



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-PK-05-JP** **Clinical Study Report Appendix 16.1.9** **Bioanalytical Documentation**

**Study Title:** A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum

**Short Title:** Nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)

**Study Number:** ZRHM-PK-05-JP

**Product Name:** Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)

**Study Initiated (first subject screened):** 01 August 2013

**Study Completed (last subject last visit):** 16 November 2013

**Principal Investigator and Affiliation:** F. Nobuoka, MD  
Ageo Medical Clinic  
3133 Haraichi, Ageo City  
Saitama 362-0021, Japan

**Sponsor:** Philip Morris Products S.A.  
PMI Research & Development  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland

**Sponsor Signatories:** Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist  
Andrea Donelli, Clinical Scientist  
Nicola Lama, PhD, Biostatistician  
Patrick Picavet, MD, Medical Safety Officer

**Version:** 1.0

**Date:** 12 May 2015

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

---

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.

---





---

## Table of Contents

16.1.9.1 STANDARDIZATION AND LABORATORY REFERENCE RANGES.....	3
16.1.9.2 LAB CERTIFICATES.....	5
16.1.9.3 BIOANALYTICAL REPORTS .....	14
16.1.9.4 BIOANALYTICAL REFERENCES.....	436



### **16.1.9.1 STANDARDIZATION AND LABORATORY REFERENCE RANGES**

Categories	Analyte Name	Testing Lab	Apply to Panic Alert *	Analyte Code	Method	Reference Ranges	Unit
Hematology	Hematocrit	02		83004	Electrical Resistivity Method	M:39.7~52.4 F:34.8~45.0	%
	Hemoglobin	02	*	83003	Spectrophotometry (Based on Cyanmethemoglobin Method)	M:13.5~17.5 F:11.5~15.0	g/dL
	MCH	02		83006	Calculation	28.0~34.0	pg
	MCHC	02		83007	Calculation	30.2~35.1	%
	MCV	02		83005	Calculation	85~102	fL
	Platelet count	02	*	83008	Electrical Resistivity Method	14.0~34.0	$\times 10^4/\mu\text{L}$
	RBC count	02		83002	Electrical Resistivity Method	M:430~570 F:380~500	$\times 10^4/\mu\text{L}$
	WBC count	02	*	83001	Electrical Resistivity Method	3300~9000	$/\mu\text{L}$
	Differential WBC	02	*	83200	VCS Flow Cytometry Blood Film Slides: Visual Inspection	—	—
	Neutrophils (rel)	02		83201		40.0~75.0	%
	Lymphocytes (rel)	02		83204		18.0~49.0	%
	Monocytes (rel)	02		83205		2.0~10.0	%
	Eosinophils (rel)	02		83206		0.0~8.0	%
	Basophils (rel)	02		83207		0.0~2.0	%
	Neutrophils (abs)	02		83251		—	$/\mu\text{L}$
	Lymphocytes (abs)	02		83254		—	$/\mu\text{L}$
Clinical Chemistry	Monocytes (abs)	02		83255	Calculation	—	$/\mu\text{L}$
	Eosinophils (abs)	02		83256	Calculation	—	$/\mu\text{L}$
	Basophils (abs)	02		83257	Calculation	—	$/\mu\text{L}$
	Albumin	02		81002	BCG Method	3.8~5.3	g/dL
	Total protein	02	*	81001	Biuret Method	6.7~8.3	g/dL
	AP	02	*	81024	JSCC Standardization Method	100~325	U/L
	ALT	02	*	81022	UV Method (JSCC Standardization Method)	5~45	U/L
	AST	02	*	81021	UV Method (JSCC Standardization Method)	10~40	U/L
	BUN	02	*	81044	Urease-UV Method (Enzymatic Assay)	8~23	mg/dL
	Creatinine	02	*	81041	Enzymatic Assay	M:0.61~1.04 F:0.47~0.79	mg/dL
	GGT	02		81025	JSCC Standardization Method	M: $\leq 80$ F: $\leq 30$	U/L
	Fasting Glucose	02		81031	HK/G6PDH Method	70~109	mg/dL
	LDH	02	*	81023	UV Method (JSCC Standardization Method)	120~240	U/L
	Potassium	02	*	81077	ISE Method	3.5~5.0	mEq/L
	Sodium	02	*	81076	ISE Method	137~147	mEq/L
	Total bilirubin	02	*	81011	Bilirubin oxidase	0.2~1.2	mg/dL
	Direct bilirubin	02		81013	Bilirubin oxidase	0.0~0.3	mg/dL
	Total cholesterol	02		81053	Cholesterol Oxidase Method	120~219	mg/dL
Urine analysis	Triglycerides	02		81052	Free Glycerol Elimination Enzymatic Assay	30~149	mg/dL
	pH	02		84002	Test Strip Method	5.0~8.0	—
	Bilirubin	02		84006	Test Strip Method	(-)	—
	Glucose	02		84003	Test Strip Method	(-)	—
	Nitrite	02		84007	Test Strip Method	(-)	—
	Occult blood	02		84008	Test Strip Method	(-)	—
	Protein	02		84004	Test Strip Method	(-)	—
	Specific gravity	02		84001	Refractive Index method	1.002~1.030	—
Biomarker	COHb	01		0379	Spectrophotometric Method	—	%
Serology	HBs antigen	01		30006	CLIA	—	—
	Pos/Neg	01		30007		(-)	—
	Concentration	01		30008		< 0.05	IU/mL
	Confirmatory test	01		30005		—	—
	Hepatitis C virus	01		2491	CLIA	—	—
	Pos/Neg	01		2492		Negative	—
	S/CO value	01		2493		< 1.00	S/CO
	HIV antigen	01		4456	CLIA	Negative (-)	—
	HIV antigen	01		4699	Western Blott Method	Negative (-)	—

01: Main Reference Laboratory (COHb test will be performed at Tokiwa Chemical Industries Co.Ltd.)

02: Clinical Testing Center





## **16.1.9.2 LAB CERTIFICATES**











*Advancing Excellence*

**Accredited  
Laboratory**



# The College of American Pathologists

*certifies that the laboratory named below*

***Celerion Inc  
Clinical Laboratory  
Lincoln, Nebraska  
Gregory R. Post, PhD***

LAP Number: 2542201  
AU-ID: 1188932  
CLIA Number: 28D0652627

*has met all applicable standards for accreditation and  
is hereby accredited by the College of American Pathologists'  
Laboratory Accreditation Program. Reinspection should occur prior  
to November 4, 2014 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership,  
or location and assumes that all interim requirements are met.

*Frank R Rudy*

Chair, Commission on Laboratory Accreditation

*Stanley H. Hobbins*

President, College of American Pathologists



LAP #: 2542201  
AU ID: 1188932  
November 7, 2014

Gregory R. Post, PhD  
Celerion Inc  
Clinical Laboratory  
PO Box 80837  
Lincoln, NE 68501-0837

Dear Dr. Post:

Celerion Inc Clinical Laboratory, in Lincoln, Nebraska under the direction of Gregory R. Post, PhD is accredited by the College of American Pathologists' CAP Accreditation Program.

Accreditation is a continual process. A laboratory remains accredited until otherwise notified. Accreditation does not necessarily terminate on the expiration date of the Accreditation certificate.

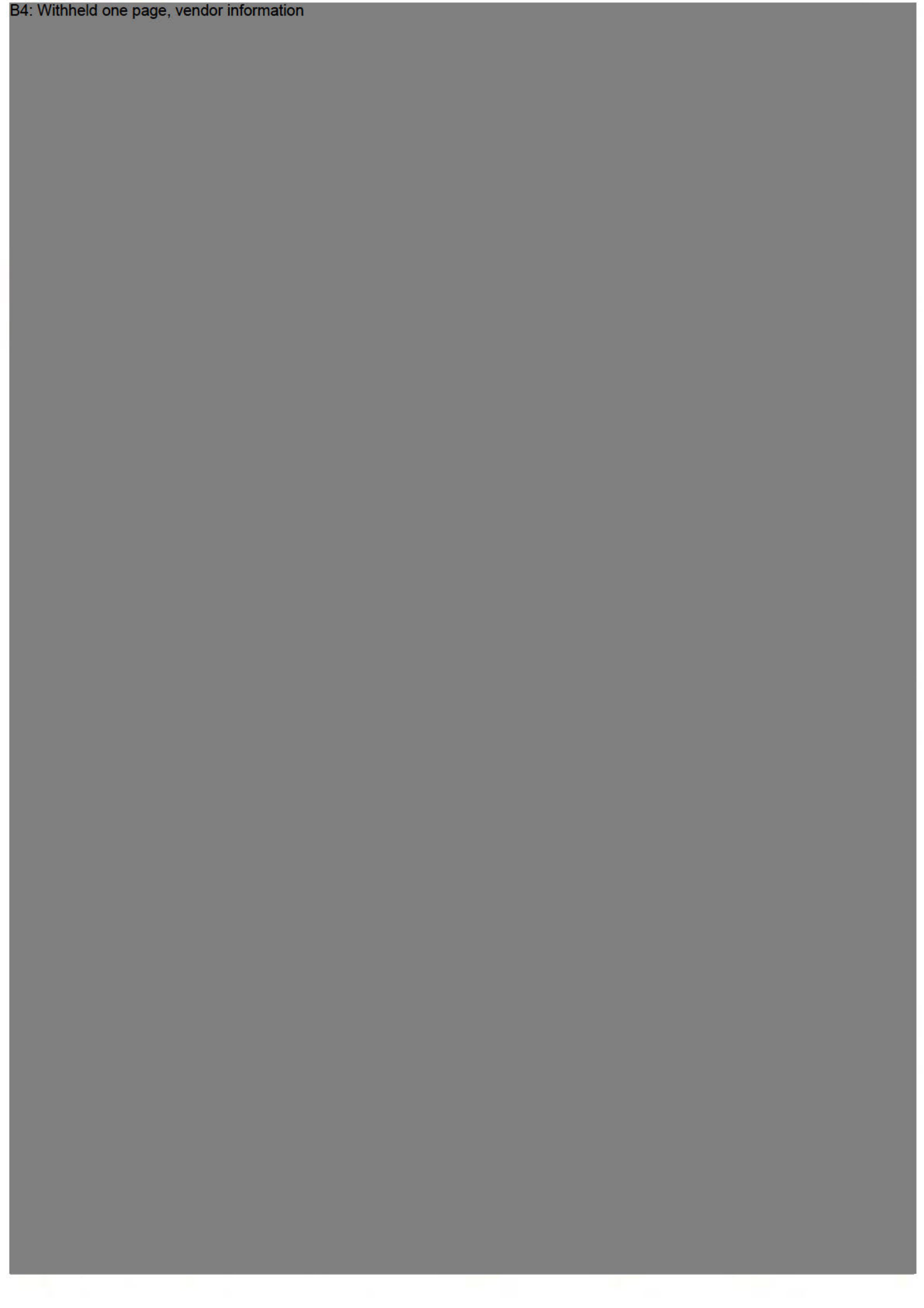
If you have any questions regarding this matter, please call 800-323-4040.

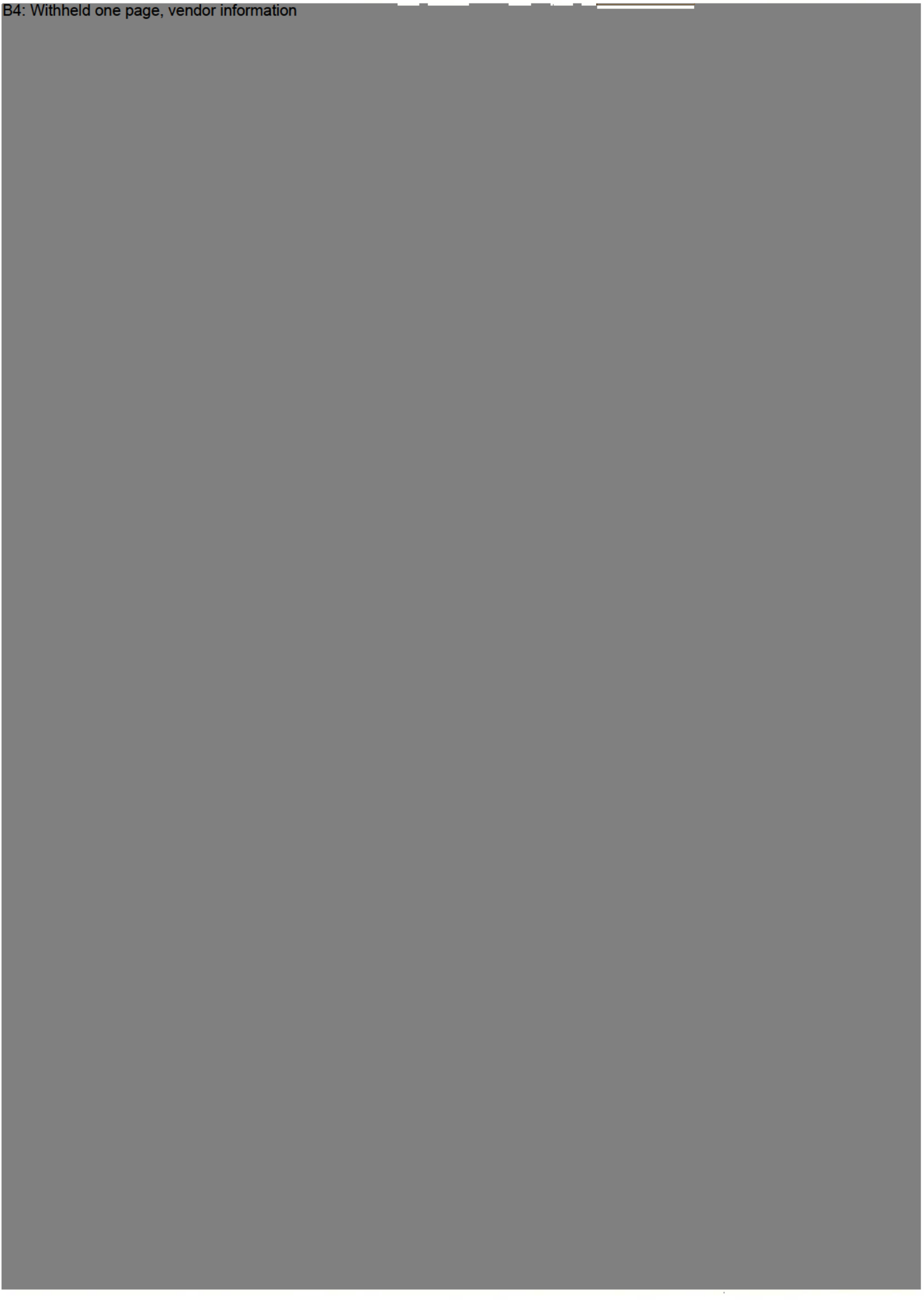
Sincerely,

CAP Accreditation Programs  
College of American Pathologists

STILACCRED













### **16.1.9.3 BIOANALYTICAL REPORTS**



621 Rose Street  
Lincoln, NE 68502 USA  
www.celerion.com  
Tel: 402-476-2811  
Toll Free: 800-776-1716  
Fax: 402-939-0428

**Determination of Nicotine in Human Plasma (K<sub>2</sub>EDTA) Samples from "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum" by LC-MS/MS**

Study: AA99122-01

Bioanalytical Final Report

Philip Morris Products S.A.  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland

Protocol ZRHM-PK-05-JP

Report Date: 30-Jun-2014

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the provisions of applicable law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

---

## STUDY LOCATION

## TEST FACILITY

Celerion Lincoln  
621 Rose Street  
Lincoln, NE 68502 USA  
Phone: 402-437-4719  
Fax: 402-939-0428

Role	Name, Title	E-mail Address
Bioanalytical Principal Investigator	Kirk Newland, B.S.	Kirk.Newland@celerion.com
Deputy Bioanalytical Principal Investigator	Erica Nachi, B.S.	Erica.Nachi@celerion.com
Test Facility Manager	Rafiqul Islam, M.S.	Rafiqul.Islam@celerion.com
Quality Assurance Manager	Crystal Bickford, B.A.	Crystal.Bickford@celerion.com

## SPONSOR

Philip Morris Products S.A.  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland  
Phone: +41 58 242 2625

Role	Name, Title	E-mail Address
Manager Clinical Science	Christelle Haziza, Ph.D.	Christelle.Haziza@pmi.com

## CLINICAL CENTRAL LABORATORY

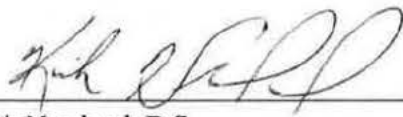
Covance CCLS  
Rue Moïse Marcinhes 7  
CH-1216 Meyrin, Geneva Switzerland  
Phone: +41 58 822 7732  
Fax: +41 58 822 6999

Role	Name, Title	E-mail Address
Project Manager	Nathalie Mathieux, Ph.D.	Nathalie.Mathieux@covance.com

**APPROVAL SIGNATURES**

**TEST FACILITY**  
**Celerion:**

Bioanalytical Principal Investigator



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

30-Jun-2014

Date

Test Facility Management



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

30-Jun-2014

Date

Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

---

**SPONSOR**

**Philip Morris Products, S.A.:**

Manager Clinical Science



---

Christelle Haziza, PhD

09.07.2014.

---

Date

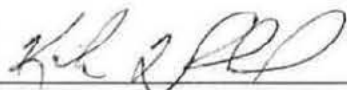
## STATEMENT OF COMPLIANCE

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

---

30-Jun-2014

Date

## 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	16-Jul-2013	16-Jul-2013	18-Jul-2013
Critical Phase Inspection	17, 18-Oct-2013	18-Oct-2013	18-Oct-2013
Database	02, 03-Jan-2014	03-Jan-2014	17-Feb-2014
Bioanalytical Report (Final Draft)	18, 19-Feb-2014	19-Feb-2014	19-Feb-2014
Bioanalytical Report (Final)	19-Jun-2014	19-Jun-2014	30-Jun-2014

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.



Pat Curl  
Quality Assurance Auditor

  
Date



## TABLE OF CONTENTS

STUDY LOCATION .....	2
TEST FACILITY .....	2
SPONSOR .....	2
CLINICAL CENTRAL LABORATORY .....	2
APPROVAL SIGNATURES .....	3
STATEMENT OF COMPLIANCE .....	5
QUALITY ASSURANCE STATEMENT .....	6
1. INTRODUCTION .....	10
2. EXPERIMENTAL .....	10
2.1. Test Item .....	10
2.2. Reference Items and Internal Standards .....	10
2.3. Biological Matrix.....	11
2.4. Test System .....	11
2.4.1. Procedure and Instruments .....	11
2.4.2. Computer Application Software .....	11
2.5. Calibration Standards, Quality Control Samples and Dilution Quality Control Samples .....	11
2.6. Study Samples .....	12
2.6.1. Sample Source and Date of Receipt.....	12
2.6.2. Sample Identification .....	12
2.6.3. Sample Storage and Stability.....	12
2.6.4. Sample Summary .....	12
3. SAMPLE ANALYSIS .....	13
3.1. Analytical Method .....	13
3.2. Acceptance Criteria .....	13
3.2.1. Analytical Run Acceptance Criteria .....	13

---

3.2.2. Acceptance Criteria for System Suitability Testing.....	14
3.2.3. Acceptance Criteria for Sample Dilution .....	15
3.2.4. Acceptance Criteria for ISR .....	15
4. RESULTS.....	15
4.1. Quality Control and Dilution Quality Control Sample Performance .....	15
4.2. Calibration Standard Performance.....	15
4.3. Standard Curve Parameters .....	15
4.4. Study Sample Concentrations .....	15
4.5. Reassays .....	16
4.5.1. Reassays for Analytical Reasons .....	16
4.5.2. Reassays for Non-analytical Reasons (Value Requiring Confirmation, VRC)..	16
4.5.3. Sponsor Selected Reassays.....	16
4.5.4. Incurred Sample Reproducibility.....	16
5. CHROMATOGRAMS.....	16
6. DEVIATIONS .....	16
7. EVENTS.....	17
8. ANALYTICAL NOTES .....	17
9. ARCHIVES .....	19
10. CONCLUSION.....	19
11. REFERENCES .....	19
RESULT TABLES .....	21
FIGURES .....	120
ATTACHMENTS.....	121

## RESULT TABLES

Table 1	Summary of Analytical Runs Performed .....	21
Table 2	Quality Control and Dilution Quality Control Sample Data (Between- Analytical Run Precision and Accuracy) .....	22
Table 3	Back-calculated Calibration Standard Concentrations .....	24
Table 4	Standard Curve Parameters .....	26
Table 5	Study Sample Concentrations .....	27
Table 6	Summary of Reassay for Analytical Reasons .....	98
Table 7	Incurred Sample Reproducibility Assessment .....	113

## FIGURES

Figure 1	Calibration Curve for Nicotine in Control Matrix, Watson Run ID 2.....	120
----------	--	-----

## ATTACHMENTS

Attachment 1	General List of Abbreviations used at Celerion .....	121
Attachment 2	Temperature Definitions at Celerion .....	124
Attachment 3	Procedure for VRC and SSR Reassays and Reporting of Reassay Results.....	125
Attachment 4	General List of Calculation Formulae .....	126
Attachment 5	Reassay Descriptions .....	127
Attachment 6	Certificates of Analysis.....	128
Attachment 7	Bioanalytical Method Summary .....	147
Attachment 8	Chromatograms .....	150

<b>Total Number of Pages</b>		<b>231</b>
------------------------------	--	------------



## 1. INTRODUCTION

The purpose of this bioanalytical study (hereafter referred to as study) was to determine the concentration of nicotine in human plasma (K<sub>2</sub>EDTA) samples by a validated LC-MS/MS method [5]. The study samples were collected in the clinical trial ZRHM-PK-05-JP, entitled, "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum" [3]. Sample analysis was conducted between 17-Oct-2013 and 30-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 <sub>4</sub> -Nicotine
Source	Cerilliant Corporation / Synthèse AptoChem Inc.	Cerilliant Corporation
Lot No.	FN092410-01 / AC0105001	FN083010-01
Purity / Concentration	99.5% (1.00 mg/mL) / 99.7% (914 µg/mL)	98.1% (100 µg/mL)
Celerion Assigned Correction Factor	1.0000	1.0000
Expiry Date	30-Sep-2015 / 02-Apr-2014	30-Sep-2015
Storage Conditions	5°C, protected from light	5°C, protected from light

The certificate 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. The expired reference materials are denoted as expired within the Labnotes system. They may be stored for the establishment of extended long-term stability.

### 2.3. Biological Matrix

Human plasma, with K<sub>2</sub>EDTA as anticoagulant, was purchased from (b) (4) and collected in-house at Celerion, Lincoln, Nebraska. Human plasma stored at -20°C may be stored for a period less than 24 months prior to use. Human plasma (EDTA), free of significant interference at the retention time and mass transitions of nicotine and d<sub>4</sub>-nicotine (IS) was used to prepare quality control (QC) samples. Deionized water was used to prepare calibration standards and used as control matrix.

### 2.4. Test System

#### 2.4.1. Procedure and Instruments

Procedure and Instrumentation	
Extraction Method	Solid phase extraction
Chromatography System	PerkinElmer® Series 200 Micro Pump or equivalent <sup>^</sup>
MS/MS System	AB SCIEX API 4000™ or API 5000™ <sup>^</sup>
Regression Type	Weighted linear (1/concentration <sup>2</sup> )
Quantitation Method	Peak area ratio
Assay Volume	0.300 mL
Acceptable Level of Hemolysis	5%

<sup>^</sup> = Qualified systems

#### 2.4.2. Computer Application Software

Software	
LC-MS/MS Software	Applied Biosystems Analyst® 1.5.1 <sup>^</sup>
LIMS	Thermo Electron Corporation Watson™ 7.3 Bioanalytical LIMS 7.3 <sup>^</sup>
LIMS Application	Inspector Version 1.1.1 <sup>^</sup>
Laboratory Documentation System	Labnotes™ Web Client 1.21 <sup>^</sup>
Office Applications	Microsoft® Office 2007 Package

<sup>^</sup> = Validated systems

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

Non-zero calibration standards were prepared fresh daily at the concentration levels of 0.200, 0.400, 0.800, 1.00, 2.50, 5.00, 7.50, 9.00, 10.0 ng/mL from calibration standard spiking solutions which were prepared in bulk on 12-Aug-2013, 19-Aug-2013, 02-Dec-2013, and 20-Dec-2013, and stored at -20°C for a period of time up to 323 days.

Quality control (QC) samples at the concentration levels of 0.600, 2.00, 5.00, 8.00 ng/mL and dilution quality control (DQC) samples at the concentration levels of 20.0 ng/mL were prepared in bulk on 22-Aug-2013, 03-Sep-2013, 15-Oct-2013, 15-Nov-2013, 13-Dec-2013, 18-Dec-2013, and 22-Dec-2013, aliquoted and stored at -20°C. Quality control samples were stored with the clinical samples after receipt at the bioanalytical laboratory. The QC samples were stored for a period less than 1041 days prior to use for analysis.

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

## 2.6. Study Samples

### 2.6.1. Sample Source and Date of Receipt

Study samples were collected between 18-Aug-2013 and 08-Nov-2013 and were received frozen on dry ice between 17-Sep-2013 and 06-Dec-2013 from Covance Clinical Research, Singapore.

### 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 on-site from sample collection to the end of sample analysis at a nominal temperature of -20°C for a duration not exceeding 135 days.

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

Stability Summary [5]	
Long-term Stability	1041 days in polypropylene tubes at -20°C
Short-term Stability	27 hours in polypropylene tubes at ambient temperature under white light
Freeze-thaw Stability	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light
Post-preparative Stability	73 hours in a polypropylene 96 well plate at 5°C
Processed Sample Integrity	139 hours in a polypropylene 96 well plate at 5°C
Sample Shipping Stability	19 days in polypropylene tubes at -80°C

### 2.6.4. Sample Summary

The Sponsor's protocol specifies that clinical samples will be collected from 62 subjects with 16 sampling times in each of 2 periods [3]. During the study, a single subject discontinued during



the clinical phase. The samples were analyzed and the results reported. Additional information regarding the subject discontinuance is provided in [Section 8.4](#).

	No. of Samples
Specified “for analysis” samples in protocol/received	1984/1965
Time points lost due to subject discontinuance	19
Back-up samples received	1965
Total number of study samples analyzed	1965

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

### 3. SAMPLE ANALYSIS

#### 3.1. Analytical Method

The determination of nicotine in human plasma samples was carried out over a calibration range of 0.200 ng/mL to 10.0 ng/mL. The analytical procedure was performed at Celerion, Lincoln, Nebraska and is documented in the Method Validation Report for Celerion Study AA33664-06 [5]. The analytical method is documented in BAM SOP AA33664-06 [6]. See [Attachment 7](#).

An aliquot of human plasma (EDTA) containing the analyte and internal standard was extracted using a solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an AB SCIEX API 4000™ or API 5000™ 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/concentration<sup>2</sup>) of peak area ratios of the analyte and internal standard.

#### 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 ±15.0% (±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 ±15.0% of their nominal concentration,
- at least 50% of the standard zero samples are free of interference at the retention time of the analyte(s) of interest,

- at least 50% of the blank samples are free of interference both at the retention time of the analyte(s) of interest and at the retention time of the IS,
- at least two-thirds of all blank and standard zero samples fulfilled the above described interference criteria.

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

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

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

### 3.2.2. Acceptance Criteria for 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. Carryover acceptance criteria is specified in the bioanalytical method for each assay.

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



### 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.

### 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 0.600, 2.00, 5.00, and 8.00 ng/mL are summarized in [Table 2](#). The accuracy of sample dilution was verified by the performance of dilution QC samples. Results for dilution QC samples are summarized in [Table 2](#).

### 4.2. Calibration Standard Performance

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

### 4.3. Standard Curve Parameters

Standard curve parameters from 19 successful analytical runs are provided in [Table 4](#). A representative calibration curve is illustrated in [Figure 1](#).

### 4.4. Study Sample Concentrations

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

Study samples, if any, with no significant peak at the mass transition and retention time of nicotine, 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](#) are identified in [Table 6](#). Reassay descriptions are provided in [Attachment 5](#).

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

There were no study samples that were reassayed due to non-analytical reasons. The procedure for VRC reassays and reporting of reassay results is provided in [Attachment 3](#).

##### **4.5.3. Sponsor Selected Reassays**

There were no Sponsor selected reassays. The procedure for SSR reassays and reporting of reassay results is provided in [Attachment 3](#).

##### **4.5.4. Incurred Sample Reproducibility**

The method for the determination of nicotine in human plasma was considered reproducible, 97.1% out of 170 repeat analyses met acceptance criteria as defined in [section 3.2.4](#). Results are presented in [Table 7](#).

#### **5. CHROMATOGRAMS**

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

#### **6. DEVIATIONS**

**6.1.** Deviation DEV-LNK-14-0022 from BAM SOP Section 5.5 was initiated when working standard spiking solutions were not sub-aliquoted before being stored and were left in bulk for use on all analytical runs in the study. There is no impact as the working standard spiking solutions have been shown to be consistent throughout the study. The subaliquoting step in the method was implemented to avoid the possibility of contaminating the standards from a possible inadequately washed pipette tip. Long-term stock solution stability established for a period of time up to 323 days was not exceeded.

## 7. EVENTS

**7.1.** Event Observation EO-LNK-AA99122-01-13-0486 was initiated due injections 145 through 156 on Analytical Run 2 not having an internal standard peak present. It appeared that the analyst failed to aliquot the internal standard into these samples. Test injections were requested to compare with the original results. The extraction analyst appeared to have inadvertently skipped a row of samples while spiking the working internal standard solution. There was no impact, as the samples were coded ISP and were reassayed.

**7.2.** Event Observation EO-LNK-AA99122-01-13-0629 was initiated due to a single sample (Subject 142, Period 2, Day 3, 0 Hr, 8 Min) failing ISR testing, as it was 78.52% different from the original value. Event Resolution ER-LNK-AA99122-01-13-0163 was then initiated. During the investigation, it was noted that the incorrect sample (Subject 148, Period 1, Day 1, 0 hr, 45 min) was racked. The ISR for the sample in question also closely matched the original concentration for the sample from Subject 148. The data was left in the ISR table and was reported as a failure. There was no impact, as the ISRs were acceptable.

**7.3.** Event Observation EO-LNK-AA99122-01-13-0636 was initiated due to a STD A sample on RUN-026 having an analyte peak greater than the STD B. The STD D on the analytical run also had a very small analyte peak and did not contain an internal standard peak. Test injections were performed and confirmed the original data. The impact was that the STD B was dropped and the STD C was designated as the LLOQ. All clinical samples below the STD C concentration were reassayed.

## 8. ANALYTICAL NOTES

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

<u>Run ID</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
1	Nicotine	Analytical Run 1 was reassayed as Analytical Run 10 due to 2 of 2 QC As not meeting acceptance criteria.
20	Nicotine	Analytical Run 20 was reassayed as Analytical Run 23 due to 2 of 2 QC Es not meeting acceptance criteria.

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

<u>Run ID</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
3	Nicotine	Analytical Run 3 was reinjected as Analytical Run 8 due to unacceptable chromatography.
4	Nicotine	Analytical Run 4 was reinjected as Analytical Run 9 due to unacceptable chromatography.
13	Nicotine	Analytical Run 13 was reinjected as Analytical Run 20 due to unacceptable chromatography.
15	Nicotine	Analytical Run 15 was reinjected as Analytical Run 21 due to unacceptable chromatography.
17	Nicotine	Analytical Run 17 was reinjected as Analytical Run 22 due to sst failure-carryover.

**8.3.** During the naming of analytical runs, number 28 was not used.

**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 possible impacted studies included ZRHM-PK-05-JP (AA99122). A single subject, 0107, discontinued from the clinical phase post-randomization. After verification of the subject discontinuance of the subject by the Bioanalytical Principal Investigator, the samples for Subject 0107 were analyzed. No notification of a possible consent issue was provided by the Sponsor, Project Management for the central laboratory, or the clinical site.

Through a Sponsor CAPA process, the documentation of the subject intent was provided by the Principal Investigator from the clinical site. It was confirmed that Subject 0107 had not removed consent for the analysis of the clinical samples taken prior to subject discontinuance. Documentation from the Principal Investigator was provided to Celerion and is archived with the study correspondence for this study. The results from the clinical samples taken from Subject 0107 are included within this report



## 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

## 10. CONCLUSION

In this bioanalytical study the concentration of nicotine was determined in a total of 1965 human plasma (K<sub>2</sub>EDTA) samples collected in the Philip Morris International Research and Development clinical study ZRHM-PK-05-JP 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 ZRHM-PK-05-JP: "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum"

- [4] Study Plan Bioanalysis: Determination of Nicotine in Human Plasma (K<sub>2</sub>EDTA) Samples from "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum" by LC-MS/MS, Celerion Study AA99122-01
- [5] Validation of an LC-MS/MS Method for the Determination of Nicotine and Cotinine in Human Plasma (EDTA), Celerion Study AA33664-06
- [6] Bioanalytical Method SOP for the Determination of Nicotine and Cotinine in Human Plasma (EDTA), Celerion Study AA33664-06

## RESULT TABLES

Table 1 Summary of Analytical Runs Performed

Run ID	Regression Status	Extraction Date	Assay Date	Description	Comment
1	Rejected	17-Oct-2013	18-Oct-2013	SUB 0002,0004,0005,0010,0073 PD 1-2	std/qc fail acceptance
2	Accepted	17-Oct-2013	19-Oct-2013	SUB 0013, 0017, 0018, 0022 PD 1-2	OK
5	Accepted	17-Oct-2013	19-Oct-2013	SUB 0043, 0045, 0049, 0050 PD 1-2	OK
6	Accepted	17-Oct-2013	20-Oct-2013	SUB 0051, 0052, 0054, 0060, 0063, 0072 PD 1-2	OK
7	Accepted	08-Dec-2013	10-Dec-2013	SUBS 0061, 0066 PD 1-2 + REASSAYS	OK
8	Accepted	17-Oct-2013	21-Oct-2013	RI of Run-003 (SUB 0024, 0025, 0027, 0031 PD 1-2)	OK
9	Accepted	17-Oct-2013	22-Oct-2013	RI of Run-004 (SUB 0035, 0036, 0039, 0040 PD 1-2)	OK
10	Accepted	08-Dec-2013	11-Dec-2013	RR FAILED BATCH 1	OK
11	Accepted	27-Nov-2013	28-Nov-2013	SUBS 0067, 0070, 0071, 0074 PD 1-2	OK
12	Accepted	08-Dec-2013	10-Dec-2013	SUBS 0075, 0076, 0078, 0082 PD 1-2	OK
14	Accepted	09-Dec-2013	11-Dec-2013	SUBS 0093, 0095, 0097, 0102 PD 1-2	OK
16	Accepted	11-Dec-2013	12-Dec-2013	SUBS 0120, 0123, 0128, 0129 PD 1-2 + REASSAYS	OK
17	Rejected	11-Dec-2013	13-Dec-2013	SUBS 0132, 0134, 0135, 0136 PD 1-2	sst failure-carryover
18	Accepted	11-Dec-2013	13-Dec-2013	SUBS 0139, 0140, 0142, 0148 PD 1-2	OK
19	Accepted	19-Dec-2013	21-Dec-2013	SUB 0152 + REASSAYS	OK
20	Rejected	09-Dec-2013	14-Dec-2013	RI of Run-013 (SUBS 0083, 0084, 0089, 0090 PD 1-2)	std/qc fail acceptance
21	Accepted	09-Dec-2013	14-Dec-2013	SUBS 0105, 0107, 0113, 0119 PD 1-2 (RI of RUN-015)	OK
22	Accepted	11-Dec-2013	16-Dec-2013	RI of Run-017 (SUBS 0132, 0134, 0135, 0136 PD 1-2)	OK
23	Accepted	20-Dec-2013	20-Dec-2013	RR FAILED RUN 20 AND REASSAYS	OK
24	Accepted	20-Dec-2013	21-Dec-2013	ISRs	OK
25	Accepted	20-Dec-2013	21-Dec-2013	ISRs + REASSAYS	OK
26	Accepted	27-Dec-2013	27-Dec-2013	SUBS 0060, 0063, 0072, 0073 (PD 2 only)	OK
27	Accepted	30-Dec-2013	30-Dec-2013	REASSAYS	OK

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

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

Assay Date	Run ID	QC A 0.600 ng/mL	QC E 2.00 ng/mL	QC F 5.00 ng/mL	QC F DF2 5.00 ng/mL	QC G 8.00 ng/mL	QC D DF10 20.0 ng/mL	QC D DF4 20.0 ng/mL	QC D DF5 20.0 ng/mL
19-Oct-2013	2	0.605	2.11	5.18		8.18			
		0.587	2.07	5.00		7.93			
19-Oct-2013	5	0.589	1.96	4.88		7.98			
		0.581	2.05	5.51		8.71			
20-Oct-2013	6	0.582	2.09	5.15		8.33			
		0.618	2.16	5.53		8.39			
21-Oct-2013	8	0.609	2.09	5.18		8.06			
		0.573	2.07	5.14		8.19			
22-Oct-2013	9	0.549	2.05	5.04		7.71			
		0.579	2.03	4.95		8.03			
28-Nov-2013	11	0.585	2.03	5.18		8.01			
		0.572	2.05	5.02		7.90			
10-Dec-2013	7	0.605	2.15	5.21		8.14	19.1		
		0.606	2.25	5.14		8.42	19.0		
							19.2		
10-Dec-2013	12	0.594	2.01	5.05		8.46			
		0.539	2.19	5.50		8.34			
11-Dec-2013	10	0.566	~2.40	5.24		8.66			20.2
		0.606	2.24	5.39		8.60			18.4
									19.5
11-Dec-2013	14	0.539	2.19	5.35		8.67			
		0.568	2.03	5.38		~9.28			
12-Dec-2013	16	0.591	2.16	5.44		7.92	18.7		
		0.599	2.08	5.16		8.34	18.2		
							18.3		
13-Dec-2013	18	0.604	2.06	5.08		8.33			



Assay Date	Run ID	QC A 0.600 ng/mL	QC E 2.00 ng/mL	QC F 5.00 ng/mL	QC F DF2 5.00 ng/mL	QC G 8.00 ng/mL	QC D DF10 20.0 ng/mL	QC D DF4 20.0 ng/mL	QC D DF5 20.0 ng/mL
14-Dec-2013	21	0.629	~2.36	5.46		8.65			
		0.578	2.11	5.00		8.21			
		0.593	2.05	5.02		8.27			
16-Dec-2013	22	0.626	2.10	5.28		8.47			
		0.616	2.19	4.96		8.12			
20-Dec-2013	23	0.586	1.94	5.04		7.81	18.4		
		0.608	2.02	4.83		7.99	18.0		
							17.6		
21-Dec-2013	19	~0.729	2.10	5.08		8.91	18.4		
		0.683	2.12	5.31		9.01	19.2		
							19.7		
21-Dec-2013	25	0.666	2.26	5.17	5.33	8.22	18.6	18.2	
		0.672	2.10	5.34	5.15	8.40	18.9	18.2	
					5.11		18.9	18.3	
27-Dec-2013	26	~0.691	1.97	4.93		7.31			
		0.689	2.12	4.62		7.39			
30-Dec-2013	27	0.623	1.97	5.13		7.62	19.8		
		0.665	1.96	5.32		8.00	21.2		
							21.5		
Mean		0.608	2.10	5.16	5.20	8.24	19.0	18.2	19.4
S.D.		0.0436	0.104	0.205	0.117	0.413	1.01	0.0577	0.907
%CV		7.2	5.0	4.0	2.3	5.0	5.3	0.3	4.7
%Theoretical		101.3	105.0	103.2	104.0	103.0	95.0	91.0	97.0
%Bias		1.3	5.0	3.2	4.0	3.0	-5.0	-9.0	-3.0
n		38	38	38	3	38	18	3	3

~> 15%Bias

Table 3 Back-calculated Calibration Standard Concentrations

Assay Date	Run ID	STD B 0.200 ng/mL	STD C 0.400 ng/mL	STD D 0.800 ng/mL	STD E 1.00 ng/mL	STD F 2.50 ng/mL	STD G 5.00 ng/mL	STD H 7.50 ng/mL	STD I 9.00 ng/mL	STD J 10.0 ng/mL
19-Oct-2013	2	0.201	0.402	0.762	1.02	2.45	5.06	7.72	8.92	9.99
19-Oct-2013	5	0.200	0.390	0.852	0.977	2.54	5.02	7.23	8.82	10.2
20-Oct-2013	6	0.202	0.399	0.769	0.998	2.51	5.02	7.35	9.28	10.2
21-Oct-2013	8	0.206	0.388	0.745	1.00	2.53	5.07	7.53	9.30	10.0
22-Oct-2013	9	0.204	0.392	0.764	0.995	2.52	5.07	7.37	8.96	10.5
28-Nov-2013	11	0.205	0.394	0.758	0.981	2.49	5.33	7.37	9.01	10.2
10-Dec-2013	7	0.210	0.368	0.726	1.06	2.42	4.85	7.60	9.31	10.7
10-Dec-2013	12	0.203	0.396	0.781	0.990	2.51	4.98	7.25	9.85	9.74
11-Dec-2013	10	0.201	0.386	0.836	1.02	2.46	4.86	7.55	8.68	10.4
11-Dec-2013	14	0.200	0.402	0.778	1.02	2.40	4.94	7.41	9.12	10.5
12-Dec-2013	16	0.212	0.371	0.702	1.01	2.60	5.05	7.44	9.29	10.5
13-Dec-2013	18	0.206	0.398	0.733	0.953	2.51	5.05	7.76	9.28	10.3
14-Dec-2013	21	0.205	0.396	0.765	0.953	2.53	5.00	7.33	9.47	10.4

Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

Assay Date	Run ID	STD B 0.200 ng/mL	STD C 0.400 ng/mL	STD D 0.800 ng/mL	STD E 1.00 ng/mL	STD F 2.50 ng/mL	STD G 5.00 ng/mL	STD H 7.50 ng/mL	STD I 9.00 ng/mL	STD J 10.0 ng/mL
16-Dec-2013	22	0.214	0.369	0.735	0.929	2.56	5.26	7.52	9.47	10.3
20-Dec-2013	23	0.211	0.380	0.684	1.00	2.51	5.07	7.77	8.89	10.9
21-Dec-2013	19	0.205	0.391	0.730	1.04	2.41	5.14	7.49	8.96	10.5
21-Dec-2013	25	0.207	0.389	0.722	1.02	2.51	4.93	7.32	8.75	11.3
27-Dec-2013	26	*0.257	0.402	**No Value	0.991	2.50	4.70	7.38	9.00	10.8
30-Dec-2013	27	0.204	**No Value	0.734	1.00	2.44	5.03	7.19	9.27	10.9
Mean		0.205	0.390	0.754	0.998	2.49	5.02	7.45	9.14	10.4
S.D.		0.00414	0.0110	0.0416	0.0311	0.0525	0.140	0.172	0.292	0.371
%CV		2.0	2.8	5.5	3.1	2.1	2.8	2.3	3.2	3.6
%Bias		2.5	-2.5	-5.8	-0.2	-0.4	0.4	-0.7	1.6	4.0
n		18	18	18	19	19	19	19	19	19

Reasons Deactivated  
\* Not Used (Interference)  
\*\* UISR

Table 4 Standard Curve Parameters

Assay Date	Run ID	Slope	Intercept	R-Squared
19-Oct-2013	2	0.642010904	-0.0115024705	0.9992
19-Oct-2013	5	2.06663859	-0.0423591923	0.9986
20-Oct-2013	6	2.03415643	-0.0241082422	0.9994
21-Oct-2013	8	2.02927015	-0.00103704713	0.9986
22-Oct-2013	9	2.06185955	-0.0581080648	0.9989
28-Nov-2013	11	2.12528938	-0.0612090936	0.9984
10-Dec-2013	7	2.09286535	-0.0555659891	0.9948
10-Dec-2013	12	2.00732625	-0.0467238293	0.9979
11-Dec-2013	10	2.06095978	-0.0684437668	0.9987
11-Dec-2013	14	2.00726346	-0.0383471931	0.9990
12-Dec-2013	16	2.02696832	0.0657160717	0.9949
13-Dec-2013	18	1.93861077	-0.0480416838	0.9977
14-Dec-2013	21	2.02841276	-0.0482326135	0.9983
16-Dec-2013	22	2.00259385	-0.0679946143	0.9948
20-Dec-2013	23	0.469922135	-0.0107127264	0.9935
21-Dec-2013	19	2.10284366	-0.0605231615	0.9972
21-Dec-2013	25	2.30009779	-0.0600691787	0.9946
27-Dec-2013	26	0.484900581	-0.0181910321	0.9977
30-Dec-2013	27	2.14248216	0.0149578353	0.9967
Mean		1.82234062	-0.0337103154	0.9973
S.D.		0.579548959	0.0341430417	0.0019
%CV		31.8	-101.3	0.2
n		19	19	19

Table 5 Study Sample Concentrations

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000001	10	0002	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000002	10	0002	3	0	2	5.44	1	OK		Nicotine
05110800000003	10	0002	3	0	4	11.3	1	OK		Nicotine
05110800000004	10	0002	3	0	6	12.1	1	OK		Nicotine
05110800000005	10	0002	3	0	8	11.2	1	OK		Nicotine
05110800000006	10	0002	3	0	10	12.1	1	OK		Nicotine
05110800000007	10	0002	3	0	15	8.82	1	OK		Nicotine
05110800000008	10	0002	3	0	30	6.38	1	OK		Nicotine
05110800000009	10	0002	3	0	45	4.52	1	OK		Nicotine
05110800000010	10	0002	3	1	0	3.99	1	OK		Nicotine
05110800000011	10	0002	3	2	0	2.36	1	OK		Nicotine
05110800000012	10	0002	3	4	0	1.17	1	OK		Nicotine
05110800000013	10	0002	3	6	0	0.538	1	OK		Nicotine
05110800000014	10	0002	3	9	0	0.302	1	OK		Nicotine
05110800000015	10	0002	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000016	10	0002	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000017	10	0002	1	0	-15	0.317	1	OK		Nicotine
05110800000018	10	0002	1	0	2	2.62	1	OK		Nicotine
05110800000019	10	0002	1	0	4	13.8	1	OK		Nicotine
05110800000020	10	0002	1	0	6	16.2	1	OK		Nicotine
05110800000021	10	0002	1	0	8	15.9	1	OK		Nicotine
05110800000022	10	0002	1	0	10	16.7	1	OK		Nicotine
05110800000023	10	0002	1	0	15	13.1	1	OK		Nicotine
05110800000024	10	0002	1	0	30	8.74	1	OK		Nicotine
05110800000025	10	0002	1	0	45	6.31	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000026	10	0002	1	1	0	5.80	1	OK		Nicotine
05110800000027	10	0002	1	2	0	3.34	1	OK		Nicotine
05110800000028	10	0002	1	4	0	1.46	1	OK		Nicotine
05110800000029	10	0002	1	6	0	0.631	1	OK		Nicotine
05110800000030	10	0002	1	9	0	0.304	1	OK		Nicotine
05110800000031	10	0002	1	12	0	0.280	1	OK		Nicotine
05110800000032	10	0002	1	24	0	0.234	1	OK		Nicotine
05110800000033	10	0010	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000034	10	0010	3	0	2	9.00	1	OK		Nicotine
05110800000035	10	0010	3	0	4	13.8	1	OK		Nicotine
05110800000036	10	0010	3	0	6	17.6	1	OK		Nicotine
05110800000037	10	0010	3	0	8	11.1	1	OK		Nicotine
05110800000038	10	0010	3	0	10	8.89	1	OK		Nicotine
05110800000039	10	0010	3	0	15	6.74	1	OK		Nicotine
05110800000040	10	0010	3	0	30	4.82	1	OK		Nicotine
05110800000041	10	0010	3	0	45	4.27	1	OK		Nicotine
05110800000042	10	0010	3	1	0	3.84	1	OK		Nicotine
05110800000043	10	0010	3	2	0	2.40	1	OK		Nicotine
05110800000044	10	0010	3	4	0	1.03	1	OK		Nicotine
05110800000045	10	0010	3	6	0	0.555	1	OK		Nicotine
05110800000046	10	0010	3	9	0	0.368	1	OK		Nicotine
05110800000047	10	0010	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000048	10	0010	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000049	10	0010	1	0	-15	0.323	1	OK		Nicotine
05110800000050	10	0010	1	0	2	0.976	1	OK		Nicotine
05110800000051	10	0010	1	0	4	2.51	1	OK		Nicotine
05110800000052	10	0010	1	0	6	3.16	1	OK		Nicotine
05110800000053	10	0010	1	0	8	4.60	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000054	19	0010	1	0	10	11.8	1	OK		Nicotine
05110800000055	19	0010	1	0	15	5.28	1	OK		Nicotine
05110800000056	10	0010	1	0	30	4.81	1	OK		Nicotine
05110800000057	10	0010	1	0	45	4.43	1	OK		Nicotine
05110800000058	10	0010	1	1	0	4.51	1	OK		Nicotine
05110800000059	10	0010	1	2	0	2.59	1	OK		Nicotine
05110800000060	10	0010	1	4	0	1.22	1	OK		Nicotine
05110800000061	10	0010	1	6	0	0.646	1	OK		Nicotine
05110800000062	10	0010	1	9	0	0.357	1	OK		Nicotine
05110800000063	10	0010	1	12	0	0.344	1	OK		Nicotine
05110800000064	10	0010	1	24	0	0.328	1	OK		Nicotine
05110800000065	10	0004	3	0	-15	0.221	1	OK		Nicotine
05110800000066	10	0004	3	0	10	0.670	1	OK		Nicotine
05110800000068	10	0004	3	0	25	2.39	1	OK		Nicotine
05110800000069	10	0004	3	0	30	2.52	1	OK		Nicotine
05110800000070	10	0004	3	0	35	2.26	1	OK		Nicotine
05110800000071	10	0004	3	0	40	2.68	1	OK		Nicotine
05110800000072	10	0004	3	0	45	2.50	1	OK		Nicotine
05110800000073	10	0004	3	1	0	2.40	1	OK		Nicotine
05110800000074	10	0004	3	2	0	1.61	1	OK		Nicotine
05110800000075	10	0004	3	3	0	1.05	1	OK		Nicotine
05110800000076	10	0004	3	4	0	0.902	1	OK		Nicotine
05110800000077	10	0004	3	6	0	0.473	1	OK		Nicotine
05110800000078	10	0004	3	9	0	0.335	1	OK		Nicotine
05110800000079	10	0004	3	12	0	0.235	1	OK		Nicotine
05110800000080	10	0004	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000081	10	0004	1	0	-15	0.325	1	OK		Nicotine
05110800000082	10	0004	1	0	2	3.87	1	OK		Nicotine

Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000083	10	0004	1	0	4	4.63	1	OK		Nicotine
05110800000084	10	0004	1	0	6	5.41	1	OK		Nicotine
05110800000085	10	0004	1	0	8	5.77	1	OK		Nicotine
05110800000086	10	0004	1	0	10	6.97	1	OK		Nicotine
05110800000087	10	0004	1	0	15	4.29	1	OK		Nicotine
05110800000088	10	0004	1	0	30	3.67	1	OK		Nicotine
05110800000089	10	0004	1	0	45	3.40	1	OK		Nicotine
05110800000090	10	0004	1	1	0	2.58	1	OK		Nicotine
05110800000091	10	0004	1	2	0	1.66	1	OK		Nicotine
05110800000092	10	0004	1	4	0	0.836	1	OK		Nicotine
05110800000093	10	0004	1	6	0	0.462	1	OK		Nicotine
05110800000094	10	0004	1	9	0	0.621	1	OK		Nicotine
05110800000095	10	0004	1	12	0	0.277	1	OK		Nicotine
05110800000096	10	0004	1	24	0	0.332	1	OK		Nicotine
05110800000097	2	0017	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000098	2	0017	3	0	2	0.252	1	OK		Nicotine
05110800000099	2	0017	3	0	4	0.597	1	OK		Nicotine
05110800000100	2	0017	3	0	6	1.99	1	OK		Nicotine
05110800000101	2	0017	3	0	8	2.45	1	OK		Nicotine
05110800000102	2	0017	3	0	10	2.79	1	OK		Nicotine
05110800000103	2	0017	3	0	15	2.55	1	OK		Nicotine
05110800000104	2	0017	3	0	30	1.91	1	OK		Nicotine
05110800000105	2	0017	3	0	45	2.15	1	OK		Nicotine
05110800000106	2	0017	3	1	0	1.86	1	OK		Nicotine
05110800000107	2	0017	3	2	0	1.49	1	OK		Nicotine
05110800000108	2	0017	3	4	0	0.837	1	OK		Nicotine
05110800000109	2	0017	3	6	0	0.596	1	OK		Nicotine
05110800000110	2	0017	3	9	0	0.376	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000111	2	0017	3	12	0	0.288	1	OK		Nicotine
05110800000112	2	0017	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000113	2	0017	1	0	-15	0.433	1	OK		Nicotine
05110800000114	2	0017	1	0	10	1.67	1	OK		Nicotine
05110800000115	2	0017	1	0	20	6.58	1	OK		Nicotine
05110800000116	2	0017	1	0	25	7.10	1	OK		Nicotine
05110800000117	2	0017	1	0	30	8.92	1	OK		Nicotine
05110800000118	2	0017	1	0	35	8.32	1	OK		Nicotine
05110800000119	2	0017	1	0	40	8.59	1	OK		Nicotine
05110800000120	2	0017	1	0	45	8.71	1	OK		Nicotine
05110800000121	2	0017	1	1	0	7.58	1	OK		Nicotine
05110800000122	2	0017	1	2	0	4.40	1	OK		Nicotine
05110800000123	2	0017	1	3	0	3.73	1	OK		Nicotine
05110800000124	2	0017	1	4	0	2.93	1	OK		Nicotine
05110800000125	2	0017	1	6	0	1.88	1	OK		Nicotine
05110800000126	2	0017	1	9	0	1.20	1	OK		Nicotine
05110800000127	2	0017	1	12	0	0.818	1	OK		Nicotine
05110800000128	2	0017	1	24	0	0.349	1	OK		Nicotine
05110800000129	10	0005	3	0	-15	0.203	1	OK		Nicotine
05110800000130	10	0005	3	0	2	20.9	1	OK		Nicotine
05110800000131	10	0005	3	0	4	30.5	1	OK		Nicotine
05110800000132	10	0005	3	0	6	31.5	1	OK		Nicotine
05110800000133	10	0005	3	0	8	17.8	1	OK		Nicotine
05110800000134	10	0005	3	0	10	16.5	1	OK		Nicotine
05110800000135	10	0005	3	0	15	8.33	1	OK		Nicotine
05110800000136	10	0005	3	0	30	7.78	1	OK		Nicotine
05110800000137	10	0005	3	0	45	6.21	1	OK		Nicotine
05110800000138	10	0005	3	1	0	7.01	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000139	10	0005	3	2	0	4.21	1	OK		Nicotine
05110800000140	10	0005	3	4	0	2.50	1	OK		Nicotine
05110800000141	10	0005	3	6	0	1.73	1	OK		Nicotine
05110800000142	10	0005	3	9	0	0.914	1	OK		Nicotine
05110800000143	10	0005	3	12	0	0.528	1	OK		Nicotine
05110800000144	10	0005	3	24	0	0.221	1	OK		Nicotine
05110800000145	10	0005	1	0	-15	0.372	1	OK		Nicotine
05110800000146	10	0005	1	0	2	2.62	1	OK		Nicotine
05110800000147	10	0005	1	0	4	11.7	1	OK		Nicotine
05110800000148	10	0005	1	0	6	18.6	1	OK		Nicotine
05110800000149	19	0005	1	0	8	11.0	1	OK		Nicotine
05110800000150	10	0005	1	0	10	8.17	1	OK		Nicotine
05110800000151	10	0005	1	0	15	3.01	1	OK		Nicotine
05110800000152	10	0005	1	0	30	3.02	1	OK		Nicotine
05110800000153	10	0005	1	0	45	3.09	1	OK		Nicotine
05110800000154	10	0005	1	1	0	2.36	1	OK		Nicotine
05110800000155	10	0005	1	2	0	1.85	1	OK		Nicotine
05110800000156	10	0005	1	4	0	1.32	1	OK		Nicotine
05110800000157	10	0005	1	6	0	0.995	1	OK		Nicotine
05110800000158	10	0005	1	9	0	0.523	1	OK		Nicotine
05110800000159	10	0005	1	12	0	0.363	1	OK		Nicotine
05110800000160	10	0005	1	24	0	0.308	1	OK		Nicotine
05110800000161	8	0024	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000162	8	0024	3	0	2	4.15	1	OK		Nicotine
05110800000163	7	0024	3	0	4	12.6	1	OK		Nicotine
05110800000164	7	0024	3	0	6	18.1	1	OK		Nicotine
05110800000165	7	0024	3	0	8	13.6	1	OK		Nicotine
05110800000166	8	0024	3	0	10	9.92	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000167	8	0024	3	0	15	6.32	1	OK		Nicotine
05110800000168	8	0024	3	0	30	5.08	1	OK		Nicotine
05110800000169	8	0024	3	0	45	4.54	1	OK		Nicotine
05110800000170	8	0024	3	1	0	3.27	1	OK		Nicotine
05110800000171	8	0024	3	2	0	2.85	1	OK		Nicotine
05110800000172	8	0024	3	4	0	1.30	1	OK		Nicotine
05110800000173	8	0024	3	6	0	0.790	1	OK		Nicotine
05110800000174	8	0024	3	9	0	0.405	1	OK		Nicotine
05110800000175	8	0024	3	12	0	0.308	1	OK		Nicotine
05110800000176	8	0024	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000177	8	0024	1	0	-15	0.337	1	OK		Nicotine
05110800000178	8	0024	1	0	2	2.86	1	OK		Nicotine
05110800000179	7	0024	1	0	4	16.6	1	OK		Nicotine
05110800000180	7	0024	1	0	6	19.7	1	OK		Nicotine
05110800000181	7	0024	1	0	8	19.1	1	OK		Nicotine
05110800000182	7	0024	1	0	10	14.4	1	OK		Nicotine
05110800000183	8	0024	1	0	15	8.54	1	OK		Nicotine
05110800000184	8	0024	1	0	30	6.79	1	OK		Nicotine
05110800000186	8	0024	1	1	0	5.56	1	OK		Nicotine
05110800000187	8	0024	1	2	0	3.80	1	OK		Nicotine
05110800000188	8	0024	1	4	0	1.94	1	OK		Nicotine
05110800000189	8	0024	1	6	0	1.26	1	OK		Nicotine
05110800000190	8	0024	1	9	0	0.734	1	OK		Nicotine
05110800000191	8	0024	1	12	0	0.431	1	OK		Nicotine
05110800000192	8	0024	1	24	0	0.366	1	OK		Nicotine
05110800000193	8	0027	3	0	-15	0.388	1	OK		Nicotine
05110800000194	8	0027	3	0	2	2.63	1	OK		Nicotine
05110800000195	8	0027	3	0	4	8.96	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000196	7	0027	3	0	6	13.2	1	OK		Nicotine
05110800000197	7	0027	3	0	8	13.2	1	OK		Nicotine
05110800000198	7	0027	3	0	10	15.8	1	OK		Nicotine
05110800000199	8	0027	3	0	15	6.48	1	OK		Nicotine
05110800000200	8	0027	3	0	30	7.83	1	OK		Nicotine
05110800000201	8	0027	3	0	45	5.93	1	OK		Nicotine
05110800000202	8	0027	3	1	0	7.00	1	OK		Nicotine
05110800000203	8	0027	3	2	0	5.68	1	OK		Nicotine
05110800000204	8	0027	3	4	0	3.79	1	OK		Nicotine
05110800000205	8	0027	3	6	0	2.80	1	OK		Nicotine
05110800000206	8	0027	3	9	0	1.86	1	OK		Nicotine
05110800000207	8	0027	3	12	0	1.27	1	OK		Nicotine
05110800000208	8	0027	3	24	0	0.500	1	OK		Nicotine
05110800000209	8	0027	1	0	-15	0.687	1	OK		Nicotine
05110800000210	8	0027	1	0	2	3.56	1	OK		Nicotine
05110800000211	7	0027	1	0	4	11.7	1	OK		Nicotine
05110800000212	7	0027	1	0	6	14.0	1	OK		Nicotine
05110800000213	7	0027	1	0	8	14.5	1	OK		Nicotine
05110800000214	7	0027	1	0	10	13.6	1	OK		Nicotine
05110800000215	8	0027	1	0	15	6.69	1	OK		Nicotine
05110800000216	8	0027	1	0	30	7.25	1	OK		Nicotine
05110800000217	8	0027	1	0	45	7.40	1	OK		Nicotine
05110800000218	8	0027	1	1	0	7.31	1	OK		Nicotine
05110800000219	8	0027	1	2	0	6.04	1	OK		Nicotine
05110800000220	8	0027	1	4	0	4.62	1	OK		Nicotine
05110800000221	8	0027	1	6	0	3.67	1	OK		Nicotine
05110800000222	8	0027	1	9	0	2.23	1	OK		Nicotine
05110800000223	8	0027	1	12	0	1.53	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000224	8	0027	1	24	0	2.92	1	OK		Nicotine
05110800000225	9	0039	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000226	9	0039	3	0	2	2.53	1	OK		Nicotine
05110800000227	9	0039	3	0	4	5.03	1	OK		Nicotine
05110800000228	9	0039	3	0	6	6.78	1	OK		Nicotine
05110800000229	9	0039	3	0	8	6.06	1	OK		Nicotine
05110800000230	9	0039	3	0	10	6.55	1	OK		Nicotine
05110800000231	9	0039	3	0	15	8.76	1	OK		Nicotine
05110800000232	9	0039	3	0	30	7.11	1	OK		Nicotine
05110800000233	9	0039	3	0	45	7.61	1	OK		Nicotine
05110800000234	9	0039	3	1	0	7.74	1	OK		Nicotine
05110800000235	9	0039	3	2	0	5.73	1	OK		Nicotine
05110800000236	9	0039	3	4	0	3.83	1	OK		Nicotine
05110800000237	9	0039	3	6	0	2.91	1	OK		Nicotine
05110800000238	9	0039	3	9	0	1.97	1	OK		Nicotine
05110800000239	9	0039	3	12	0	1.20	1	OK		Nicotine
05110800000240	9	0039	3	24	0	0.444	1	OK		Nicotine
05110800000241	9	0039	1	0	-15	0.559	1	OK		Nicotine
05110800000242	7	0039	1	0	2	11.7	1	OK		Nicotine
05110800000243	7	0039	1	0	4	15.7	1	OK		Nicotine
05110800000244	7	0039	1	0	6	16.8	1	OK		Nicotine
05110800000245	7	0039	1	0	8	12.6	1	OK		Nicotine
05110800000246	7	0039	1	0	10	13.1	1	OK		Nicotine
05110800000247	9	0039	1	0	15	7.31	1	OK		Nicotine
05110800000248	9	0039	1	0	30	7.31	1	OK		Nicotine
05110800000249	9	0039	1	0	45	7.00	1	OK		Nicotine
05110800000250	9	0039	1	1	0	6.61	1	OK		Nicotine
05110800000251	9	0039	1	2	0	5.58	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000252	9	0039	1	4	0	3.57	1	OK		Nicotine
05110800000253	9	0039	1	6	0	2.70	1	OK		Nicotine
05110800000254	9	0039	1	9	0	1.88	1	OK		Nicotine
05110800000255	9	0039	1	12	0	1.34	1	OK		Nicotine
05110800000256	9	0039	1	24	0	0.457	1	OK		Nicotine
05110800000257	5	0045	3	0	-15	0.340	1	OK		Nicotine
05110800000258	5	0045	3	0	2	3.59	1	OK		Nicotine
05110800000259	7	0045	3	0	4	19.7	1	OK		Nicotine
05110800000260	7	0045	3	0	6	15.6	1	OK		Nicotine
05110800000261	7	0045	3	0	8	14.1	1	OK		Nicotine
05110800000262	7	0045	3	0	10	12.3	1	OK		Nicotine
05110800000263	5	0045	3	0	15	9.78	1	OK		Nicotine
05110800000264	5	0045	3	0	30	8.43	1	OK		Nicotine
05110800000265	5	0045	3	0	45	7.26	1	OK		Nicotine
05110800000266	5	0045	3	1	0	7.13	1	OK		Nicotine
05110800000267	5	0045	3	2	0	6.80	1	OK		Nicotine
05110800000268	5	0045	3	4	0	4.89	1	OK		Nicotine
05110800000269	5	0045	3	6	0	3.79	1	OK		Nicotine
05110800000270	5	0045	3	9	0	2.68	1	OK		Nicotine
05110800000271	5	0045	3	12	0	1.76	1	OK		Nicotine
05110800000272	5	0045	3	24	0	0.673	1	OK		Nicotine
05110800000273	5	0045	1	0	-15	2.15	1	OK		Nicotine
05110800000274	5	0045	1	0	2	2.95	1	OK		Nicotine
05110800000275	5	0045	1	0	4	8.86	1	OK		Nicotine
05110800000276	7	0045	1	0	6	21.1	1	OK		Nicotine
05110800000277	7	0045	1	0	8	16.4	1	OK		Nicotine
05110800000278	7	0045	1	0	10	15.3	1	OK		Nicotine
05110800000279	5	0045	1	0	15	6.62	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000280	5	0045	1	0	30	7.11	1	OK		Nicotine
05110800000281	5	0045	1	0	45	6.50	1	OK		Nicotine
05110800000282	5	0045	1	1	0	7.00	1	OK		Nicotine
05110800000283	5	0045	1	2	0	6.07	1	OK		Nicotine
05110800000284	5	0045	1	4	0	4.27	1	OK		Nicotine
05110800000285	5	0045	1	6	0	3.71	1	OK		Nicotine
05110800000286	5	0045	1	9	0	2.60	1	OK		Nicotine
05110800000287	5	0045	1	12	0	1.86	1	OK		Nicotine
05110800000288	5	0045	1	24	0	0.860	1	OK		Nicotine
05110800000289	5	0049	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000290	5	0049	3	0	2	1.32	1	OK		Nicotine
05110800000291	5	0049	3	0	4	4.34	1	OK		Nicotine
05110800000292	5	0049	3	0	6	8.06	1	OK		Nicotine
05110800000293	5	0049	3	0	8	8.47	1	OK		Nicotine
05110800000294	5	0049	3	0	10	8.22	1	OK		Nicotine
05110800000295	5	0049	3	0	15	9.21	1	OK		Nicotine
05110800000296	7	0049	3	0	30	11.4	1	OK		Nicotine
05110800000297	5	0049	3	0	45	9.33	1	OK		Nicotine
05110800000298	5	0049	3	1	0	9.13	1	OK		Nicotine
05110800000299	5	0049	3	2	0	6.60	1	OK		Nicotine
05110800000300	5	0049	3	4	0	3.48	1	OK		Nicotine
05110800000301	5	0049	3	6	0	2.00	1	OK		Nicotine
05110800000302	5	0049	3	9	0	1.06	1	OK		Nicotine
05110800000303	5	0049	3	12	0	0.618	1	OK		Nicotine
05110800000304	5	0049	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000305	5	0049	1	0	-15	0.297	1	OK		Nicotine
05110800000306	5	0049	1	0	2	9.65	1	OK		Nicotine
05110800000307	7	0049	1	0	4	22.5	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000308	7	0049	1	0	6	12.6	1	OK		Nicotine
05110800000309	5	0049	1	0	8	8.97	1	OK		Nicotine
05110800000310	5	0049	1	0	10	9.11	1	OK		Nicotine
05110800000311	5	0049	1	0	15	6.79	1	OK		Nicotine
05110800000312	5	0049	1	0	30	6.08	1	OK		Nicotine
05110800000313	5	0049	1	0	45	5.79	1	OK		Nicotine
05110800000314	5	0049	1	1	0	5.24	1	OK		Nicotine
05110800000315	5	0049	1	2	0	4.48	1	OK		Nicotine
05110800000316	5	0049	1	4	0	2.43	1	OK		Nicotine
05110800000317	5	0049	1	6	0	1.73	1	OK		Nicotine
05110800000318	5	0049	1	9	0	0.878	1	OK		Nicotine
05110800000319	5	0049	1	12	0	0.628	1	OK		Nicotine
05110800000320	5	0049	1	24	0	0.333	1	OK		Nicotine
05110800000321	6	0052	3	0	-15	0.205	1	OK		Nicotine
05110800000322	6	0052	3	0	2	2.91	1	OK		Nicotine
05110800000323	6	0052	3	0	4	5.18	1	OK		Nicotine
05110800000324	6	0052	3	0	6	6.05	1	OK		Nicotine
05110800000325	6	0052	3	0	8	6.06	1	OK		Nicotine
05110800000326	6	0052	3	0	10	6.02	1	OK		Nicotine
05110800000327	6	0052	3	0	15	6.12	1	OK		Nicotine
05110800000328	6	0052	3	0	30	6.19	1	OK		Nicotine
05110800000329	6	0052	3	0	45	5.46	1	OK		Nicotine
05110800000330	6	0052	3	1	0	5.18	1	OK		Nicotine
05110800000331	6	0052	3	2	0	3.51	1	OK		Nicotine
05110800000332	6	0052	3	4	0	2.13	1	OK		Nicotine
05110800000333	6	0052	3	6	0	1.44	1	OK		Nicotine
05110800000334	6	0052	3	9	0	1.01	1	OK		Nicotine
05110800000335	6	0052	3	12	0	0.773	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000336	6	0052	3	24	0	0.265	1	OK		Nicotine
05110800000337	6	0052	1	0	-15	0.514	1	OK		Nicotine
05110800000338	6	0052	1	0	2	1.87	1	OK		Nicotine
05110800000339	6	0052	1	0	4	6.51	1	OK		Nicotine
05110800000340	6	0052	1	0	6	9.16	1	OK		Nicotine
05110800000341	6	0052	1	0	8	9.65	1	OK		Nicotine
05110800000342	6	0052	1	0	10	8.30	1	OK		Nicotine
05110800000343	7	0052	1	0	15	12.3	1	OK		Nicotine
05110800000344	6	0052	1	0	30	9.77	1	OK		Nicotine
05110800000345	6	0052	1	0	45	8.56	1	OK		Nicotine
05110800000346	6	0052	1	1	0	8.68	1	OK		Nicotine
05110800000347	6	0052	1	2	0	5.91	1	OK		Nicotine
05110800000348	6	0052	1	4	0	4.12	1	OK		Nicotine
05110800000349	6	0052	1	6	0	2.89	1	OK		Nicotine
05110800000350	6	0052	1	9	0	2.21	1	OK		Nicotine
05110800000351	6	0052	1	12	0	1.16	1	OK		Nicotine
05110800000352	6	0052	1	24	0	0.483	1	OK		Nicotine
05110800000353	2	0013	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000354	2	0013	3	0	2	3.64	1	OK		Nicotine
05110800000355	7	0013	3	0	4	10.7	1	OK		Nicotine
05110800000356	7	0013	3	0	6	19.9	1	OK		Nicotine
05110800000357	7	0013	3	0	8	29.7	1	OK		Nicotine
05110800000358	7	0013	3	0	10	26.3	1	OK		Nicotine
05110800000359	7	0013	3	0	15	16.7	1	OK		Nicotine
05110800000360	7	0013	3	0	30	11.9	1	OK		Nicotine
05110800000361	2	0013	3	0	45	9.29	1	OK		Nicotine
05110800000362	2	0013	3	1	0	8.26	1	OK		Nicotine
05110800000363	2	0013	3	2	0	5.52	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000364	2	0013	3	4	0	3.35	1	OK		Nicotine
05110800000365	2	0013	3	6	0	1.74	1	OK		Nicotine
05110800000366	2	0013	3	9	0	0.881	1	OK		Nicotine
05110800000367	2	0013	3	12	0	0.459	1	OK		Nicotine
05110800000368	2	0013	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000369	2	0013	1	0	-15	0.330	1	OK		Nicotine
05110800000370	2	0013	1	0	2	2.32	1	OK		Nicotine
05110800000371	2	0013	1	0	4	7.34	1	OK		Nicotine
05110800000372	7	0013	1	0	6	18.4	1	OK		Nicotine
05110800000373	7	0013	1	0	8	13.3	1	OK		Nicotine
05110800000374	7	0013	1	0	10	19.2	1	OK		Nicotine
05110800000375	2	0013	1	0	15	8.34	1	OK		Nicotine
05110800000376	2	0013	1	0	30	8.34	1	OK		Nicotine
05110800000377	2	0013	1	0	45	7.05	1	OK		Nicotine
05110800000378	2	0013	1	1	0	6.33	1	OK		Nicotine
05110800000379	2	0013	1	2	0	4.88	1	OK		Nicotine
05110800000380	2	0013	1	4	0	2.65	1	OK		Nicotine
05110800000381	2	0013	1	6	0	1.52	1	OK		Nicotine
05110800000382	2	0013	1	9	0	0.872	1	OK		Nicotine
05110800000383	2	0013	1	12	0	0.533	1	OK		Nicotine
05110800000384	2	0013	1	24	0	0.301	1	OK		Nicotine
05110800000385	8	0025	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000386	8	0025	3	0	2	9.18	1	OK		Nicotine
05110800000387	7	0025	3	0	4	14.8	1	OK		Nicotine
05110800000388	7	0025	3	0	6	26.1	1	OK		Nicotine
05110800000389	7	0025	3	0	8	16.1	1	OK		Nicotine
05110800000390	7	0025	3	0	10	14.8	1	OK		Nicotine
05110800000391	8	0025	3	0	15	9.75	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000392	8	0025	3	0	30	6.48	1	OK		Nicotine
05110800000393	8	0025	3	0	45	5.18	1	OK		Nicotine
05110800000394	8	0025	3	1	0	4.19	1	OK		Nicotine
05110800000395	8	0025	3	2	0	2.68	1	OK		Nicotine
05110800000396	8	0025	3	4	0	1.80	1	OK		Nicotine
05110800000397	8	0025	3	6	0	0.984	1	OK		Nicotine
05110800000398	8	0025	3	9	0	0.603	1	OK		Nicotine
05110800000399	8	0025	3	12	0	0.303	1	OK		Nicotine
05110800000400	8	0025	3	24	0	0.221	1	OK		Nicotine
05110800000401	8	0025	1	0	-15	0.218	1	OK		Nicotine
05110800000402	8	0025	1	0	2	6.55	1	OK		Nicotine
05110800000403	7	0025	1	0	4	19.3	1	OK		Nicotine
05110800000404	7	0025	1	0	6	30.3	1	OK		Nicotine
05110800000405	7	0025	1	0	8	19.8	1	OK		Nicotine
05110800000406	7	0025	1	0	10	14.0	1	OK		Nicotine
05110800000407	7	0025	1	0	15	12.8	1	OK		Nicotine
05110800000408	8	0025	1	0	30	7.63	1	OK		Nicotine
05110800000409	8	0025	1	0	45	6.02	1	OK		Nicotine
05110800000410	8	0025	1	1	0	5.14	1	OK		Nicotine
05110800000411	8	0025	1	2	0	3.21	1	OK		Nicotine
05110800000412	8	0025	1	4	0	1.91	1	OK		Nicotine
05110800000413	8	0025	1	6	0	1.13	1	OK		Nicotine
05110800000414	8	0025	1	9	0	0.658	1	OK		Nicotine
05110800000415	8	0025	1	12	0	0.462	1	OK		Nicotine
05110800000416	8	0025	1	24	0	0.227	1	OK		Nicotine
05110800000417	8	0031	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000418	8	0031	3	0	2	1.80	1	OK		Nicotine
05110800000419	8	0031	3	0	4	5.86	1	OK		Nicotine

Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000420	7	0031	3	0	6	10.8	1	OK		Nicotine
05110800000421	7	0031	3	0	8	13.4	1	OK		Nicotine
05110800000422	7	0031	3	0	10	13.3	1	OK		Nicotine
05110800000423	7	0031	3	0	15	11.9	1	OK		Nicotine
05110800000424	8	0031	3	0	30	8.69	1	OK		Nicotine
05110800000425	8	0031	3	0	45	8.76	1	OK		Nicotine
05110800000426	8	0031	3	1	0	7.40	1	OK		Nicotine
05110800000427	8	0031	3	2	0	5.15	1	OK		Nicotine
05110800000428	8	0031	3	4	0	1.94	1	OK		Nicotine
05110800000429	8	0031	3	6	0	1.02	1	OK		Nicotine
05110800000430	8	0031	3	9	0	0.500	1	OK		Nicotine
05110800000431	8	0031	3	12	0	0.266	1	OK		Nicotine
05110800000432	8	0031	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000433	8	0031	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000434	8	0031	1	0	2	2.08	1	OK		Nicotine
05110800000435	8	0031	1	0	4	7.33	1	OK		Nicotine
05110800000436	8	0031	1	0	6	9.63	1	OK		Nicotine
05110800000437	7	0031	1	0	8	12.9	1	OK		Nicotine
05110800000438	7	0031	1	0	10	13.4	1	OK		Nicotine
05110800000439	7	0031	1	0	15	12.3	1	OK		Nicotine
05110800000440	8	0031	1	0	30	8.96	1	OK		Nicotine
05110800000441	8	0031	1	0	45	7.64	1	OK		Nicotine
05110800000442	8	0031	1	1	0	6.91	1	OK		Nicotine
05110800000443	8	0031	1	2	0	4.28	1	OK		Nicotine
05110800000444	8	0031	1	4	0	2.07	1	OK		Nicotine
05110800000445	8	0031	1	6	0	1.27	1	OK		Nicotine
05110800000446	8	0031	1	9	0	0.532	1	OK		Nicotine
05110800000447	8	0031	1	12	0	0.304	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000448	8	0031	1	24	0	0.219	1	OK		Nicotine
05110800000449	9	0040	3	0	-15	0.212	1	OK		Nicotine
05110800000450	9	0040	3	0	2	0.245	1	OK		Nicotine
05110800000451	9	0040	3	0	4	1.85	1	OK		Nicotine
05110800000452	9	0040	3	0	6	3.70	1	OK		Nicotine
05110800000453	9	0040	3	0	8	5.05	1	OK		Nicotine
05110800000454	9	0040	3	0	10	5.79	1	OK		Nicotine
05110800000455	9	0040	3	0	15	5.71	1	OK		Nicotine
05110800000456	9	0040	3	0	30	5.46	1	OK		Nicotine
05110800000457	9	0040	3	0	45	5.94	1	OK		Nicotine
05110800000458	9	0040	3	1	0	5.80	1	OK		Nicotine
05110800000459	9	0040	3	2	0	4.29	1	OK		Nicotine
05110800000460	9	0040	3	4	0	3.46	1	OK		Nicotine
05110800000461	9	0040	3	6	0	2.62	1	OK		Nicotine
05110800000462	9	0040	3	9	0	1.99	1	OK		Nicotine
05110800000463	9	0040	3	12	0	1.23	1	OK		Nicotine
05110800000464	9	0040	3	24	0	0.450	1	OK		Nicotine
05110800000465	9	0040	1	0	-15	0.855	1	OK		Nicotine
05110800000466	9	0040	1	0	2	1.77	1	OK		Nicotine
05110800000467	9	0040	1	0	4	6.05	1	OK		Nicotine
05110800000468	9	0040	1	0	6	7.90	1	OK		Nicotine
05110800000469	9	0040	1	0	8	7.74	1	OK		Nicotine
05110800000470	9	0040	1	0	10	7.85	1	OK		Nicotine
05110800000471	9	0040	1	0	15	5.69	1	OK		Nicotine
05110800000472	9	0040	1	0	30	5.67	1	OK		Nicotine
05110800000473	9	0040	1	0	45	5.39	1	OK		Nicotine
05110800000474	9	0040	1	1	0	5.67	1	OK		Nicotine
05110800000475	9	0040	1	2	0	4.75	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000476	9	0040	1	4	0	3.55	1	OK		Nicotine
05110800000477	9	0040	1	6	0	3.03	1	OK		Nicotine
05110800000478	9	0040	1	9	0	2.13	1	OK		Nicotine
05110800000479	9	0040	1	12	0	1.68	1	OK		Nicotine
05110800000480	9	0040	1	24	0	0.603	1	OK		Nicotine
05110800000481	5	0043	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000482	5	0043	3	0	2	0.486	1	OK		Nicotine
05110800000483	5	0043	3	0	4	4.39	1	OK		Nicotine
05110800000484	5	0043	3	0	6	9.05	1	OK		Nicotine
05110800000485	7	0043	3	0	8	11.2	1	OK		Nicotine
05110800000486	7	0043	3	0	10	14.0	1	OK		Nicotine
05110800000487	5	0043	3	0	15	8.13	1	OK		Nicotine
05110800000488	5	0043	3	0	30	4.19	1	OK		Nicotine
05110800000489	5	0043	3	0	45	4.27	1	OK		Nicotine
05110800000490	5	0043	3	1	0	4.42	1	OK		Nicotine
05110800000491	5	0043	3	2	0	3.00	1	OK		Nicotine
05110800000492	5	0043	3	4	0	1.34	1	OK		Nicotine
05110800000493	5	0043	3	6	0	0.738	1	OK		Nicotine
05110800000494	5	0043	3	9	0	0.416	1	OK		Nicotine
05110800000495	5	0043	3	12	0	0.237	1	OK		Nicotine
05110800000496	5	0043	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000497	5	0043	1	0	-15	0.389	1	OK		Nicotine
05110800000498	5	0043	1	0	2	2.46	1	OK		Nicotine
05110800000499	7	0043	1	0	4	12.9	1	OK		Nicotine
05110800000500	7	0043	1	0	6	15.9	1	OK		Nicotine
05110800000501	7	0043	1	0	8	11.5	1	OK		Nicotine
05110800000502	5	0043	1	0	10	7.51	1	OK		Nicotine
05110800000503	5	0043	1	0	15	4.82	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000504	5	0043	1	0	30	2.86	1	OK		Nicotine
05110800000505	5	0043	1	0	45	3.05	1	OK		Nicotine
05110800000506	5	0043	1	1	0	2.71	1	OK		Nicotine
05110800000507	5	0043	1	2	0	1.54	1	OK		Nicotine
05110800000508	5	0043	1	4	0	0.815	1	OK		Nicotine
05110800000509	5	0043	1	6	0	0.697	1	OK		Nicotine
05110800000510	5	0043	1	9	0	0.453	1	OK		Nicotine
05110800000511	5	0043	1	12	0	0.284	1	OK		Nicotine
05110800000512	5	0043	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000513	5	0050	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000514	5	0050	3	0	2	1.57	1	OK		Nicotine
05110800000515	7	0050	3	0	4	16.0	1	OK		Nicotine
05110800000516	7	0050	3	0	6	15.2	1	OK		Nicotine
05110800000517	7	0050	3	0	8	13.2	1	OK		Nicotine
05110800000518	5	0050	3	0	10	9.38	1	OK		Nicotine
05110800000519	5	0050	3	0	15	5.49	1	OK		Nicotine
05110800000520	5	0050	3	0	30	3.88	1	OK		Nicotine
05110800000521	5	0050	3	0	45	3.06	1	OK		Nicotine
05110800000522	5	0050	3	1	0	3.22	1	OK		Nicotine
05110800000523	5	0050	3	2	0	2.27	1	OK		Nicotine
05110800000524	5	0050	3	4	0	1.08	1	OK		Nicotine
05110800000525	5	0050	3	6	0	1.01	1	OK		Nicotine
05110800000526	5	0050	3	9	0	0.316	1	OK		Nicotine
05110800000527	5	0050	3	12	0	0.209	1	OK		Nicotine
05110800000528	5	0050	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000529	5	0050	1	0	-15	0.208	1	OK		Nicotine
05110800000530	5	0050	1	0	2	1.69	1	OK		Nicotine
05110800000531	5	0050	1	0	4	8.13	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000532	7	0050	1	0	6	12.2	1	OK		Nicotine
05110800000533	5	0050	1	0	8	7.12	1	OK		Nicotine
05110800000534	5	0050	1	0	10	6.91	1	OK		Nicotine
05110800000535	5	0050	1	0	15	6.07	1	OK		Nicotine
05110800000536	5	0050	1	0	30	5.16	1	OK		Nicotine
05110800000537	5	0050	1	0	45	4.98	1	OK		Nicotine
05110800000538	5	0050	1	1	0	4.04	1	OK		Nicotine
05110800000539	5	0050	1	2	0	2.68	1	OK		Nicotine
05110800000540	5	0050	1	4	0	1.32	1	OK		Nicotine
05110800000541	5	0050	1	6	0	0.866	1	OK		Nicotine
05110800000542	5	0050	1	9	0	0.457	1	OK		Nicotine
05110800000543	5	0050	1	12	0	0.281	1	OK		Nicotine
05110800000544	5	0050	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000545	6	0054	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000546	6	0054	3	0	2	1.27	1	OK		Nicotine
05110800000547	6	0054	3	0	4	4.19	1	OK		Nicotine
05110800000548	6	0054	3	0	6	6.25	1	OK		Nicotine
05110800000549	6	0054	3	0	8	6.67	1	OK		Nicotine
05110800000550	6	0054	3	0	10	6.88	1	OK		Nicotine
05110800000551	6	0054	3	0	15	8.24	1	OK		Nicotine
05110800000552	6	0054	3	0	30	5.60	1	OK		Nicotine
05110800000553	6	0054	3	0	45	6.98	1	OK		Nicotine
05110800000554	6	0054	3	1	0	5.46	1	OK		Nicotine
05110800000555	6	0054	3	2	0	3.04	1	OK		Nicotine
05110800000556	6	0054	3	4	0	1.61	1	OK		Nicotine
05110800000557	6	0054	3	6	0	0.675	1	OK		Nicotine
05110800000558	6	0054	3	9	0	0.270	1	OK		Nicotine
05110800000559	6	0054	3	12	0	BLQ<(0.200)	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000560	6	0054	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000561	6	0054	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000562	6	0054	1	0	2	1.57	1	OK		Nicotine
05110800000563	6	0054	1	0	4	5.41	1	OK		Nicotine
05110800000564	6	0054	1	0	6	6.54	1	OK		Nicotine
05110800000565	6	0054	1	0	8	7.25	1	OK		Nicotine
05110800000566	6	0054	1	0	10	5.54	1	OK		Nicotine
05110800000567	6	0054	1	0	15	7.97	1	OK		Nicotine
05110800000568	6	0054	1	0	30	7.14	1	OK		Nicotine
05110800000569	6	0054	1	0	45	5.51	1	OK		Nicotine
05110800000570	6	0054	1	1	0	6.10	1	OK		Nicotine
05110800000571	6	0054	1	2	0	3.63	1	OK		Nicotine
05110800000572	6	0054	1	4	0	1.55	1	OK		Nicotine
05110800000573	6	0054	1	6	0	0.743	1	OK		Nicotine
05110800000574	6	0054	1	9	0	0.331	1	OK		Nicotine
05110800000575	6	0054	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000576	6	0054	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000577	2	0018	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000578	2	0018	3	0	10	2.45	1	OK		Nicotine
05110800000579	2	0018	3	0	20	5.76	1	OK		Nicotine
05110800000580	2	0018	3	0	25	7.81	1	OK		Nicotine
05110800000581	2	0018	3	0	30	8.26	1	OK		Nicotine
05110800000582	2	0018	3	0	35	6.31	1	OK		Nicotine
05110800000583	2	0018	3	0	40	9.37	1	OK		Nicotine
05110800000584	2	0018	3	0	45	9.14	1	OK		Nicotine
05110800000585	2	0018	3	1	0	6.77	1	OK		Nicotine
05110800000586	2	0018	3	2	0	4.88	1	OK		Nicotine
05110800000587	2	0018	3	3	0	3.84	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000588	2	0018	3	4	0	2.93	1	OK		Nicotine
05110800000589	2	0018	3	6	0	1.69	1	OK		Nicotine
05110800000590	2	0018	3	9	0	0.845	1	OK		Nicotine
05110800000591	2	0018	3	12	0	0.494	1	OK		Nicotine
05110800000592	2	0018	3	24	0	0.449	1	OK		Nicotine
05110800000593	2	0018	1	0	-15	0.268	1	OK		Nicotine
05110800000594	7	0018	1	0	2	30.2	1	OK		Nicotine
05110800000595	7	0018	1	0	4	45.3	1	OK		Nicotine
05110800000596	7	0018	1	0	6	45.8	1	OK		Nicotine
05110800000597	7	0018	1	0	8	28.9	1	OK		Nicotine
05110800000598	7	0018	1	0	10	22.1	1	OK		Nicotine
05110800000599	7	0018	1	0	15	13.4	1	OK		Nicotine
05110800000600	2	0018	1	0	30	9.26	1	OK		Nicotine
05110800000601	2	0018	1	0	45	8.27	1	OK		Nicotine
05110800000602	2	0018	1	1	0	7.47	1	OK		Nicotine
05110800000603	2	0018	1	2	0	5.28	1	OK		Nicotine
05110800000604	2	0018	1	4	0	3.21	1	OK		Nicotine
05110800000605	2	0018	1	6	0	2.05	1	OK		Nicotine
05110800000606	2	0018	1	9	0	1.01	1	OK		Nicotine
05110800000607	2	0018	1	12	0	0.552	1	OK		Nicotine
05110800000608	2	0018	1	24	0	0.292	1	OK		Nicotine
05110800000609	9	0036	3	0	-15	0.237	1	OK		Nicotine
05110800000610	9	0036	3	0	10	0.697	1	OK		Nicotine
05110800000611	9	0036	3	0	20	1.93	1	OK		Nicotine
05110800000612	9	0036	3	0	25	2.73	1	OK		Nicotine
05110800000613	9	0036	3	0	30	3.33	1	OK		Nicotine
05110800000614	9	0036	3	0	35	5.10	1	OK		Nicotine
05110800000615	9	0036	3	0	40	5.24	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000616	9	0036	3	0	45	5.20	1	OK		Nicotine
05110800000617	9	0036	3	1	0	6.79	1	OK		Nicotine
05110800000618	9	0036	3	2	0	6.58	1	OK		Nicotine
05110800000619	9	0036	3	3	0	5.39	1	OK		Nicotine
05110800000620	9	0036	3	4	0	4.90	1	OK		Nicotine
05110800000621	9	0036	3	6	0	3.66	1	OK		Nicotine
05110800000622	9	0036	3	9	0	2.79	1	OK		Nicotine
05110800000623	9	0036	3	12	0	1.51	1	OK		Nicotine
05110800000624	9	0036	3	24	0	0.496	1	OK		Nicotine
05110800000625	9	0036	1	0	-15	0.821	1	OK		Nicotine
05110800000626	9	0036	1	0	2	8.46	1	OK		Nicotine
05110800000627	7	0036	1	0	4	23.7	1	OK		Nicotine
05110800000628	7	0036	1	0	6	21.4	1	OK		Nicotine
05110800000629	7	0036	1	0	8	15.5	1	OK		Nicotine
05110800000630	7	0036	1	0	10	12.7	1	OK		Nicotine
05110800000631	9	0036	1	0	15	5.77	1	OK		Nicotine
05110800000632	9	0036	1	0	30	5.67	1	OK		Nicotine
05110800000633	9	0036	1	0	45	6.22	1	OK		Nicotine
05110800000634	9	0036	1	1	0	5.16	1	OK		Nicotine
05110800000635	9	0036	1	2	0	4.68	1	OK		Nicotine
05110800000636	9	0036	1	4	0	3.29	1	OK		Nicotine
05110800000637	9	0036	1	6	0	2.56	1	OK		Nicotine
05110800000638	9	0036	1	9	0	1.85	1	OK		Nicotine
05110800000639	9	0036	1	12	0	1.26	1	OK		Nicotine
05110800000640	9	0036	1	24	0	0.510	1	OK		Nicotine
05110800000641	6	0051	3	0	-15	0.215	1	OK		Nicotine
05110800000642	6	0051	3	0	10	2.32	1	OK		Nicotine
05110800000643	6	0051	3	0	20	3.95	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000644	6	0051	3	0	25	3.84	1	OK		Nicotine
05110800000645	6	0051	3	0	30	5.02	1	OK		Nicotine
05110800000646	6	0051	3	0	35	3.60	1	OK		Nicotine
05110800000647	6	0051	3	0	40	4.72	1	OK		Nicotine
05110800000648	6	0051	3	0	45	4.23	1	OK		Nicotine
05110800000649	6	0051	3	1	0	5.18	1	OK		Nicotine
05110800000650	6	0051	3	2	0	4.55	1	OK		Nicotine
05110800000651	6	0051	3	3	0	3.07	1	OK		Nicotine
05110800000652	6	0051	3	4	0	2.61	1	OK		Nicotine
05110800000653	6	0051	3	6	0	1.70	1	OK		Nicotine
05110800000654	6	0051	3	9	0	0.852	1	OK		Nicotine
05110800000655	6	0051	3	12	0	0.484	1	OK		Nicotine
05110800000656	6	0051	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000657	6	0051	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000658	6	0051	1	0	2	1.97	1	OK		Nicotine
05110800000659	6	0051	1	0	4	5.67	1	OK		Nicotine
05110800000660	6	0051	1	0	6	7.13	1	OK		Nicotine
05110800000661	6	0051	1	0	8	5.75	1	OK		Nicotine
05110800000662	6	0051	1	0	10	9.97	1	OK		Nicotine
05110800000663	6	0051	1	0	15	6.22	1	OK		Nicotine
05110800000664	6	0051	1	0	30	5.37	1	OK		Nicotine
05110800000665	6	0051	1	0	45	5.39	1	OK		Nicotine
05110800000666	6	0051	1	1	0	4.54	1	OK		Nicotine
05110800000667	6	0051	1	2	0	3.58	1	OK		Nicotine
05110800000668	6	0051	1	4	0	2.00	1	OK		Nicotine
05110800000669	6	0051	1	6	0	1.35	1	OK		Nicotine
05110800000670	6	0051	1	9	0	0.799	1	OK		Nicotine
05110800000671	6	0051	1	12	0	0.522	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000672	6	0051	1	24	0	0.237	1	OK		Nicotine
05110800000673	2	0022	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000674	2	0022	3	0	2	1.38	1	OK		Nicotine
05110800000675	2	0022	3	0	4	3.45	1	OK		Nicotine
05110800000676	2	0022	3	0	6	4.04	1	OK		Nicotine
05110800000677	7	0022	3	0	8	4.78	1	OK		Nicotine
05110800000678	7	0022	3	0	10	4.94	1	OK		Nicotine
05110800000679	7	0022	3	0	15	4.47	1	OK		Nicotine
05110800000680	7	0022	3	0	30	4.38	1	OK		Nicotine
05110800000681	7	0022	3	0	45	4.70	1	OK		Nicotine
05110800000682	7	0022	3	1	0	3.82	1	OK		Nicotine
05110800000683	7	0022	3	2	0	2.44	1	OK		Nicotine
05110800000684	19	0022	3	4	0	1.58	1	OK		Nicotine
05110800000685	19	0022	3	6	0	0.833	1	OK		Nicotine
05110800000686	19	0022	3	9	0	0.409	1	OK		Nicotine
05110800000687	19	0022	3	12	0	0.262	1	OK		Nicotine
05110800000689	2	0022	1	0	-15	0.328	1	OK		Nicotine
05110800000690	2	0022	1	0	10	0.670	1	OK		Nicotine
05110800000691	2	0022	1	0	20	1.80	1	OK		Nicotine
05110800000692	2	0022	1	0	25	2.58	1	OK		Nicotine
05110800000693	2	0022	1	0	30	3.38	1	OK		Nicotine
05110800000694	2	0022	1	0	35	3.52	1	OK		Nicotine
05110800000695	2	0022	1	0	40	4.43	1	OK		Nicotine
05110800000696	2	0022	1	0	45	4.51	1	OK		Nicotine
05110800000697	2	0022	1	1	0	5.80	1	OK		Nicotine
05110800000698	2	0022	1	2	0	3.96	1	OK		Nicotine
05110800000699	2	0022	1	3	0	3.43	1	OK		Nicotine
05110800000700	2	0022	1	4	0	2.80	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000701	2	0022	1	6	0	1.57	1	OK		Nicotine
05110800000702	2	0022	1	9	0	0.929	1	OK		Nicotine
05110800000703	2	0022	1	12	0	0.530	1	OK		Nicotine
05110800000704	2	0022	1	24	0	0.205	1	OK		Nicotine
05110800000705	9	0035	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000706	9	0035	3	0	2	1.68	1	OK		Nicotine
05110800000707	9	0035	3	0	4	5.37	1	OK		Nicotine
05110800000708	9	0035	3	0	6	8.52	1	OK		Nicotine
05110800000709	9	0035	3	0	8	7.17	1	OK		Nicotine
05110800000710	9	0035	3	0	10	6.47	1	OK		Nicotine
05110800000711	9	0035	3	0	15	9.07	1	OK		Nicotine
05110800000712	9	0035	3	0	30	6.33	1	OK		Nicotine
05110800000713	9	0035	3	0	45	5.86	1	OK		Nicotine
05110800000714	9	0035	3	1	0	5.37	1	OK		Nicotine
05110800000715	9	0035	3	2	0	3.16	1	OK		Nicotine
05110800000716	9	0035	3	4	0	1.50	1	OK		Nicotine
05110800000717	9	0035	3	6	0	0.592	1	OK		Nicotine
05110800000718	9	0035	3	9	0	0.211	1	OK		Nicotine
05110800000719	9	0035	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000720	9	0035	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000721	9	0035	1	0	-15	0.211	1	OK		Nicotine
05110800000722	9	0035	1	0	10	1.09	1	OK		Nicotine
05110800000723	9	0035	1	0	20	2.65	1	OK		Nicotine
05110800000724	9	0035	1	0	25	2.87	1	OK		Nicotine
05110800000725	9	0035	1	0	30	4.12	1	OK		Nicotine
05110800000726	9	0035	1	0	35	4.34	1	OK		Nicotine
05110800000727	9	0035	1	0	40	4.29	1	OK		Nicotine
05110800000728	9	0035	1	0	45	4.34	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000729	9	0035	1	1	0	4.34	1	OK		Nicotine
05110800000730	9	0035	1	2	0	2.16	1	OK		Nicotine
05110800000731	9	0035	1	3	0	1.59	1	OK		Nicotine
05110800000732	9	0035	1	4	0	1.12	1	OK		Nicotine
05110800000733	9	0035	1	6	0	0.399	1	OK		Nicotine
05110800000734	9	0035	1	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800000735	9	0035	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000736	9	0035	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000737	7	0066	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000738	7	0066	3	0	2	2.76	1	OK		Nicotine
05110800000739	19	0066	3	0	4	11.5	1	OK		Nicotine
05110800000740	19	0066	3	0	6	14.7	1	OK		Nicotine
05110800000741	19	0066	3	0	8	16.3	1	OK		Nicotine
05110800000742	19	0066	3	0	10	12.4	1	OK		Nicotine
05110800000743	19	0066	3	0	15	12.2	1	OK		Nicotine
05110800000744	7	0066	3	0	30	8.80	1	OK		Nicotine
05110800000745	7	0066	3	0	45	7.28	1	OK		Nicotine
05110800000746	7	0066	3	1	0	6.25	1	OK		Nicotine
05110800000747	7	0066	3	2	0	4.14	1	OK		Nicotine
05110800000748	7	0066	3	4	0	1.69	1	OK		Nicotine
05110800000749	7	0066	3	6	0	0.839	1	OK		Nicotine
05110800000750	7	0066	3	9	0	0.384	1	OK		Nicotine
05110800000751	7	0066	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000752	7	0066	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000753	7	0066	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000754	7	0066	1	0	2	1.12	1	OK		Nicotine
05110800000755	7	0066	1	0	4	4.27	1	OK		Nicotine
05110800000756	7	0066	1	0	6	6.23	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000757	7	0066	1	0	8	6.91	1	OK		Nicotine
05110800000758	7	0066	1	0	10	7.85	1	OK		Nicotine
05110800000759	7	0066	1	0	15	7.02	1	OK		Nicotine
05110800000760	7	0066	1	0	30	5.85	1	OK		Nicotine
05110800000761	7	0066	1	0	45	4.96	1	OK		Nicotine
05110800000762	7	0066	1	1	0	4.57	1	OK		Nicotine
05110800000763	7	0066	1	2	0	3.59	1	OK		Nicotine
05110800000764	7	0066	1	4	0	1.41	1	OK		Nicotine
05110800000765	7	0066	1	6	0	0.735	1	OK		Nicotine
05110800000766	7	0066	1	9	0	0.396	1	OK		Nicotine
05110800000767	7	0066	1	12	0	0.258	1	OK		Nicotine
05110800000768	7	0066	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000769	11	0071	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000770	11	0071	3	0	2	4.25	1	OK		Nicotine
05110800000771	11	0071	3	0	4	9.98	1	OK		Nicotine
05110800000772	11	0071	3	0	6	8.97	1	OK		Nicotine
05110800000773	11	0071	3	0	8	7.57	1	OK		Nicotine
05110800000774	11	0071	3	0	10	7.63	1	OK		Nicotine
05110800000775	11	0071	3	0	15	7.79	1	OK		Nicotine
05110800000776	11	0071	3	0	30	6.01	1	OK		Nicotine
05110800000777	11	0071	3	0	45	5.94	1	OK		Nicotine
05110800000778	11	0071	3	1	0	5.02	1	OK		Nicotine
05110800000779	11	0071	3	2	0	3.34	1	OK		Nicotine
05110800000780	11	0071	3	4	0	0.846	1	OK		Nicotine
05110800000781	11	0071	3	6	0	0.477	1	OK		Nicotine
05110800000782	11	0071	3	9	0	0.200	1	OK		Nicotine
05110800000783	11	0071	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000784	11	0071	3	24	0	BLQ<(0.200)	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000785	11	0071	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000786	11	0071	1	0	2	7.57	1	OK		Nicotine
05110800000787	16	0071	1	0	4	14.1	1	OK		Nicotine
05110800000788	11	0071	1	0	6	9.27	1	OK		Nicotine
05110800000789	11	0071	1	0	8	6.96	1	OK		Nicotine
05110800000790	11	0071	1	0	10	8.50	1	OK		Nicotine
05110800000791	11	0071	1	0	15	7.94	1	OK		Nicotine
05110800000792	11	0071	1	0	30	6.34	1	OK		Nicotine
05110800000793	11	0071	1	0	45	5.54	1	OK		Nicotine
05110800000794	11	0071	1	1	0	5.36	1	OK		Nicotine
05110800000795	11	0071	1	2	0	3.21	1	OK		Nicotine
05110800000796	11	0071	1	4	0	1.02	1	OK		Nicotine
05110800000797	11	0071	1	6	0	0.587	1	OK		Nicotine
05110800000798	11	0071	1	9	0	0.207	1	OK		Nicotine
05110800000799	11	0071	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000800	11	0071	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000801	11	0074	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000802	16	0074	3	0	2	13.4	1	OK		Nicotine
05110800000803	16	0074	3	0	4	16.1	1	OK		Nicotine
05110800000804	16	0074	3	0	6	17.9	1	OK		Nicotine
05110800000805	11	0074	3	0	8	7.14	1	OK		Nicotine
05110800000806	11	0074	3	0	10	6.55	1	OK		Nicotine
05110800000807	11	0074	3	0	15	6.02	1	OK		Nicotine
05110800000808	11	0074	3	0	30	5.07	1	OK		Nicotine
05110800000809	11	0074	3	0	45	4.92	1	OK		Nicotine
05110800000810	11	0074	3	1	0	4.42	1	OK		Nicotine
05110800000811	11	0074	3	2	0	3.61	1	OK		Nicotine
05110800000812	11	0074	3	4	0	2.01	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000813	11	0074	3	6	0	1.54	1	OK		Nicotine
05110800000814	11	0074	3	9	0	0.825	1	OK		Nicotine
05110800000815	11	0074	3	12	0	0.535	1	OK		Nicotine
05110800000816	11	0074	3	24	0	0.211	1	OK		Nicotine
05110800000817	11	0074	1	0	-15	0.319	1	OK		Nicotine
05110800000818	11	0074	1	0	2	5.46	1	OK		Nicotine
05110800000819	16	0074	1	0	4	11.4	1	OK		Nicotine
05110800000820	11	0074	1	0	6	7.93	1	OK		Nicotine
05110800000821	16	0074	1	0	8	20.8	1	OK		Nicotine
05110800000822	16	0074	1	0	10	12.9	1	OK		Nicotine
05110800000823	16	0074	1	0	15	15.4	1	OK		Nicotine
05110800000824	16	0074	1	0	30	13.1	1	OK		Nicotine
05110800000825	16	0074	1	0	45	11.5	1	OK		Nicotine
05110800000826	11	0074	1	1	0	9.87	1	OK		Nicotine
05110800000827	11	0074	1	2	0	8.75	1	OK		Nicotine
05110800000828	11	0074	1	4	0	5.06	1	OK		Nicotine
05110800000829	11	0074	1	6	0	3.56	1	OK		Nicotine
05110800000830	11	0074	1	9	0	2.20	1	OK		Nicotine
05110800000831	11	0074	1	12	0	1.25	1	OK		Nicotine
05110800000832	11	0074	1	24	0	0.406	1	OK		Nicotine
05110800000833	12	0076	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000834	12	0076	3	0	2	1.69	1	OK		Nicotine
05110800000835	12	0076	3	0	4	1.21	1	OK		Nicotine
05110800000836	12	0076	3	0	6	2.38	1	OK		Nicotine
05110800000837	12	0076	3	0	8	2.62	1	OK		Nicotine
05110800000838	12	0076	3	0	10	2.49	1	OK		Nicotine
05110800000839	12	0076	3	0	15	1.31	1	OK		Nicotine
05110800000840	12	0076	3	0	30	2.03	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000841	12	0076	3	0	45	1.66	1	OK		Nicotine
05110800000842	12	0076	3	1	0	1.58	1	OK		Nicotine
05110800000843	12	0076	3	2	0	0.886	1	OK		Nicotine
05110800000844	12	0076	3	4	0	0.397	1	OK		Nicotine
05110800000845	12	0076	3	6	0	0.221	1	OK		Nicotine
05110800000846	12	0076	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800000847	12	0076	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000848	12	0076	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000849	12	0076	1	0	-15	0.304	1	OK		Nicotine
05110800000850	12	0076	1	0	2	1.70	1	OK		Nicotine
05110800000851	12	0076	1	0	4	5.14	1	OK		Nicotine
05110800000852	12	0076	1	0	6	7.92	1	OK		Nicotine
05110800000853	12	0076	1	0	8	7.91	1	OK		Nicotine
05110800000854	12	0076	1	0	10	7.83	1	OK		Nicotine
05110800000855	12	0076	1	0	15	4.60	1	OK		Nicotine
05110800000856	12	0076	1	0	30	6.32	1	OK		Nicotine
05110800000857	12	0076	1	0	45	5.18	1	OK		Nicotine
05110800000858	12	0076	1	1	0	4.24	1	OK		Nicotine
05110800000859	12	0076	1	2	0	2.39	1	OK		Nicotine
05110800000860	12	0076	1	4	0	1.24	1	OK		Nicotine
05110800000861	12	0076	1	6	0	0.676	1	OK		Nicotine
05110800000862	12	0076	1	9	0	0.505	1	OK		Nicotine
05110800000863	12	0076	1	12	0	0.362	1	OK		Nicotine
05110800000864	12	0076	1	24	0	0.225	1	OK		Nicotine
05110800000865	12	0082	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000866	19	0082	3	0	2	14.5	1	OK		Nicotine
05110800000867	19	0082	3	0	4	30.8	1	OK		Nicotine
05110800000868	19	0082	3	0	6	18.5	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000869	19	0082	3	0	8	12.9	1	OK		Nicotine
05110800000870	12	0082	3	0	10	9.91	1	OK		Nicotine
05110800000871	12	0082	3	0	15	7.11	1	OK		Nicotine
05110800000872	12	0082	3	0	30	4.63	1	OK		Nicotine
05110800000873	12	0082	3	0	45	3.14	1	OK		Nicotine
05110800000874	12	0082	3	1	0	2.80	1	OK		Nicotine
05110800000875	12	0082	3	2	0	1.29	1	OK		Nicotine
05110800000876	12	0082	3	4	0	0.550	1	OK		Nicotine
05110800000877	12	0082	3	6	0	0.334	1	OK		Nicotine
05110800000878	12	0082	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800000879	12	0082	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000880	12	0082	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000881	12	0082	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000882	12	0082	1	0	2	8.20	1	OK		Nicotine
05110800000883	19	0082	1	0	4	15.9	1	OK		Nicotine
05110800000884	19	0082	1	0	6	16.3	1	OK		Nicotine
05110800000885	19	0082	1	0	8	12.7	1	OK		Nicotine
05110800000886	19	0082	1	0	10	10.5	1	OK		Nicotine
05110800000887	19	0082	1	0	15	10.7	1	OK		Nicotine
05110800000888	12	0082	1	0	30	7.27	1	OK		Nicotine
05110800000889	12	0082	1	0	45	5.47	1	OK		Nicotine
05110800000890	12	0082	1	1	0	4.54	1	OK		Nicotine
05110800000891	12	0082	1	2	0	2.45	1	OK		Nicotine
05110800000892	12	0082	1	4	0	0.764	1	OK		Nicotine
05110800000893	12	0082	1	6	0	0.371	1	OK		Nicotine
05110800000894	12	0082	1	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800000895	12	0082	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000896	12	0082	1	24	0	BLQ<(0.200)	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000897	23	0084	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000898	23	0084	3	0	2	0.665	1	OK		Nicotine
05110800000899	23	0084	3	0	4	2.92	1	OK		Nicotine
05110800000900	23	0084	3	0	6	4.94	1	OK		Nicotine
05110800000901	23	0084	3	0	8	5.77	1	OK		Nicotine
05110800000902	23	0084	3	0	10	9.93	1	OK		Nicotine
05110800000903	23	0084	3	0	15	6.96	1	OK		Nicotine
05110800000904	23	0084	3	0	30	4.89	1	OK		Nicotine
05110800000905	23	0084	3	0	45	5.39	1	OK		Nicotine
05110800000906	23	0084	3	1	0	4.96	1	OK		Nicotine
05110800000907	23	0084	3	2	0	4.01	1	OK		Nicotine
05110800000908	23	0084	3	4	0	2.32	1	OK		Nicotine
05110800000909	23	0084	3	6	0	1.65	1	OK		Nicotine
05110800000910	23	0084	3	9	0	0.841	1	OK		Nicotine
05110800000911	23	0084	3	12	0	0.600	1	OK		Nicotine
05110800000912	23	0084	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000913	23	0084	1	0	-15	0.269	1	OK		Nicotine
05110800000914	23	0084	1	0	2	1.30	1	OK		Nicotine
05110800000915	23	0084	1	0	4	3.92	1	OK		Nicotine
05110800000916	23	0084	1	0	6	6.50	1	OK		Nicotine
05110800000917	23	0084	1	0	8	6.98	1	OK		Nicotine
05110800000918	23	0084	1	0	10	7.47	1	OK		Nicotine
05110800000919	23	0084	1	0	15	7.99	1	OK		Nicotine
05110800000920	23	0084	1	0	30	7.19	1	OK		Nicotine
05110800000921	23	0084	1	0	45	7.21	1	OK		Nicotine
05110800000922	23	0084	1	1	0	6.71	1	OK		Nicotine
05110800000923	23	0084	1	2	0	5.20	1	OK		Nicotine
05110800000924	23	0084	1	4	0	3.89	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000925	23	0084	1	6	0	2.41	1	OK		Nicotine
05110800000926	23	0084	1	9	0	1.50	1	OK		Nicotine
05110800000927	23	0084	1	12	0	10.6	1	OK		Nicotine
05110800000928	23	0084	1	24	0	0.313	1	OK		Nicotine
05110800000929	11	0067	3	0	-15	0.345	1	OK		Nicotine
05110800000930	11	0067	3	0	2	3.48	1	OK		Nicotine
05110800000931	11	0067	3	0	4	7.23	1	OK		Nicotine
05110800000932	11	0067	3	0	6	5.30	1	OK		Nicotine
05110800000933	11	0067	3	0	8	4.39	1	OK		Nicotine
05110800000934	11	0067	3	0	10	4.13	1	OK		Nicotine
05110800000935	11	0067	3	0	15	3.90	1	OK		Nicotine
05110800000936	11	0067	3	0	30	3.10	1	OK		Nicotine
05110800000937	11	0067	3	0	45	2.60	1	OK		Nicotine
05110800000938	11	0067	3	1	0	2.52	1	OK		Nicotine
05110800000939	11	0067	3	2	0	2.05	1	OK		Nicotine
05110800000940	11	0067	3	4	0	1.29	1	OK		Nicotine
05110800000941	11	0067	3	6	0	0.970	1	OK		Nicotine
05110800000942	11	0067	3	9	0	0.702	1	OK		Nicotine
05110800000943	11	0067	3	12	0	0.543	1	OK		Nicotine
05110800000944	11	0067	3	24	0	0.271	1	OK		Nicotine
05110800000945	11	0067	1	0	-15	1.21	1	OK		Nicotine
05110800000946	16	0067	1	0	2	18.4	1	OK		Nicotine
05110800000947	16	0067	1	0	4	23.3	1	OK		Nicotine
05110800000948	16	0067	1	0	6	32.7	1	OK		Nicotine
05110800000949	16	0067	1	0	8	24.2	1	OK		Nicotine
05110800000950	16	0067	1	0	10	19.8	1	OK		Nicotine
05110800000951	16	0067	1	0	15	10.7	1	OK		Nicotine
05110800000952	16	0067	1	0	30	11.3	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000953	16	0067	1	0	45	11.9	1	OK		Nicotine
05110800000954	11	0067	1	1	0	9.10	1	OK		Nicotine
05110800000955	11	0067	1	2	0	7.74	1	OK		Nicotine
05110800000956	11	0067	1	4	0	5.17	1	OK		Nicotine
05110800000957	11	0067	1	6	0	4.50	1	OK		Nicotine
05110800000958	11	0067	1	9	0	2.91	1	OK		Nicotine
05110800000959	11	0067	1	12	0	2.10	1	OK		Nicotine
05110800000960	11	0067	1	24	0	0.924	1	OK		Nicotine
05110800000961	11	0070	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000962	11	0070	3	0	2	1.87	1	OK		Nicotine
05110800000963	11	0070	3	0	4	5.45	1	OK		Nicotine
05110800000964	11	0070	3	0	6	7.31	1	OK		Nicotine
05110800000965	11	0070	3	0	8	7.06	1	OK		Nicotine
05110800000966	11	0070	3	0	10	6.64	1	OK		Nicotine
05110800000967	11	0070	3	0	15	6.86	1	OK		Nicotine
05110800000968	11	0070	3	0	30	5.21	1	OK		Nicotine
05110800000969	11	0070	3	0	45	5.08	1	OK		Nicotine
05110800000970	11	0070	3	1	0	4.03	1	OK		Nicotine
05110800000971	11	0070	3	2	0	2.41	1	OK		Nicotine
05110800000972	11	0070	3	4	0	0.851	1	OK		Nicotine
05110800000973	11	0070	3	6	0	0.447	1	OK		Nicotine
05110800000974	11	0070	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800000975	11	0070	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000976	11	0070	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000977	11	0070	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000978	11	0070	1	0	2	6.62	1	OK		Nicotine
05110800000979	16	0070	1	0	4	23.2	1	OK		Nicotine
05110800000980	16	0070	1	0	6	13.6	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800000981	11	0070	1	0	8	9.60	1	OK		Nicotine
05110800000982	11	0070	1	0	10	9.57	1	OK		Nicotine
05110800000983	11	0070	1	0	15	8.15	1	OK		Nicotine
05110800000984	11	0070	1	0	30	5.68	1	OK		Nicotine
05110800000985	11	0070	1	0	45	5.67	1	OK		Nicotine
05110800000986	11	0070	1	1	0	7.06	1	OK		Nicotine
05110800000987	11	0070	1	2	0	4.07	1	OK		Nicotine
05110800000988	11	0070	1	4	0	1.29	1	OK		Nicotine
05110800000989	11	0070	1	6	0	0.706	1	OK		Nicotine
05110800000990	11	0070	1	9	0	0.368	1	OK		Nicotine
05110800000991	11	0070	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800000992	11	0070	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800000993	27	0073	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800000994	26	0073	3	0	2	0.978	1	OK		Nicotine
05110800000995	26	0073	3	0	4	3.03	1	OK		Nicotine
05110800000996	26	0073	3	0	6	5.85	1	OK		Nicotine
05110800000997	26	0073	3	0	8	7.00	1	OK		Nicotine
05110800000998	26	0073	3	0	10	6.50	1	OK		Nicotine
05110800000999	26	0073	3	0	15	4.62	1	OK		Nicotine
05110800001000	26	0073	3	0	30	5.32	1	OK		Nicotine
05110800001001	26	0073	3	0	45	4.67	1	OK		Nicotine
05110800001002	26	0073	3	1	0	4.52	1	OK		Nicotine
05110800001003	26	0073	3	2	0	2.31	1	OK		Nicotine
05110800001004	26	0073	3	4	0	1.52	1	OK		Nicotine
05110800001005	26	0073	3	6	0	0.735	1	OK		Nicotine
05110800001007	27	0073	3	12	0	0.223	1	OK		Nicotine
05110800001008	27	0073	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001009	10	0073	1	0	-15	0.354	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001010	10	0073	1	0	2	1.56	1	OK		Nicotine
05110800001011	10	0073	1	0	4	4.71	1	OK		Nicotine
05110800001012	10	0073	1	0	6	5.16	1	OK		Nicotine
05110800001013	10	0073	1	0	8	5.33	1	OK		Nicotine
05110800001014	10	0073	1	0	10	4.59	1	OK		Nicotine
05110800001015	10	0073	1	0	15	3.98	1	OK		Nicotine
05110800001016	10	0073	1	0	30	2.67	1	OK		Nicotine
05110800001017	10	0073	1	0	45	2.46	1	OK		Nicotine
05110800001018	10	0073	1	1	0	2.07	1	OK		Nicotine
05110800001019	10	0073	1	2	0	1.57	1	OK		Nicotine
05110800001020	10	0073	1	4	0	0.838	1	OK		Nicotine
05110800001021	10	0073	1	6	0	0.519	1	OK		Nicotine
05110800001022	10	0073	1	9	0	0.356	1	OK		Nicotine
05110800001023	10	0073	1	12	0	0.363	1	OK		Nicotine
05110800001024	10	0073	1	24	0	0.217	1	OK		Nicotine
05110800001025	12	0075	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001026	12	0075	3	0	2	0.341	1	OK		Nicotine
05110800001027	12	0075	3	0	4	1.43	1	OK		Nicotine
05110800001028	12	0075	3	0	6	1.33	1	OK		Nicotine
05110800001029	12	0075	3	0	8	1.39	1	OK		Nicotine
05110800001030	12	0075	3	0	10	1.30	1	OK		Nicotine
05110800001031	12	0075	3	0	15	1.23	1	OK		Nicotine
05110800001032	12	0075	3	0	30	1.28	1	OK		Nicotine
05110800001033	12	0075	3	0	45	1.38	1	OK		Nicotine
05110800001034	12	0075	3	1	0	1.20	1	OK		Nicotine
05110800001035	12	0075	3	2	0	1.08	1	OK		Nicotine
05110800001036	12	0075	3	4	0	0.777	1	OK		Nicotine
05110800001037	12	0075	3	6	0	0.535	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001038	12	0075	3	9	0	0.411	1	OK		Nicotine
05110800001039	12	0075	3	12	0	0.272	1	OK		Nicotine
05110800001040	12	0075	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001041	12	0075	1	0	-15	0.712	1	OK		Nicotine
05110800001042	19	0075	1	0	2	13.4	1	OK		Nicotine
05110800001043	19	0075	1	0	4	28.6	1	OK		Nicotine
05110800001044	19	0075	1	0	6	10.7	1	OK		Nicotine
05110800001045	19	0075	1	0	8	18.0	1	OK		Nicotine
05110800001046	19	0075	1	0	10	23.8	1	OK		Nicotine
05110800001047	12	0075	1	0	15	8.22	1	OK		Nicotine
05110800001048	12	0075	1	0	30	8.24	1	OK		Nicotine
05110800001049	12	0075	1	0	45	7.81	1	OK		Nicotine
05110800001050	12	0075	1	1	0	7.64	1	OK		Nicotine
05110800001051	12	0075	1	2	0	6.50	1	OK		Nicotine
05110800001052	12	0075	1	4	0	4.31	1	OK		Nicotine
05110800001053	12	0075	1	6	0	3.23	1	OK		Nicotine
05110800001054	12	0075	1	9	0	2.25	1	OK		Nicotine
05110800001055	12	0075	1	12	0	1.37	1	OK		Nicotine
05110800001056	12	0075	1	24	0	0.615	1	OK		Nicotine
05110800001057	7	0061	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001058	7	0061	3	0	10	4.17	1	OK		Nicotine
05110800001059	7	0061	3	0	20	7.04	1	OK		Nicotine
05110800001060	7	0061	3	0	25	8.63	1	OK		Nicotine
05110800001061	7	0061	3	0	30	7.59	1	OK		Nicotine
05110800001062	7	0061	3	0	35	6.27	1	OK		Nicotine
05110800001063	7	0061	3	0	40	7.72	1	OK		Nicotine
05110800001064	7	0061	3	0	45	7.54	1	OK		Nicotine
05110800001065	7	0061	3	1	0	6.25	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001066	7	0061	3	2	0	2.86	1	OK		Nicotine
05110800001067	7	0061	3	3	0	1.88	1	OK		Nicotine
05110800001068	7	0061	3	4	0	1.08	1	OK		Nicotine
05110800001069	7	0061	3	6	0	0.420	1	OK		Nicotine
05110800001070	7	0061	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800001071	7	0061	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800001072	7	0061	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001073	7	0061	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001074	7	0061	1	0	2	7.23	1	OK		Nicotine
05110800001075	19	0061	1	0	4	11.5	1	OK		Nicotine
05110800001076	7	0061	1	0	6	9.84	1	OK		Nicotine
05110800001077	7	0061	1	0	8	8.63	1	OK		Nicotine
05110800001078	7	0061	1	0	10	7.22	1	OK		Nicotine
05110800001079	7	0061	1	0	15	7.61	1	OK		Nicotine
05110800001080	7	0061	1	0	30	7.12	1	OK		Nicotine
05110800001081	7	0061	1	0	45	5.58	1	OK		Nicotine
05110800001082	7	0061	1	1	0	5.24	1	OK		Nicotine
05110800001083	7	0061	1	2	0	2.87	1	OK		Nicotine
05110800001084	7	0061	1	4	0	0.796	1	OK		Nicotine
05110800001085	7	0061	1	6	0	0.355	1	OK		Nicotine
05110800001086	7	0061	1	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800001087	7	0061	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800001088	7	0061	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001089	12	0078	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001090	12	0078	3	0	10	1.71	1	OK		Nicotine
05110800001091	12	0078	3	0	20	5.17	1	OK		Nicotine
05110800001092	12	0078	3	0	25	3.45	1	OK		Nicotine
05110800001093	12	0078	3	0	30	6.13	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001094	12	0078	3	0	35	4.94	1	OK		Nicotine
05110800001095	12	0078	3	0	40	7.19	1	OK		Nicotine
05110800001096	12	0078	3	0	45	5.72	1	OK		Nicotine
05110800001097	12	0078	3	1	0	4.85	1	OK		Nicotine
05110800001098	12	0078	3	2	0	3.41	1	OK		Nicotine
05110800001099	12	0078	3	3	0	1.63	1	OK		Nicotine
05110800001100	12	0078	3	4	0	1.15	1	OK		Nicotine
05110800001101	12	0078	3	6	0	0.622	1	OK		Nicotine
05110800001102	12	0078	3	9	0	0.255	1	OK		Nicotine
05110800001103	12	0078	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800001104	12	0078	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001105	12	0078	1	0	-15	0.252	1	OK		Nicotine
05110800001106	12	0078	1	0	2	4.81	1	OK		Nicotine
05110800001107	12	0078	1	0	4	5.21	1	OK		Nicotine
05110800001108	12	0078	1	0	6	7.18	1	OK		Nicotine
05110800001109	12	0078	1	0	8	4.35	1	OK		Nicotine
05110800001110	12	0078	1	0	10	6.24	1	OK		Nicotine
05110800001111	12	0078	1	0	15	3.33	1	OK		Nicotine
05110800001112	12	0078	1	0	30	3.11	1	OK		Nicotine
05110800001113	12	0078	1	0	45	2.57	1	OK		Nicotine
05110800001114	12	0078	1	1	0	2.19	1	OK		Nicotine
05110800001115	12	0078	1	2	0	1.37	1	OK		Nicotine
05110800001116	12	0078	1	4	0	0.645	1	OK		Nicotine
05110800001117	12	0078	1	6	0	0.319	1	OK		Nicotine
05110800001118	12	0078	1	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800001119	12	0078	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800001120	12	0078	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001121	27	0060	3	0	-15	BLQ<(0.200)	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001122	26	0060	3	0	2	3.18	1	OK		Nicotine
05110800001123	27	0060	3	0	4	12.8	1	OK		Nicotine
05110800001124	27	0060	3	0	6	20.3	1	OK		Nicotine
05110800001125	27	0060	3	0	8	15.8	1	OK		Nicotine
05110800001126	27	0060	3	0	10	13.8	1	OK		Nicotine
05110800001127	26	0060	3	0	15	7.37	1	OK		Nicotine
05110800001128	26	0060	3	0	30	5.66	1	OK		Nicotine
05110800001129	26	0060	3	0	45	4.59	1	OK		Nicotine
05110800001130	26	0060	3	1	0	4.03	1	OK		Nicotine
05110800001131	26	0060	3	2	0	2.92	1	OK		Nicotine
05110800001132	26	0060	3	4	0	1.80	1	OK		Nicotine
05110800001133	26	0060	3	6	0	1.01	1	OK		Nicotine
05110800001134	26	0060	3	9	0	0.574	1	OK		Nicotine
05110800001135	27	0060	3	12	0	0.288	1	OK		Nicotine
05110800001136	26	0060	3	24	0	0.497	1	OK		Nicotine
05110800001137	6	0060	1	0	-15	0.288	1	OK		Nicotine
05110800001138	6	0060	1	0	10	2.66	1	OK		Nicotine
05110800001139	6	0060	1	0	20	6.17	1	OK		Nicotine
05110800001140	6	0060	1	0	25	6.66	1	OK		Nicotine
05110800001141	6	0060	1	0	30	6.62	1	OK		Nicotine
05110800001142	6	0060	1	0	35	8.01	1	OK		Nicotine
05110800001143	6	0060	1	0	40	7.54	1	OK		Nicotine
05110800001144	6	0060	1	0	45	6.74	1	OK		Nicotine
05110800001145	6	0060	1	1	0	5.86	1	OK		Nicotine
05110800001146	6	0060	1	2	0	3.66	1	OK		Nicotine
05110800001147	6	0060	1	3	0	2.17	1	OK		Nicotine
05110800001148	6	0060	1	4	0	1.55	1	OK		Nicotine
05110800001149	6	0060	1	6	0	0.983	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001150	6	0060	1	9	0	0.524	1	OK		Nicotine
05110800001151	6	0060	1	12	0	0.435	1	OK		Nicotine
05110800001152	6	0060	1	24	0	0.279	1	OK		Nicotine
05110800001154	26	0063	3	0	2	1.47	1	OK		Nicotine
05110800001155	26	0063	3	0	4	2.80	1	OK		Nicotine
05110800001156	26	0063	3	0	6	3.65	1	OK		Nicotine
05110800001157	26	0063	3	0	8	3.00	1	OK		Nicotine
05110800001158	26	0063	3	0	10	3.56	1	OK		Nicotine
05110800001159	26	0063	3	0	15	3.71	1	OK		Nicotine
05110800001160	26	0063	3	0	30	2.49	1	OK		Nicotine
05110800001161	26	0063	3	0	45	2.38	1	OK		Nicotine
05110800001162	26	0063	3	1	0	2.10	1	OK		Nicotine
05110800001163	26	0063	3	2	0	1.80	1	OK		Nicotine
05110800001164	26	0063	3	4	0	1.19	1	OK		Nicotine
05110800001165	26	0063	3	6	0	0.853	1	OK		Nicotine
05110800001166	26	0063	3	9	0	0.487	1	OK		Nicotine
05110800001167	27	0063	3	12	0	0.328	1	OK		Nicotine
05110800001168	27	0063	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001169	6	0063	1	0	-15	0.584	1	OK		Nicotine
05110800001170	6	0063	1	0	10	1.94	1	OK		Nicotine
05110800001171	6	0063	1	0	20	5.70	1	OK		Nicotine
05110800001172	6	0063	1	0	25	5.78	1	OK		Nicotine
05110800001173	6	0063	1	0	30	5.84	1	OK		Nicotine
05110800001174	6	0063	1	0	35	9.81	1	OK		Nicotine
05110800001175	6	0063	1	0	40	8.72	1	OK		Nicotine
05110800001176	7	0063	1	0	45	11.1	1	OK		Nicotine
05110800001177	6	0063	1	1	0	10.0	1	OK		Nicotine
05110800001178	6	0063	1	2	0	8.89	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001179	6	0063	1	3	0	7.30	1	OK		Nicotine
05110800001180	6	0063	1	4	0	6.42	1	OK		Nicotine
05110800001181	6	0063	1	6	0	4.43	1	OK		Nicotine
05110800001182	6	0063	1	9	0	2.85	1	OK		Nicotine
05110800001183	6	0063	1	12	0	1.76	1	OK		Nicotine
05110800001184	6	0063	1	24	0	0.608	1	OK		Nicotine
05110800001185	27	0072	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001186	26	0072	3	0	2	1.21	1	OK		Nicotine
05110800001187	26	0072	3	0	4	3.51	1	OK		Nicotine
05110800001188	26	0072	3	0	6	3.28	1	OK		Nicotine
05110800001189	26	0072	3	0	8	2.55	1	OK		Nicotine
05110800001190	26	0072	3	0	10	2.27	1	OK		Nicotine
05110800001191	26	0072	3	0	15	2.11	1	OK		Nicotine
05110800001192	26	0072	3	0	30	1.80	1	OK		Nicotine
05110800001193	26	0072	3	0	45	1.37	1	OK		Nicotine
05110800001194	26	0072	3	1	0	1.36	1	OK		Nicotine
05110800001195	26	0072	3	2	0	0.690	1	OK		Nicotine
05110800001196	26	0072	3	4	0	0.417	1	OK		Nicotine
05110800001197	27	0072	3	6	0	BLQ<(0.200)	1	OK		Nicotine
05110800001198	27	0072	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800001199	27	0072	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800001200	27	0072	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001201	6	0072	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001202	6	0072	1	0	10	0.660	1	OK		Nicotine
05110800001203	6	0072	1	0	20	6.19	1	OK		Nicotine
05110800001204	6	0072	1	0	25	4.85	1	OK		Nicotine
05110800001205	6	0072	1	0	30	5.53	1	OK		Nicotine
05110800001206	6	0072	1	0	35	6.22	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001207	6	0072	1	0	40	6.89	1	OK		Nicotine
05110800001208	6	0072	1	0	45	7.53	1	OK		Nicotine
05110800001209	6	0072	1	1	0	5.95	1	OK		Nicotine
05110800001210	6	0072	1	2	0	4.56	1	OK		Nicotine
05110800001211	6	0072	1	3	0	2.70	1	OK		Nicotine
05110800001212	6	0072	1	4	0	1.59	1	OK		Nicotine
05110800001213	6	0072	1	6	0	0.799	1	OK		Nicotine
05110800001214	6	0072	1	9	0	0.382	1	OK		Nicotine
05110800001215	6	0072	1	12	0	0.205	1	OK		Nicotine
05110800001216	6	0072	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001217	23	0083	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800001218	23	0083	3	0	2	0.773	1	OK		Nicotine
05110800001219	23	0083	3	0	4	1.09	1	OK		Nicotine
05110800001220	23	0083	3	0	6	1.19	1	OK		Nicotine
05110800001221	23	0083	3	0	8	1.23	1	OK		Nicotine
05110800001222	23	0083	3	0	10	1.08	1	OK		Nicotine
05110800001223	23	0083	3	0	15	1.26	1	OK		Nicotine
05110800001224	23	0083	3	0	30	1.29	1	OK		Nicotine
05110800001225	23	0083	3	0	45	1.21	1	OK		Nicotine
05110800001226	23	0083	3	1	0	1.06	1	OK		Nicotine
05110800001227	23	0083	3	2	0	0.798	1	OK		Nicotine
05110800001228	23	0083	3	4	0	0.584	1	OK		Nicotine
05110800001229	23	0083	3	6	0	0.459	1	OK		Nicotine
05110800001230	23	0083	3	9	0	0.294	1	OK		Nicotine
05110800001231	23	0083	3	12	0	0.224	1	OK		Nicotine
05110800001232	23	0083	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800001233	23	0083	1	0	-15	0.488	1	OK		Nicotine
05110800001234	23	0083	1	0	10	1.34	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800001235	23	0083	1	0	20	2.45	1	OK		Nicotine
05110800001236	23	0083	1	0	25	3.67	1	OK		Nicotine
05110800001237	23	0083	1	0	30	4.44	1	OK		Nicotine
05110800001238	23	0083	1	0	35	5.22	1	OK		Nicotine
05110800001239	23	0083	1	0	40	6.02	1	OK		Nicotine
05110800001240	23	0083	1	0	45	6.89	1	OK		Nicotine
05110800001241	23	0083	1	1	0	34.1	1	OK		Nicotine
05110800001242	23	0083	1	2	0	8.50	1	OK		Nicotine
05110800001243	23	0083	1	3	0	6.85	1	OK		Nicotine
05110800001244	23	0083	1	4	0	6.29	1	OK		Nicotine
05110800001245	23	0083	1	6	0	4.18	1	OK		Nicotine
05110800001246	23	0083	1	9	0	2.77	1	OK		Nicotine
05110800001247	23	0083	1	12	0	1.93	1	OK		Nicotine
05110800001248	23	0083	1	24	0	0.625	1	OK		Nicotine
05110800001315	19	0004	3	0	20	1.79	2	OK		Nicotine
05110800001433	19	0024	1	0	45	5.58	2	OK		Nicotine
05110800001936	19	0022	3	24	0	BLQ<(0.200)	2	OK		Nicotine
05110800002254	27	0073	3	9	0	0.308	2	OK		Nicotine
05110800002401	27	0063	3	0	-15	BLQ<(0.200)	2	OK		Nicotine
05110800002513	14	0097	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002514	14	0097	3	0	2	8.15	1	OK		Nicotine
05110800002515	19	0097	3	0	4	13.0	1	OK		Nicotine
05110800002516	14	0097	3	0	6	7.05	1	OK		Nicotine
05110800002517	14	0097	3	0	8	5.27	1	OK		Nicotine
05110800002518	14	0097	3	0	10	5.00	1	OK		Nicotine
05110800002519	14	0097	3	0	15	3.96	1	OK		Nicotine
05110800002520	14	0097	3	0	30	2.87	1	OK		Nicotine
05110800002521	14	0097	3	0	45	2.71	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002522	14	0097	3	1	0	2.33	1	OK		Nicotine
05110800002523	14	0097	3	2	0	1.58	1	OK		Nicotine
05110800002524	14	0097	3	4	0	0.663	1	OK		Nicotine
05110800002525	14	0097	3	6	0	0.437	1	OK		Nicotine
05110800002526	14	0097	3	9	0	0.240	1	OK		Nicotine
05110800002527	14	0097	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002528	14	0097	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002545	14	0097	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002546	14	0097	1	0	2	6.42	1	OK		Nicotine
05110800002547	19	0097	1	0	4	12.7	1	OK		Nicotine
05110800002548	14	0097	1	0	6	7.59	1	OK		Nicotine
05110800002549	14	0097	1	0	8	5.10	1	OK		Nicotine
05110800002550	14	0097	1	0	10	4.25	1	OK		Nicotine
05110800002551	14	0097	1	0	15	3.82	1	OK		Nicotine
05110800002552	14	0097	1	0	30	2.31	1	OK		Nicotine
05110800002553	14	0097	1	0	45	2.37	1	OK		Nicotine
05110800002554	14	0097	1	1	0	1.76	1	OK		Nicotine
05110800002555	14	0097	1	2	0	1.26	1	OK		Nicotine
05110800002556	14	0097	1	4	0	0.565	1	OK		Nicotine
05110800002557	14	0097	1	6	0	0.454	1	OK		Nicotine
05110800002558	14	0097	1	9	0	0.222	1	OK		Nicotine
05110800002559	14	0097	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002560	14	0097	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002592	21	0107	1	6	0	1.13	1	OK		Nicotine
05110800002609	21	0107	1	0	-15	0.212	1	OK		Nicotine
05110800002610	21	0107	1	0	2	5.01	1	OK		Nicotine
05110800002611	23	0107	1	0	4	11.8	1	OK		Nicotine
05110800002612	23	0107	1	0	6	11.4	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002613	23	0107	1	0	8	9.86	1	OK		Nicotine
05110800002614	21	0107	1	0	10	9.39	1	OK		Nicotine
05110800002615	21	0107	1	0	15	7.60	1	OK		Nicotine
05110800002616	21	0107	1	0	30	5.95	1	OK		Nicotine
05110800002617	21	0107	1	0	45	4.59	1	OK		Nicotine
05110800002618	21	0107	1	1	0	4.76	1	OK		Nicotine
05110800002619	21	0107	1	2	0	3.16	1	OK		Nicotine
05110800002620	21	0107	1	4	0	1.87	1	OK		Nicotine
05110800002641	21	0113	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002642	23	0113	3	0	2	29.0	1	OK		Nicotine
05110800002643	23	0113	3	0	4	34.2	1	OK		Nicotine
05110800002644	23	0113	3	0	6	19.4	1	OK		Nicotine
05110800002645	23	0113	3	0	8	16.3	1	OK		Nicotine
05110800002646	23	0113	3	0	10	12.9	1	OK		Nicotine
05110800002647	21	0113	3	0	15	8.55	1	OK		Nicotine
05110800002648	21	0113	3	0	30	5.42	1	OK		Nicotine
05110800002649	21	0113	3	0	45	6.04	1	OK		Nicotine
05110800002650	21	0113	3	1	0	5.24	1	OK		Nicotine
05110800002651	21	0113	3	2	0	2.93	1	OK		Nicotine
05110800002652	21	0113	3	4	0	1.16	1	OK		Nicotine
05110800002653	21	0113	3	6	0	0.581	1	OK		Nicotine
05110800002654	21	0113	3	9	0	0.244	1	OK		Nicotine
05110800002655	21	0113	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002656	21	0113	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002673	21	0113	1	0	-15	0.262	1	OK		Nicotine
05110800002674	23	0113	1	0	2	35.1	1	OK		Nicotine
05110800002675	23	0113	1	0	4	38.1	1	OK		Nicotine
05110800002676	23	0113	1	0	6	24.1	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002677	23	0113	1	0	8	18.1	1	OK		Nicotine
05110800002678	23	0113	1	0	10	15.2	1	OK		Nicotine
05110800002679	23	0113	1	0	15	11.3	1	OK		Nicotine
05110800002680	21	0113	1	0	30	8.12	1	OK		Nicotine
05110800002681	21	0113	1	0	45	5.61	1	OK		Nicotine
05110800002682	21	0113	1	1	0	4.77	1	OK		Nicotine
05110800002683	21	0113	1	2	0	2.87	1	OK		Nicotine
05110800002684	21	0113	1	4	0	1.47	1	OK		Nicotine
05110800002685	21	0113	1	6	0	0.811	1	OK		Nicotine
05110800002686	21	0113	1	9	0	0.485	1	OK		Nicotine
05110800002687	21	0113	1	12	0	0.230	1	OK		Nicotine
05110800002688	21	0113	1	24	0	0.338	1	OK		Nicotine
05110800002705	23	0089	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002706	23	0089	3	0	2	4.67	1	OK		Nicotine
05110800002707	23	0089	3	0	4	17.4	1	OK		Nicotine
05110800002708	23	0089	3	0	6	19.9	1	OK		Nicotine
05110800002709	23	0089	3	0	8	19.3	1	OK		Nicotine
05110800002710	23	0089	3	0	10	15.8	1	OK		Nicotine
05110800002711	23	0089	3	0	15	12.2	1	OK		Nicotine
05110800002712	23	0089	3	0	30	10.4	1	OK		Nicotine
05110800002713	23	0089	3	0	45	10.2	1	OK		Nicotine
05110800002714	23	0089	3	1	0	9.26	1	OK		Nicotine
05110800002715	23	0089	3	2	0	8.28	1	OK		Nicotine
05110800002716	23	0089	3	4	0	3.92	1	OK		Nicotine
05110800002717	23	0089	3	6	0	2.71	1	OK		Nicotine
05110800002718	23	0089	3	9	0	1.36	1	OK		Nicotine
05110800002719	23	0089	3	12	0	0.678	1	OK		Nicotine
05110800002720	23	0089	3	24	0	0.215	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002737	23	0089	1	0	-15	0.510	1	OK		Nicotine
05110800002738	23	0089	1	0	2	4.29	1	OK		Nicotine
05110800002739	23	0089	1	0	4	8.40	1	OK		Nicotine
05110800002740	23	0089	1	0	6	5.47	1	OK		Nicotine
05110800002741	23	0089	1	0	8	6.25	1	OK		Nicotine
05110800002742	23	0089	1	0	10	6.59	1	OK		Nicotine
05110800002743	23	0089	1	0	15	5.76	1	OK		Nicotine
05110800002744	23	0089	1	0	30	5.23	1	OK		Nicotine
05110800002745	23	0089	1	0	45	6.06	1	OK		Nicotine
05110800002746	23	0089	1	1	0	5.44	1	OK		Nicotine
05110800002747	23	0089	1	2	0	4.03	1	OK		Nicotine
05110800002748	23	0089	1	4	0	2.23	1	OK		Nicotine
05110800002749	23	0089	1	6	0	1.33	1	OK		Nicotine
05110800002750	23	0089	1	9	0	0.723	1	OK		Nicotine
05110800002751	23	0089	1	12	0	0.456	1	OK		Nicotine
05110800002752	23	0089	1	24	0	0.306	1	OK		Nicotine
05110800002769	23	0090	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002770	23	0090	3	0	2	3.75	1	OK		Nicotine
05110800002771	23	0090	3	0	4	5.07	1	OK		Nicotine
05110800002772	23	0090	3	0	6	9.24	1	OK		Nicotine
05110800002773	23	0090	3	0	8	4.06	1	OK		Nicotine
05110800002774	23	0090	3	0	10	3.69	1	OK		Nicotine
05110800002775	23	0090	3	0	15	2.29	1	OK		Nicotine
05110800002776	23	0090	3	0	30	1.88	1	OK		Nicotine
05110800002777	23	0090	3	0	45	1.30	1	OK		Nicotine
05110800002778	23	0090	3	1	0	1.41	1	OK		Nicotine
05110800002779	23	0090	3	2	0	0.935	1	OK		Nicotine
05110800002780	23	0090	3	4	0	0.361	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002781	23	0090	3	6	0	0.234	1	OK		Nicotine
05110800002782	23	0090	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800002783	23	0090	3	12	0	0.202	1	OK		Nicotine
05110800002784	23	0090	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002801	23	0090	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002802	23	0090	1	0	2	2.57	1	OK		Nicotine
05110800002803	23	0090	1	0	4	3.47	1	OK		Nicotine
05110800002804	23	0090	1	0	6	2.67	1	OK		Nicotine
05110800002805	23	0090	1	0	8	2.68	1	OK		Nicotine
05110800002806	23	0090	1	0	10	2.53	1	OK		Nicotine
05110800002807	23	0090	1	0	15	2.67	1	OK		Nicotine
05110800002808	23	0090	1	0	30	1.79	1	OK		Nicotine
05110800002809	23	0090	1	0	45	1.47	1	OK		Nicotine
05110800002810	23	0090	1	1	0	1.53	1	OK		Nicotine
05110800002811	23	0090	1	2	0	0.944	1	OK		Nicotine
05110800002812	23	0090	1	4	0	0.413	1	OK		Nicotine
05110800002813	23	0090	1	6	0	0.230	1	OK		Nicotine
05110800002814	23	0090	1	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800002815	23	0090	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002816	23	0090	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002833	14	0093	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002834	14	0093	3	0	2	2.77	1	OK		Nicotine
05110800002835	14	0093	3	0	4	7.45	1	OK		Nicotine
05110800002836	14	0093	3	0	6	4.45	1	OK		Nicotine
05110800002837	14	0093	3	0	8	5.22	1	OK		Nicotine
05110800002838	14	0093	3	0	10	4.18	1	OK		Nicotine
05110800002839	14	0093	3	0	15	3.26	1	OK		Nicotine
05110800002840	14	0093	3	0	30	2.03	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002841	14	0093	3	0	45	2.15	1	OK		Nicotine
05110800002842	14	0093	3	1	0	1.79	1	OK		Nicotine
05110800002843	14	0093	3	2	0	1.15	1	OK		Nicotine
05110800002844	14	0093	3	4	0	0.490	1	OK		Nicotine
05110800002845	14	0093	3	6	0	0.282	1	OK		Nicotine
05110800002846	14	0093	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800002847	14	0093	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002848	14	0093	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002865	14	0093	1	0	-15	0.204	1	OK		Nicotine
05110800002866	14	0093	1	0	2	9.03	1	OK		Nicotine
05110800002867	19	0093	1	0	4	17.3	1	OK		Nicotine
05110800002868	19	0093	1	0	6	11.3	1	OK		Nicotine
05110800002869	14	0093	1	0	8	8.48	1	OK		Nicotine
05110800002870	14	0093	1	0	10	8.76	1	OK		Nicotine
05110800002871	14	0093	1	0	15	5.47	1	OK		Nicotine
05110800002872	14	0093	1	0	30	4.41	1	OK		Nicotine
05110800002873	14	0093	1	0	45	3.80	1	OK		Nicotine
05110800002874	14	0093	1	1	0	3.46	1	OK		Nicotine
05110800002875	14	0093	1	2	0	2.14	1	OK		Nicotine
05110800002876	14	0093	1	4	0	0.915	1	OK		Nicotine
05110800002877	14	0093	1	6	0	0.480	1	OK		Nicotine
05110800002878	14	0093	1	9	0	0.247	1	OK		Nicotine
05110800002879	14	0093	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002880	14	0093	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002897	14	0102	3	0	-15	0.329	1	OK		Nicotine
05110800002898	19	0102	3	0	2	12.6	1	OK		Nicotine
05110800002899	19	0102	3	0	4	26.5	1	OK		Nicotine
05110800002900	19	0102	3	0	6	34.8	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002901	19	0102	3	0	8	23.6	1	OK		Nicotine
05110800002902	19	0102	3	0	10	23.4	1	OK		Nicotine
05110800002903	19	0102	3	0	15	17.2	1	OK		Nicotine
05110800002904	19	0102	3	0	30	11.8	1	OK		Nicotine
05110800002905	19	0102	3	0	45	13.6	1	OK		Nicotine
05110800002906	19	0102	3	1	0	12.3	1	OK		Nicotine
05110800002907	19	0102	3	2	0	10.6	1	OK		Nicotine
05110800002908	14	0102	3	4	0	6.68	1	OK		Nicotine
05110800002909	14	0102	3	6	0	4.93	1	OK		Nicotine
05110800002910	14	0102	3	9	0	3.91	1	OK		Nicotine
05110800002911	14	0102	3	12	0	2.64	1	OK		Nicotine
05110800002912	14	0102	3	24	0	1.05	1	OK		Nicotine
05110800002929	14	0102	1	0	-15	1.40	1	OK		Nicotine
05110800002930	19	0102	1	0	2	21.9	1	OK		Nicotine
05110800002931	19	0102	1	0	4	32.2	1	OK		Nicotine
05110800002932	19	0102	1	0	6	17.4	1	OK		Nicotine
05110800002933	19	0102	1	0	8	16.0	1	OK		Nicotine
05110800002934	19	0102	1	0	10	14.1	1	OK		Nicotine
05110800002935	14	0102	1	0	15	8.53	1	OK		Nicotine
05110800002936	14	0102	1	0	30	7.63	1	OK		Nicotine
05110800002937	14	0102	1	0	45	7.44	1	OK		Nicotine
05110800002938	14	0102	1	1	0	6.74	1	OK		Nicotine
05110800002939	14	0102	1	2	0	5.38	1	OK		Nicotine
05110800002940	14	0102	1	4	0	3.82	1	OK		Nicotine
05110800002941	14	0102	1	6	0	3.22	1	OK		Nicotine
05110800002942	14	0102	1	9	0	2.26	1	OK		Nicotine
05110800002943	14	0102	1	12	0	1.68	1	OK		Nicotine
05110800002944	14	0102	1	24	0	0.754	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800002961	21	0105	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002962	21	0105	3	0	2	0.636	1	OK		Nicotine
05110800002963	21	0105	3	0	4	2.75	1	OK		Nicotine
05110800002964	21	0105	3	0	6	5.33	1	OK		Nicotine
05110800002965	21	0105	3	0	8	6.15	1	OK		Nicotine
05110800002966	21	0105	3	0	10	5.82	1	OK		Nicotine
05110800002967	21	0105	3	0	15	9.33	1	OK		Nicotine
05110800002968	21	0105	3	0	30	6.69	1	OK		Nicotine
05110800002969	21	0105	3	0	45	7.97	1	OK		Nicotine
05110800002970	21	0105	3	1	0	5.68	1	OK		Nicotine
05110800002971	21	0105	3	2	0	3.78	1	OK		Nicotine
05110800002972	21	0105	3	4	0	1.69	1	OK		Nicotine
05110800002973	21	0105	3	6	0	0.950	1	OK		Nicotine
05110800002974	21	0105	3	9	0	0.335	1	OK		Nicotine
05110800002975	21	0105	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800002976	21	0105	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800002993	21	0105	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800002994	21	0105	1	0	2	8.31	1	OK		Nicotine
05110800002995	23	0105	1	0	4	20.0	1	OK		Nicotine
05110800002996	23	0105	1	0	6	24.4	1	OK		Nicotine
05110800002997	23	0105	1	0	8	20.4	1	OK		Nicotine
05110800002998	23	0105	1	0	10	20.1	1	OK		Nicotine
05110800002999	23	0105	1	0	15	12.7	1	OK		Nicotine
05110800003000	21	0105	1	0	30	8.27	1	OK		Nicotine
05110800003001	21	0105	1	0	45	6.13	1	OK		Nicotine
05110800003002	21	0105	1	1	0	5.68	1	OK		Nicotine
05110800003003	21	0105	1	2	0	3.28	1	OK		Nicotine
05110800003004	21	0105	1	4	0	1.40	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003005	21	0105	1	6	0	0.685	1	OK		Nicotine
05110800003006	21	0105	1	9	0	0.318	1	OK		Nicotine
05110800003007	21	0105	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003008	21	0105	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003025	14	0095	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003026	14	0095	3	0	10	1.70	1	OK		Nicotine
05110800003027	14	0095	3	0	20	2.21	1	OK		Nicotine
05110800003028	14	0095	3	0	25	2.23	1	OK		Nicotine
05110800003029	14	0095	3	0	30	3.20	1	OK		Nicotine
05110800003030	14	0095	3	0	35	2.69	1	OK		Nicotine
05110800003031	14	0095	3	0	40	3.47	1	OK		Nicotine
05110800003032	14	0095	3	0	45	4.05	1	OK		Nicotine
05110800003033	14	0095	3	1	0	4.88	1	OK		Nicotine
05110800003034	14	0095	3	2	0	2.72	1	OK		Nicotine
05110800003035	14	0095	3	3	0	2.29	1	OK		Nicotine
05110800003036	14	0095	3	4	0	1.67	1	OK		Nicotine
05110800003037	14	0095	3	6	0	0.921	1	OK		Nicotine
05110800003038	14	0095	3	9	0	0.449	1	OK		Nicotine
05110800003039	14	0095	3	12	0	0.239	1	OK		Nicotine
05110800003040	14	0095	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003057	14	0095	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003058	14	0095	1	0	2	5.56	1	OK		Nicotine
05110800003059	19	0095	1	0	4	14.0	1	OK		Nicotine
05110800003060	14	0095	1	0	6	8.90	1	OK		Nicotine
05110800003061	14	0095	1	0	8	7.13	1	OK		Nicotine
05110800003062	14	0095	1	0	10	6.86	1	OK		Nicotine
05110800003063	14	0095	1	0	15	4.39	1	OK		Nicotine
05110800003064	14	0095	1	0	30	2.83	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003065	14	0095	1	0	45	2.14	1	OK		Nicotine
05110800003066	14	0095	1	1	0	2.34	1	OK		Nicotine
05110800003067	14	0095	1	2	0	1.61	1	OK		Nicotine
05110800003068	14	0095	1	4	0	0.749	1	OK		Nicotine
05110800003069	14	0095	1	6	0	0.515	1	OK		Nicotine
05110800003070	14	0095	1	9	0	0.330	1	OK		Nicotine
05110800003071	14	0095	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003072	14	0095	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003089	21	0119	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003090	21	0119	3	0	10	0.988	1	OK		Nicotine
05110800003091	21	0119	3	0	20	2.84	1	OK		Nicotine
05110800003092	21	0119	3	0	25	4.96	1	OK		Nicotine
05110800003093	21	0119	3	0	30	4.63	1	OK		Nicotine
05110800003094	21	0119	3	0	35	5.19	1	OK		Nicotine
05110800003095	21	0119	3	0	40	5.92	1	OK		Nicotine
05110800003096	21	0119	3	0	45	6.50	1	OK		Nicotine
05110800003097	21	0119	3	1	0	5.89	1	OK		Nicotine
05110800003098	21	0119	3	2	0	4.29	1	OK		Nicotine
05110800003099	21	0119	3	3	0	2.80	1	OK		Nicotine
05110800003100	21	0119	3	4	0	1.61	1	OK		Nicotine
05110800003101	21	0119	3	6	0	0.870	1	OK		Nicotine
05110800003102	21	0119	3	9	0	0.450	1	OK		Nicotine
05110800003103	21	0119	3	12	0	0.214	1	OK		Nicotine
05110800003104	21	0119	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003121	21	0119	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003122	21	0119	1	0	2	4.64	1	OK		Nicotine
05110800003123	21	0119	1	0	4	7.50	1	OK		Nicotine
05110800003124	21	0119	1	0	6	4.96	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003125	21	0119	1	0	8	5.15	1	OK		Nicotine
05110800003126	21	0119	1	0	10	4.31	1	OK		Nicotine
05110800003127	21	0119	1	0	15	3.42	1	OK		Nicotine
05110800003128	21	0119	1	0	30	3.01	1	OK		Nicotine
05110800003129	21	0119	1	0	45	2.88	1	OK		Nicotine
05110800003130	21	0119	1	1	0	2.27	1	OK		Nicotine
05110800003131	21	0119	1	2	0	1.41	1	OK		Nicotine
05110800003132	21	0119	1	4	0	0.899	1	OK		Nicotine
05110800003133	21	0119	1	6	0	0.395	1	OK		Nicotine
05110800003134	21	0119	1	9	0	0.221	1	OK		Nicotine
05110800003135	21	0119	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003136	21	0119	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003153	16	0128	3	0	-15	0.308	1	OK		Nicotine
05110800003154	16	0128	3	0	2	6.69	1	OK		Nicotine
05110800003155	16	0128	3	0	4	7.67	1	OK		Nicotine
05110800003156	16	0128	3	0	6	9.13	1	OK		Nicotine
05110800003157	16	0128	3	0	8	8.30	1	OK		Nicotine
05110800003158	16	0128	3	0	10	7.18	1	OK		Nicotine
05110800003159	16	0128	3	0	15	4.96	1	OK		Nicotine
05110800003160	16	0128	3	0	30	4.07	1	OK		Nicotine
05110800003161	16	0128	3	0	45	4.74	1	OK		Nicotine
05110800003162	16	0128	3	1	0	4.02	1	OK		Nicotine
05110800003163	16	0128	3	2	0	3.74	1	OK		Nicotine
05110800003164	16	0128	3	4	0	2.33	1	OK		Nicotine
05110800003165	16	0128	3	6	0	1.77	1	OK		Nicotine
05110800003166	16	0128	3	9	0	1.10	1	OK		Nicotine
05110800003167	16	0128	3	12	0	0.735	1	OK		Nicotine
05110800003168	16	0128	3	24	0	0.329	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003185	16	0128	1	0	-15	1.28	1	OK		Nicotine
05110800003186	25	0128	1	0	2	19.2	1	OK		Nicotine
05110800003187	25	0128	1	0	4	31.3	1	OK		Nicotine
05110800003188	25	0128	1	0	6	26.2	1	OK		Nicotine
05110800003189	25	0128	1	0	8	21.8	1	OK		Nicotine
05110800003190	25	0128	1	0	10	18.4	1	OK		Nicotine
05110800003191	25	0128	1	0	15	11.4	1	OK		Nicotine
05110800003192	25	0128	1	0	30	12.1	1	OK		Nicotine
05110800003193	16	0128	1	0	45	8.85	1	OK		Nicotine
05110800003194	25	0128	1	1	0	10.7	1	OK		Nicotine
05110800003195	16	0128	1	2	0	8.79	1	OK		Nicotine
05110800003196	16	0128	1	4	0	6.21	1	OK		Nicotine
05110800003197	16	0128	1	6	0	4.37	1	OK		Nicotine
05110800003198	16	0128	1	9	0	3.01	1	OK		Nicotine
05110800003199	16	0128	1	12	0	2.02	1	OK		Nicotine
05110800003200	16	0128	1	24	0	0.823	1	OK		Nicotine
05110800003217	22	0134	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003218	22	0134	3	0	2	0.978	1	OK		Nicotine
05110800003219	22	0134	3	0	4	2.46	1	OK		Nicotine
05110800003220	22	0134	3	0	6	3.56	1	OK		Nicotine
05110800003221	22	0134	3	0	8	3.94	1	OK		Nicotine
05110800003222	22	0134	3	0	10	3.72	1	OK		Nicotine
05110800003223	22	0134	3	0	15	3.89	1	OK		Nicotine
05110800003224	22	0134	3	0	30	3.69	1	OK		Nicotine
05110800003225	22	0134	3	0	45	3.80	1	OK		Nicotine
05110800003226	22	0134	3	1	0	3.53	1	OK		Nicotine
05110800003227	22	0134	3	2	0	2.69	1	OK		Nicotine
05110800003228	22	0134	3	4	0	1.82	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003229	22	0134	3	6	0	0.907	1	OK		Nicotine
05110800003230	22	0134	3	9	0	0.624	1	OK		Nicotine
05110800003231	22	0134	3	12	0	0.302	1	OK		Nicotine
05110800003232	22	0134	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003249	22	0134	1	0	-15	0.221	1	OK		Nicotine
05110800003250	22	0134	1	0	2	0.256	1	OK		Nicotine
05110800003251	22	0134	1	0	4	1.15	1	OK		Nicotine
05110800003252	22	0134	1	0	6	2.12	1	OK		Nicotine
05110800003253	22	0134	1	0	8	3.05	1	OK		Nicotine
05110800003254	22	0134	1	0	10	3.18	1	OK		Nicotine
05110800003255	22	0134	1	0	15	4.65	1	OK		Nicotine
05110800003256	22	0134	1	0	30	2.87	1	OK		Nicotine
05110800003257	22	0134	1	0	45	3.05	1	OK		Nicotine
05110800003258	22	0134	1	1	0	4.20	1	OK		Nicotine
05110800003259	22	0134	1	2	0	2.61	1	OK		Nicotine
05110800003260	22	0134	1	4	0	1.64	1	OK		Nicotine
05110800003261	22	0134	1	6	0	1.09	1	OK		Nicotine
05110800003262	22	0134	1	9	0	0.633	1	OK		Nicotine
05110800003263	22	0134	1	12	0	5.76	1	OK		Nicotine
05110800003264	22	0134	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003281	22	0136	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003282	22	0136	3	0	2	BLQ<(0.200)	1	OK		Nicotine
05110800003283	22	0136	3	0	4	0.904	1	OK		Nicotine
05110800003284	22	0136	3	0	6	1.38	1	OK		Nicotine
05110800003285	22	0136	3	0	8	1.35	1	OK		Nicotine
05110800003286	22	0136	3	0	10	2.28	1	OK		Nicotine
05110800003287	22	0136	3	0	15	2.23	1	OK		Nicotine
05110800003288	22	0136	3	0	30	2.14	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003289	22	0136	3	0	45	1.96	1	OK		Nicotine
05110800003290	22	0136	3	1	0	1.68	1	OK		Nicotine
05110800003291	22	0136	3	2	0	1.22	1	OK		Nicotine
05110800003292	22	0136	3	4	0	0.629	1	OK		Nicotine
05110800003293	22	0136	3	6	0	0.372	1	OK		Nicotine
05110800003294	22	0136	3	9	0	0.295	1	OK		Nicotine
05110800003295	22	0136	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003296	22	0136	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003313	22	0136	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003314	22	0136	1	0	2	0.746	1	OK		Nicotine
05110800003315	22	0136	1	0	4	2.20	1	OK		Nicotine
05110800003316	22	0136	1	0	6	3.22	1	OK		Nicotine
05110800003317	22	0136	1	0	8	3.44	1	OK		Nicotine
05110800003318	22	0136	1	0	10	3.86	1	OK		Nicotine
05110800003319	22	0136	1	0	15	4.80	1	OK		Nicotine
05110800003320	22	0136	1	0	30	3.75	1	OK		Nicotine
05110800003321	22	0136	1	0	45	4.46	1	OK		Nicotine
05110800003322	22	0136	1	1	0	3.72	1	OK		Nicotine
05110800003323	22	0136	1	2	0	2.69	1	OK		Nicotine
05110800003324	22	0136	1	4	0	1.34	1	OK		Nicotine
05110800003325	22	0136	1	6	0	0.799	1	OK		Nicotine
05110800003326	22	0136	1	9	0	0.401	1	OK		Nicotine
05110800003327	22	0136	1	12	0	0.225	1	OK		Nicotine
05110800003328	22	0136	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003345	18	0142	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003346	18	0142	3	0	2	0.857	1	OK		Nicotine
05110800003347	18	0142	3	0	4	3.59	1	OK		Nicotine
05110800003348	18	0142	3	0	6	6.13	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003349	18	0142	3	0	8	8.49	1	OK		Nicotine
05110800003350	18	0142	3	0	10	7.51	1	OK		Nicotine
05110800003351	18	0142	3	0	15	7.07	1	OK		Nicotine
05110800003352	18	0142	3	0	30	7.87	1	OK		Nicotine
05110800003353	18	0142	3	0	45	5.79	1	OK		Nicotine
05110800003354	18	0142	3	1	0	6.14	1	OK		Nicotine
05110800003355	18	0142	3	2	0	4.61	1	OK		Nicotine
05110800003356	18	0142	3	4	0	3.09	1	OK		Nicotine
05110800003357	18	0142	3	6	0	2.08	1	OK		Nicotine
05110800003358	18	0142	3	9	0	1.15	1	OK		Nicotine
05110800003359	18	0142	3	12	0	0.662	1	OK		Nicotine
05110800003360	18	0142	3	24	0	0.226	1	OK		Nicotine
05110800003377	18	0142	1	0	-15	0.413	1	OK		Nicotine
05110800003378	18	0142	1	0	2	1.22	1	OK		Nicotine
05110800003379	18	0142	1	0	4	1.54	1	OK		Nicotine
05110800003380	18	0142	1	0	6	2.93	1	OK		Nicotine
05110800003381	18	0142	1	0	8	3.67	1	OK		Nicotine
05110800003382	18	0142	1	0	10	3.63	1	OK		Nicotine
05110800003383	18	0142	1	0	15	3.84	1	OK		Nicotine
05110800003384	18	0142	1	0	30	4.57	1	OK		Nicotine
05110800003385	18	0142	1	0	45	4.42	1	OK		Nicotine
05110800003386	18	0142	1	1	0	4.91	1	OK		Nicotine
05110800003387	18	0142	1	2	0	3.29	1	OK		Nicotine
05110800003388	18	0142	1	4	0	2.10	1	OK		Nicotine
05110800003389	18	0142	1	6	0	1.55	1	OK		Nicotine
05110800003390	18	0142	1	9	0	0.944	1	OK		Nicotine
05110800003391	18	0142	1	12	0	0.644	1	OK		Nicotine
05110800003392	18	0142	1	24	0	0.307	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003409	18	0148	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003410	18	0148	3	0	2	2.22	1	OK		Nicotine
05110800003411	18	0148	3	0	4	4.97	1	OK		Nicotine
05110800003412	18	0148	3	0	6	5.39	1	OK		Nicotine
05110800003413	18	0148	3	0	8	5.05	1	OK		Nicotine
05110800003414	18	0148	3	0	10	5.03	1	OK		Nicotine
05110800003415	18	0148	3	0	15	6.93	1	OK		Nicotine
05110800003416	18	0148	3	0	30	4.67	1	OK		Nicotine
05110800003417	18	0148	3	0	45	5.77	1	OK		Nicotine
05110800003418	18	0148	3	1	0	4.56	1	OK		Nicotine
05110800003419	18	0148	3	2	0	2.56	1	OK		Nicotine
05110800003420	18	0148	3	4	0	1.09	1	OK		Nicotine
05110800003421	18	0148	3	6	0	0.530	1	OK		Nicotine
05110800003422	18	0148	3	9	0	0.237	1	OK		Nicotine
05110800003423	18	0148	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003424	18	0148	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003441	18	0148	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003442	18	0148	1	0	2	1.44	1	OK		Nicotine
05110800003443	18	0148	1	0	4	4.58	1	OK		Nicotine
05110800003444	18	0148	1	0	6	4.49	1	OK		Nicotine
05110800003445	18	0148	1	0	8	4.42	1	OK		Nicotine
05110800003446	18	0148	1	0	10	4.40	1	OK		Nicotine
05110800003447	18	0148	1	0	15	5.67	1	OK		Nicotine
05110800003448	18	0148	1	0	30	5.37	1	OK		Nicotine
05110800003449	18	0148	1	0	45	3.64	1	OK		Nicotine
05110800003450	18	0148	1	1	0	3.80	1	OK		Nicotine
05110800003451	18	0148	1	2	0	2.14	1	OK		Nicotine
05110800003452	18	0148	1	4	0	0.880	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003453	18	0148	1	6	0	0.459	1	OK		Nicotine
05110800003454	18	0148	1	9	0	0.254	1	OK		Nicotine
05110800003455	18	0148	1	12	0	0.208	1	OK		Nicotine
05110800003456	18	0148	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003473	16	0129	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003474	16	0129	3	0	2	0.332	1	OK		Nicotine
05110800003475	16	0129	3	0	4	0.379	1	OK		Nicotine
05110800003476	16	0129	3	0	6	0.363	1	OK		Nicotine
05110800003477	16	0129	3	0	8	0.380	1	OK		Nicotine
05110800003478	16	0129	3	0	10	0.275	1	OK		Nicotine
05110800003479	16	0129	3	0	15	0.320	1	OK		Nicotine
05110800003480	16	0129	3	0	30	0.323	1	OK		Nicotine
05110800003481	16	0129	3	0	45	BLQ<(0.200)	1	OK		Nicotine
05110800003482	16	0129	3	1	0	0.233	1	OK		Nicotine
05110800003483	16	0129	3	2	0	0.220	1	OK		Nicotine
05110800003484	16	0129	3	4	0	BLQ<(0.200)	1	OK		Nicotine
05110800003485	16	0129	3	6	0	0.333	1	OK		Nicotine
05110800003486	16	0129	3	9	0	BLQ<(0.200)	1	OK		Nicotine
05110800003487	16	0129	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003488	16	0129	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003505	16	0129	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003506	16	0129	1	0	2	0.438	1	OK		Nicotine
05110800003507	16	0129	1	0	4	2.21	1	OK		Nicotine
05110800003508	16	0129	1	0	6	4.92	1	OK		Nicotine
05110800003509	16	0129	1	0	8	6.36	1	OK		Nicotine
05110800003510	16	0129	1	0	10	4.50	1	OK		Nicotine
05110800003511	16	0129	1	0	15	2.57	1	OK		Nicotine
05110800003512	16	0129	1	0	30	1.97	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003513	16	0129	1	0	45	1.84	1	OK		Nicotine
05110800003514	16	0129	1	1	0	1.59	1	OK		Nicotine
05110800003515	16	0129	1	2	0	1.28	1	OK		Nicotine
05110800003516	16	0129	1	4	0	0.788	1	OK		Nicotine
05110800003517	16	0129	1	6	0	0.470	1	OK		Nicotine
05110800003518	16	0129	1	9	0	0.307	1	OK		Nicotine
05110800003519	16	0129	1	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003520	16	0129	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003537	22	0135	3	0	-15	0.224	1	OK		Nicotine
05110800003538	25	0135	3	0	2	11.4	1	OK		Nicotine
05110800003539	25	0135	3	0	4	30.2	1	OK		Nicotine
05110800003540	25	0135	3	0	6	43.8	1	OK		Nicotine
05110800003541	25	0135	3	0	8	27.5	1	OK		Nicotine
05110800003542	25	0135	3	0	10	24.3	1	OK		Nicotine
05110800003543	25	0135	3	0	15	20.4	1	OK		Nicotine
05110800003544	25	0135	3	0	30	13.3	1	OK		Nicotine
05110800003545	22	0135	3	0	45	9.63	1	OK		Nicotine
05110800003546	25	0135	3	1	0	10.9	1	OK		Nicotine
05110800003547	22	0135	3	2	0	8.23	1	OK		Nicotine
05110800003548	22	0135	3	4	0	5.08	1	OK		Nicotine
05110800003549	22	0135	3	6	0	3.11	1	OK		Nicotine
05110800003550	22	0135	3	9	0	2.45	1	OK		Nicotine
05110800003551	22	0135	3	12	0	1.38	1	OK		Nicotine
05110800003552	22	0135	3	24	0	0.537	1	OK		Nicotine
05110800003569	22	0135	1	0	-15	0.814	1	OK		Nicotine
05110800003570	25	0135	1	0	2	36.6	1	OK		Nicotine
05110800003571	25	0135	1	0	4	47.6	1	OK		Nicotine
05110800003572	25	0135	1	0	6	58.1	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003573	25	0135	1	0	8	36.0	1	OK		Nicotine
05110800003574	25	0135	1	0	10	31.5	1	OK		Nicotine
05110800003575	25	0135	1	0	15	20.0	1	OK		Nicotine
05110800003576	25	0135	1	0	30	14.7	1	OK		Nicotine
05110800003577	25	0135	1	0	45	15.2	1	OK		Nicotine
05110800003578	25	0135	1	1	0	13.4	1	OK		Nicotine
05110800003579	22	0135	1	2	0	9.37	1	OK		Nicotine
05110800003580	22	0135	1	4	0	5.58	1	OK		Nicotine
05110800003581	22	0135	1	6	0	4.04	1	OK		Nicotine
05110800003582	22	0135	1	9	0	2.84	1	OK		Nicotine
05110800003583	22	0135	1	12	0	1.86	1	OK		Nicotine
05110800003584	22	0135	1	24	0	0.589	1	OK		Nicotine
05110800003601	18	0139	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003602	18	0139	3	0	2	1.56	1	OK		Nicotine
05110800003603	18	0139	3	0	4	5.67	1	OK		Nicotine
05110800003604	18	0139	3	0	6	9.23	1	OK		Nicotine
05110800003605	18	0139	3	0	8	7.53	1	OK		Nicotine
05110800003606	18	0139	3	0	10	7.21	1	OK		Nicotine
05110800003607	18	0139	3	0	15	5.62	1	OK		Nicotine
05110800003608	18	0139	3	0	30	4.22	1	OK		Nicotine
05110800003609	18	0139	3	0	45	3.78	1	OK		Nicotine
05110800003610	18	0139	3	1	0	3.71	1	OK		Nicotine
05110800003611	18	0139	3	2	0	2.47	1	OK		Nicotine
05110800003612	18	0139	3	4	0	1.76	1	OK		Nicotine
05110800003613	18	0139	3	6	0	1.13	1	OK		Nicotine
05110800003614	18	0139	3	9	0	0.715	1	OK		Nicotine
05110800003615	18	0139	3	12	0	0.398	1	OK		Nicotine
05110800003616	18	0139	3	24	0	BLQ<(0.200)	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003633	18	0139	1	0	-15	0.442	1	OK		Nicotine
05110800003634	18	0139	1	0	2	2.32	1	OK		Nicotine
05110800003635	18	0139	1	0	4	7.31	1	OK		Nicotine
05110800003636	18	0139	1	0	6	7.34	1	OK		Nicotine
05110800003637	18	0139	1	0	8	9.54	1	OK		Nicotine
05110800003638	18	0139	1	0	10	8.54	1	OK		Nicotine
05110800003639	18	0139	1	0	15	5.74	1	OK		Nicotine
05110800003640	18	0139	1	0	30	5.70	1	OK		Nicotine
05110800003641	18	0139	1	0	45	4.98	1	OK		Nicotine
05110800003642	18	0139	1	1	0	4.26	1	OK		Nicotine
05110800003643	18	0139	1	2	0	3.15	1	OK		Nicotine
05110800003644	18	0139	1	4	0	1.82	1	OK		Nicotine
05110800003645	18	0139	1	6	0	1.34	1	OK		Nicotine
05110800003646	18	0139	1	9	0	0.889	1	OK		Nicotine
05110800003647	18	0139	1	12	0	0.489	1	OK		Nicotine
05110800003648	18	0139	1	24	0	0.292	1	OK		Nicotine
05110800003665	18	0140	3	0	-15	0.466	1	OK		Nicotine
05110800003666	18	0140	3	0	2	1.33	1	OK		Nicotine
05110800003667	18	0140	3	0	4	2.21	1	OK		Nicotine
05110800003668	18	0140	3	0	6	3.99	1	OK		Nicotine
05110800003669	18	0140	3	0	8	4.48	1	OK		Nicotine
05110800003670	18	0140	3	0	10	4.32	1	OK		Nicotine
05110800003671	18	0140	3	0	15	4.89	1	OK		Nicotine
05110800003672	18	0140	3	0	30	6.33	1	OK		Nicotine
05110800003673	18	0140	3	0	45	5.28	1	OK		Nicotine
05110800003674	18	0140	3	1	0	6.44	1	OK		Nicotine
05110800003675	18	0140	3	2	0	4.28	1	OK		Nicotine
05110800003676	18	0140	3	4	0	3.79	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003677	18	0140	3	6	0	2.55	1	OK		Nicotine
05110800003678	18	0140	3	9	0	1.76	1	OK		Nicotine
05110800003679	18	0140	3	12	0	1.29	1	OK		Nicotine
05110800003680	18	0140	3	24	0	0.550	1	OK		Nicotine
05110800003697	18	0140	1	0	-15	1.96	1	OK		Nicotine
05110800003698	18	0140	1	0	2	3.35	1	OK		Nicotine
05110800003699	18	0140	1	0	4	7.74	1	OK		Nicotine
05110800003700	18	0140	1	0	6	8.05	1	OK		Nicotine
05110800003701	18	0140	1	0	8	10.0	1	OK		Nicotine
05110800003702	23	0140	1	0	10	9.60	1	OK		Nicotine
05110800003703	23	0140	1	0	15	12.2	1	OK		Nicotine
05110800003704	23	0140	1	0	30	12.1	1	OK		Nicotine
05110800003705	23	0140	1	0	45	11.5	1	OK		Nicotine
05110800003706	23	0140	1	1	0	12.1	1	OK		Nicotine
05110800003707	23	0140	1	2	0	9.87	1	OK		Nicotine
05110800003708	18	0140	1	4	0	6.64	1	OK		Nicotine
05110800003709	18	0140	1	6	0	5.65	1	OK		Nicotine
05110800003710	18	0140	1	9	0	3.82	1	OK		Nicotine
05110800003711	18	0140	1	12	0	2.97	1	OK		Nicotine
05110800003712	18	0140	1	24	0	1.31	1	OK		Nicotine
05110800003729	19	0152	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003730	19	0152	3	0	2	0.245	1	OK		Nicotine
05110800003731	19	0152	3	0	4	0.321	1	OK		Nicotine
05110800003732	19	0152	3	0	6	0.658	1	OK		Nicotine
05110800003733	19	0152	3	0	8	0.689	1	OK		Nicotine
05110800003734	19	0152	3	0	10	0.684	1	OK		Nicotine
05110800003735	19	0152	3	0	15	0.872	1	OK		Nicotine
05110800003736	19	0152	3	0	30	0.902	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003737	19	0152	3	0	45	0.988	1	OK		Nicotine
05110800003738	19	0152	3	1	0	0.923	1	OK		Nicotine
05110800003739	19	0152	3	2	0	0.777	1	OK		Nicotine
05110800003740	19	0152	3	4	0	0.422	1	OK		Nicotine
05110800003741	19	0152	3	6	0	0.264	1	OK		Nicotine
05110800003742	19	0152	3	9	0	0.248	1	OK		Nicotine
05110800003743	19	0152	3	12	0	BLQ<(0.200)	1	OK		Nicotine
05110800003744	19	0152	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003761	19	0152	1	0	-15	0.245	1	OK		Nicotine
05110800003762	19	0152	1	0	2	0.403	1	OK		Nicotine
05110800003763	19	0152	1	0	4	0.417	1	OK		Nicotine
05110800003764	19	0152	1	0	6	1.20	1	OK		Nicotine
05110800003765	19	0152	1	0	8	1.87	1	OK		Nicotine
05110800003766	19	0152	1	0	10	2.64	1	OK		Nicotine
05110800003767	19	0152	1	0	15	2.60	1	OK		Nicotine
05110800003768	19	0152	1	0	30	2.27	1	OK		Nicotine
05110800003769	19	0152	1	0	45	2.53	1	OK		Nicotine
05110800003770	19	0152	1	1	0	2.28	1	OK		Nicotine
05110800003771	19	0152	1	2	0	1.45	1	OK		Nicotine
05110800003772	19	0152	1	4	0	0.785	1	OK		Nicotine
05110800003773	19	0152	1	6	0	0.585	1	OK		Nicotine
05110800003774	19	0152	1	9	0	0.535	1	OK		Nicotine
05110800003775	19	0152	1	12	0	0.382	1	OK		Nicotine
05110800003776	19	0152	1	24	0	0.221	1	OK		Nicotine
05110800003793	16	0123	3	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003794	16	0123	3	0	10	1.15	1	OK		Nicotine
05110800003795	16	0123	3	0	20	2.96	1	OK		Nicotine
05110800003796	16	0123	3	0	25	3.71	1	OK		Nicotine



Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003797	16	0123	3	0	30	4.45	1	OK		Nicotine
05110800003798	16	0123	3	0	35	4.29	1	OK		Nicotine
05110800003799	16	0123	3	0	40	5.42	1	OK		Nicotine
05110800003800	16	0123	3	0	45	5.67	1	OK		Nicotine
05110800003801	16	0123	3	1	0	6.47	1	OK		Nicotine
05110800003802	16	0123	3	2	0	3.82	1	OK		Nicotine
05110800003803	16	0123	3	3	0	2.40	1	OK		Nicotine
05110800003804	16	0123	3	4	0	1.66	1	OK		Nicotine
05110800003805	16	0123	3	6	0	0.941	1	OK		Nicotine
05110800003806	16	0123	3	9	0	0.384	1	OK		Nicotine
05110800003807	16	0123	3	12	0	0.243	1	OK		Nicotine
05110800003808	16	0123	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003825	16	0123	1	0	-15	BLQ<(0.200)	1	OK		Nicotine
05110800003826	16	0123	1	0	2	4.17	1	OK		Nicotine
05110800003827	16	0123	1	0	4	8.17	1	OK		Nicotine
05110800003828	25	0123	1	0	6	11.0	1	OK		Nicotine
05110800003829	16	0123	1	0	8	9.06	1	OK		Nicotine
05110800003830	16	0123	1	0	10	7.78	1	OK		Nicotine
05110800003831	16	0123	1	0	15	8.60	1	OK		Nicotine
05110800003832	16	0123	1	0	30	6.45	1	OK		Nicotine
05110800003833	16	0123	1	0	45	5.25	1	OK		Nicotine
05110800003834	16	0123	1	1	0	4.31	1	OK		Nicotine
05110800003835	16	0123	1	2	0	2.61	1	OK		Nicotine
05110800003836	16	0123	1	4	0	1.34	1	OK		Nicotine
05110800003837	16	0123	1	6	0	0.826	1	OK		Nicotine
05110800003838	16	0123	1	9	0	0.448	1	OK		Nicotine
05110800003839	16	0123	1	12	0	0.276	1	OK		Nicotine
05110800003840	16	0123	1	24	0	BLQ<(0.200)	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003857	16	0120	3	0	-15	0.878	1	OK		Nicotine
05110800003858	16	0120	3	0	2	1.48	1	OK		Nicotine
05110800003859	16	0120	3	0	4	2.27	1	OK		Nicotine
05110800003860	16	0120	3	0	6	2.13	1	OK		Nicotine
05110800003861	16	0120	3	0	8	2.06	1	OK		Nicotine
05110800003862	16	0120	3	0	10	2.09	1	OK		Nicotine
05110800003863	16	0120	3	0	15	2.35	1	OK		Nicotine
05110800003864	16	0120	3	0	30	1.90	1	OK		Nicotine
05110800003865	16	0120	3	0	45	1.86	1	OK		Nicotine
05110800003866	16	0120	3	1	0	1.84	1	OK		Nicotine
05110800003867	16	0120	3	2	0	1.32	1	OK		Nicotine
05110800003868	16	0120	3	4	0	0.967	1	OK		Nicotine
05110800003869	16	0120	3	6	0	0.721	1	OK		Nicotine
05110800003870	16	0120	3	9	0	0.519	1	OK		Nicotine
05110800003871	16	0120	3	12	0	0.335	1	OK		Nicotine
05110800003872	16	0120	3	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003889	16	0120	1	0	-15	0.522	1	OK		Nicotine
05110800003890	16	0120	1	0	10	1.87	1	OK		Nicotine
05110800003891	16	0120	1	0	20	3.78	1	OK		Nicotine
05110800003892	16	0120	1	0	25	3.63	1	OK		Nicotine
05110800003893	16	0120	1	0	30	4.27	1	OK		Nicotine
05110800003894	16	0120	1	0	35	5.21	1	OK		Nicotine
05110800003895	16	0120	1	0	40	6.79	1	OK		Nicotine
05110800003896	16	0120	1	0	45	6.01	1	OK		Nicotine
05110800003897	16	0120	1	1	0	9.98	1	OK		Nicotine
05110800003898	16	0120	1	2	0	7.58	1	OK		Nicotine
05110800003899	16	0120	1	3	0	5.77	1	OK		Nicotine
05110800003900	16	0120	1	4	0	4.56	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003901	16	0120	1	6	0	2.86	1	OK		Nicotine
05110800003902	16	0120	1	9	0	1.46	1	OK		Nicotine
05110800003903	16	0120	1	12	0	0.945	1	OK		Nicotine
05110800003904	16	0120	1	24	0	BLQ<(0.200)	1	OK		Nicotine
05110800003921	22	0132	3	0	-15	0.262	1	OK		Nicotine
05110800003922	22	0132	3	0	2	1.60	1	OK		Nicotine
05110800003923	22	0132	3	0	4	5.73	1	OK		Nicotine
05110800003924	22	0132	3	0	6	7.69	1	OK		Nicotine
05110800003925	22	0132	3	0	8	6.76	1	OK		Nicotine
05110800003926	22	0132	3	0	10	8.17	1	OK		Nicotine
05110800003927	25	0132	3	0	15	10.9	1	OK		Nicotine
05110800003928	22	0132	3	0	30	7.46	1	OK		Nicotine
05110800003929	22	0132	3	0	45	7.37	1	OK		Nicotine
05110800003930	22	0132	3	1	0	7.78	1	OK		Nicotine
05110800003931	22	0132	3	2	0	4.95	1	OK		Nicotine
05110800003932	22	0132	3	4	0	3.03	1	OK		Nicotine
05110800003933	22	0132	3	6	0	2.02	1	OK		Nicotine
05110800003934	22	0132	3	9	0	1.21	1	OK		Nicotine
05110800003935	22	0132	3	12	0	0.837	1	OK		Nicotine
05110800003936	22	0132	3	24	0	0.335	1	OK		Nicotine
05110800003953	22	0132	1	0	-15	0.922	1	OK		Nicotine
05110800003954	22	0132	1	0	10	1.42	1	OK		Nicotine
05110800003955	22	0132	1	0	20	3.04	1	OK		Nicotine
05110800003956	22	0132	1	0	25	4.28	1	OK		Nicotine
05110800003957	22	0132	1	0	30	5.81	1	OK		Nicotine
05110800003958	22	0132	1	0	35	6.87	1	OK		Nicotine
05110800003959	22	0132	1	0	40	8.24	1	OK		Nicotine
05110800003960	22	0132	1	0	45	9.26	1	OK		Nicotine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Split	Sample Condition	Sample Comments	Analyte
05110800003961	25	0132	1	1	0	10.2	1	OK		Nicotine
05110800003962	22	0132	1	2	0	8.86	1	OK		Nicotine
05110800003963	22	0132	1	3	0	6.72	1	OK		Nicotine
05110800003964	22	0132	1	4	0	5.11	1	OK		Nicotine
05110800003965	22	0132	1	6	0	3.50	1	OK		Nicotine
05110800003966	22	0132	1	9	0	2.59	1	OK		Nicotine
05110800003967	22	0132	1	12	0	1.82	1	OK		Nicotine
05110800003968	22	0132	1	24	0	0.706	1	OK		Nicotine

Table 6 Summary of Reassay for Analytical Reasons

Run ID	Reason	Sample Name
1	Fail	AA99122-01 05110800000017 0002 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
1	Fail	AA99122-01 05110800000018 0002 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
1	AAR/Fail	AA99122-01 05110800000019 0002 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
1	AAR/Fail	AA99122-01 05110800000020 0002 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
1	AAR/Fail	AA99122-01 05110800000021 0002 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
1	AAR/Fail	AA99122-01 05110800000022 0002 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
1	AAR/Fail	AA99122-01 05110800000023 0002 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
1	Fail	AA99122-01 05110800000024 0002 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
1	Fail	AA99122-01 05110800000025 0002 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
1	Fail	AA99122-01 05110800000026 0002 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
1	Fail	AA99122-01 05110800000027 0002 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
1	Fail	AA99122-01 05110800000028 0002 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1
1	Fail	AA99122-01 05110800000029 0002 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
1	Fail	AA99122-01 05110800000030 0002 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
1	Fail	AA99122-01 05110800000031 0002 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
1	Fail	AA99122-01 05110800000032 0002 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
1	Fail	AA99122-01 05110800000001 0002 CC P2 PRE DAY3 / Day 3 0h -15m PL-1
1	Fail	AA99122-01 05110800000002 0002 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
1	AAR/Fail	AA99122-01 05110800000003 0002 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
1	AAR/Fail	AA99122-01 05110800000004 0002 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
1	AAR/Fail	AA99122-01 05110800000005 0002 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
1	AAR/Fail	AA99122-01 05110800000006 0002 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
1	Fail	AA99122-01 05110800000007 0002 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
1	Fail	AA99122-01 05110800000008 0002 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
1	Fail	AA99122-01 05110800000009 0002 CC P2 T8 DAY3 / Day 3 0h 45m PL-1
1	Fail	AA99122-01 05110800000010 0002 CC P2 T9 DAY3 / Day 3 1h 0m PL-1
1	Fail	AA99122-01 05110800000011 0002 CC P2 T10 DAY3 / Day 3 2h 0m PL-1
1	Fail	AA99122-01 05110800000012 0002 CC P2 T11 DAY3 / Day 3 4h 0m PL-1
1	Fail	AA99122-01 05110800000013 0002 CC P2 T12 DAY3 / Day 3 6h 0m PL-1
1	Fail	AA99122-01 05110800000014 0002 CC P2 T13 DAY3 / Day 3 9h 0m PL-1
1	Fail	AA99122-01 05110800000015 0002 CC P2 T14 DAY3 / Day 3 12h 0m PL-1
1	Fail	AA99122-01 05110800000016 0002 CC P2 T15 DAY3 / Day 3 24h 0m PL-1
1	Fail	AA99122-01 05110800000081 0004 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
1	Fail	AA99122-01 05110800000082 0004 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
1	Fail	AA99122-01 05110800000083 0004 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
1	Fail	AA99122-01 05110800000084 0004 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
1	Fail	AA99122-01 05110800000085 0004 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
1	Fail	AA99122-01 05110800000086 0004 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
1	Fail	AA99122-01 05110800000087 0004 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1

Run ID	Reason	Sample Name
1	Fail	AA99122-01 05110800000088 0004 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
1	Fail	AA99122-01 05110800000089 0004 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
1	Fail	AA99122-01 05110800000090 0004 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
1	Fail	AA99122-01 05110800000091 0004 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
1	Fail	AA99122-01 05110800000092 0004 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1
1	Fail	AA99122-01 05110800000093 0004 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
1	Fail	AA99122-01 05110800000094 0004 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
1	Fail	AA99122-01 05110800000095 0004 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
1	Fail	AA99122-01 05110800000096 0004 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
1	Fail	AA99122-01 05110800000065 0004 NRT gum P2 PRE DAY3 / Day 3 0h -15m PL-1
1	Fail	AA99122-01 05110800000066 0004 NRT gum P2 T1 DAY3 / Day 3 0h 10m PL-1
1	Fail	AA99122-01 05110800000067 0004 NRT gum P2 T2 DAY3 / Day 3 0h 20m PL-1
1	Fail	AA99122-01 05110800000068 0004 NRT gum P2 T3 DAY3 / Day 3 0h 25m PL-1
1	Fail	AA99122-01 05110800000069 0004 NRT gum P2 T4 DAY3 / Day 3 0h 30m PL-1
1	Fail	AA99122-01 05110800000070 0004 NRT gum P2 T5 DAY3 / Day 3 0h 35m PL-1
1	Fail	AA99122-01 05110800000071 0004 NRT gum P2 T6 DAY3 / Day 3 0h 40m PL-1
1	Fail	AA99122-01 05110800000072 0004 NRT gum P2 T7 DAY3 / Day 3 0h 45m PL-1
1	Fail	AA99122-01 05110800000073 0004 NRT gum P2 T8 DAY3 / Day 3 1h 0m PL-1
1	Fail	AA99122-01 05110800000074 0004 NRT gum P2 T9 DAY3 / Day 3 2h 0m PL-1
1	Fail	AA99122-01 05110800000075 0004 NRT gum P2 T10 DAY3 / Day 3 3h 0m PL-1
1	Fail	AA99122-01 05110800000076 0004 NRT gum P2 T11 DAY3 / Day 3 4h 0m PL-1
1	Fail	AA99122-01 05110800000077 0004 NRT gum P2 T12 DAY3 / Day 3 6h 0m PL-1
1	Fail	AA99122-01 05110800000078 0004 NRT gum P2 T13 DAY3 / Day 3 9h 0m PL-1
1	Fail	AA99122-01 05110800000079 0004 NRT gum P2 T14 DAY3 / Day 3 12h 0m PL-1
1	Fail	AA99122-01 05110800000080 0004 NRT gum P2 T15 DAY3 / Day 3 24h 0m PL-1
1	Fail	AA99122-01 05110800000145 0005 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
1	Fail	AA99122-01 05110800000146 0005 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
1	AAR/Fail	AA99122-01 05110800000147 0005 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
1	AAR/Fail	AA99122-01 05110800000148 0005 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
1	Fail	AA99122-01 05110800000149 0005 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
1	Fail	AA99122-01 05110800000150 0005 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
1	Fail	AA99122-01 05110800000151 0005 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
1	Fail	AA99122-01 05110800000152 0005 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
1	Fail	AA99122-01 05110800000153 0005 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
1	Fail	AA99122-01 05110800000154 0005 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
1	Fail	AA99122-01 05110800000155 0005 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
1	Fail	AA99122-01 05110800000156 0005 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1
1	Fail	AA99122-01 05110800000157 0005 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
1	Fail	AA99122-01 05110800000158 0005 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
1	Fail	AA99122-01 05110800000159 0005 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
1	Fail	AA99122-01 05110800000160 0005 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
1	Fail	AA99122-01 05110800000129 0005 CC P2 PRE DAY3 / Day 3 0h -15m PL-1
1	AAR/Fail	AA99122-01 05110800000130 0005 CC P2 T1 DAY3 / Day 3 0h 2m PL-1



Run ID	Reason	Sample Name
1	AAR/Fail	AA99122-01 05110800000131 0005 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
1	AAR/Fail	AA99122-01 05110800000132 0005 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
1	AAR/Fail	AA99122-01 05110800000133 0005 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
1	AAR/Fail	AA99122-01 05110800000134 0005 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
1	Fail	AA99122-01 05110800000135 0005 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
1	Fail	AA99122-01 05110800000136 0005 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
1	Fail	AA99122-01 05110800000137 0005 CC P2 T8 DAY3 / Day 3 0h 45m PL-1
1	Fail	AA99122-01 05110800000138 0005 CC P2 T9 DAY3 / Day 3 1h 0m PL-1
1	Fail	AA99122-01 05110800000139 0005 CC P2 T10 DAY3 / Day 3 2h 0m PL-1
1	Fail	AA99122-01 05110800000140 0005 CC P2 T11 DAY3 / Day 3 4h 0m PL-1
1	Fail	AA99122-01 05110800000141 0005 CC P2 T12 DAY3 / Day 3 6h 0m PL-1
1	Fail	AA99122-01 05110800000142 0005 CC P2 T13 DAY3 / Day 3 9h 0m PL-1
1	Fail	AA99122-01 05110800000143 0005 CC P2 T14 DAY3 / Day 3 12h 0m PL-1
1	Fail	AA99122-01 05110800000144 0005 CC P2 T15 DAY3 / Day 3 24h 0m PL-1
1	Fail	AA99122-01 05110800000049 0010 CC P1 PRE DAY1 / Day 1 0h -15m PL-1
1	Fail	AA99122-01 05110800000050 0010 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
1	Fail	AA99122-01 05110800000051 0010 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
1	Fail	AA99122-01 05110800000052 0010 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
1	Fail	AA99122-01 05110800000053 0010 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
1	Fail	AA99122-01 05110800000054 0010 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
1	Fail	AA99122-01 05110800000055 0010 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
1	Fail	AA99122-01 05110800000056 0010 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
1	Fail	AA99122-01 05110800000057 0010 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
1	Fail	AA99122-01 05110800000058 0010 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
1	Fail	AA99122-01 05110800000059 0010 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
1	Fail	AA99122-01 05110800000060 0010 CC P1 T11 DAY1 / Day 1 4h 0m PL-1
1	Fail	AA99122-01 05110800000061 0010 CC P1 T12 DAY1 / Day 1 6h 0m PL-1
1	Fail	AA99122-01 05110800000062 0010 CC P1 T13 DAY1 / Day 1 9h 0m PL-1
1	Fail	AA99122-01 05110800000063 0010 CC P1 T14 DAY1 / Day 1 12h 0m PL-1
1	Fail	AA99122-01 05110800000064 0010 CC P1 T15 DAY1 / Day 1 24h 0m PL-1
1	Fail	AA99122-01 05110800000033 0010 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
1	Fail	AA99122-01 05110800000034 0010 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
1	AAR/Fail	AA99122-01 05110800000035 0010 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
1	AAR/Fail	AA99122-01 05110800000036 0010 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
1	AAR/Fail	AA99122-01 05110800000037 0010 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
1	Fail	AA99122-01 05110800000038 0010 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
1	Fail	AA99122-01 05110800000039 0010 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
1	Fail	AA99122-01 05110800000040 0010 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
1	Fail	AA99122-01 05110800000041 0010 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
1	Fail	AA99122-01 05110800000042 0010 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
1	Fail	AA99122-01 05110800000043 0010 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
1	Fail	AA99122-01 05110800000044 0010 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
1	Fail	AA99122-01 05110800000045 0010 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1



Run ID	Reason	Sample Name
1	Fail	AA99122-01 05110800000046 0010 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
1	Fail	AA99122-01 05110800000047 0010 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
1	Fail	AA99122-01 05110800000048 0010 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
1	Fail	AA99122-01 05110800001009 0073 CC P1 PRE DAY1 / Day 1 0h -15m PL-1
1	Fail	AA99122-01 05110800001010 0073 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
1	Fail	AA99122-01 05110800001011 0073 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
1	Fail	AA99122-01 05110800001012 0073 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
1	Fail	AA99122-01 05110800001013 0073 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
1	Fail	AA99122-01 05110800001014 0073 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
1	Fail	AA99122-01 05110800001015 0073 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
1	Fail	AA99122-01 05110800001016 0073 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
1	Fail	AA99122-01 05110800001017 0073 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
1	Fail	AA99122-01 05110800001018 0073 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
1	Fail	AA99122-01 05110800001019 0073 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
1	Fail	AA99122-01 05110800001020 0073 CC P1 T11 DAY1 / Day 1 4h 0m PL-1
1	Fail	AA99122-01 05110800001021 0073 CC P1 T12 DAY1 / Day 1 6h 0m PL-1
1	Fail	AA99122-01 05110800001022 0073 CC P1 T13 DAY1 / Day 1 9h 0m PL-1
1	Fail	AA99122-01 05110800001023 0073 CC P1 T14 DAY1 / Day 1 12h 0m PL-1
1	Fail	AA99122-01 05110800001024 0073 CC P1 T15 DAY1 / Day 1 24h 0m PL-1
2	AAR	AA99122-01 05110800000372 0013 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
2	AAR	AA99122-01 05110800000373 0013 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
2	AAR	AA99122-01 05110800000374 0013 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
2	AAR	AA99122-01 05110800000355 0013 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
2	AAR	AA99122-01 05110800000356 0013 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
2	AAR	AA99122-01 05110800000357 0013 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
2	AAR	AA99122-01 05110800000358 0013 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
2	AAR	AA99122-01 05110800000359 0013 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
2	AAR	AA99122-01 05110800000360 0013 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
2	AAR	AA99122-01 05110800000594 0018 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
2	AAR	AA99122-01 05110800000595 0018 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
2	AAR	AA99122-01 05110800000596 0018 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
2	AAR	AA99122-01 05110800000597 0018 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
2	AAR	AA99122-01 05110800000598 0018 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
2	AAR	AA99122-01 05110800000599 0018 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
5	AAR	AA99122-01 05110800000499 0043 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
5	AAR	AA99122-01 05110800000500 0043 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
5	AAR	AA99122-01 05110800000501 0043 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
5	AAR	AA99122-01 05110800000485 0043 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
5	AAR	AA99122-01 05110800000486 0043 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
5	AAR	AA99122-01 05110800000276 0045 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
5	AAR	AA99122-01 05110800000277 0045 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
5	AAR	AA99122-01 05110800000278 0045 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
5	AAR	AA99122-01 05110800000259 0045 CC P2 T2 DAY3 / Day 3 0h 4m PL-1

Run ID	Reason	Sample Name
5	AAR	AA99122-01 05110800000260 0045 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
5	AAR	AA99122-01 05110800000261 0045 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
5	AAR	AA99122-01 05110800000262 0045 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
5	AAR	AA99122-01 05110800000307 0049 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
5	AAR	AA99122-01 05110800000308 0049 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
5	AAR	AA99122-01 05110800000296 0049 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
5	AAR	AA99122-01 05110800000532 0050 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
5	AAR	AA99122-01 05110800000515 0050 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
5	AAR	AA99122-01 05110800000516 0050 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
5	AAR	AA99122-01 05110800000517 0050 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
6	AAR	AA99122-01 05110800000343 0052 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
6	AAR	AA99122-01 05110800001176 0063 NRT gum P1 T7 DAY1 / Day 1 0h 45m PL-1
7	AAR	AA99122-01 05110800001075 0061 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
7	AAR	AA99122-01 05110800000739 0066 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
7	AAR	AA99122-01 05110800000740 0066 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
7	AAR	AA99122-01 05110800000741 0066 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
7	AAR	AA99122-01 05110800000742 0066 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
7	AAR	AA99122-01 05110800000743 0066 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
7	DCU	AA99122-01 05110800000684 0022 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
7	DCU	AA99122-01 05110800000685 0022 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
7	DCU	AA99122-01 05110800000686 0022 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
7	DCU	AA99122-01 05110800000687 0022 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
7	DCU	AA99122-01 05110800000688 0022 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
8	AAR	AA99122-01 05110800000179 0024 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
8	AAR	AA99122-01 05110800000180 0024 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
8	AAR	AA99122-01 05110800000181 0024 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
8	AAR	AA99122-01 05110800000182 0024 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
8	AAR	AA99122-01 05110800000163 0024 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
8	AAR	AA99122-01 05110800000164 0024 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
8	AAR	AA99122-01 05110800000165 0024 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
8	AAR	AA99122-01 05110800000403 0025 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
8	AAR	AA99122-01 05110800000404 0025 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
8	AAR	AA99122-01 05110800000405 0025 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
8	AAR	AA99122-01 05110800000406 0025 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
8	AAR	AA99122-01 05110800000407 0025 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
8	AAR	AA99122-01 05110800000387 0025 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
8	AAR	AA99122-01 05110800000388 0025 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
8	AAR	AA99122-01 05110800000389 0025 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
8	AAR	AA99122-01 05110800000390 0025 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
8	AAR	AA99122-01 05110800000211 0027 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
8	AAR	AA99122-01 05110800000212 0027 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
8	AAR	AA99122-01 05110800000213 0027 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
8	AAR	AA99122-01 05110800000214 0027 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1

Run ID	Reason	Sample Name
8	AAR	AA99122-01 05110800000196 0027 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
8	AAR	AA99122-01 05110800000197 0027 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
8	AAR	AA99122-01 05110800000198 0027 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
8	AAR	AA99122-01 05110800000437 0031 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
8	AAR	AA99122-01 05110800000438 0031 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
8	AAR	AA99122-01 05110800000439 0031 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
8	AAR	AA99122-01 05110800000420 0031 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
8	AAR	AA99122-01 05110800000421 0031 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
8	AAR	AA99122-01 05110800000422 0031 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
8	AAR	AA99122-01 05110800000423 0031 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
9	AAR	AA99122-01 05110800000627 0036 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
9	AAR	AA99122-01 05110800000628 0036 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
9	AAR	AA99122-01 05110800000629 0036 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
9	AAR	AA99122-01 05110800000630 0036 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
9	AAR	AA99122-01 05110800000242 0039 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
9	AAR	AA99122-01 05110800000243 0039 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
9	AAR	AA99122-01 05110800000244 0039 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
9	AAR	AA99122-01 05110800000245 0039 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
9	AAR	AA99122-01 05110800000246 0039 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
10	AAR	AA99122-01 05110800000149 0005 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
10	AAR	AA99122-01 05110800000054 0010 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
10	UISR	AA99122-01 05110800000055 0010 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
11	AAR	AA99122-01 05110800000946 0067 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
11	AAR	AA99122-01 05110800000947 0067 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
11	AAR	AA99122-01 05110800000948 0067 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
11	AAR	AA99122-01 05110800000949 0067 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
11	AAR	AA99122-01 05110800000950 0067 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
11	AAR	AA99122-01 05110800000951 0067 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
11	AAR	AA99122-01 05110800000952 0067 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
11	AAR	AA99122-01 05110800000953 0067 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
11	AAR	AA99122-01 05110800000979 0070 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
11	AAR	AA99122-01 05110800000980 0070 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
11	AAR	AA99122-01 05110800000787 0071 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
11	AAR	AA99122-01 05110800000819 0074 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
11	AAR	AA99122-01 05110800000821 0074 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
11	AAR	AA99122-01 05110800000822 0074 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
11	AAR	AA99122-01 05110800000823 0074 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
11	AAR	AA99122-01 05110800000824 0074 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
11	AAR	AA99122-01 05110800000825 0074 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
11	AAR	AA99122-01 05110800000802 0074 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
11	AAR	AA99122-01 05110800000803 0074 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
11	AAR	AA99122-01 05110800000804 0074 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
12	AAR	AA99122-01 051108000001042 0075 CC P1 T1 DAY1 / Day 1 0h 2m PL-1

Run ID	Reason	Sample Name
12	AAR	AA99122-01 05110800001043 0075 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
12	AAR	AA99122-01 05110800001044 0075 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
12	AAR	AA99122-01 05110800001045 0075 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
12	AAR	AA99122-01 05110800001046 0075 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
12	AAR	AA99122-01 05110800000883 0082 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
12	AAR	AA99122-01 05110800000884 0082 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
12	AAR	AA99122-01 05110800000885 0082 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
12	AAR	AA99122-01 05110800000886 0082 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
12	AAR	AA99122-01 05110800000887 0082 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
12	AAR	AA99122-01 05110800000866 0082 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
12	AAR	AA99122-01 05110800000867 0082 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
12	AAR	AA99122-01 05110800000868 0082 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
12	AAR	AA99122-01 05110800000869 0082 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
14	AAR	AA99122-01 05110800002867 0093 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
14	AAR	AA99122-01 05110800002868 0093 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
14	AAR	AA99122-01 05110800003059 0095 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
14	AAR	AA99122-01 05110800002547 0097 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
14	AAR	AA99122-01 05110800002515 0097 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
14	AAR	AA99122-01 05110800002930 0102 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
14	AAR	AA99122-01 05110800002931 0102 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
14	AAR	AA99122-01 05110800002932 0102 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
14	AAR	AA99122-01 05110800002933 0102 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
14	AAR	AA99122-01 05110800002934 0102 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
14	AAR	AA99122-01 05110800002898 0102 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
14	AAR	AA99122-01 05110800002899 0102 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
14	AAR	AA99122-01 05110800002900 0102 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
14	AAR	AA99122-01 05110800002901 0102 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
14	AAR	AA99122-01 05110800002902 0102 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
14	AAR	AA99122-01 05110800002903 0102 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
14	AAR	AA99122-01 05110800002904 0102 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
14	AAR	AA99122-01 05110800002905 0102 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
14	AAR	AA99122-01 05110800002906 0102 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
14	AAR	AA99122-01 05110800002907 0102 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
16	AAR	AA99122-01 05110800003828 0123 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
16	AAR	AA99122-01 05110800003186 0128 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
16	AAR	AA99122-01 05110800003187 0128 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
16	AAR	AA99122-01 05110800003188 0128 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
16	AAR	AA99122-01 05110800003189 0128 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
16	AAR	AA99122-01 05110800003190 0128 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
16	AAR	AA99122-01 05110800003191 0128 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
16	AAR	AA99122-01 05110800003192 0128 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
16	AAR	AA99122-01 05110800003194 0128 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003953 0132 NRT gum P1 PRE DAY1 / Day 1 0h -15m PL-1



Run ID	Reason	Sample Name
17	Fail	AA99122-01 05110800003954 0132 NRT gum P1 T1 DAY1 / Day 1 0h 10m PL-1
17	Fail	AA99122-01 05110800003955 0132 NRT gum P1 T2 DAY1 / Day 1 0h 20m PL-1
17	Fail	AA99122-01 05110800003956 0132 NRT gum P1 T3 DAY1 / Day 1 0h 25m PL-1
17	Fail	AA99122-01 05110800003957 0132 NRT gum P1 T4 DAY1 / Day 1 0h 30m PL-1
17	Fail	AA99122-01 05110800003958 0132 NRT gum P1 T5 DAY1 / Day 1 0h 35m PL-1
17	Fail	AA99122-01 05110800003959 0132 NRT gum P1 T6 DAY1 / Day 1 0h 40m PL-1
17	Fail	AA99122-01 05110800003960 0132 NRT gum P1 T7 DAY1 / Day 1 0h 45m PL-1
17	Fail	AA99122-01 05110800003961 0132 NRT gum P1 T8 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003962 0132 NRT gum P1 T9 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003963 0132 NRT gum P1 T10 DAY1 / Day 1 3h 0m PL-1
17	Fail	AA99122-01 05110800003964 0132 NRT gum P1 T11 DAY1 / Day 1 4h 0m PL-1
17	Fail	AA99122-01 05110800003965 0132 NRT gum P1 T12 DAY1 / Day 1 6h 0m PL-1
17	Fail	AA99122-01 05110800003966 0132 NRT gum P1 T13 DAY1 / Day 1 9h 0m PL-1
17	Fail	AA99122-01 05110800003967 0132 NRT gum P1 T14 DAY1 / Day 1 12h 0m PL-1
17	Fail	AA99122-01 05110800003968 0132 NRT gum P1 T15 DAY1 / Day 1 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003921 0132 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
17	Fail	AA99122-01 05110800003922 0132 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
17	Fail	AA99122-01 05110800003923 0132 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
17	Fail	AA99122-01 05110800003924 0132 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
17	Fail	AA99122-01 05110800003925 0132 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
17	Fail	AA99122-01 05110800003926 0132 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
17	AAR/Fail	AA99122-01 05110800003927 0132 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
17	Fail	AA99122-01 05110800003928 0132 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
17	Fail	AA99122-01 05110800003929 0132 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
17	Fail	AA99122-01 05110800003930 0132 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
17	Fail	AA99122-01 05110800003931 0132 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
17	Fail	AA99122-01 05110800003932 0132 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
17	Fail	AA99122-01 05110800003933 0132 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
17	Fail	AA99122-01 05110800003934 0132 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
17	Fail	AA99122-01 05110800003935 0132 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003936 0132 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003249 0134 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
17	LSR/Fail	AA99122-01 05110800003250 0134 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
17	Fail	AA99122-01 05110800003251 0134 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
17	Fail	AA99122-01 05110800003252 0134 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
17	Fail	AA99122-01 05110800003253 0134 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
17	Fail	AA99122-01 05110800003254 0134 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
17	Fail	AA99122-01 05110800003255 0134 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
17	Fail	AA99122-01 05110800003256 0134 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
17	Fail	AA99122-01 05110800003257 0134 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
17	Fail	AA99122-01 05110800003258 0134 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003259 0134 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
17	Fail	AA99122-01 05110800003260 0134 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1

Run ID	Reason	Sample Name
17	Fail	AA99122-01 05110800003261 0134 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
17	Fail	AA99122-01 05110800003262 0134 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
17	Fail	AA99122-01 05110800003263 0134 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003264 0134 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003217 0134 CC P2 PRE DAY3 / Day 3 0h -15m PL-1
17	Fail	AA99122-01 05110800003218 0134 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
17	Fail	AA99122-01 05110800003219 0134 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
17	Fail	AA99122-01 05110800003220 0134 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
17	Fail	AA99122-01 05110800003221 0134 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
17	Fail	AA99122-01 05110800003222 0134 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
17	Fail	AA99122-01 05110800003223 0134 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
17	Fail	AA99122-01 05110800003224 0134 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
17	Fail	AA99122-01 05110800003225 0134 CC P2 T8 DAY3 / Day 3 0h 45m PL-1
17	Fail	AA99122-01 05110800003226 0134 CC P2 T9 DAY3 / Day 3 1h 0m PL-1
17	Fail	AA99122-01 05110800003227 0134 CC P2 T10 DAY3 / Day 3 2h 0m PL-1
17	Fail	AA99122-01 05110800003228 0134 CC P2 T11 DAY3 / Day 3 4h 0m PL-1
17	Fail	AA99122-01 05110800003229 0134 CC P2 T12 DAY3 / Day 3 6h 0m PL-1
17	Fail	AA99122-01 05110800003230 0134 CC P2 T13 DAY3 / Day 3 9h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003231 0134 CC P2 T14 DAY3 / Day 3 12h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003232 0134 CC P2 T15 DAY3 / Day 3 24h 0m PL-1
17	Fail	AA99122-01 05110800003569 0135 CC P1 PRE DAY1 / Day 1 0h -15m PL-1
17	AAR/Fail	AA99122-01 05110800003570 0135 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
17	AAR/Fail	AA99122-01 05110800003571 0135 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
17	AAR/Fail	AA99122-01 05110800003572 0135 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
17	AAR/Fail	AA99122-01 05110800003573 0135 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
17	AAR/Fail	AA99122-01 05110800003574 0135 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
17	AAR/Fail	AA99122-01 05110800003575 0135 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
17	AAR/Fail	AA99122-01 05110800003576 0135 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
17	AAR/Fail	AA99122-01 05110800003577 0135 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
17	AAR/Fail	AA99122-01 05110800003578 0135 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003579 0135 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
17	Fail	AA99122-01 05110800003580 0135 CC P1 T11 DAY1 / Day 1 4h 0m PL-1
17	Fail	AA99122-01 05110800003581 0135 CC P1 T12 DAY1 / Day 1 6h 0m PL-1
17	Fail	AA99122-01 05110800003582 0135 CC P1 T13 DAY1 / Day 1 9h 0m PL-1
17	Fail	AA99122-01 05110800003583 0135 CC P1 T14 DAY1 / Day 1 12h 0m PL-1
17	Fail	AA99122-01 05110800003584 0135 CC P1 T15 DAY1 / Day 1 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003537 0135 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
17	AAR/Fail	AA99122-01 05110800003538 0135 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
17	AAR/Fail	AA99122-01 05110800003539 0135 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
17	AAR/Fail	AA99122-01 05110800003540 0135 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
17	AAR/Fail	AA99122-01 05110800003541 0135 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
17	AAR/Fail	AA99122-01 05110800003542 0135 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
17	AAR/Fail	AA99122-01 05110800003543 0135 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1

Run ID	Reason	Sample Name
17	AAR/Fail	AA99122-01 05110800003544 0135 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
17	Fail	AA99122-01 05110800003545 0135 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
17	Fail	AA99122-01 05110800003546 0135 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
17	Fail	AA99122-01 05110800003547 0135 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
17	Fail	AA99122-01 05110800003548 0135 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
17	Fail	AA99122-01 05110800003549 0135 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
17	Fail	AA99122-01 05110800003550 0135 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
17	Fail	AA99122-01 05110800003551 0135 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
17	Fail	AA99122-01 05110800003552 0135 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003313 0136 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
17	Fail	AA99122-01 05110800003314 0136 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
17	Fail	AA99122-01 05110800003315 0136 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
17	Fail	AA99122-01 05110800003316 0136 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
17	Fail	AA99122-01 05110800003317 0136 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
17	Fail	AA99122-01 05110800003318 0136 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
17	Fail	AA99122-01 05110800003319 0136 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
17	Fail	AA99122-01 05110800003320 0136 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
17	Fail	AA99122-01 05110800003321 0136 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
17	Fail	AA99122-01 05110800003322 0136 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
17	Fail	AA99122-01 05110800003323 0136 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
17	Fail	AA99122-01 05110800003324 0136 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1
17	Fail	AA99122-01 05110800003325 0136 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003326 0136 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003327 0136 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003328 0136 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003281 0136 CC P2 PRE DAY3 / Day 3 0h -15m PL-1
17	LSR/Fail	AA99122-01 05110800003282 0136 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
17	Fail	AA99122-01 05110800003283 0136 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
17	Fail	AA99122-01 05110800003284 0136 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
17	Fail	AA99122-01 05110800003285 0136 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
17	Fail	AA99122-01 05110800003286 0136 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
17	Fail	AA99122-01 05110800003287 0136 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
17	Fail	AA99122-01 05110800003288 0136 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
17	Fail	AA99122-01 05110800003289 0136 CC P2 T8 DAY3 / Day 3 0h 45m PL-1
17	Fail	AA99122-01 05110800003290 0136 CC P2 T9 DAY3 / Day 3 1h 0m PL-1
17	Fail	AA99122-01 05110800003291 0136 CC P2 T10 DAY3 / Day 3 2h 0m PL-1
17	LSR/Fail	AA99122-01 05110800003292 0136 CC P2 T11 DAY3 / Day 3 4h 0m PL-1
17	LSR	AA99122-01 05110800003293 0136 CC P2 T12 DAY3 / Day 3 6h 0m PL-1
17	LSR	AA99122-01 05110800003294 0136 CC P2 T13 DAY3 / Day 3 9h 0m PL-1
17	LSR	AA99122-01 05110800003295 0136 CC P2 T14 DAY3 / Day 3 12h 0m PL-1
17	LSR	AA99122-01 05110800003296 0136 CC P2 T15 DAY3 / Day 3 24h 0m PL-1
18	AAR	AA99122-01 05110800003702 0140 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
18	AAR	AA99122-01 05110800003703 0140 CC P1 T6 DAY1 / Day 1 0h 15m PL-1



Run ID	Reason	Sample Name
18	AAR	AA99122-01 05110800003704 0140 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
18	AAR	AA99122-01 05110800003705 0140 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
18	AAR	AA99122-01 05110800003706 0140 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
18	AAR	AA99122-01 05110800003707 0140 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
20	Fail	AA99122-01 05110800001233 0083 NRT gum P1 PRE DAY1 / Day 1 0h -15m PL-1
20	Fail	AA99122-01 05110800001234 0083 NRT gum P1 T1 DAY1 / Day 1 0h 10m PL-1
20	Fail	AA99122-01 05110800001235 0083 NRT gum P1 T2 DAY1 / Day 1 0h 20m PL-1
20	Fail	AA99122-01 05110800001236 0083 NRT gum P1 T3 DAY1 / Day 1 0h 25m PL-1
20	Fail	AA99122-01 05110800001237 0083 NRT gum P1 T4 DAY1 / Day 1 0h 30m PL-1
20	Fail	AA99122-01 05110800001238 0083 NRT gum P1 T5 DAY1 / Day 1 0h 35m PL-1
20	Fail	AA99122-01 05110800001239 0083 NRT gum P1 T6 DAY1 / Day 1 0h 40m PL-1
20	Fail	AA99122-01 05110800001240 0083 NRT gum P1 T7 DAY1 / Day 1 0h 45m PL-1
20	AAR/Fail	AA99122-01 05110800001241 0083 NRT gum P1 T8 DAY1 / Day 1 1h 0m PL-1
20	Fail	AA99122-01 05110800001242 0083 NRT gum P1 T9 DAY1 / Day 1 2h 0m PL-1
20	Fail	AA99122-01 05110800001243 0083 NRT gum P1 T10 DAY1 / Day 1 3h 0m PL-1
20	Fail	AA99122-01 05110800001244 0083 NRT gum P1 T11 DAY1 / Day 1 4h 0m PL-1
20	Fail	AA99122-01 05110800001245 0083 NRT gum P1 T12 DAY1 / Day 1 6h 0m PL-1
20	Fail	AA99122-01 05110800001246 0083 NRT gum P1 T13 DAY1 / Day 1 9h 0m PL-1
20	Fail	AA99122-01 05110800001247 0083 NRT gum P1 T14 DAY1 / Day 1 12h 0m PL-1
20	Fail	AA99122-01 05110800001248 0083 NRT gum P1 T15 DAY1 / Day 1 24h 0m PL-1
20	Fail	AA99122-01 05110800001217 0083 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
20	Fail	AA99122-01 05110800001218 0083 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
20	Fail	AA99122-01 05110800001219 0083 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
20	Fail	AA99122-01 05110800001220 0083 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
20	Fail	AA99122-01 05110800001221 0083 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
20	Fail	AA99122-01 05110800001222 0083 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
20	Fail	AA99122-01 05110800001223 0083 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
20	Fail	AA99122-01 05110800001224 0083 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
20	Fail	AA99122-01 05110800001225 0083 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
20	Fail	AA99122-01 05110800001226 0083 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
20	Fail	AA99122-01 05110800001227 0083 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
20	Fail	AA99122-01 05110800001228 0083 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
20	Fail	AA99122-01 05110800001229 0083 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
20	Fail	AA99122-01 05110800001230 0083 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
20	Fail	AA99122-01 05110800001231 0083 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
20	Fail	AA99122-01 05110800001232 0083 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
20	Fail	AA99122-01 05110800000913 0084 THS 2.2 P1 PRE DAY1 / Day 1 0h -15m PL-1
20	Fail	AA99122-01 05110800000914 0084 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
20	Fail	AA99122-01 05110800000915 0084 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
20	Fail	AA99122-01 05110800000916 0084 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
20	Fail	AA99122-01 05110800000917 0084 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
20	Fail	AA99122-01 05110800000918 0084 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
20	Fail	AA99122-01 05110800000919 0084 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1

Run ID	Reason	Sample Name
20	Fail	AA99122-01 05110800000920 0084 THS 2.2 P1 T7 DAY1 / Day 1 0h 30m PL-1
20	Fail	AA99122-01 05110800000921 0084 THS 2.2 P1 T8 DAY1 / Day 1 0h 45m PL-1
20	Fail	AA99122-01 05110800000922 0084 THS 2.2 P1 T9 DAY1 / Day 1 1h 0m PL-1
20	Fail	AA99122-01 05110800000923 0084 THS 2.2 P1 T10 DAY1 / Day 1 2h 0m PL-1
20	Fail	AA99122-01 05110800000924 0084 THS 2.2 P1 T11 DAY1 / Day 1 4h 0m PL-1
20	Fail	AA99122-01 05110800000925 0084 THS 2.2 P1 T12 DAY1 / Day 1 6h 0m PL-1
20	Fail	AA99122-01 05110800000926 0084 THS 2.2 P1 T13 DAY1 / Day 1 9h 0m PL-1
20	AAR/Fail	AA99122-01 05110800000927 0084 THS 2.2 P1 T14 DAY1 / Day 1 12h 0m PL-1
20	Fail	AA99122-01 05110800000928 0084 THS 2.2 P1 T15 DAY1 / Day 1 24h 0m PL-1
20	Fail	AA99122-01 05110800000897 0084 CC P2 PRE DAY3 / Day 3 0h -15m PL-1
20	Fail	AA99122-01 05110800000898 0084 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
20	Fail	AA99122-01 05110800000899 0084 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
20	Fail	AA99122-01 05110800000900 0084 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
20	Fail	AA99122-01 05110800000901 0084 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
20	AAR/Fail	AA99122-01 05110800000902 0084 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
20	Fail	AA99122-01 05110800000903 0084 CC P2 T6 DAY3 / Day 3 0h 15m PL-1
20	Fail	AA99122-01 05110800000904 0084 CC P2 T7 DAY3 / Day 3 0h 30m PL-1
20	Fail	AA99122-01 05110800000905 0084 CC P2 T8 DAY3 / Day 3 0h 45m PL-1
20	Fail	AA99122-01 05110800000906 0084 CC P2 T9 DAY3 / Day 3 1h 0m PL-1
20	Fail	AA99122-01 05110800000907 0084 CC P2 T10 DAY3 / Day 3 2h 0m PL-1
20	Fail	AA99122-01 05110800000908 0084 CC P2 T11 DAY3 / Day 3 4h 0m PL-1
20	Fail	AA99122-01 05110800000909 0084 CC P2 T12 DAY3 / Day 3 6h 0m PL-1
20	Fail	AA99122-01 05110800000910 0084 CC P2 T13 DAY3 / Day 3 9h 0m PL-1
20	Fail	AA99122-01 05110800000911 0084 CC P2 T14 DAY3 / Day 3 12h 0m PL-1
20	Fail	AA99122-01 05110800000912 0084 CC P2 T15 DAY3 / Day 3 24h 0m PL-1
20	Fail	AA99122-01 05110800002737 0089 CC P1 PRE DAY1 / Day 1 0h -15m PL-1
20	Fail	AA99122-01 05110800002738 0089 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
20	Fail	AA99122-01 05110800002739 0089 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
20	Fail	AA99122-01 05110800002740 0089 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
20	Fail	AA99122-01 05110800002741 0089 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
20	Fail	AA99122-01 05110800002742 0089 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
20	Fail	AA99122-01 05110800002743 0089 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
20	Fail	AA99122-01 05110800002744 0089 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
20	Fail	AA99122-01 05110800002745 0089 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
20	Fail	AA99122-01 05110800002746 0089 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
20	Fail	AA99122-01 05110800002747 0089 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
20	Fail	AA99122-01 05110800002748 0089 CC P1 T11 DAY1 / Day 1 4h 0m PL-1
20	Fail	AA99122-01 05110800002749 0089 CC P1 T12 DAY1 / Day 1 6h 0m PL-1
20	Fail	AA99122-01 05110800002750 0089 CC P1 T13 DAY1 / Day 1 9h 0m PL-1
20	Fail	AA99122-01 05110800002751 0089 CC P1 T14 DAY1 / Day 1 12h 0m PL-1
20	Fail	AA99122-01 05110800002752 0089 CC P1 T15 DAY1 / Day 1 24h 0m PL-1
20	Fail	AA99122-01 05110800002705 0089 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
20	Fail	AA99122-01 05110800002706 0089 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1

Run ID	Reason	Sample Name
20	AAR/Fail	AA99122-01 05110800002707 0089 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
20	AAR/Fail	AA99122-01 05110800002708 0089 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
20	AAR/Fail	AA99122-01 05110800002709 0089 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
20	AAR/Fail	AA99122-01 05110800002710 0089 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
20	AAR/Fail	AA99122-01 05110800002711 0089 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
20	AAR/Fail	AA99122-01 05110800002712 0089 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
20	AAR/Fail	AA99122-01 05110800002713 0089 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
20	AAR/Fail	AA99122-01 05110800002714 0089 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
20	Fail	AA99122-01 05110800002715 0089 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
20	Fail	AA99122-01 05110800002716 0089 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
20	Fail	AA99122-01 05110800002717 0089 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
20	Fail	AA99122-01 05110800002718 0089 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
20	Fail	AA99122-01 05110800002719 0089 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
20	Fail	AA99122-01 05110800002720 0089 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
20	Fail	AA99122-01 05110800002801 0090 CC P1 PRE DAY1 / Day 1 0h -15m PL-1
20	Fail	AA99122-01 05110800002802 0090 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
20	Fail	AA99122-01 05110800002803 0090 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
20	Fail	AA99122-01 05110800002804 0090 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
20	Fail	AA99122-01 05110800002805 0090 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
20	Fail	AA99122-01 05110800002806 0090 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
20	Fail	AA99122-01 05110800002807 0090 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
20	Fail	AA99122-01 05110800002808 0090 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
20	Fail	AA99122-01 05110800002809 0090 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
20	Fail	AA99122-01 05110800002810 0090 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
20	Fail	AA99122-01 05110800002811 0090 CC P1 T10 DAY1 / Day 1 2h 0m PL-1
20	Fail	AA99122-01 05110800002812 0090 CC P1 T11 DAY1 / Day 1 4h 0m PL-1
20	Fail	AA99122-01 05110800002813 0090 CC P1 T12 DAY1 / Day 1 6h 0m PL-1
20	Fail	AA99122-01 05110800002814 0090 CC P1 T13 DAY1 / Day 1 9h 0m PL-1
20	Fail	AA99122-01 05110800002815 0090 CC P1 T14 DAY1 / Day 1 12h 0m PL-1
20	Fail	AA99122-01 05110800002816 0090 CC P1 T15 DAY1 / Day 1 24h 0m PL-1
20	Fail	AA99122-01 05110800002769 0090 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
20	Fail	AA99122-01 05110800002770 0090 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
20	Fail	AA99122-01 05110800002771 0090 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
20	Fail	AA99122-01 05110800002772 0090 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
20	Fail	AA99122-01 05110800002773 0090 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
20	Fail	AA99122-01 05110800002774 0090 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
20	Fail	AA99122-01 05110800002775 0090 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
20	Fail	AA99122-01 05110800002776 0090 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
20	Fail	AA99122-01 05110800002777 0090 THS 2.2 P2 T8 DAY3 / Day 3 0h 45m PL-1
20	Fail	AA99122-01 05110800002778 0090 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
20	Fail	AA99122-01 05110800002779 0090 THS 2.2 P2 T10 DAY3 / Day 3 2h 0m PL-1
20	Fail	AA99122-01 05110800002780 0090 THS 2.2 P2 T11 DAY3 / Day 3 4h 0m PL-1
20	Fail	AA99122-01 05110800002781 0090 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1

Run ID	Reason	Sample Name
20	Fail	AA99122-01 05110800002782 0090 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
20	Fail	AA99122-01 05110800002783 0090 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
20	Fail	AA99122-01 05110800002784 0090 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
21	AAR	AA99122-01 05110800002995 0105 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
21	AAR	AA99122-01 05110800002996 0105 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
21	AAR	AA99122-01 05110800002997 0105 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
21	AAR	AA99122-01 05110800002998 0105 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
21	AAR	AA99122-01 05110800002999 0105 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
21	AAR	AA99122-01 05110800002611 0107 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
21	AAR	AA99122-01 05110800002612 0107 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
21	AAR	AA99122-01 05110800002613 0107 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
21	AAR	AA99122-01 05110800002674 0113 THS 2.2 P1 T1 DAY1 / Day 1 0h 2m PL-1
21	AAR	AA99122-01 05110800002675 0113 THS 2.2 P1 T2 DAY1 / Day 1 0h 4m PL-1
21	AAR	AA99122-01 05110800002676 0113 THS 2.2 P1 T3 DAY1 / Day 1 0h 6m PL-1
21	AAR	AA99122-01 05110800002677 0113 THS 2.2 P1 T4 DAY1 / Day 1 0h 8m PL-1
21	AAR	AA99122-01 05110800002678 0113 THS 2.2 P1 T5 DAY1 / Day 1 0h 10m PL-1
21	AAR	AA99122-01 05110800002679 0113 THS 2.2 P1 T6 DAY1 / Day 1 0h 15m PL-1
21	AAR	AA99122-01 05110800002642 0113 CC P2 T1 DAY3 / Day 3 0h 2m PL-1
21	AAR	AA99122-01 05110800002643 0113 CC P2 T2 DAY3 / Day 3 0h 4m PL-1
21	AAR	AA99122-01 05110800002644 0113 CC P2 T3 DAY3 / Day 3 0h 6m PL-1
21	AAR	AA99122-01 05110800002645 0113 CC P2 T4 DAY3 / Day 3 0h 8m PL-1
21	AAR	AA99122-01 05110800002646 0113 CC P2 T5 DAY3 / Day 3 0h 10m PL-1
22	AAR	AA99122-01 05110800003961 0132 NRT gum P1 T8 DAY1 / Day 1 1h 0m PL-1
22	AAR	AA99122-01 05110800003927 0132 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
22	AAR	AA99122-01 05110800003570 0135 CC P1 T1 DAY1 / Day 1 0h 2m PL-1
22	AAR	AA99122-01 05110800003571 0135 CC P1 T2 DAY1 / Day 1 0h 4m PL-1
22	AAR	AA99122-01 05110800003572 0135 CC P1 T3 DAY1 / Day 1 0h 6m PL-1
22	AAR	AA99122-01 05110800003573 0135 CC P1 T4 DAY1 / Day 1 0h 8m PL-1
22	AAR	AA99122-01 05110800003574 0135 CC P1 T5 DAY1 / Day 1 0h 10m PL-1
22	AAR	AA99122-01 05110800003575 0135 CC P1 T6 DAY1 / Day 1 0h 15m PL-1
22	AAR	AA99122-01 05110800003576 0135 CC P1 T7 DAY1 / Day 1 0h 30m PL-1
22	AAR	AA99122-01 05110800003577 0135 CC P1 T8 DAY1 / Day 1 0h 45m PL-1
22	AAR	AA99122-01 05110800003578 0135 CC P1 T9 DAY1 / Day 1 1h 0m PL-1
22	AAR	AA99122-01 05110800003538 0135 THS 2.2 P2 T1 DAY3 / Day 3 0h 2m PL-1
22	AAR	AA99122-01 05110800003539 0135 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1
22	AAR	AA99122-01 05110800003540 0135 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
22	AAR	AA99122-01 05110800003541 0135 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
22	AAR	AA99122-01 05110800003542 0135 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
22	AAR	AA99122-01 05110800003543 0135 THS 2.2 P2 T6 DAY3 / Day 3 0h 15m PL-1
22	AAR	AA99122-01 05110800003544 0135 THS 2.2 P2 T7 DAY3 / Day 3 0h 30m PL-1
22	AAR	AA99122-01 05110800003546 0135 THS 2.2 P2 T9 DAY3 / Day 3 1h 0m PL-1
26	LSR	AA99122-01 05110800001121 0060 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
26	AAR	AA99122-01 05110800001123 0060 THS 2.2 P2 T2 DAY3 / Day 3 0h 4m PL-1

Run ID	Reason	Sample Name
26	AAR	AA99122-01 05110800001124 0060 THS 2.2 P2 T3 DAY3 / Day 3 0h 6m PL-1
26	AAR	AA99122-01 05110800001125 0060 THS 2.2 P2 T4 DAY3 / Day 3 0h 8m PL-1
26	AAR	AA99122-01 05110800001126 0060 THS 2.2 P2 T5 DAY3 / Day 3 0h 10m PL-1
26	LSR	AA99122-01 05110800001135 0060 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
26	LSR	AA99122-01 05110800001153 0063 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
26	LSR	AA99122-01 05110800001167 0063 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
26	LSR	AA99122-01 05110800001168 0063 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
26	LSR	AA99122-01 05110800001185 0072 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
26	LSR	AA99122-01 05110800001197 0072 THS 2.2 P2 T12 DAY3 / Day 3 6h 0m PL-1
26	LSR	AA99122-01 05110800001198 0072 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
26	LSR	AA99122-01 05110800001199 0072 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
26	LSR	AA99122-01 05110800001200 0072 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1
26	LSR	AA99122-01 05110800000993 0073 THS 2.2 P2 PRE DAY3 / Day 3 0h -15m PL-1
26	LSR	AA99122-01 05110800001006 0073 THS 2.2 P2 T13 DAY3 / Day 3 9h 0m PL-1
26	LSR	AA99122-01 05110800001007 0073 THS 2.2 P2 T14 DAY3 / Day 3 12h 0m PL-1
26	LSR	AA99122-01 05110800001008 0073 THS 2.2 P2 T15 DAY3 / Day 3 24h 0m PL-1



Table 7 Incurred Sample Reproducibility Assessment

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0002	2	Day 3 0h 45m	Nicotine	ng/mL	4.52	4.76	4.64	5.17	Pass	No	97.1
0002	1	Day 1 0h 6m	Nicotine	ng/mL	16.2	16.8	16.5	3.64	Pass	No	
0002	1	Day 1 6h 0m	Nicotine	ng/mL	0.631	0.719	0.675	13.04	Pass	No	
0010	2	Day 3 0h 30m	Nicotine	ng/mL	4.82	5.19	5.01	7.39	Pass	No	97.1
0010	2	Day 3 0h 6m	Nicotine	ng/mL	17.6	17.4	17.5	1.14	Pass	No	
0010	1	Day 1 6h 0m	Nicotine	ng/mL	0.646	0.653	0.650	1.08	Pass	No	
0004	2	Day 3 0h 10m	Nicotine	ng/mL	0.670	0.736	0.703	9.39	Pass	No	97.1
0004	2	Day 3 2h 0m	Nicotine	ng/mL	1.61	1.60	1.61	0.62	Pass	No	
0004	1	Day 1 0h 10m	Nicotine	ng/mL	6.97	6.37	6.67	9.00	Pass	No	
0017	2	Day 3 0h 10m	Nicotine	ng/mL	2.79	2.76	2.78	1.08	Pass	No	97.1
0017	1	Day 1 0h 30m	Nicotine	ng/mL	8.92	9.46	9.19	5.88	Pass	No	
0017	1	Day 1 12h 0m	Nicotine	ng/mL	0.818	0.788	0.803	3.74	Pass	No	
0005	2	Day 3 0h 30m	Nicotine	ng/mL	7.78	6.34	7.06	20.40	Fail	No	97.1
0005	2	Day 3 0h 4m	Nicotine	ng/mL	30.5	27.8	29.2	9.25	Pass	No	
0005	1	Day 1 4h 0m	Nicotine	ng/mL	1.32	1.42	1.37	7.30	Pass	No	
0024	2	Day 3 0h 2m	Nicotine	ng/mL	4.15	3.78	3.97	9.32	Pass	No	97.1
0024	1	Day 1 0h 6m	Nicotine	ng/mL	19.7	21.2	20.5	7.32	Pass	No	
0027	2	Day 3 0h 10m	Nicotine	ng/mL	15.8	13.6	14.7	14.97	Pass	No	
0027	2	Day 3 12h 0m	Nicotine	ng/mL	1.27	1.22	1.25	4.00	Pass	No	97.1
0027	1	Day 1 6h 0m	Nicotine	ng/mL	3.67	3.29	3.48	10.92	Pass	No	
0039	2	Day 3 0h 4m	Nicotine	ng/mL	5.03	4.75	4.89	5.73	Pass	No	
0039	1	Day 1 0h 6m	Nicotine	ng/mL	16.8	15.6	16.2	7.41	Pass	No	97.1
0039	1	Day 1 12h 0m	Nicotine	ng/mL	1.34	1.47	1.41	9.22	Pass	No	
0045	2	Day 3 0h 2m	Nicotine	ng/mL	3.59	3.33	3.46	7.51	Pass	No	

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0045	2	Day 3 24h 0m	Nicotine	ng/mL	0.673	0.650	0.662	3.47	Pass	No	
0045	1	Day 1 0h 6m	Nicotine	ng/mL	21.1	18.7	19.9	12.06	Pass	No	
0049	1	Day 1 0h 45m	Nicotine	ng/mL	5.79	5.59	5.69	3.51	Pass	No	
0049	1	Day 1 0h 4m	Nicotine	ng/mL	22.5	19.6	21.1	13.74	Pass	No	
0049	1	Day 1 12h 0m	Nicotine	ng/mL	0.628	0.642	0.635	2.20	Pass	No	
0052	2	Day 3 0h 30m	Nicotine	ng/mL	6.19	6.29	6.24	1.60	Pass	No	
0052	2	Day 3 12h 0m	Nicotine	ng/mL	0.773	0.827	0.800	6.75	Pass	No	
0052	1	Day 1 0h 15m	Nicotine	ng/mL	12.3	10.8	11.6	12.93	Pass	No	
0013	2	Day 3 0h 45m	Nicotine	ng/mL	9.29	8.82	9.06	5.19	Pass	No	
0013	2	Day 3 0h 8m	Nicotine	ng/mL	29.7	26.6	28.2	10.99	Pass	No	
0013	1	Day 1 9h 0m	Nicotine	ng/mL	0.872	0.925	0.899	5.90	Pass	No	
0025	2	Day 3 0h 6m	Nicotine	ng/mL	26.1	23.7	24.9	9.64	Pass	No	
0025	2	Day 3 1h 0m	Nicotine	ng/mL	4.19	4.07	4.13	2.91	Pass	No	
0025	1	Day 1 9h 0m	Nicotine	ng/mL	0.658	0.673	0.666	2.25	Pass	No	
0031	2	Day 3 0h 4m	Nicotine	ng/mL	5.86	5.82	5.84	0.68	Pass	No	
0031	1	Day 1 0h 10m	Nicotine	ng/mL	13.4	11.7	12.6	13.49	Pass	No	
0031	1	Day 1 6h 0m	Nicotine	ng/mL	1.27	1.25	1.26	1.59	Pass	No	
0040	1	Day 1 0h 15m	Nicotine	ng/mL	5.69	5.06	5.38	11.71	Pass	No	
0040	1	Day 1 0h 6m	Nicotine	ng/mL	7.90	7.73	7.82	2.17	Pass	No	
0040	1	Day 1 24h 0m	Nicotine	ng/mL	0.603	0.622	0.613	3.10	Pass	No	
0043	2	Day 3 0h 10m	Nicotine	ng/mL	14.0	12.8	13.4	8.96	Pass	No	
0043	1	Day 1 0h 15m	Nicotine	ng/mL	4.82	4.87	4.85	1.03	Pass	No	
0043	1	Day 1 0h 6m	Nicotine	ng/mL	15.9	13.7	14.8	14.86	Pass	No	
0043	1	Day 1 6h 0m	Nicotine	ng/mL	0.697	0.691	0.694	0.86	Pass	No	
0050	2	Day 3 0h 4m	Nicotine	ng/mL	16.0	14.8	15.4	7.79	Pass	No	
0050	2	Day 3 1h 0m	Nicotine	ng/mL	3.22	3.37	3.30	4.55	Pass	No	
0050	1	Day 1 6h 0m	Nicotine	ng/mL	0.866	0.926	0.896	6.70	Pass	No	



Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0054	2	Day 3 0h 15m	Nicotine	ng/mL	8.24	8.15	8.20	1.10	Pass	No	
0054	2	Day 3 0h 4m	Nicotine	ng/mL	4.19	4.27	4.23	1.89	Pass	No	
0054	2	Day 3 6h 0m	Nicotine	ng/mL	0.675	0.682	0.679	1.03	Pass	No	
0018	2	Day 3 9h 0m	Nicotine	ng/mL	0.845	0.878	0.862	3.83	Pass	No	
0018	1	Day 1 0h 6m	Nicotine	ng/mL	45.8	43.3	44.6	5.61	Pass	No	
0018	1	Day 1 1h 0m	Nicotine	ng/mL	7.47	7.29	7.38	2.44	Pass	No	
0036	2	Day 3 0h 10m	Nicotine	ng/mL	0.697	0.682	0.690	2.17	Pass	No	
0036	1	Day 1 0h 4m	Nicotine	ng/mL	23.7	21.2	22.5	11.11	Pass	No	
0036	1	Day 1 4h 0m	Nicotine	ng/mL	3.29	3.25	3.27	1.22	Pass	No	
0051	2	Day 3 3h 0m	Nicotine	ng/mL	3.07	3.08	3.08	0.32	Pass	No	
0051	1	Day 1 0h 10m	Nicotine	ng/mL	9.97	9.98	9.98	0.10	Pass	No	
0051	1	Day 1 9h 0m	Nicotine	ng/mL	0.799	0.728	0.764	9.29	Pass	No	
0022	2	Day 3 0h 10m	Nicotine	ng/mL	4.94	4.22	4.58	15.72	Pass	No	
0022	1	Day 1 0h 10m	Nicotine	ng/mL	0.670	0.668	0.669	0.30	Pass	No	
0022	1	Day 1 0h 25m	Nicotine	ng/mL	2.58	2.57	2.58	0.39	Pass	No	
0035	2	Day 3 0h 15m	Nicotine	ng/mL	9.07	9.51	9.29	4.74	Pass	No	
0035	1	Day 1 0h 10m	Nicotine	ng/mL	1.09	1.11	1.10	1.82	Pass	No	
0035	1	Day 1 2h 0m	Nicotine	ng/mL	2.16	2.35	2.26	8.41	Pass	No	
0066	2	Day 3 0h 30m	Nicotine	ng/mL	8.80	8.30	8.55	5.85	Pass	No	
0066	1	Day 1 2h 0m	Nicotine	ng/mL	3.59	3.18	3.39	12.09	Pass	No	
0066	1	Day 1 6h 0m	Nicotine	ng/mL	0.735	0.773	0.754	5.04	Pass	No	
0071	2	Day 3 0h 8m	Nicotine	ng/mL	7.57	6.58	7.08	13.98	Pass	No	
0071	2	Day 3 4h 0m	Nicotine	ng/mL	0.846	0.834	0.840	1.43	Pass	No	
0071	1	Day 1 0h 4m	Nicotine	ng/mL	14.1	12.9	13.5	8.89	Pass	No	
0074	2	Day 3 1h 0m	Nicotine	ng/mL	4.42	4.14	4.28	6.54	Pass	No	
0074	2	Day 3 9h 0m	Nicotine	ng/mL	0.825	0.849	0.837	2.87	Pass	No	
0074	1	Day 1 0h 8m	Nicotine	ng/mL	20.8	17.8	19.3	15.54	Pass	No	

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0076	1	Day 1 0h 2m	Nicotine	ng/mL	1.70	1.59	1.65	6.67	Pass	No	
0076	1	Day 1 0h 6m	Nicotine	ng/mL	7.92	7.07	7.50	11.33	Pass	No	
0076	1	Day 1 6h 0m	Nicotine	ng/mL	0.676	0.657	0.667	2.85	Pass	No	
0082	2	Day 3 0h 10m	Nicotine	ng/mL	9.91	9.81	9.86	1.01	Pass	No	
0082	2	Day 3 0h 30m	Nicotine	ng/mL	4.63	4.56	4.60	1.52	Pass	No	
0082	1	Day 1 4h 0m	Nicotine	ng/mL	0.764	0.773	0.769	1.17	Pass	No	
0067	2	Day 3 9h 0m	Nicotine	ng/mL	0.702	0.697	0.700	0.71	Pass	No	
0067	1	Day 1 0h 6m	Nicotine	ng/mL	32.7	29.4	31.1	10.61	Pass	No	
0067	1	Day 1 2h 0m	Nicotine	ng/mL	7.74	7.69	7.72	0.65	Pass	No	
0070	1	Day 1 0h 4m	Nicotine	ng/mL	23.2	15.2	19.2	41.67	Fail	No	
0070	1	Day 1 2h 0m	Nicotine	ng/mL	4.07	3.85	3.96	5.56	Pass	No	
0070	1	Day 1 6h 0m	Nicotine	ng/mL	0.706	0.704	0.705	0.28	Pass	No	
0073	1	Day 1 0h 8m	Nicotine	ng/mL	5.33	5.22	5.28	2.08	Pass	No	
0073	1	Day 1 4h 0m	Nicotine	ng/mL	0.838	0.866	0.852	3.29	Pass	No	
0075	1	Day 1 0h 30m	Nicotine	ng/mL	8.24	7.59	7.92	8.21	Pass	No	
0075	1	Day 1 24h 0m	Nicotine	ng/mL	0.615	0.582	0.599	5.51	Pass	No	
0075	1	Day 1 6h 0m	Nicotine	ng/mL	3.23	3.66	3.45	12.46	Pass	No	
0061	1	Day 1 0h 6m	Nicotine	ng/mL	9.84	9.84	9.84	0.00	Pass	No	
0061	1	Day 1 2h 0m	Nicotine	ng/mL	2.87	2.83	2.85	1.40	Pass	No	
0061	1	Day 1 4h 0m	Nicotine	ng/mL	0.796	0.747	0.772	6.35	Pass	No	
0078	2	Day 3 0h 40m	Nicotine	ng/mL	7.19	6.68	6.94	7.35	Pass	No	
0078	2	Day 3 1h 0m	Nicotine	ng/mL	4.85	5.02	4.94	3.44	Pass	No	
0078	2	Day 3 6h 0m	Nicotine	ng/mL	0.622	0.632	0.627	1.59	Pass	No	
0060	1	Day 1 0h 10m	Nicotine	ng/mL	2.66	2.49	2.58	6.59	Pass	No	
0060	1	Day 1 0h 35m	Nicotine	ng/mL	8.01	7.57	7.79	5.65	Pass	No	
0060	1	Day 1 6h 0m	Nicotine	ng/mL	0.983	0.924	0.954	6.18	Pass	No	
0063	1	Day 1 0h 45m	Nicotine	ng/mL	11.1	9.58	10.3	14.76	Pass	No	

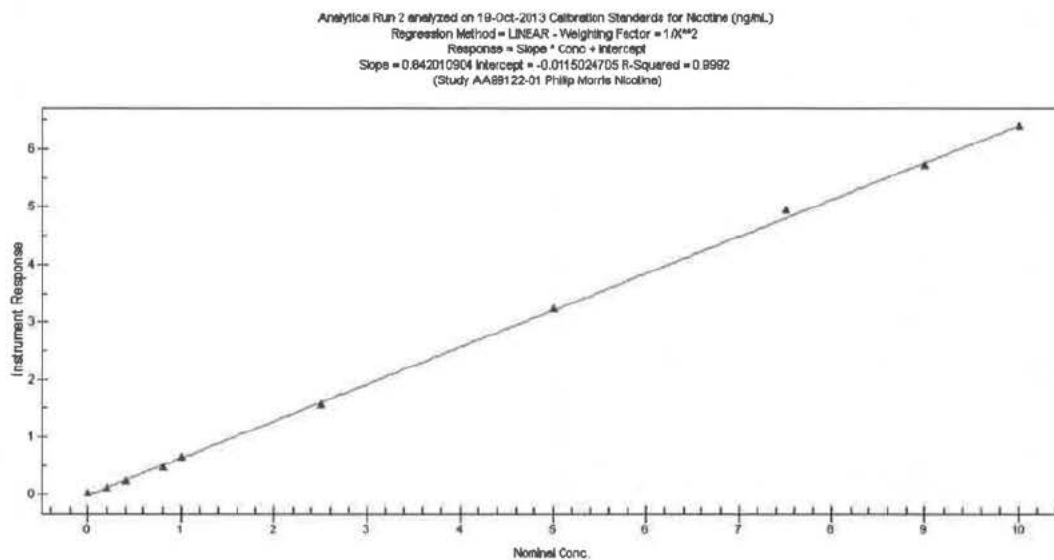
Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0063	1	Day 1 24h 0m	Nicotine	ng/mL	0.608	0.634	0.621	4.19	Pass	No	
0063	1	Day 1 6h 0m	Nicotine	ng/mL	4.43	4.12	4.28	7.24	Pass	No	
0072	1	Day 1 0h 10m	Nicotine	ng/mL	0.660	0.654	0.657	0.91	Pass	No	
0072	1	Day 1 0h 45m	Nicotine	ng/mL	7.53	7.36	7.45	2.28	Pass	No	
0072	1	Day 1 2h 0m	Nicotine	ng/mL	4.56	4.58	4.57	0.44	Pass	No	
0097	2	Day 3 0h 2m	Nicotine	ng/mL	8.15	8.94	8.55	9.24	Pass	No	
0097	2	Day 3 4h 0m	Nicotine	ng/mL	0.663	0.640	0.652	3.53	Pass	No	
0097	1	Day 1 0h 10m	Nicotine	ng/mL	4.25	4.71	4.48	10.27	Pass	No	
0107	2	Day 3 24h 0m	Nicotine	ng/mL	1.13	1.23	1.18	8.47	Pass	No	
0107	1	Day 1 0h 10m	Nicotine	ng/mL	9.39	9.05	9.22	3.69	Pass	No	
0107	1	Day 1 0h 45m	Nicotine	ng/mL	4.59	4.53	4.56	1.32	Pass	No	
0113	2	Day 3 0h 15m	Nicotine	ng/mL	8.55	8.86	8.71	3.56	Pass	No	
0113	2	Day 3 1h 0m	Nicotine	ng/mL	5.24	5.20	5.22	0.77	Pass	No	
0113	1	Day 1 6h 0m	Nicotine	ng/mL	0.811	0.785	0.798	3.26	Pass	No	
0093	1	Day 1 0h 2m	Nicotine	ng/mL	9.03	9.24	9.14	2.30	Pass	No	
0093	1	Day 1 0h 30m	Nicotine	ng/mL	4.41	4.28	4.35	2.99	Pass	No	
0093	1	Day 1 4h 0m	Nicotine	ng/mL	0.915	0.950	0.933	3.75	Pass	No	
0102	2	Day 3 9h 0m	Nicotine	ng/mL	3.91	3.45	3.68	12.50	Pass	No	
0102	1	Day 1 0h 15m	Nicotine	ng/mL	8.53	7.77	8.15	9.33	Pass	No	
0102	1	Day 1 24h 0m	Nicotine	ng/mL	0.754	0.776	0.765	2.88	Pass	No	
0105	2	Day 3 0h 15m	Nicotine	ng/mL	9.33	8.76	9.05	6.30	Pass	No	
0105	2	Day 3 0h 2m	Nicotine	ng/mL	0.636	0.590	0.613	7.50	Pass	No	
0105	2	Day 3 2h 0m	Nicotine	ng/mL	3.78	3.64	3.71	3.77	Pass	No	
0095	2	Day 3 0h 40m	Nicotine	ng/mL	3.47	3.42	3.45	1.45	Pass	No	
0095	1	Day 1 0h 6m	Nicotine	ng/mL	8.90	8.19	8.55	8.30	Pass	No	
0095	1	Day 1 4h 0m	Nicotine	ng/mL	0.749	0.765	0.757	2.11	Pass	No	
0119	2	Day 3 0h 30m	Nicotine	ng/mL	4.63	4.18	4.41	10.20	Pass	No	

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0119	2	Day 3 6h 0m	Nicotine	ng/mL	0.870	0.922	0.896	5.80	Pass	No	
0119	1	Day 1 0h 4m	Nicotine	ng/mL	7.50	7.02	7.26	6.61	Pass	No	
0128	2	Day 3 0h 2m	Nicotine	ng/mL	6.69	6.01	6.35	10.71	Pass	No	
0128	2	Day 3 0h 6m	Nicotine	ng/mL	9.13	8.27	8.70	9.89	Pass	No	
0128	2	Day 3 12h 0m	Nicotine	ng/mL	0.735	0.721	0.728	1.92	Pass	No	
0134	2	Day 3 2h 0m	Nicotine	ng/mL	2.69	2.69	2.69	0.00	Pass	No	
0134	2	Day 3 9h 0m	Nicotine	ng/mL	0.624	0.639	0.632	2.37	Pass	No	
0134	1	Day 1 12h 0m	Nicotine	ng/mL	5.76	5.72	5.74	0.70	Pass	No	
0136	2	Day 3 0h 30m	Nicotine	ng/mL	2.14	2.03	2.09	5.26	Pass	No	
0136	2	Day 3 4h 0m	Nicotine	ng/mL	0.629	0.669	0.649	6.16	Pass	No	
0136	1	Day 1 0h 15m	Nicotine	ng/mL	4.80	4.72	4.76	1.68	Pass	No	
0142	2	Day 3 0h 8m	Nicotine	ng/mL	8.49	3.70	6.10	78.52	Fail	Event	
0142	1	Day 1 0h 45m	Nicotine	ng/mL	4.42	4.44	4.43	0.45	Pass	No	
0142	1	Day 1 12h 0m	Nicotine	ng/mL	0.644	0.656	0.650	1.85	Pass	No	
0148	2	Day 3 0h 15m	Nicotine	ng/mL	6.93	7.02	6.98	1.29	Pass	No	
0148	1	Day 1 1h 0m	Nicotine	ng/mL	3.80	3.35	3.58	12.57	Pass	No	
0148	1	Day 1 4h 0m	Nicotine	ng/mL	0.880	0.939	0.910	6.48	Pass	No	
0129	1	Day 1 0h 30m	Nicotine	ng/mL	1.97	1.59	1.78	21.35	Fail	No	
0129	1	Day 1 0h 8m	Nicotine	ng/mL	6.36	4.98	5.67	24.34	Fail	No	
0129	1	Day 1 4h 0m	Nicotine	ng/mL	0.788	0.826	0.807	4.71	Pass	No	
0135	2	Day 3 0h 45m	Nicotine	ng/mL	9.63	10.1	9.87	4.76	Pass	No	
0135	1	Day 1 0h -15m	Nicotine	ng/mL	0.814	0.796	0.805	2.24	Pass	No	
0135	1	Day 1 6h 0m	Nicotine	ng/mL	4.04	4.30	4.17	6.24	Pass	No	
0139	2	Day 3 1h 0m	Nicotine	ng/mL	3.71	3.60	3.66	3.01	Pass	No	
0139	2	Day 3 9h 0m	Nicotine	ng/mL	0.715	0.723	0.719	1.11	Pass	No	
0139	1	Day 1 0h 8m	Nicotine	ng/mL	9.54	9.39	9.47	1.58	Pass	No	
0140	2	Day 3 12h 0m	Nicotine	ng/mL	1.29	1.28	1.29	0.78	Pass	No	

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0140	2	Day 3 2h 0m	Nicotine	ng/mL	4.28	4.80	4.54	11.45	Pass	No	
0140	1	Day 1 0h 8m	Nicotine	ng/mL	10.0	9.75	9.88	2.53	Pass	No	
0123	2	Day 3 0h 20m	Nicotine	ng/mL	2.96	2.80	2.88	5.56	Pass	No	
0123	1	Day 1 0h 8m	Nicotine	ng/mL	9.06	8.67	8.87	4.40	Pass	No	
0123	1	Day 1 6h 0m	Nicotine	ng/mL	0.826	0.800	0.813	3.20	Pass	No	
0120	2	Day 3 6h 0m	Nicotine	ng/mL	0.721	0.732	0.727	1.51	Pass	No	
0120	1	Day 1 0h 20m	Nicotine	ng/mL	3.78	3.39	3.59	10.86	Pass	No	
0120	1	Day 1 1h 0m	Nicotine	ng/mL	9.98	9.72	9.85	2.64	Pass	No	
0132	1	Day 1 0h 45m	Nicotine	ng/mL	9.26	8.89	9.08	4.07	Pass	No	
0132	1	Day 1 24h 0m	Nicotine	ng/mL	0.706	0.708	0.707	0.28	Pass	No	
0132	1	Day 1 4h 0m	Nicotine	ng/mL	5.11	5.77	5.44	12.13	Pass	No	

## FIGURES

Figure 1 Calibration Curve for Nicotine in Control Matrix, Watson Run ID 2<sup>1</sup>



---

<sup>1</sup> 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.

## 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	Stmospheric 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



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
LC-MS/MS	Liquid chromatography- tandem mass spectrometry
LLOQ	Lower limit of quantitation
LNK	Celerion, Lincoln site
M	Molar
mg	Milligram
mL	Millilitre, milliliter
mol	Mole
MRM	Multiple reaction monitoring
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

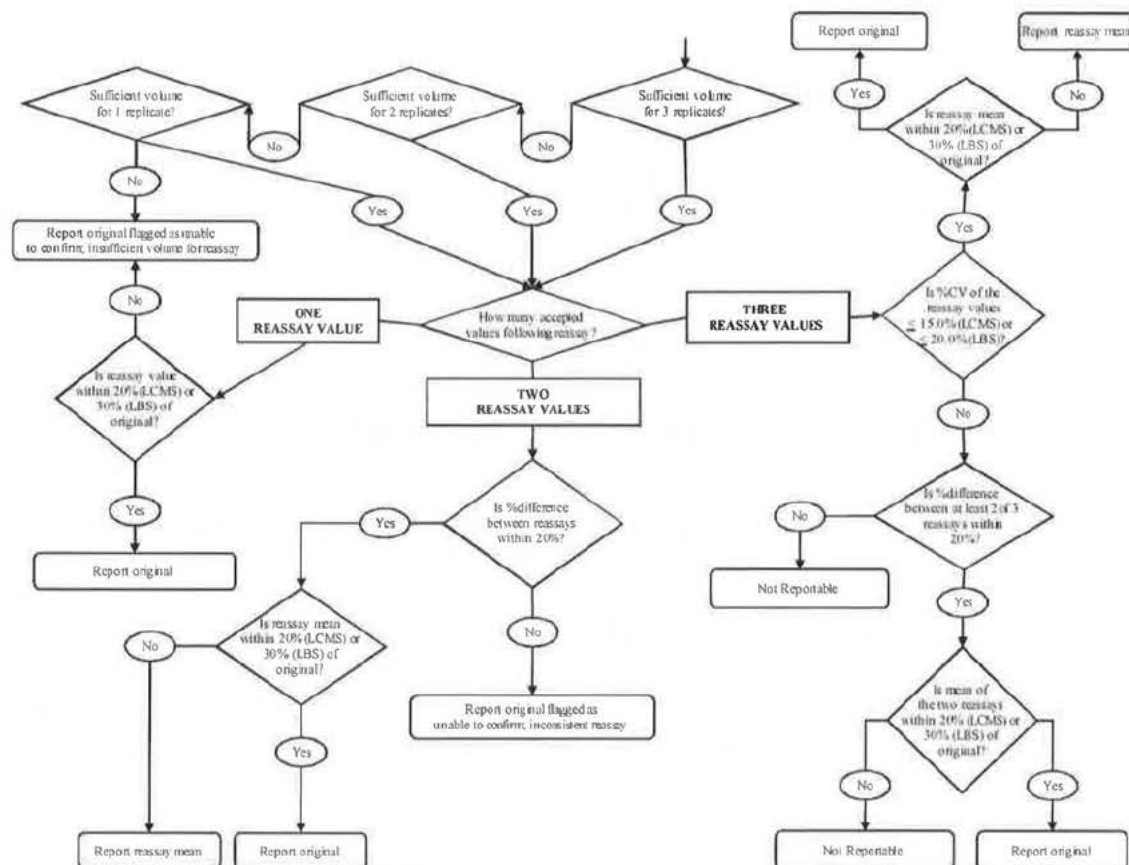
Abbreviation	Description
R.E.	Relative error
REF	Reference
RI	Reinjection
RIA	Rarioimmunoassay
RT	Room temperature
RR	Reanalysis
RVL	Remaining volume low
S.A.	Smoking Abstinence
S.D.	Standard deviation
SOP	Standard operating procedure
SPE	Solid-phase extraction
SST	System suitability test
STD	Standard
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

## 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

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



To compare reassays:

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

To compare to original:

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

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 reanalyses in this decision tree.

#### Attachment 4 General List of Calculation Formulae

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

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

Precision (RSD, CV): 
$$CV \% = (SD / x_{\text{Mean}}) \cdot 100$$

Accuracy (% Theoretical): 
$$\text{Accuracy \%} = (X / x_{\text{Nominal}}) \cdot 100$$

$$\text{Accuracy of Mean \%} = (x_{\text{Mean}} / x_{\text{Nominal}}) \cdot 100$$

Inaccuracy (% Bias, % RE): 
$$\text{Bias \%} = ((X - x_{\text{nominal}}) / x_{\text{nominal}}) \cdot 100$$

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

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

## 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).

Attachment 6 Certificates of Analysis



## Nicotine



RECEIVED  
JAN 10 2012

AS/006074

N-008  
FN092410-01  
Revision 2  
Page 1 of 7

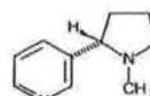
### Certificate of Analysis

#### S(-)-Nicotine

3-(1-Methyl-2-pyrrolidinyl)pyridine

ISO GUIDE 34  
ISO/IEC 17025  
ISO 9001:2008

**Catalog Number:** N-008  
**Solution Lot:** FN092410-01  
**Expiration Date:** September 2015  
**Solvent:** Methanol  
**Volume per Ampule:** Not less than 1 mL  
**Storage:** Protect from air and light, refrigerate or freeze.  
**Intended Use:** For laboratory use only. Not suitable for human or animal consumption.  
**Safety:** Flammable, Poison



- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

Component	Chromatographic Purity	Certified Concentration
S(-)-Nicotine	99.5%	1.000 ± 0.006 mg/mL

• Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of  $k = 2$  and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique.

• Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics.

#### Solution Standard Verification and Homogeneity

Standard Solution	Lot Number	Verified Concentration (mg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FN092410-01	1.013	± 3%	0.6	≤ 3%
Previous Lot	FN040108-06	0.977	± 3%	0.7	≤ 3%

• Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.

• Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot.

• The % RSD of the Previous Lot represents variability of the analysis performed at the time of release.

#### Traceability

- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against an independently prepared 4-point calibration curve gravimetrically prepared using balances calibrated to NIST.
- In addition, each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Special data is provided on subsequent pages of the COA.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.



*Lara Sparks*

Lara Sparks, Quality Assurance Director

July 9, 2012

Date

Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974

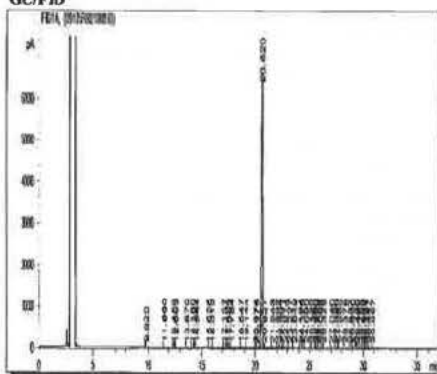
Standard Solution Assay Parameters		Calibration Curve	
Analysis Method:	GC/FID	Calibration Curve:	Linear Regression
Column:	DB-5ms 30 m x 0.53 mm ID, 1.5 µm film thickness	Number of Points:	4
Temp Program:	60°C to 200°C at 40°C/min 200°C to 260°C at 15°C/min hold 1 min	Linearity (r):	1.000
Injector Temp:	Cool-on-Column		
Detector Temp:	325°C		

Neat Material Data		
Compound Name:	S(-)-Nicotine	Chemical Formula: C <sub>10</sub> H <sub>14</sub> N <sub>2</sub>
Compound Lot:	PN072710-01	CAS Number: 54-11-5
		Molecular Weight: 162.23
Neat Material Characterization Summary		
Analytical Test	Method	Results
Primary Chromatographic Purity by GC/FID Analysis	SP10-0101	99.5%
Secondary Chromatographic Purity by HPLC/PDA Analysis	SP10-0102	99.6%
Identity by GC/MS Analysis	SP10-0105	Consistent with Structure
Identity by <sup>1</sup> H-NMR Analysis	USP <761>, SP10-0116	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	AM1087 <sup>1</sup>	0.05%
Residual Water Analysis by Karl Fischer Coulometry	USP <921>, SP10-0103	0.98%
Purity Factor		98.45%
<ul style="list-style-type: none"><li>Primary purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.</li><li>The primary chromatographic purity value is used to calculate the Purity Factor.</li><li>A secondary chromatographic purity method is utilized as a control.</li><li>Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity]/100.</li><li>Purity factor does not include adjustment for chiral and/or isotopic purity.</li></ul> <p><sup>1</sup> Validated analytical method</p>		

N-008  
FN092410-01  
Revision 2  
Page 3 of 7

**Spectral and Physical Data**

**GC/FID**



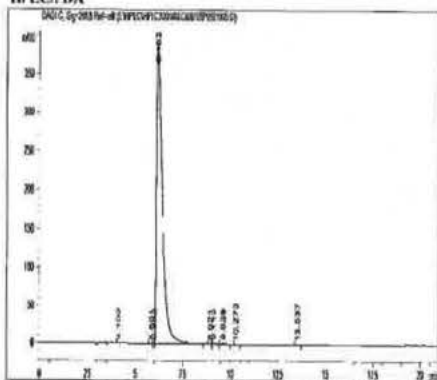
Column: DB-5ms 30 m x 0.53 mm ID, 1.5 µm film thickness  
Temp Program: 40°C to 80°C at 40°C/min  
80°C to 200°C at 5°C/min  
200°C to 280°C at 40°C/min hold 10 min  
Injector Temp: Cool-on-Column  
Detector Temp: 325°C  
Data File Name: S:\GC\GC020100910\F0921003.D  
Operator: RPC  
Instrument: GC86  
Sample Name: PN072710-01  
Method File: B01J.M  
Acquired: September 21, 2010 1:53 PM

Peak #	Ret Time	Area	Height	Area %	Peak #	Ret Time	Area	Height	Area %
1	9.82	7.10	1.22	0.02	27	23.65	1.49	0.18	0.00
2	11.56	0.46	0.12	0.00	28	24.19	2.85	0.55	0.01
3	12.45	0.92	0.18	0.00	29	24.33	4.20	0.89	0.01
4	12.60	0.67	0.16	0.00	30	24.69	10.74	1.34	0.03
5	13.67	1.02	0.21	0.00	31	25.13	2.05	0.29	0.00
6	14.18	1.02	0.15	0.00	32	25.37	32.61	6.60	0.08
7	14.39	0.48	0.11	0.00	33	25.60	0.90	0.25	0.00
8	14.54	0.73	0.16	0.00	34	25.71	1.77	0.42	0.00
9	15.63	0.71	0.19	0.00	35	25.88	0.60	0.20	0.00
10	16.01	1.33	0.33	0.00	36	26.09	0.42	0.13	0.00
11	17.16	1.10	0.20	0.00	37	26.33	0.97	0.38	0.00
12	17.40	0.51	0.10	0.00	38	27.04	0.26	0.11	0.00
13	17.56	1.01	0.21	0.00	39	27.40	0.87	0.22	0.00
14	17.78	2.48	0.56	0.01	40	27.55	0.42	0.10	0.00
15	18.65	1.60	0.38	0.00	41	27.90	32.35	8.95	0.08
16	19.14	0.80	0.15	0.00	42	28.38	1.26	0.29	0.00
17	20.07	0.93	0.19	0.00	43	28.84	7.02	1.32	0.02
18	20.18	0.96	0.18	0.00	44	29.03	2.27	0.47	0.01
19	20.62	40987.30	6657.76	99.43	45	29.45	1.74	0.49	0.00
20	20.83	2.93	0.72	0.01	46	29.50	1.93	0.46	0.00
21	21.55	8.10	1.75	0.02	47	29.77	3.56	0.71	0.01
22	21.99	0.45	0.11	0.00	48	30.01	3.38	0.47	0.01
23	22.30	7.37	1.06	0.02	49	30.12	1.68	0.34	0.00
24	22.50	2.25	0.37	0.01	50	30.28	1.71	0.31	0.00
25	22.81	67.08	11.06	0.16	51	30.45	0.98	0.21	0.00
26	23.23	3.73	0.37	0.01	52	30.87	2.90	0.53	0.01

N-008  
FN092410-01  
Revision 2  
Page 4 of 7

*Spectral and Physical Data (cont.)*

**HPLC/PDA**



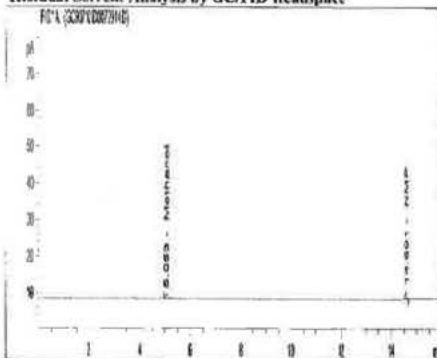
Column: Zorbex SBCN 5µ, 4.6 x 250 mm  
Mobile Phase: A: Acetonitrile  
B: 10 mM Potassium phosphate buffer  
Gradient:  
Program: Time (min) %A %B  
0.0 5 95  
15.0 60 40  
18.1 5 95  
Flow Rate: 1.0 mL/min  
Wavelength: 260 nm  
Data File Name: S:\HPLC\HPLC3\2010\LC30910\F0921005.D  
Operator: TNT  
Instrument: LCH3  
Sample Name: PM072710-01  
Method File: NICO-2.M  
Acquired: September 21, 2010 10:12 AM

Peak #	Ret Time	Area	Height	Area %
1	4.10	0.20	0.04	0.00
2	5.80	2.01	0.28	0.02
3	5.98	4.42	0.76	0.03
4	6.16	8116.88	386.82	99.62
5	8.92	1.19	0.22	0.01
6	9.11	8.27	1.07	0.10
7	9.63	14.15	1.43	0.17
8	10.27	0.43	0.03	0.01
9	13.34	0.66	0.09	0.01

N-008  
FN092410-01  
Revision 2  
Page 5 of 7

*Spectral and Physical Data (cont.)*

**Residual Solvent Analysis by GC/FID Headspace**



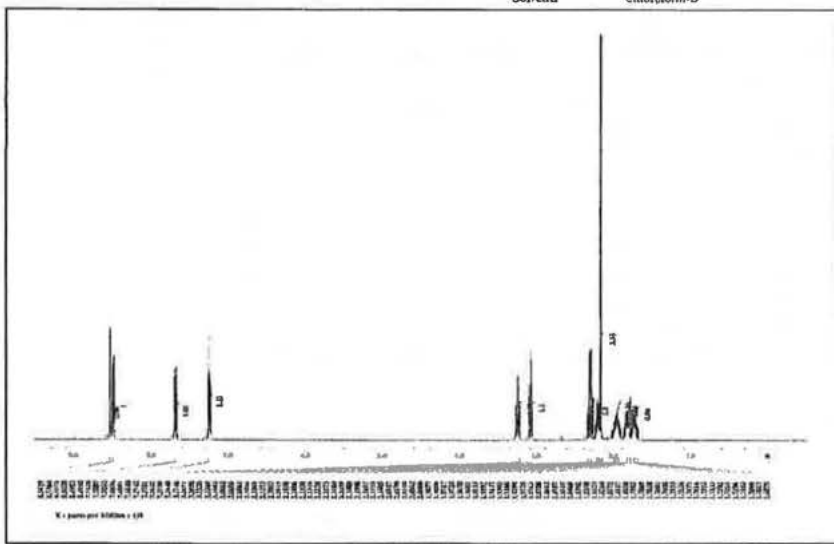
Column: DB-ALCI 30 m x 0.53 mm, 3 µm film thickness  
Temp Program: 40°C (12 min) to 220°C at 40°C/min (5.5 min)  
Carrier Gas: Helium  
Flow Rate: 2.0 mL/min  
Detector Heater Temp: 250°C  
Injector: Headspace Sampler  
HS Oven Temp: 60°C  
Vial Equilibration: 10 minutes

Data File Name: C:\CHEM32\DATA\GC90710\00072914.D  
Operator: RPC  
Instrument: GC#9  
Sample Name: PN072710-01  
Acquired: July 29, 2010 8:20 PM

Peak	Compound	Area	Weight %
1	Methanol	8.36384	0.05
2	NMP	NA	NA
Total			0.05

**<sup>1</sup>H NMR**

Instrument: JEOL ECS 400  
Solvent: Chloroform-D



Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974

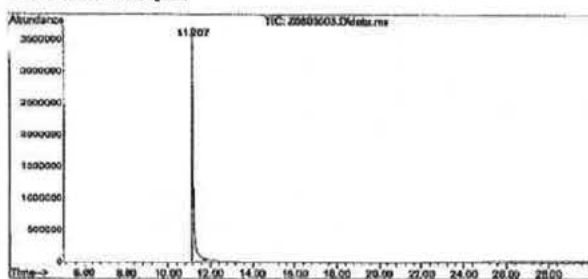
N-008  
FN092410-01  
Revision 2  
Page 6 of 7

*Spectral and Physical Data (cont.)*

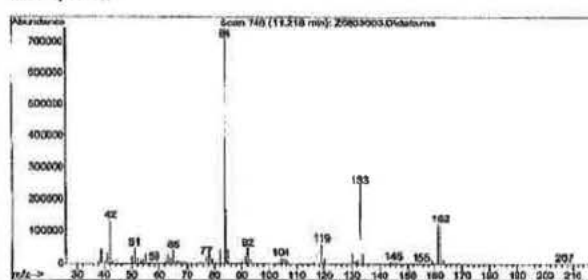
Identify by GC/MS Analysis

Compound Name : (-)-Nicotine  
Lot Number : PN072710-01  
Instrument : Agilent 6890N MSD/6890N GC  
Operator-Inet ID : KPC - C10106  
Date Reported : Thu Aug 05 09:28:36 2010  
Column Type : DB-5ms, 30m x 0.25mm ID, 0.25um film thickness  
Temp. Program : 50°C to 300°C @ 10°C/min, 3min hold  
Injector Temp. : Cool on-column  
Carrier Gas : Helium  
Flow Rate (mL/min) : 0.80 mL/min  
Transfer Line Temp. : 280°C  
Scan Range : 35-400

Total Ion Chromatogram



Mass Spectrum



N-008  
FN092410-01  
Revision 2  
Page 7 of 7

---

### Stability

<i>Short Term Stability: A summary of accelerated stability findings for this product is listed below.</i>		
Storage Condition	Mean Kinetic Temperature (MKT)	Time Period
Freezer	-15°C	No decrease in purity was noted after one week.
Refrigerator	4°C	
Room Temperature	21°C	
40°C	40°C	
<i>Transport/Shipping: Stability data supports transport of this product at ambient conditions.</i>		
<i>Short Term Storage: Stability data supports short term storage up to 1 year at Refrigerate conditions.</i>		

---

### COA Revision History

Revision No.	Date	Reason for Revision
00	10/7/2010	Initial version
01	5/9/2012	Corrected the volume listed in overfill statement from 5 mL to 1 mL.
02	7/9/2012	Added Stability Section.
		Updated Company Logo.





Synthèse AptoChem Inc.  
7171 Frederick-Banting, Montreal, QC  
H4S 1Z9, Canada  
[www.aptochem.com](http://www.aptochem.com)

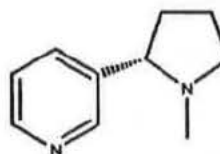
## Certificate of Analysis

Certificate Number: 3027.A-04

AS/006301  
Jan 03 Jan 2014

Compound Name: (-)-Nicotine  
Molecular Formula: C<sub>10</sub>H<sub>14</sub>N<sub>2</sub>  
Molecular Weight: 162.23  
Supplier: Synthèse AptoChem Inc.  
Reference Standard Number: 3027.A  
Reference Standard Lot Number: AC0103112  
Formulation Lot Number: AC0105001  
Appearance: Clear Solution in Methanol  
Concentration: 1.01 mg/mL  
Storage Conditions: between 0°C and 8°C

Structure:



Test Description	Results	Comments
Chromatographic Purity (HPLC)	99.7%	none
Use As Potency	90.5%	1 mL of Formulation Lot Number: AC0105001 affords 914 µg of (-)- Nicotine

Date Tested: 02-Jan-2014

Date to be retested: before 02-Apr-2014

### Issued by:

Name	Title	Signature	Date
Xiao-Ping Yu, M.Sc.	COO, Radiochemical R&D		3-Jan-14

### Approved by

Name	Title	Signature	Date
Hadi Rezaei, Ph.D.	CSO and Head of Quality Assurance		03 Jan 2014



## Chromatographic Purity by HPLC

Name: (-)-Nicotine

Reference Standard Number: 3027.A

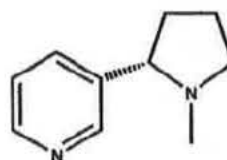
Structure:

Lot Number: AC0103112

Instrument: HPLC 002

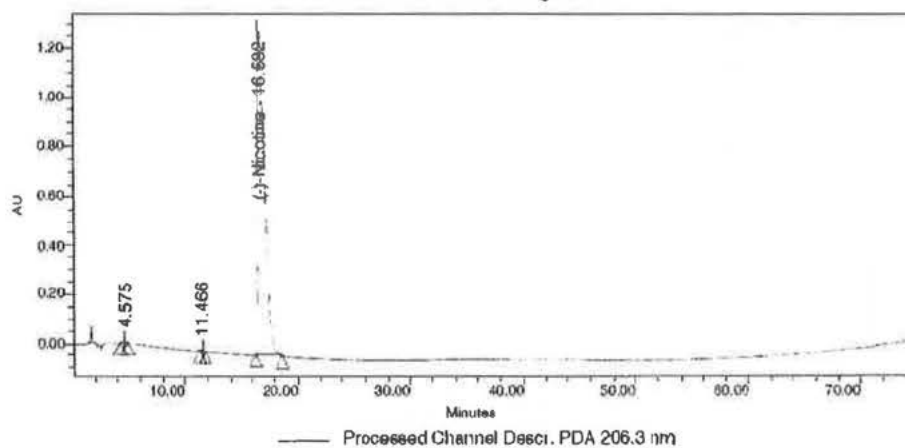
Method-Revision: LC3027-02

Date Acquired: 1/2/14 3:53:27 PM



Injection 1 of 2

Auto-Scaled Chromatogram



### Peak Results

	Name	RT	% Height	Height	Area	% Area
1		4.575	0.47	6295	111854	0.20
2		11.466	0.35	4645	88892	0.12
3	(-)-Nicotine	18.562	99.18	1324095	58096291	99.68

Acquired by / Date: *CS-JAN-2014*

QA-PCIC:\Users\AptoChem\QA\SOP\FORMS\3012\3012-02a

Approved by / Date: *CS-JAN-2014*

Page 1 of 1



### Chromatographic Purity by HPLC

Name: (-)-Nicotine

Reference Standard Number: 3027.A

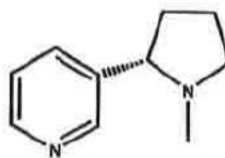
Structure:

Lot Number: AC0103112

Instrument: HPLC 002

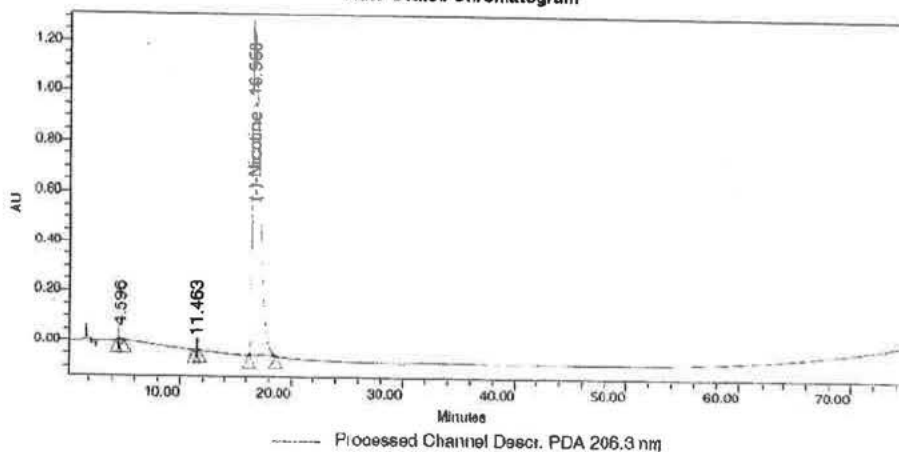
Method-Revision: LC3027-02

Date Acquired: 1/2/14 5:09:45 PM



Injection 2 of 2

Auto-Scaled Chromatogram



#### Peak Results

	Name	RT	% Height	Height	Area	% Area
1		4.596	0.52	6879	114801	0.20
2		11.463	0.40	5295	74008	0.13
3	(-)-Nicotine	16.558	99.07	1302493	58907535	99.67

Acquired by / Date: *05-JAN-2014*

QA-PCIC \Users\Aptochem\QA\SOP\FORMS\30123012-02a

Approved by / Date: *05-JAN-2014*

Page 1 of 1

**d<sub>4</sub>-Nicotine (IS)**



AS 005928-15

**RECEIVED**  
Pre 12/1/2015  
Cerilliant Key

N-048  
FN083010-01  
Revision 0  
Page 1 of 8

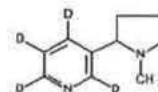
**Certificate of Analysis**

**(±)-Nicotine-D<sub>4</sub>**

2,4,5,6-Tetradeuterio-3-(1-methylpyrrolidin-2-yl)pyridine

ISO GUIDE 34  
CERTIFICATE ANALYSIS  
ISO/IEC 17025  
CERTIFICAT N° 132  
ISO 9001:2008  
CERTIFICAT N° 14

**Catalog Number:** N-048  
**Solution Lot:** FN083010-01  
**Expiration Date:** September 2015  
**Solvent:** Acetonitrile  
**Volume per Ampule:** Not less than 1 mL  
**Storage:** Protect from air and light, refrigerate or freeze.  
**Intended Use:** For laboratory use only. Not suitable for human or animal consumption.  
**Safety:** Flammable, Poison



- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

Component	Chromatographic Purity	Certified Concentration
(±)-Nicotine-D <sub>4</sub>	98.1%	100.0 ± 0.6 µg/mL

• Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 14 at the approximate 95% confidence interval using a coverage factor of  $k = 2$  and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique.

• Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics.

**Solution Standard Verification and Homogeneity**

Standard Solution	Lot Number	Verified Concentration (µg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FN083010-01	97.8	± 3%	0.8	≤ 3%
Previous Lot	FN061709-01	97.8	± 3%	0.7	≤ 3%

• Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.

• Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot.

• The % RSD of the Previous Lot represents variability of the analysis performed at the time of release.

**Traceability**

- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against an independently prepared 4-point calibration curve gravimetrically prepared using balances calibrated to NIST.
- In addition, each neat material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Spectral data is provided on subsequent pages of the COA.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.



*Lara Sparks*

Lara Sparks, Quality Assurance Director

October 8, 2010

Date

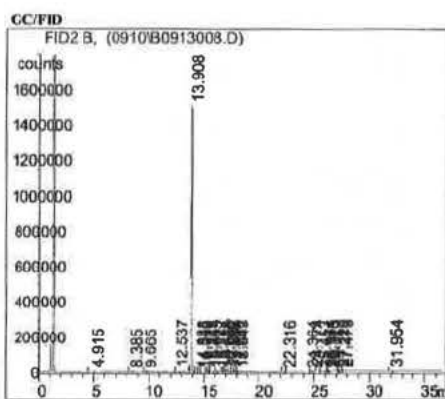
Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-648-7637 / 512-238-9974

Standard Solution Assay Parameters		Calibration Curve	
Analysis Method:	GC/FID	Calibration Curve:	Linear Regression
Column:	DB-5ms 30 m x 0.33 mm ID, 1.5 µm film thickness	Number of Points:	4
Temp Program:	60°C to 200°C at 40°C/min 200°C to 260°C at 15°C/min hold 1.5 min	Linearity (r):	1.000
Injector Temp:	Cool-on-Column		
Detector Temp:	325°C		

Neat Material Data			
Compound Name:	(±)-Nicotine-D <sub>4</sub>	Chemical Formula:	C <sub>10</sub> H <sub>10</sub> D <sub>4</sub> N <sub>2</sub>
Compound Lot:	PN082010-01	CAS Number:	350818-69-8
		Molecular Weight:	166.20
Neat Material Characterization Summary			
Analytical Test	Method	Results	
Primary Chromatographic Purity by GC/FID Analysis	SP10-0101	98.1%	
Secondary Chromatographic Purity by HPLC/PDA Analysis	SP10-0102	98.1%	
Identity by GC/MS Analysis	SP10-0105	Consistent with Structure	
Isotopic Purity by GC/MS SIM Analysis	SP10-0105	2.35% D <sub>0</sub> vs D <sub>4</sub>	
		1.08% D <sub>0</sub>	42.69% D <sub>3</sub>
		3.60% D <sub>1</sub>	44.58% D <sub>4</sub>
		8.05% D <sub>2</sub>	
Identity by LC/MS Analysis	SP10-0107	Consistent with Structure	
Isotopic Purity by LC/MS SIM Analysis	SP10-0107	0.00% D <sub>0</sub> vs D <sub>4</sub>	
		0.00% D <sub>0</sub> to D <sub>1</sub>	7.72% D <sub>3</sub>
		0.22% D <sub>2</sub>	92.05% D <sub>4</sub>
Identity by <sup>1</sup> H-NMR Analysis	USP <761>, SP10-0116	Consistent with Structure	
Residual Solvent Analysis by GC/FID Headspace	AM1087 <sup>1</sup>	Below Quantitation Limit	
Residual Water Analysis by Karl Fischer Coulometry	USP <921>, SP10-0103	0.19%	
Purity Factor		97.90%	
<ul style="list-style-type: none"><li>Primary purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.</li><li>The primary chromatographic purity value is used to calculate the Purity Factor.</li><li>A secondary chromatographic purity method is utilized as a control.</li><li>Purity Factor = ((100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100)</li><li>Purity factor does not include adjustment for chiral and/or isotopic purity.</li></ul>			
<sup>1</sup> Validated analytical method			

N-048  
FN083010-01  
Revision 0  
Page 3 of 8

*Spectral and Physical Data*



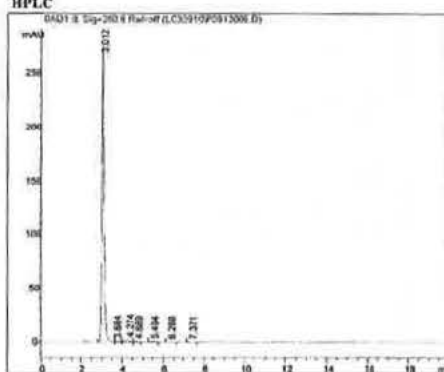
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness  
Temp Program: 40°C to 80°C at 40°C/min  
90°C to 200°C at 5°C/min  
200°C to 280°C at 40°C/min hold 10 min  
Injector Temp: Cool-on-Column  
Detector Temp: 325°C  
Data File Name: S:\GC\GC2\2010\0910\B0913008.D  
Operator: RPC  
Instrument: GC#2  
Sample Name: PN082010-01  
Method File: B011J.M  
Acquired: September 13, 2010 3:35 PM

Peak #	Ret Time	Area	Height	Area %	Peak #	Ret Time	Area	Height	Area %
1	4.92	780	163	0.01	16	17.25	1397	184	0.02
2	8.39	715	150	0.01	17	17.61	2999	648	0.04
3	9.67	1383	318	0.02	18	17.84	5591	1097	0.07
4	12.34	8732	917	0.11	19	18.04	624	124	0.01
5	13.91	7918290	1612840	98.11	20	22.32	1072	227	0.01
6	14.39	2197	472	0.03	21	24.36	1872	117	0.02
7	14.55	3399	718	0.04	22	24.77	20260	4577	0.25
8	14.75	1295	147	0.02	23	25.45	659	112	0.01
9	15.25	624	141	0.01	24	25.97	6472	3276	0.08
10	15.44	12888	2593	0.16	25	26.15	357	131	0.00
11	15.67	4247	501	0.05	26	26.32	176	115	0.00
12	16.15	6304	1364	0.08	27	27.13	2197	717	0.03
13	16.67	647	139	0.01	28	27.21	6941	3163	0.09
14	16.86	1221	252	0.02	29	27.47	1655	595	0.02
15	17.09	55190	12476	0.68	30	31.95	1065	166	0.01

N-048  
FN083010-01  
Revision 0  
Page 4 of 8

*Spectral and Physical Data (cont.)*

**HPLC**

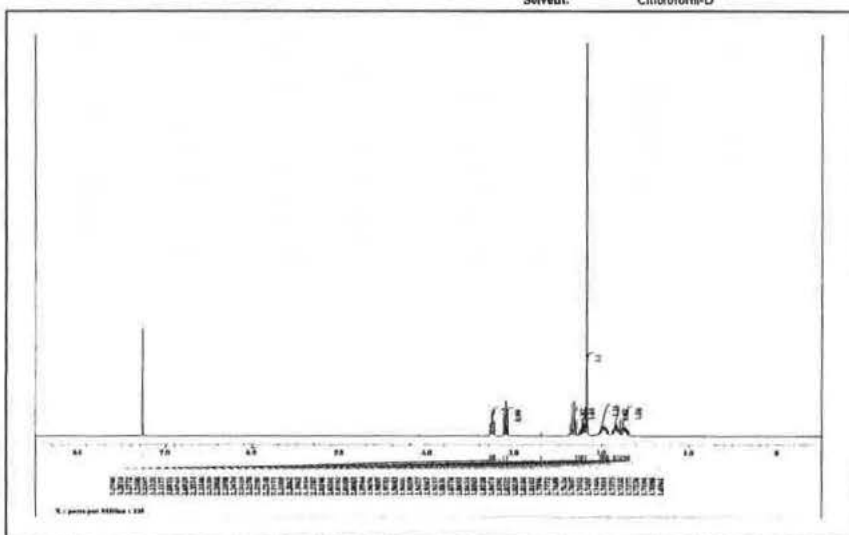


Column: Beasil Phenyl, 4.6 x 150 mm  
Mobile Phase: Acetonitrile:0.02% H<sub>3</sub>PO<sub>4</sub> (2::98)  
Flow Rate: 1.0 mL/min  
Wavelength: 260 nm  
Data File Name: S:\HPLC\HPLC3\2010\LC10910\0913006.D  
Operator: TNT  
Instrument: LCR3  
Sample Name: PN082010-01  
Method File: RMN032-1.M  
Acquired: September 13, 2010 4:23 PM

Peak #	Ret Time	Area	Height	Area %
1	3.01	1973.87	277.05	98.10
2	3.68	7.72	0.52	0.38
3	4.27	22.40	1.96	1.11
4	4.69	3.42	0.29	0.17
5	5.49	2.82	0.25	0.14
6	6.29	1.26	0.08	0.06
7	7.37	0.58	0.06	0.03

**<sup>1</sup>H NMR**

Instrument: JEOL ECS 400  
Solvent: Chloroform-D

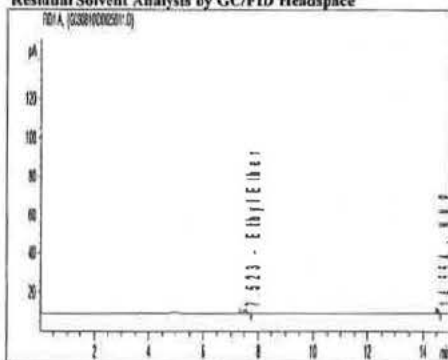




N-048  
FN083010-01  
Revision 0  
Page 5 of 8

*Spectral and Physical Data (cont.)*

**Residual Solvent Analysis by GC/FID Headspace**



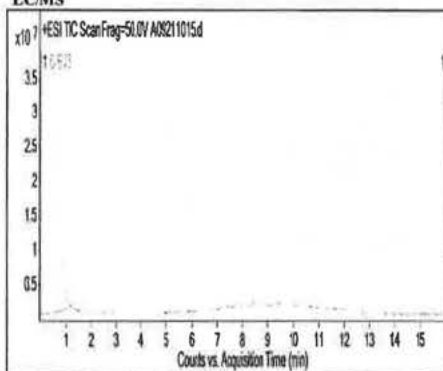
Column: DB-ALC1 30 m x 0.53 mm, 3 µm film thickness  
Temp Program: 40°C (12 min) to 220°C at 40°C/min (5.5 min)  
Carrier Gas: Helium  
Flow Rate: 2.0 mL/min  
Detector Heater Temp: 250°C  
Injector: Headspace Sampler  
HS Oven Temp: 60°C  
Vial Equilibration: 10 minutes  
Data File Name: C:\CHEM32\1\DATA\GC90810\0825011.D  
Operator: RPC  
Instrument: GC#9  
Sample Name: FN082010-01  
Acquired: August 25, 2010 7:18 PM

Peak	Compound	Area	Weight %
1	Ethyl ether	15.60783	BQL
2	NMP	NA	NA
Total			BQL

BQL - Below Quantitation Limit

*Spectral and Physical Data (cont.)*

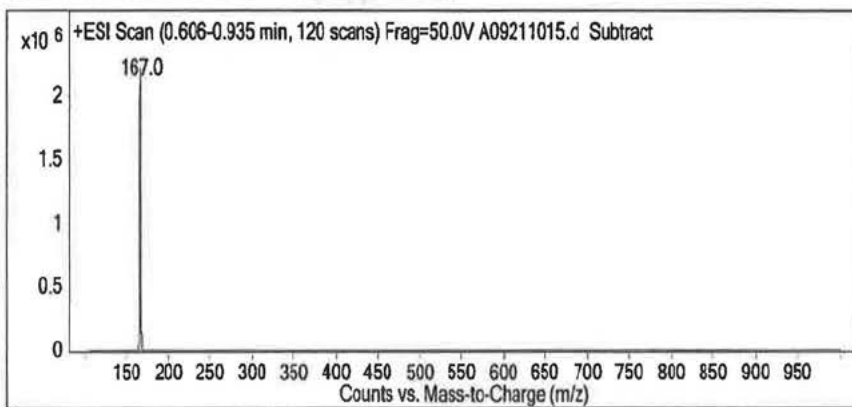
**LC/MS**



Column: Kinetex 2.6µ C<sub>18</sub>(2), 2.1 x 50 mm  
Mobile Phase: A: 0.1% Formic acid in Methanol  
B: 0.1% Formic acid in Water  
Gradient:  
Program: 

Time (mins)	%A	%B
0.0	5	95
5.0	90	10
8.5	10	90
16.0	5	95

  
Flow Rate: 0.4 mL/min  
Scan Range: 100-1000 amu  
Ionization: Electrospray, Positive Ion  
Data File Name: A09211015.d  
Operator: JDC  
Instrument: LC/MS/MS  
Sample Name: PN082010-01  
Method File: genmucan4.m  
Acquired: September 21, 2010 3:11 PM



N-048  
FN083010-01  
Revision 0  
Page 7 of 8

*Spectral and Physical Data (cont.)*

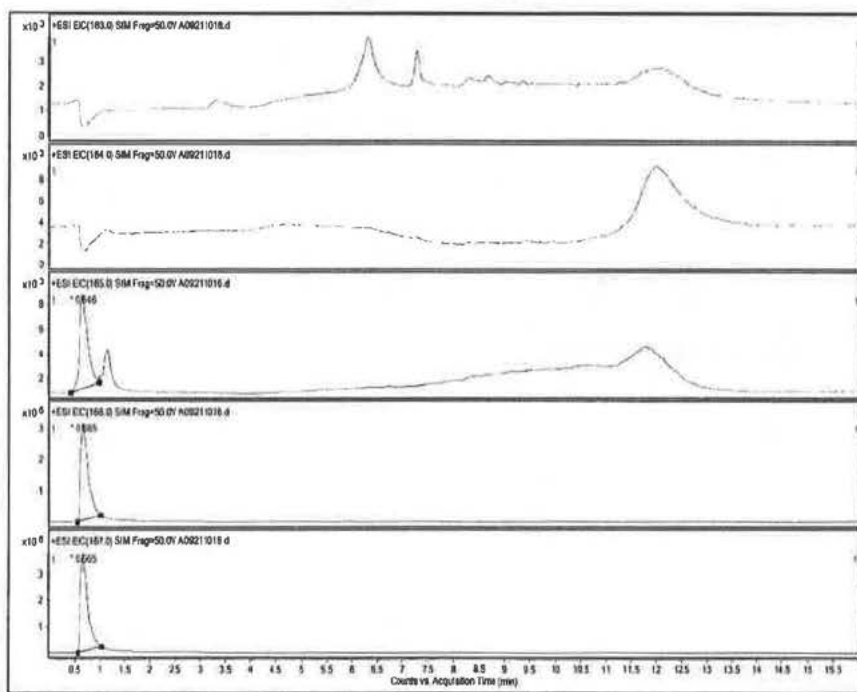
**Isotopic Purity by LC/MS SIM Analysis**

Column: Kinetex 2.6µ C<sub>18</sub> (2), 2.1 x 50 mm  
Mobile Phase: A: 0.1% Formic acid in Methanol  
B: 0.1% Formic acid in Water

Gradient	Time (mins)	%A
Program:	0.0	5
	5.0	90
	8.5	10
	16.0	5

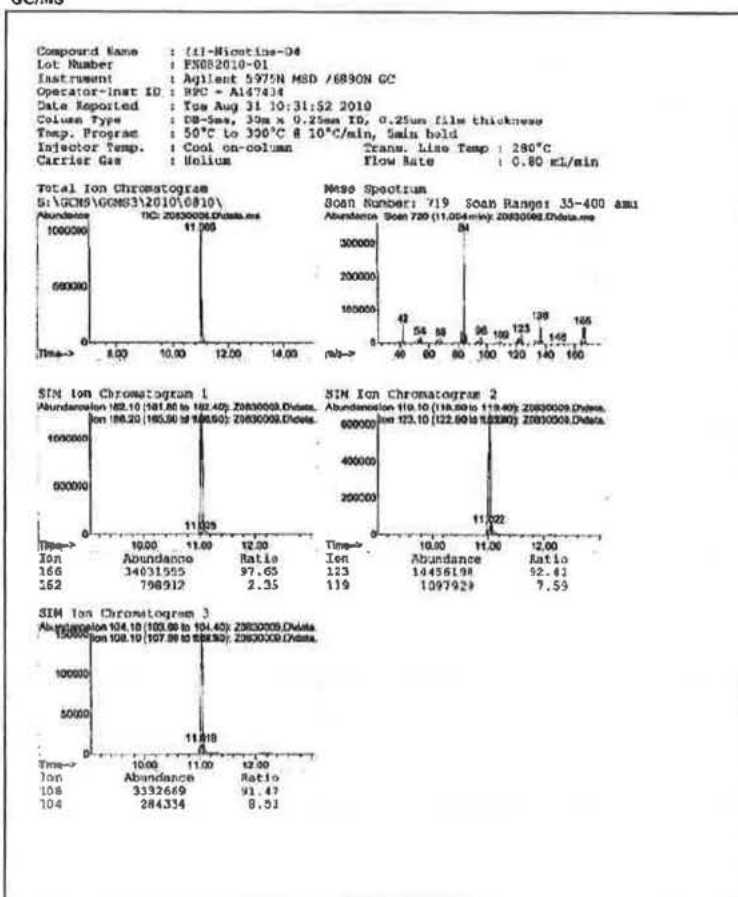
Flow Rate: 0.4 mL/min  
Scan Range: 100-1000 amu  
Ionization: Electrospray, Positive Ion

Data File Name: A09211013.d  
Operator: JDC  
Instrument: LC/MS/MS  
Sample Name: PN083010-01  
Method File: gen.msacq.m4.m  
Acquired: September 21, 2010 3:11 PM



*Spectral and Physical Data (cont.)*

GC/MS



## Attachment 7 Bioanalytical Method Summary



BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM000488 – CR204A2

Version N°: 2.0

Page 1 of 2

<b>Blomarker: Nicotine</b>		<b>Matrix: Plasma</b>
<b>MVR/SOP no. &amp; date: AA33664-06 / 22-JUL-2013</b>		<b>CRO/Laboratory: Celerion-Lincoln</b>
<b>LLOQ: 0.200 ng/mL</b>		<b>ULOQ: 10.0 ng/mL</b>
<b>Validation</b>	<input checked="" type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Cross <b>Comments (required for Partial/Cross):</b>	
<b>Assay:</b>	<input checked="" type="checkbox"/> Chromatographic <input type="checkbox"/> Ligand binding <input type="checkbox"/> Enzymatic <input type="checkbox"/> Other describe: <input type="checkbox"/> LC/MS <input checked="" type="checkbox"/> LC/MS/MS <input type="checkbox"/> GC/MS <input type="checkbox"/> GC/MS/MS <input type="checkbox"/> ELISA	
<b>Equipment and short description of extraction and analysis:</b> An aliquot of human plasma (EDTA) containing the analyte and internal standard was extracted using a solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an AB SCIEX API 4000™ or API 5000™ 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/concentration <sup>2</sup> ) of peak area ratios of the analyte and internal standard.		

<b>Selectivity/Sensitivity/Matrix effect:</b>	No significant matrix effect was observed in any of the 6 human plasma (EDTA) lots that were fortified with nicotine at the concentration of the low QC (0.600 ng/mL) or in any of the 6 human plasma (EDTA) lots that were fortified with nicotine at the concentration of the high QC (7.50 ng/mL) samples
<b>Accuracy:</b>	Intra-batch: -2.8 to 12.0% R.E. Inter-batch: -0.9 to 5.5% R.E.
<b>Precision:</b>	Intra-batch: 0.9 to 7.1% CV Inter-batch: 2.6 to 6.2% CV
<b>Recovery:</b>	81% recovery at 0.600 ng/mL in human plasma 79% recovery at 1.20 ng/mL in human plasma 84% recovery at 7.50 ng/mL in human plasma
<b>Freeze and thaw stability:</b>	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light 7 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes at -20°C under UV-shielded light
<b>Short-term temperature stability:</b>	27 hours in polypropylene tubes at ambient temperature under white light
<b>Long-term stability:</b>	1041 days in polypropylene tubes at -20°C
<b>Stock solution stability:</b>	574 days at approximately 100 µg/mL in water in a polypropylene container at -20°C
<b>Post-preparative stability:</b>	73 hours in a polypropylene 96 well plate at 5°C



PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM000496 - CR204A2

Version N°: 2.0

Page 2 of 2

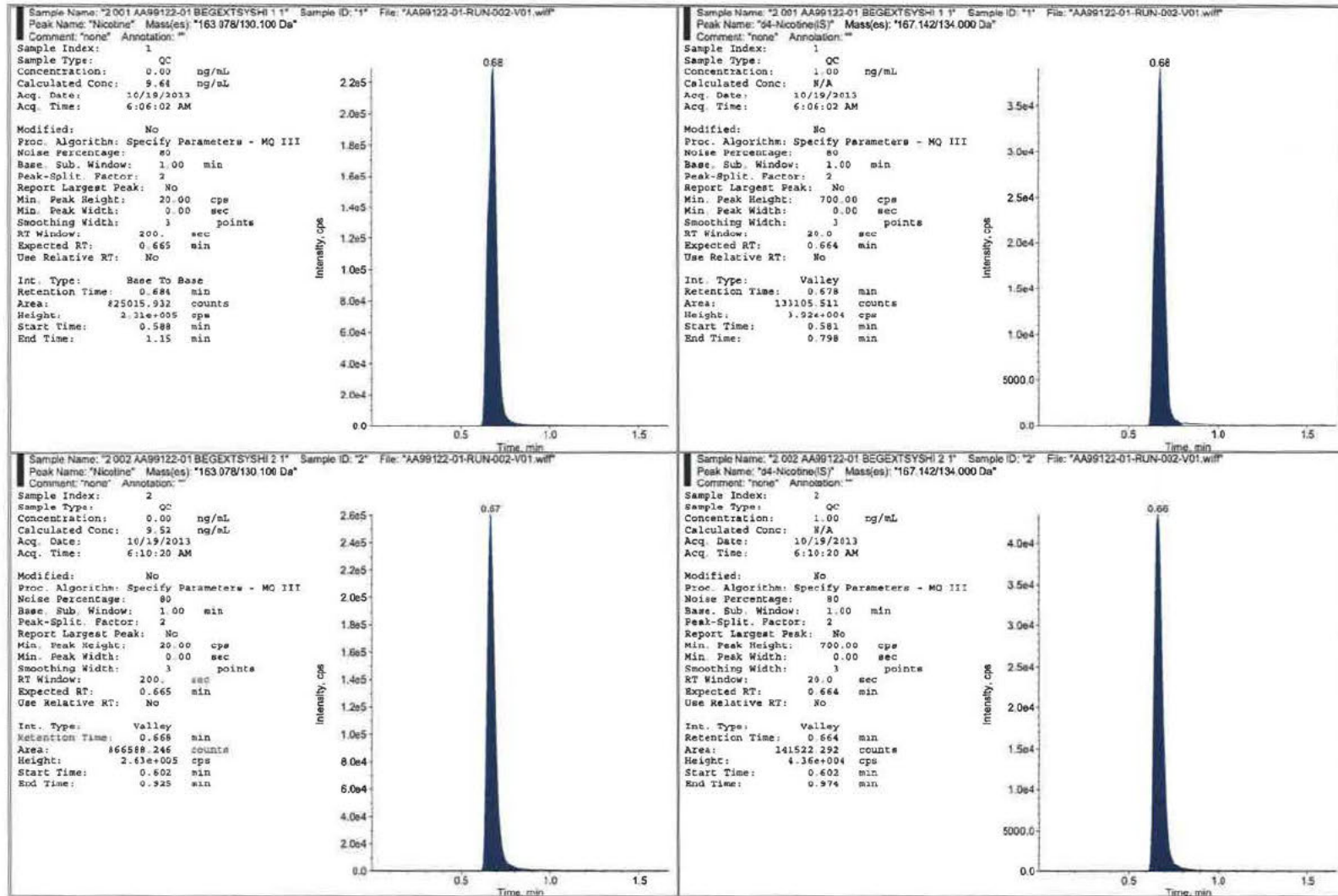
<b>Accreditation/ GLP compliance/ QA statements:</b>	<b>GLP Compliance as Assay Validation conforms to Celerion Standard Operating Procedures which were written in compliance with FDA: Guidance to Industry "Bioanalytical Method Validation"</b>	
<b>BMS completed by:</b>		
<b>Name:</b>	<b>Date:</b>	<b>Signature:</b>
Erica Nachi	29. AUG. 2013	



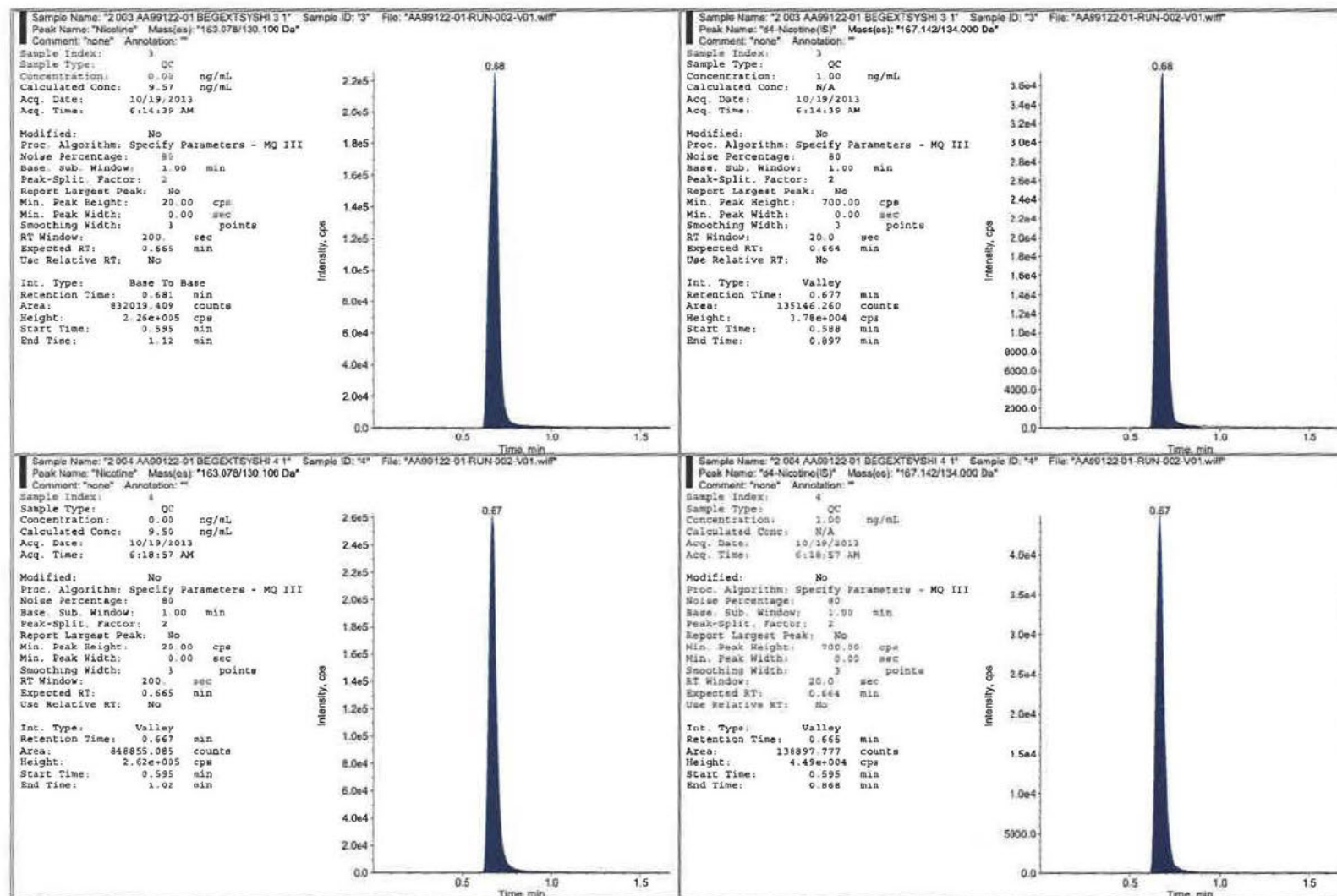
## Attachment 8 Chromatograms

Total number of pages including this page: 82

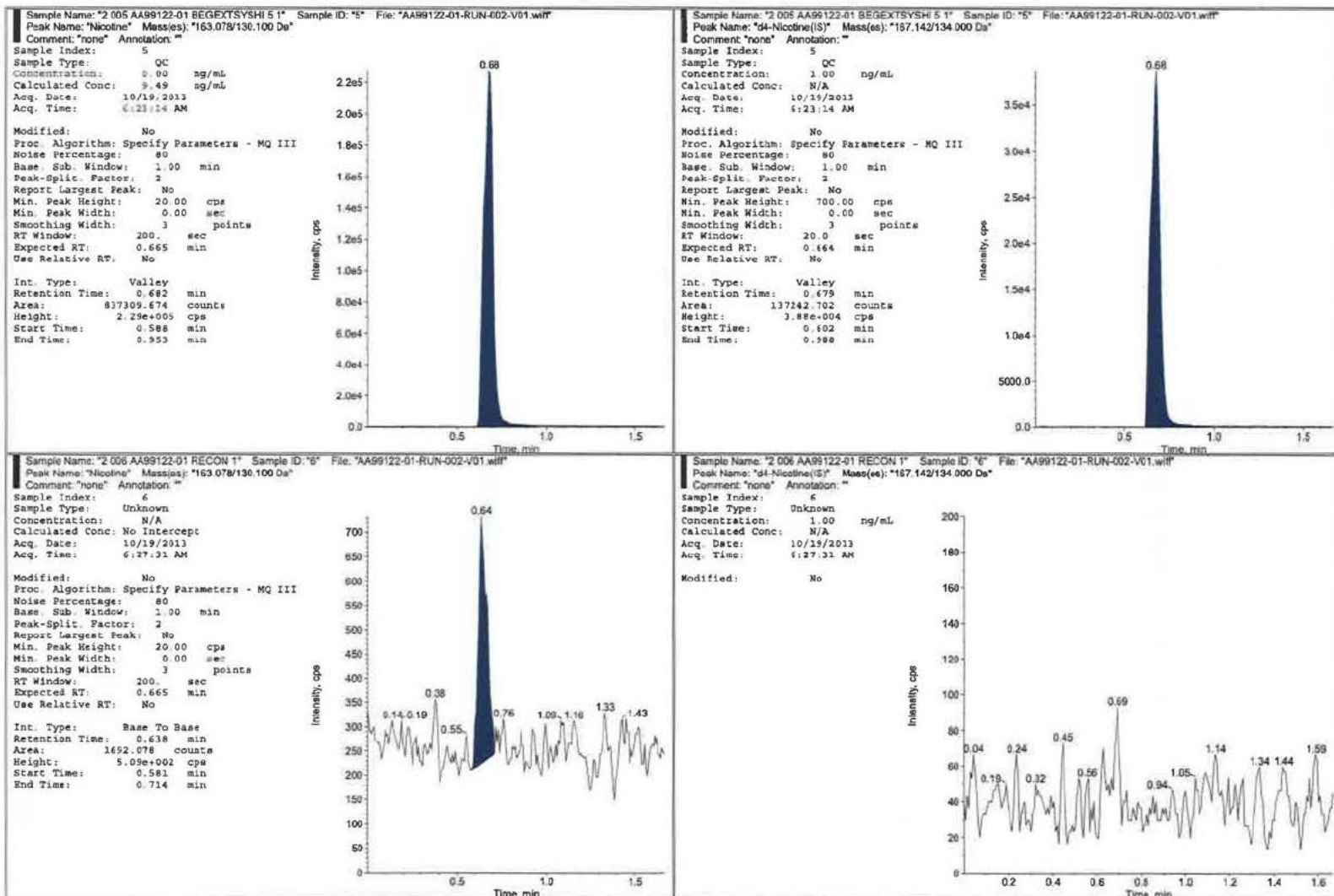
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

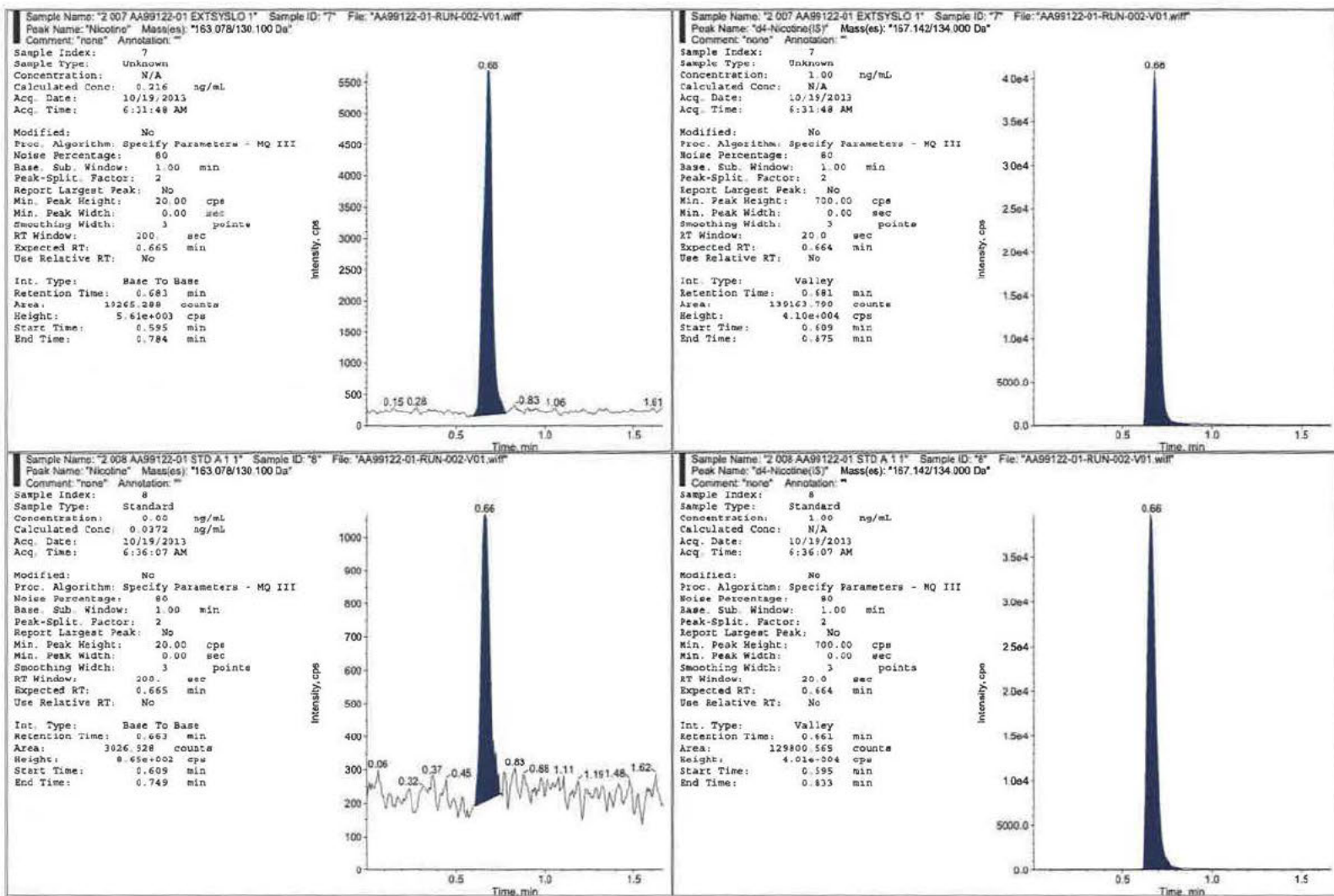


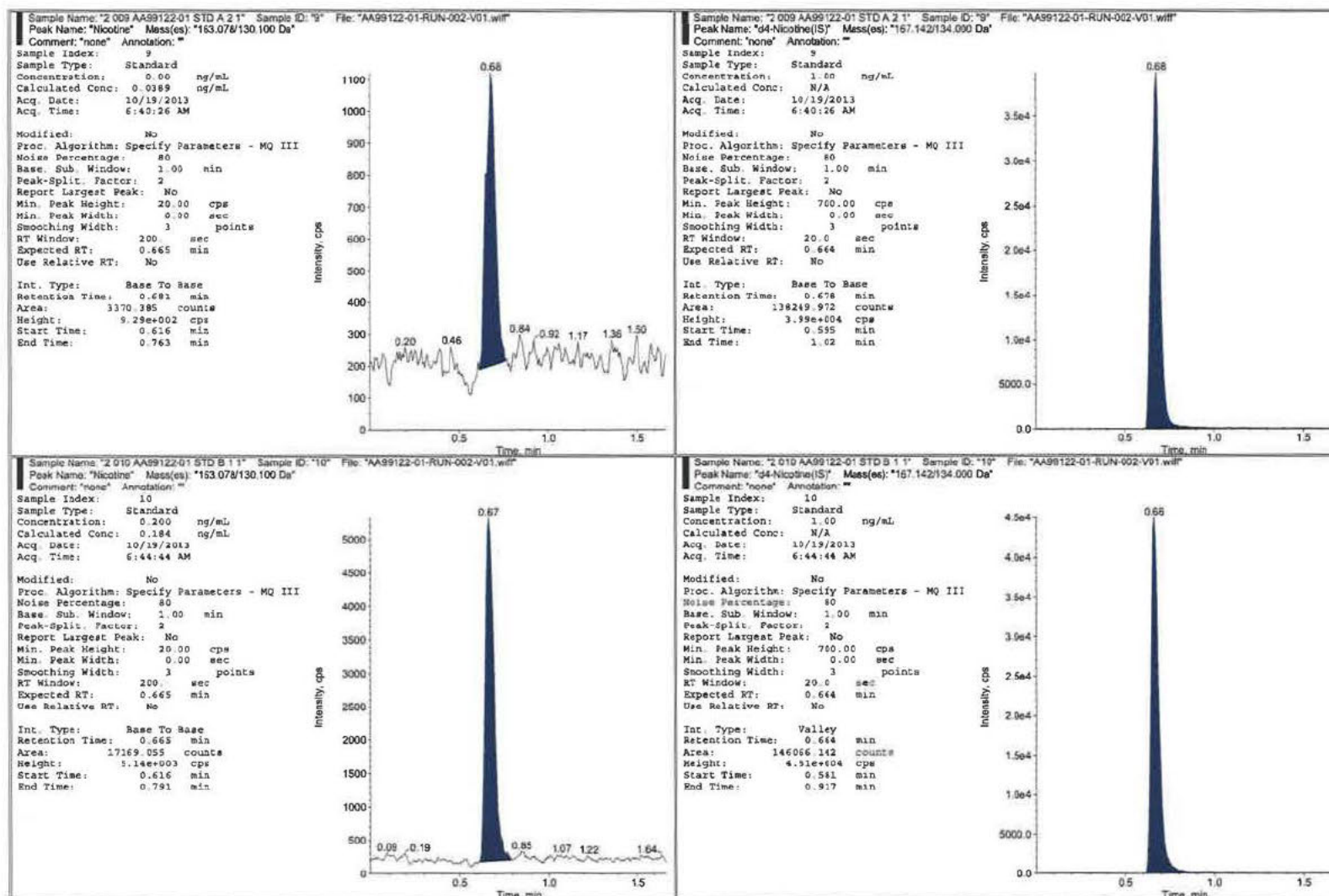
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



