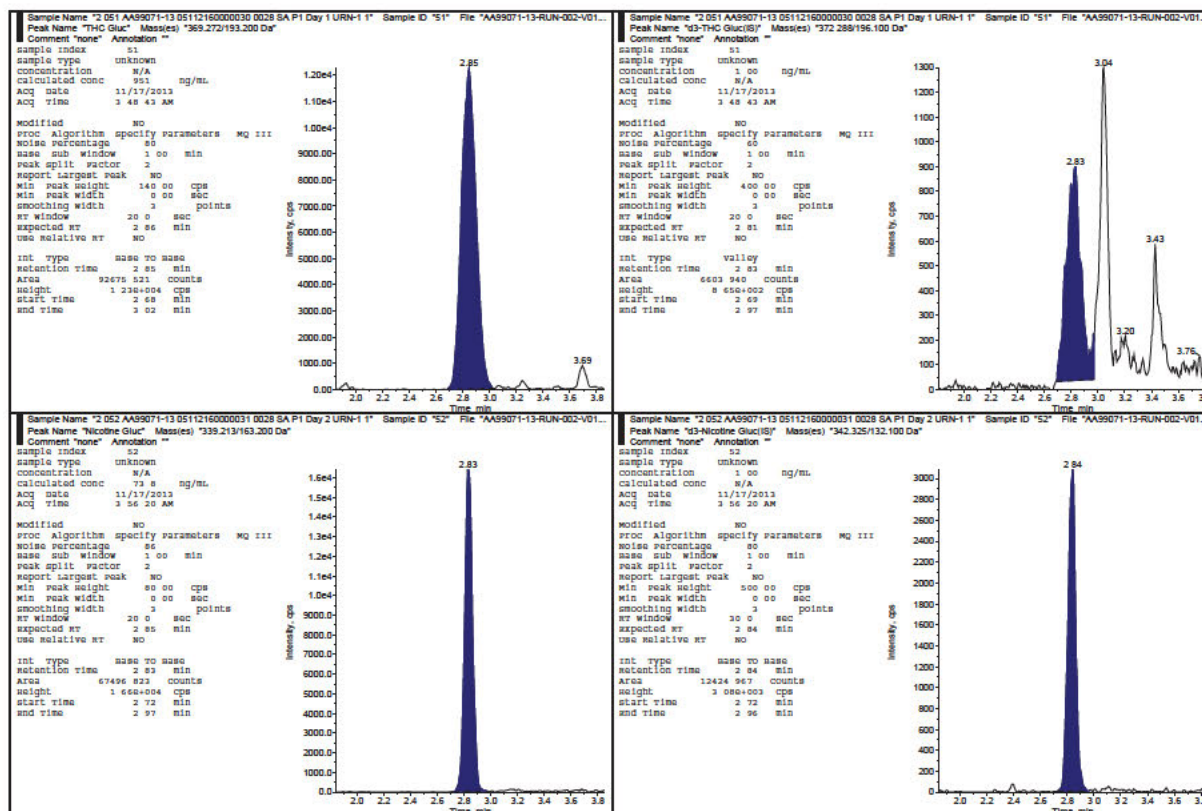


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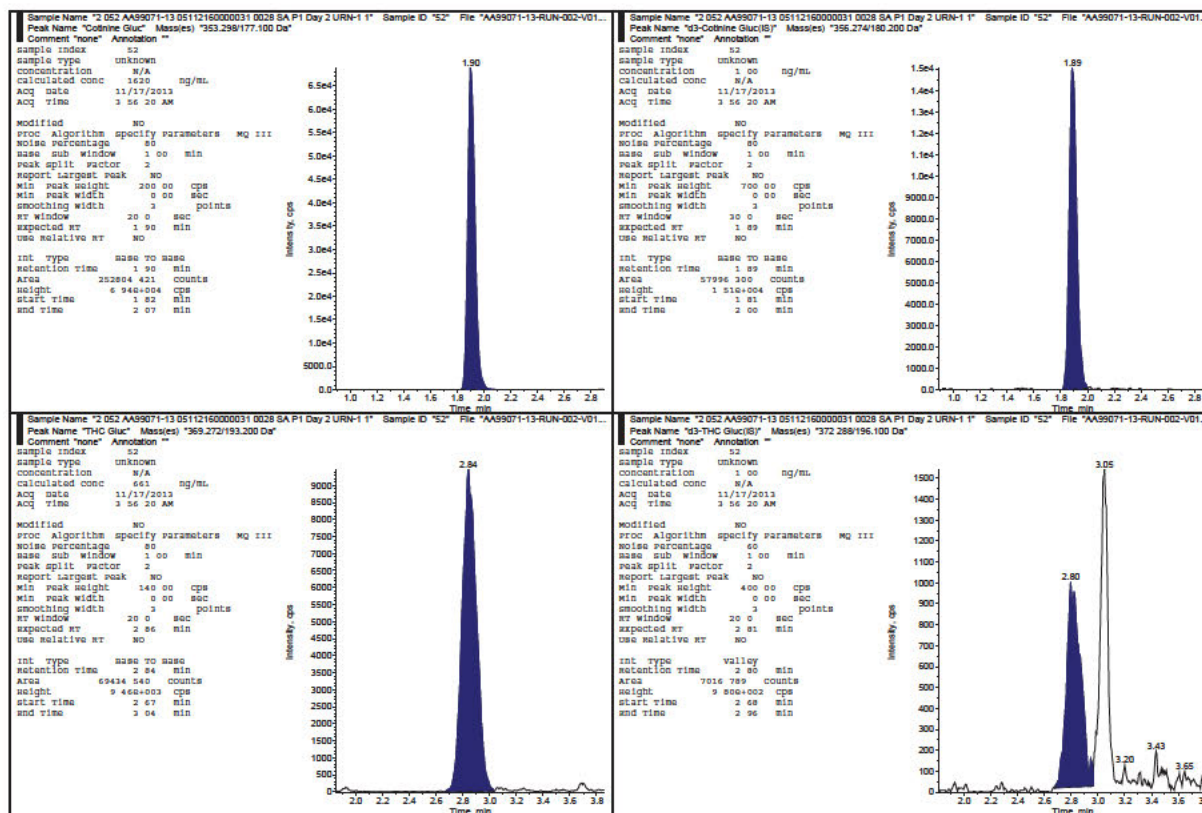


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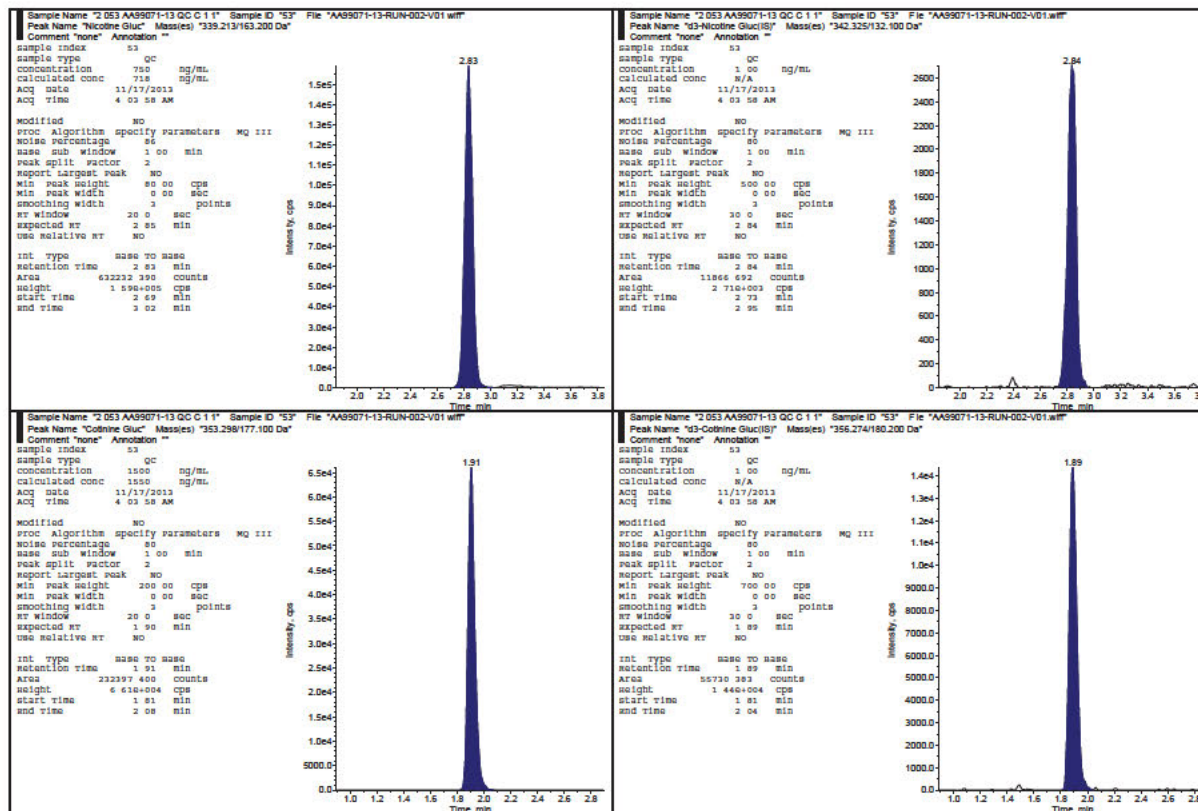


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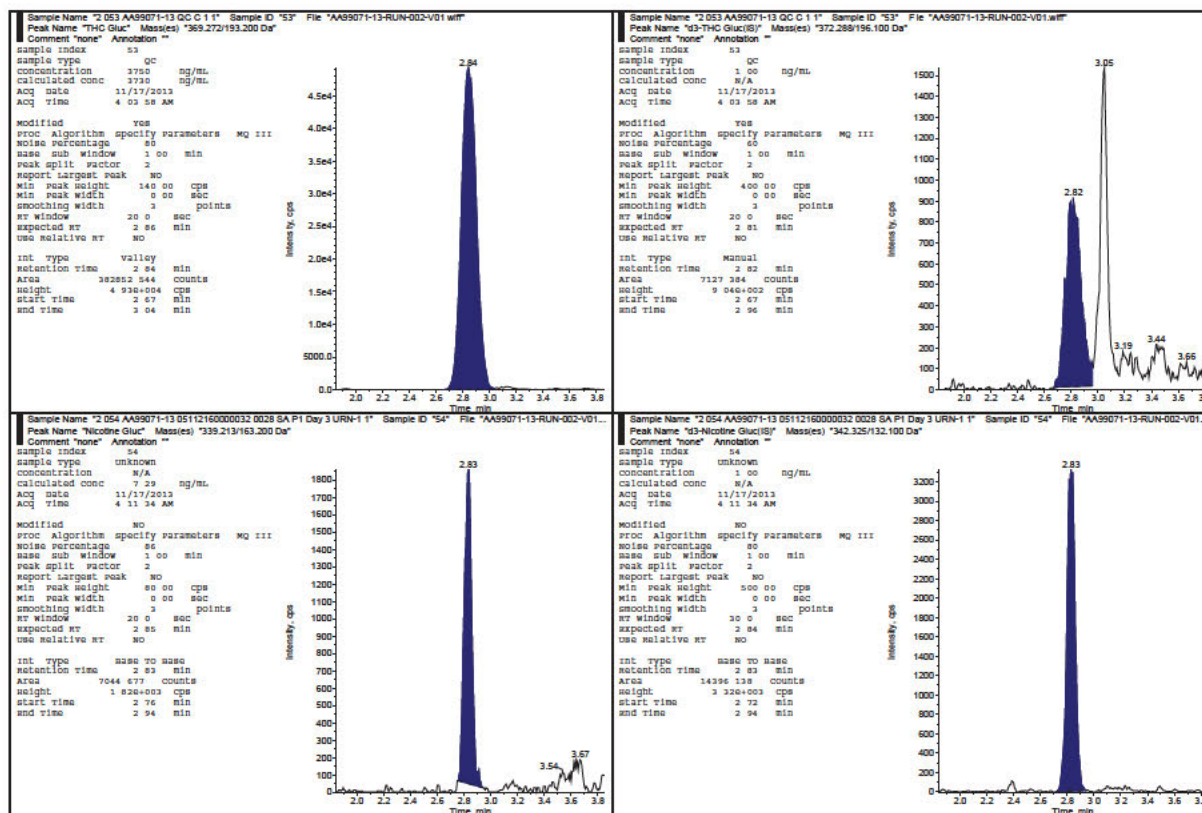


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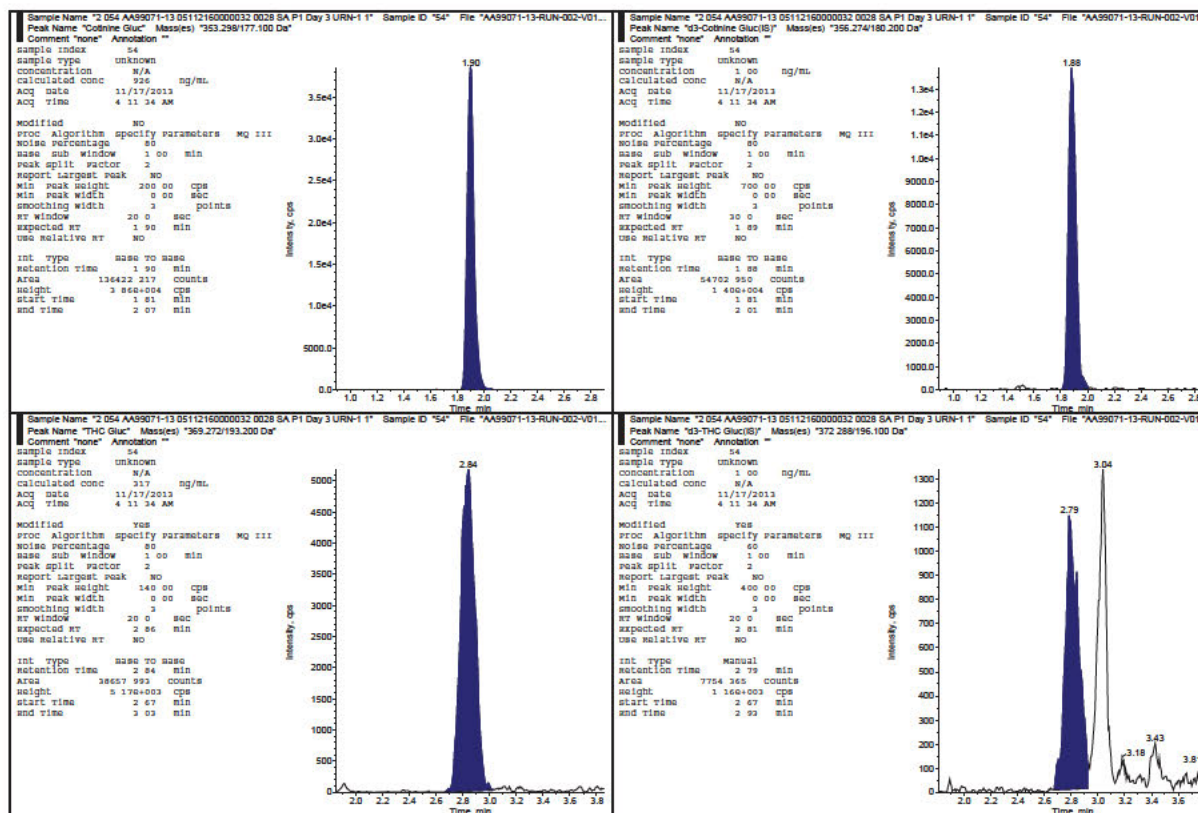


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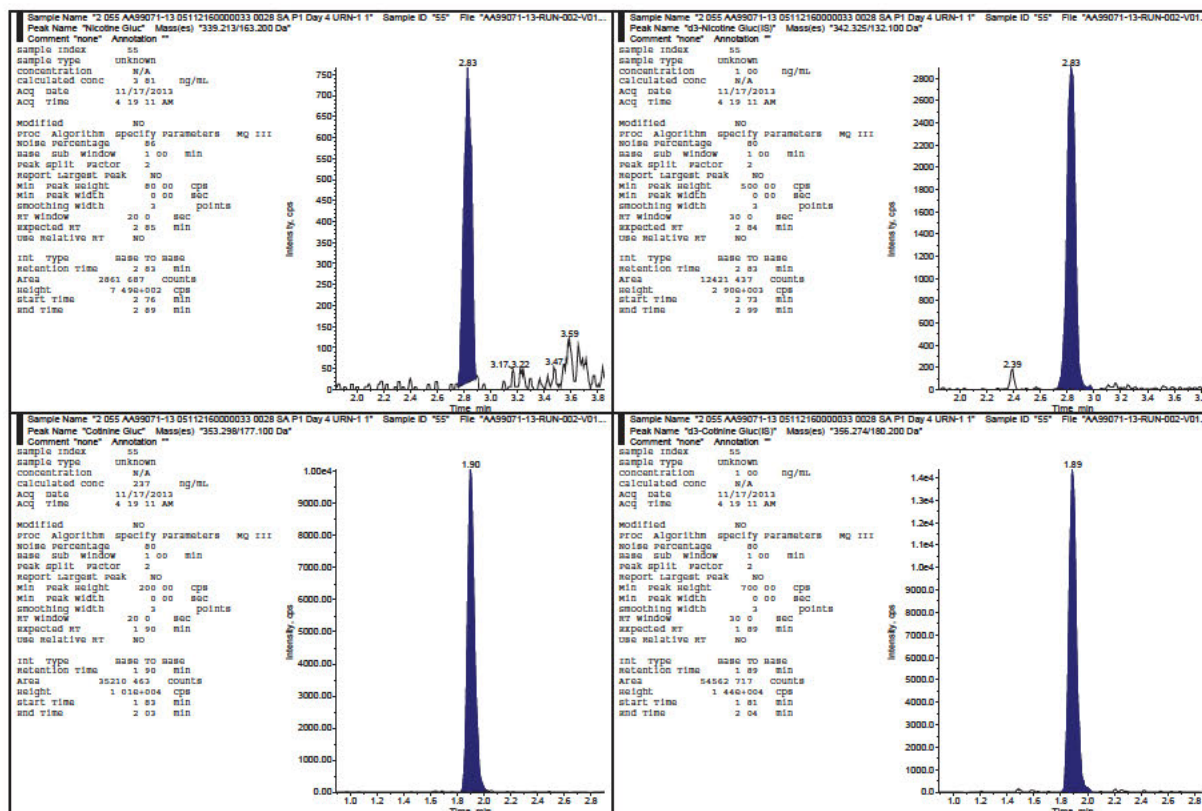


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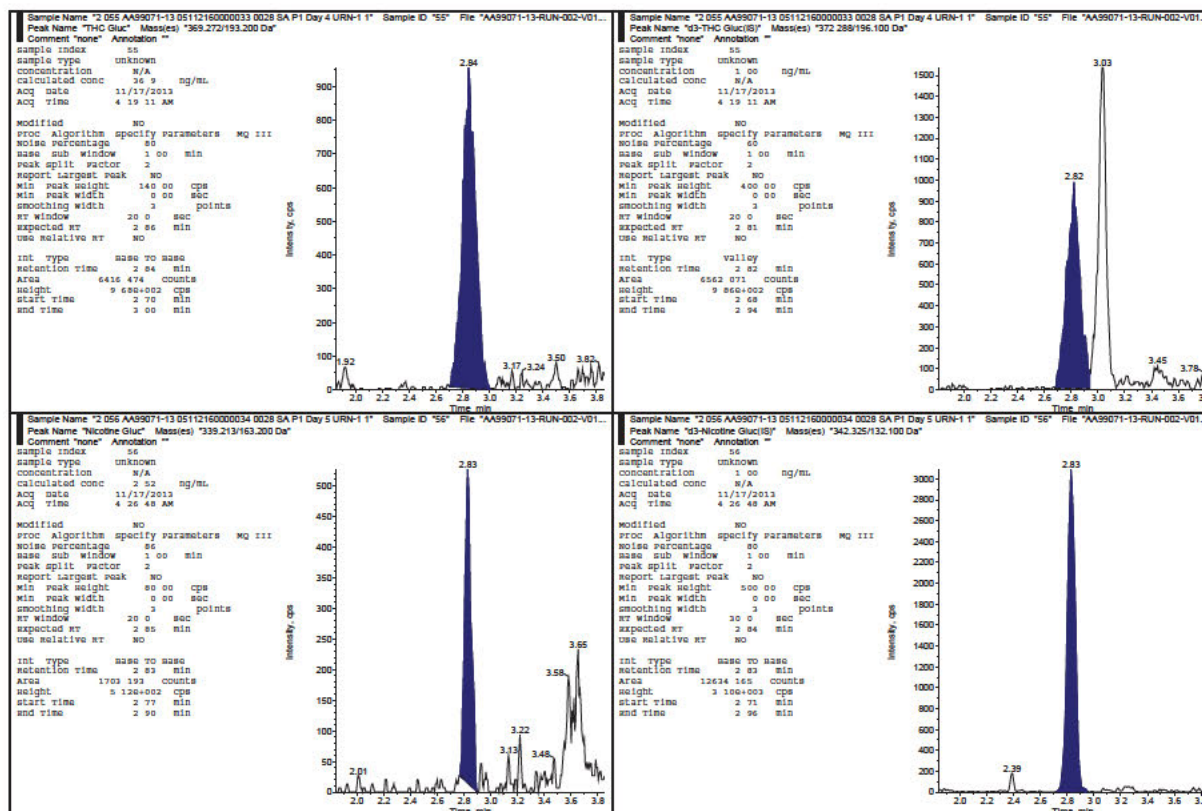


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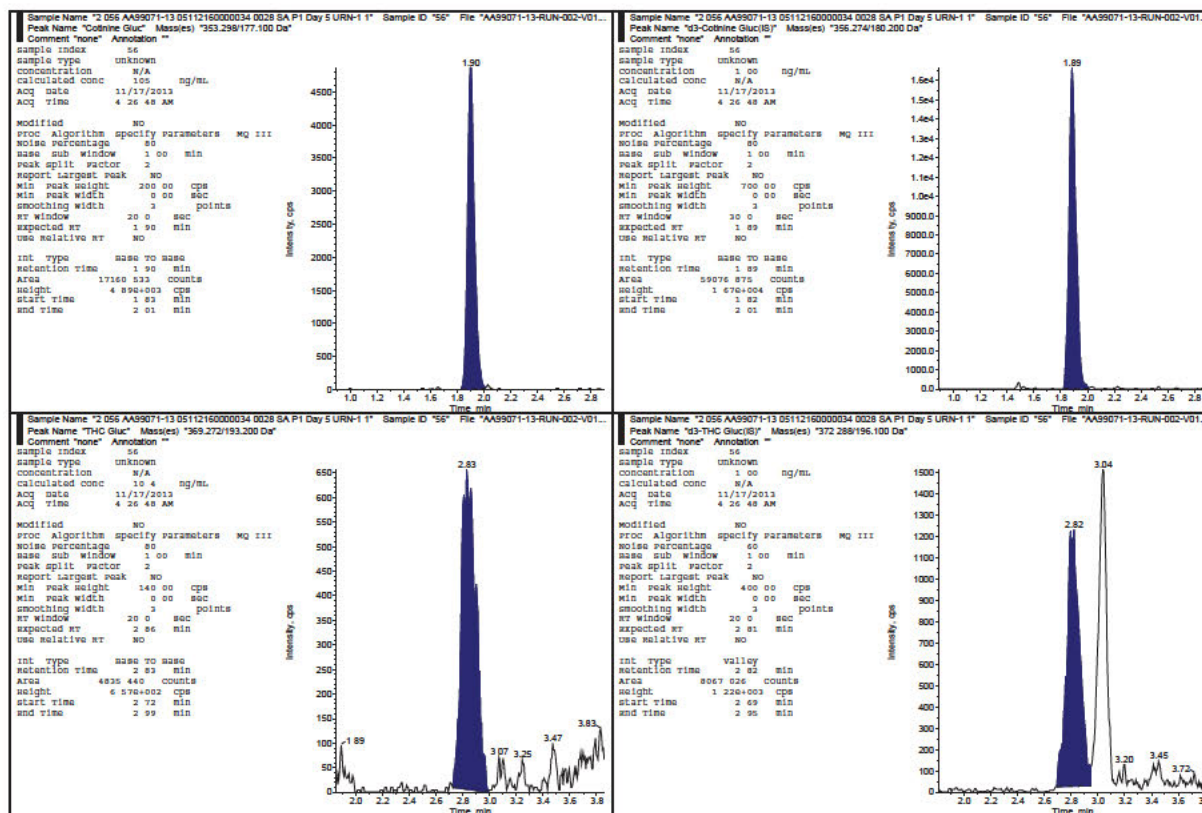


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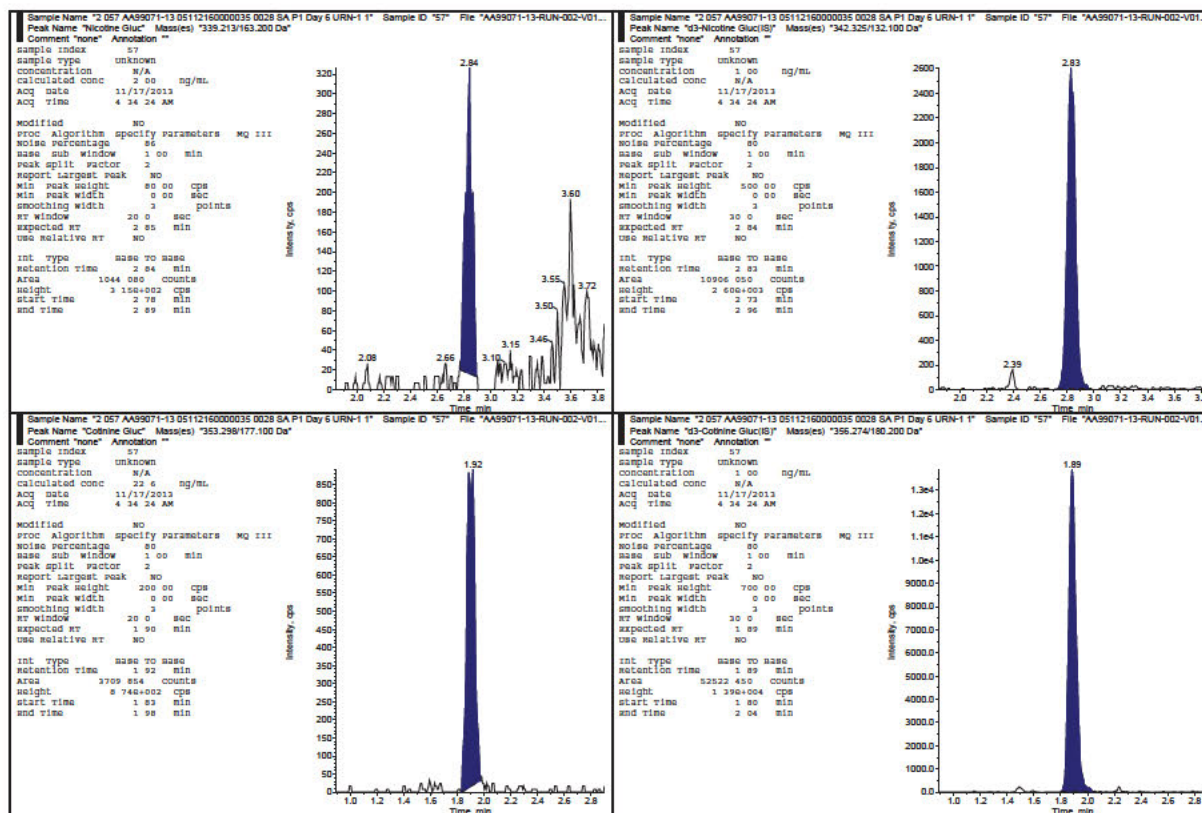


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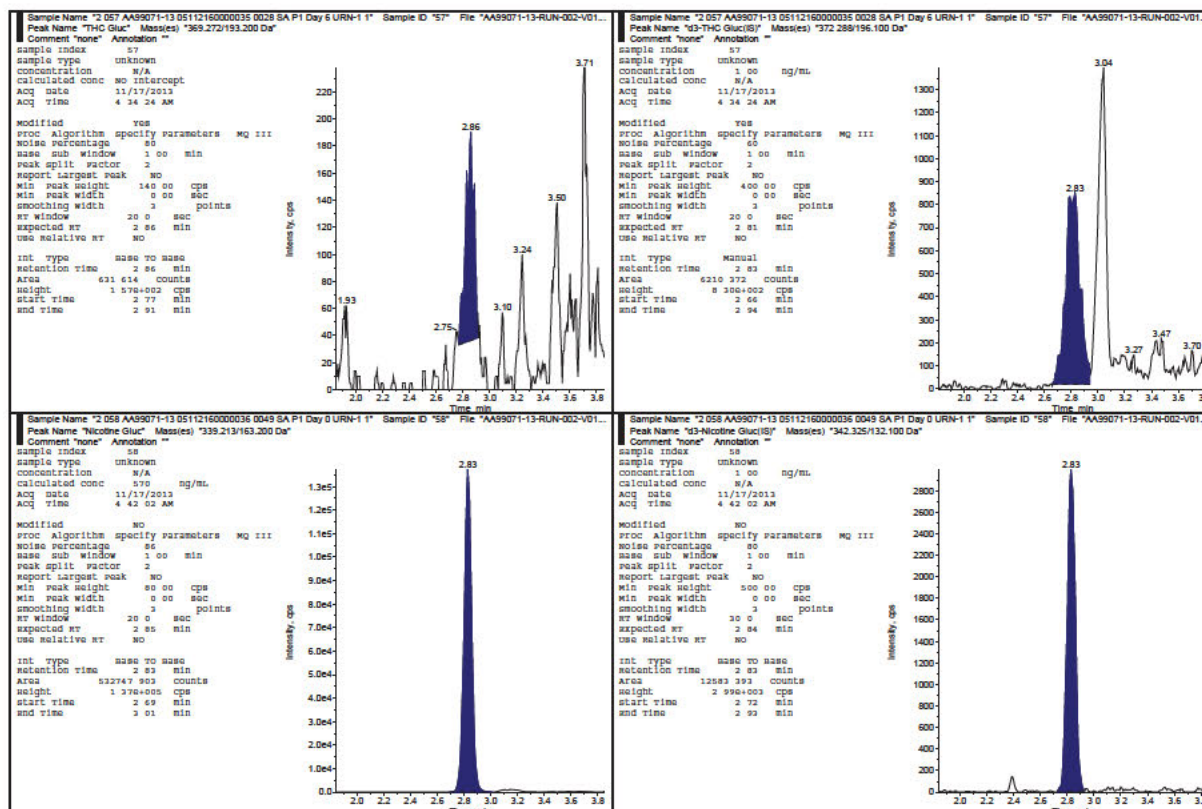


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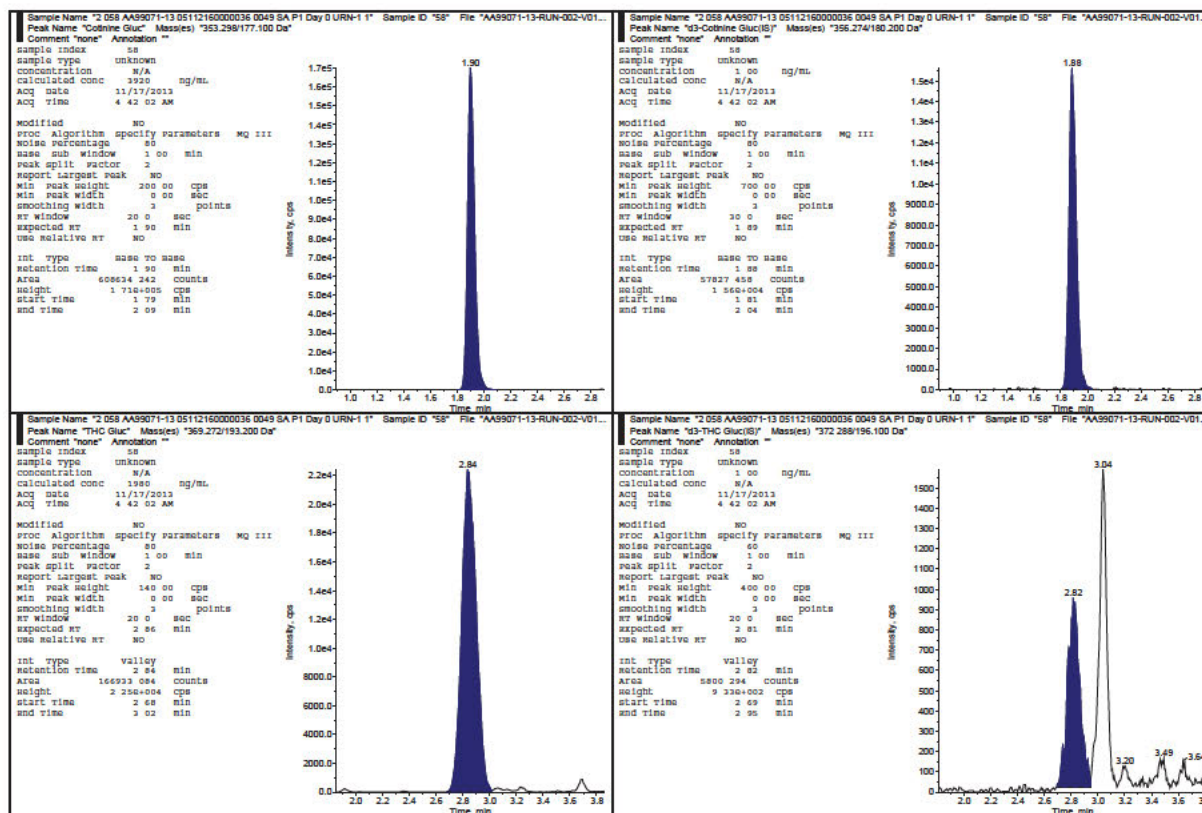


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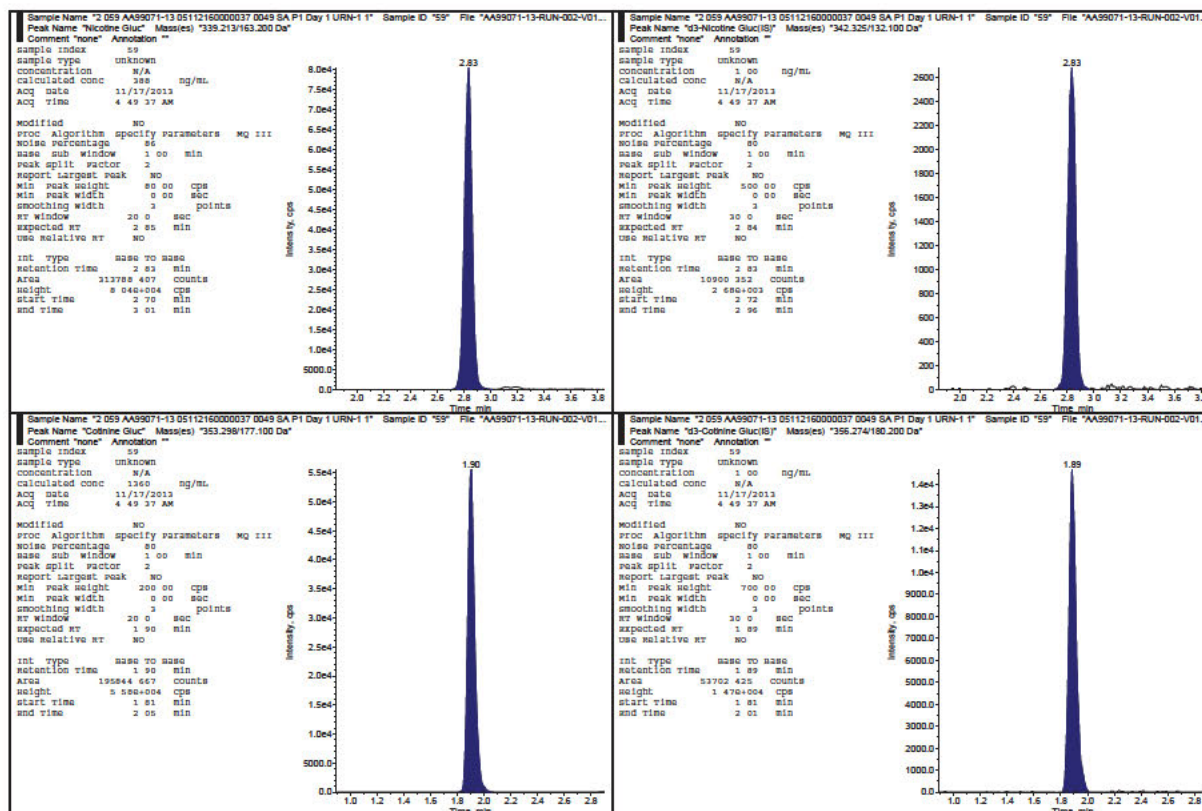


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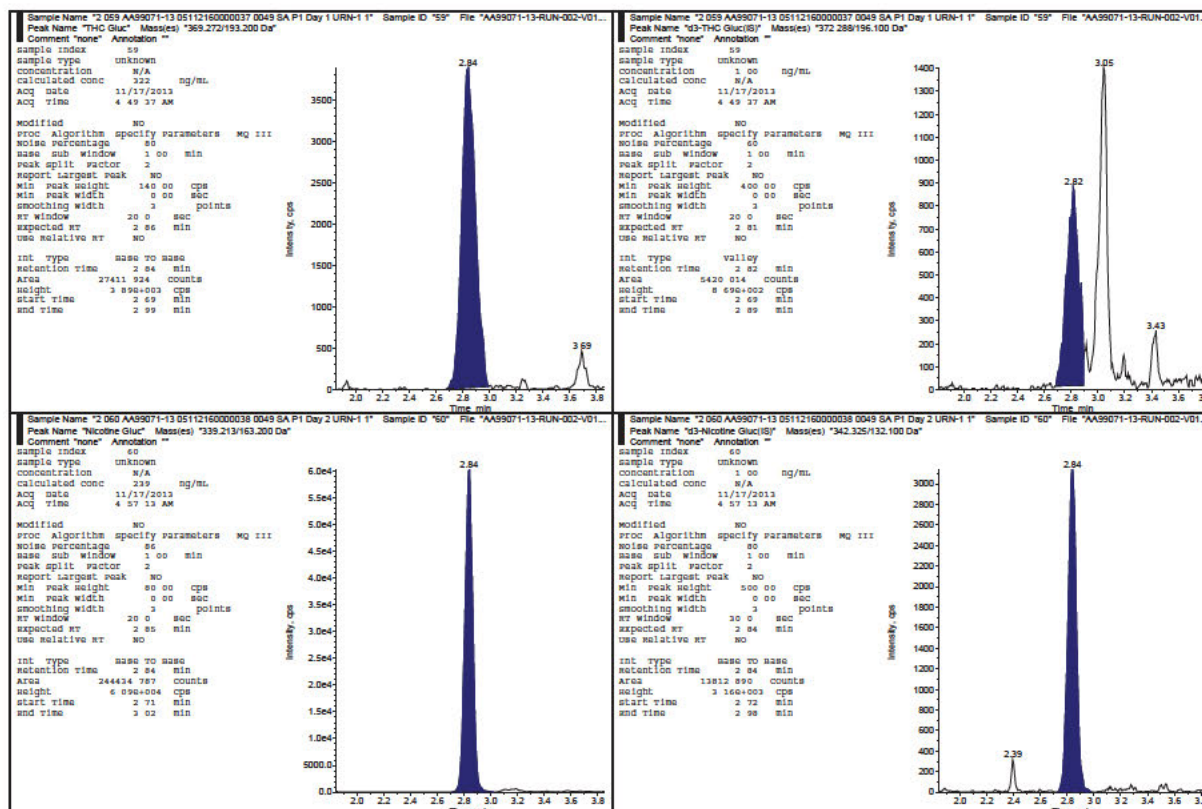


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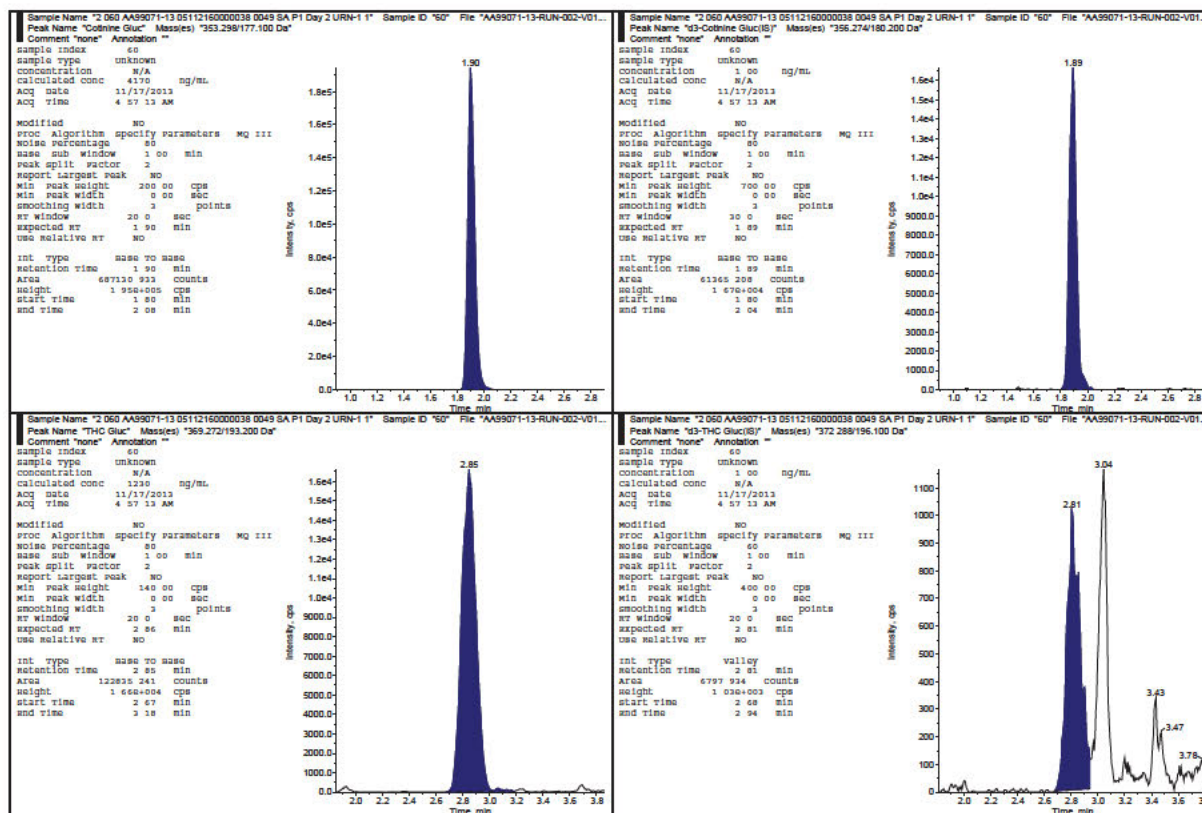


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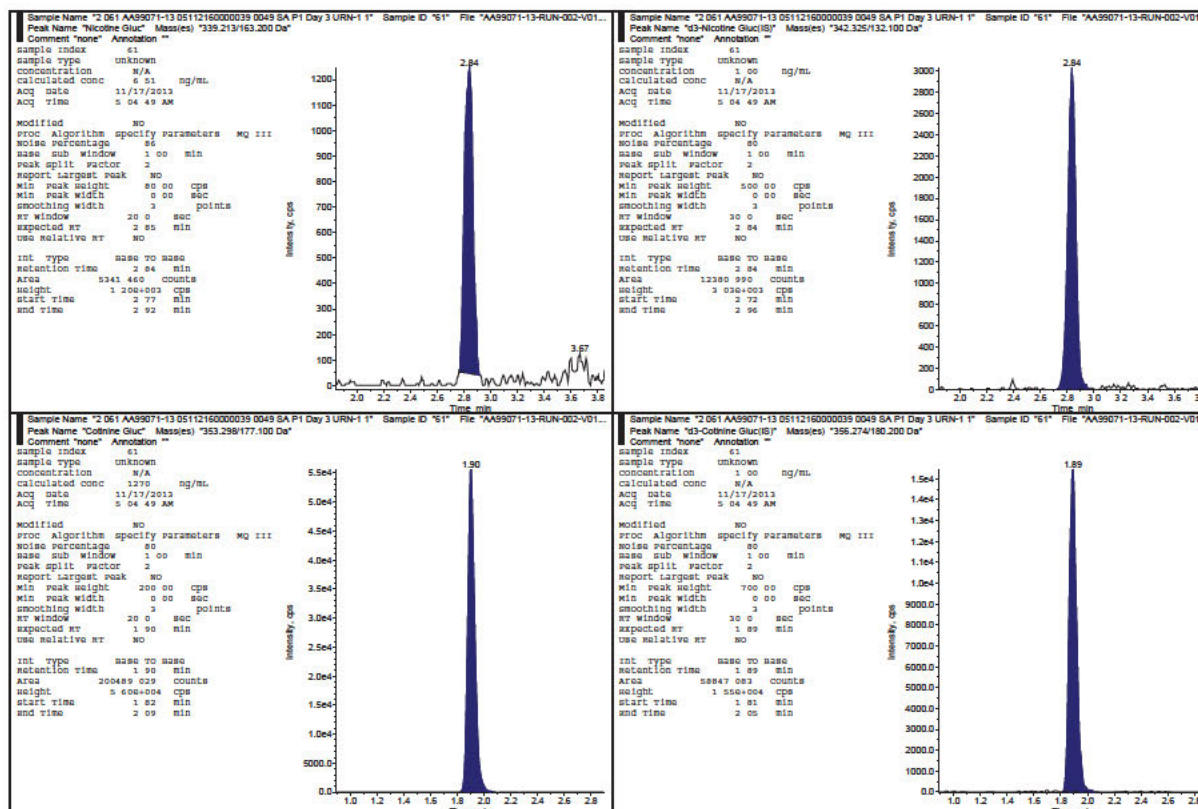


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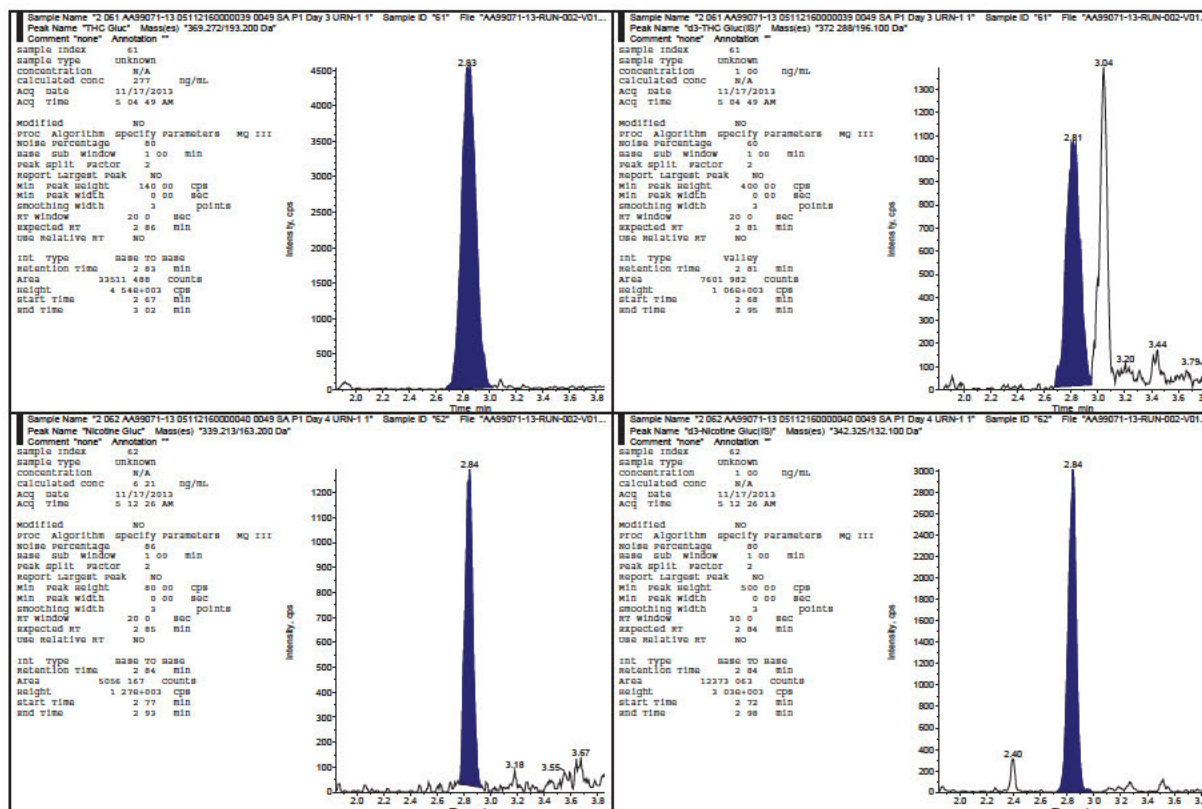