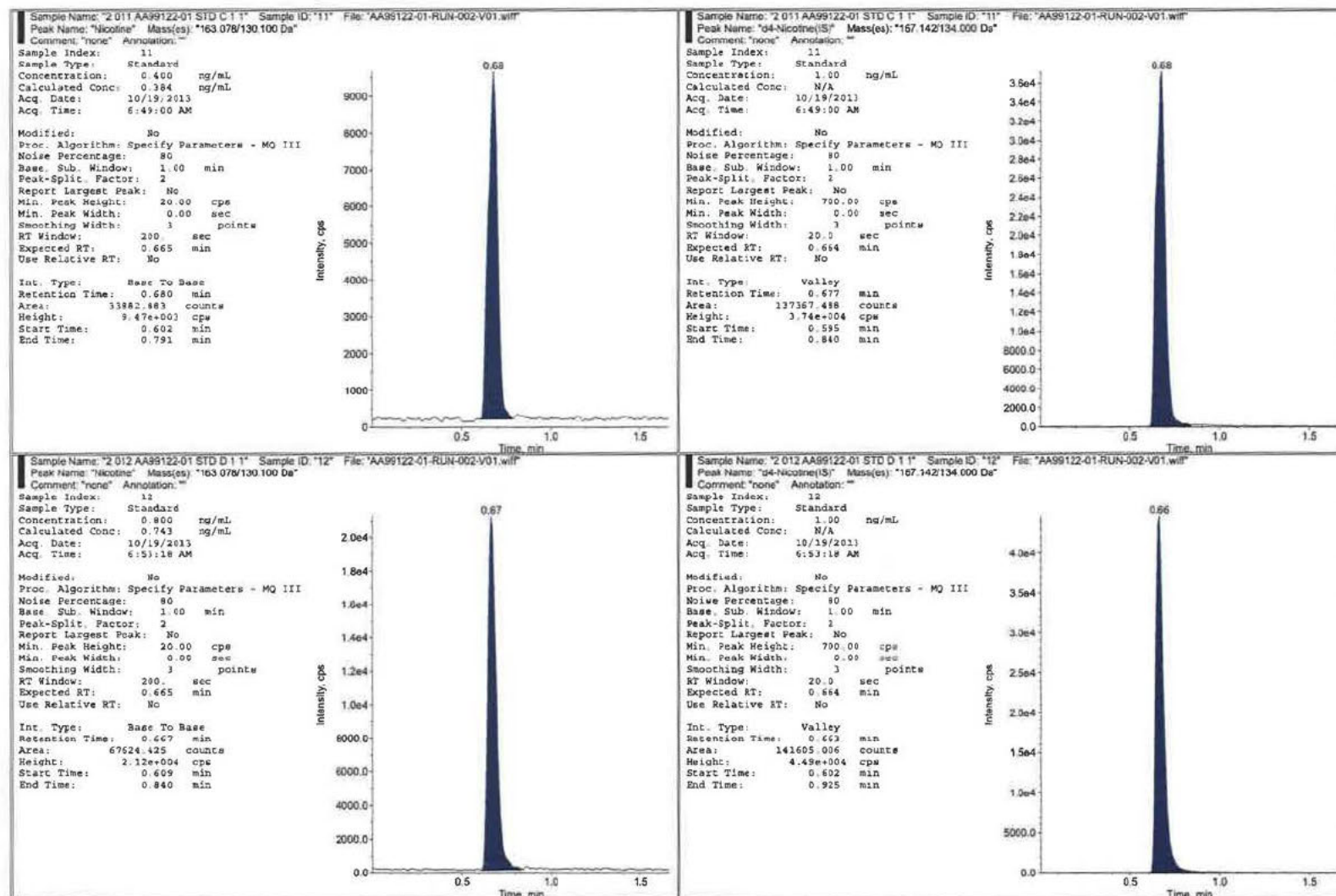


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

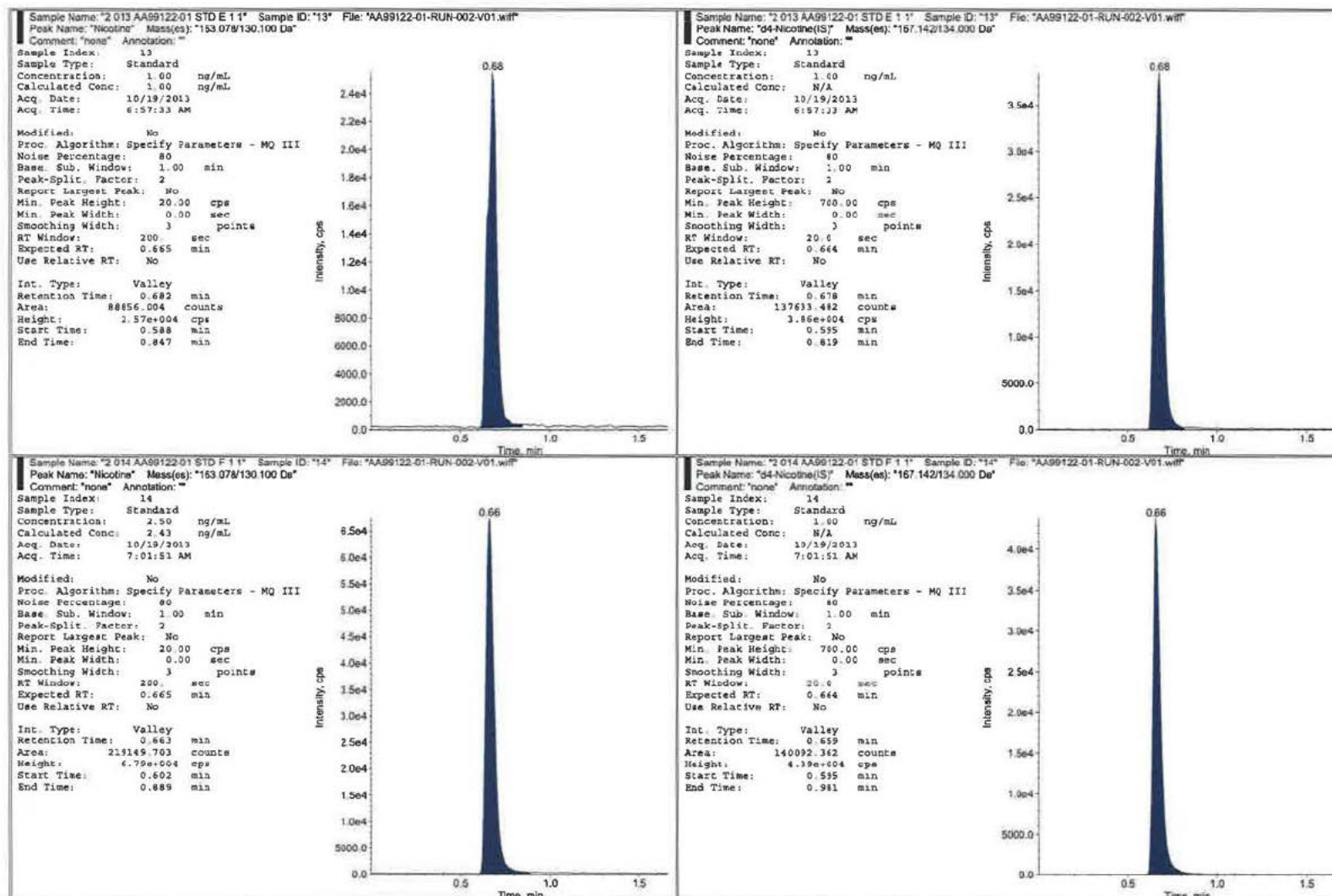




Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

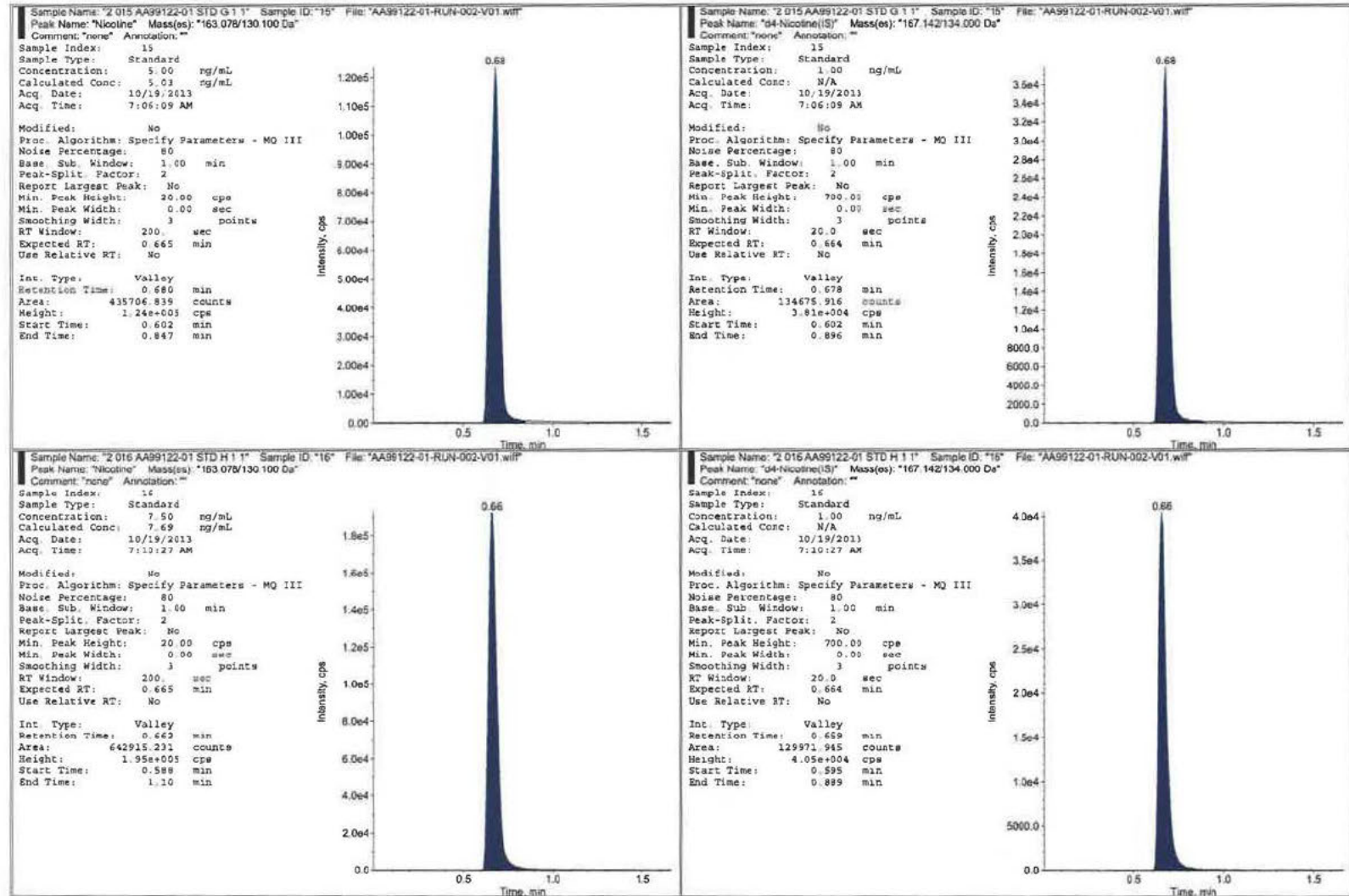




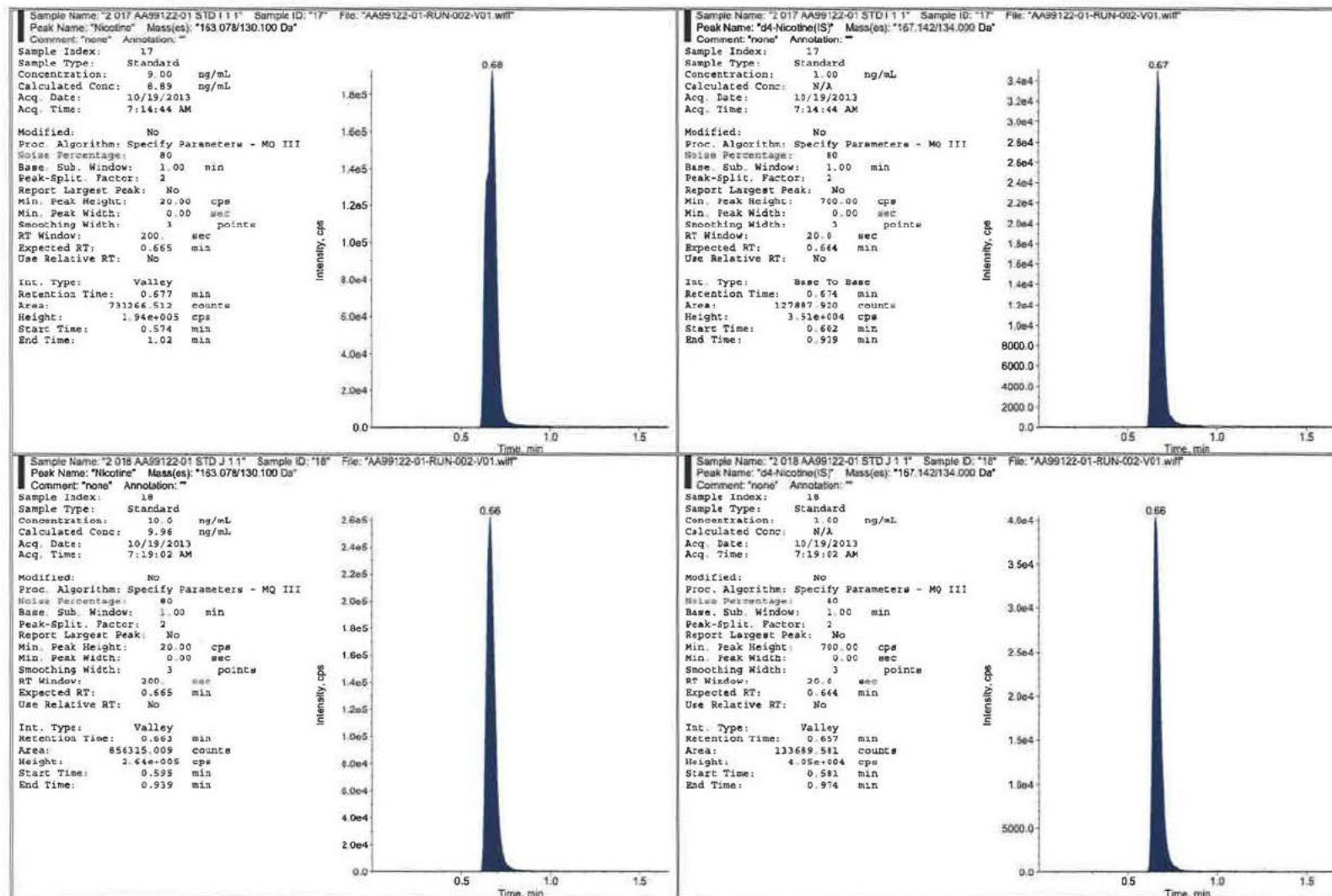




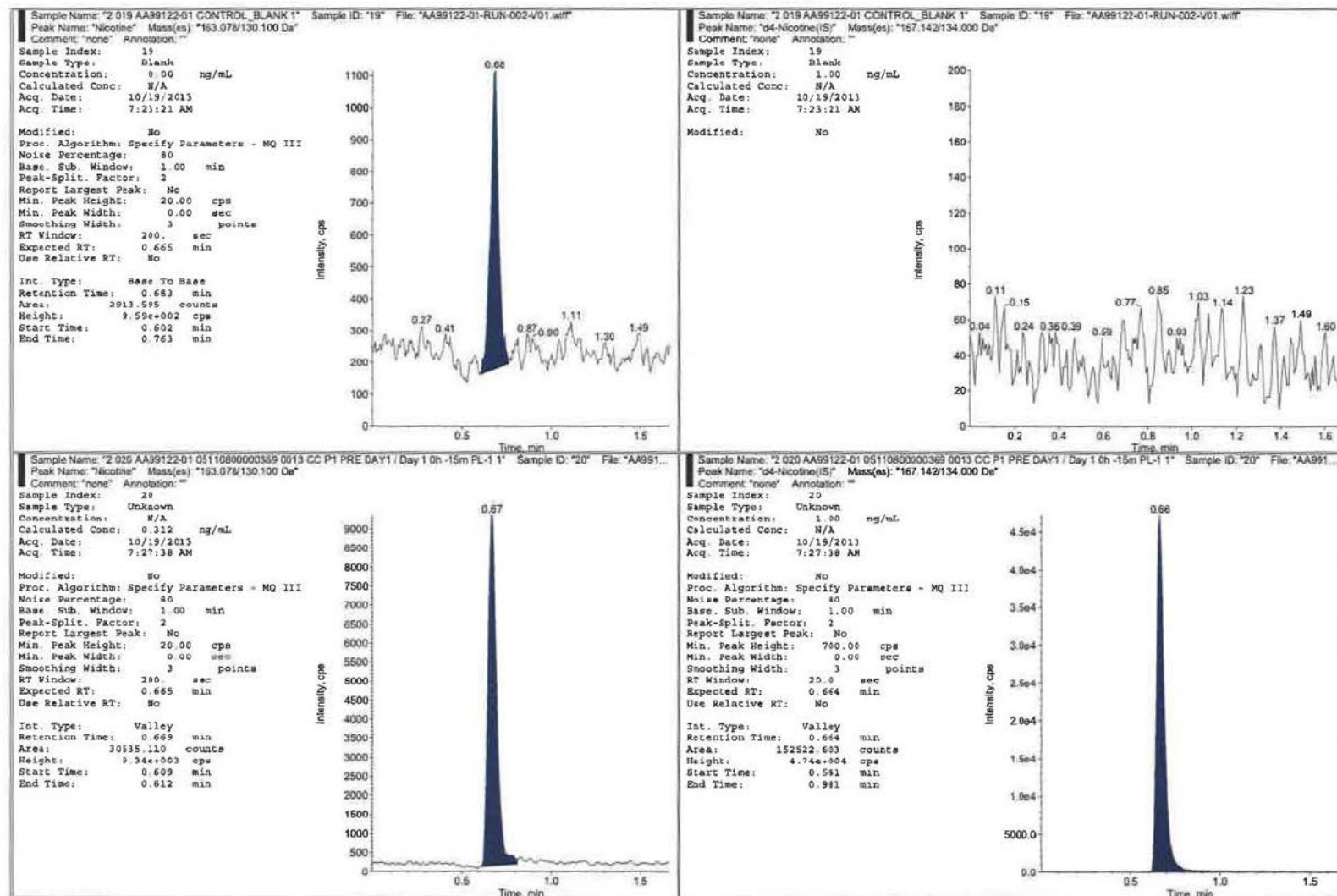
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

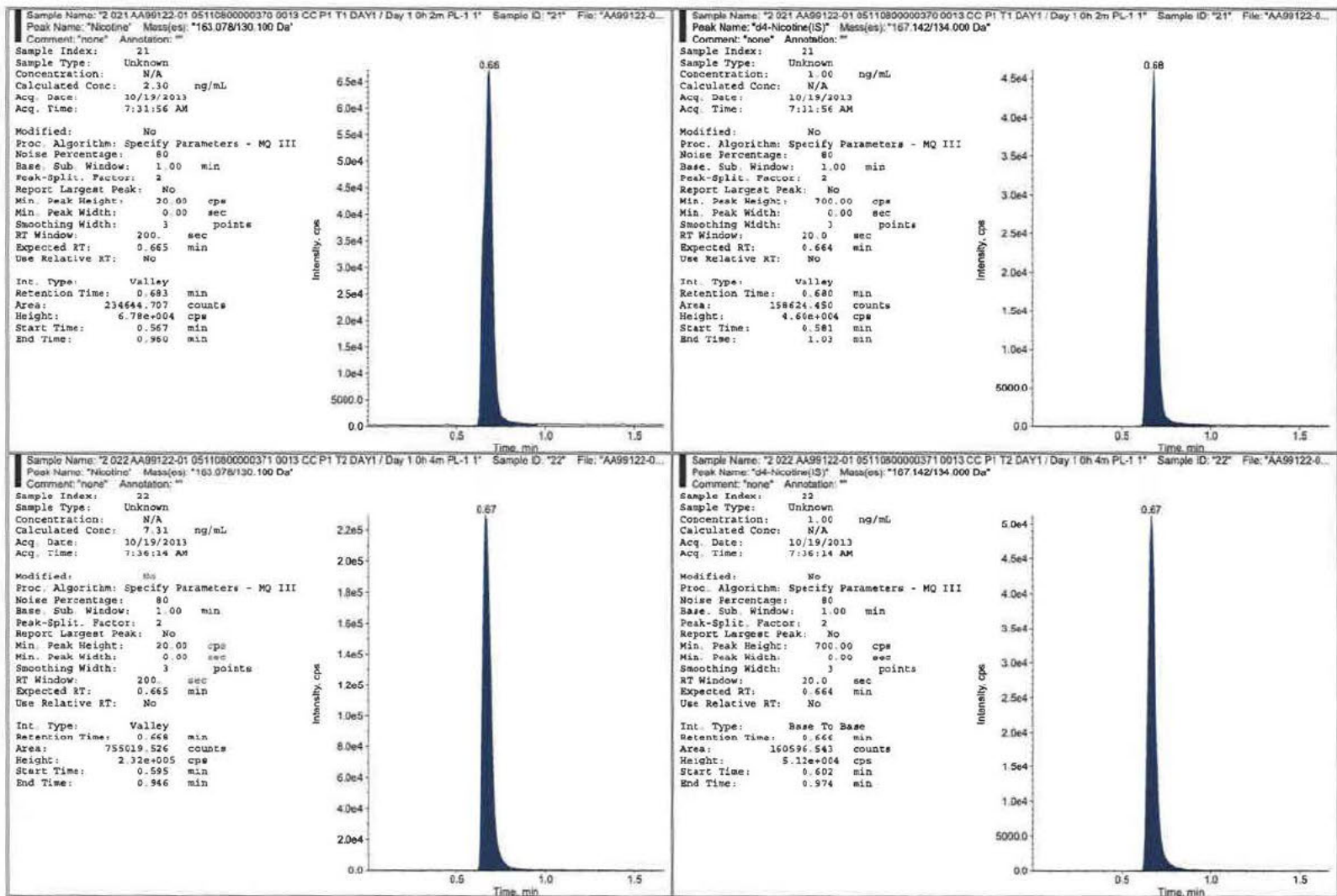


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

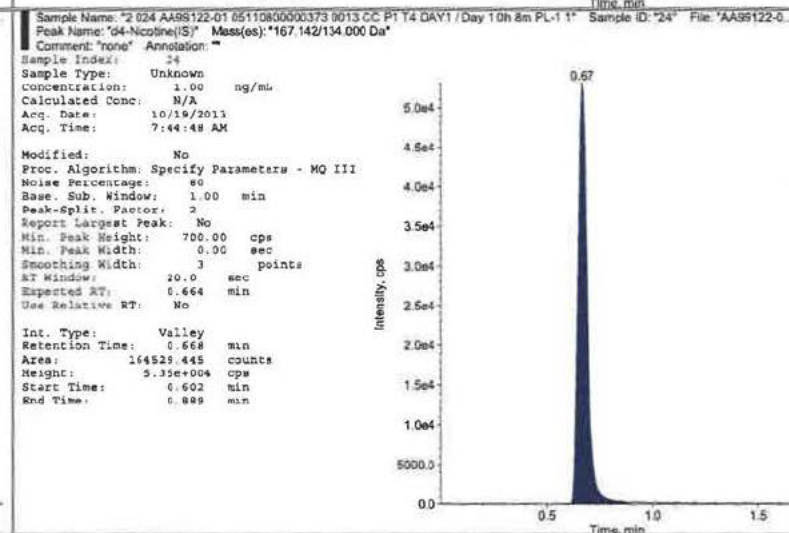
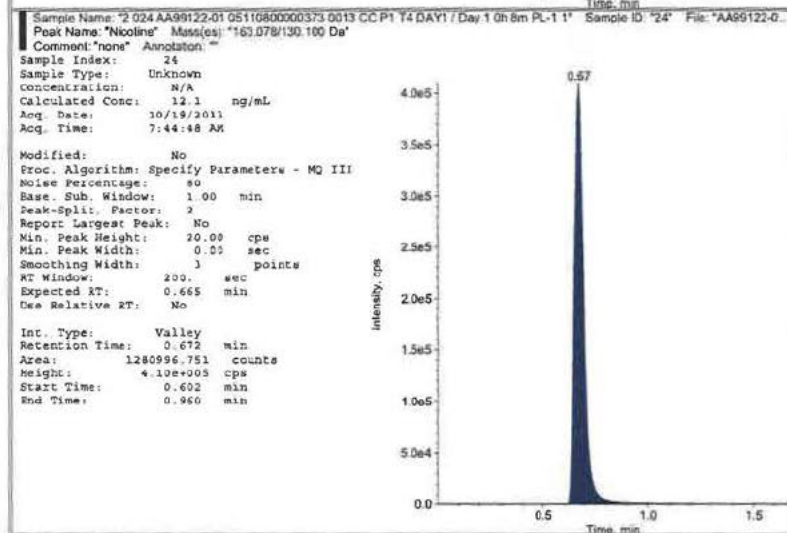
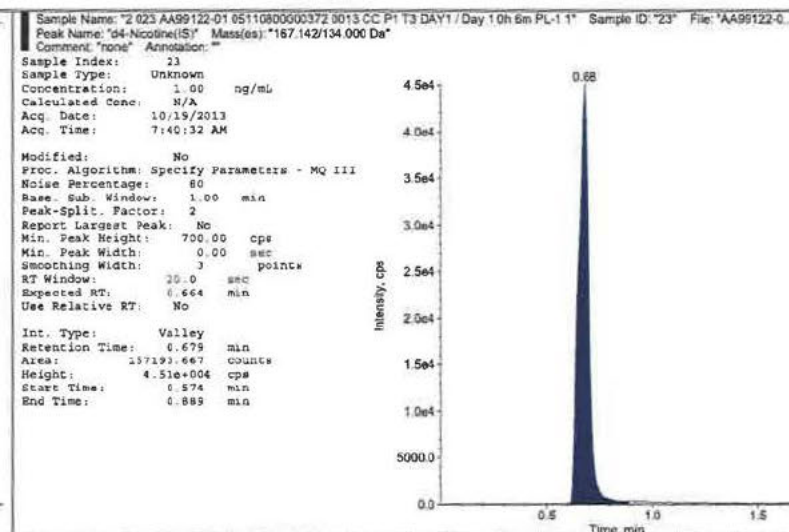
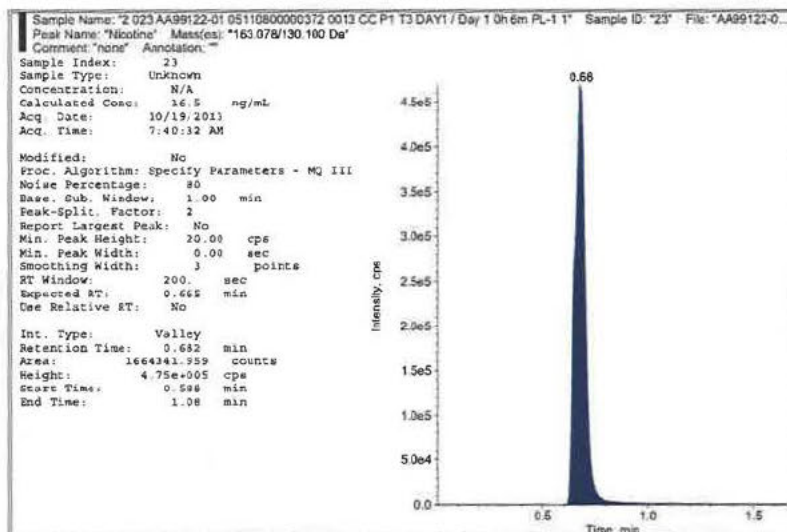




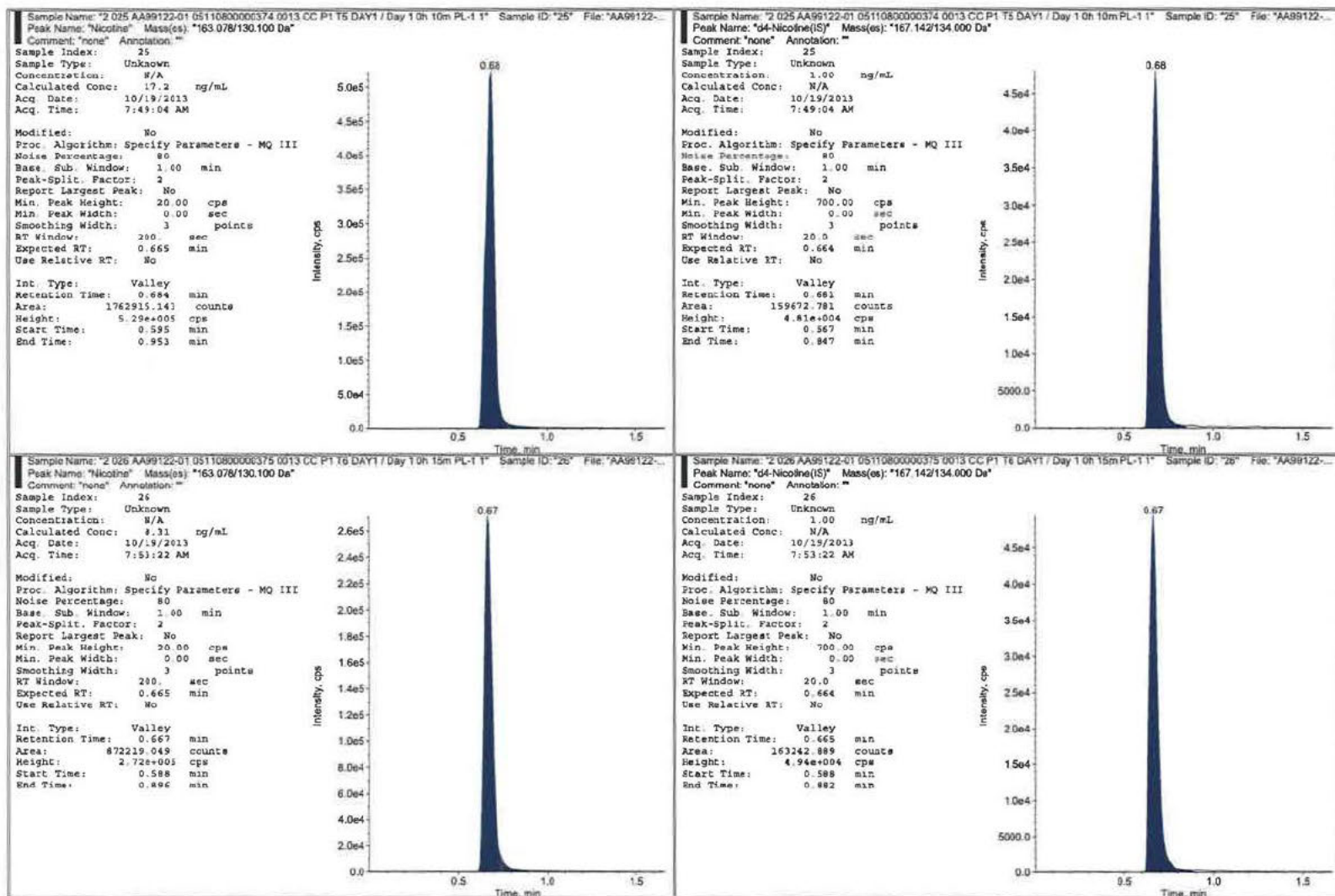
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

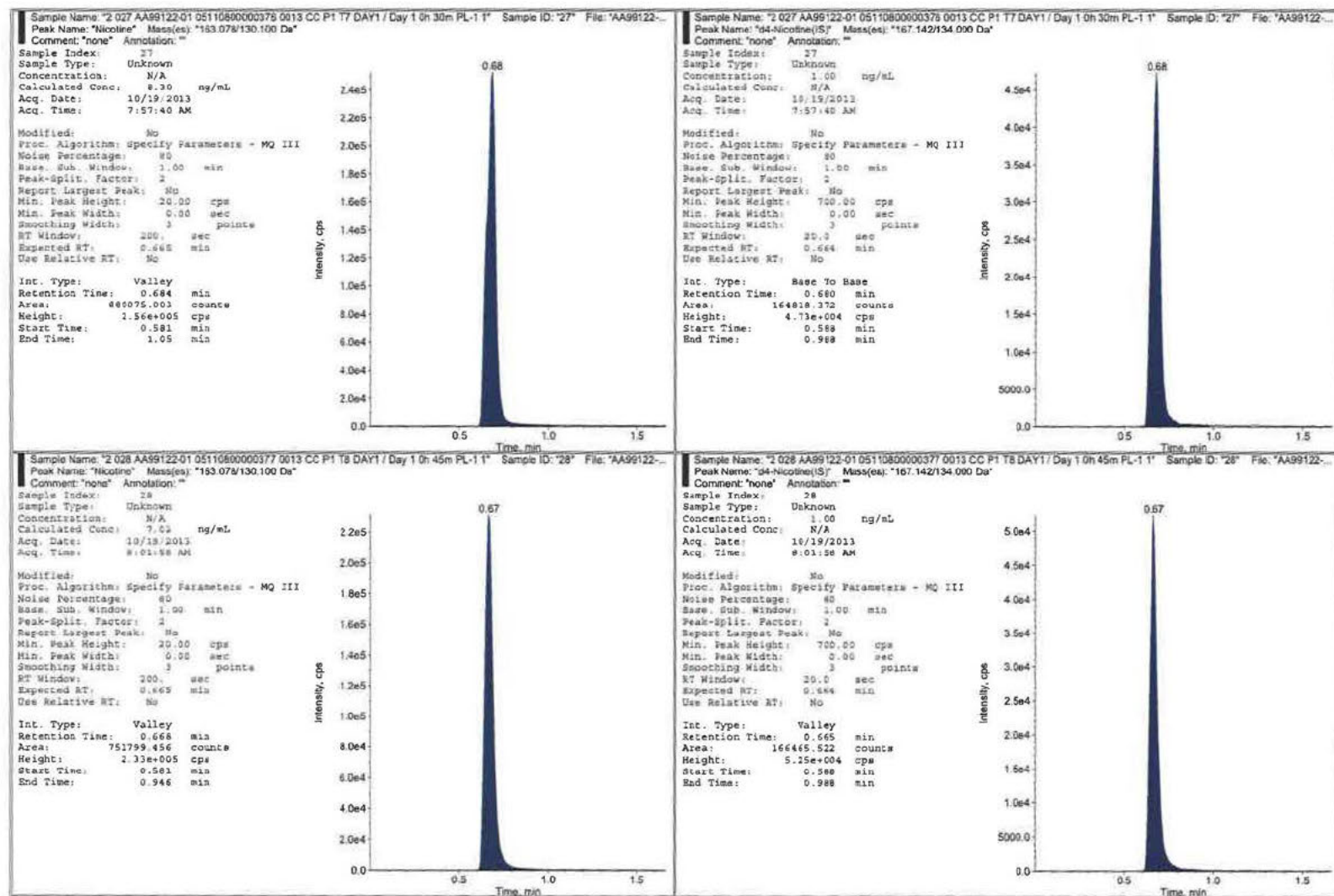


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



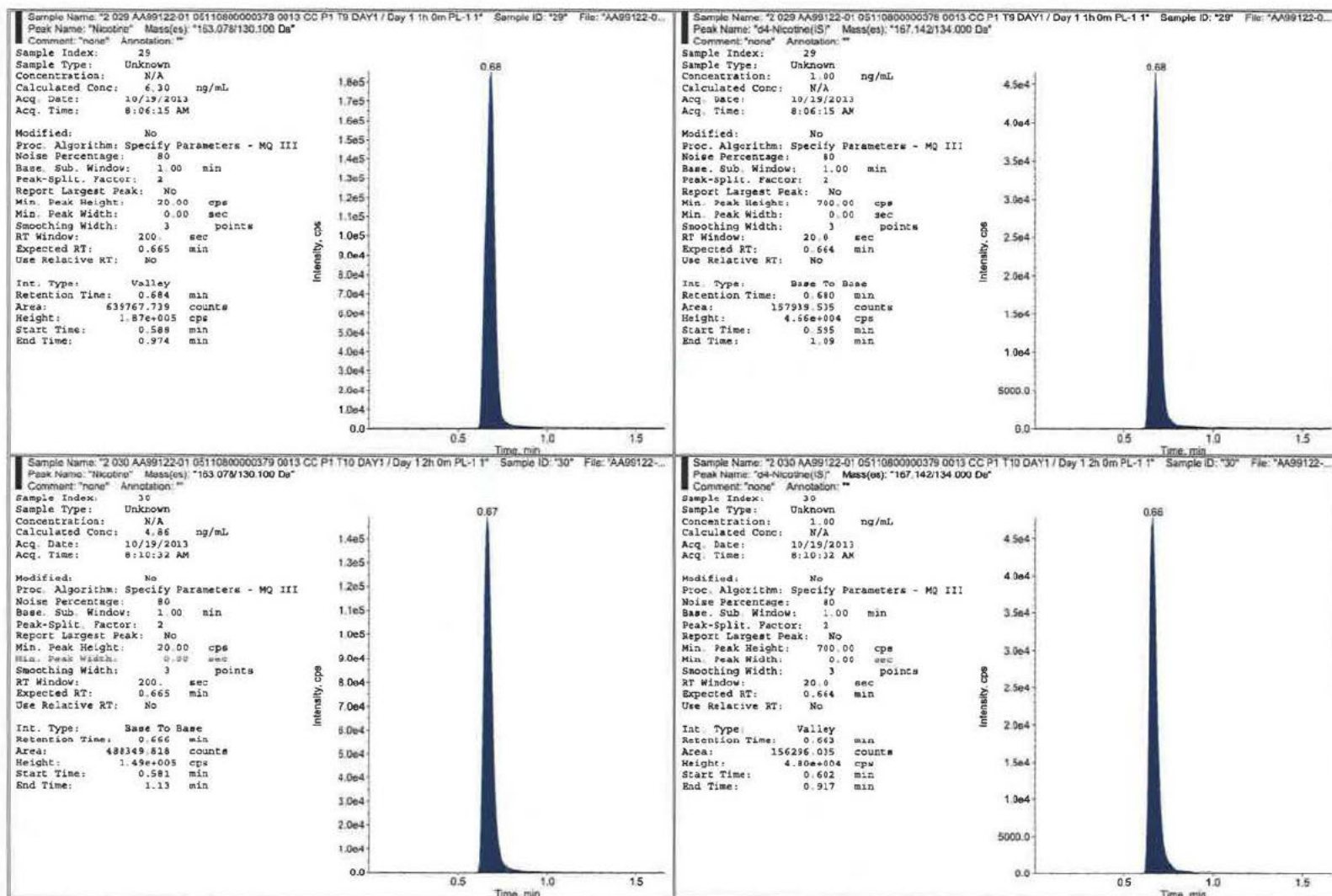


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

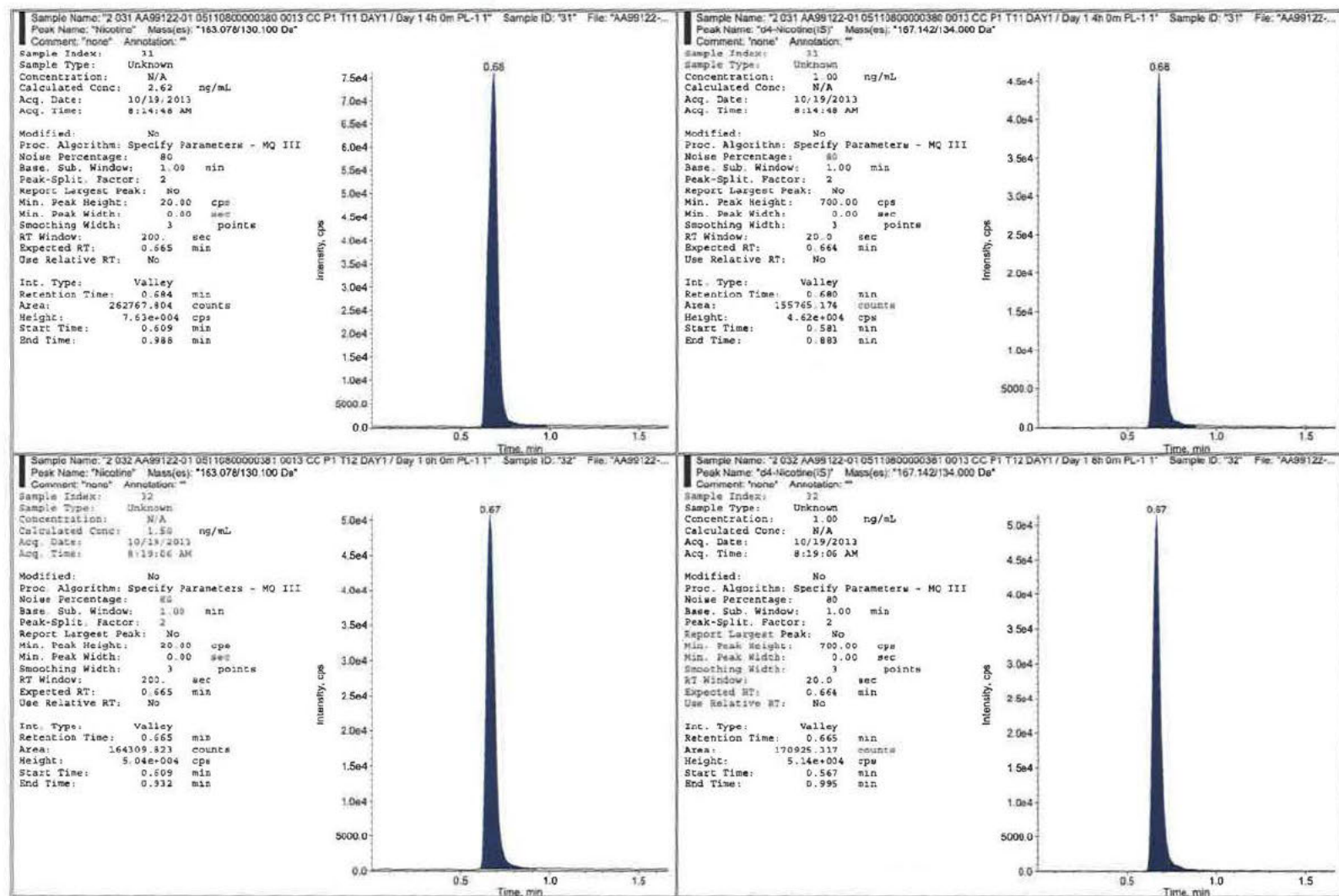


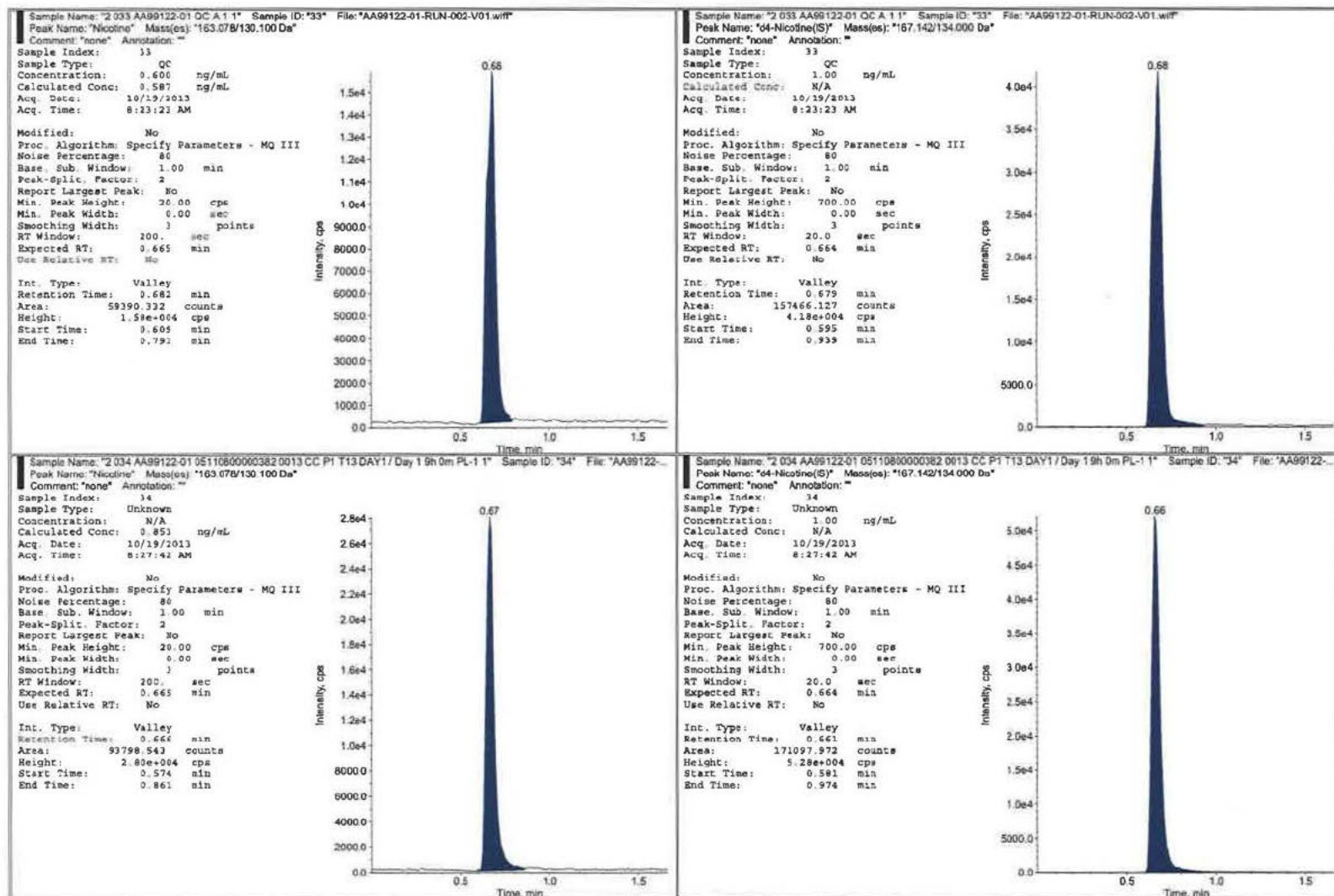


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



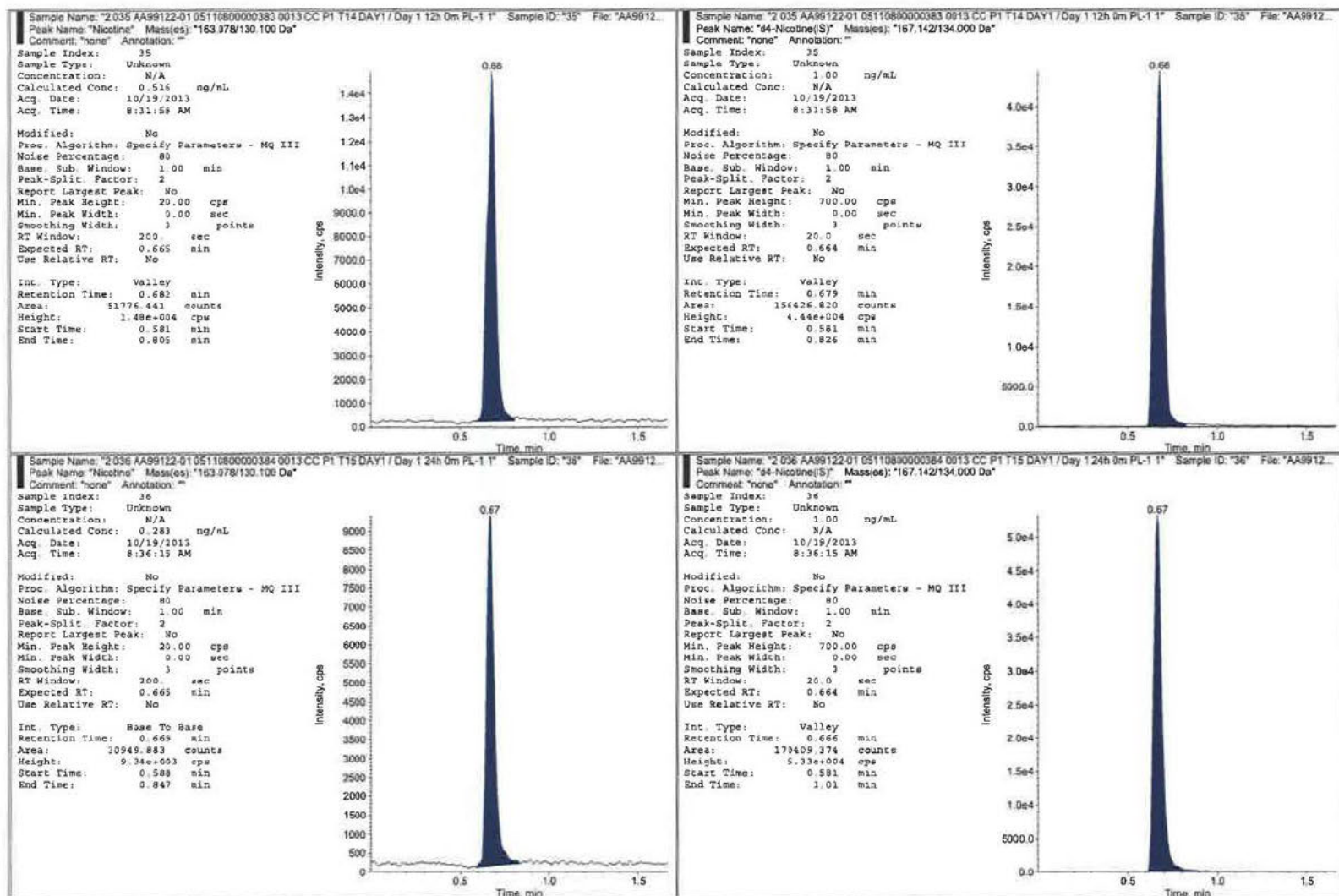
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



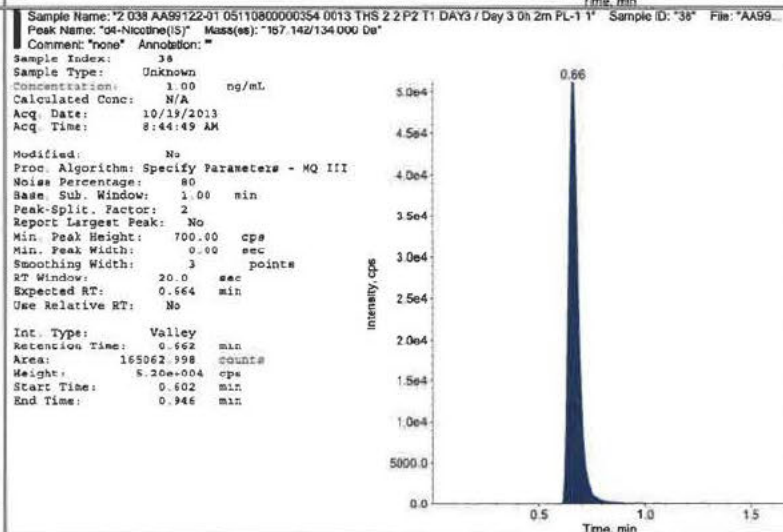
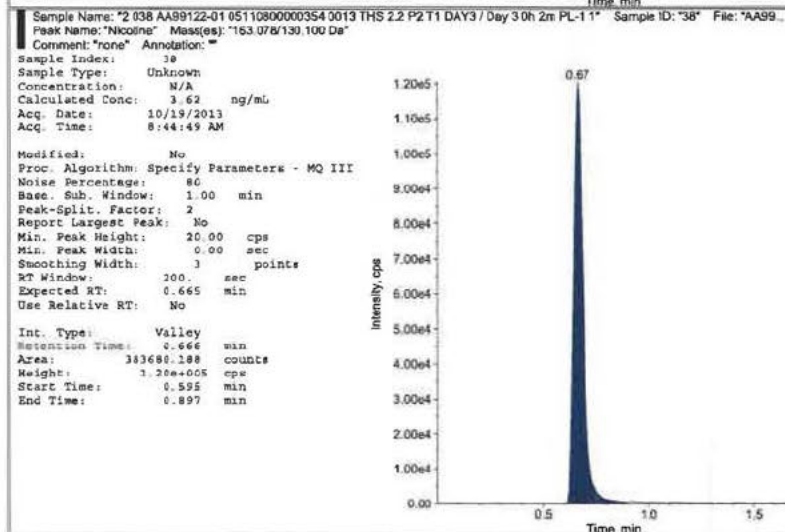
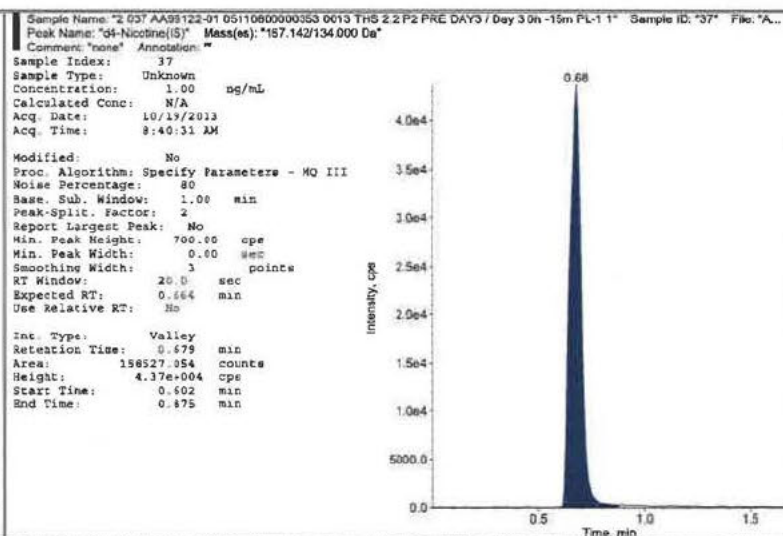
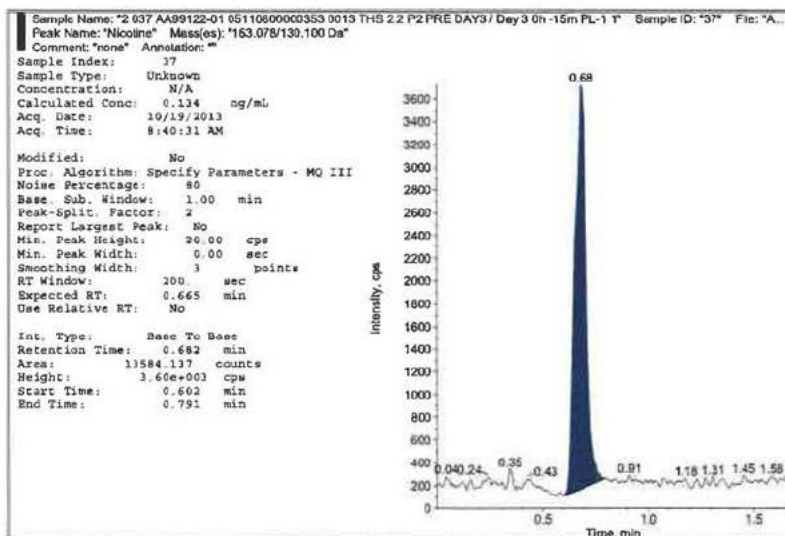


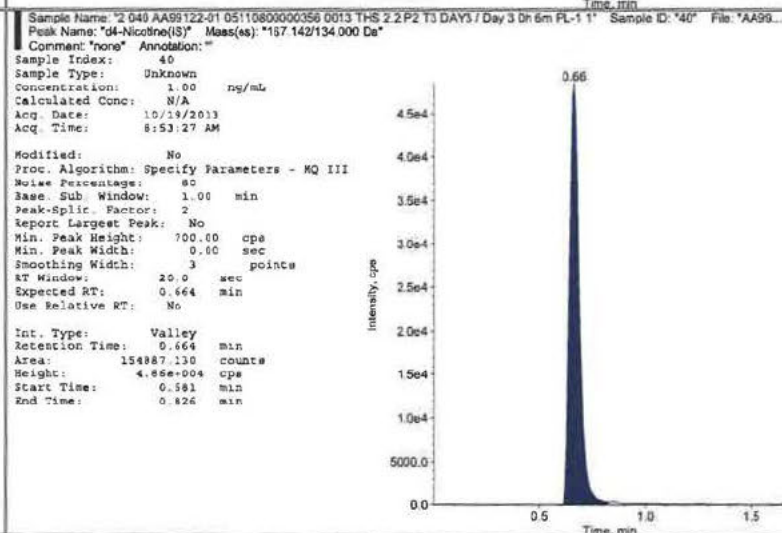
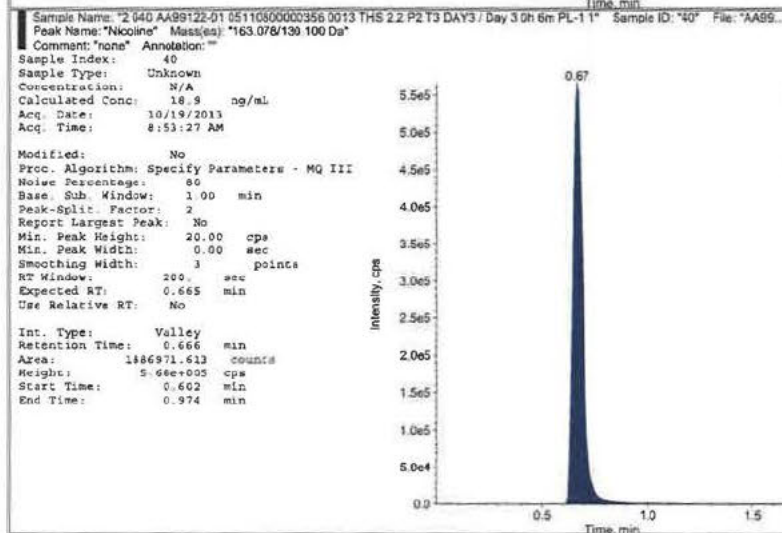
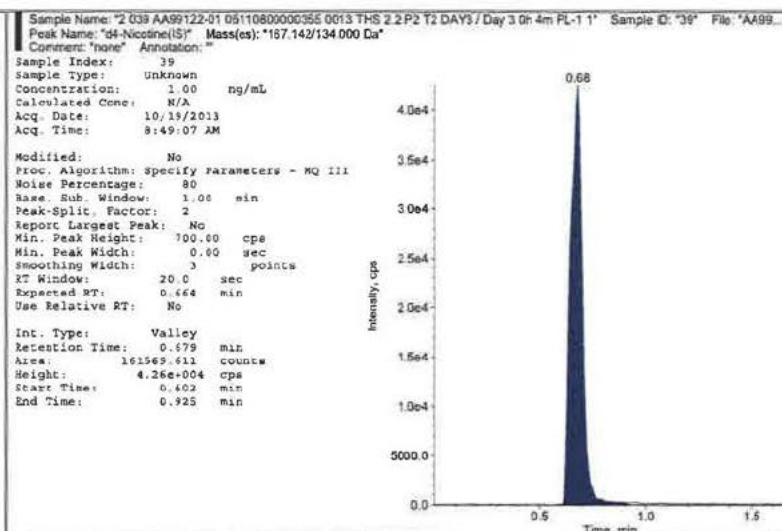
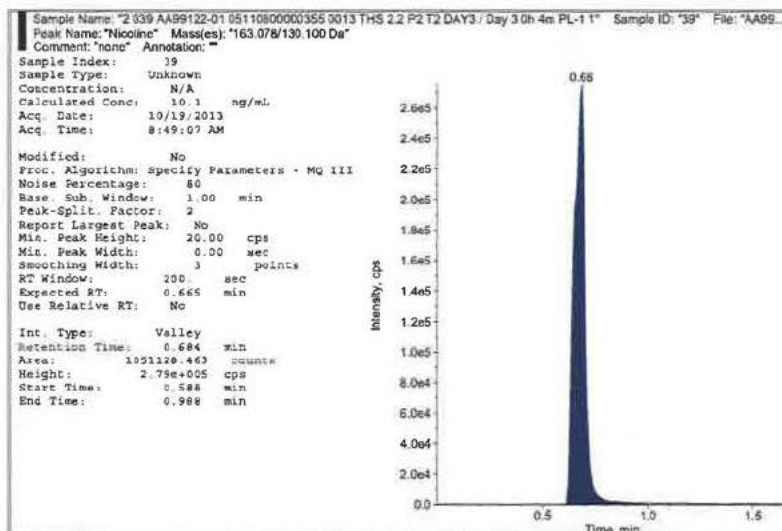


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



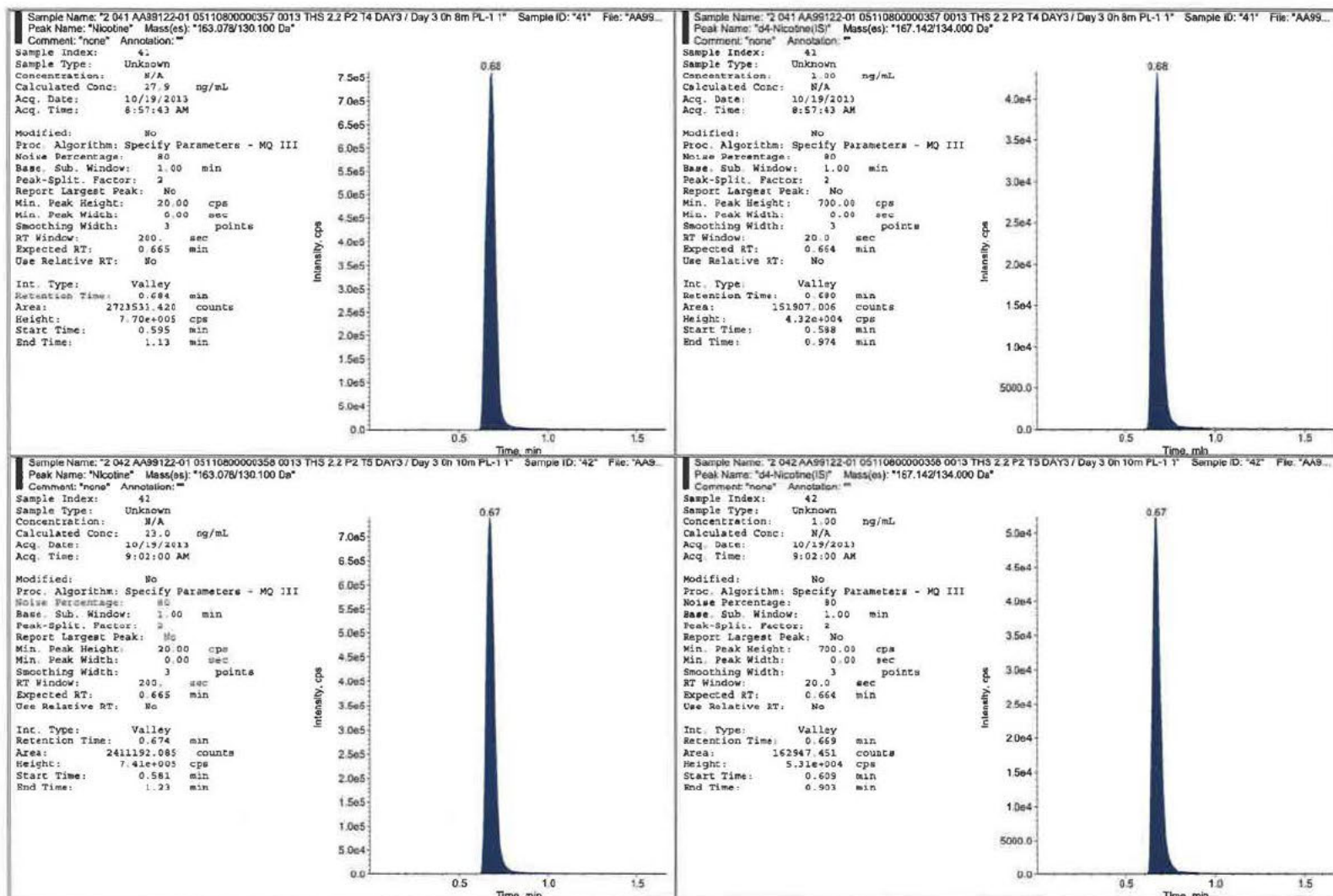
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01





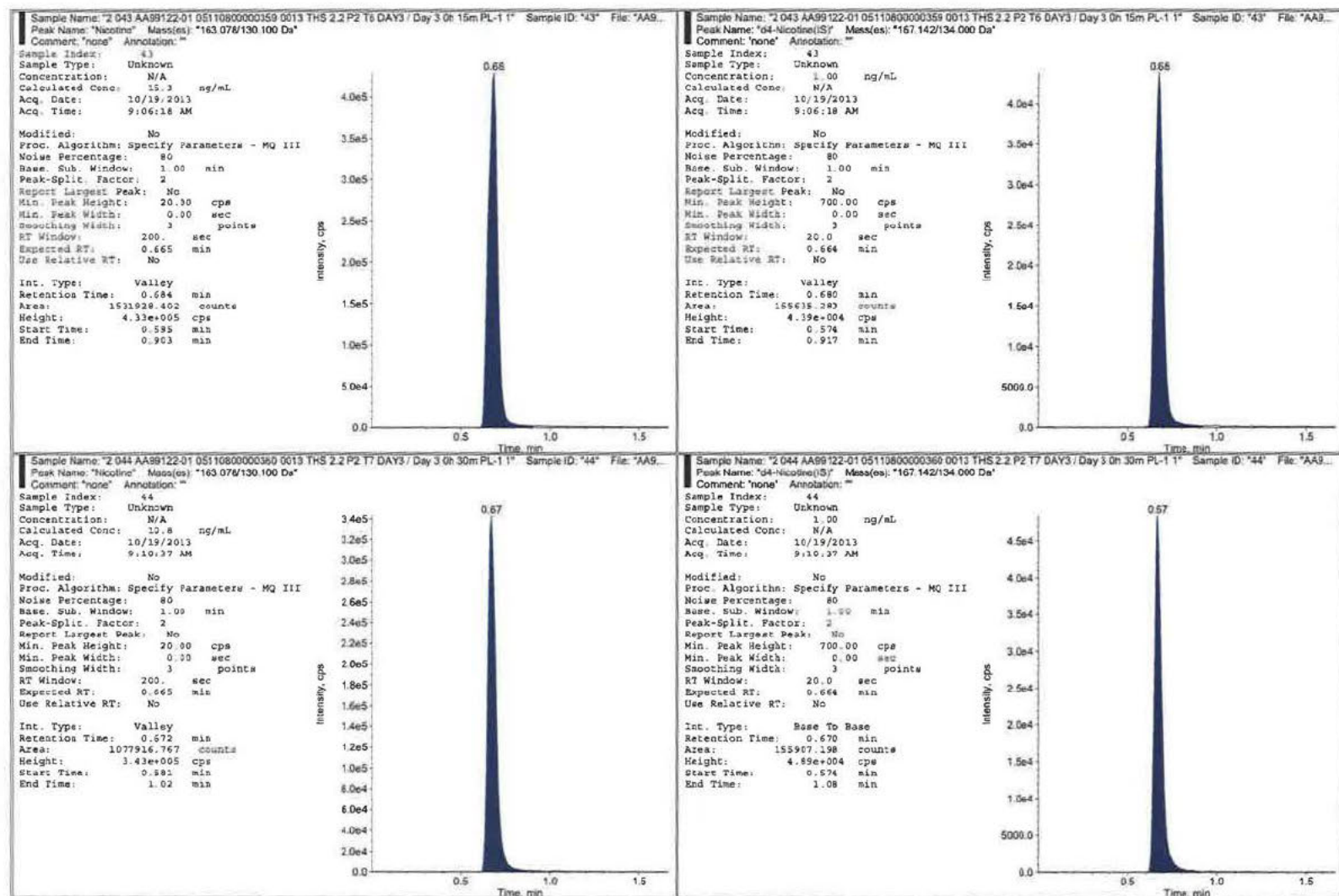


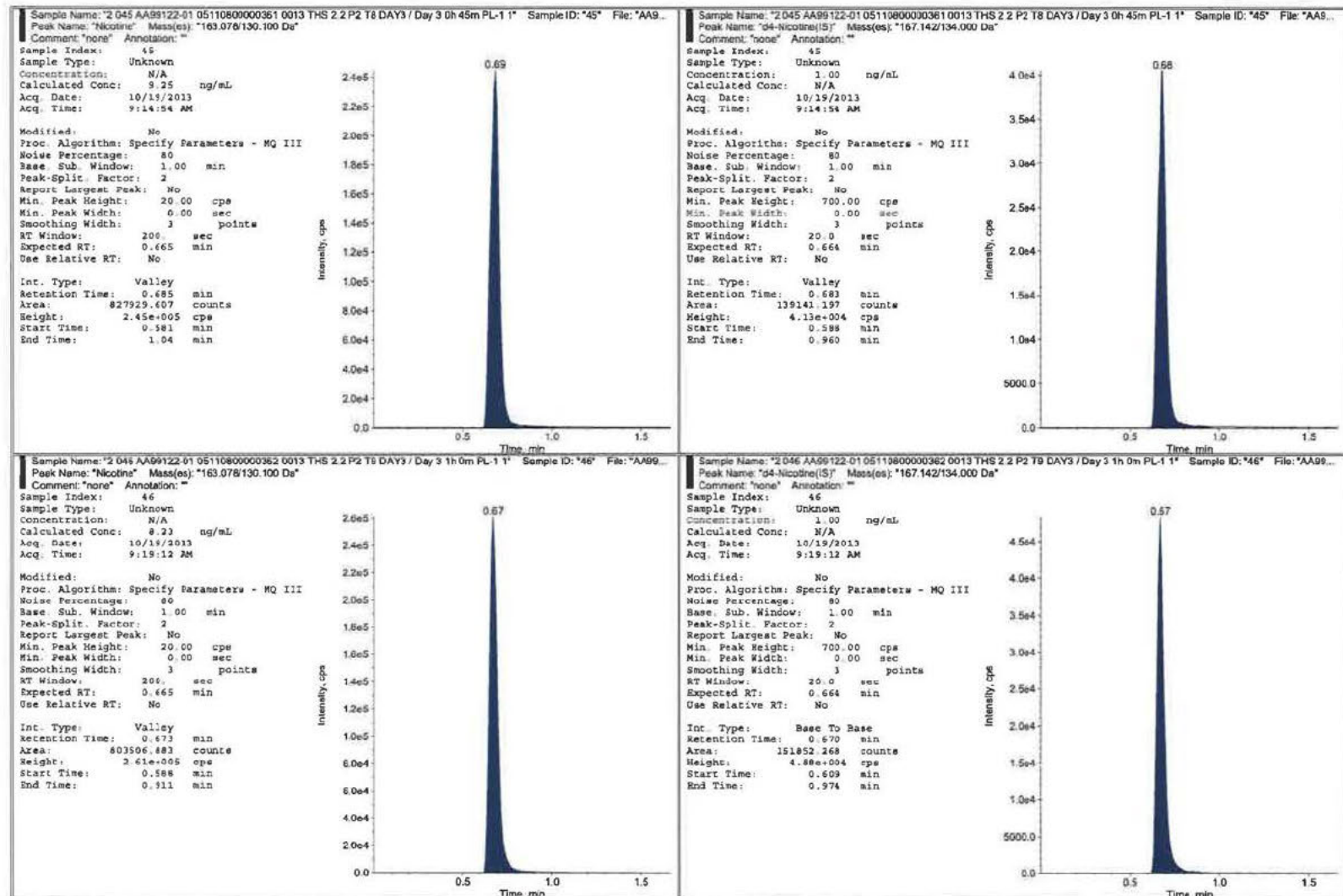
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



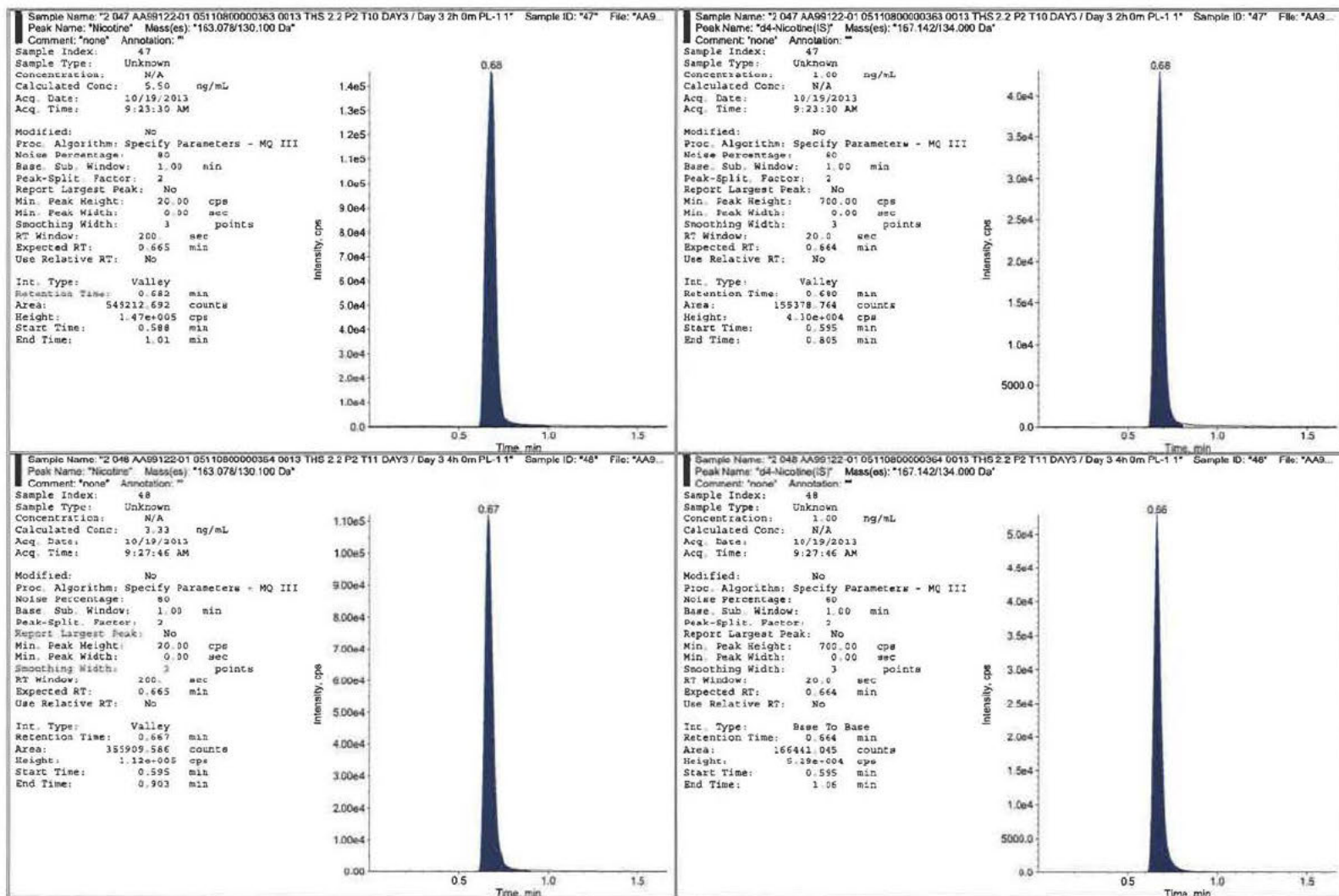


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



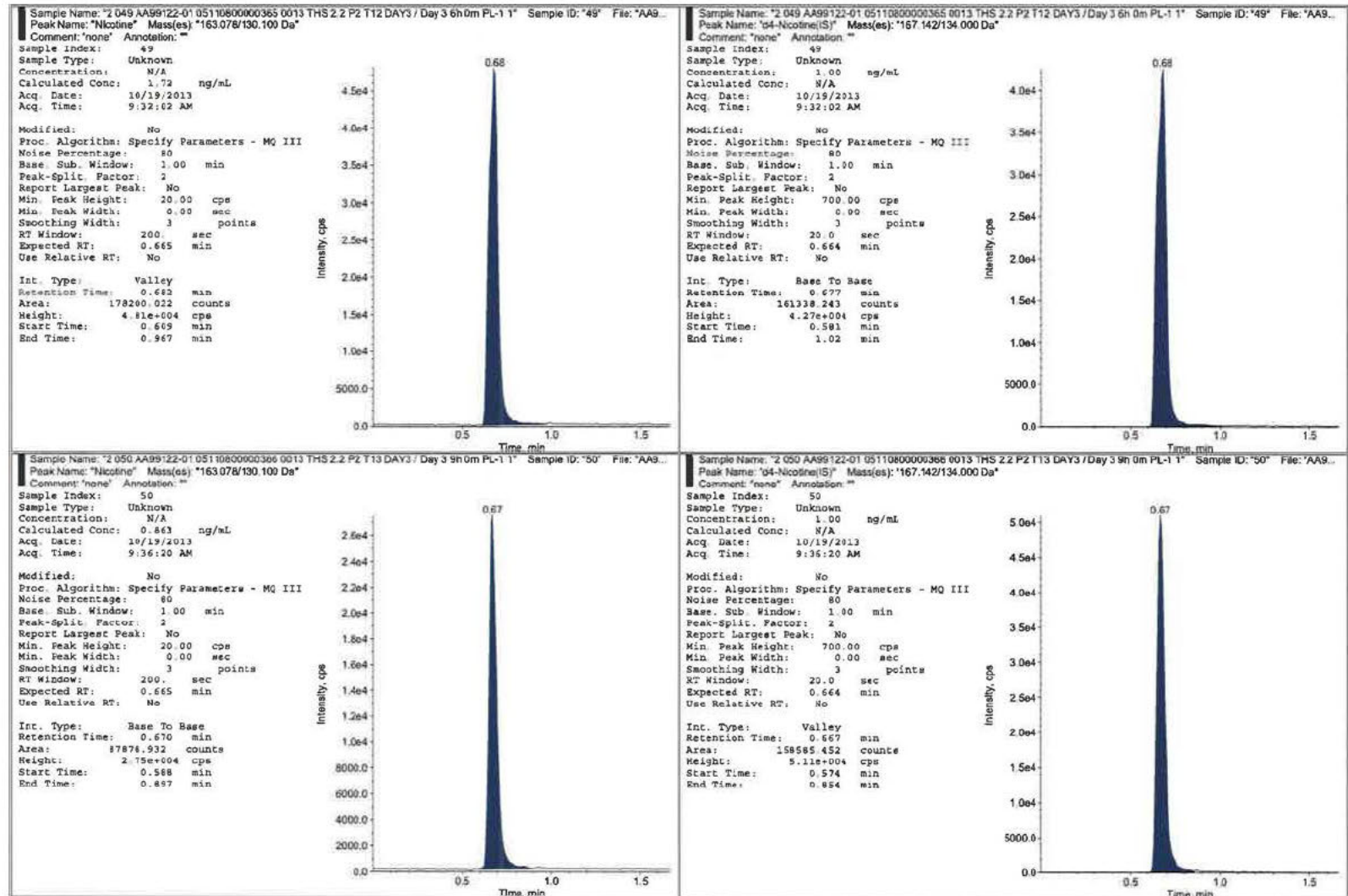


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

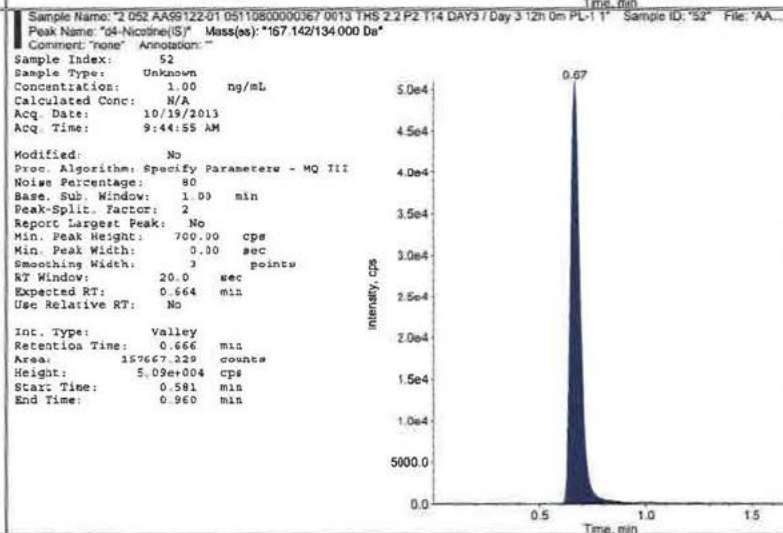
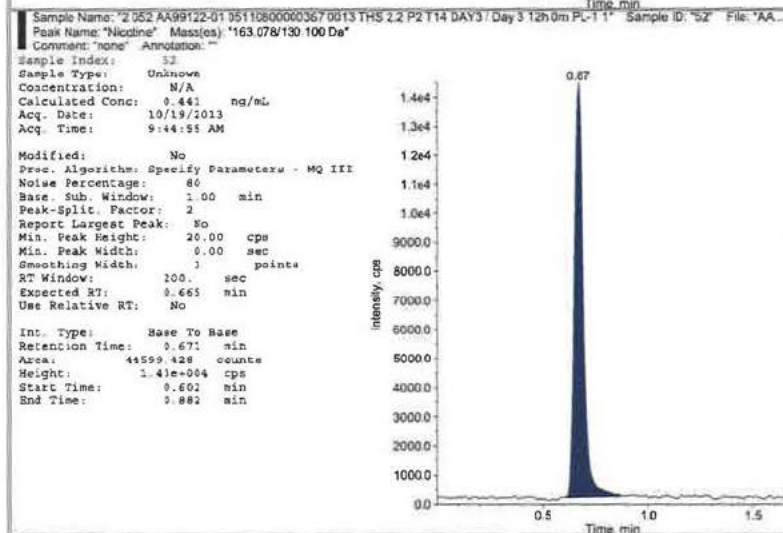
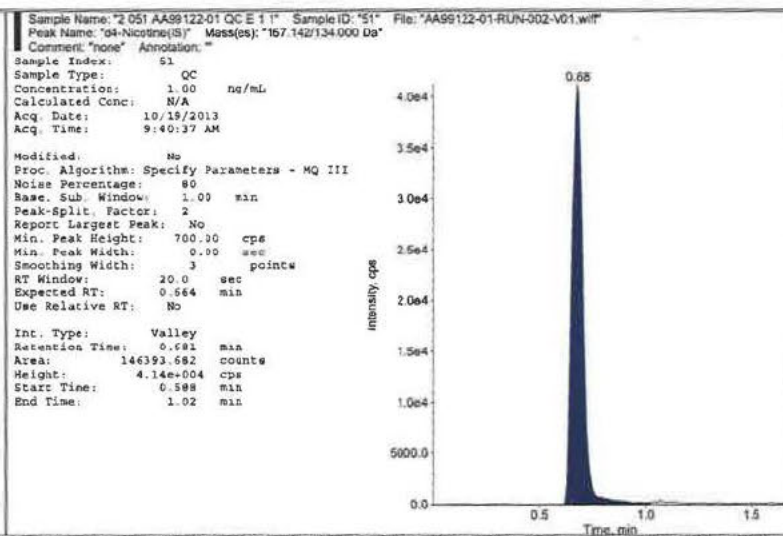
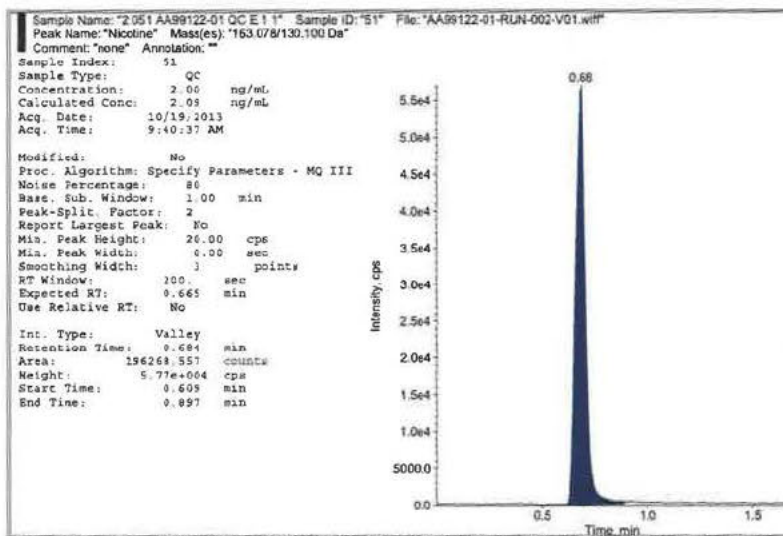