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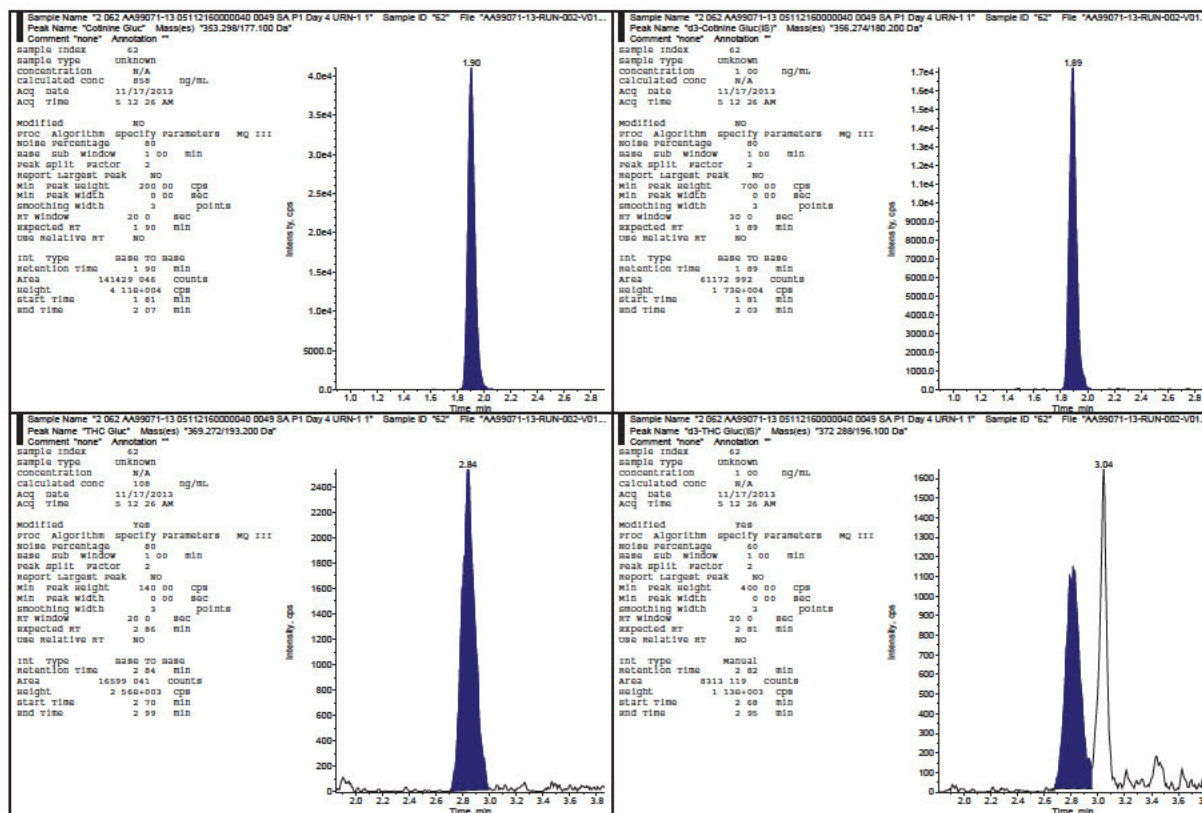


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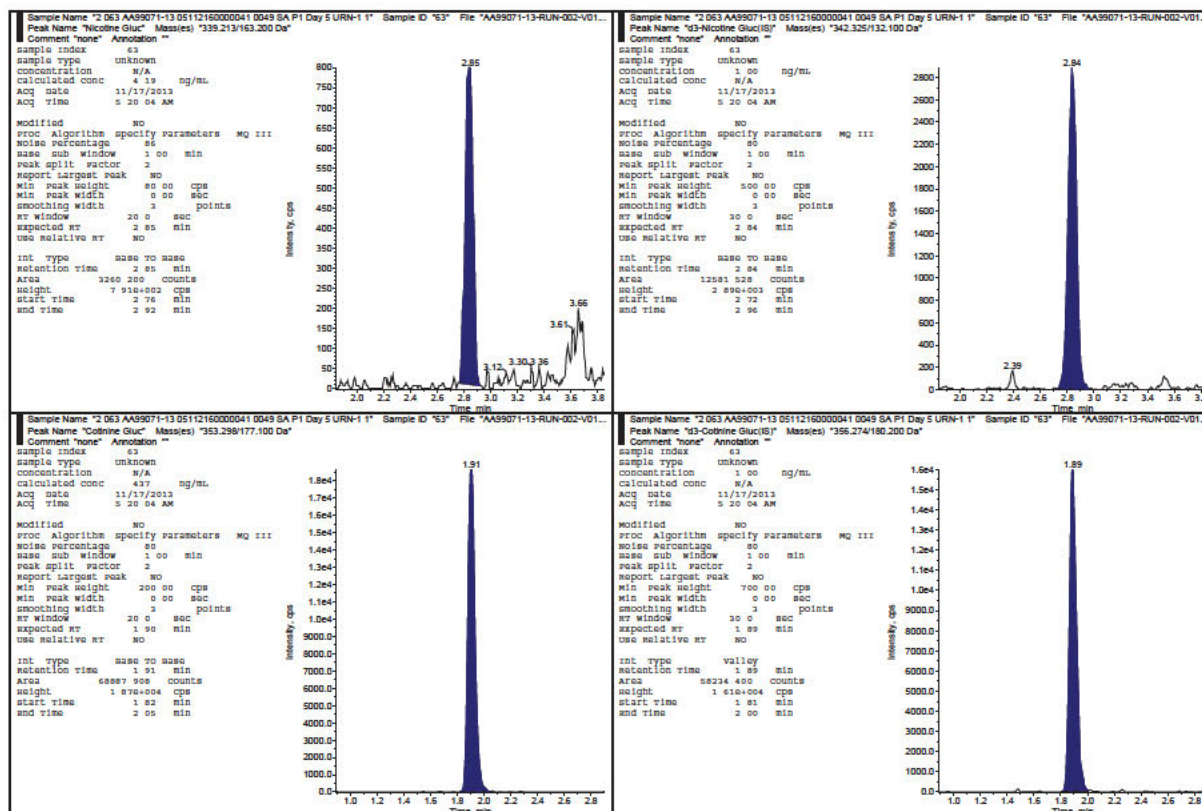


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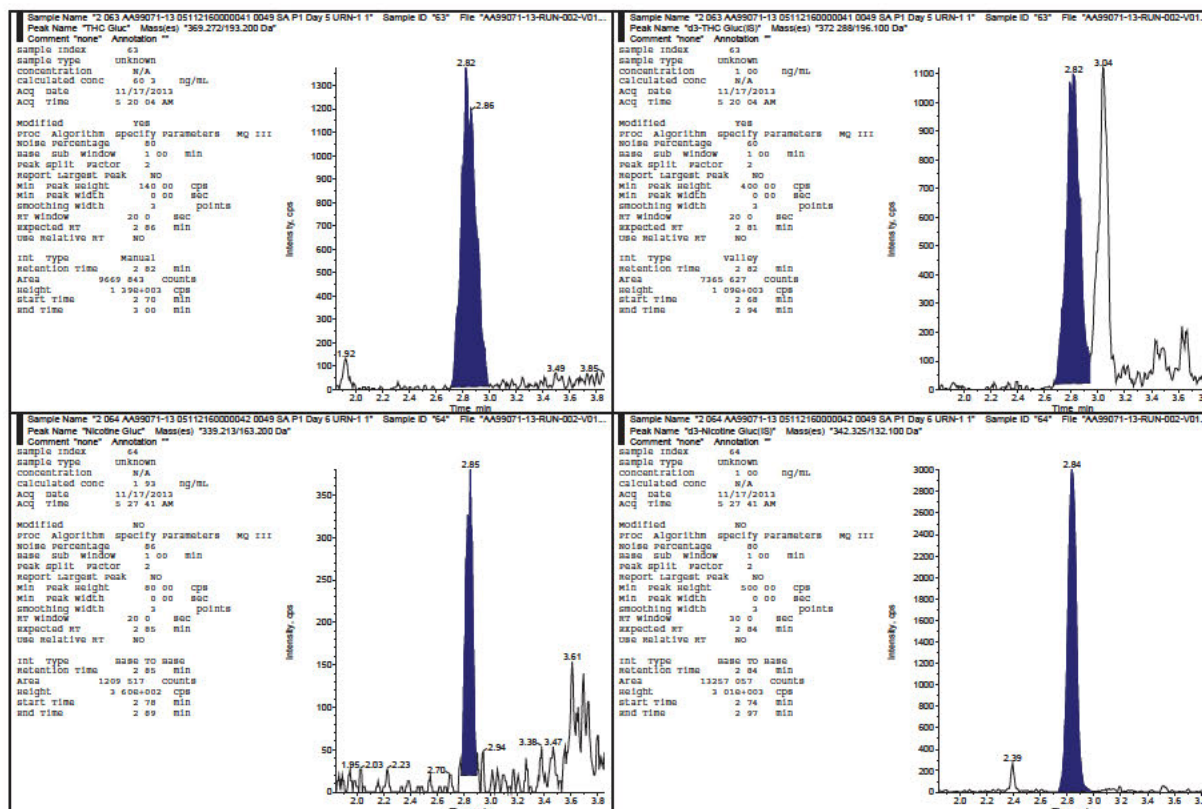


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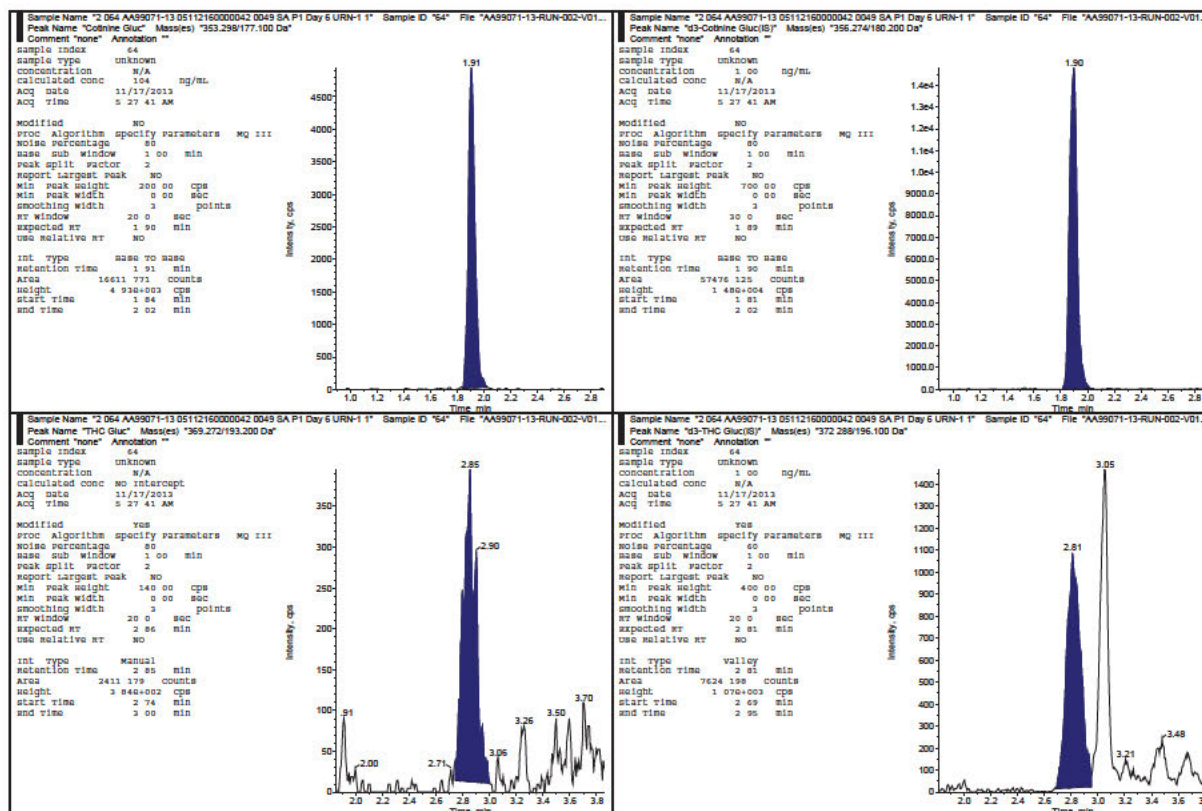


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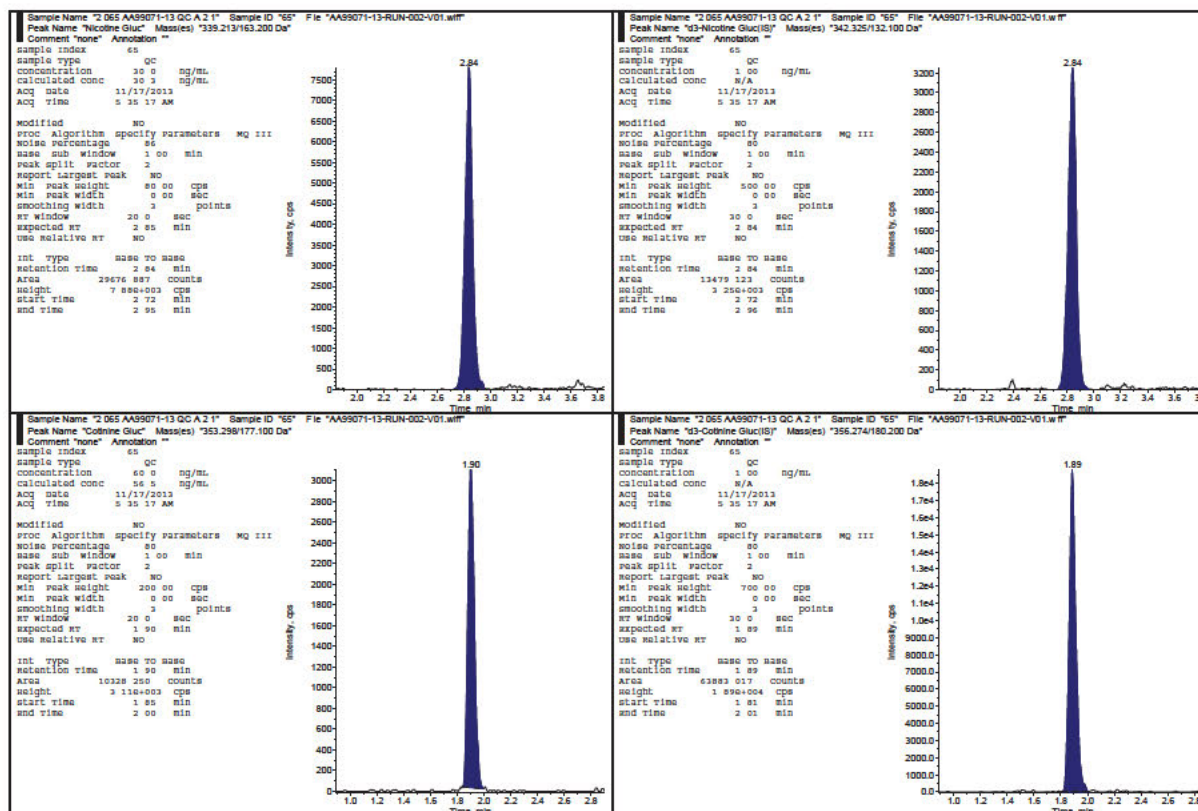


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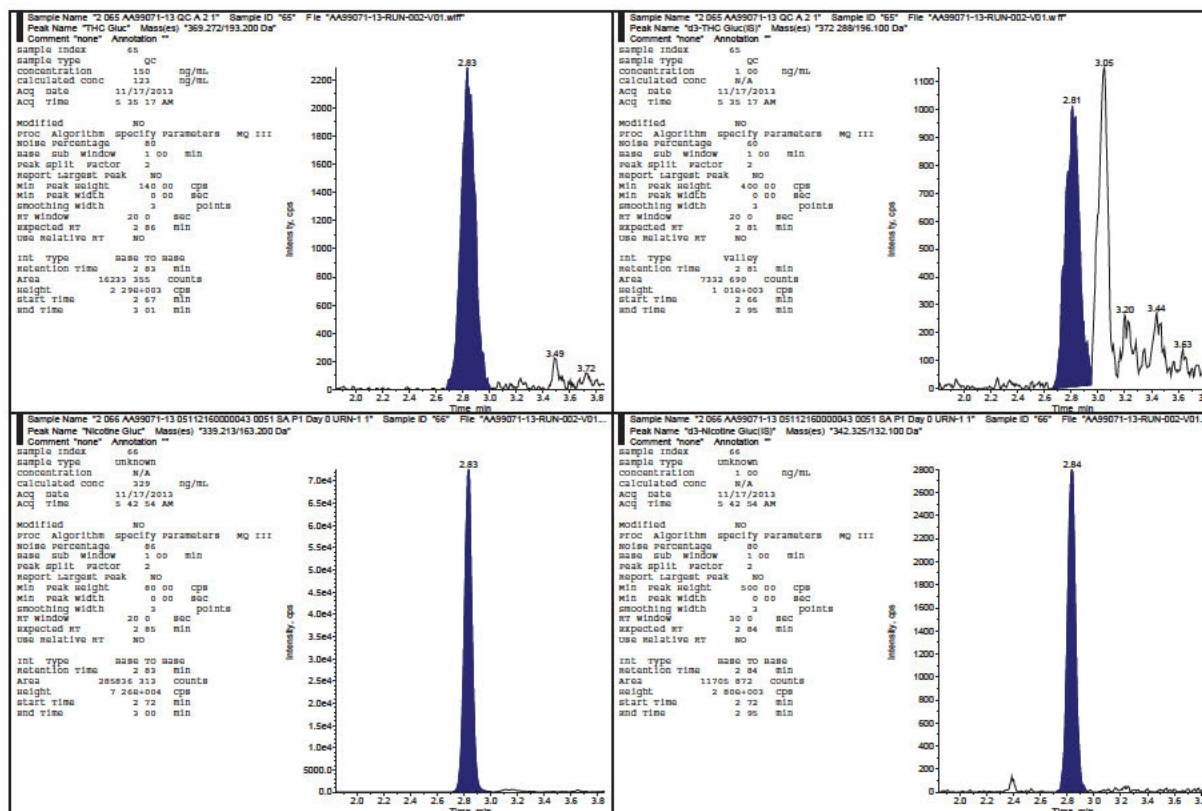


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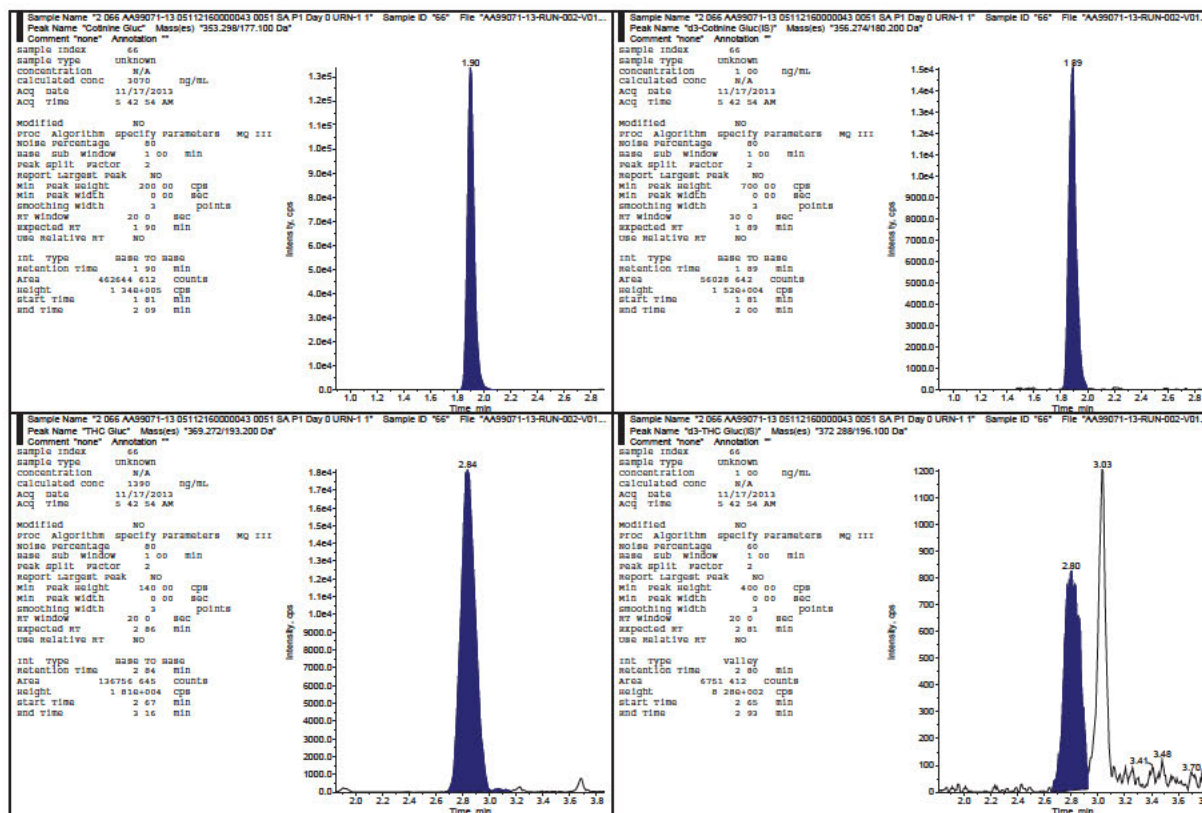


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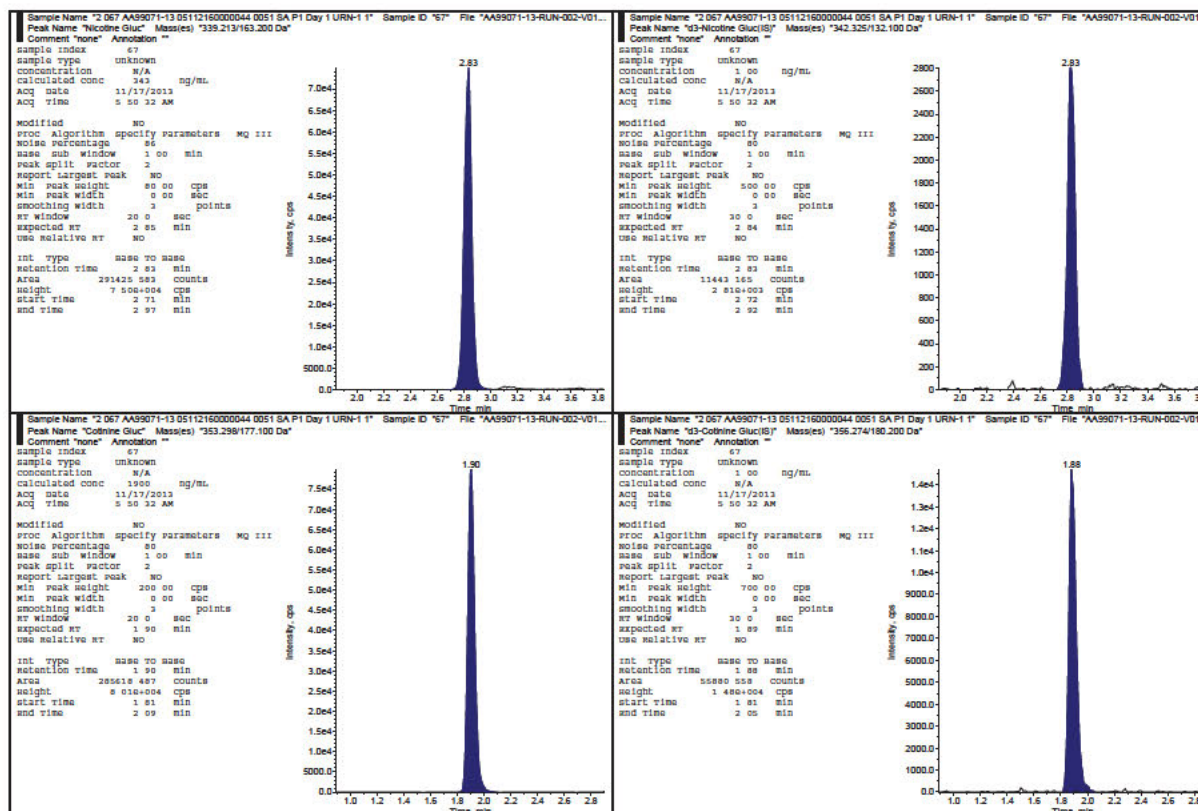


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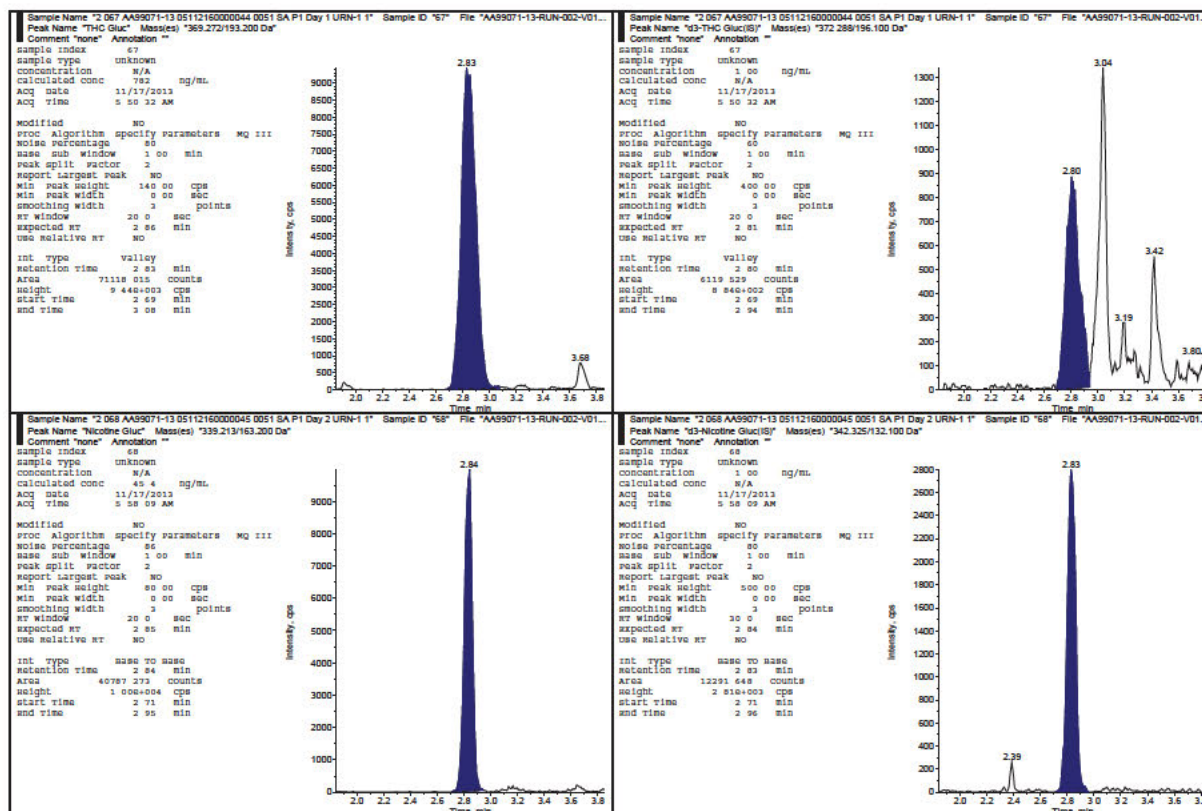


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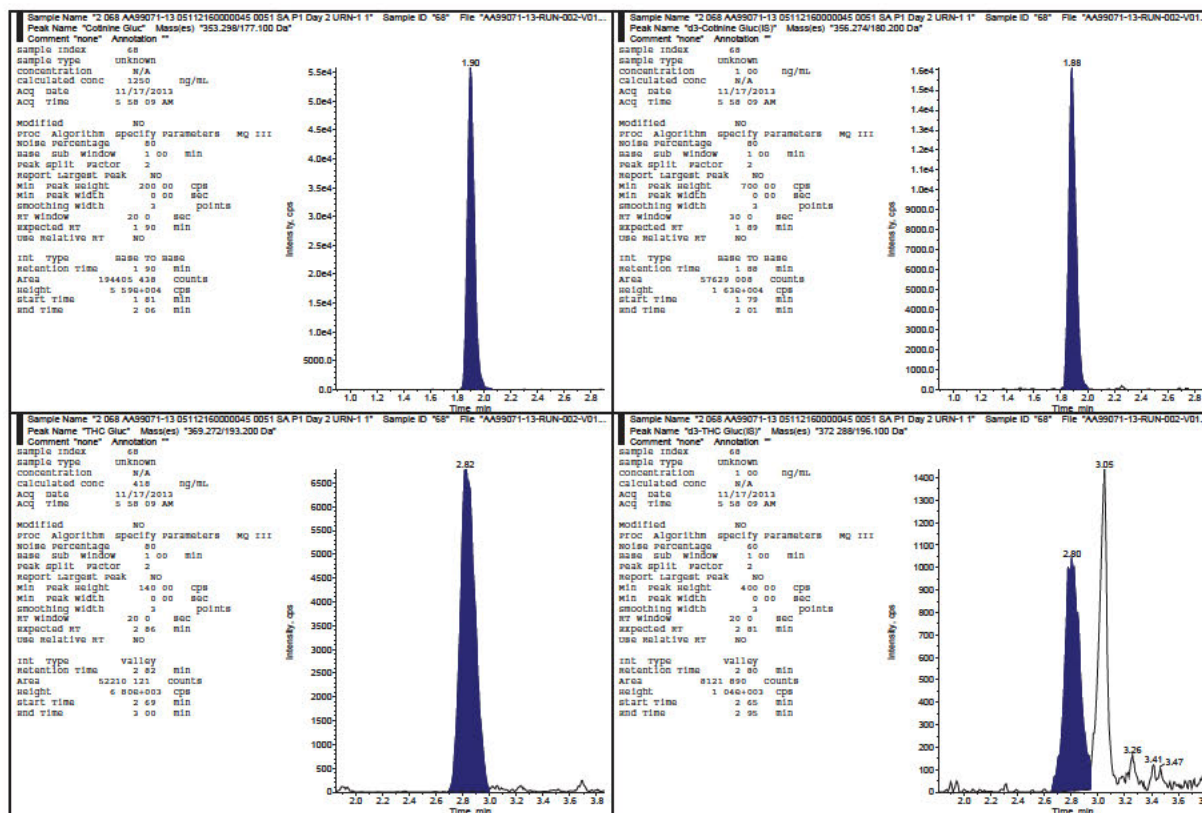


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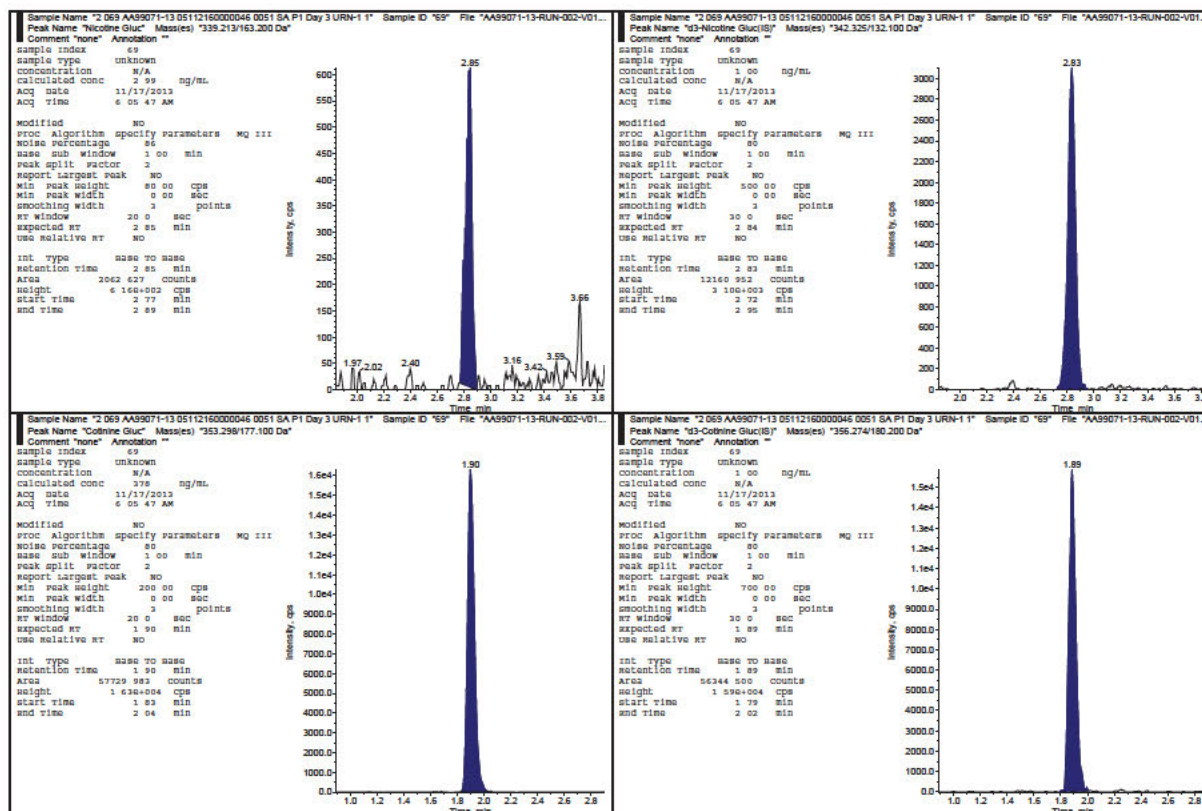


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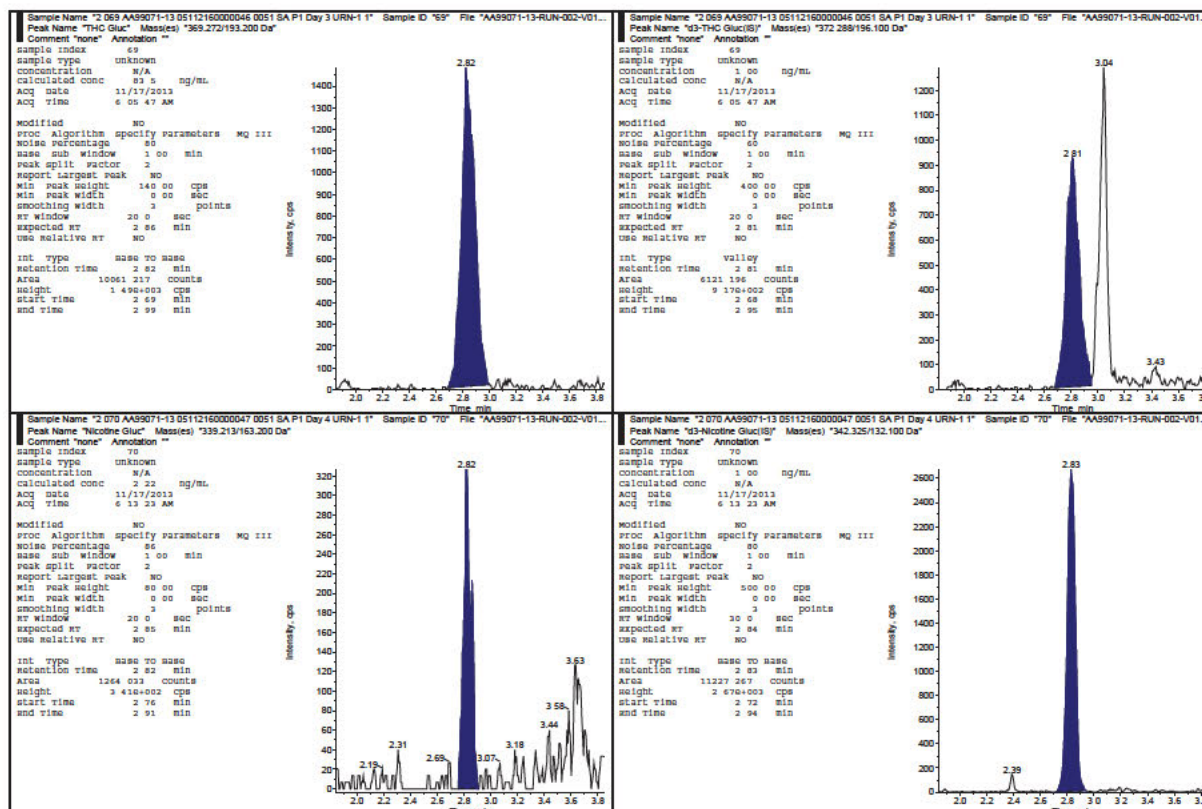


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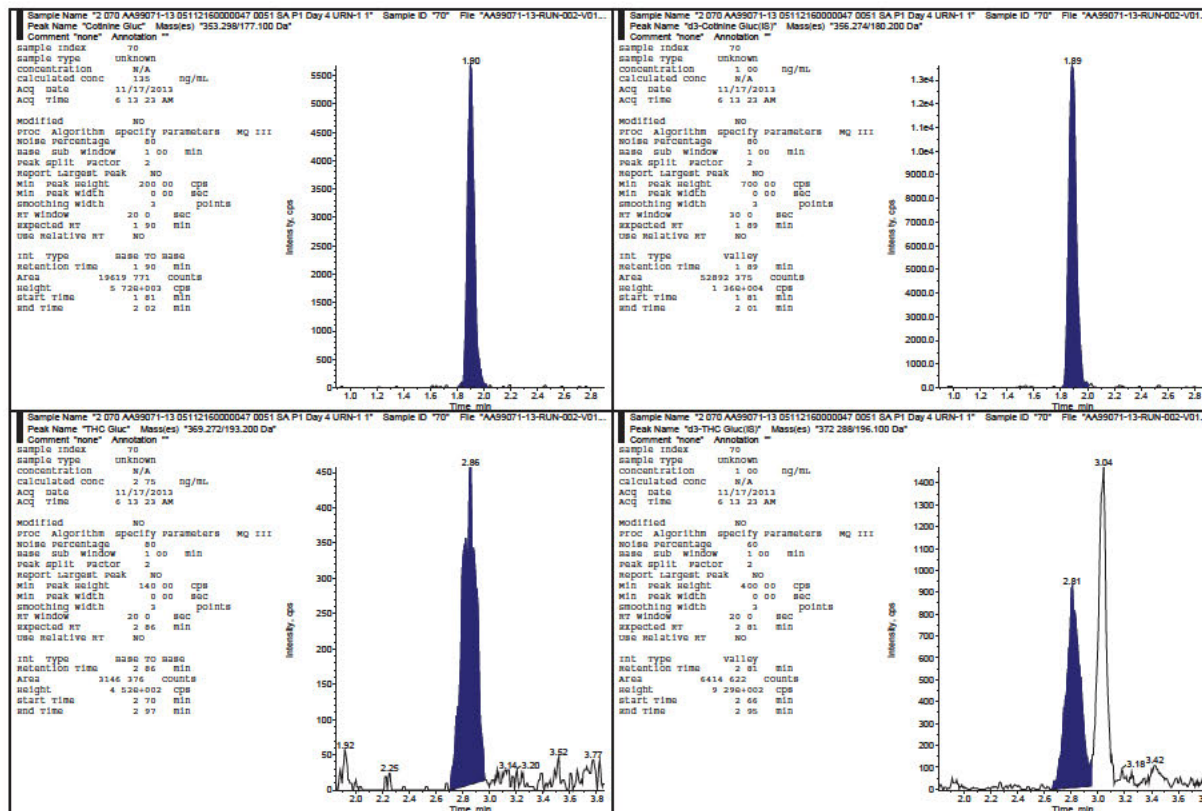


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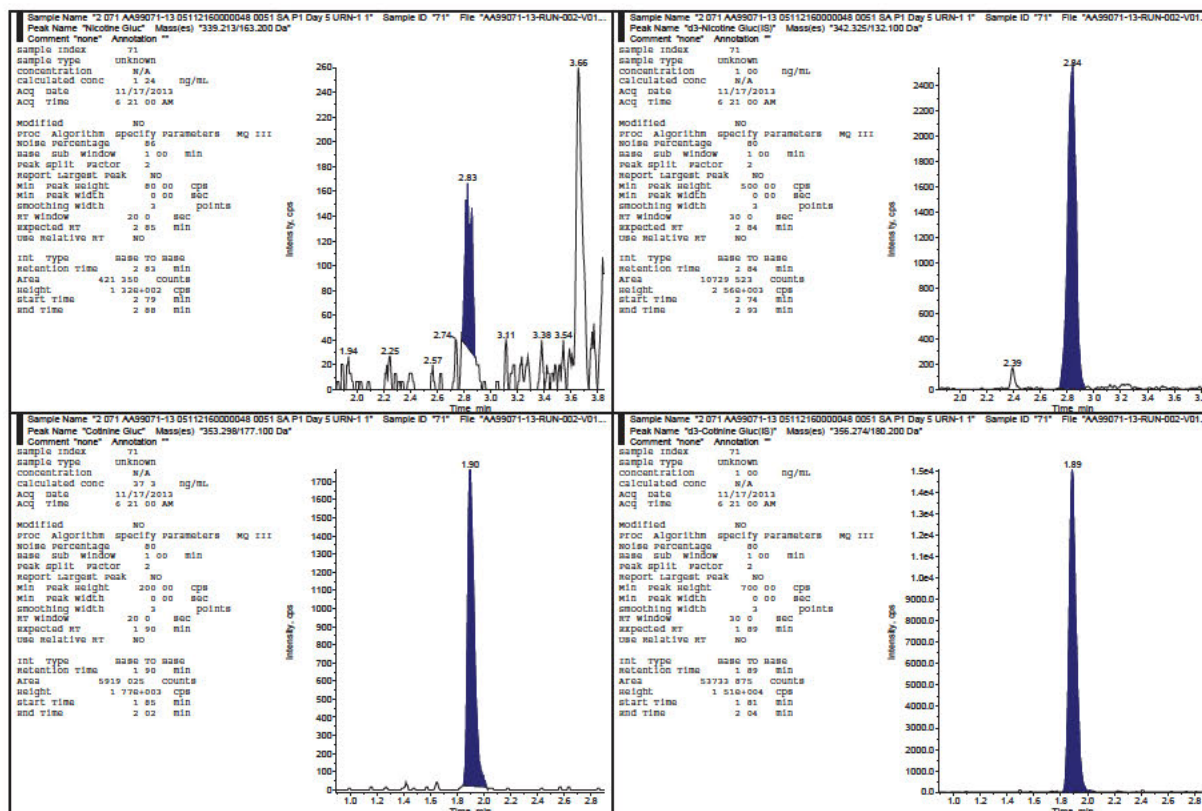


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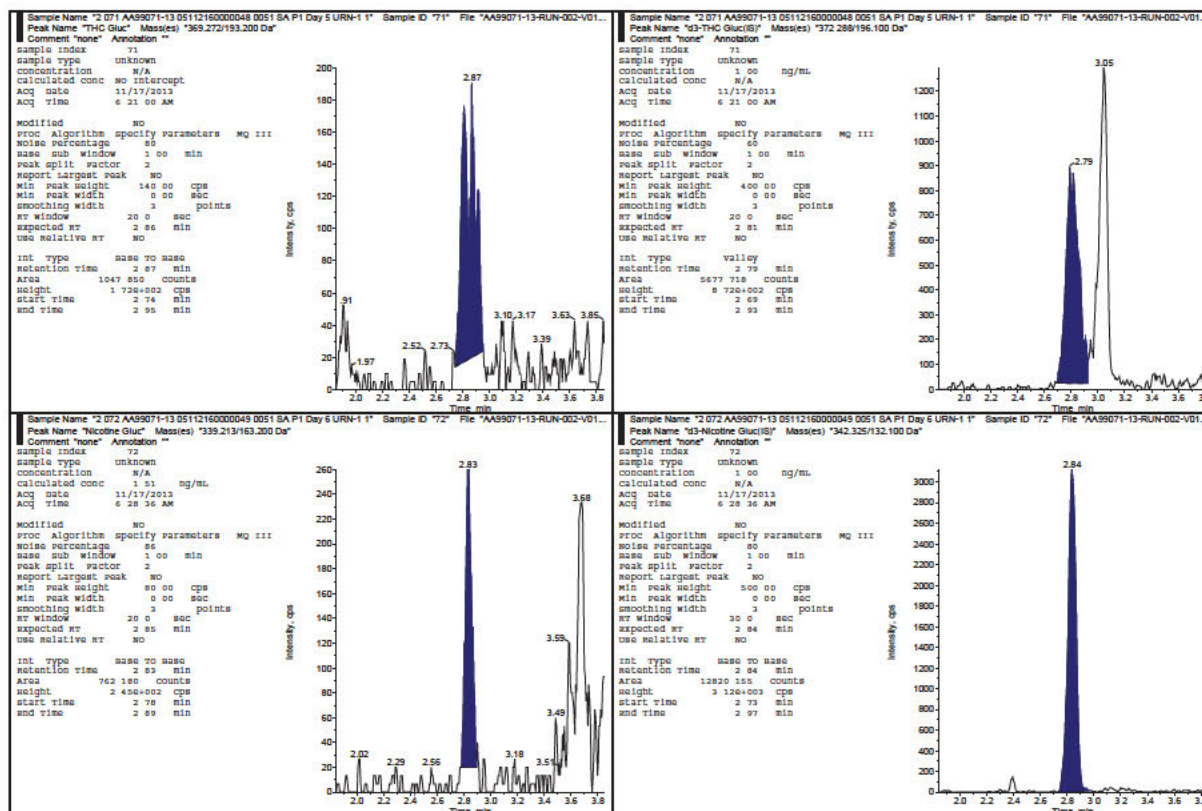