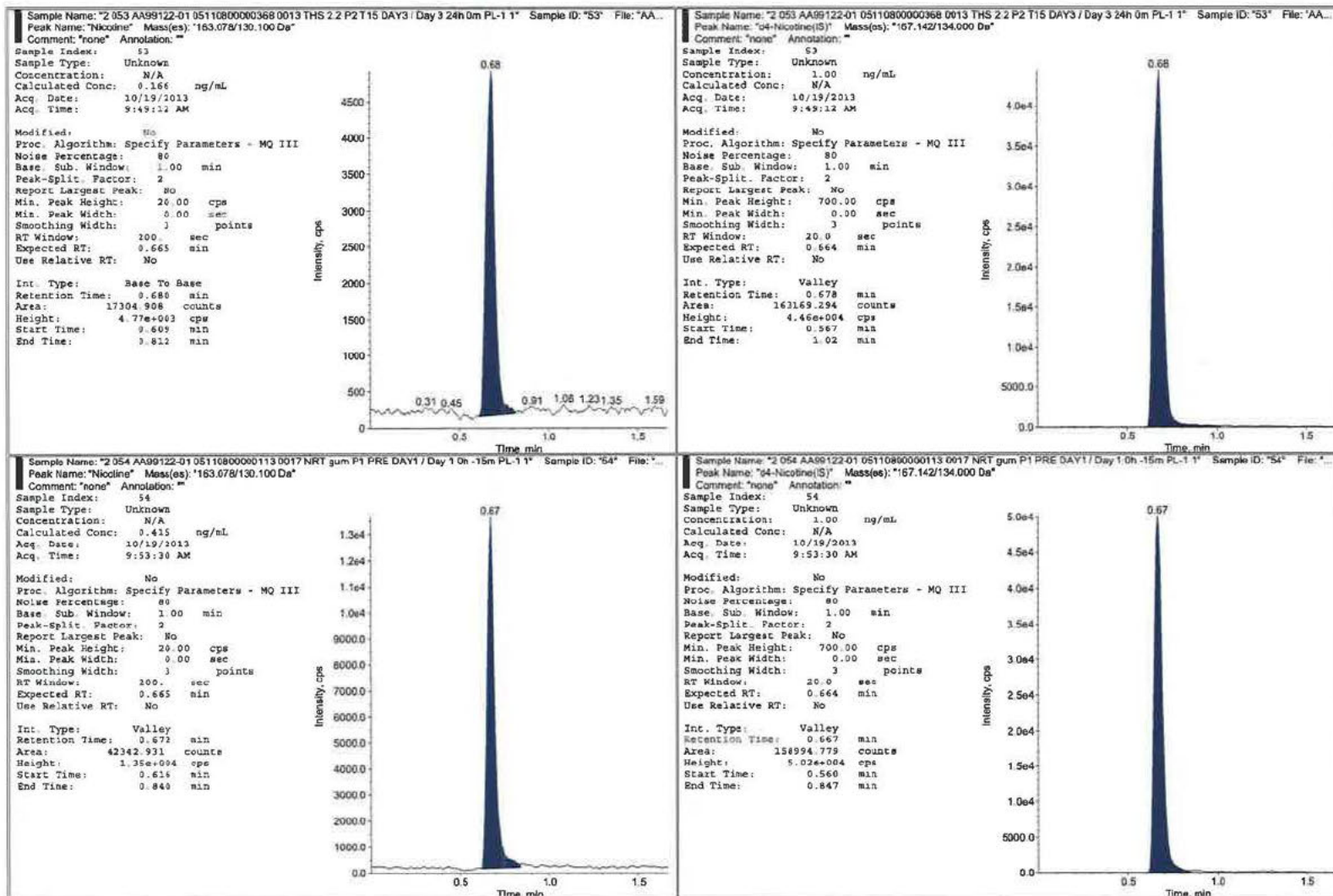


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



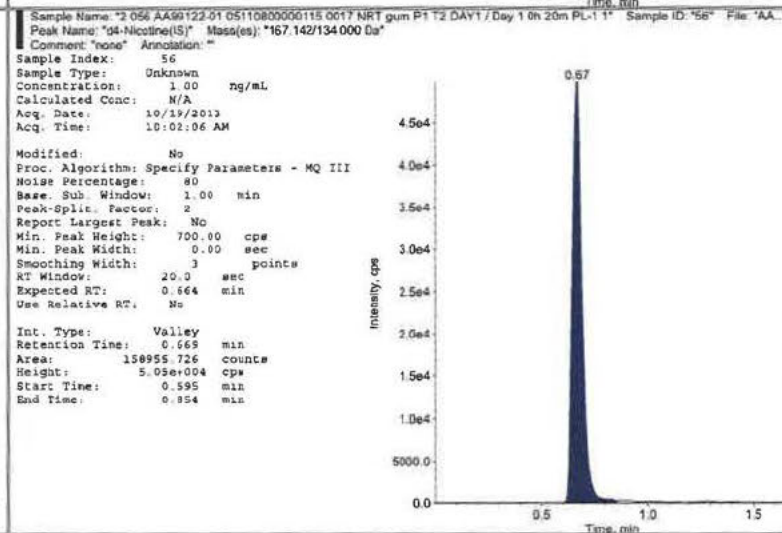
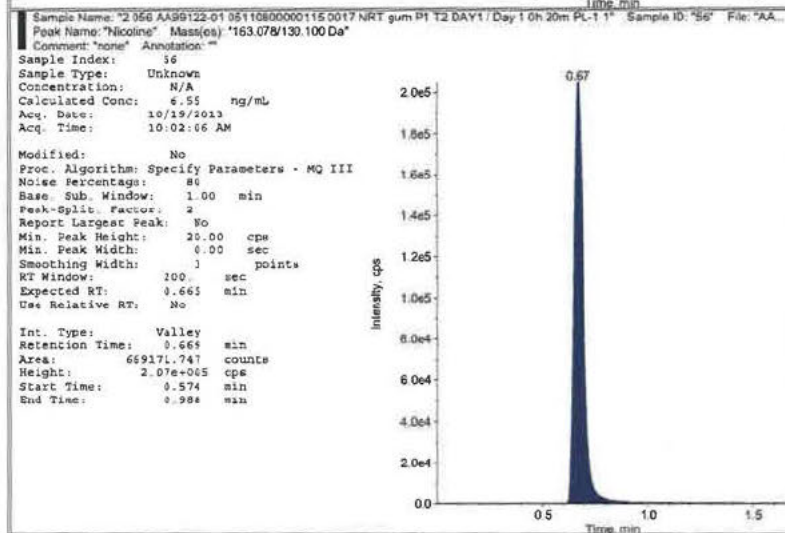
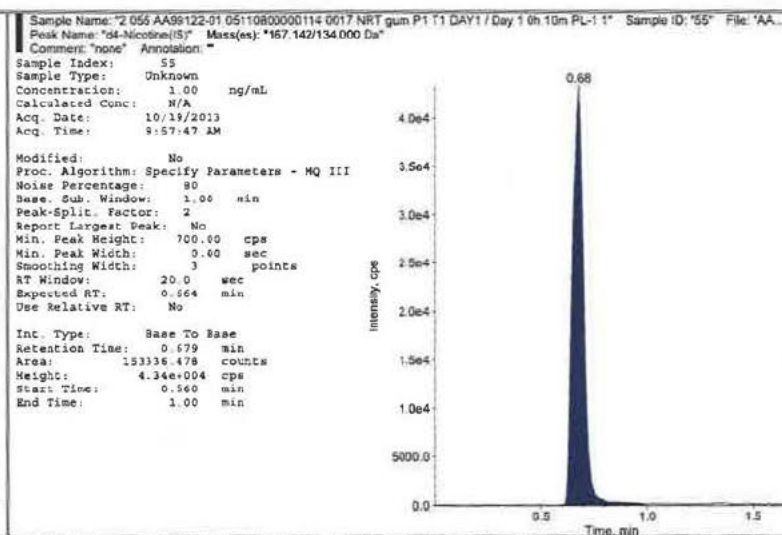
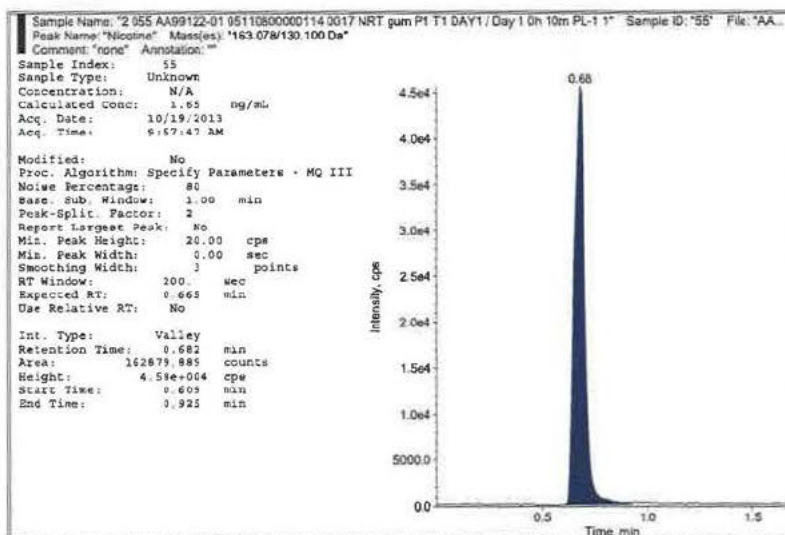
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01





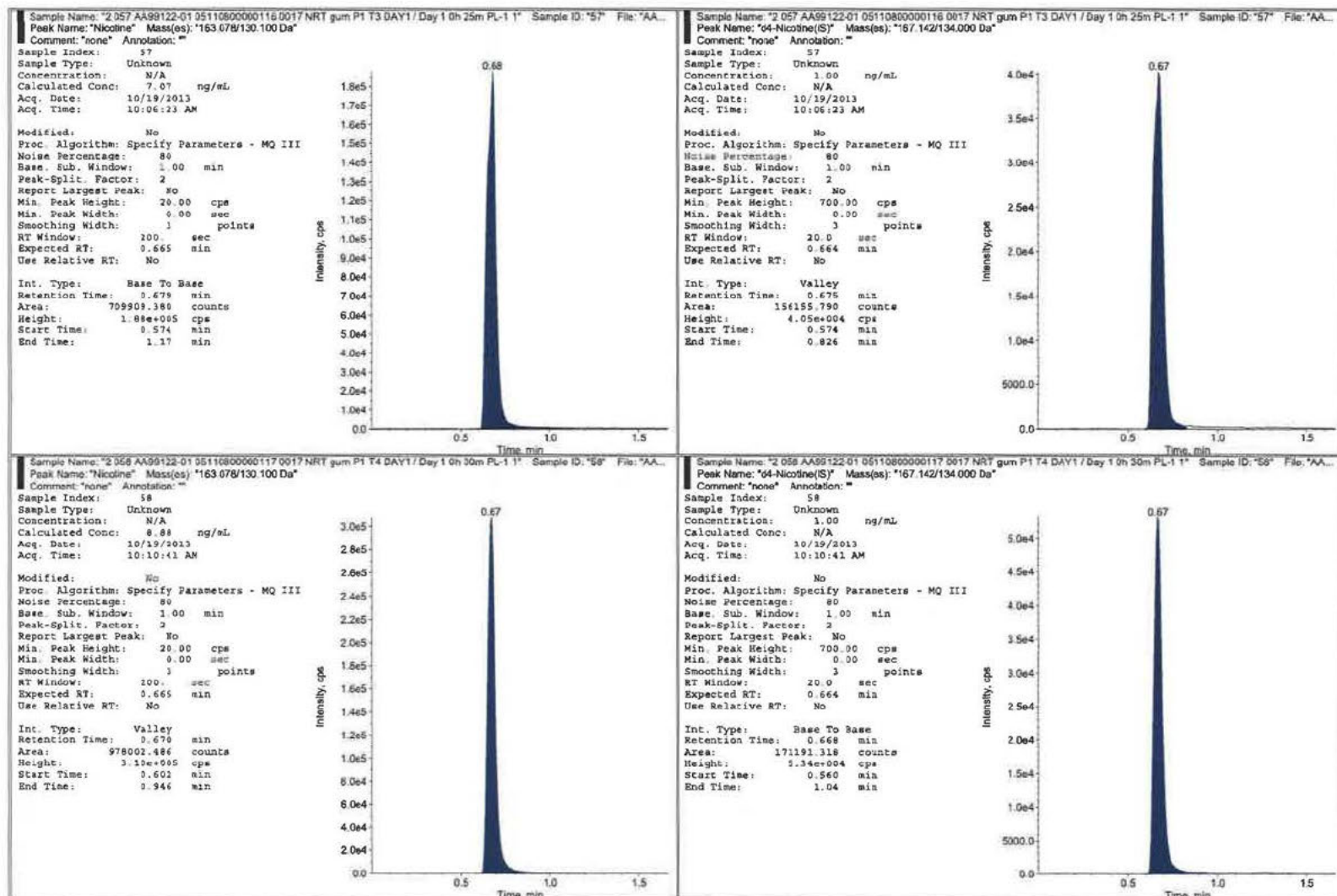


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

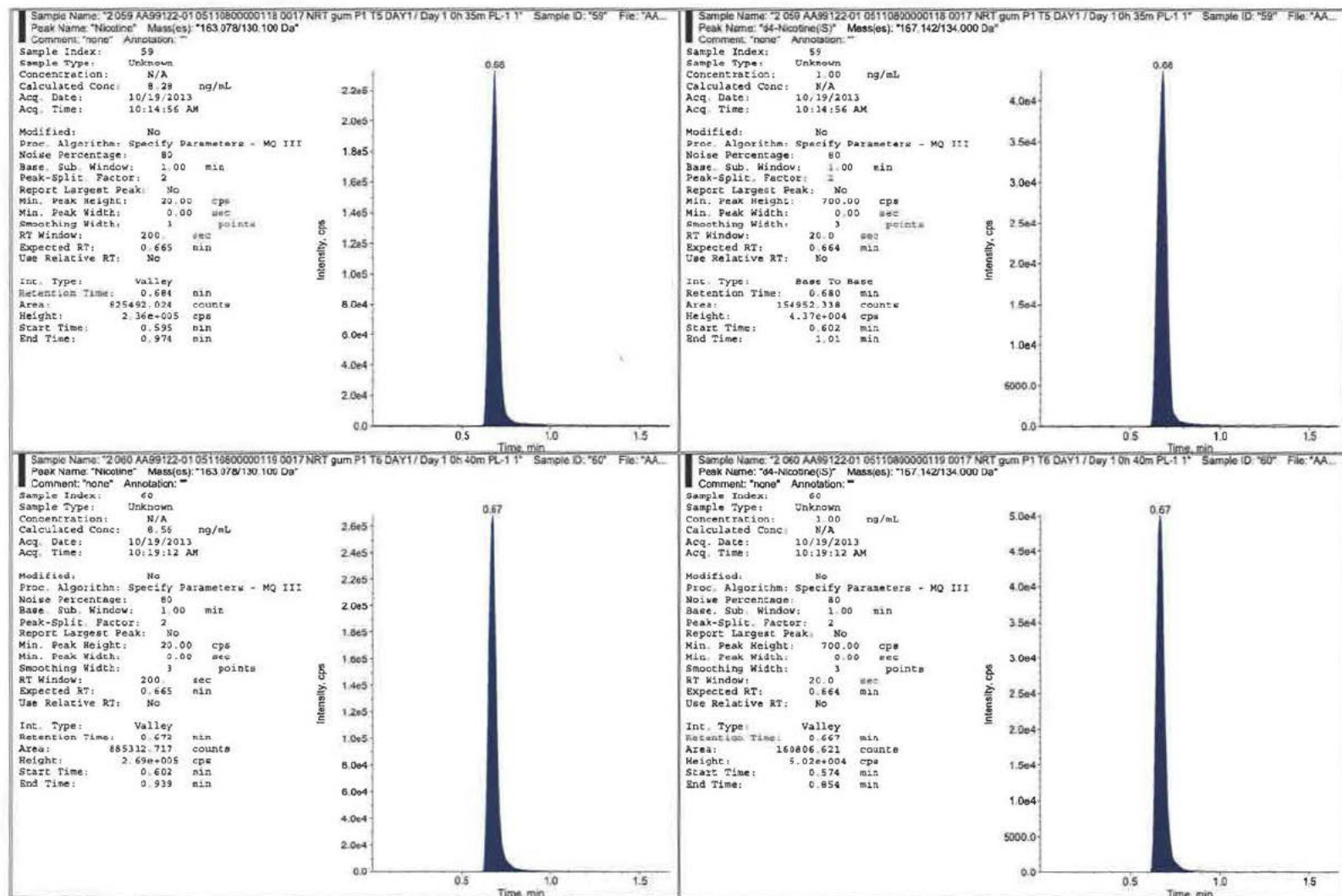




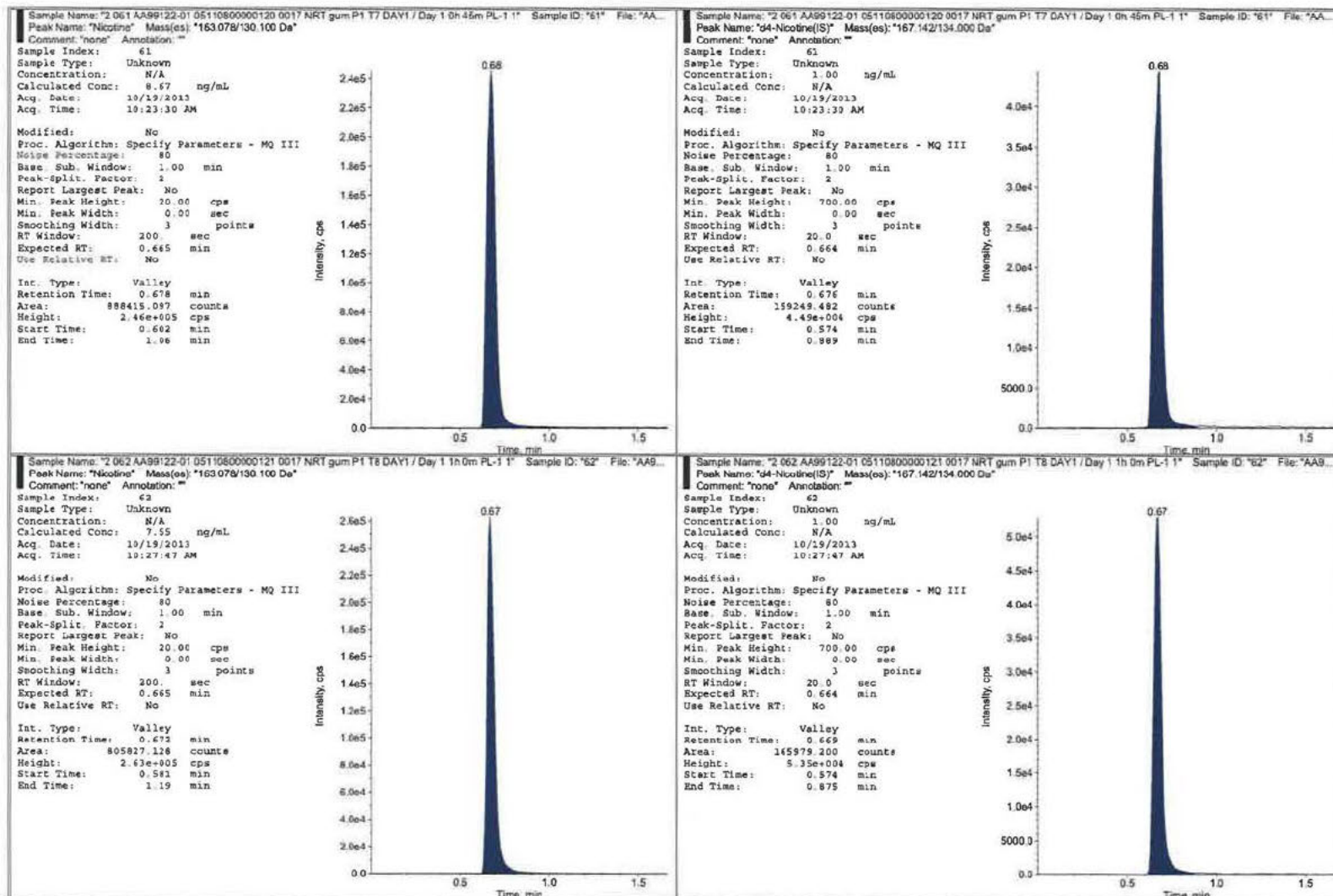
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

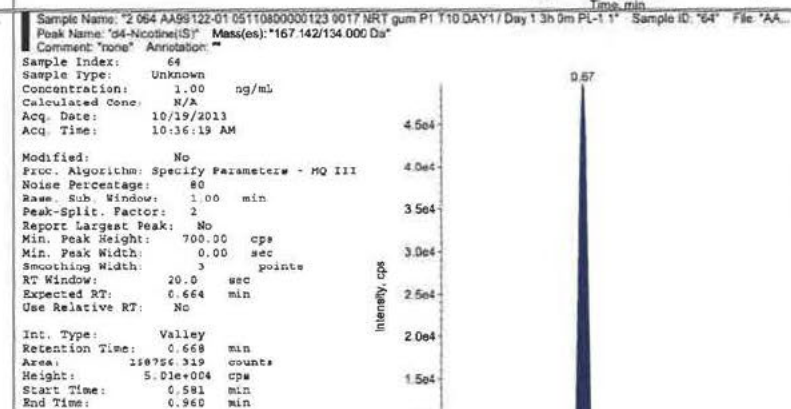
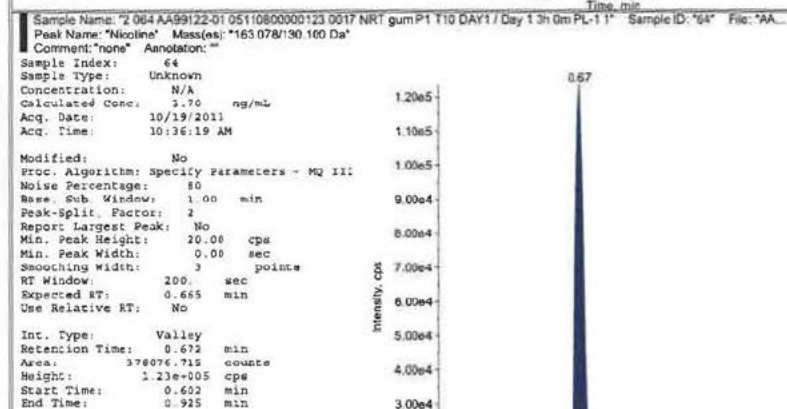
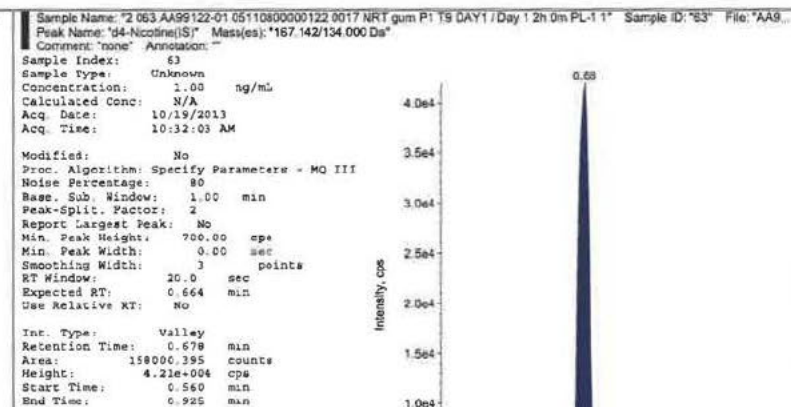
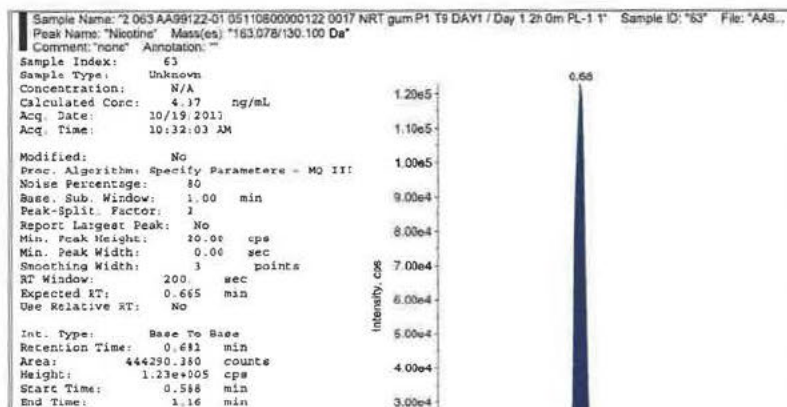


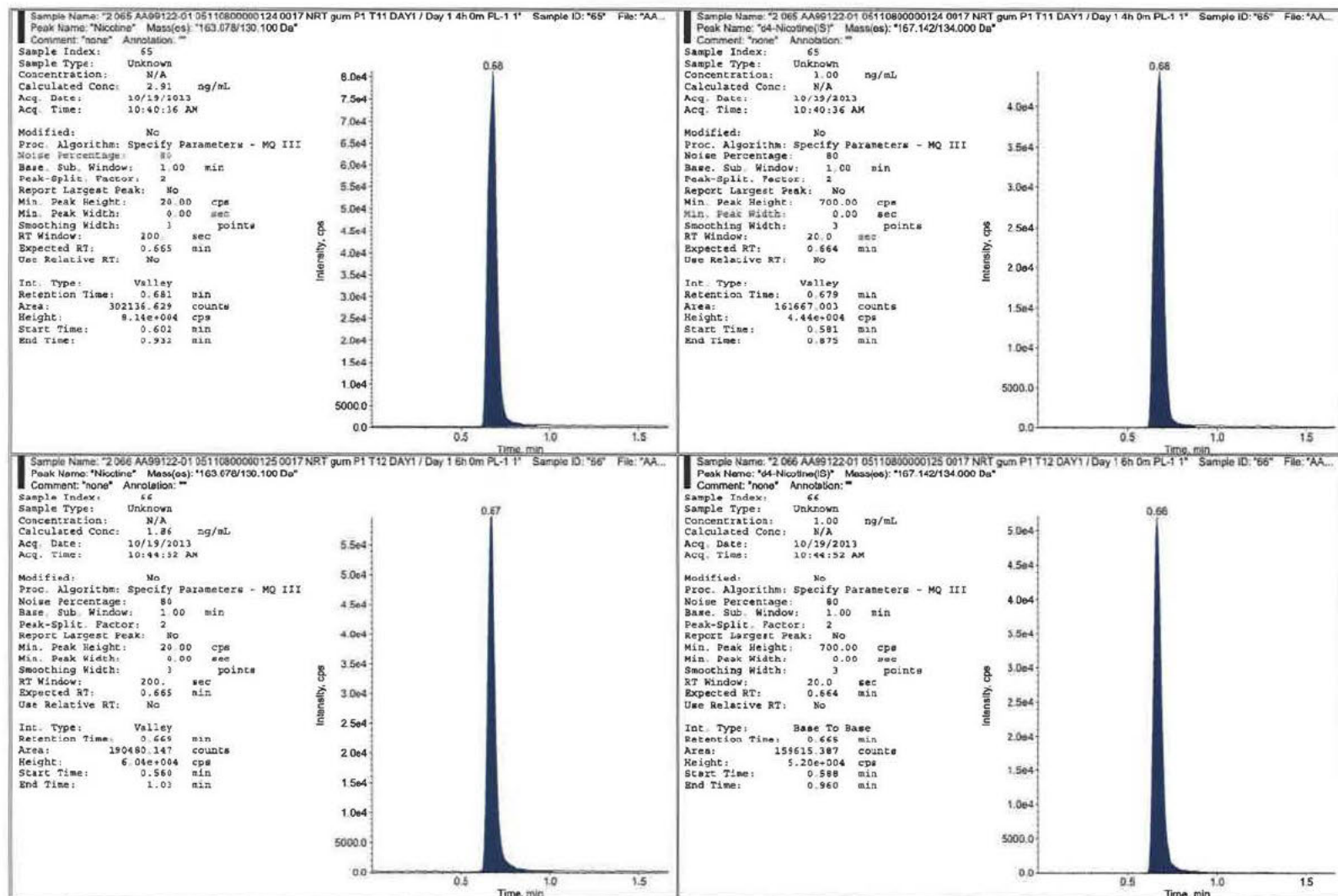
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



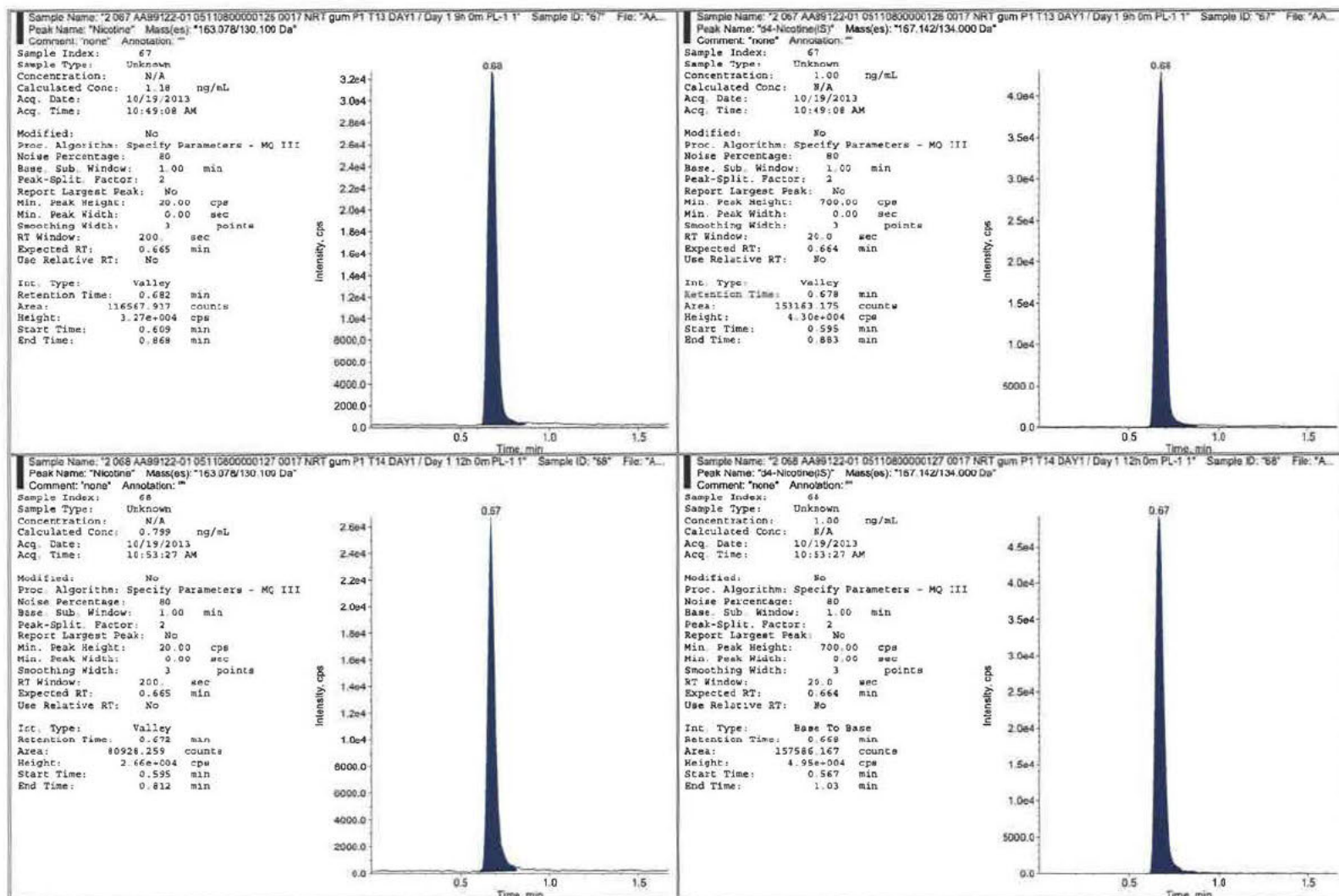


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

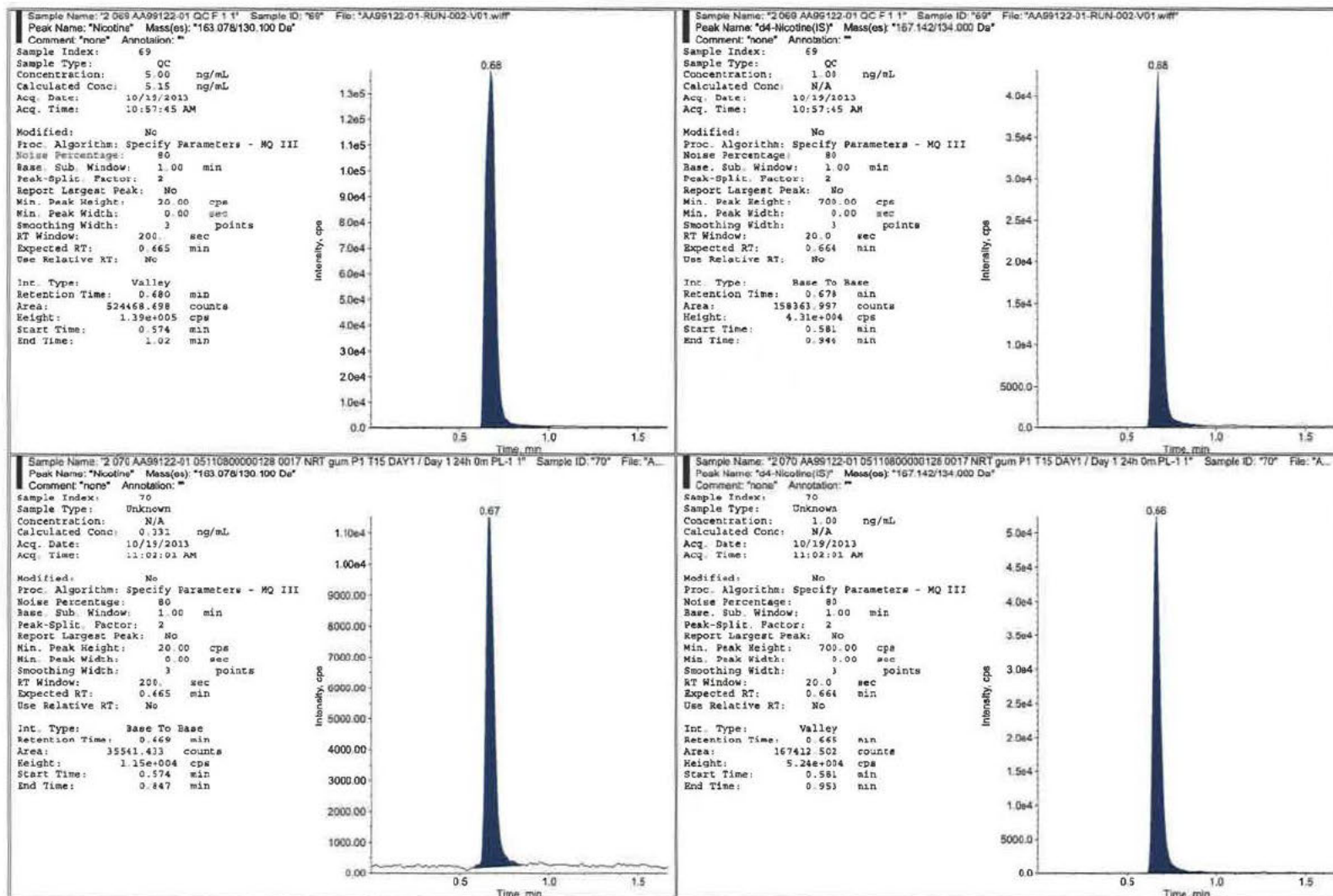




Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

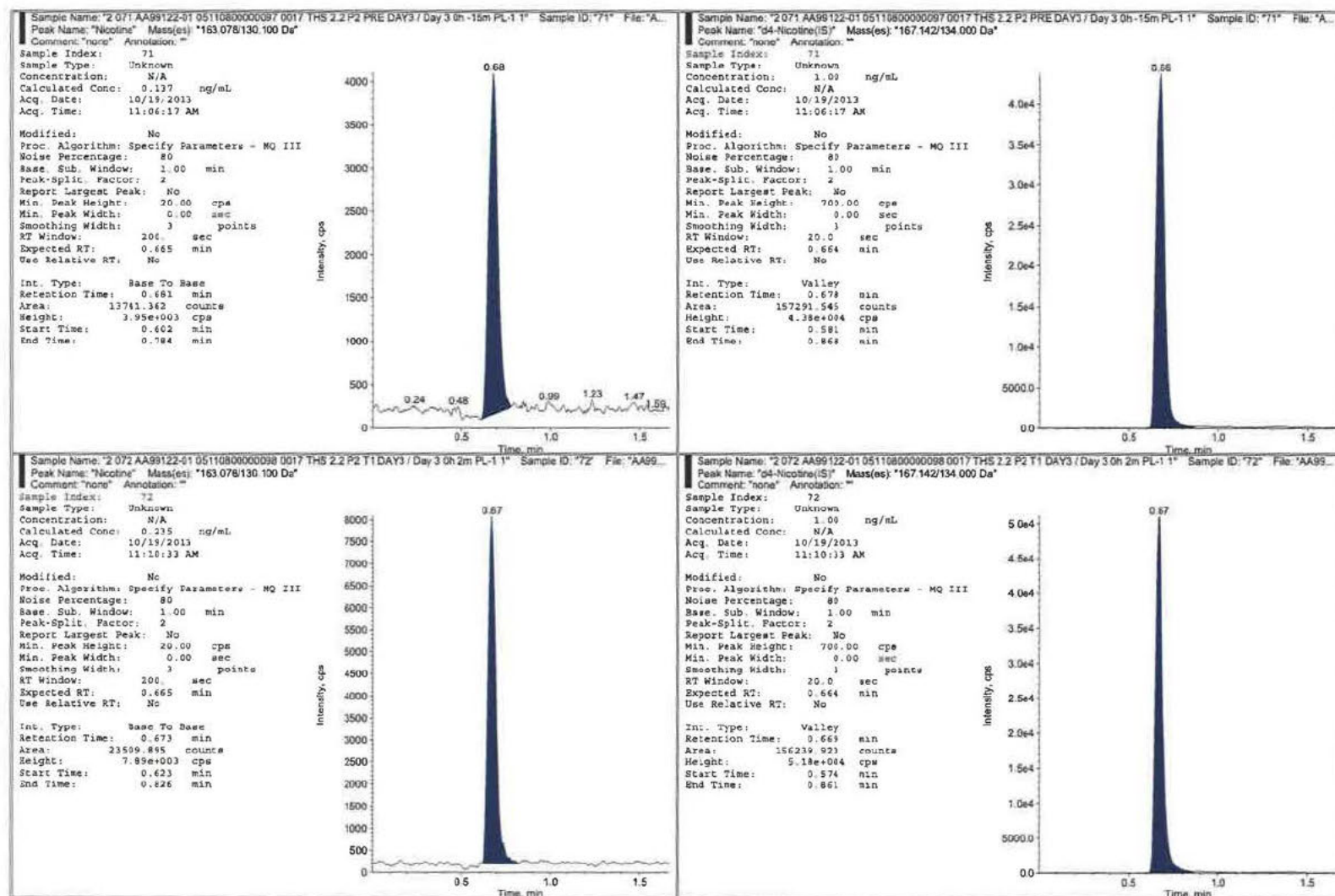




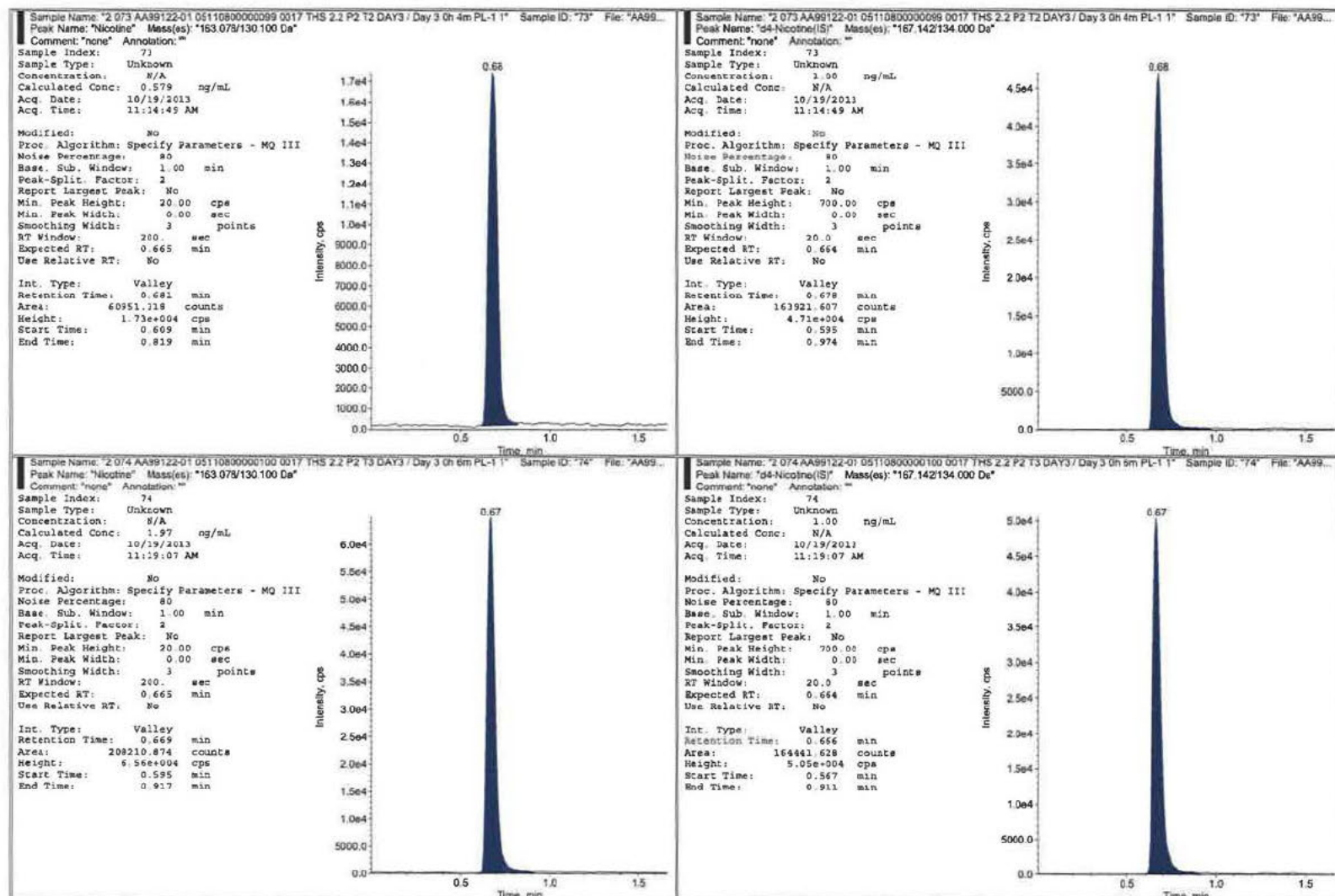




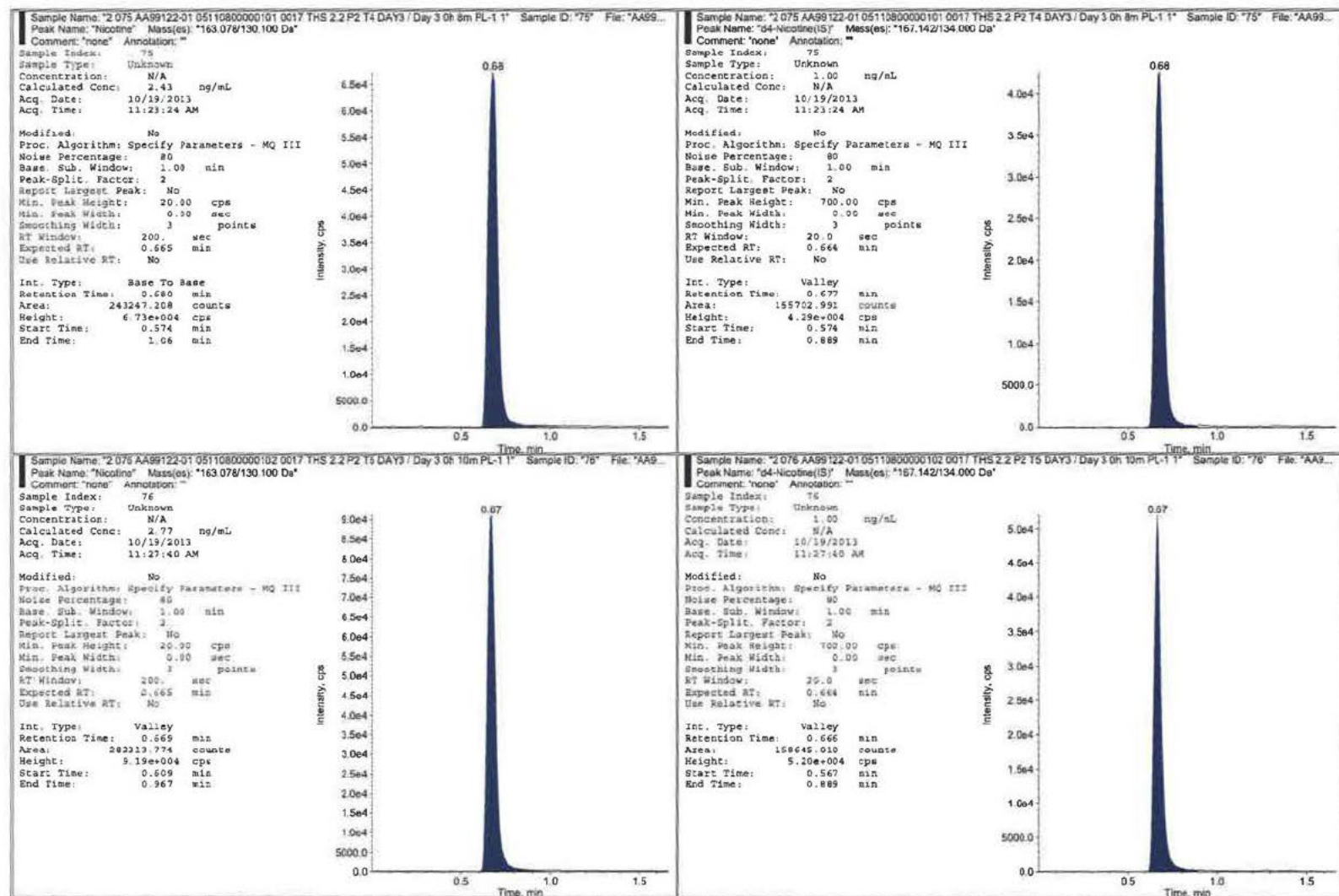
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

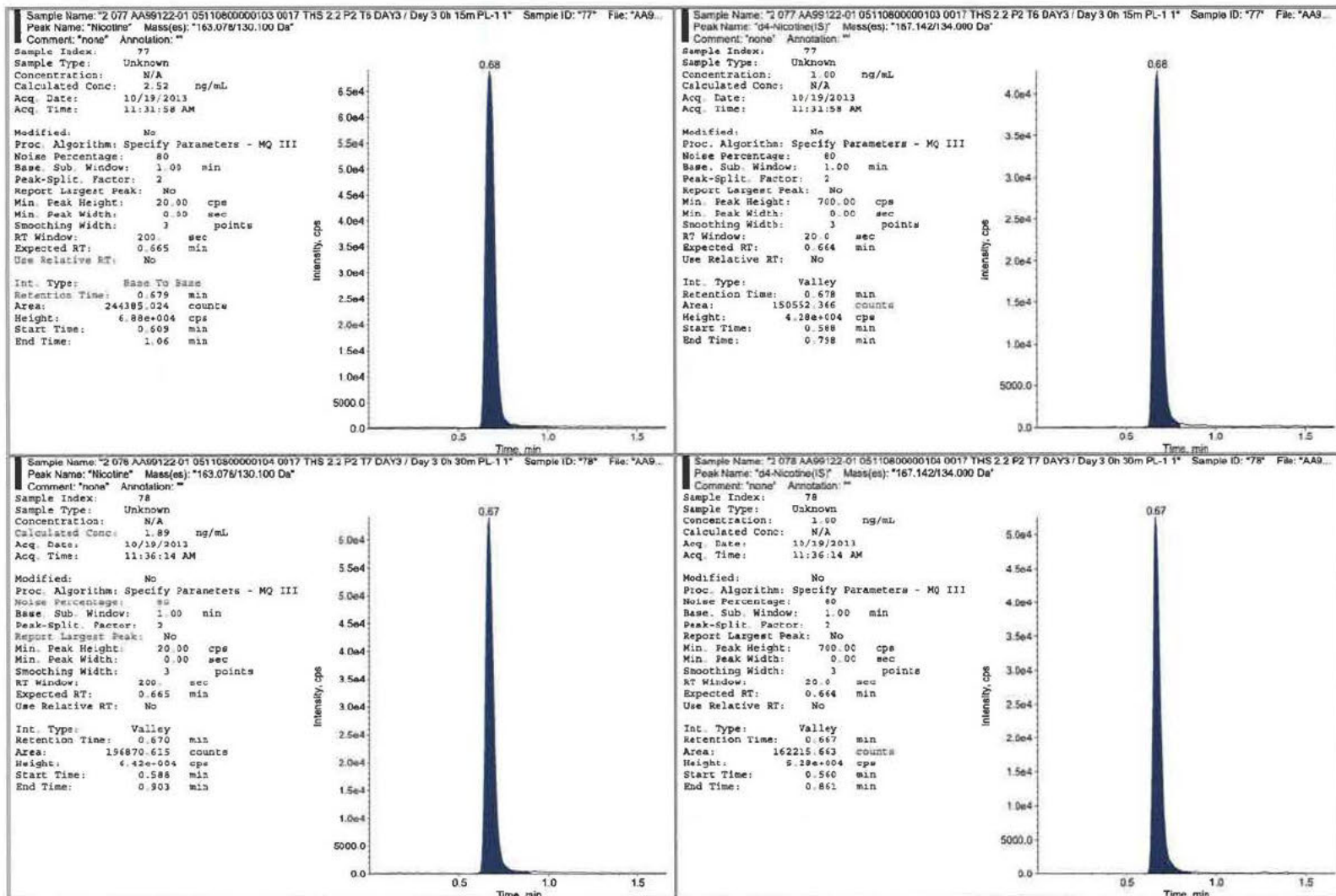


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

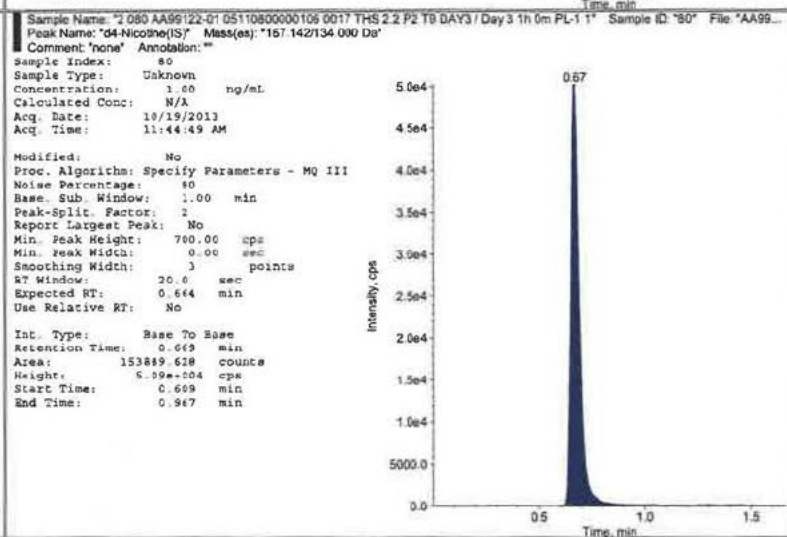
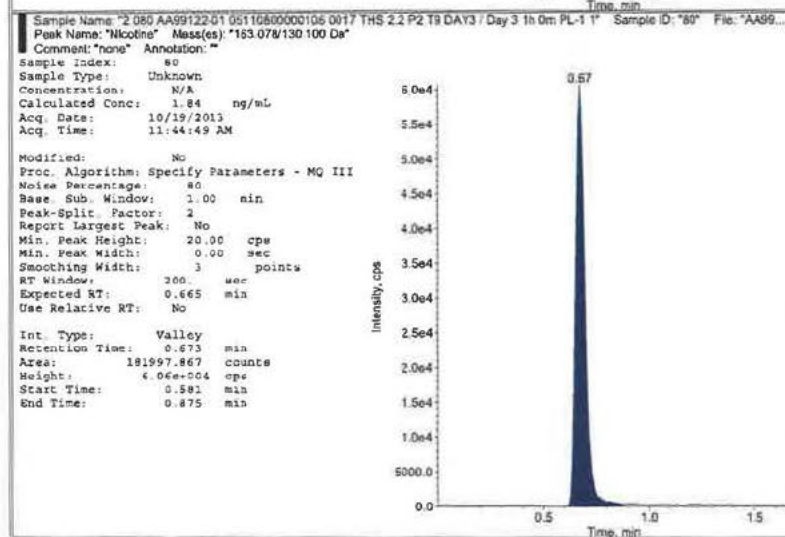
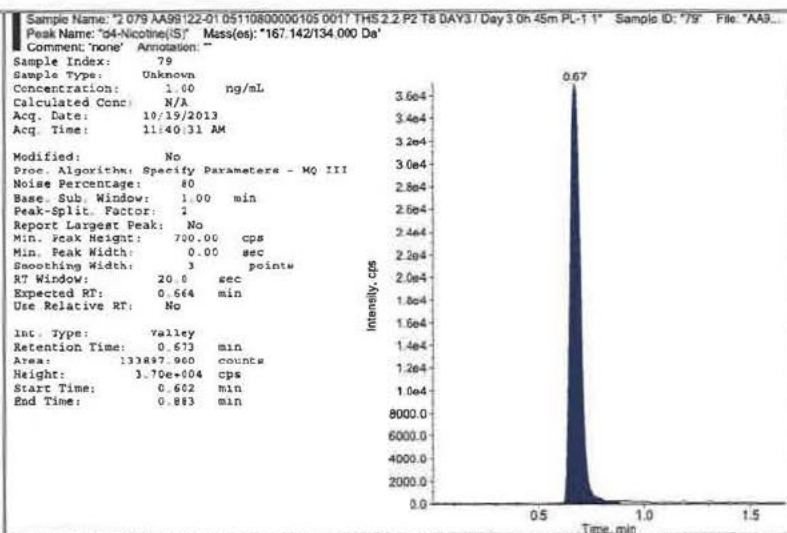
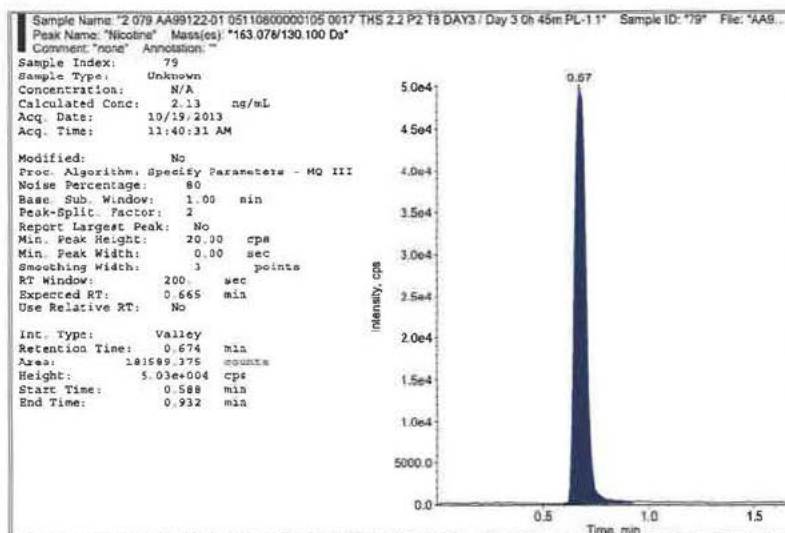




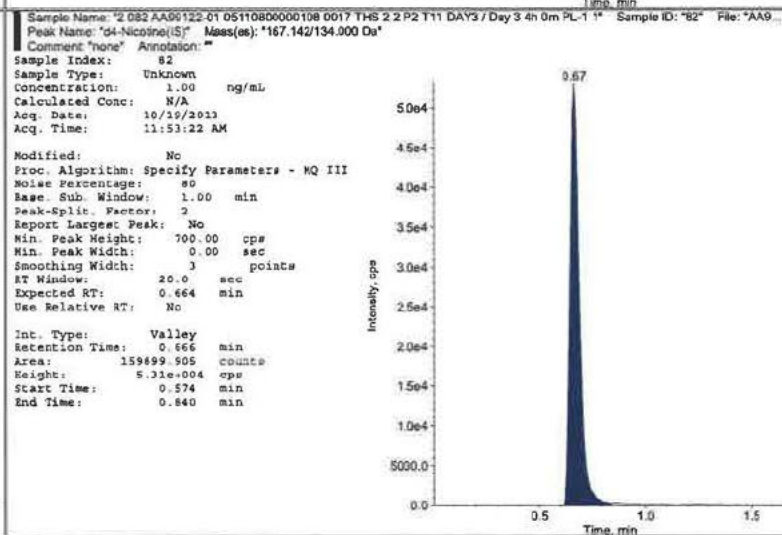
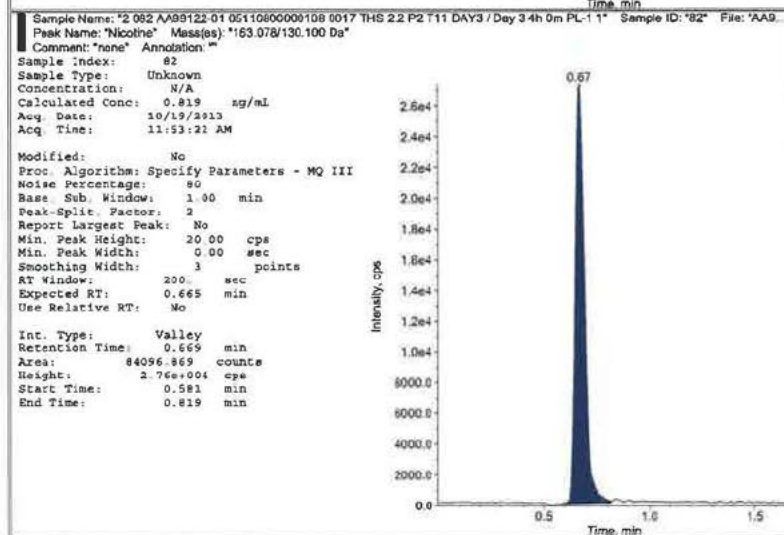
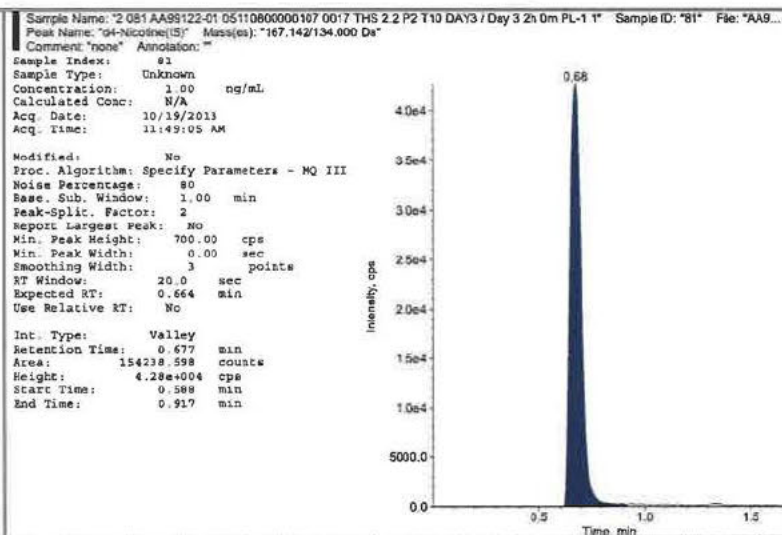
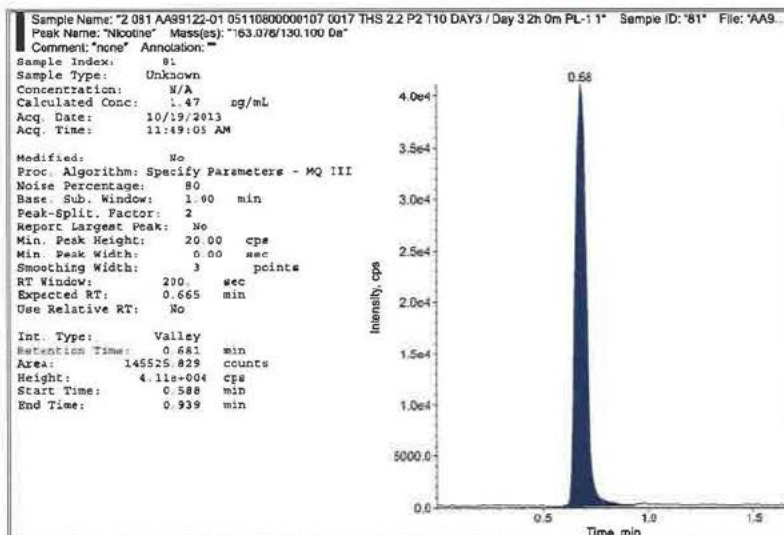
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

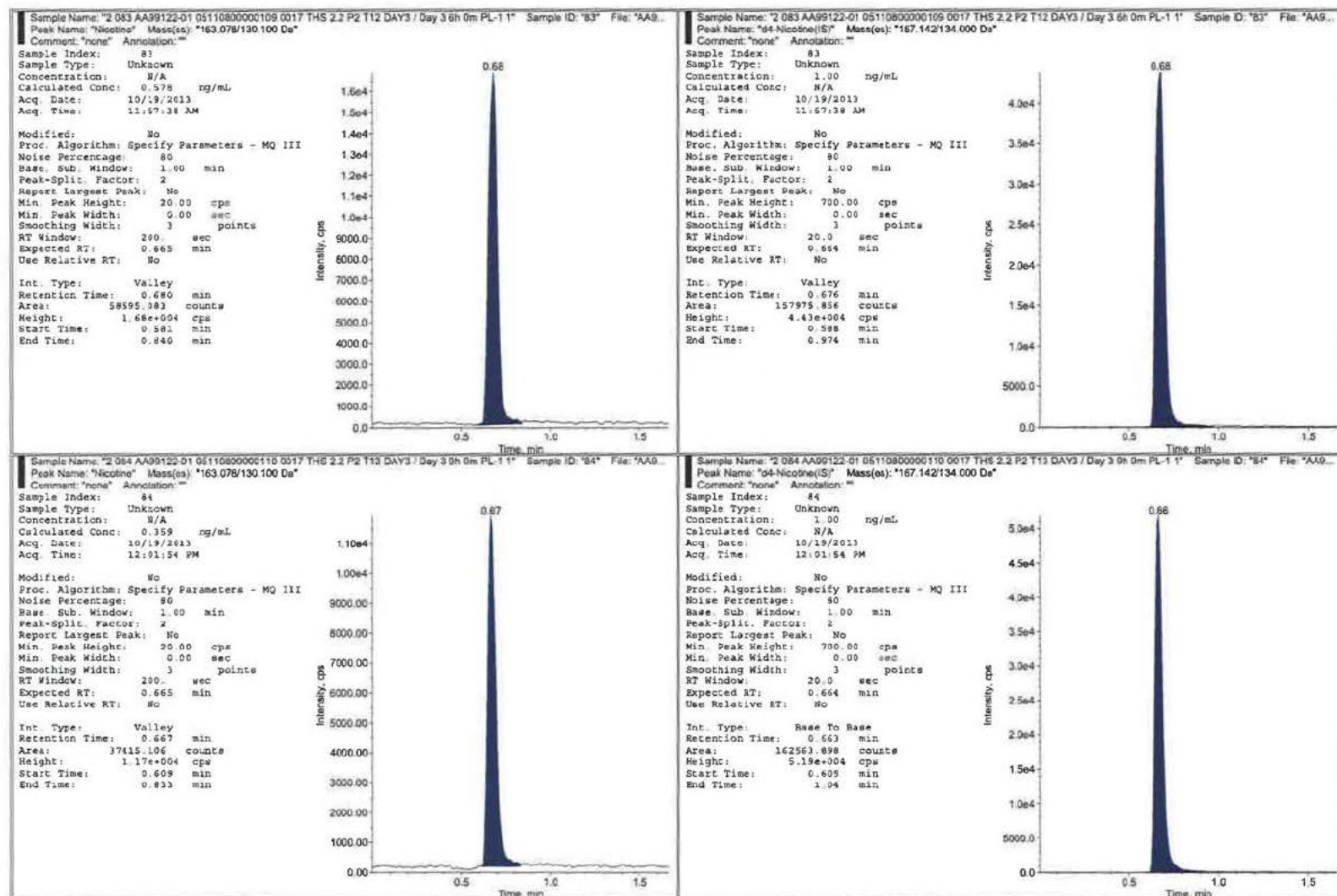


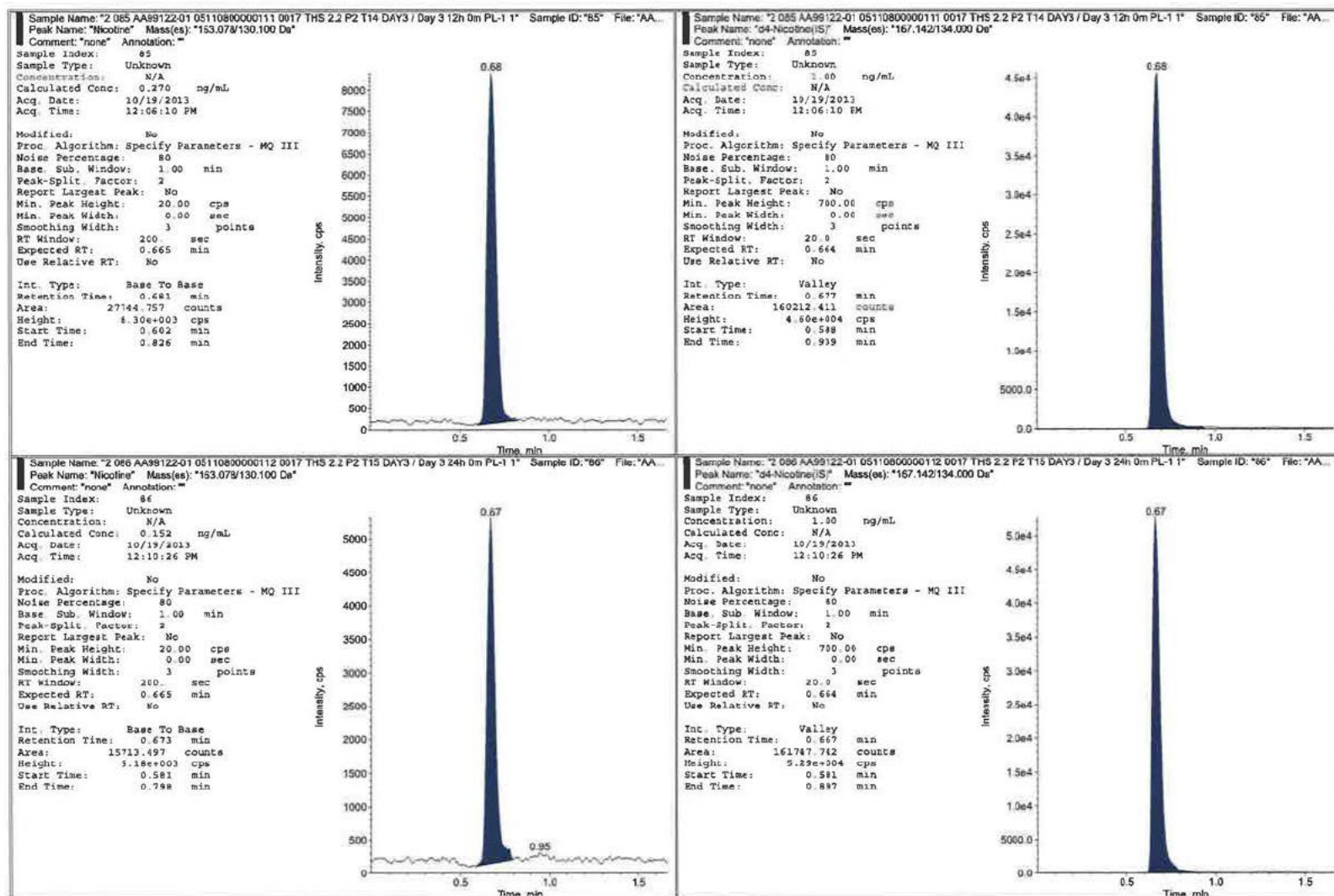
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



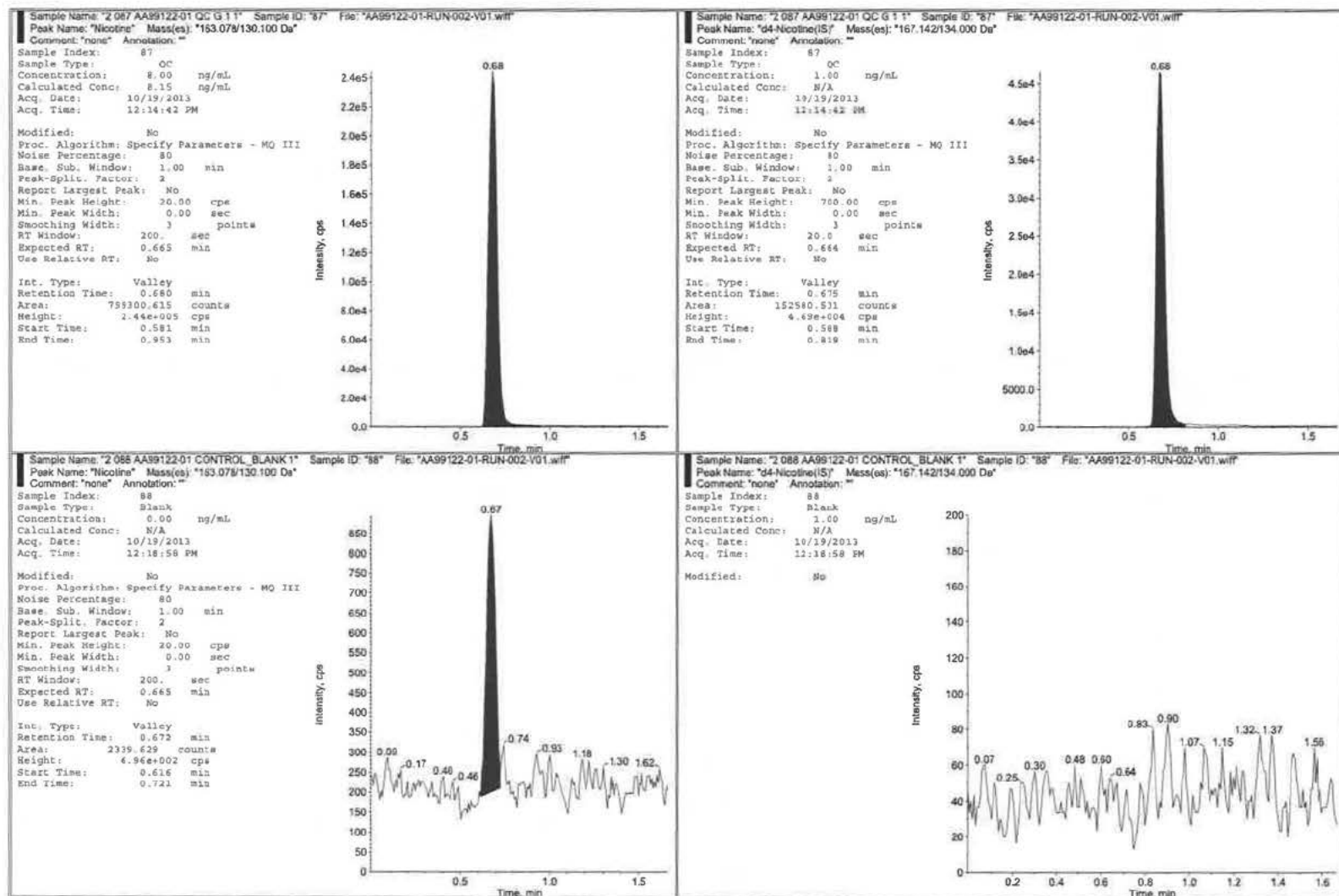


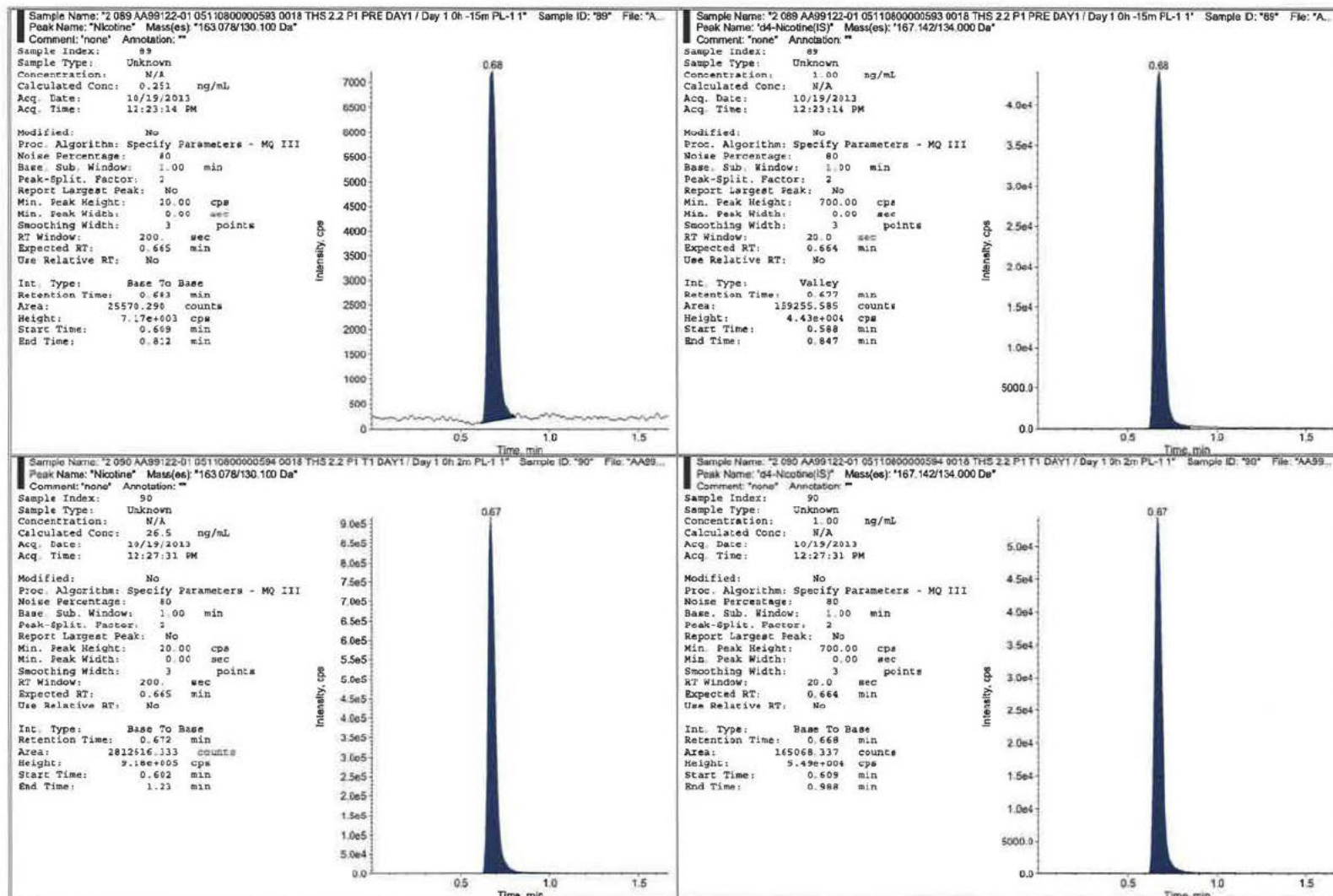
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01