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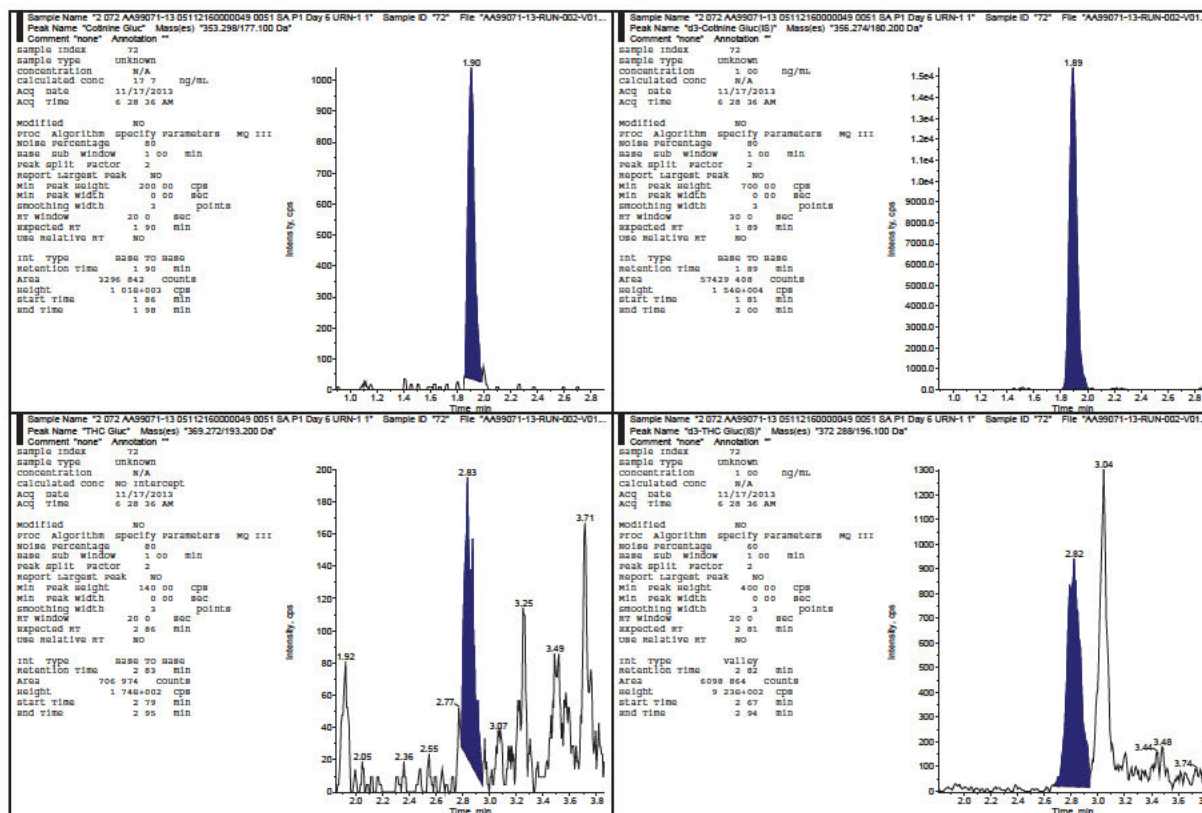


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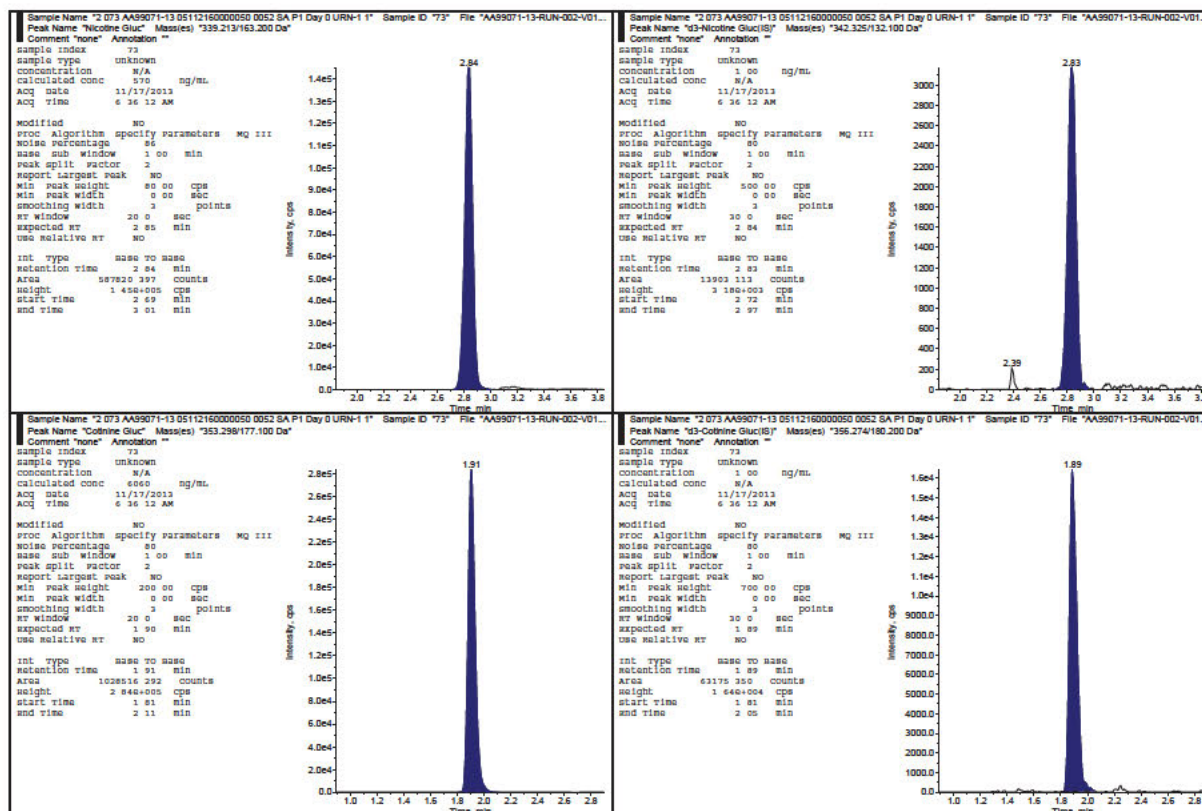


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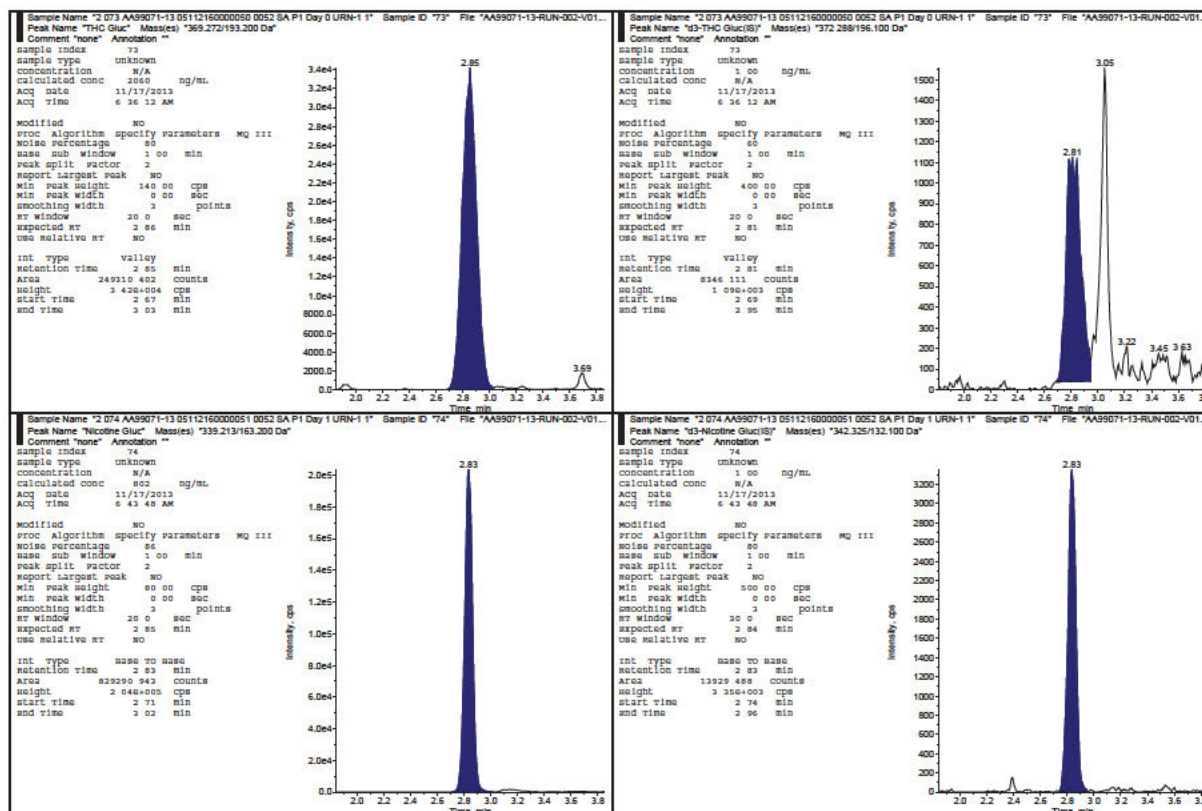


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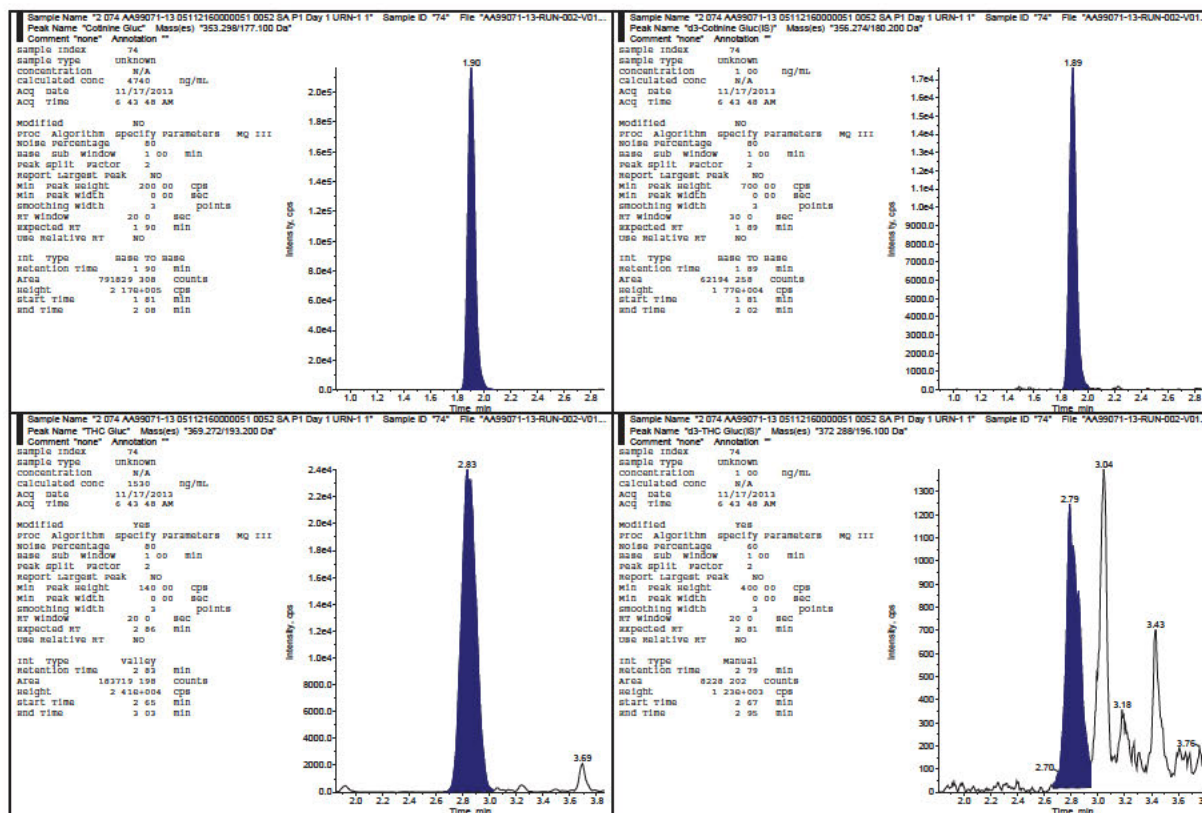


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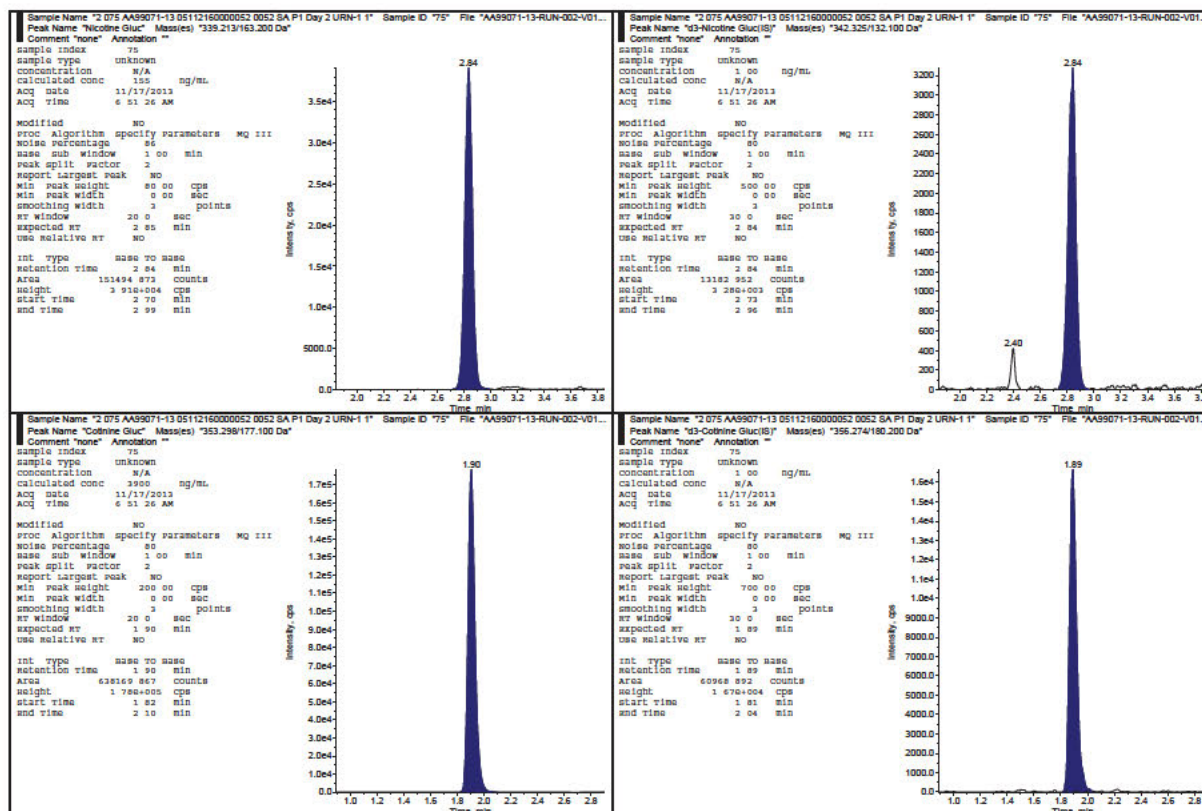


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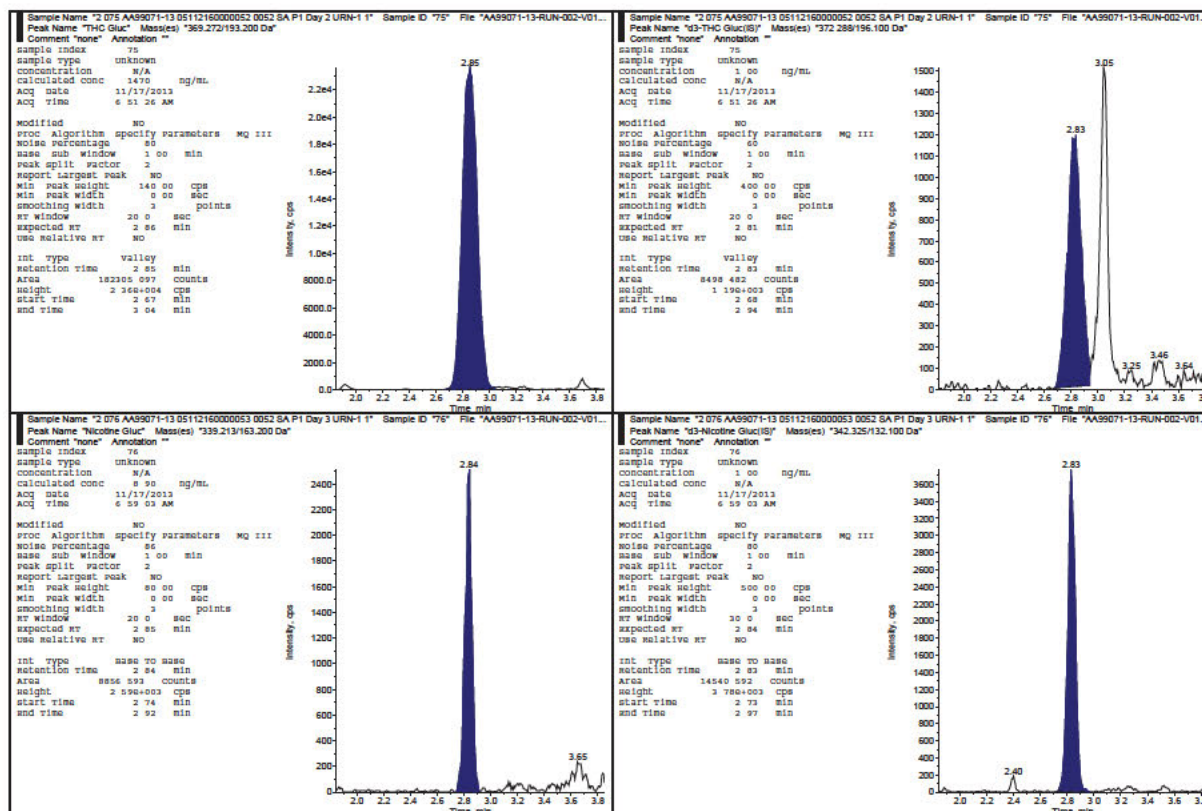


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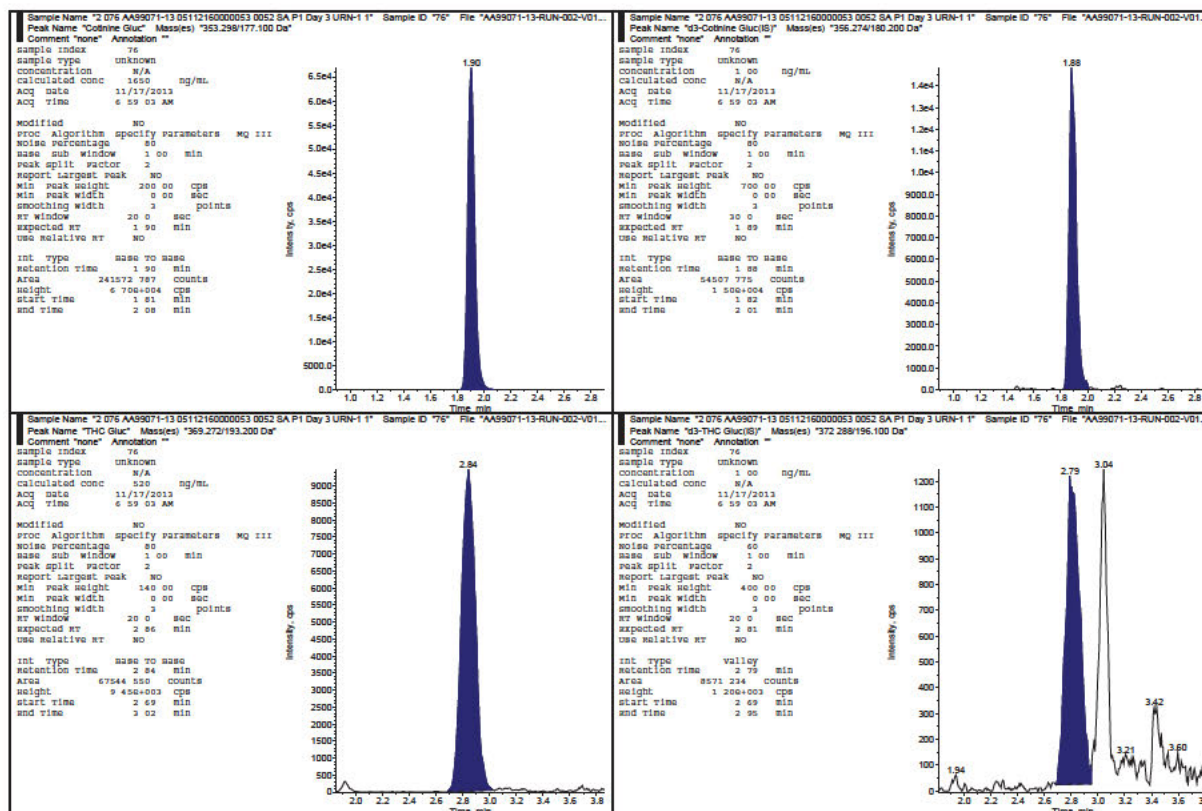


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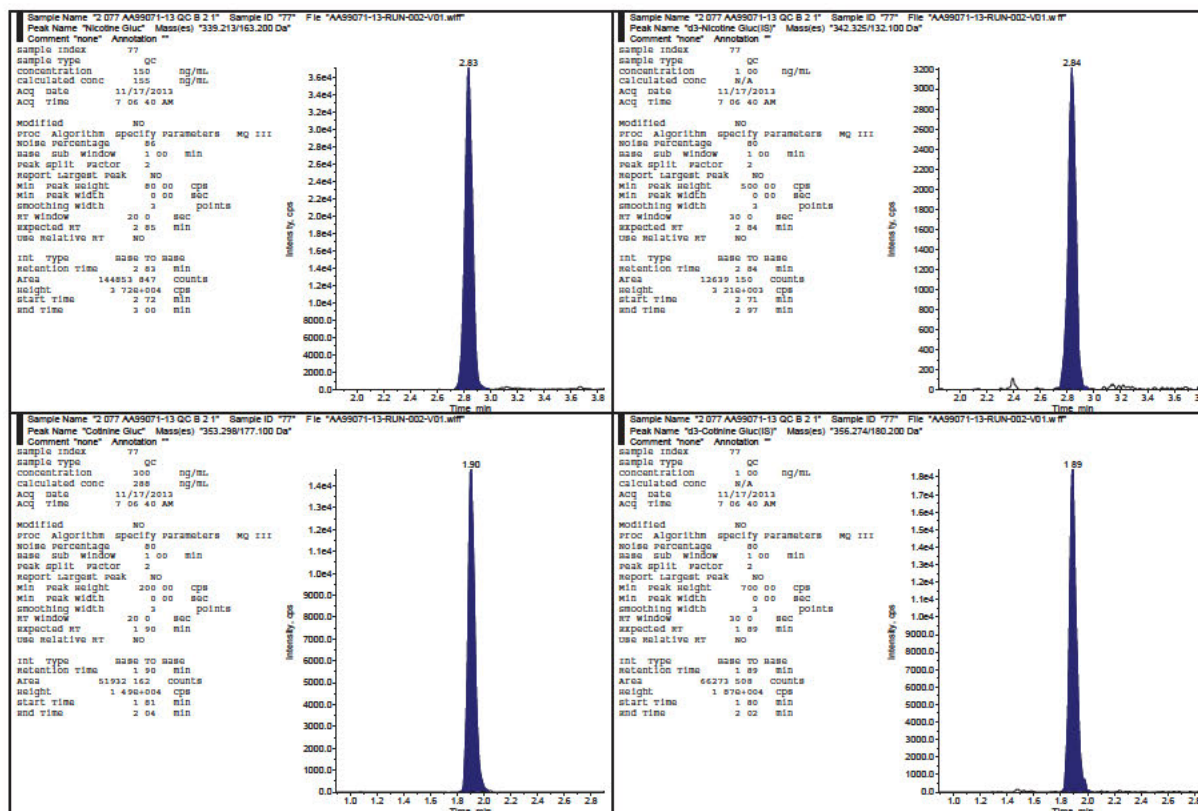