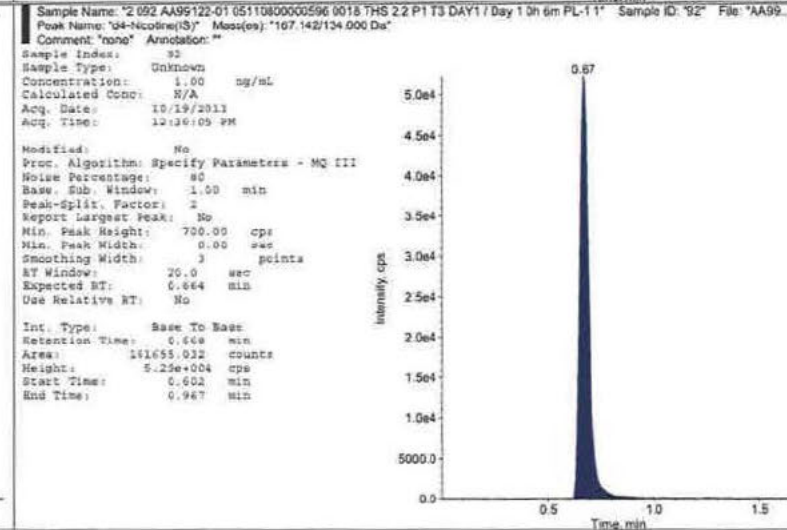
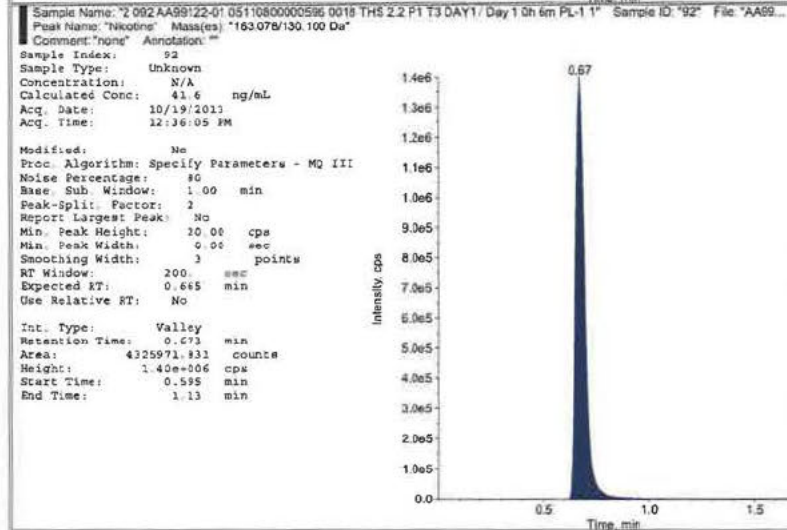
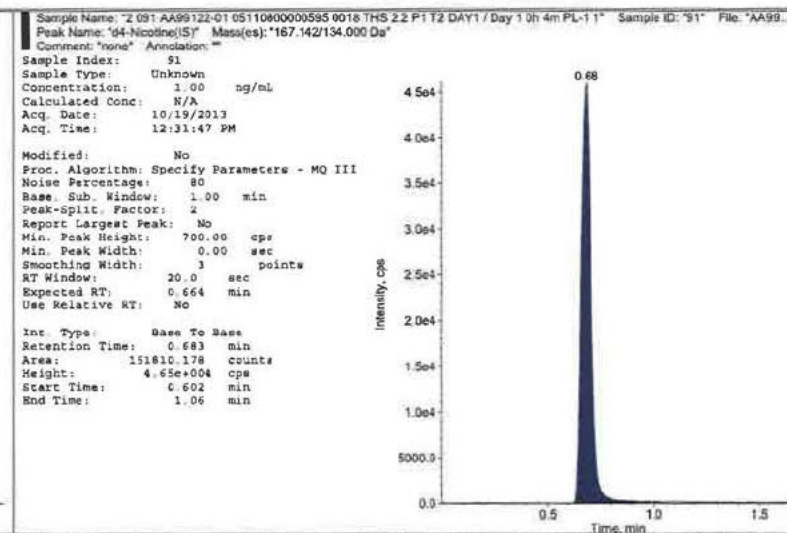
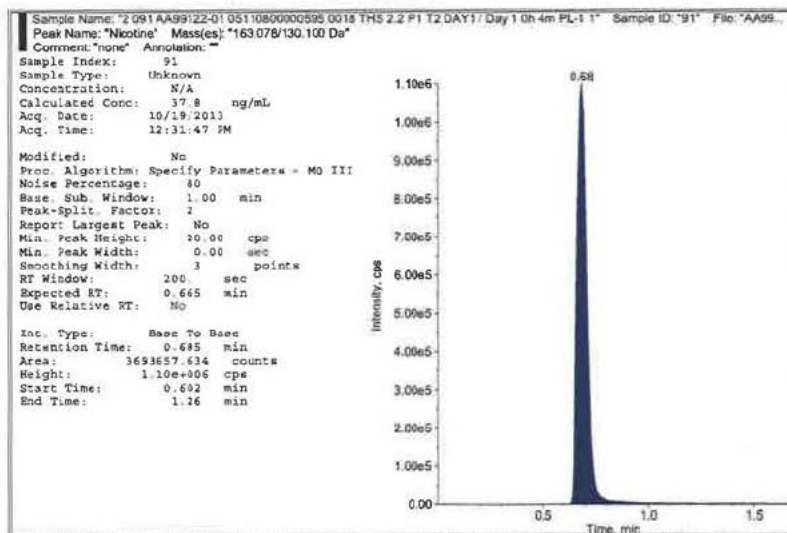
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

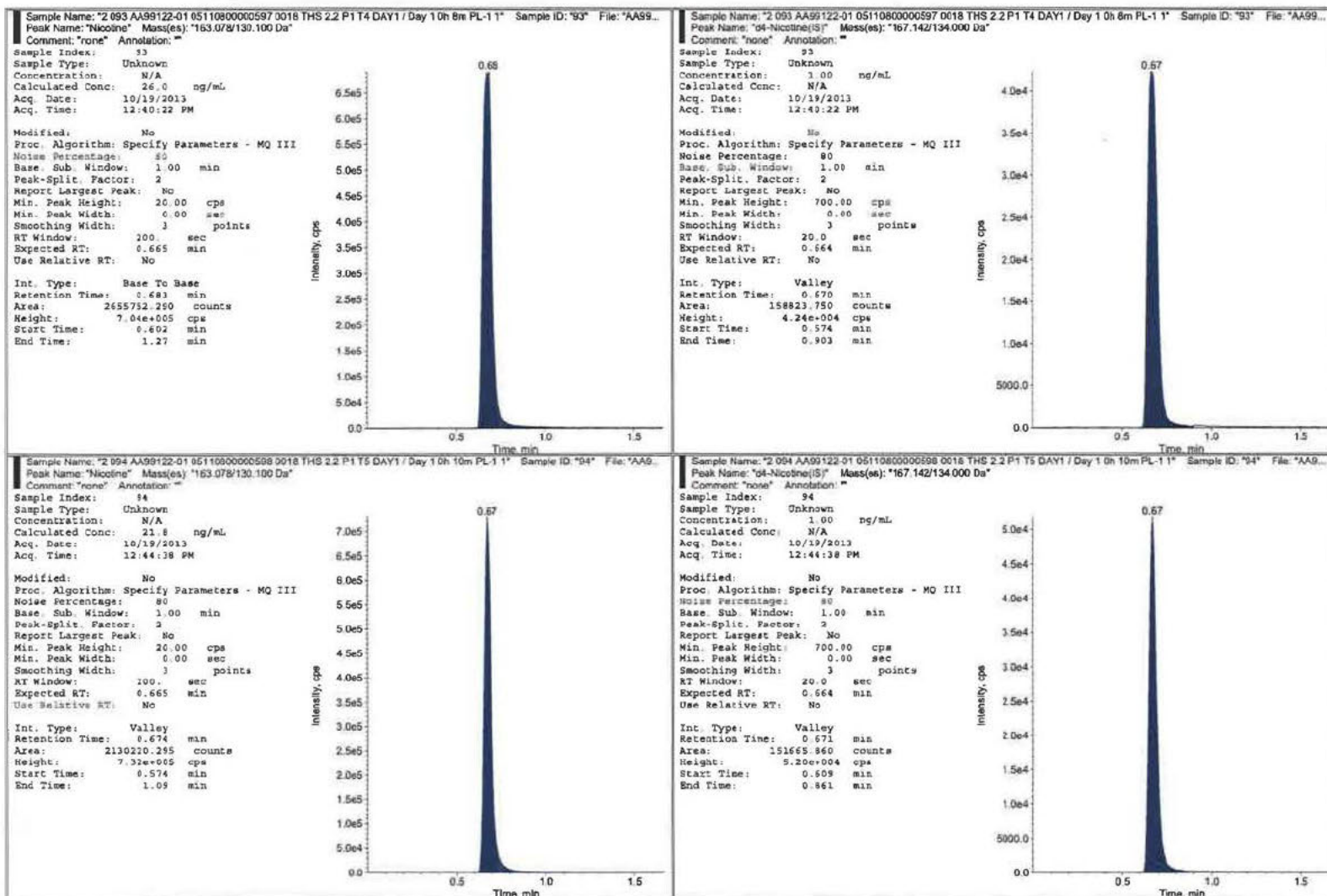






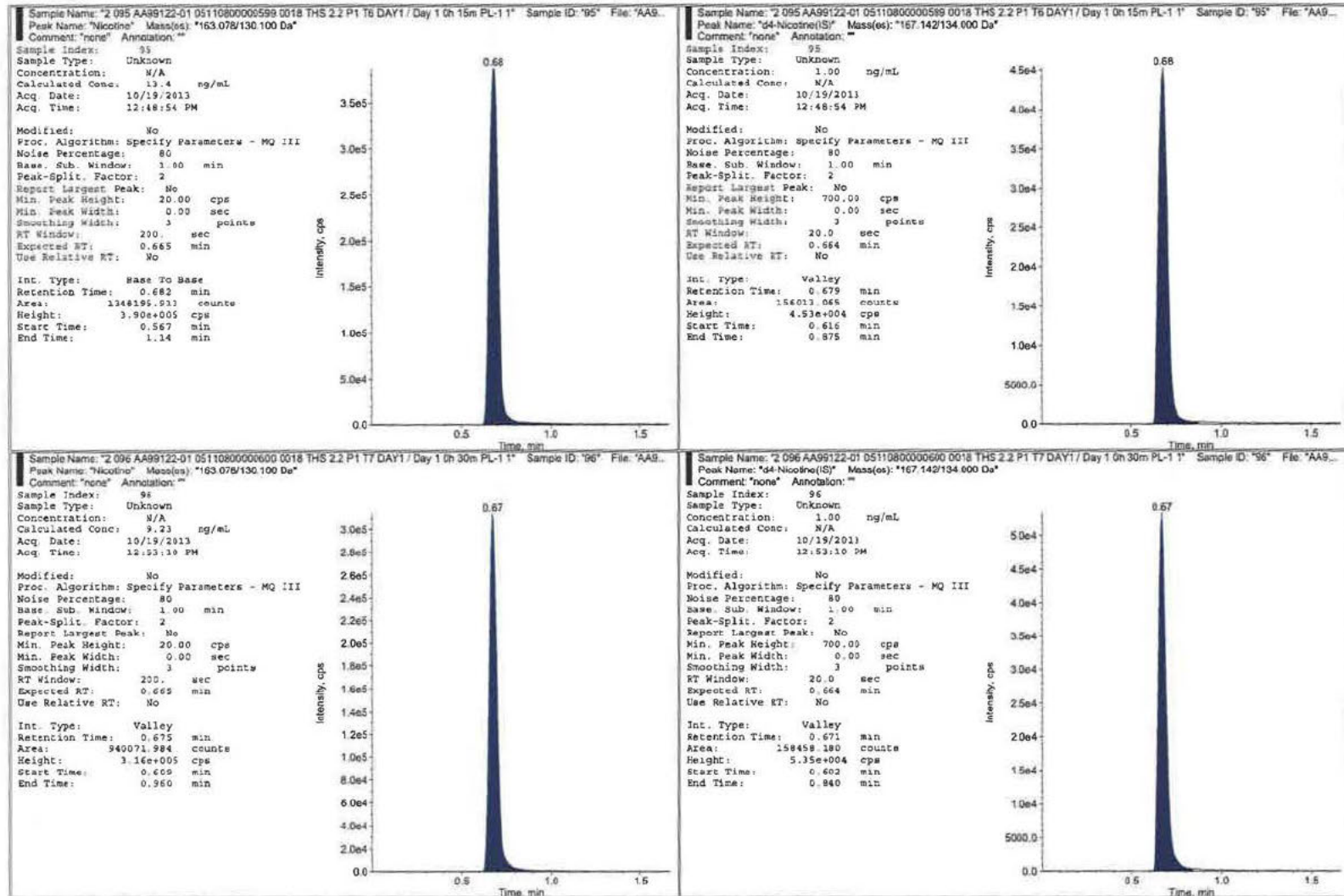
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

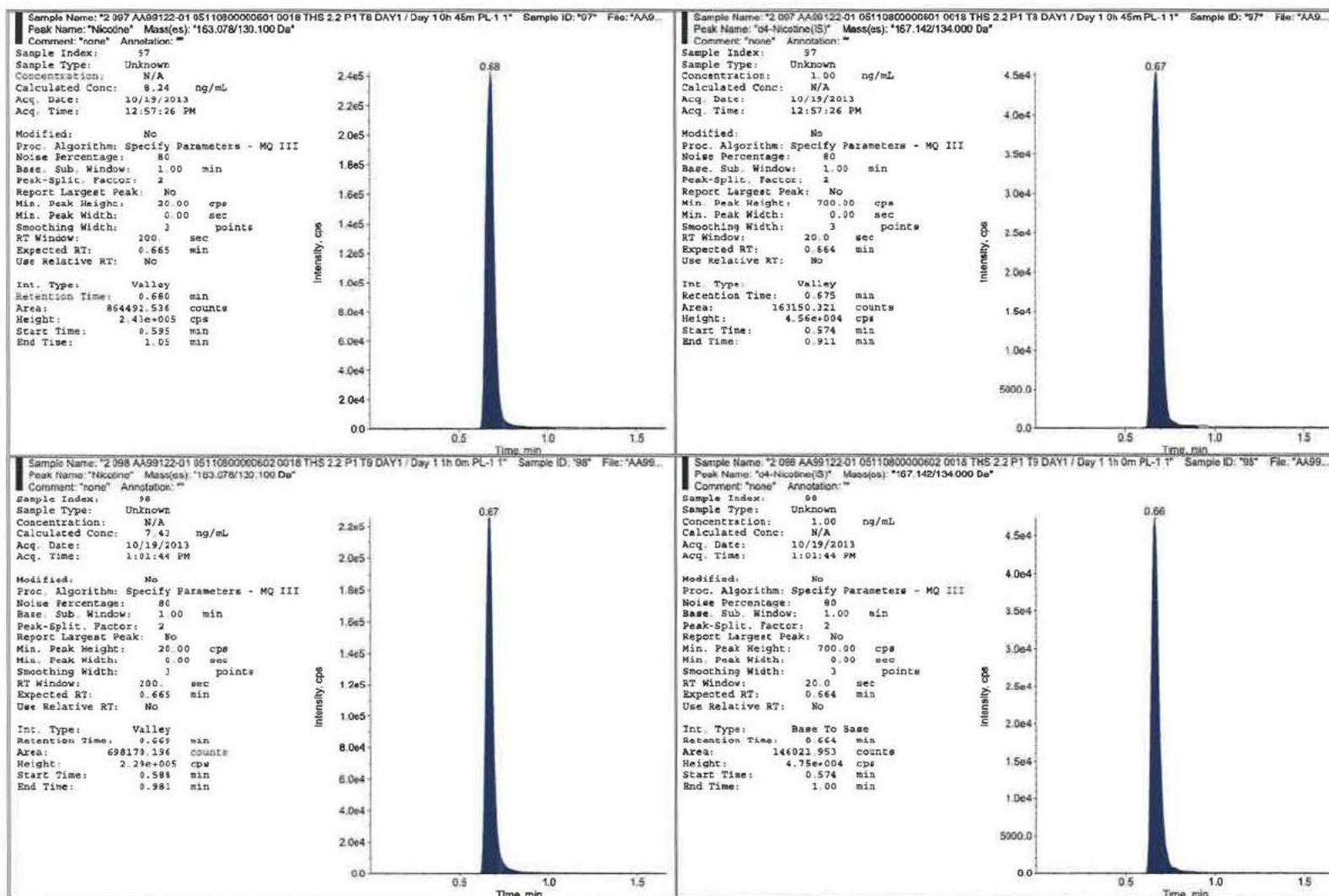




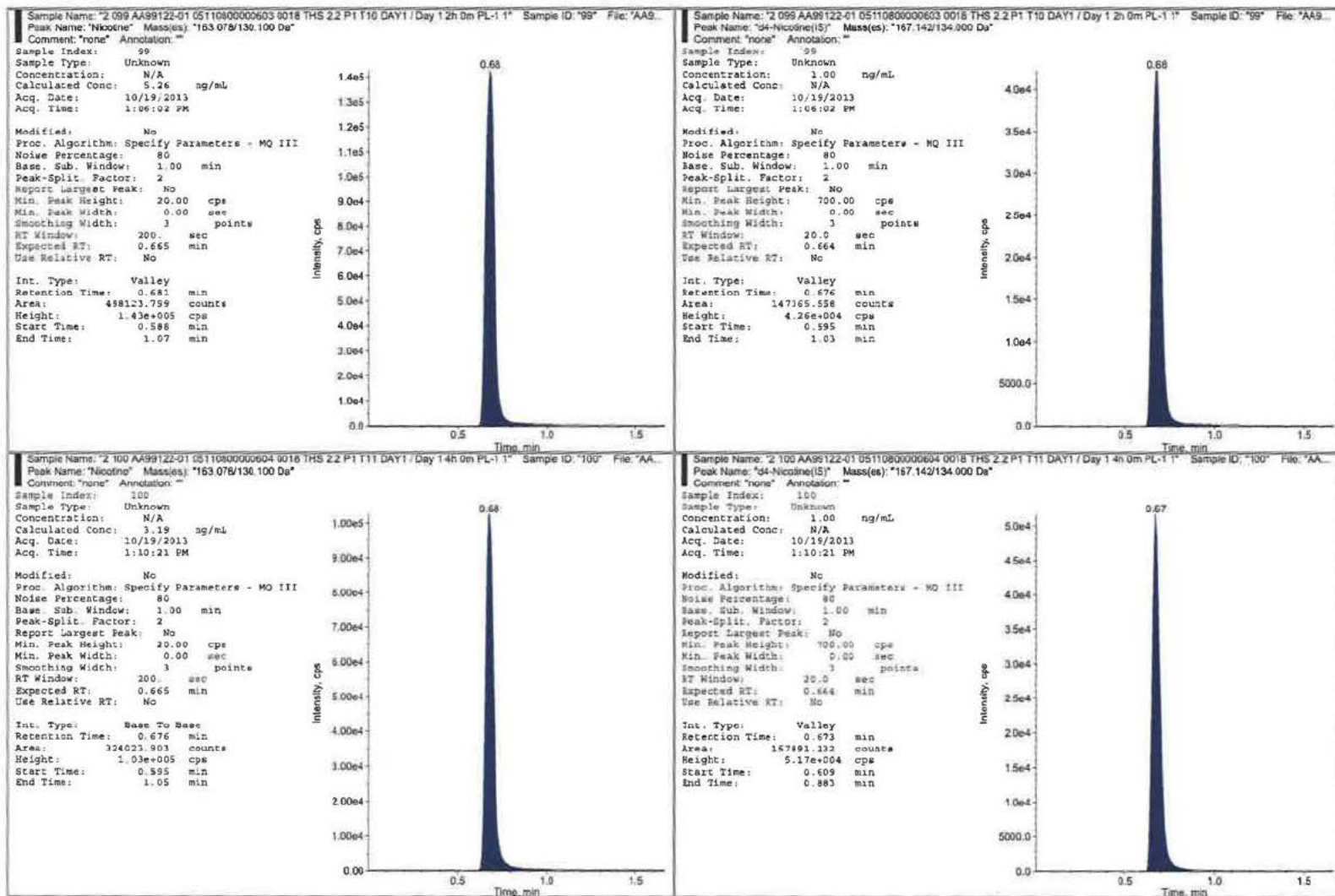


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

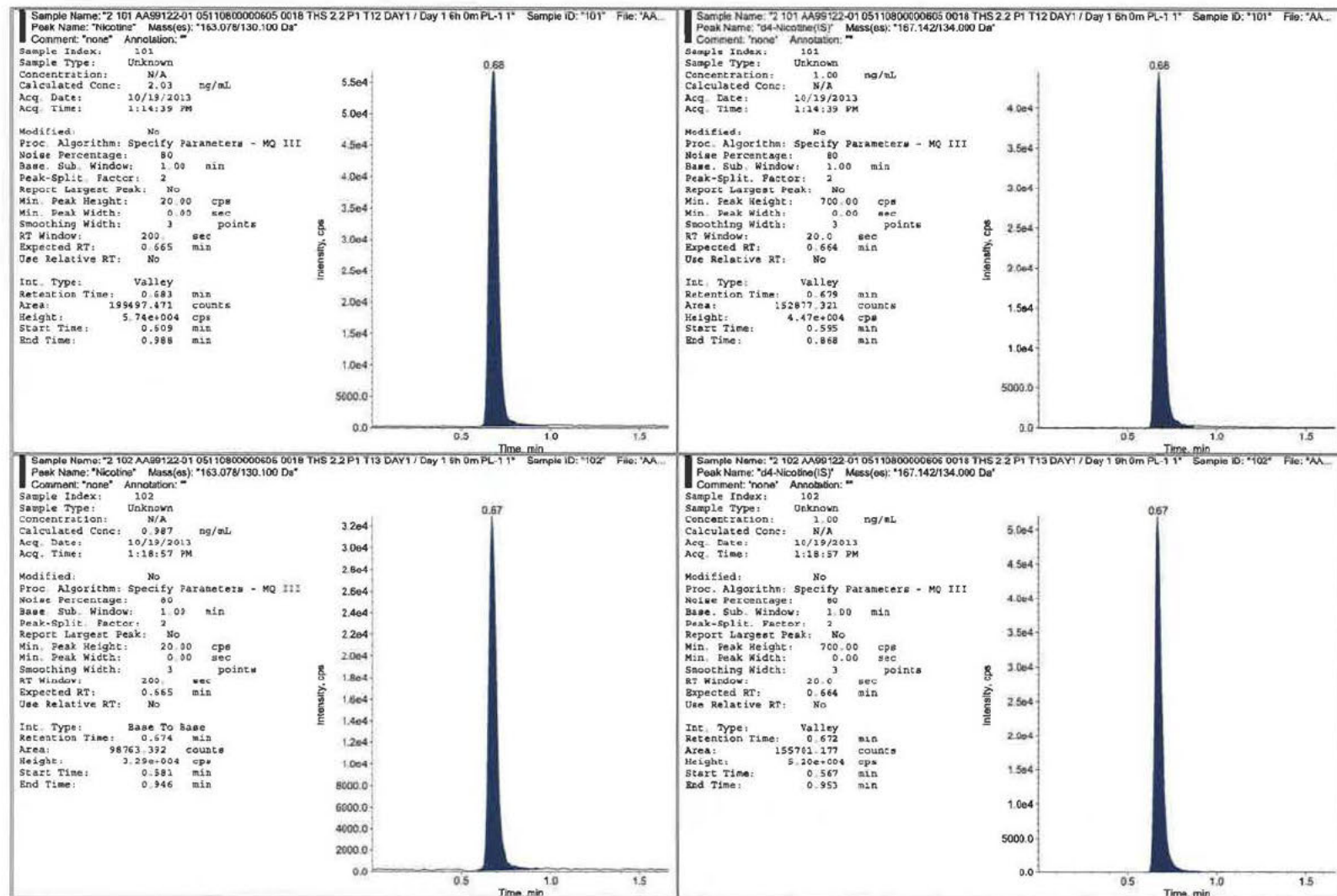




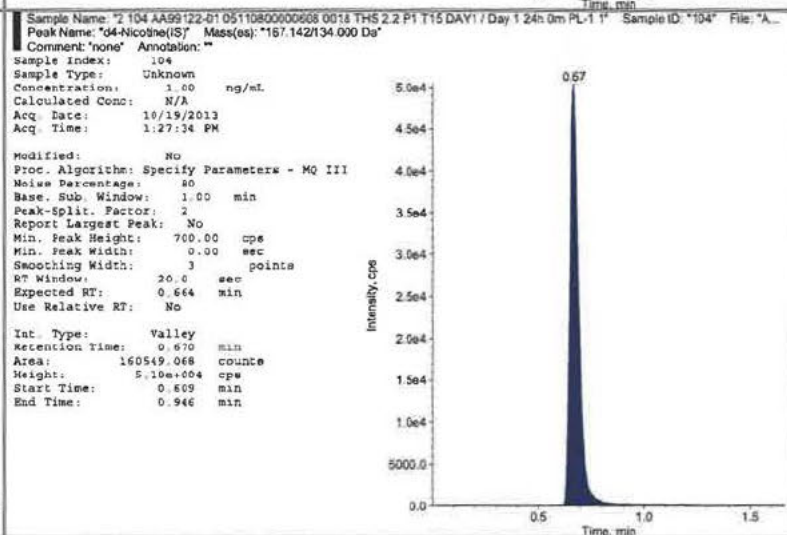
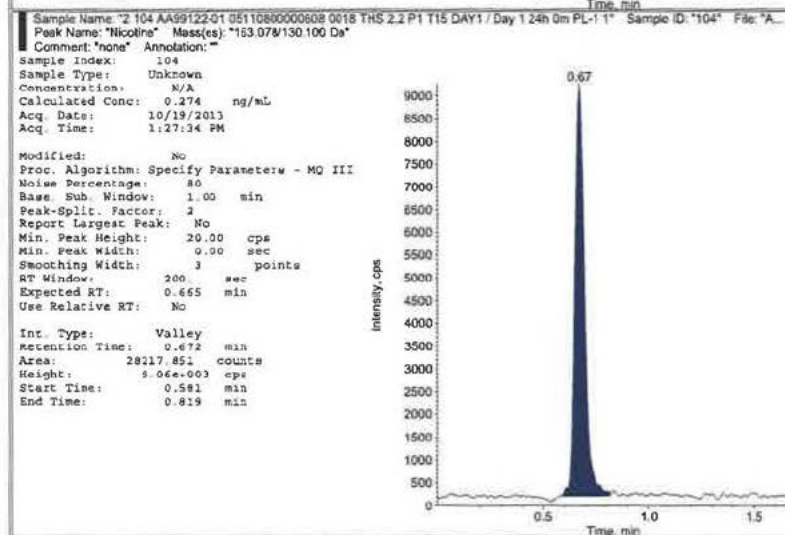
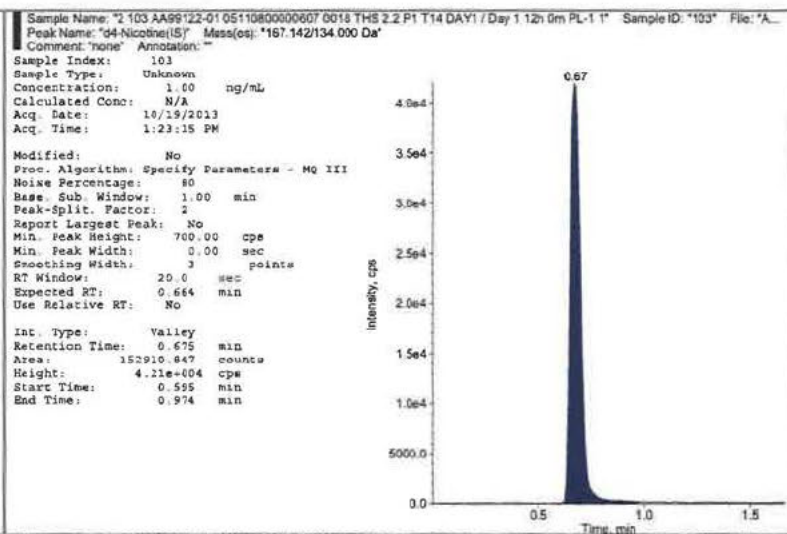
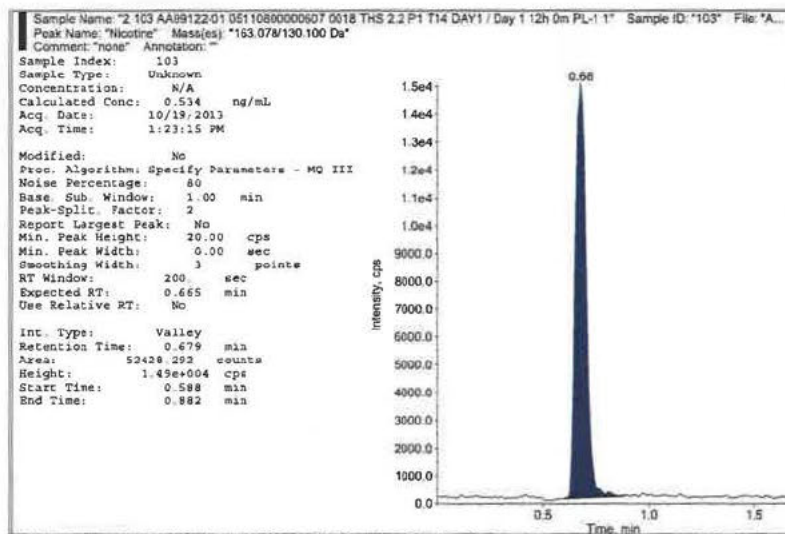
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

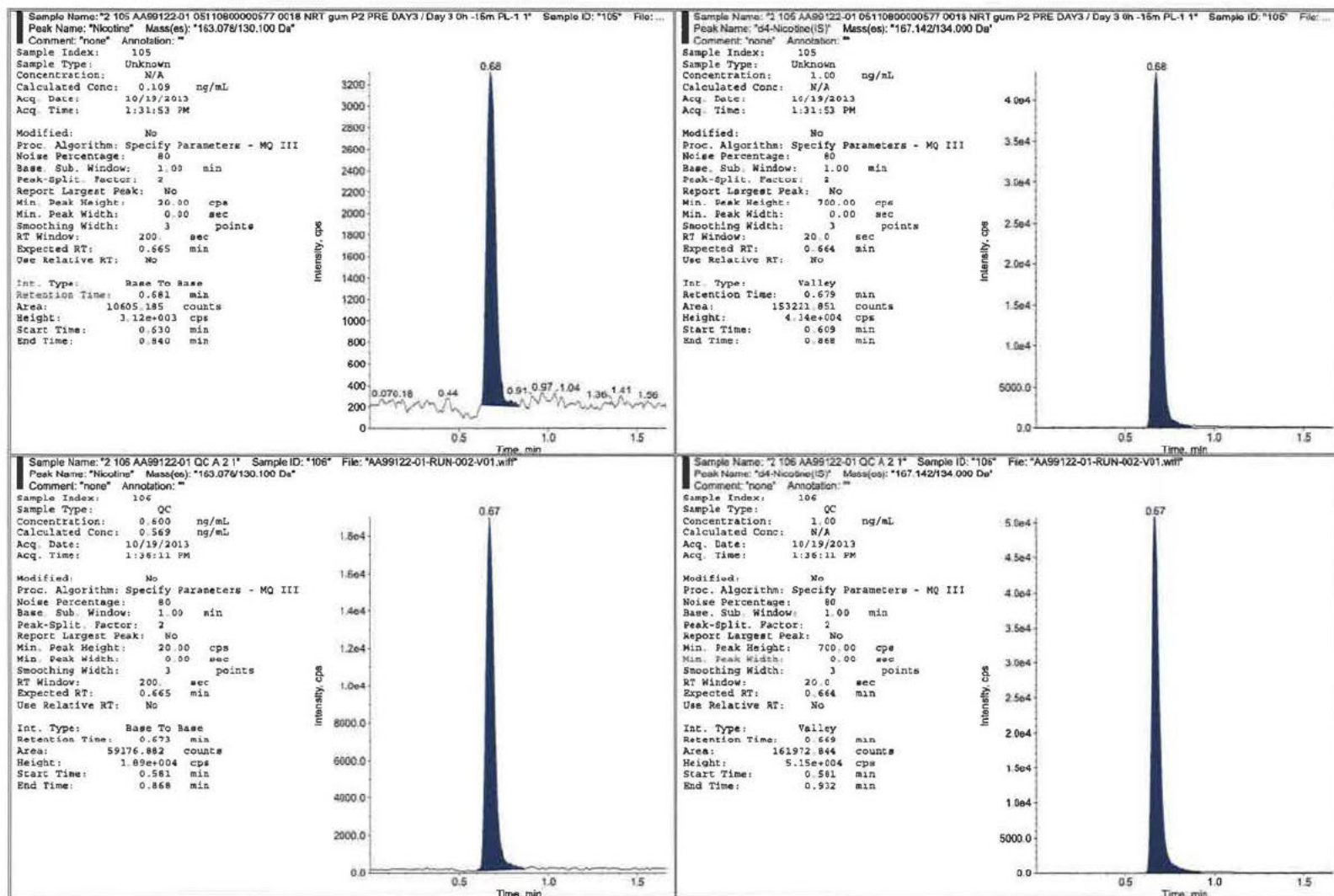






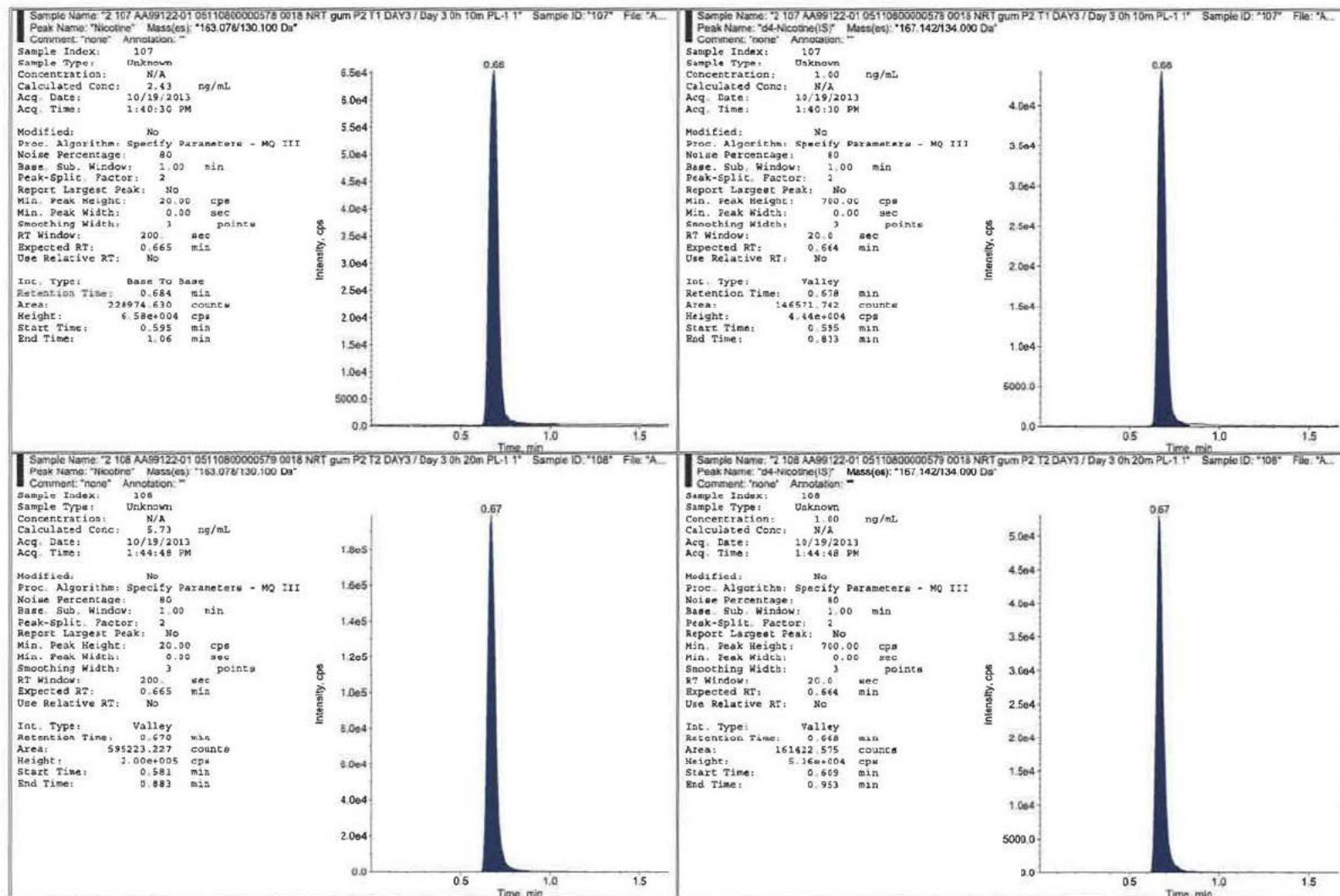
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

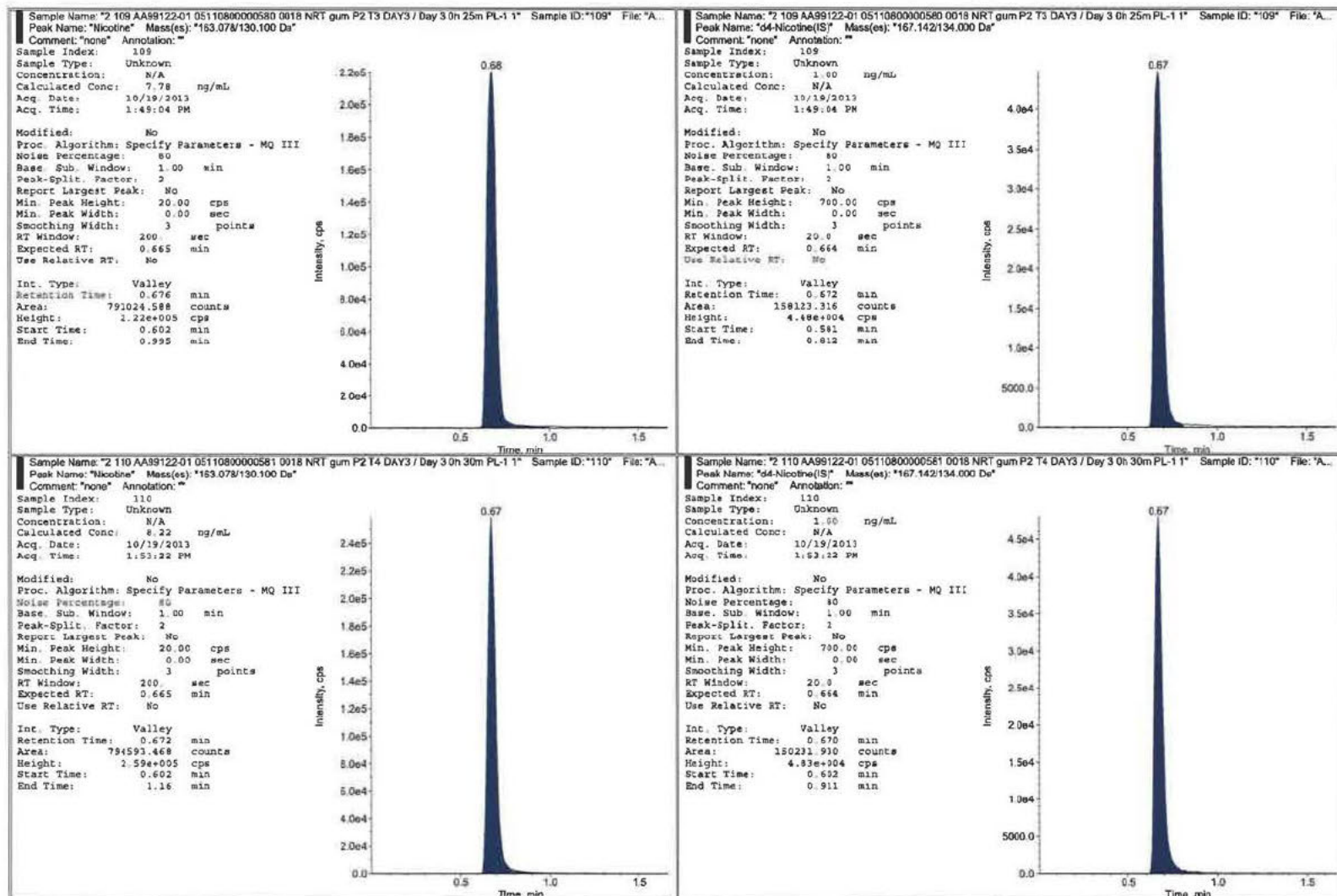




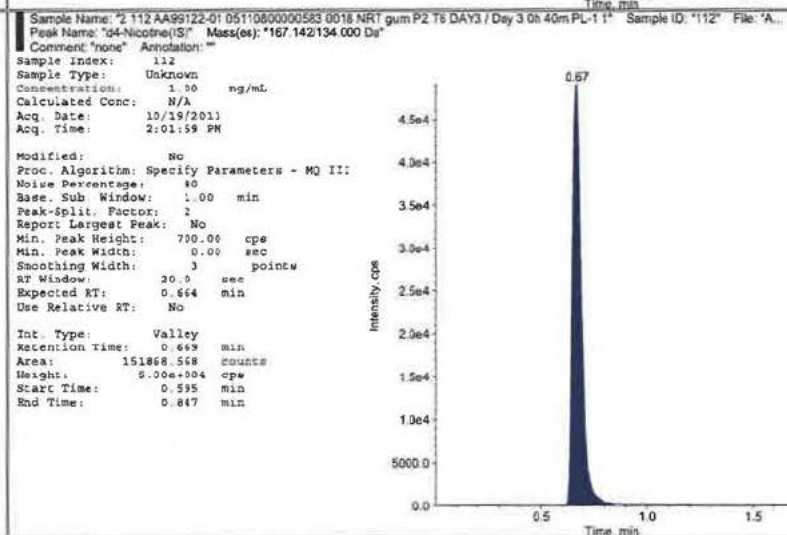
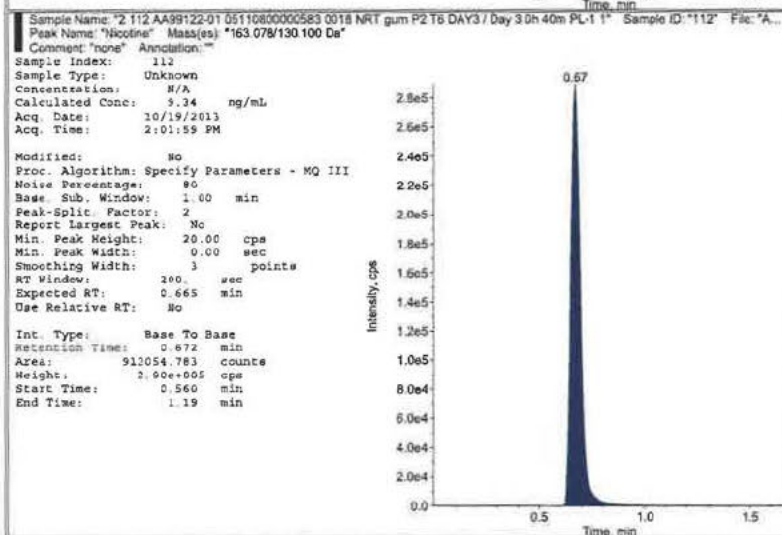
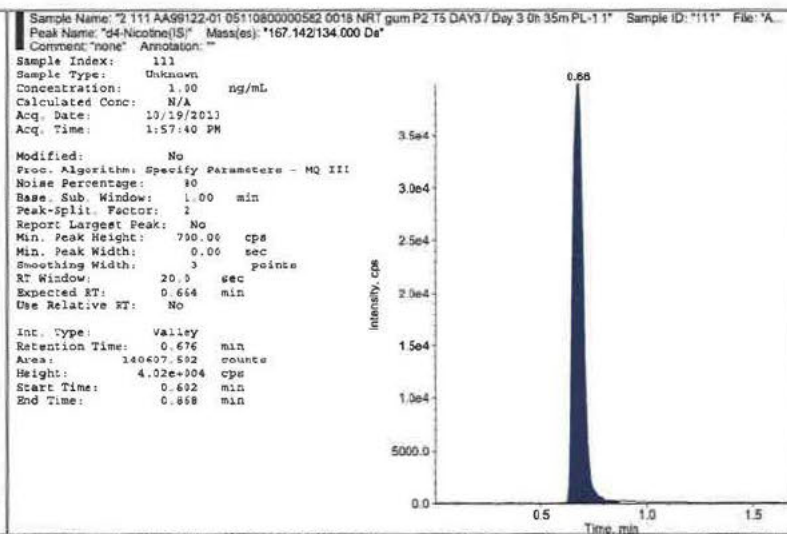
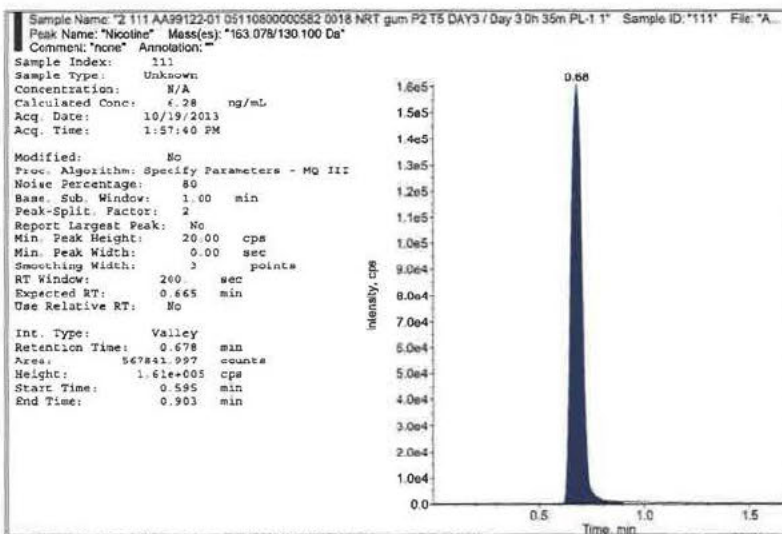


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



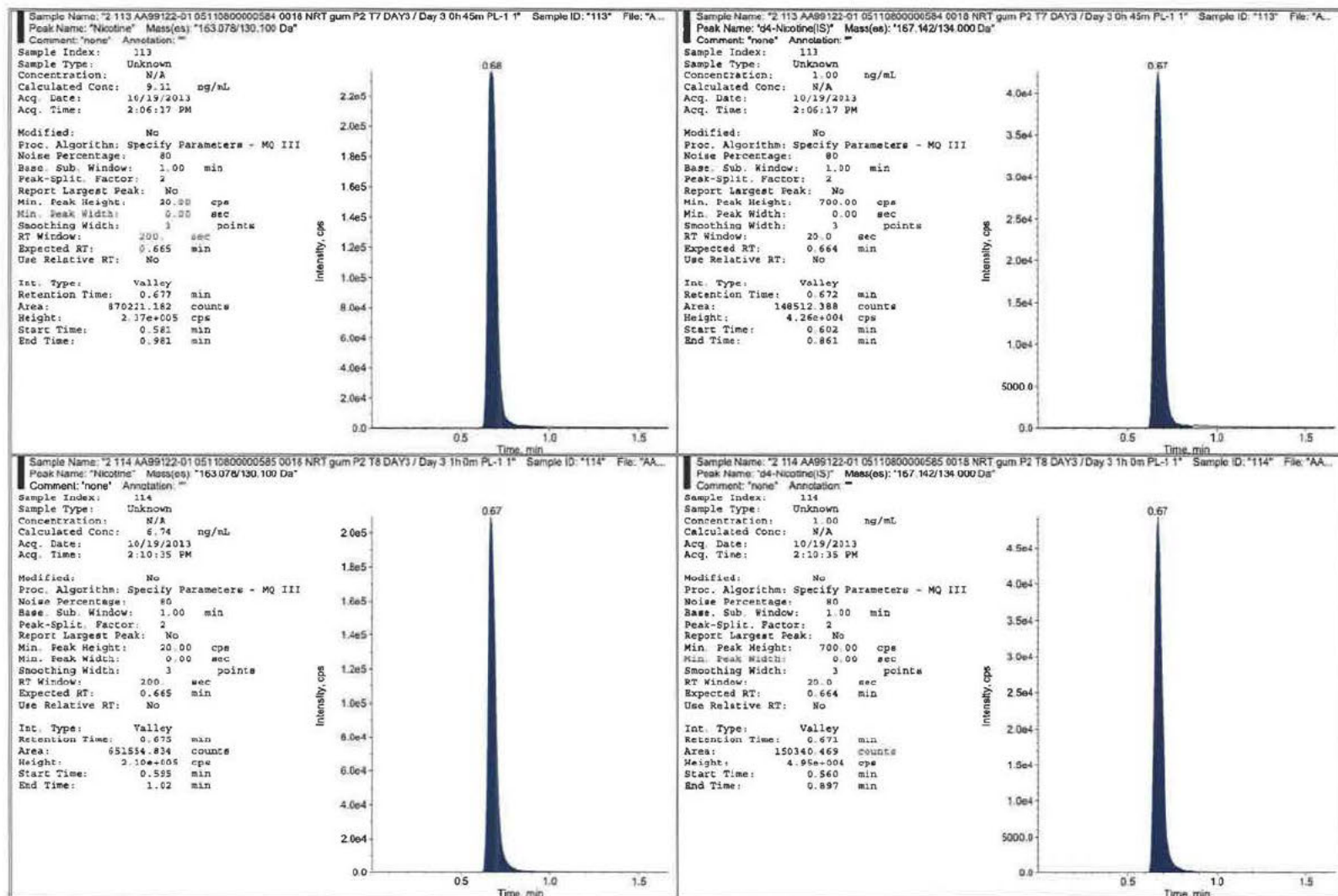


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

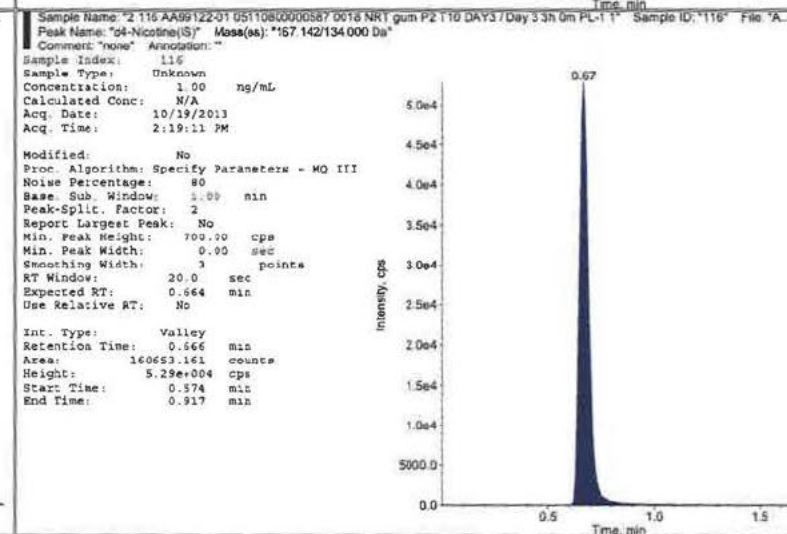
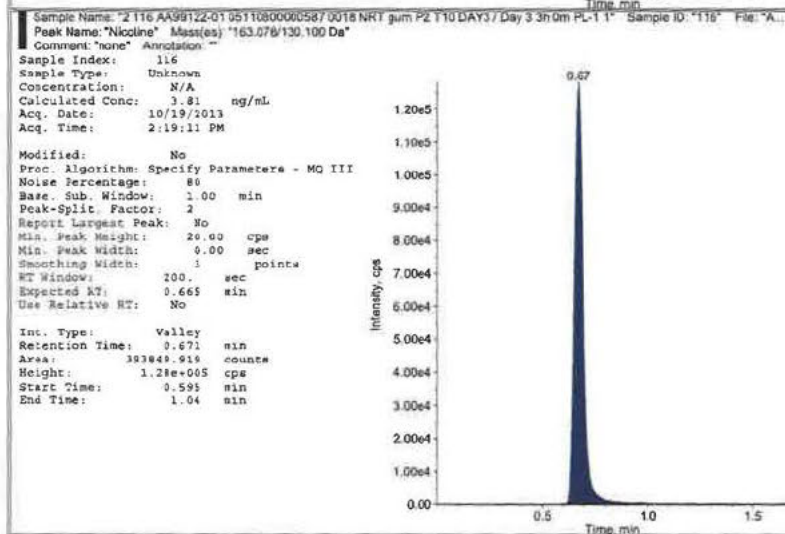
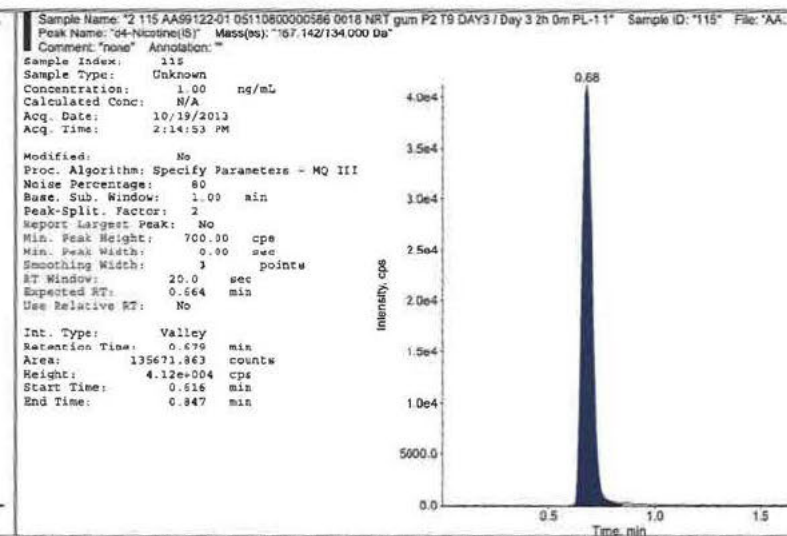
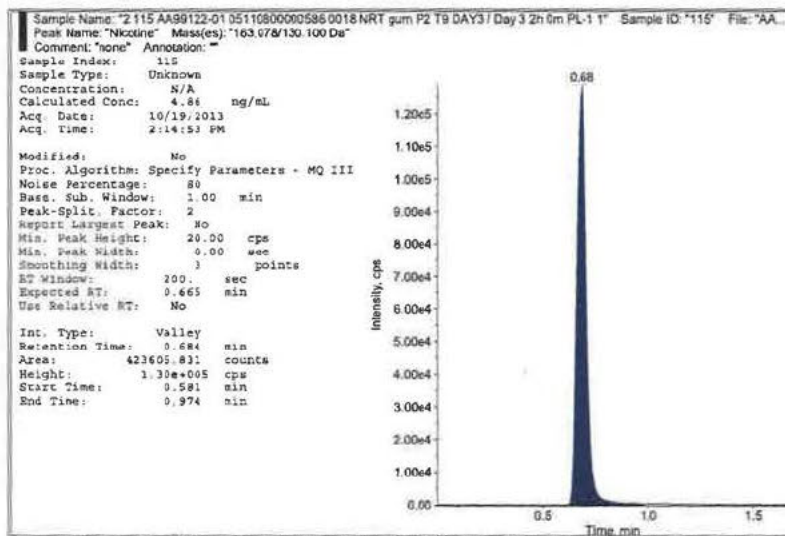




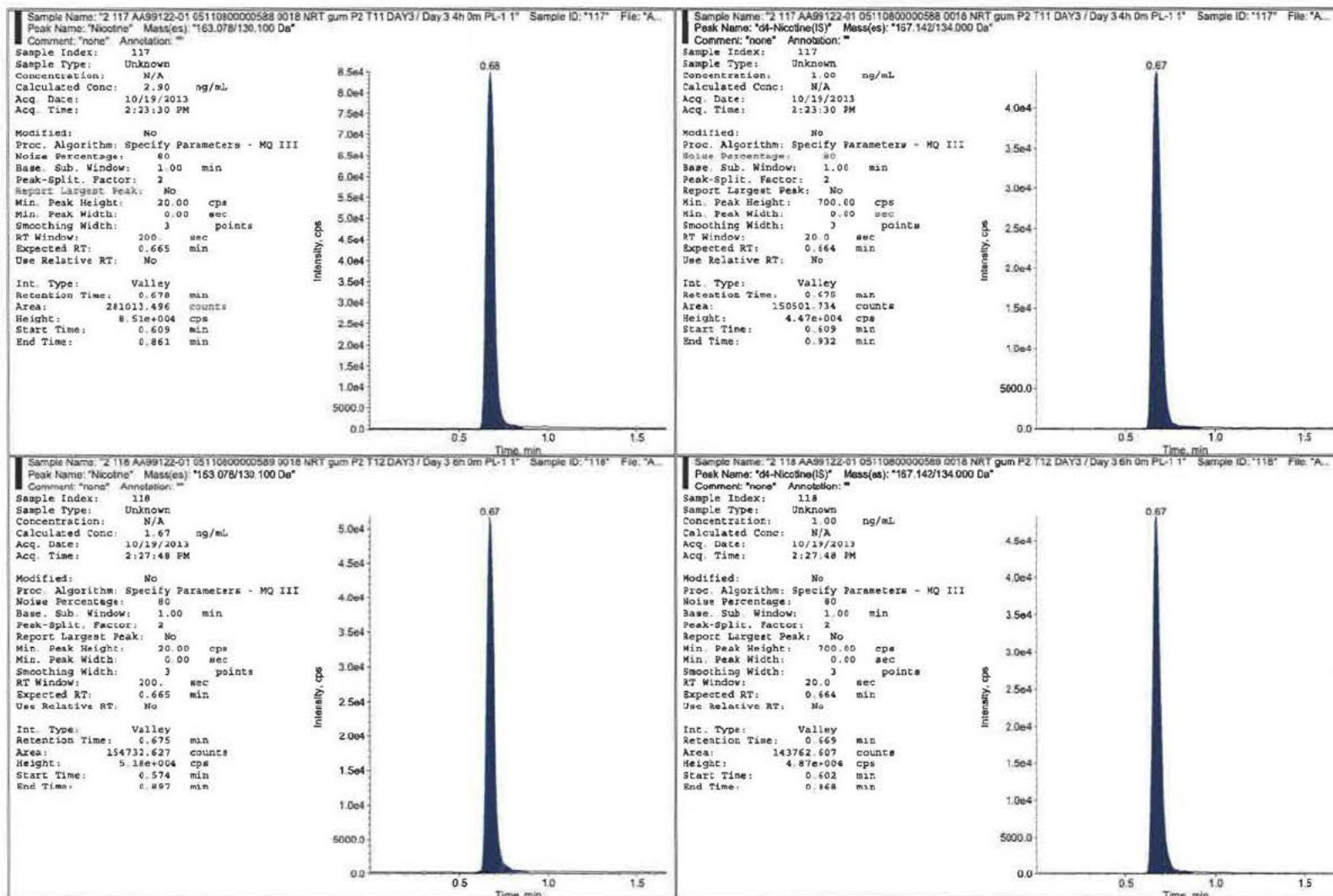
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

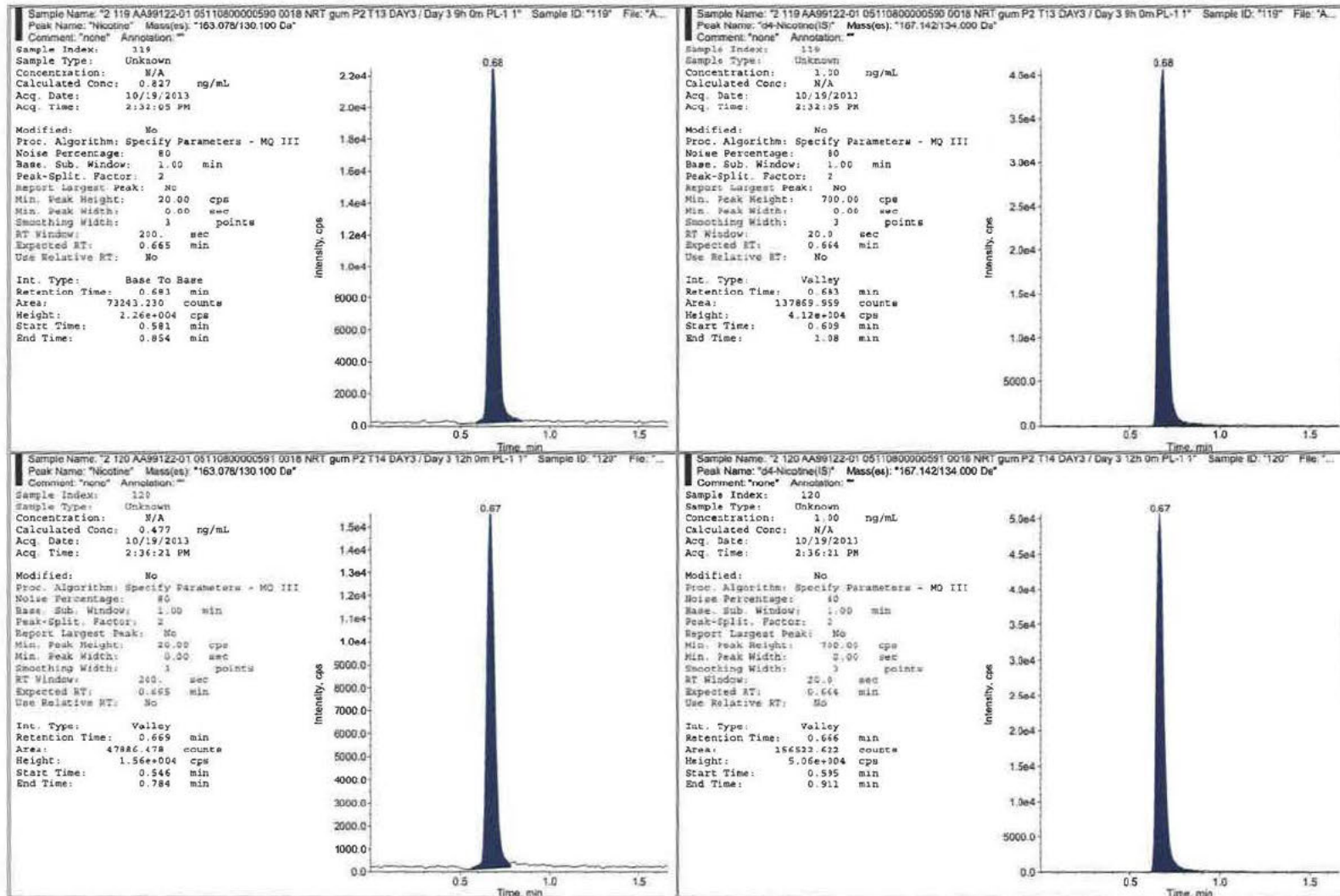


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

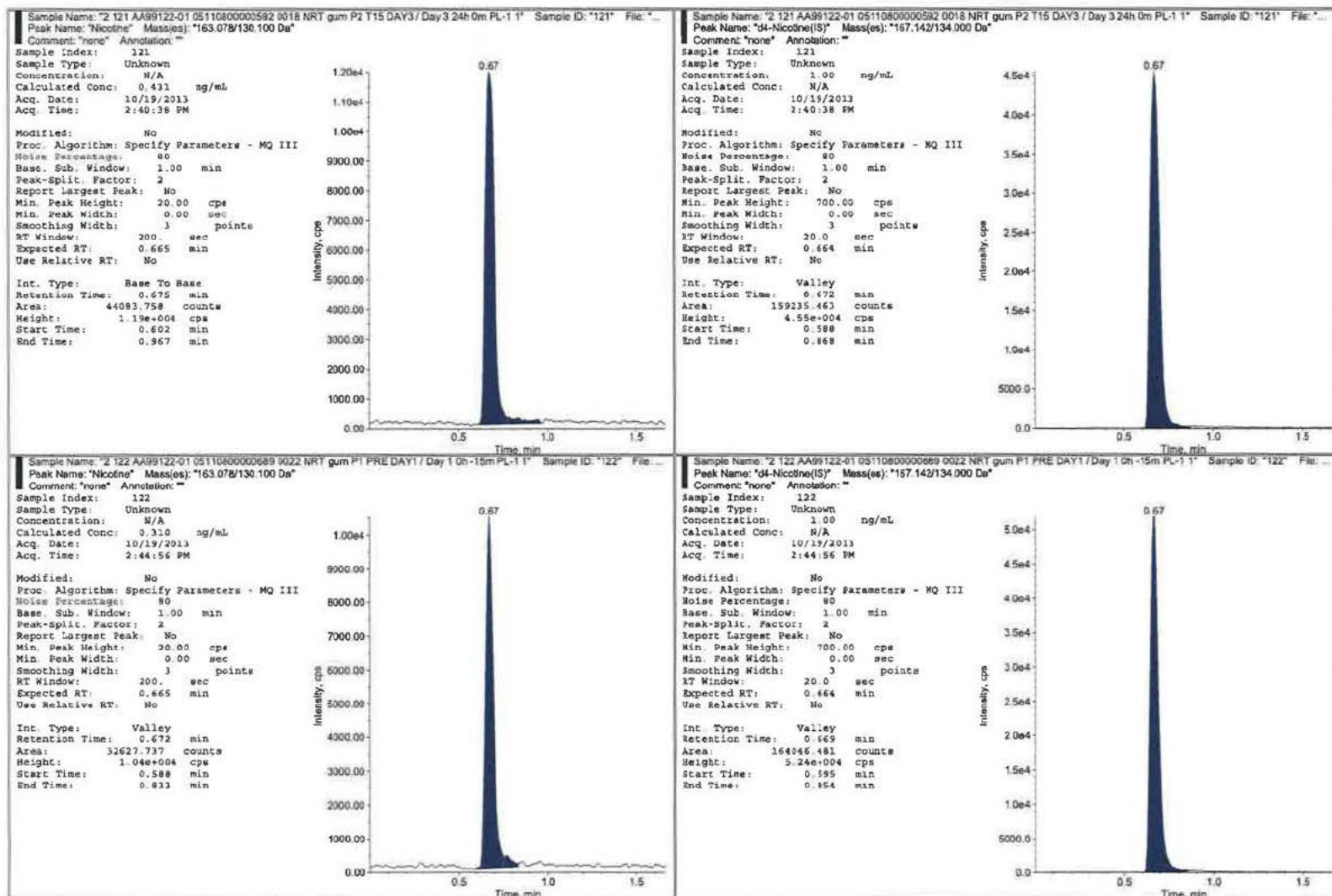




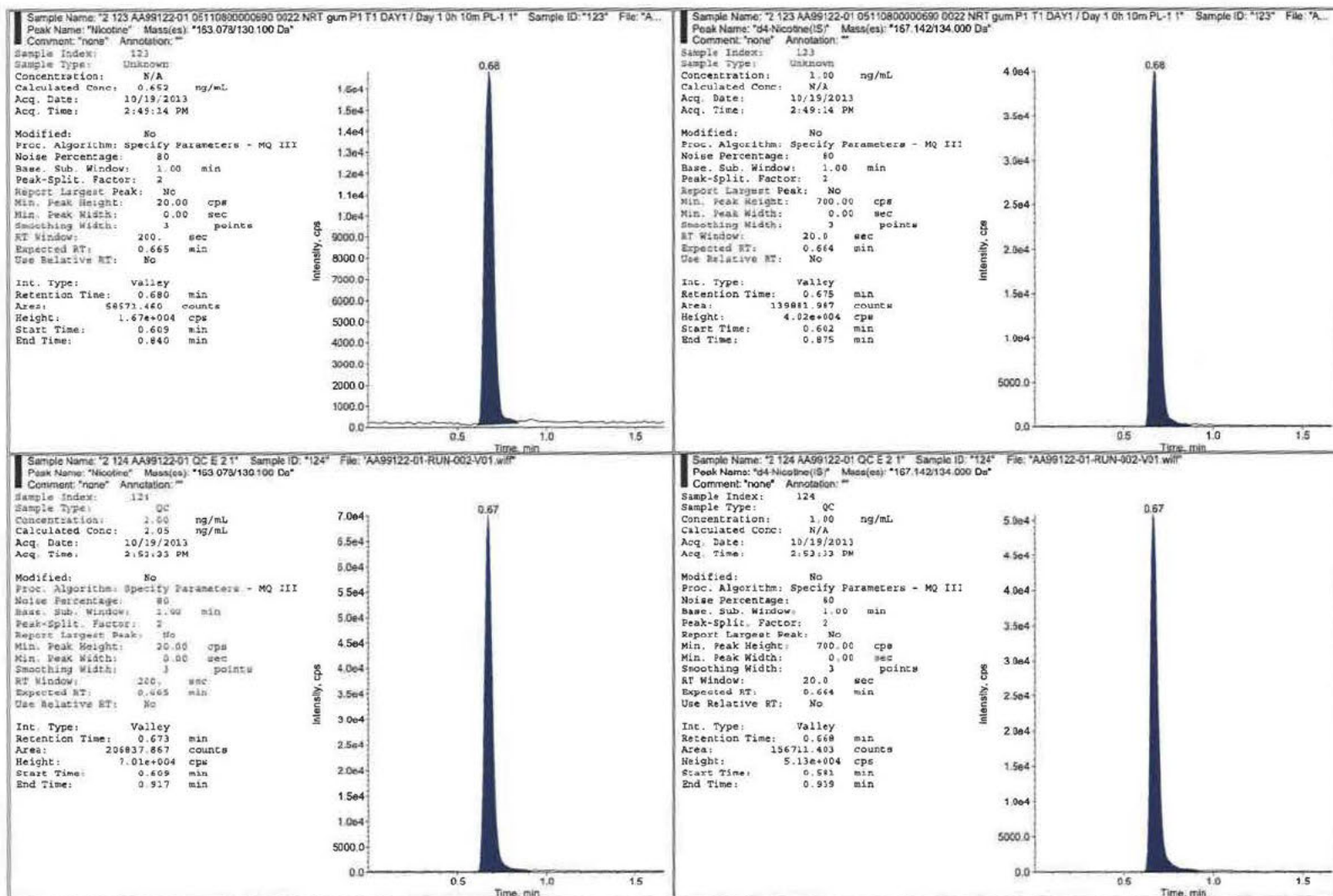
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



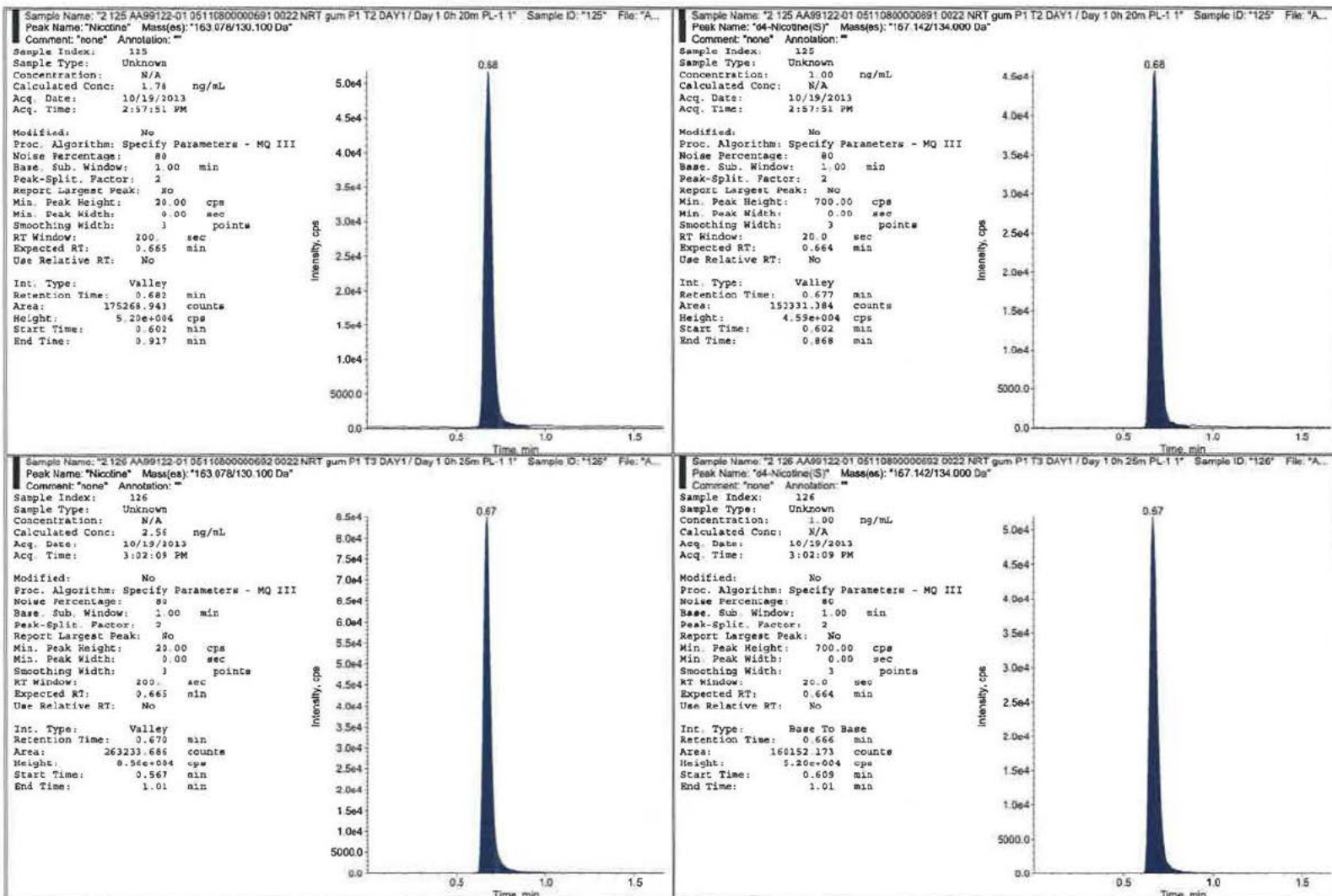
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



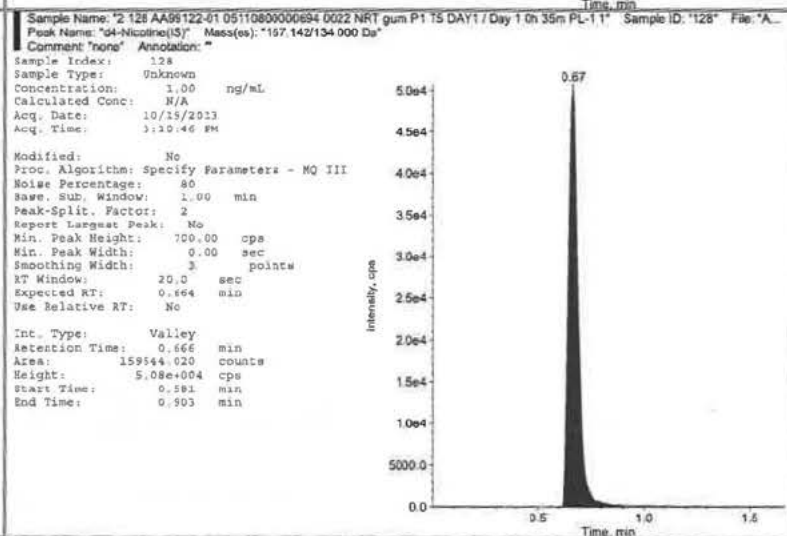
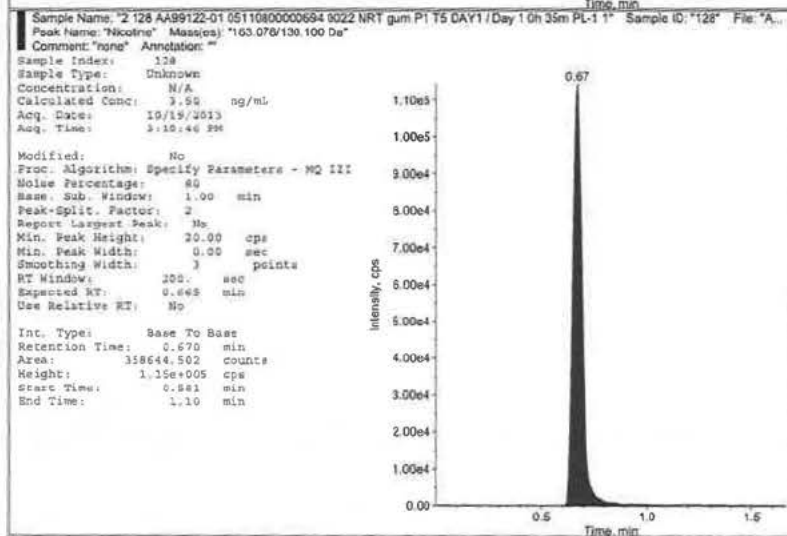
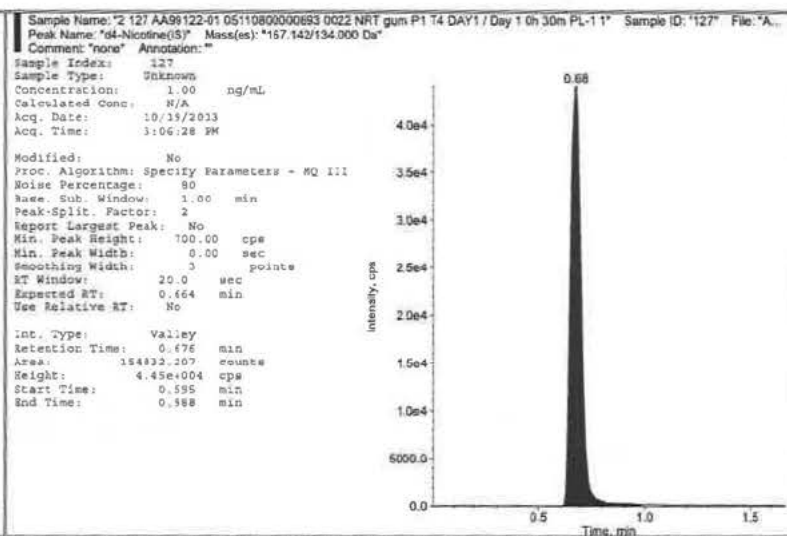
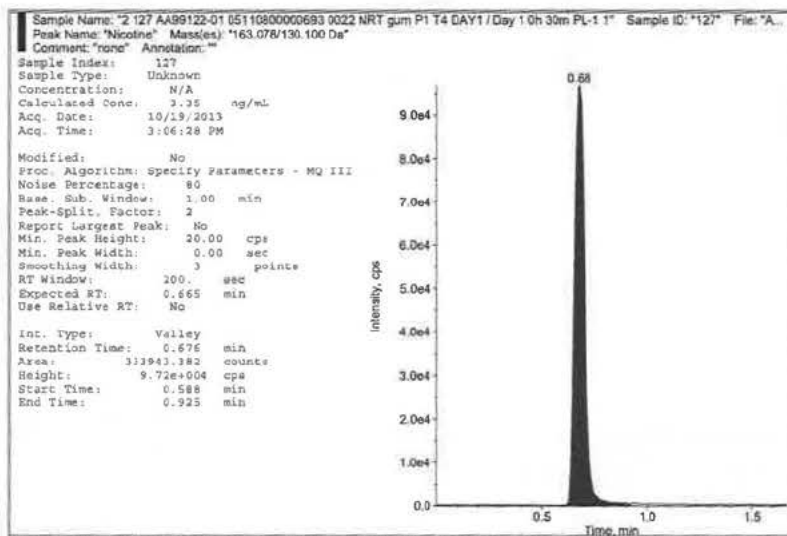
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