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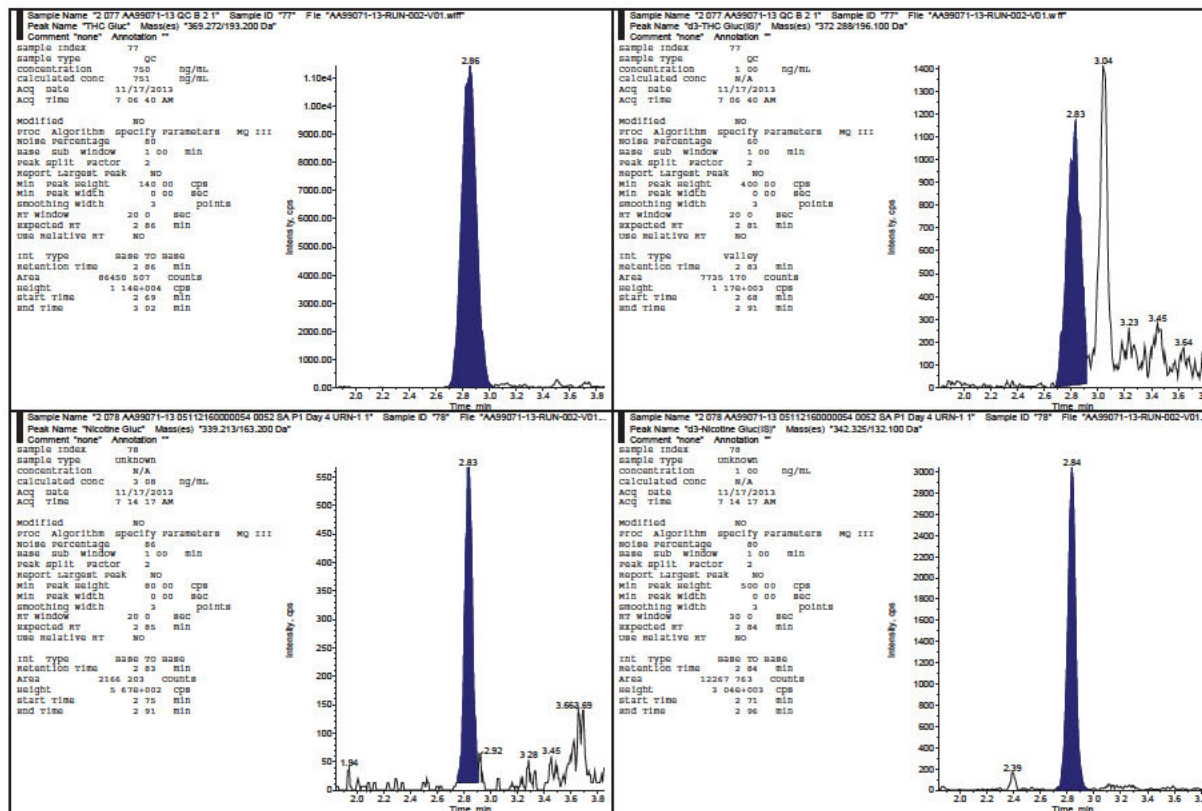


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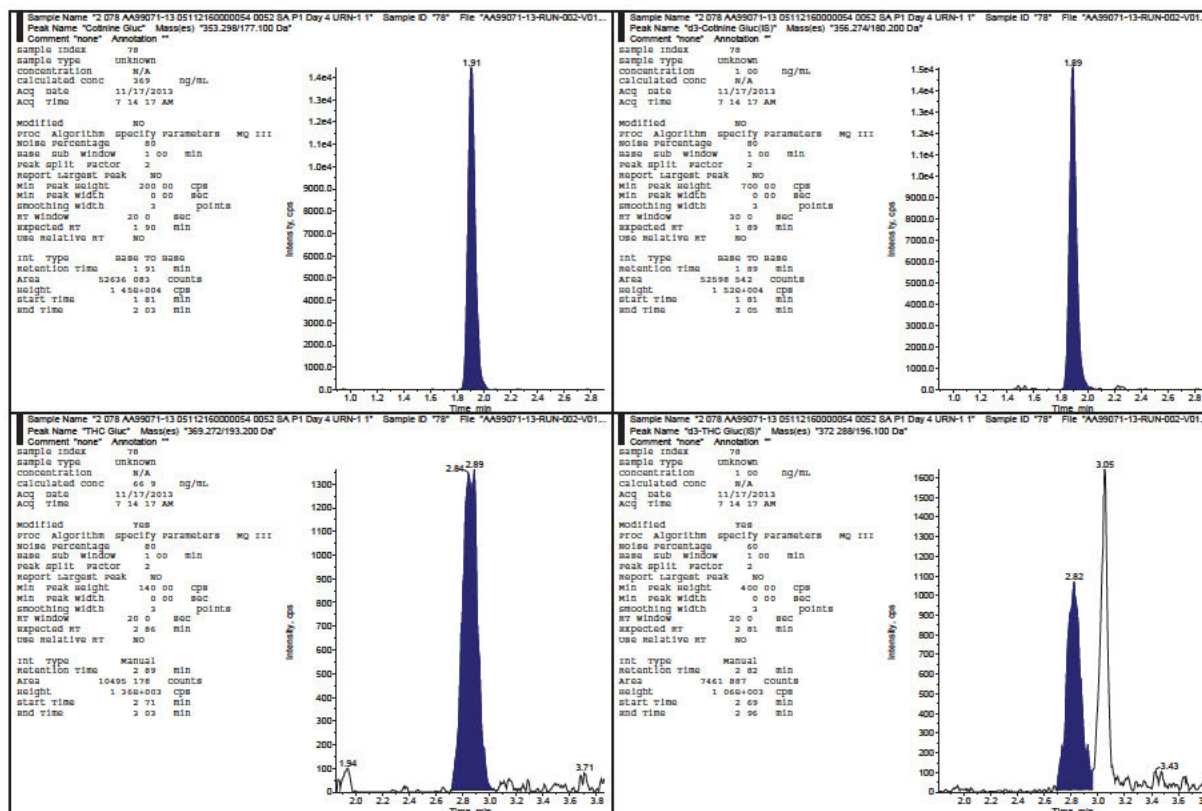


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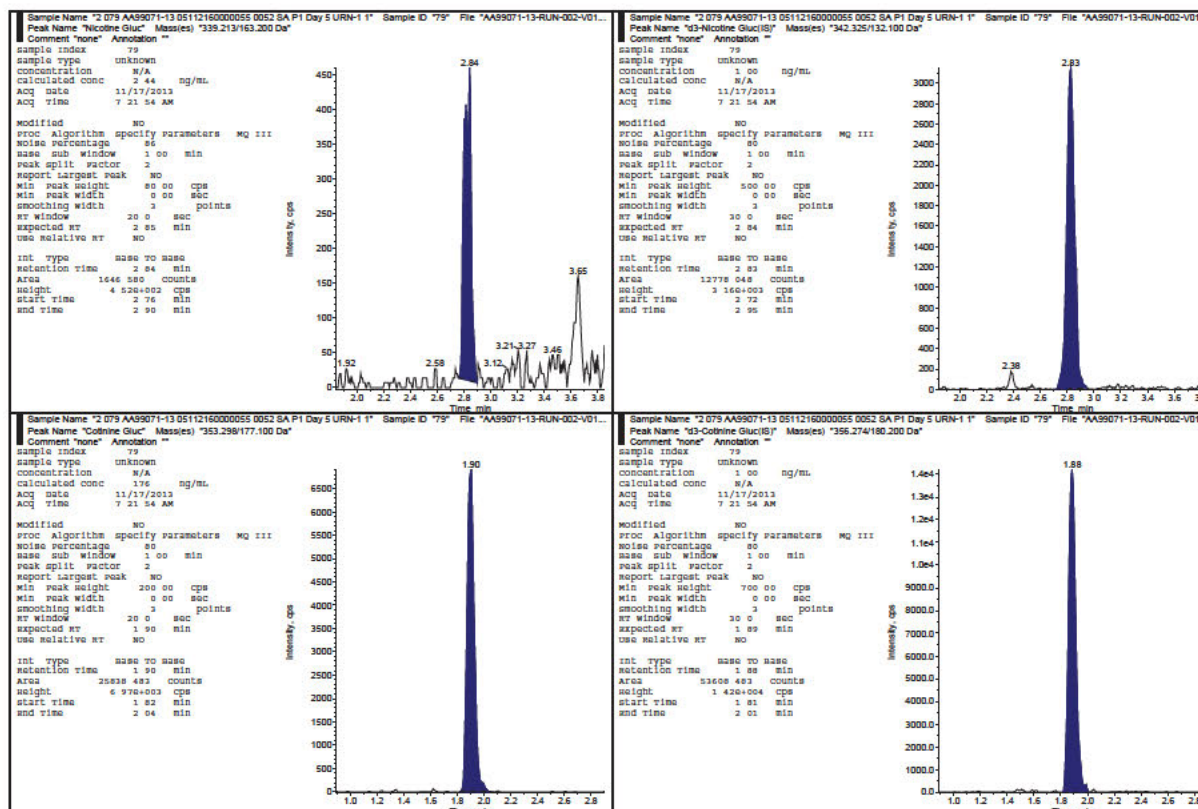


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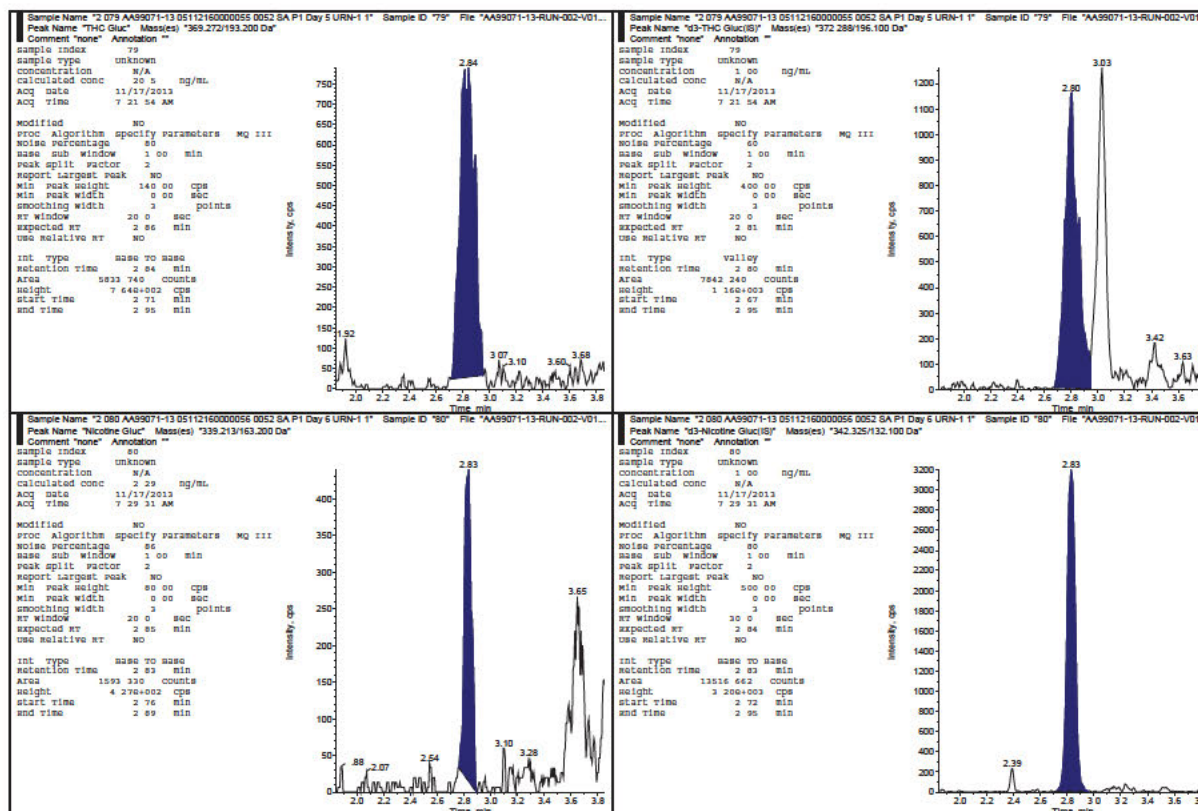


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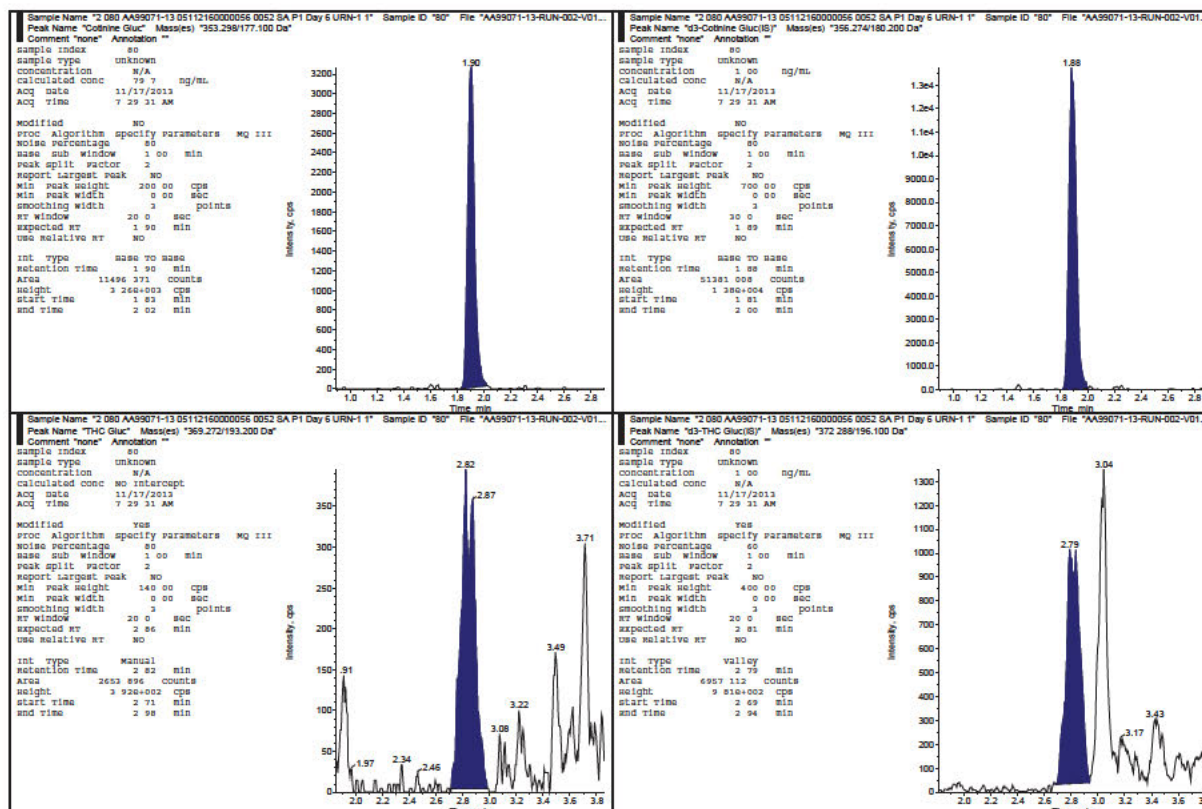


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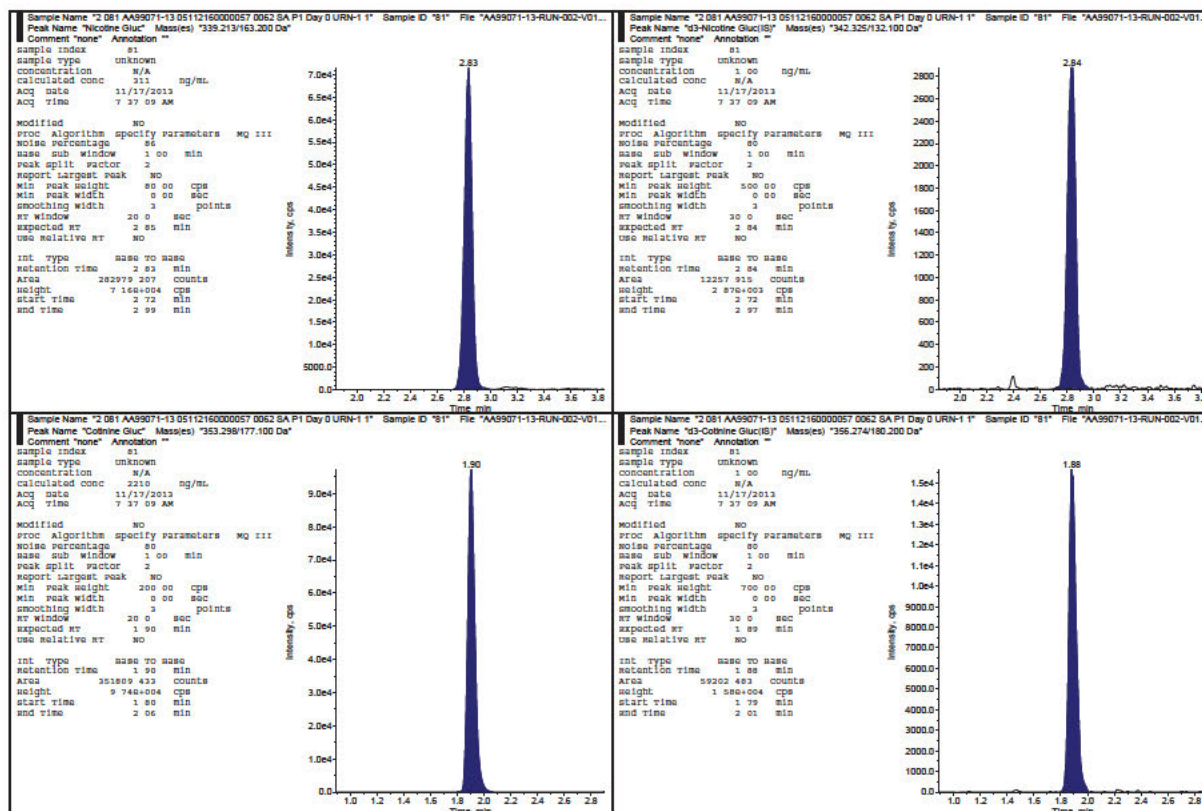


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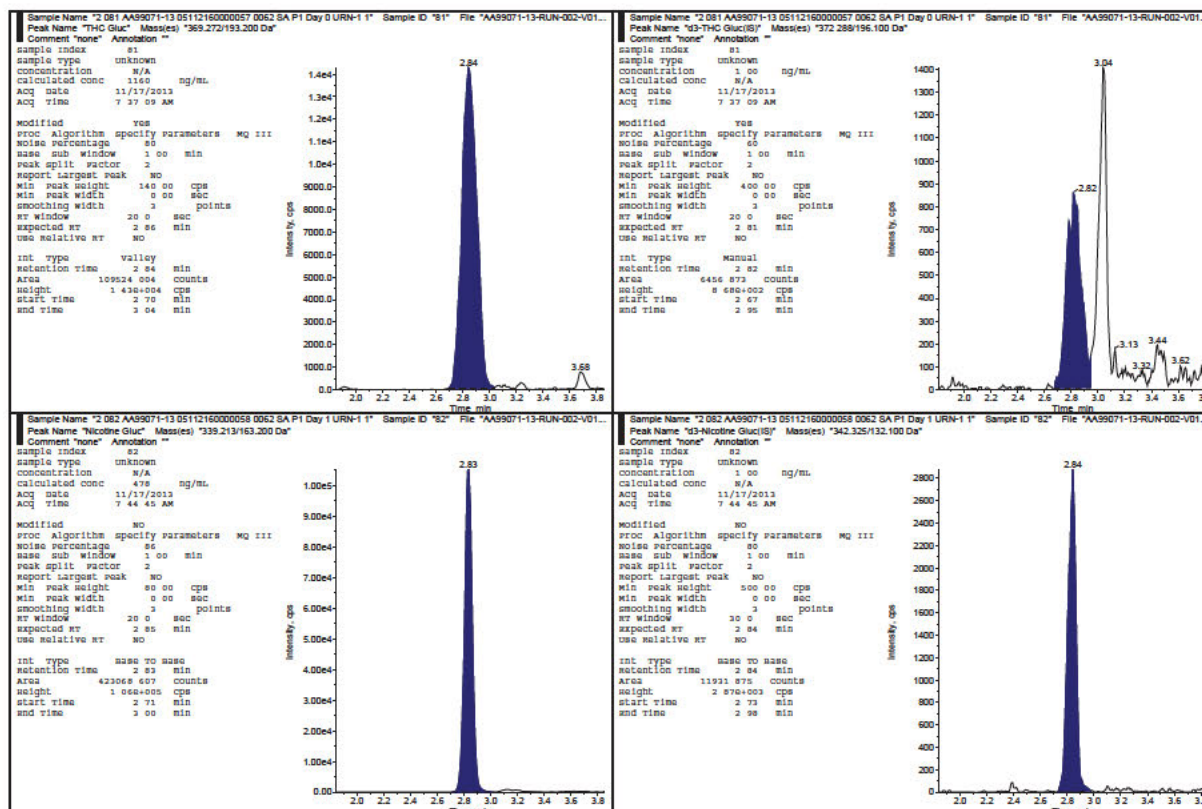


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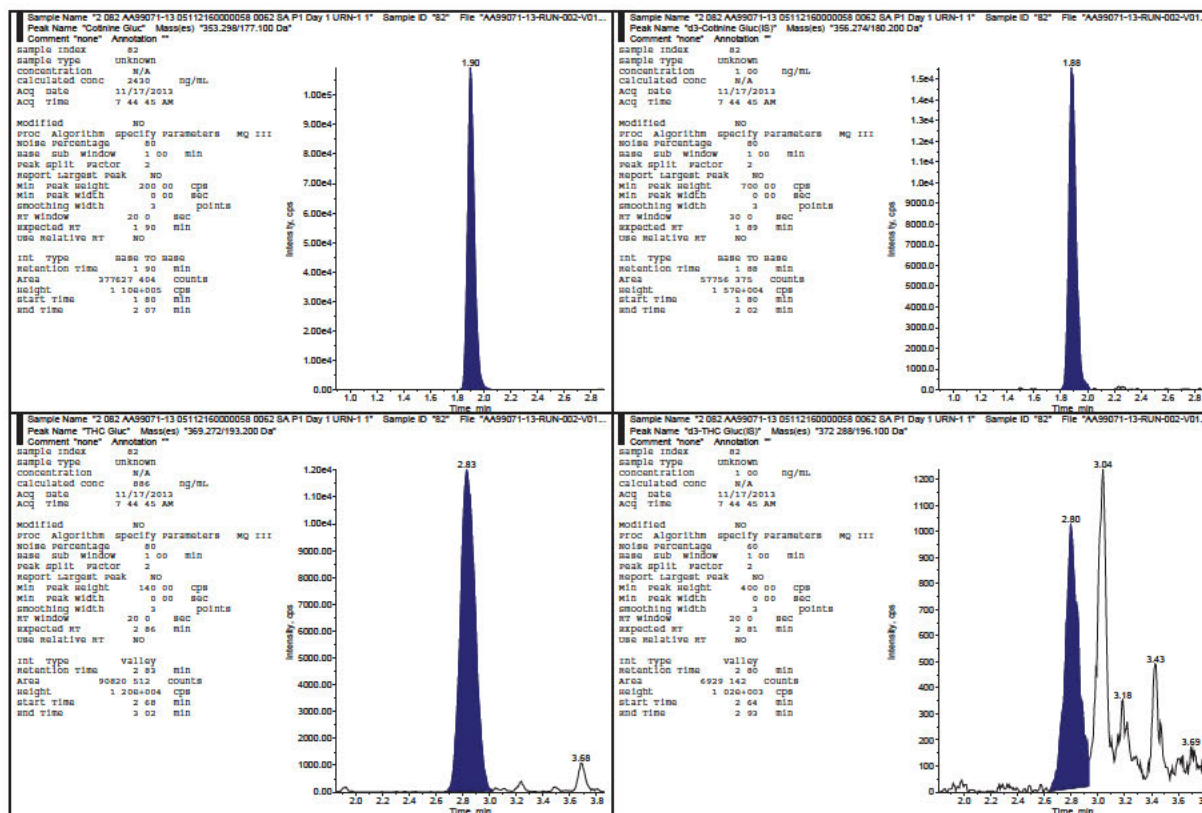


Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-*N*-Glucuronide, Cotinine-*N*-Glucuronide, and *trans*-3'-Hydroxycotinine-*O*-Glucuronide in Human Urine
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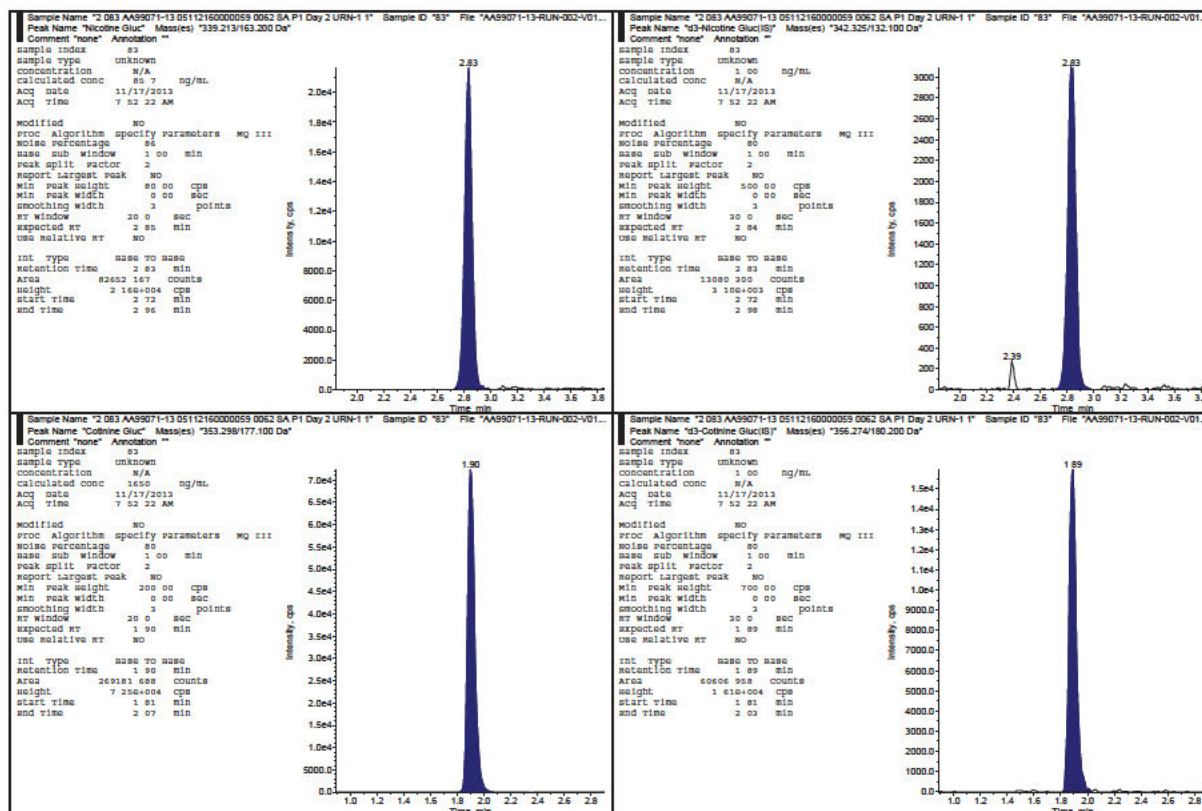


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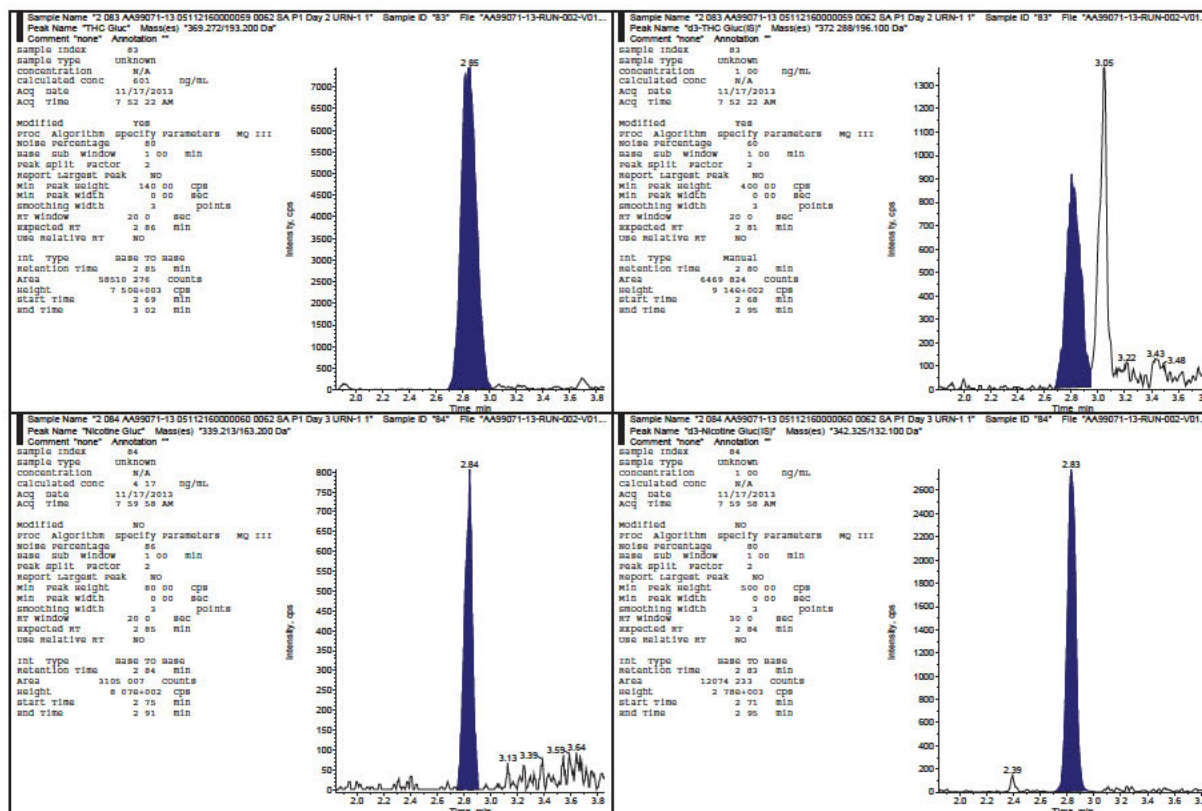


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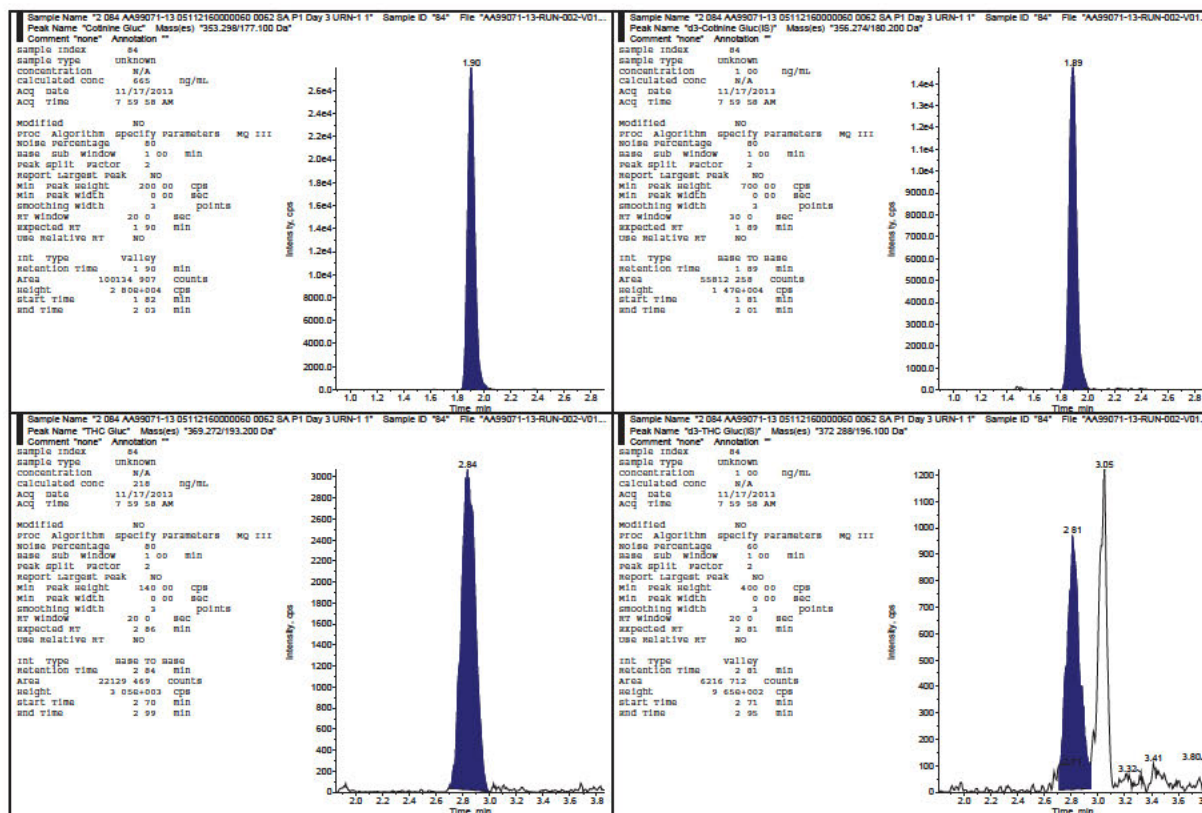


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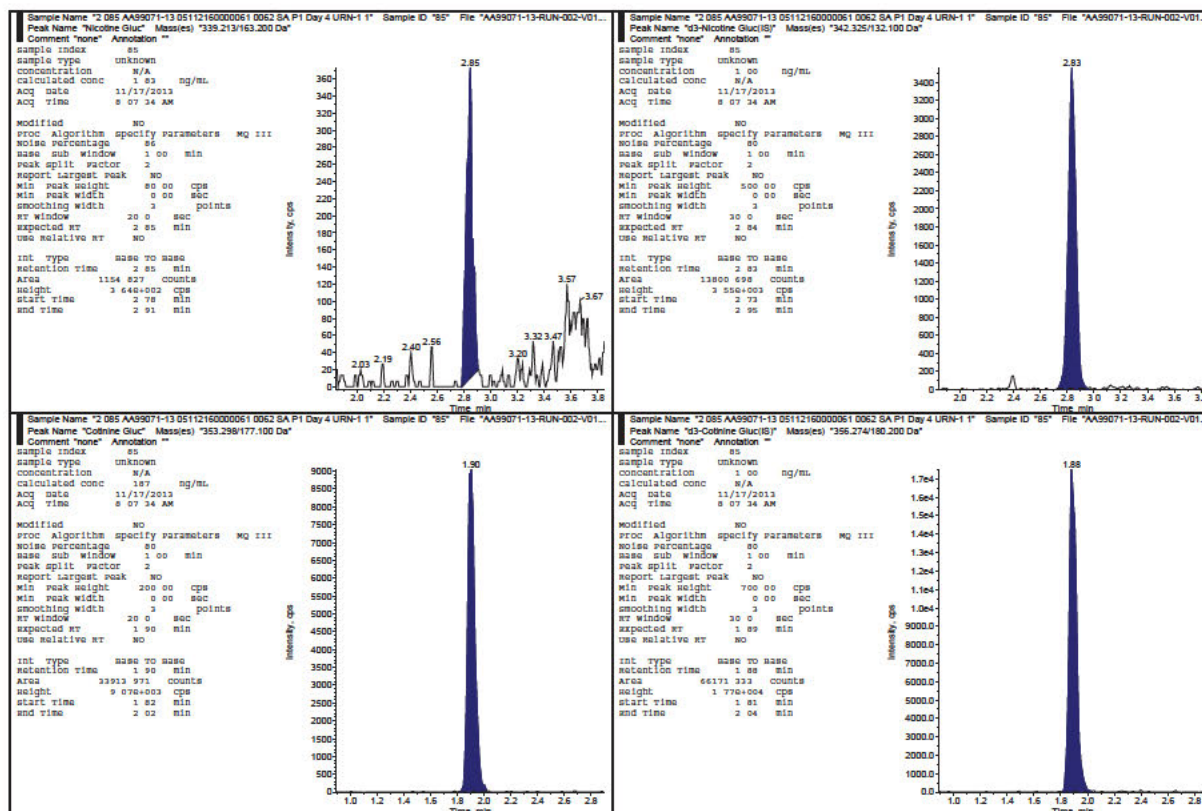


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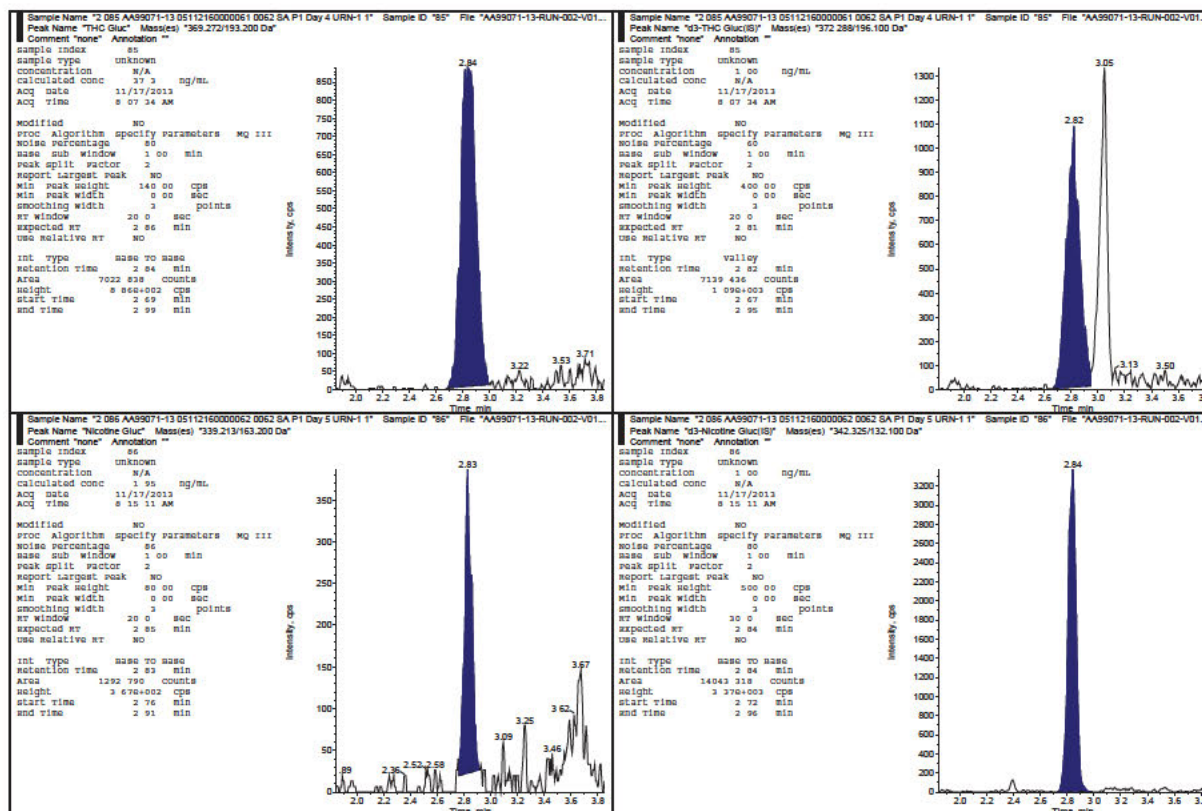


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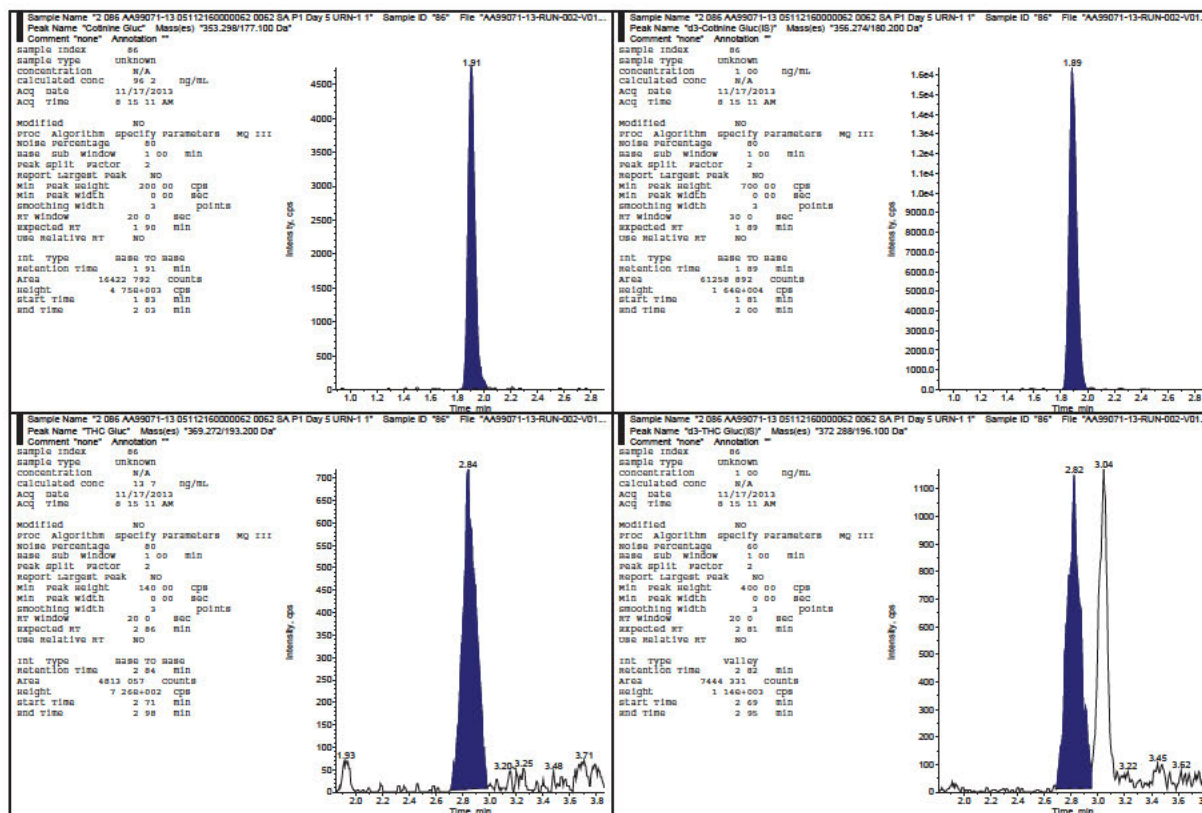


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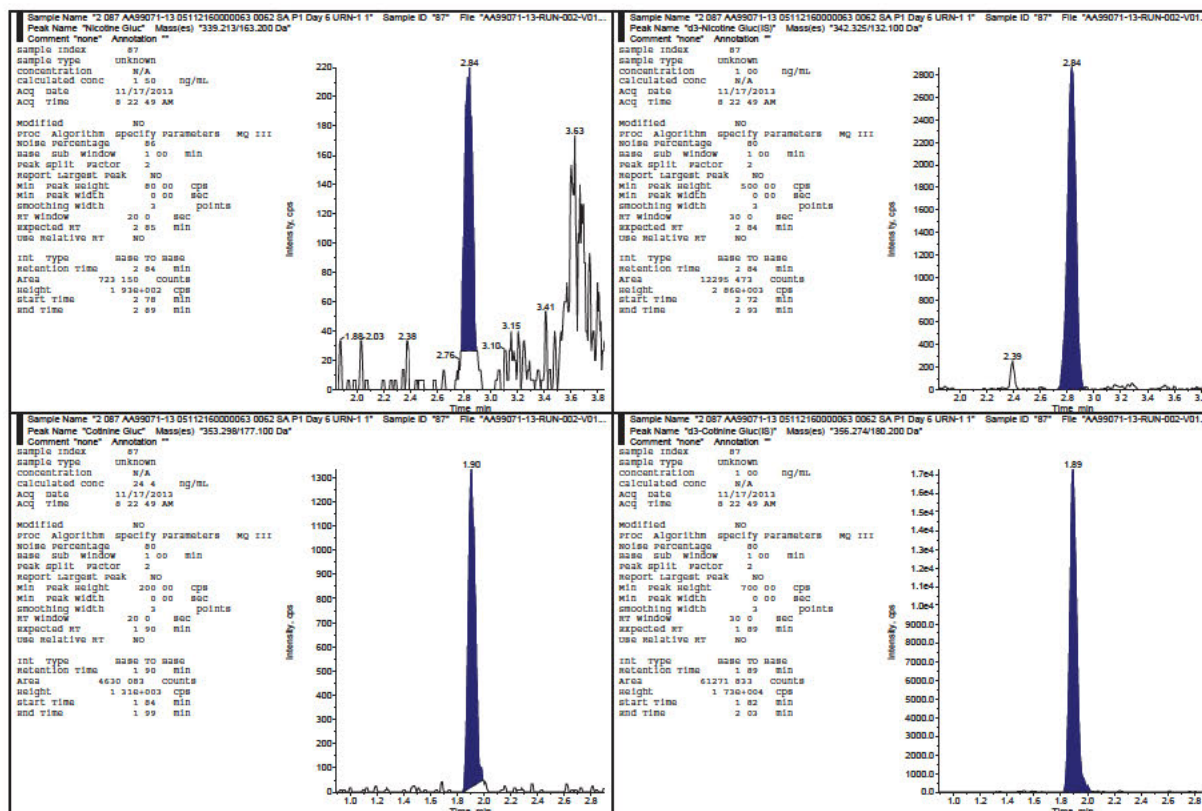


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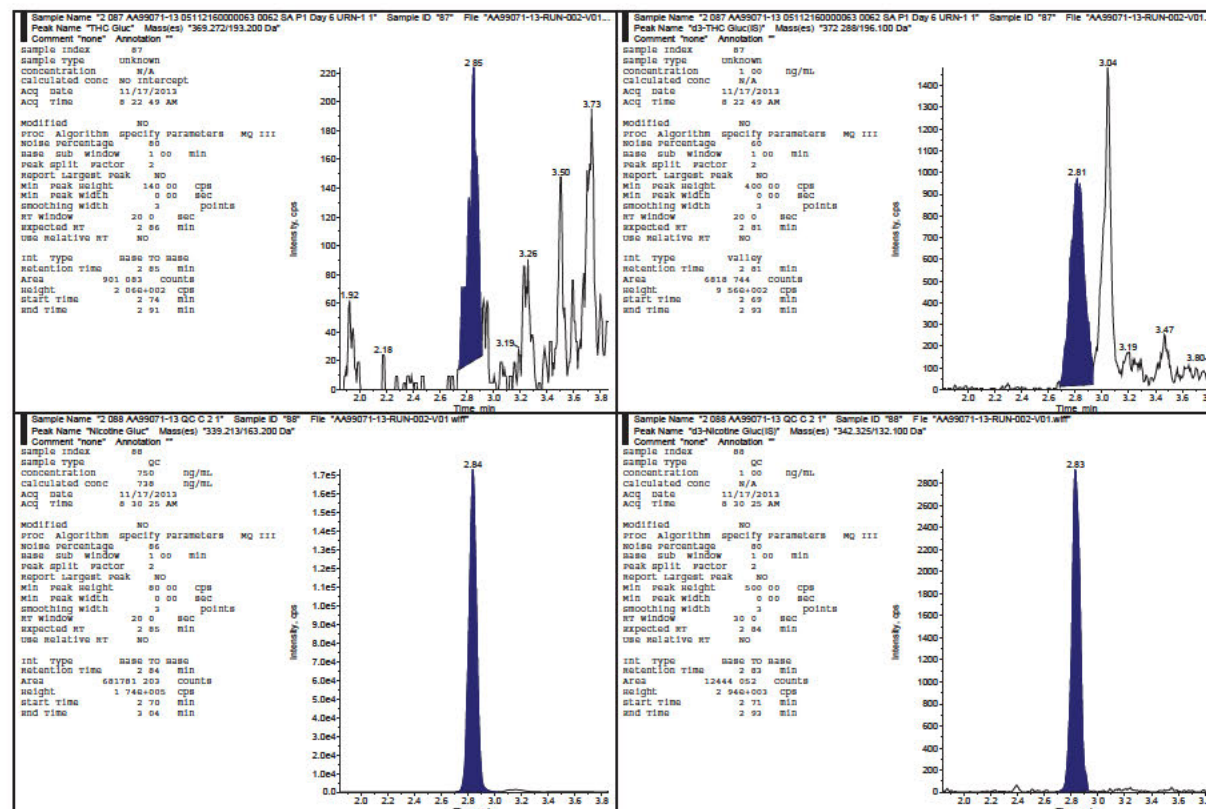


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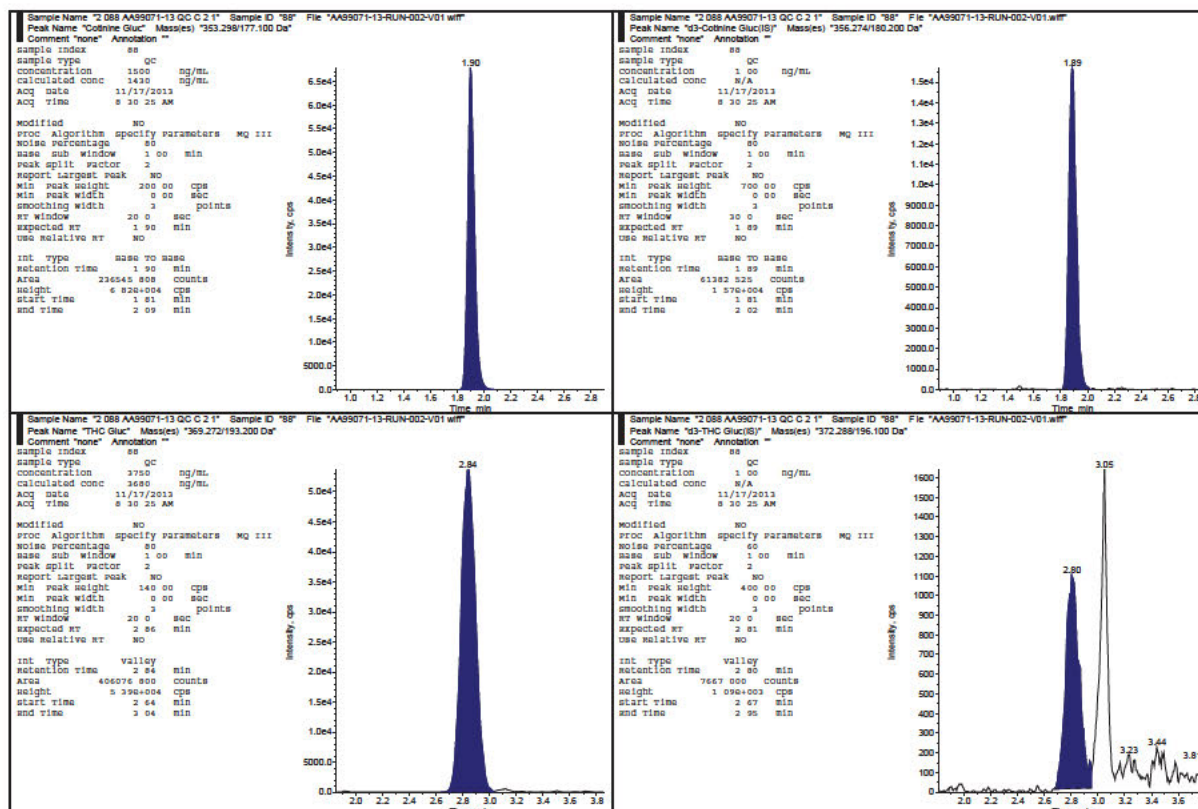


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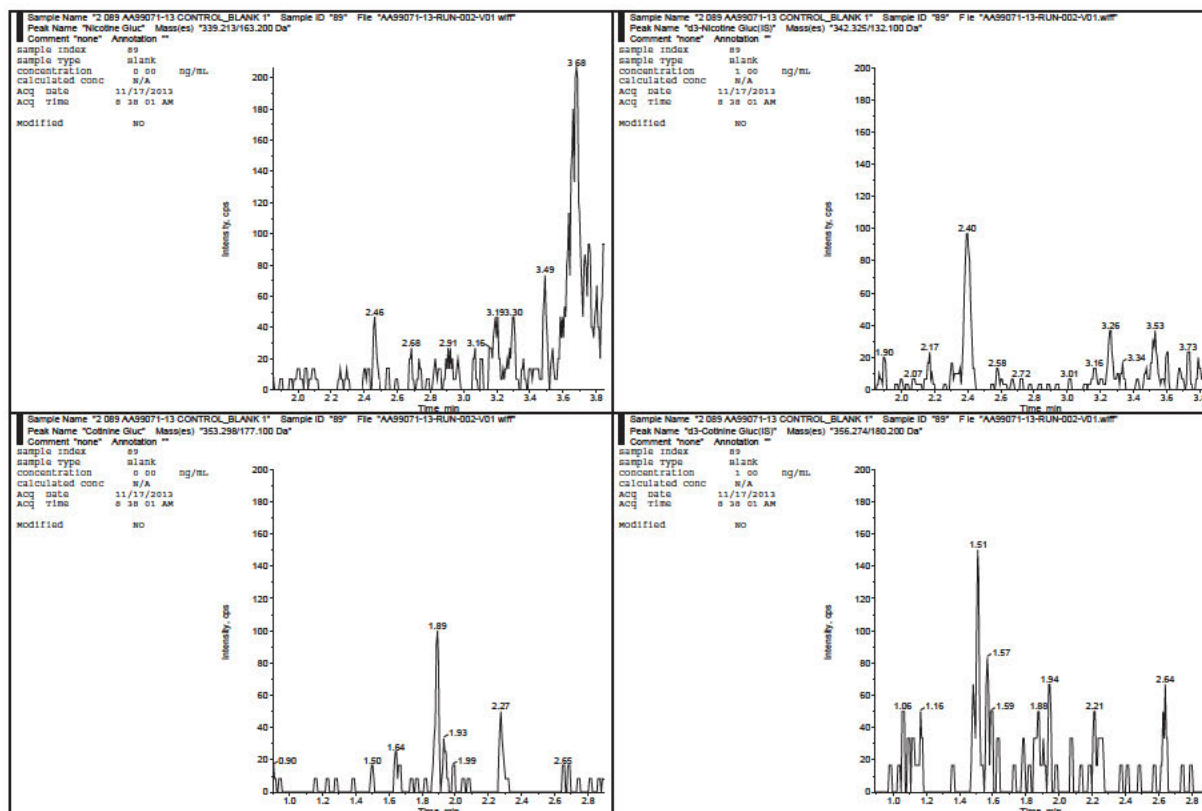


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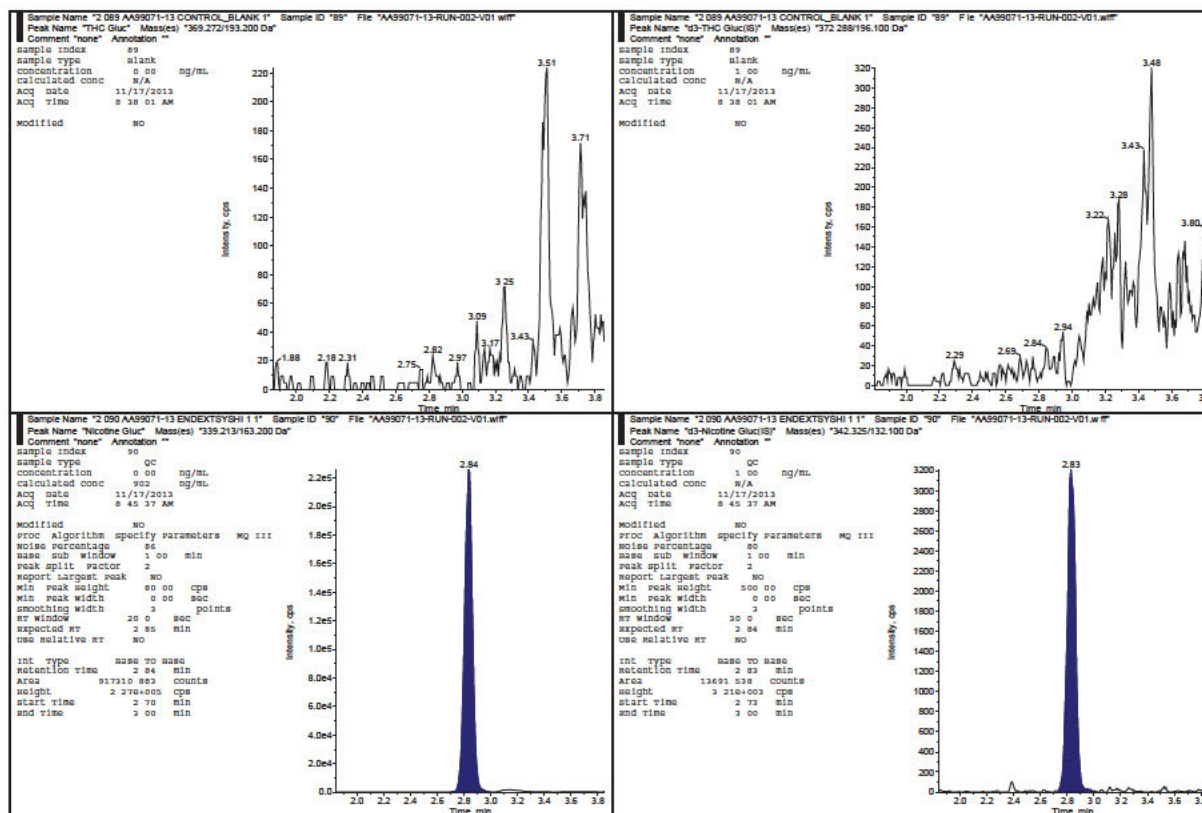


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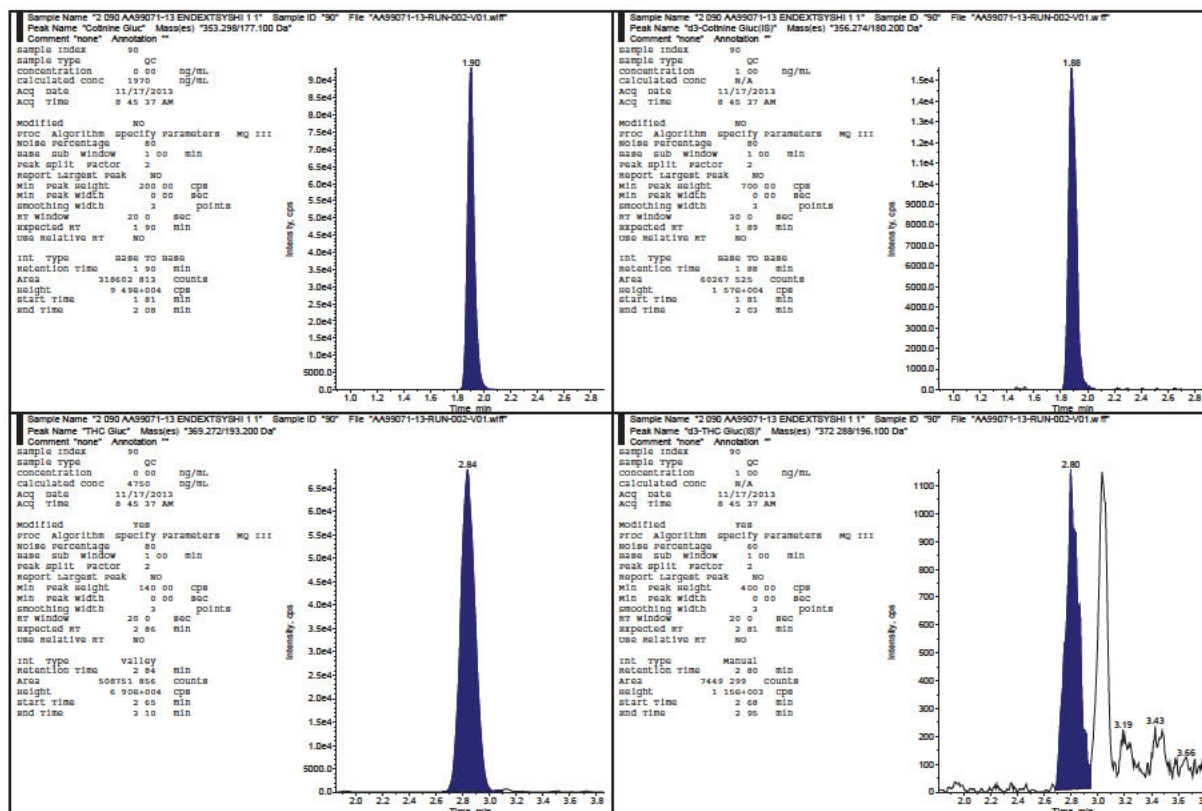


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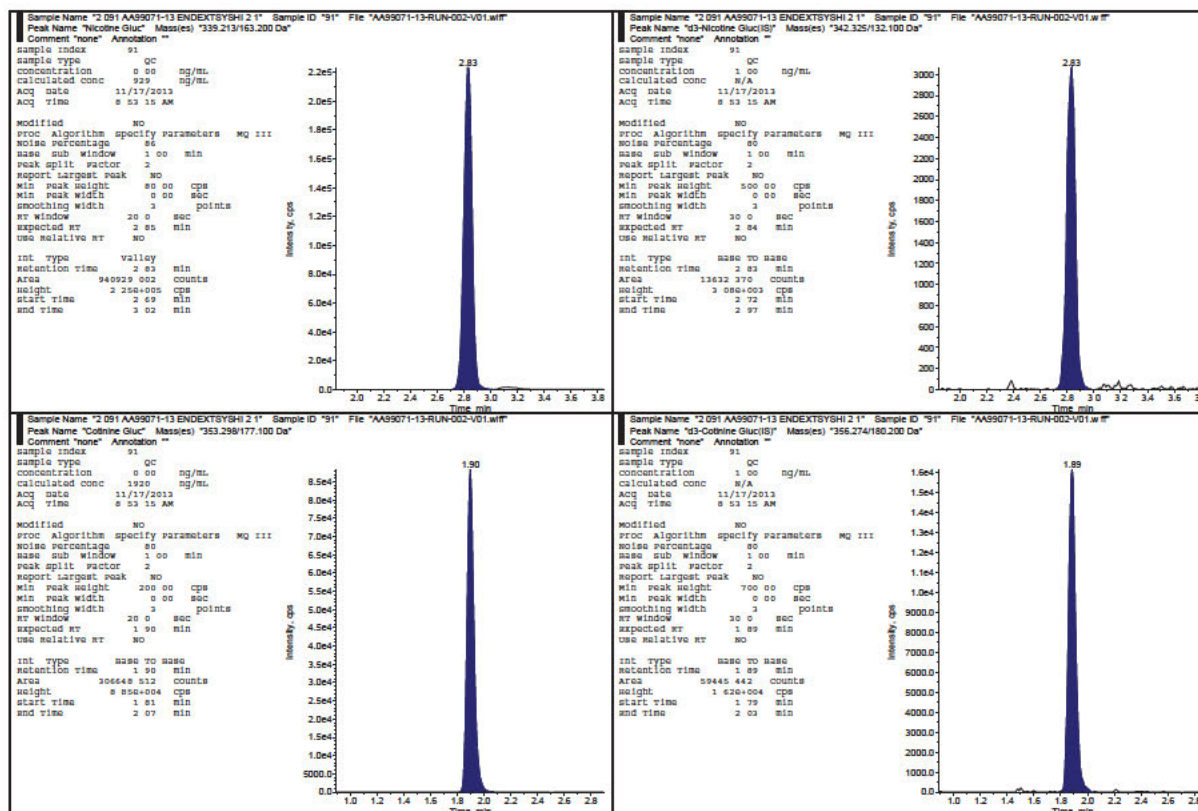


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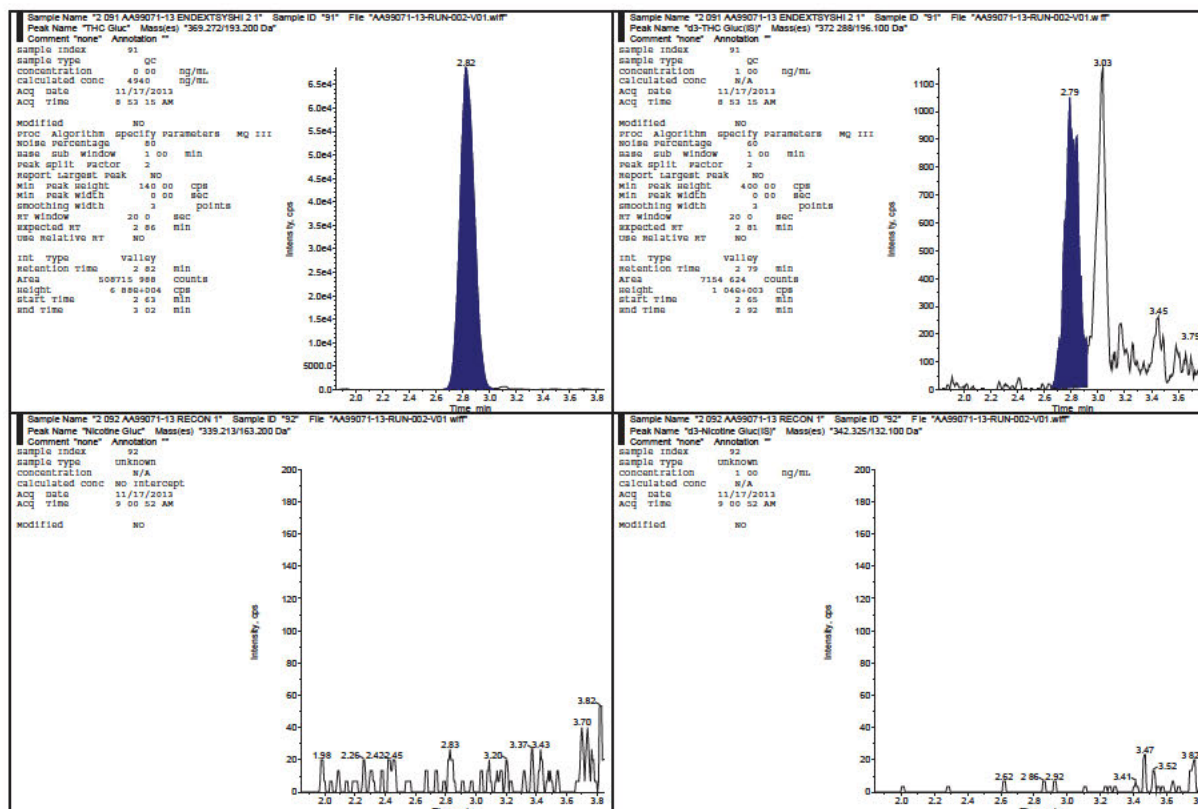


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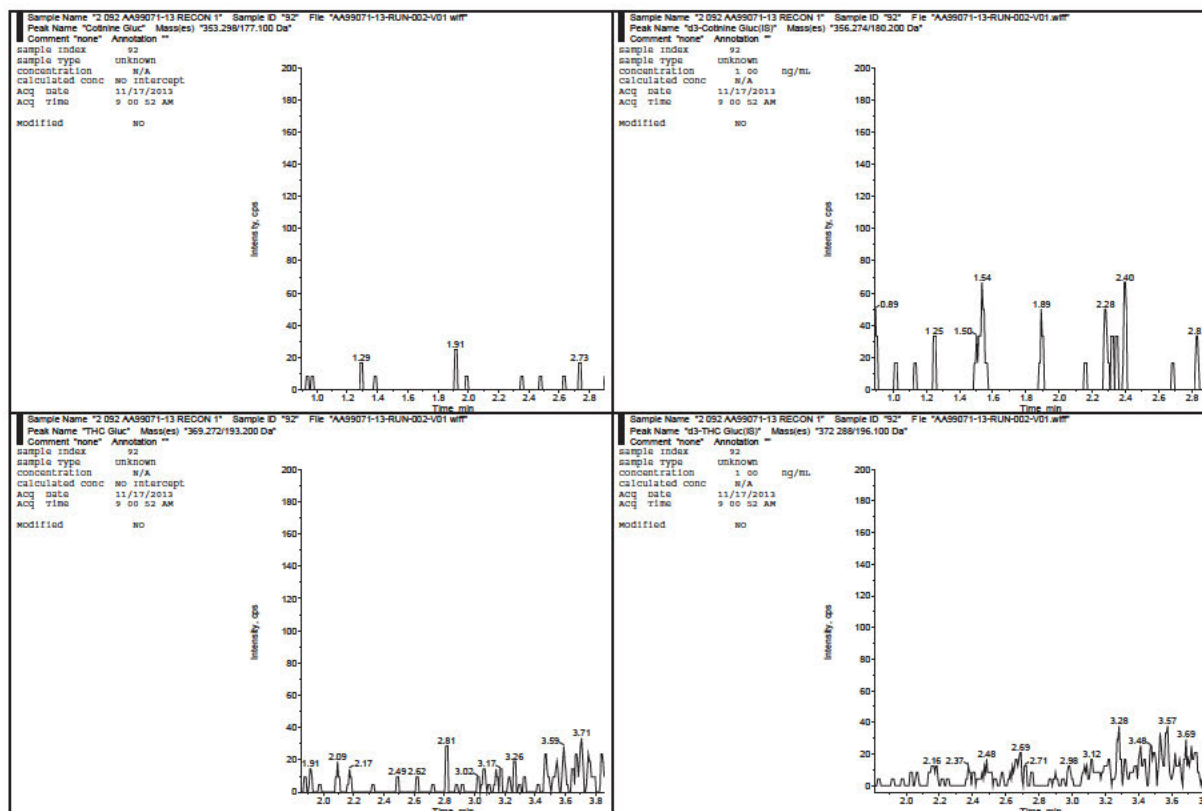


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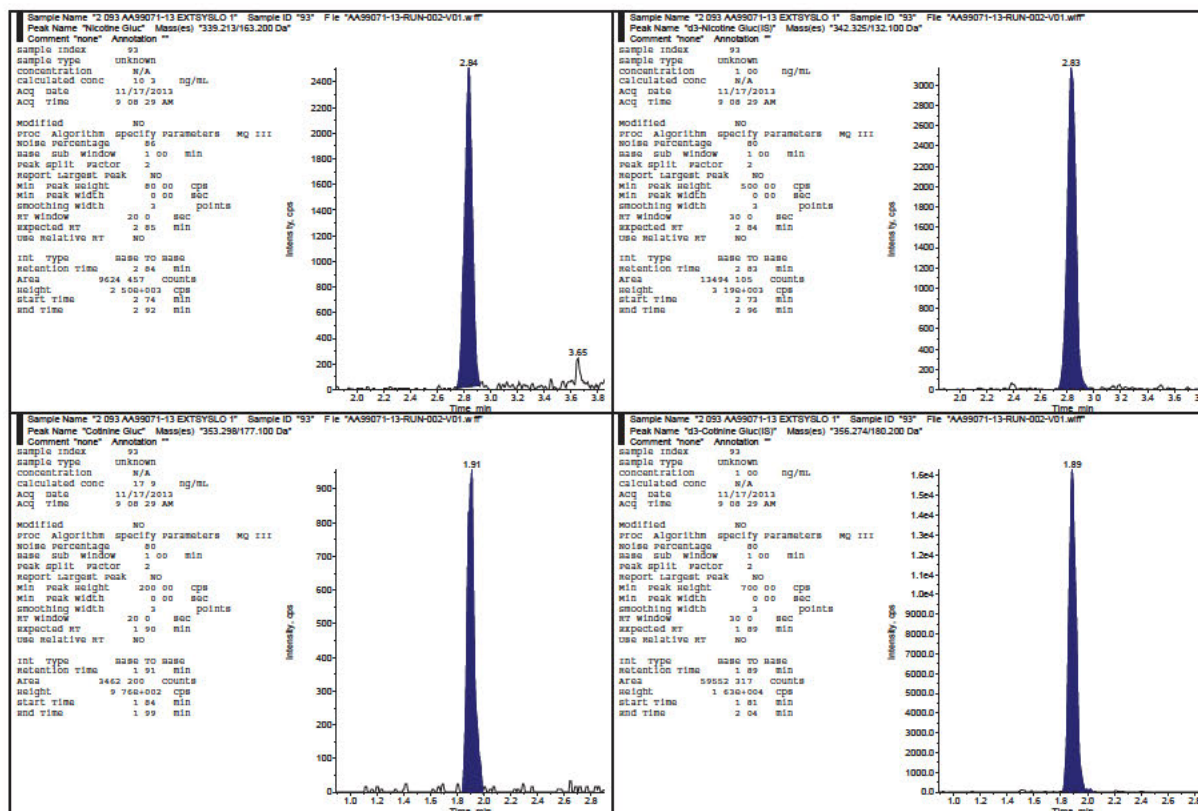


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