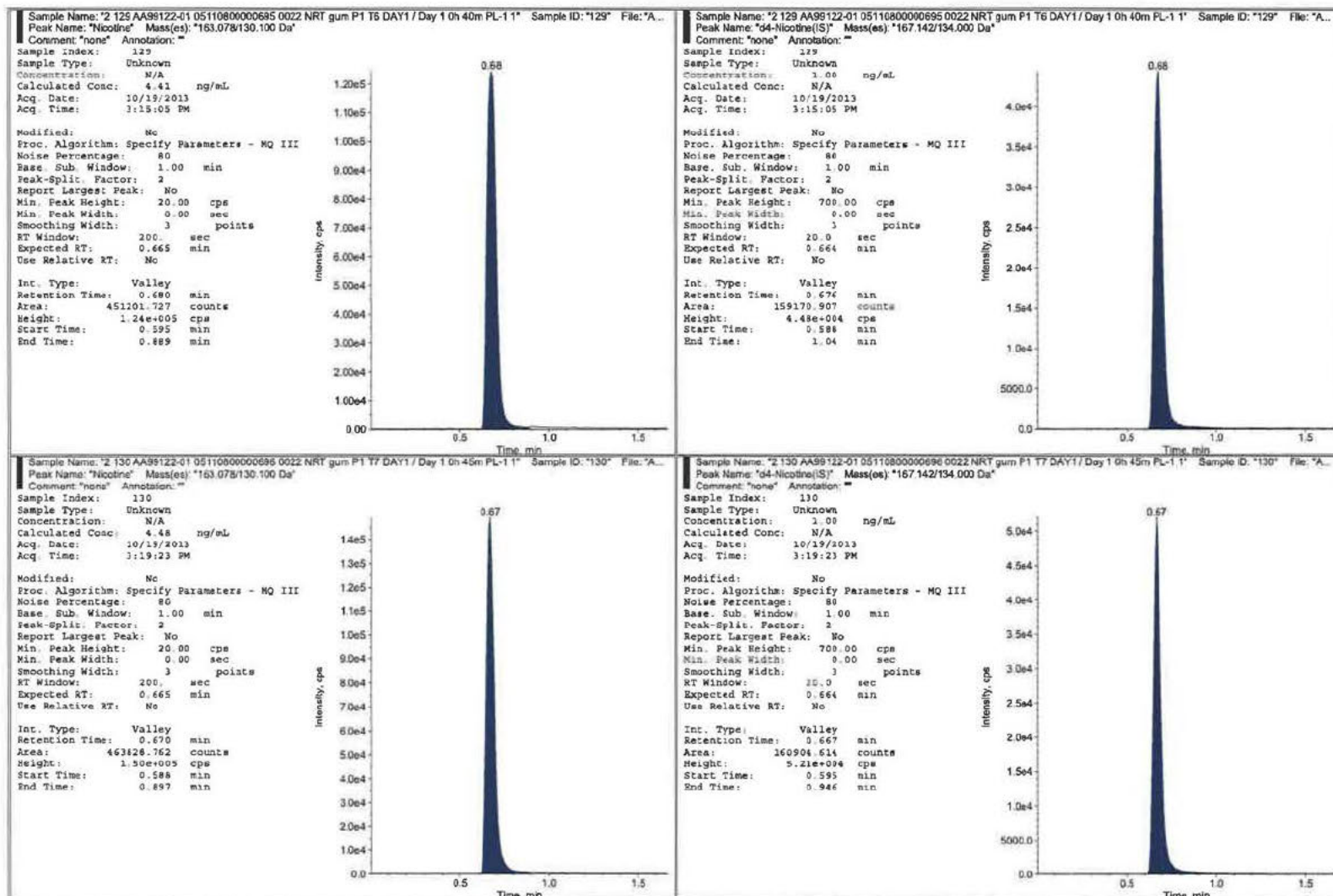






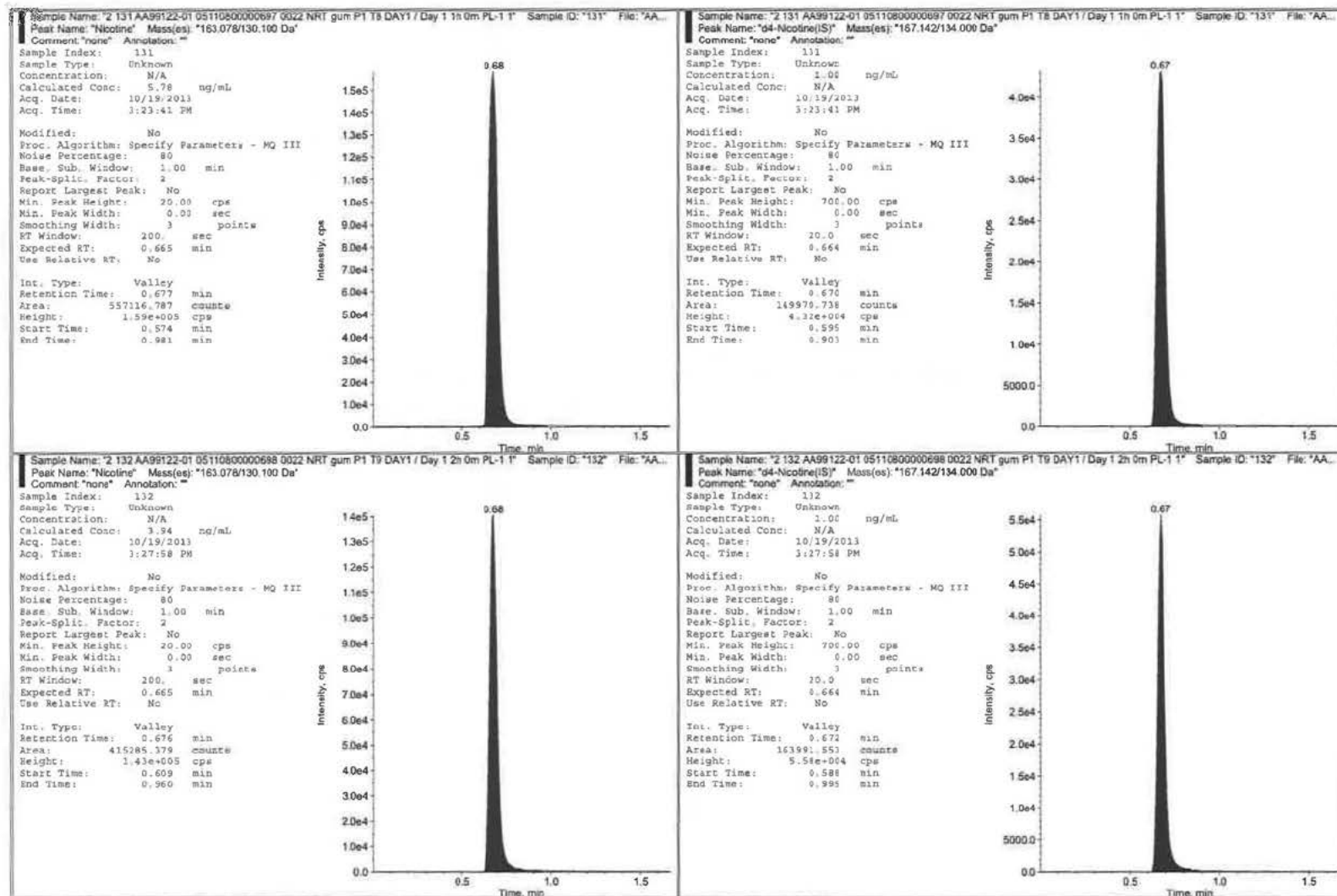
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



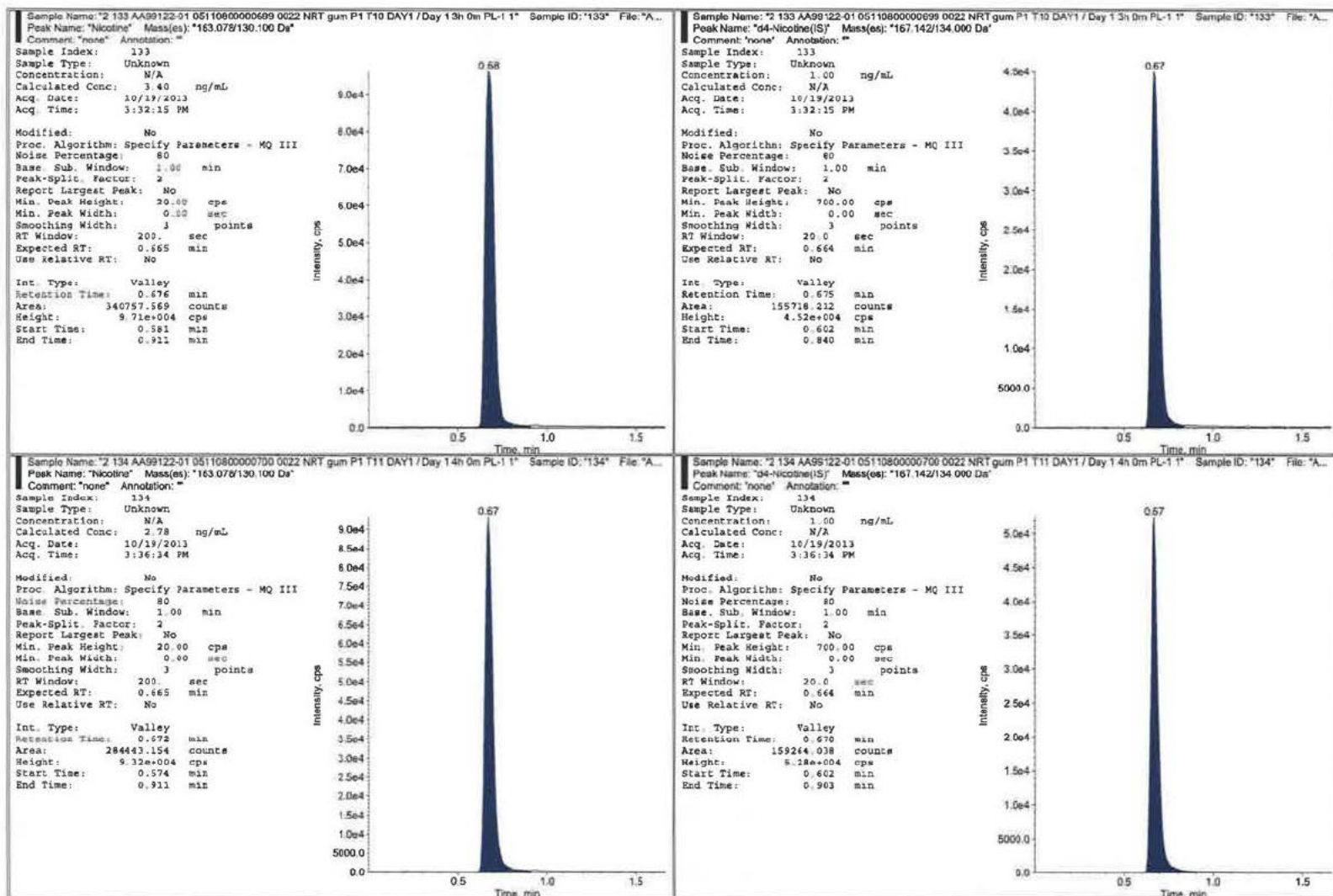


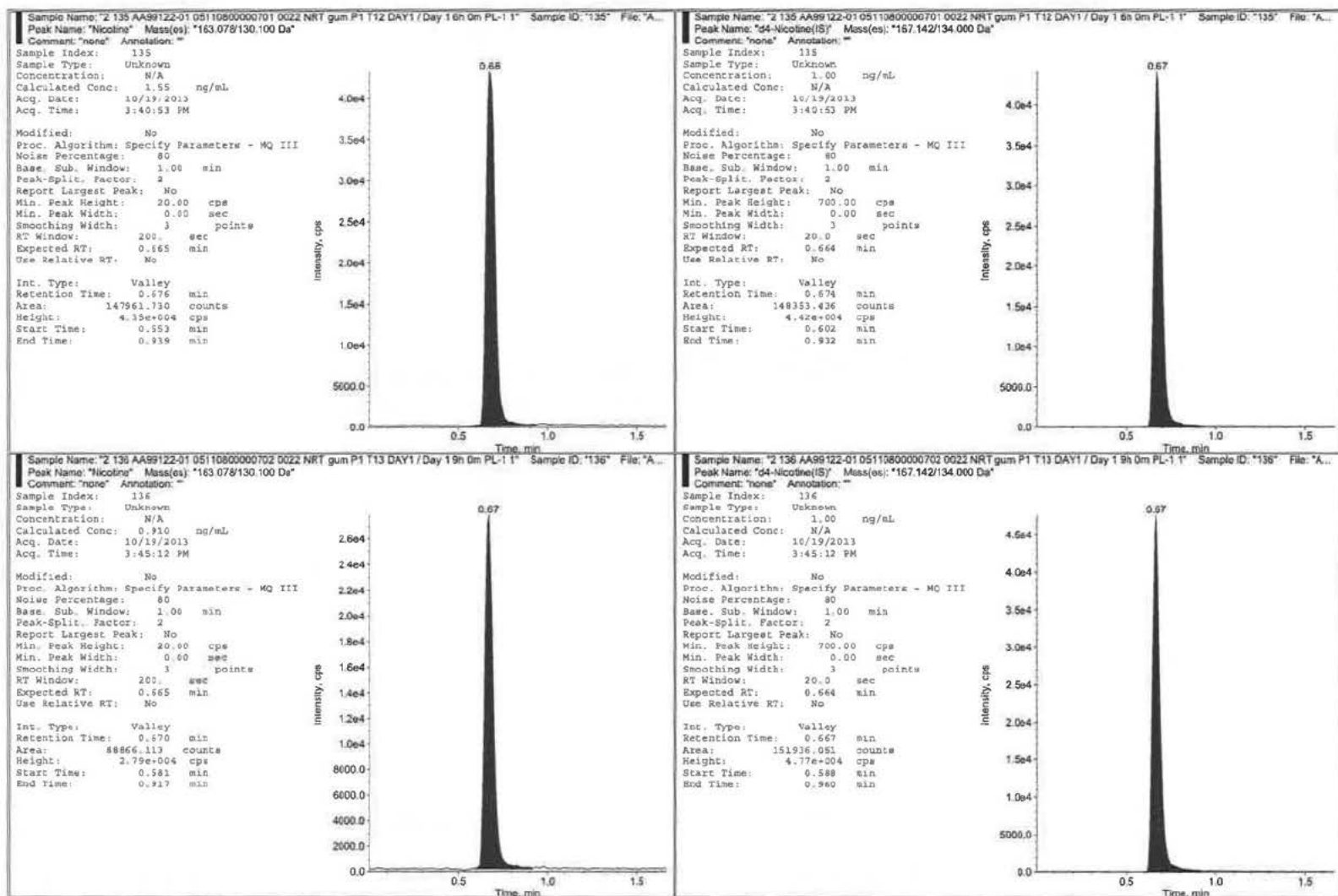


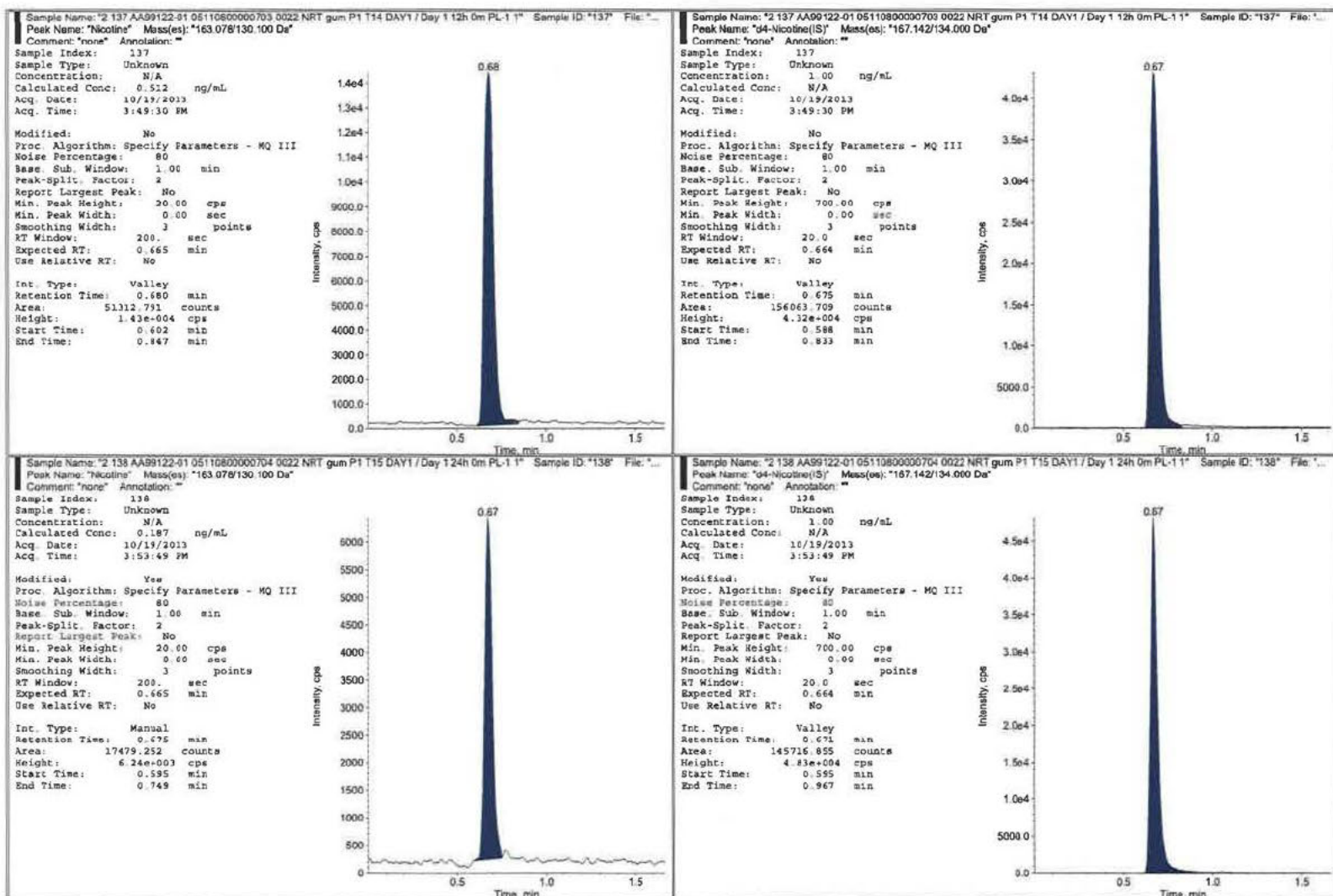
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



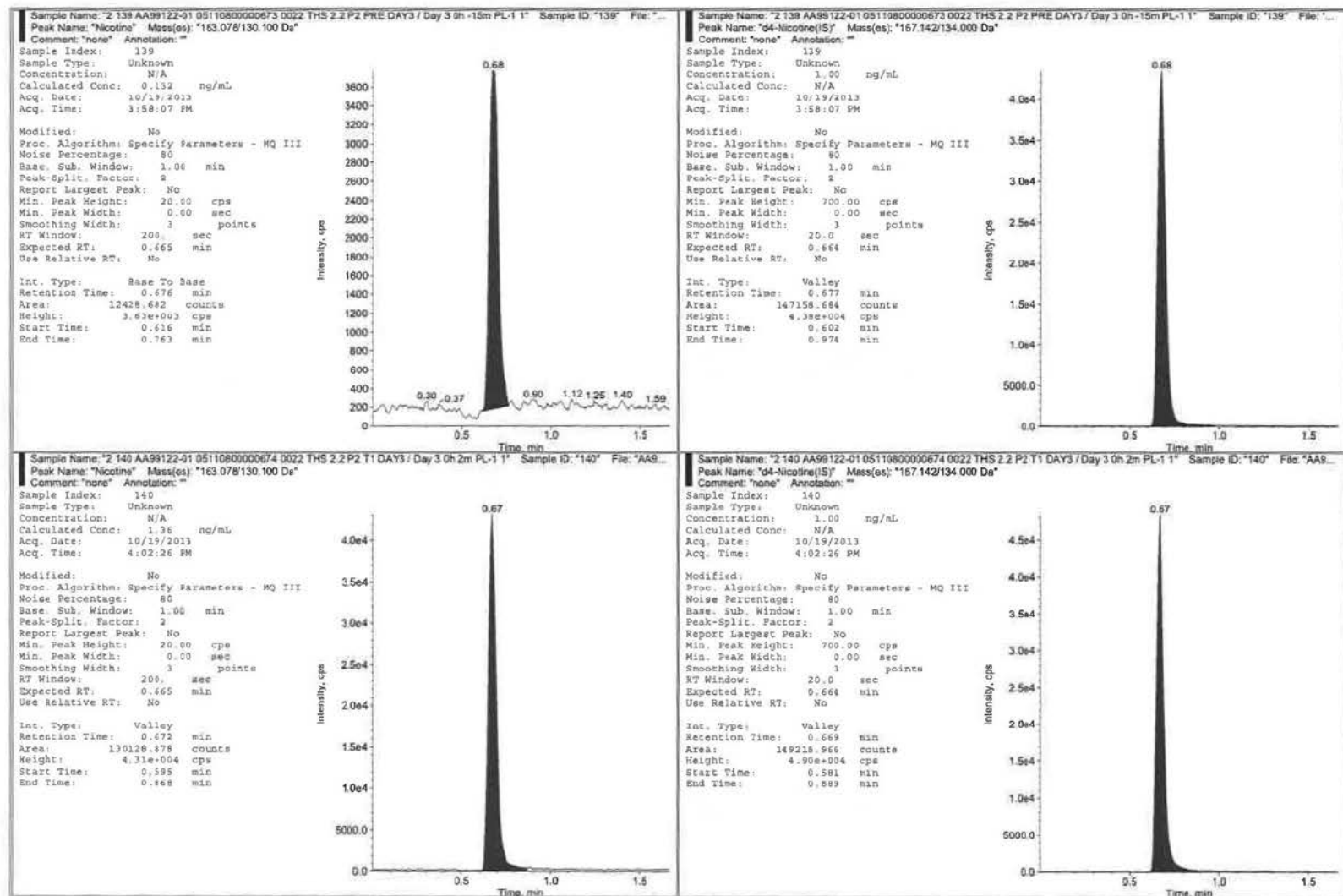
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01





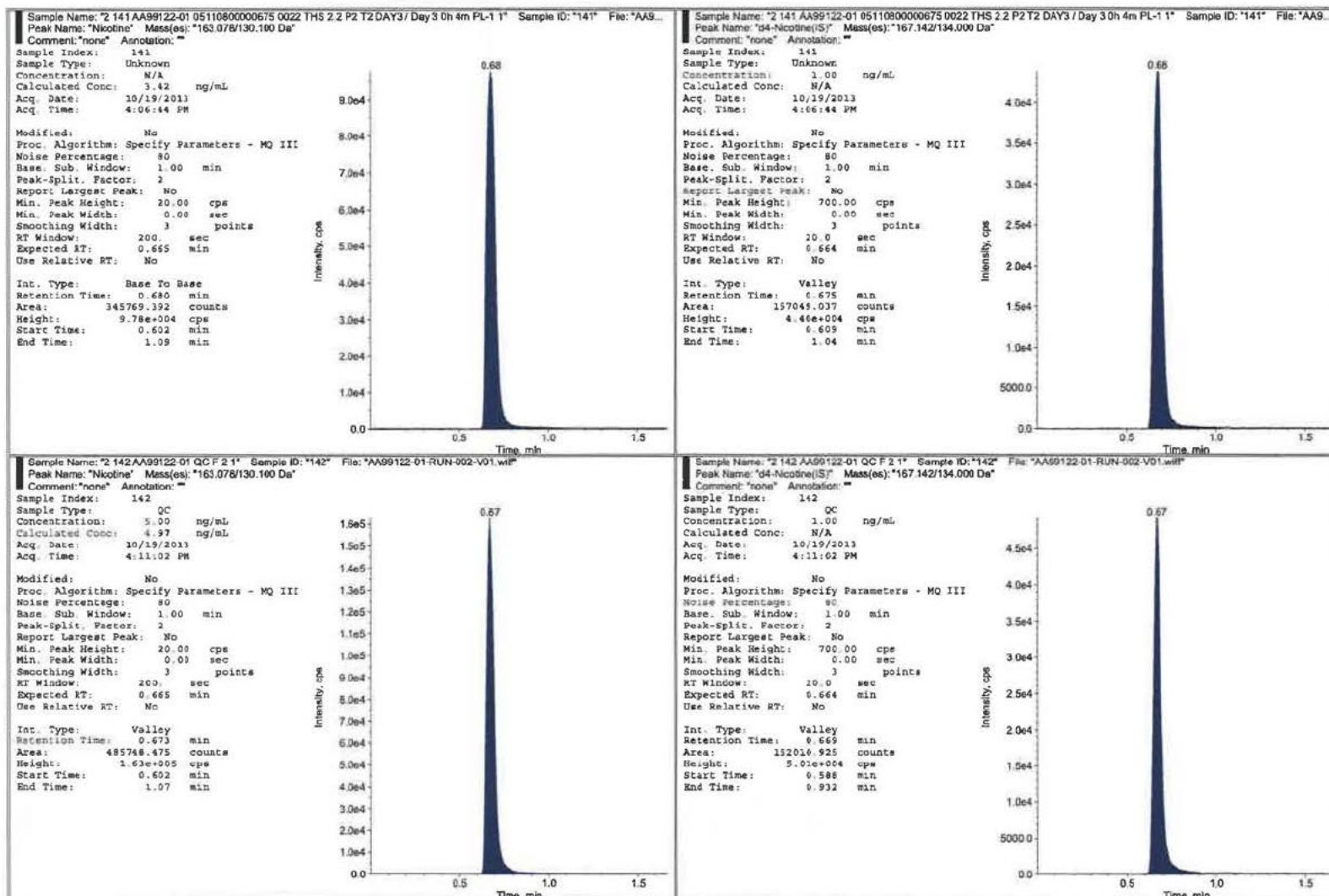


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



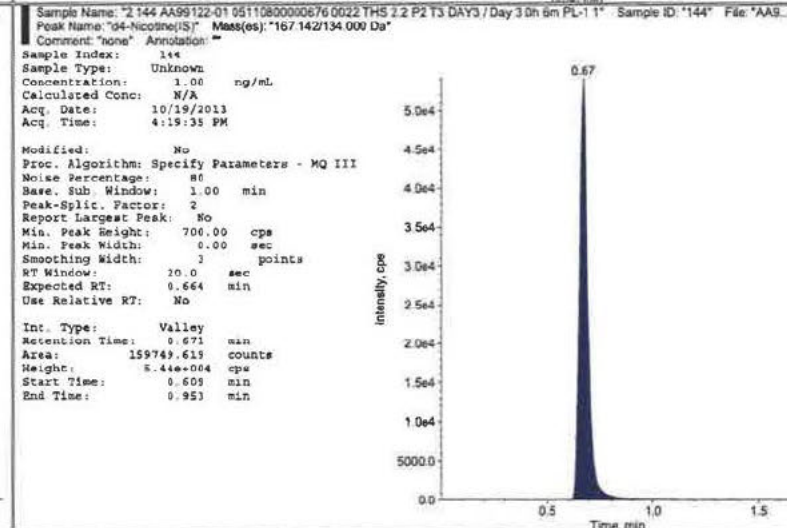
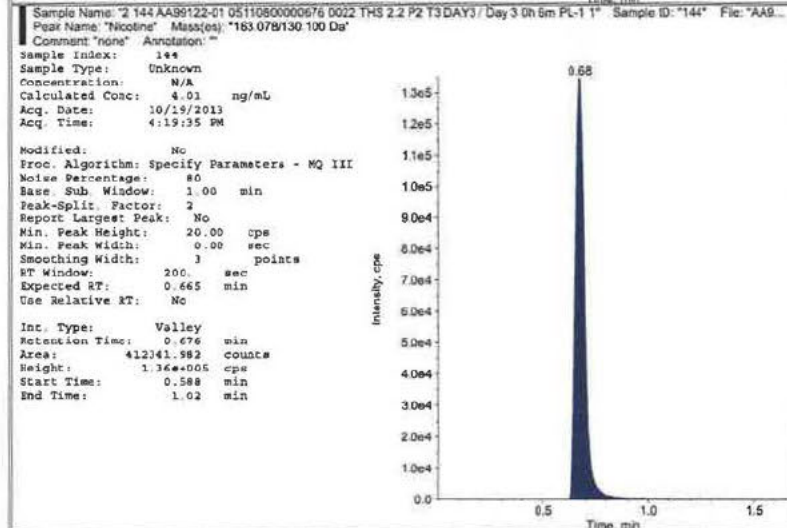
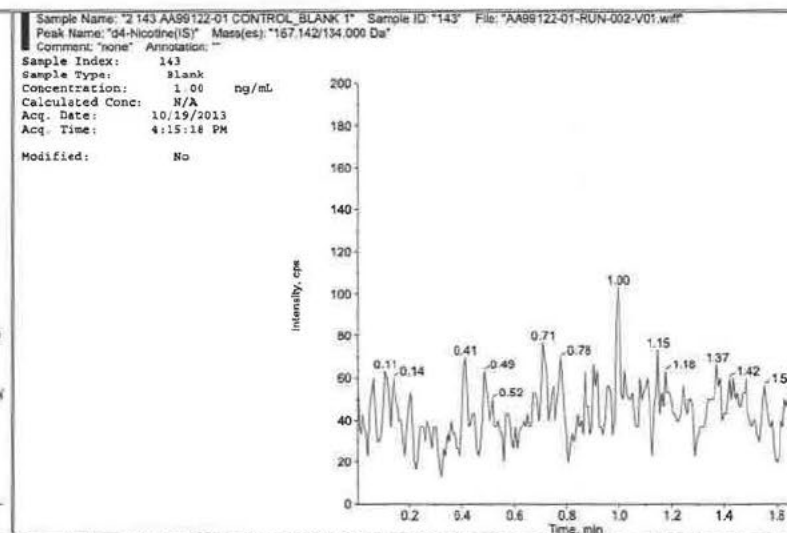
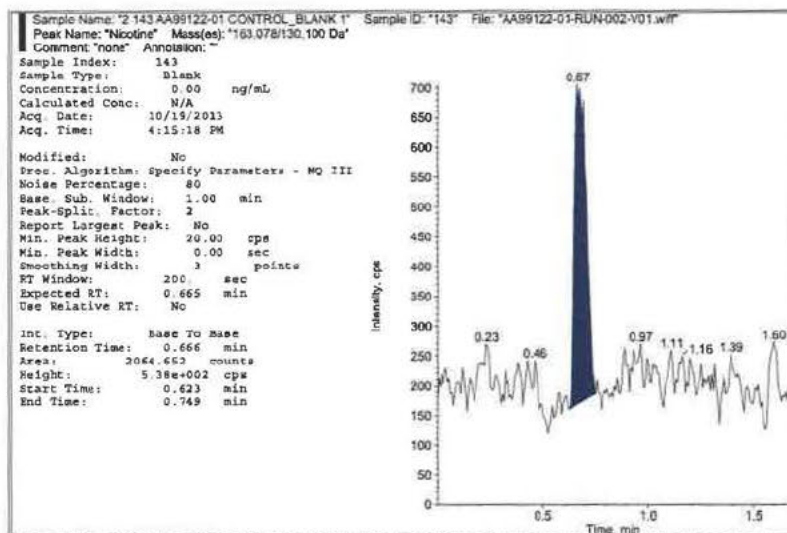


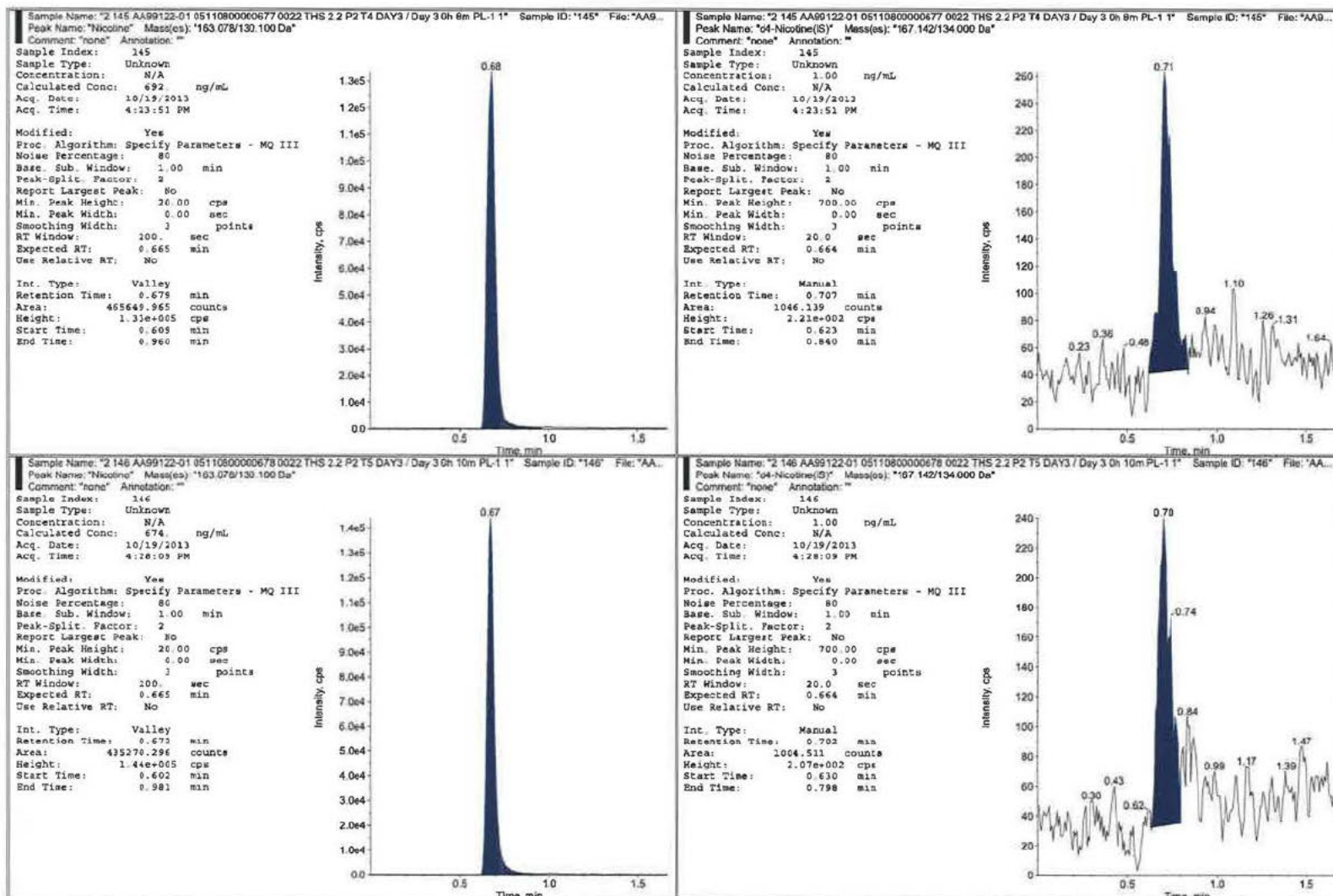
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



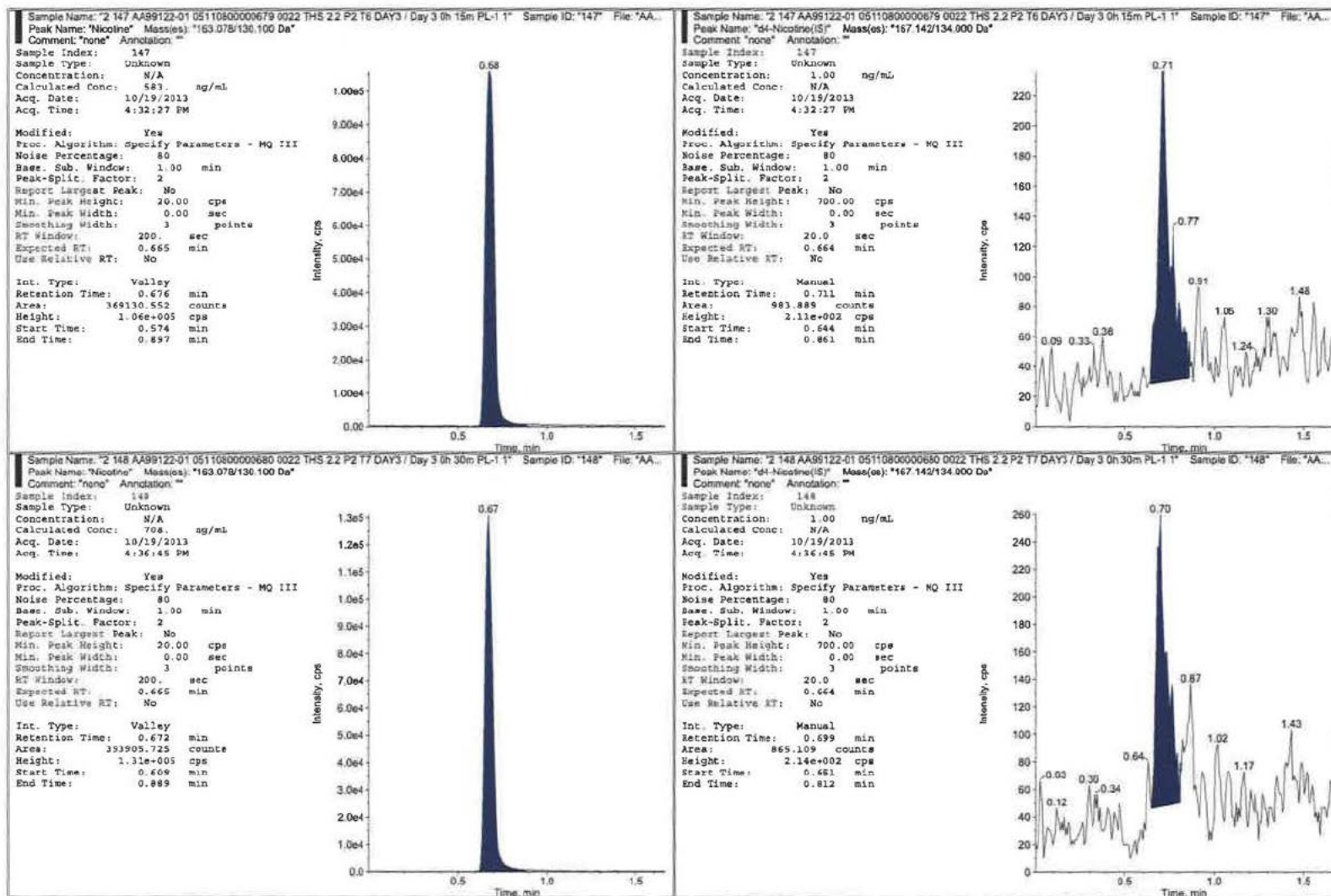


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

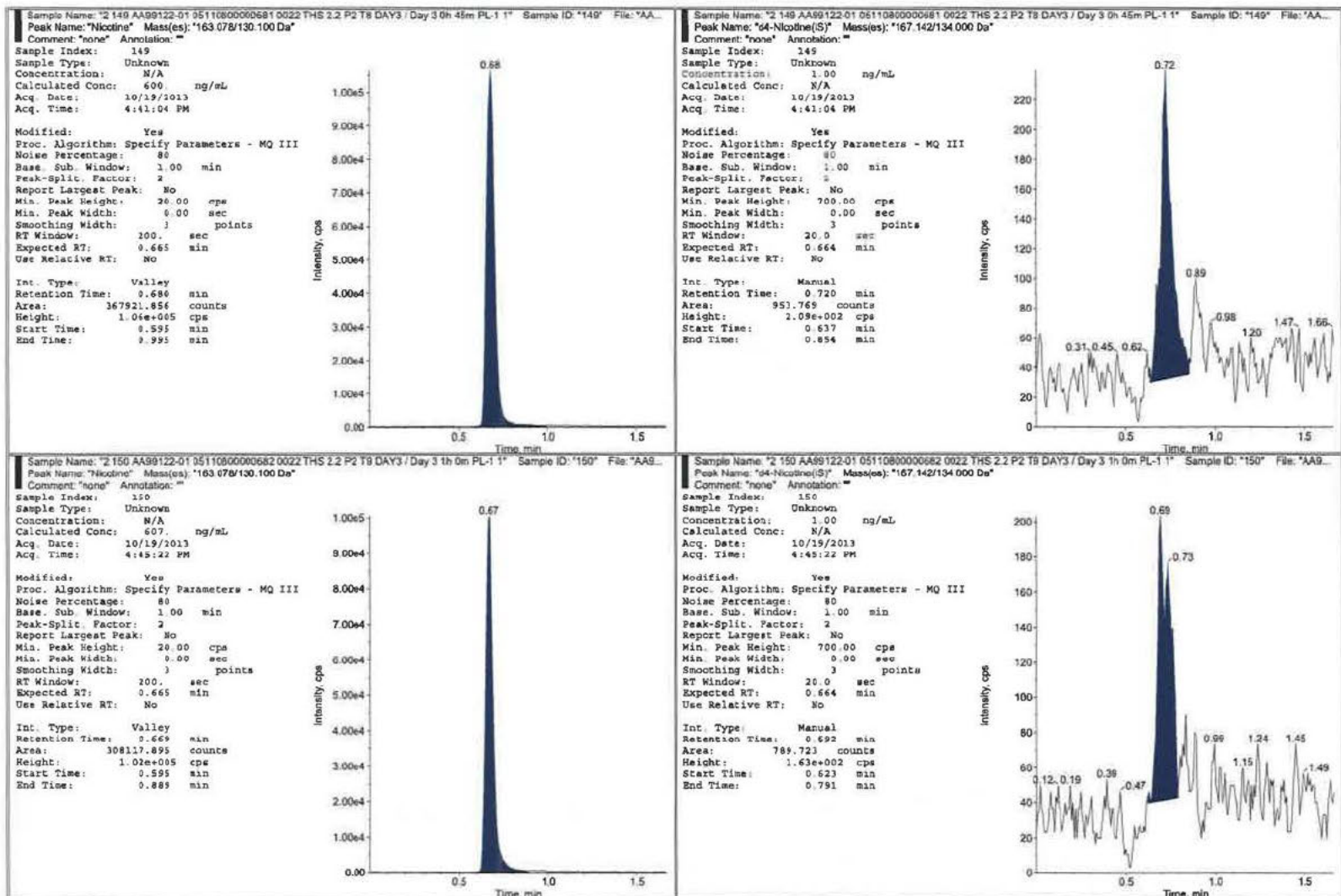




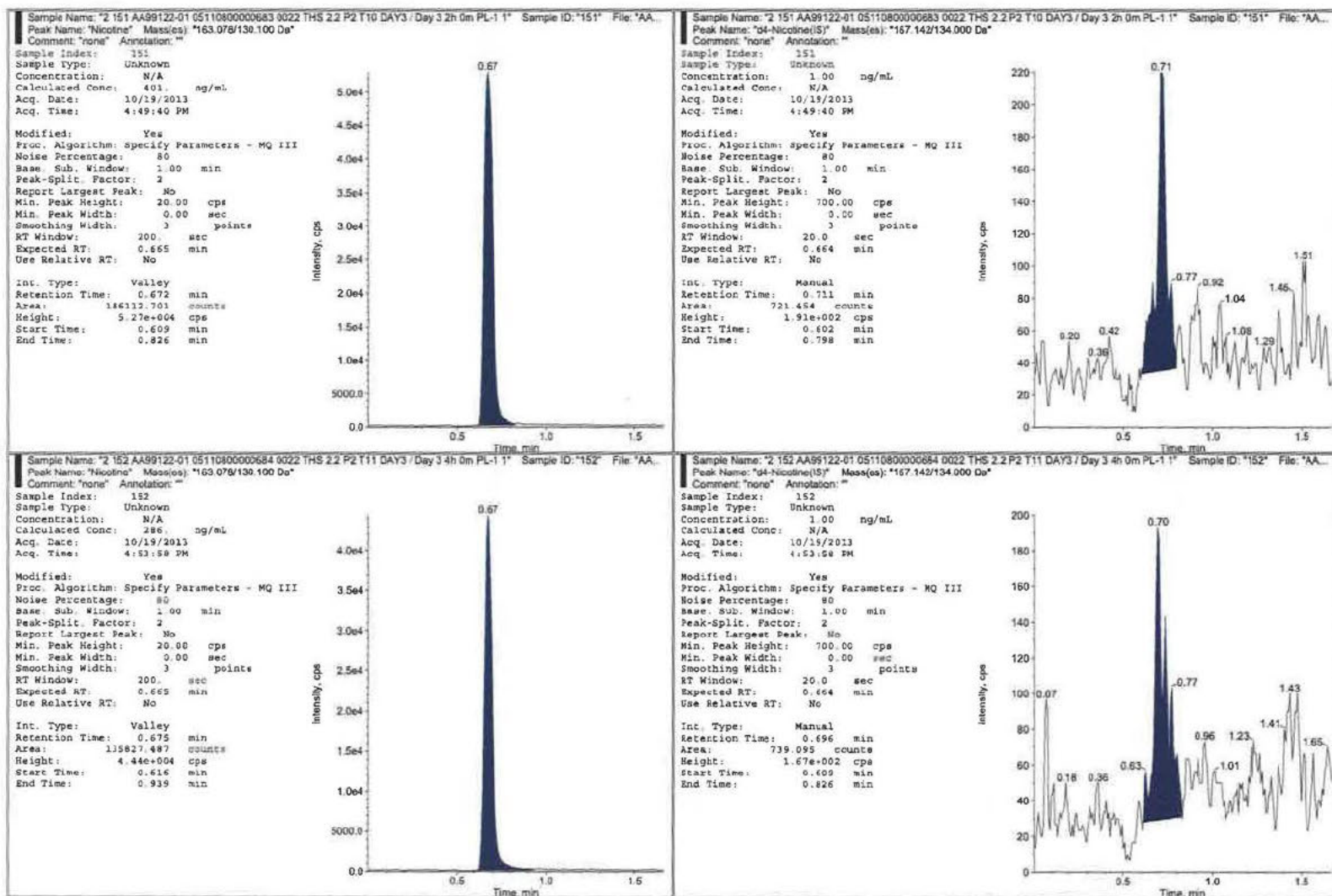
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



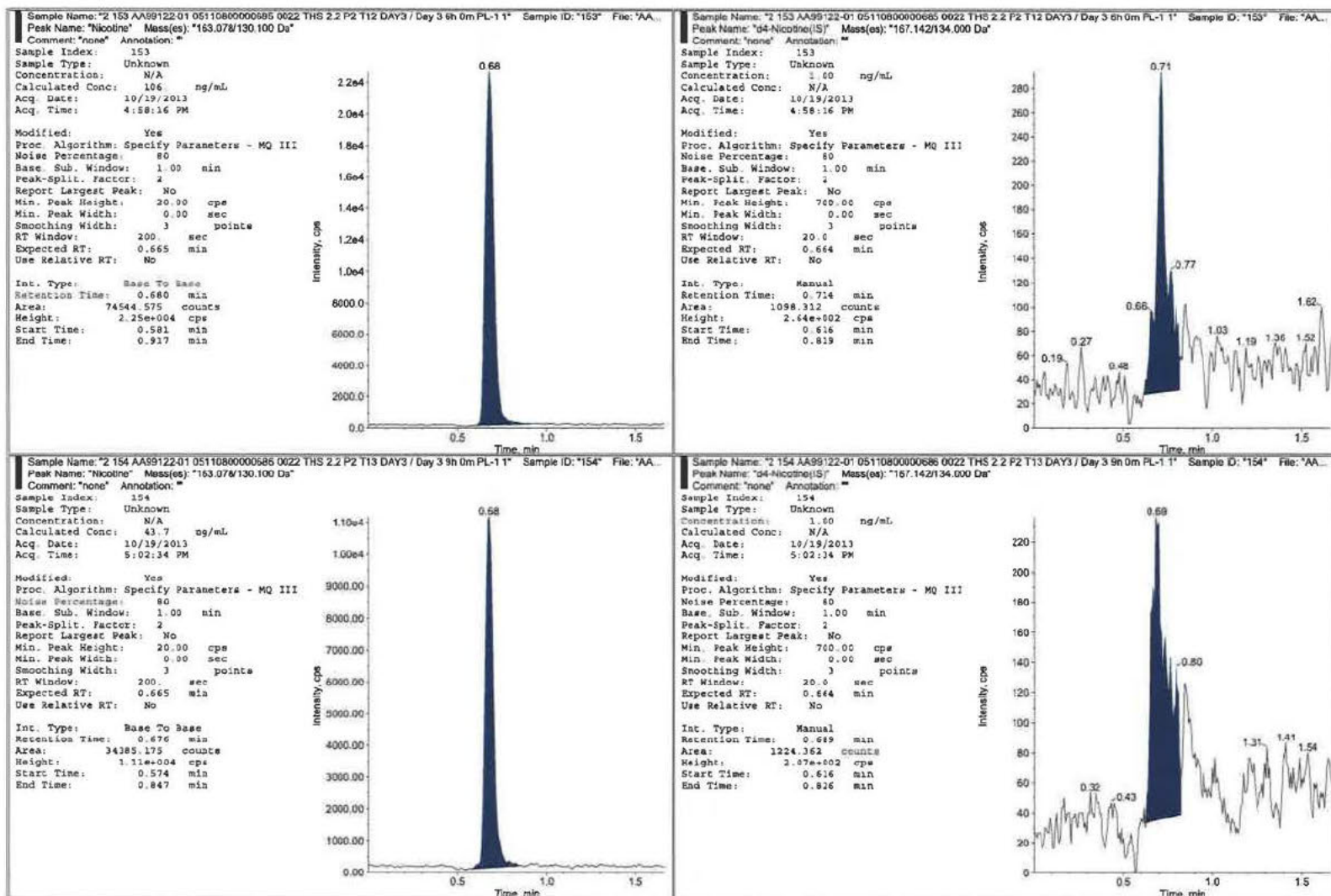




Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

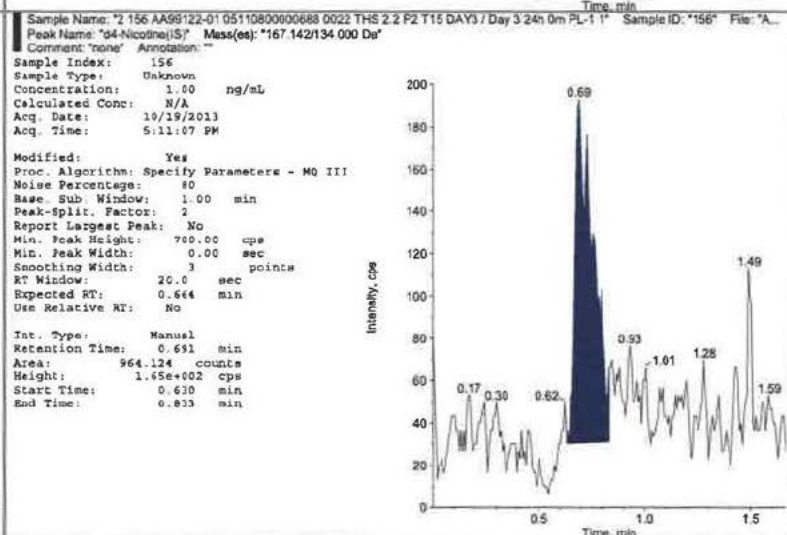
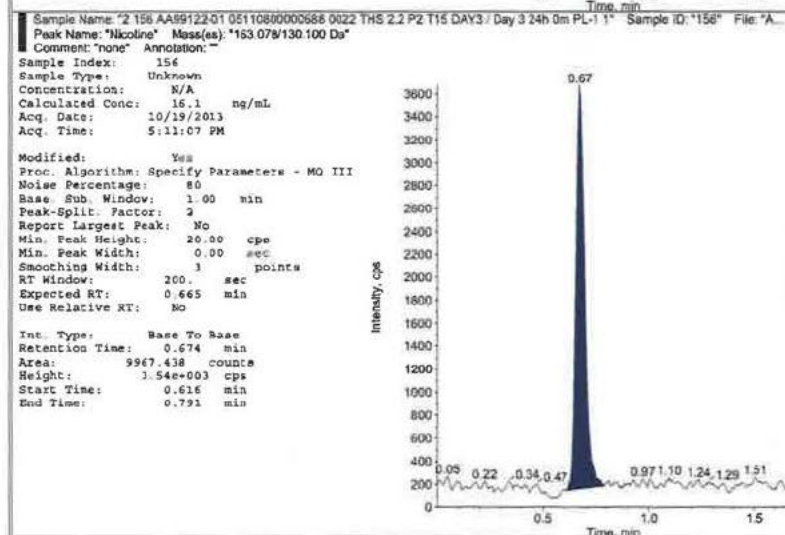
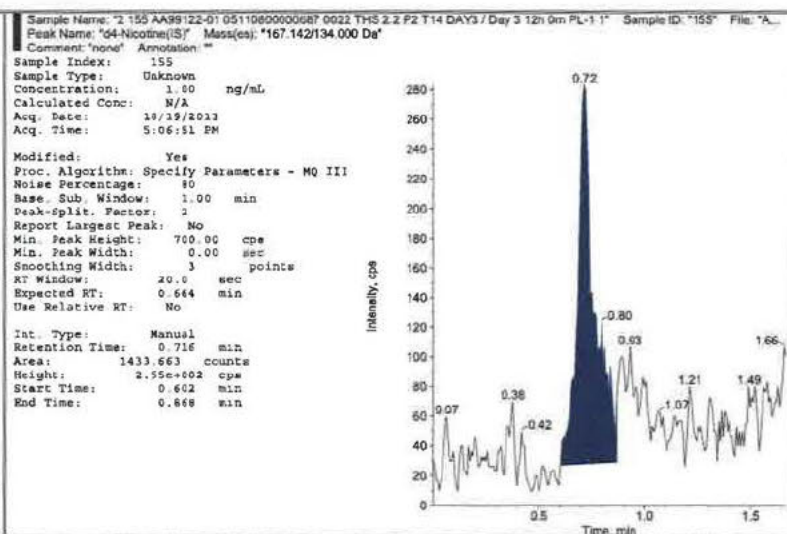
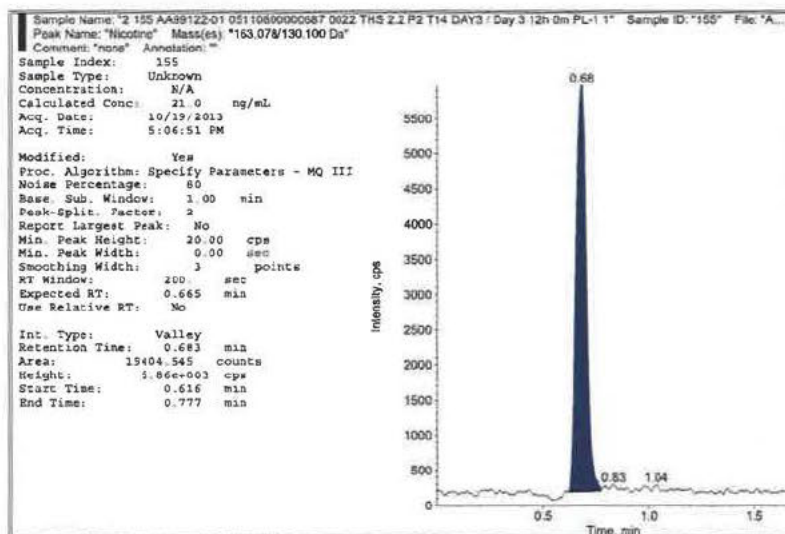


Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01

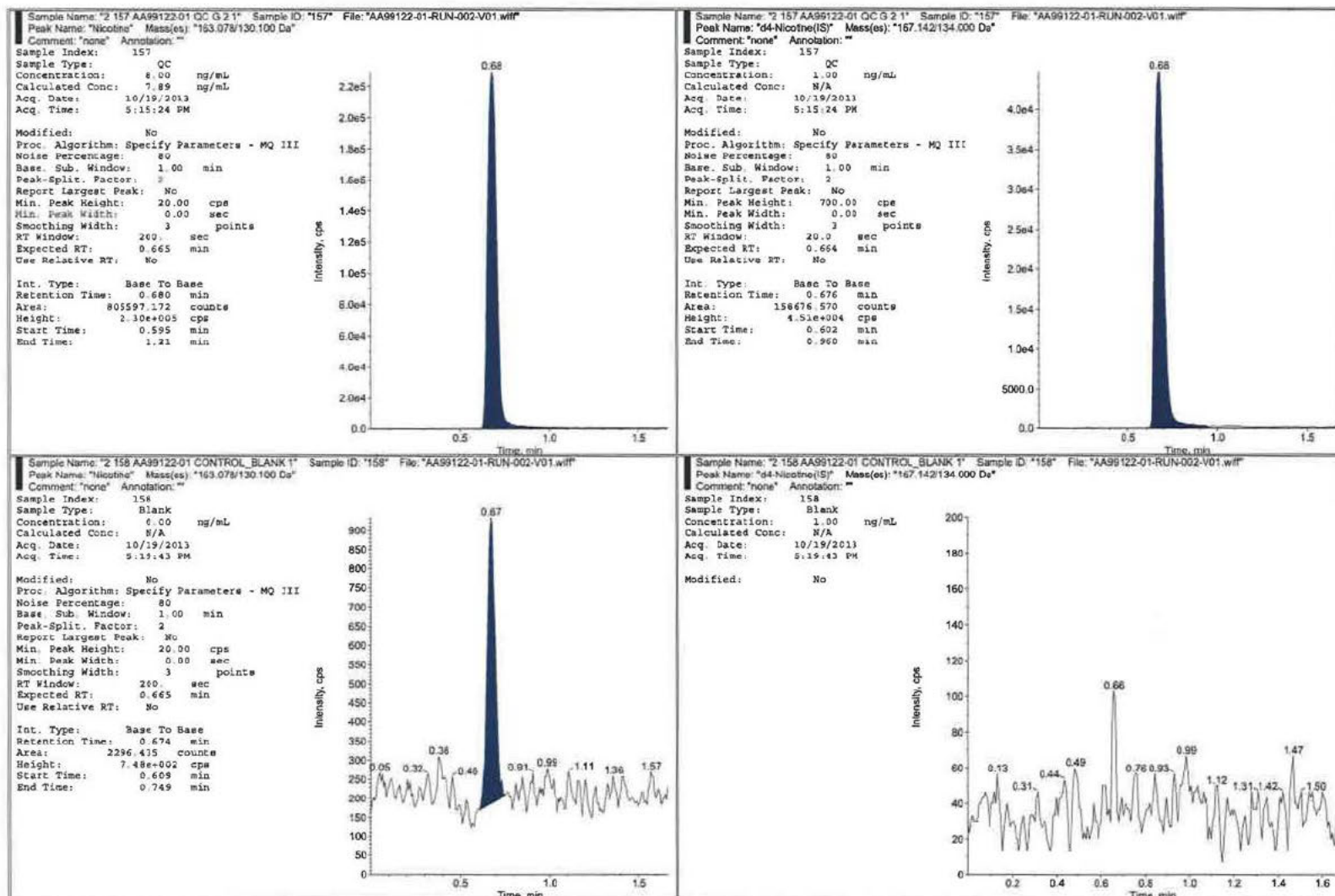




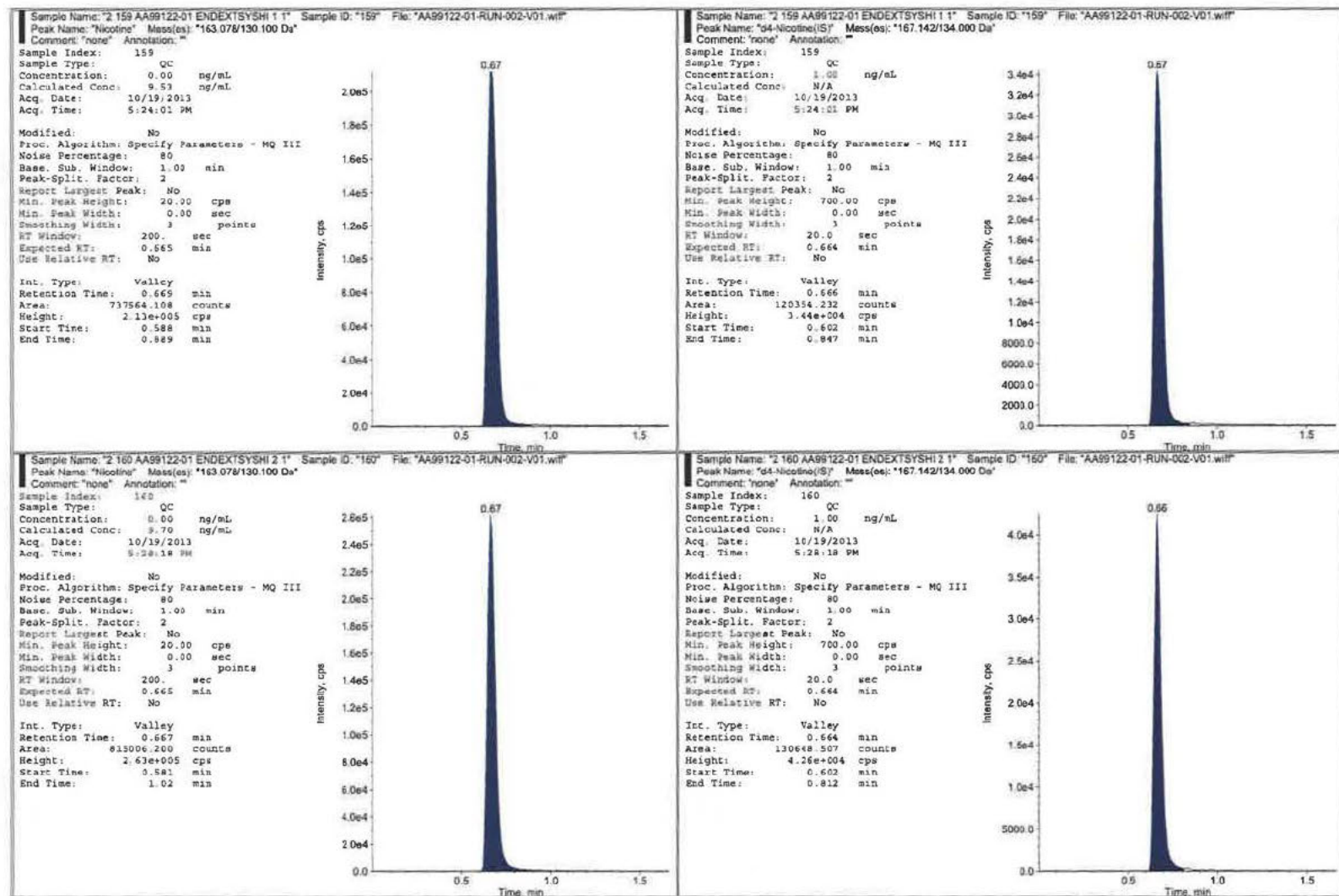
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



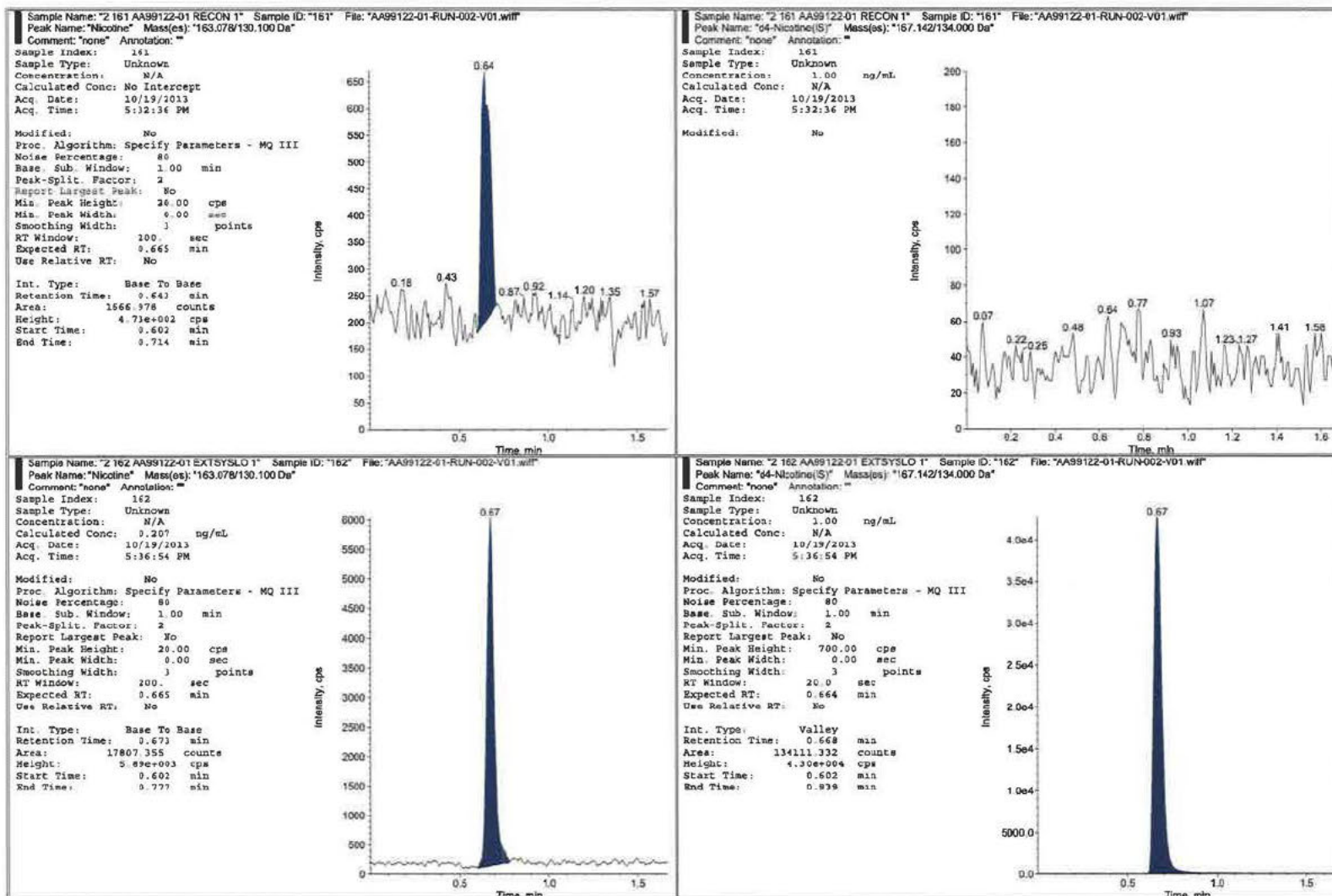
Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-01



Nicotine in Human Plasma (K<sub>2</sub>EDTA)  
 Celerion Study AA99122-01









621 Rose Street  
Lincoln, NE 68502 USA  
www.celerion.com  
Tel: 402-476-2811  
Toll Free: 800-776-1716  
Fax: 402-939-0428

**Determination of Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Samples from "A Single-center, Open-label, Randomized, Controlled, Crossover Study to  
Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2  
Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared  
to Menthol Conventional Cigarettes and Nicotine Gum" by LC-MS/MS**

Study: AA99122-02

Bioanalytical Final Report

Philip Morris Products S.A.  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland

Protocol ZRHM-PK-05-JP

Report Date: 30-Jun-2014

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the provisions of applicable law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

---

## STUDY LOCATION

## TEST FACILITY

Celerion Lincoln  
621 Rose Street  
Lincoln, NE 68502 USA  
Phone: 402-437-4719  
Fax: 402-939-0428

Role	Name, Title	E-mail Address
Bioanalytical Principal Investigator	Kirk Newland, B.S.	Kirk.Newland@celerion.com
Deputy Bioanalytical Principal Investigator	Erica Nachi, B.S.	Erica.Nachi@celerion.com
Test Facility Manager	Rafiqul Islam, M.S.	Rafiqul.Islam@celerion.com
Quality Assurance Manager	Crystal Bickford, B.A.	Crystal.Bickford@celerion.com

## SPONSOR

Philip Morris Products S.A.  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland  
Phone: +41 58 242 2625

Role	Name, Title	E-mail Address
Manager Clinical Science	Christelle Haziza, Ph.D.	Christelle.Haziza@pmi.com

## CLINICAL CENTRAL LABORATORY

Covance CCLS  
Rue Moïse Marcinhes 7  
CH-1216 Meyrin, Geneva Switzerland  
Phone: +41 58 822 7732  
Fax: +41 58 822 6999

Role	Name, Title	E-mail Address
Project Manager	Nathalie Mathieux, Ph.D.	Nathalie.Mathieux@covance.com



**APPROVAL SIGNATURES**

**TEST FACILITY**

**Celerion:**

Bioanalytical Principal Investigator



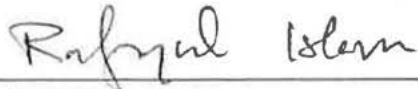
Kirk Newland, B.S.

Technical Director, Tobacco Sciences

30-Jun-2014

Date

Test Facility Management



Rafiqul Islam, M.S.

Senior Director, Bioanalytical Services

30 Jun-2014

Date

**SPONSOR**

**Philip Morris Products, S.A.:**

Manager Clinical Science



---

Christelle Haziza, PhD

09.07.2014

---

Date

## 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

30-Jun-2011

---

Date

### 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	17, 18-Jul-2013	18-Jul-2013	18-Jul-2013
Critical Phase Inspection	16, 19-Dec-2013	19-Dec-2013	20-Dec-2013
Database	30, 31-Dec-2013	31-Dec-2013	06-Jan-2014
Bioanalytical Report (Final Draft)	17-Feb-2014	17-Feb-2014	24-Jun-2014
Bioanalytical Report (Final)	27-Jun-2014	27-Jun-2014	30-Jun-2014

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.



Amy Sherwood, A.A.S.  
Quality Assurance Auditor



Date

## TABLE OF CONTENTS

STUDY LOCATION .....	2
TEST FACILITY .....	2
SPONSOR .....	2
CLINICAL CENTRAL LABORATORY .....	2
APPROVAL SIGNATURES .....	3
STATEMENT OF COMPLIANCE .....	5
QUALITY ASSURANCE STATEMENT .....	6
1. INTRODUCTION .....	11
2. EXPERIMENTAL .....	11
2.1. Test Item .....	11
2.2. Reference Items and Internal Standards .....	11
2.3. Biological Matrix.....	12
2.4. Test System .....	12
2.4.1. Procedure and Instruments .....	12
2.4.2. Computer Application Software .....	12
2.5. Calibration Standards, Quality Control Samples and Dilution Quality Control Samples .....	13
2.6. Study Samples .....	13
2.6.1. Sample Source and Date of Receipt.....	13
2.6.2. Sample Identification .....	13
2.6.3. Sample Storage and Stability.....	13
2.6.4. Sample Summary .....	14
3. SAMPLE ANALYSIS .....	14
3.1. Analytical Method .....	14
3.2. Acceptance Criteria .....	15
3.2.1. Analytical Run Acceptance Criteria .....	15
3.2.2. Acceptance Criteria for System Suitability Testing.....	15

---

3.2.3. Acceptance Criteria for Sample Dilution .....	16
3.2.4. Acceptance Criteria for ISR .....	16
4. RESULTS .....	16
4.1. Quality Control and Dilution Quality Control Sample Performance .....	16
4.2. Calibration Standard Performance.....	17
4.3. Standard Curve Parameters .....	17
4.4. Study Sample Concentrations .....	17
4.5. Reassays .....	17
4.5.1. Reassays for Analytical Reasons .....	17
4.5.2. Reassays for Non-analytical Reasons (Value Requiring Confirmation, VRC)..	17
4.5.3. Sponsor Selected Reassays.....	17
4.5.4. Incurred Sample Reproducibility .....	17
5. CHROMATOGRAMS.....	18
6. DEVIATIONS .....	18
7. EVENTS.....	18
8. ANALYTICAL NOTES .....	18
9. ARCHIVES .....	19
10. CONCLUSION.....	19
11. REFERENCES .....	19
RESULT TABLES .....	21
FIGURES .....	41
ATTACHMENTS.....	43



## RESULT TABLES

Table 1	Summary of Analytical Runs Performed.....	21
Table 2	Quality Control and Dilution Quality Control Sample Data (Between- Analytical Run Precision and Accuracy) for Cotinine .....	22
Table 3	Quality Control and Dilution Quality Control Sample Data (Between- Analytical Run Precision and Accuracy) for <i>trans</i> -3'-Hydroxycotinine.....	23
Table 4	Back-calculated Calibration Standard Concentrations for Cotinine .....	24
Table 5	Back-calculated Calibration Standard Concentrations for <i>trans</i> -3'- Hydroxycotinine.....	25
Table 6	Standard Curve Parameters for Cotinine .....	26
Table 7	Standard Curve Parameters for <i>trans</i> -3'-Hydroxycotinine.....	27
Table 8	Study Sample Concentrations for Cotinine.....	28
Table 9	Study Sample Concentrations for <i>trans</i> -3'-Hydroxycotinine .....	31
Table 10	Summary of Reassay for Analytical Reasons for Cotinine .....	34
Table 11	Summary of Reassay for Analytical Reasons for <i>trans</i> -3'-Hydroxycotinine .....	36
Table 12.	Summary of Reassays for Sample Investigation for Cotinine .....	37
Table 13.	Summary of Reassays for Sample Investigation for <i>trans</i> -3'-Hydroxycotinine.....	38
Table 14.	Incurred Sample Reproducibility Assessment for Cotinine.....	39
Table 15	Incurred Sample Reproducibility Assessment for <i>trans</i> -3'-Hydroxycotinine .....	40

## FIGURES

Figure 1	Calibration Curve for Cotinine in Control Matrix, Watson Run ID 1.....	41
Figure 2	Calibration Curve for <i>trans</i> -3'-Hydroxycotinine in Control Matrix, Watson Run ID 1.....	42

## ATTACHMENTS

Attachment 1	General List of Abbreviations used at Celerion.....	43
Attachment 2	Temperature Definitions at Celerion .....	46

---

Attachment 3	Procedure for VRC and SSR Reassays and Reporting of Reassay Results.....	47
Attachment 4	General List of Calculation Formulae .....	48
Attachment 5	Reassay Descriptions .....	49
Attachment 6	Certificates of Analysis.....	50
Attachment 7	Bioanalytical Method Summary .....	68
Attachment 8	Chromatograms .....	73
<b>Total Number of Pages</b>		<b>169</b>

## 1. INTRODUCTION

The purpose of this bioanalytical study (hereafter referred to as study) was to determine the concentration of cotinine and *trans*-3'-hydroxycotinine in human plasma (K<sub>2</sub>EDTA) samples by a validated LC-MS/MS method [5]. The study samples were collected in the clinical trial ZRHM-PK-05-JP entitled, "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum" [3]. Sample analysis was conducted between 13-Dec-2013 and 28-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	Cotinine	d <sub>3</sub> -Cotinine
Source	Cerilliant Corporation	Cerilliant Corporation
Lot No.	FN061710-01	FN102110-02
Celerion Assigned Correction Factor	1.0000	1.0000
Purity / Concentration	99.8% (1.047 mg/mL)	99.7% (100.0 µg/mL)
Expiry Date	30-Jun-2015	31-Oct-2015
Storage Conditions	Freezer (-20°C), protected from light	Freezer (-20°C), protected from light

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



The certificates 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. The expired reference materials are denoted as expired within the Labnotes system. They may be stored for the establishment of extended long-term stability.

### 2.3. Biological Matrix

Human plasma, with K<sub>2</sub>EDTA as anticoagulant, was collected in-house at Celerion in Lincoln, Nebraska. Human plasma stored at -20°C may be stored for a period less than 24 months prior to use. Human plasma (K<sub>2</sub>EDTA), free of significant interference, was used to prepare quality control (QC) samples. Deionized water was used to prepare calibration standards and used as control matrix.

### 2.4. Test System

#### 2.4.1. Procedure and Instruments

Procedure and Instrumentation	
Extraction Method	Solid-phase extraction
Chromatography System	Perkin Elmer Series 200 Micropump HPLC <sup>^</sup>
MS/MS System	AB SCIEX API 5000™ and QTRAP® 5500 <sup>^</sup>
Regression Type	Weighted linear regression curve (1/concentration <sup>2</sup> )
Quantitation Method	Peak Area Ratio
Assay Volume	0.300 mL
Accepted Level of Hemolysis	2%

<sup>^</sup> = Qualified systems

#### 2.4.2. Computer Application Software

Software	
LC-MS/MS Software	Applied Biosystems Analyst® 1.5.1 <sup>^</sup>
LIMS	Thermo Electron Corporation Watson™ 7.3 Bioanalytical LIMS 7.3 <sup>^</sup>
LIMS Application	Inspector Version 1.1.1 <sup>^</sup>
Laboratory Documentation System	Labnotes™ Web Client 1.21 <sup>^</sup>
Office Applications	Microsoft® Office 2007 Package

<sup>^</sup>=Validated systems

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

Non-zero calibration standards were prepared fresh daily at the concentration levels of 1.00, 2.00, 4.00, 10.0, 25.0, 50.0, 75.0, 90.0, and 100 ng/mL of cotinine and *trans*-3'-hydroxycotinine from calibration standard spiking solutions which were prepared on 09-Sep-2013 and 17-Dec-2013 and stored at -20°C for a period of time up to 323 days.

Quality control (QC) samples at the concentration levels of 3.00, 50.0, and 75.0 ng/mL and dilution quality control (DQC) samples at the concentration level of 200 ng/mL of cotinine and *trans*-3'-hydroxycotinine were prepared in bulk on 03-Sep-2013, aliquoted and stored at -20°C. Quality control samples were stored with the clinical samples after receipt at the bioanalytical laboratory. The QC samples were stored for a period less than 1041 days prior to use for analysis.

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

## 2.6. Study Samples

### 2.6.1. Sample Source and Date of Receipt

Study samples were collected between 16-Aug-2013 and 04-Nov-2013 and were received frozen on dry ice between 17-Sep-2013 and 02-Dec-2013 from Covance Clinical Research, Singapore.

### 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 135 days.

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

Stability Summary [S]	Cotinine and <i>trans</i> -3'-Hydroxycotinine
Long-term Stability	194 days in polypropylene tubes at -20°C
Short-term Stability	27 hours in polypropylene tubes at ambient temperature under white light
Freeze-thaw Stability	6 cycles in polypropylene tubes at -20°C under white light 7 cycles in polypropylene tubes at -20°C under UV-shielded light
Post-preparative Stability	135 hours in a polypropylene 96 well plate at 5°C
Processed Sample Integrity	93 hours in a polypropylene 96 well plate at 5°C
Sample Shipping Stability	19 days in polypropylene tubes at -80°C

#### 2.6.4. Sample Summary

The Sponsor's protocol specifies 62 subjects with 1 sampling time [3]. In study AA99122, a single subject discontinued during the clinical phase. The samples were analyzed and the results reported. Additional information regarding the subject discontinuance is provided in [Section 8](#).

	No. of Samples
Specified "for analysis" samples in protocol/received	62/73
Time points lost due to subject discontinuance	0
Back-up samples received	73
Total number of study samples analyzed	73

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

### 3. SAMPLE ANALYSIS

#### 3.1. Analytical Method

The determination of cotinine and *trans*-3'-hydroxycotinine in human plasma samples was carried out over a calibration range of 1.00 ng/mL to 100 ng/mL. The analytical procedure was performed at Celerion, Lincoln, Nebraska and is documented in the Method Validation Report for Celerion Study AA33664-01 [5]. The analytical method is documented in BAM SOP AA33664-01 [6].

An aliquot of human plasma (EDTA) containing each analyte and internal standard was extracted using a solid phase extraction procedure. The extracted samples were analyzed by an HPLC equipped with an AB SCIEX API 5000™ or QTRAP® 5500 mass spectrometer. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis ( $1/x^2$ ) of peak area ratios of each analyte and internal standard.



### 3.2. Acceptance Criteria

#### 3.2.1. Analytical Run Acceptance Criteria

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

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

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

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

Individual data of QC samples (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. Carryover acceptance criteria is specified in the bioanalytical method for each assay.

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

### 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.

### 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 3.00, 50.0, and 75.0 ng/mL are summarized in [Table 2](#) and [Table 3](#) for cotinine and *trans*-3'-hydroxycotinine, 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](#) and [Table 3](#) for cotinine and *trans*-3'-hydroxycotinine, respectively.



#### 4.2. Calibration Standard Performance

Back-calculated calibration curve standard concentrations are provided in [Table 4](#) and [Table 5](#) for cotinine and *trans*-3'-hydroxycotinine, respectively.

#### 4.3. Standard Curve Parameters

Standard curve parameters from 4 successful analytical runs are provided in [Table 6](#) and [Table 7](#) for cotinine and *trans*-3'-hydroxycotinine, respectively. A representative calibration curve is illustrated in [Figure 1](#) and [Figure 2](#) for cotinine and *trans*-3'-hydroxycotinine, respectively.

#### 4.4. Study Sample Concentrations

Study sample concentrations are provided in [Table 8](#) and [Table 9](#) for cotinine and *trans*-3'-hydroxycotinine, respectively.

Study samples, if any, with no significant peak at the mass transition and retention time of cotinine and *trans*-3'-hydroxycotinine, 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 cotinine and *trans*-3'-hydroxycotinine are identified in [Table 10](#) and [Table 11](#), respectively. Reassay descriptions are provided in [Attachment 5](#).

##### 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 reassay due to non-analytical reasons were reassayed if sufficient sample volume remained. These samples are identified in [Table 12](#) and [Table 13](#) for cotinine and *trans*-3'-hydroxycotinine, respectively. The procedure for VRC reassays and reporting of reassay results is provided in [Attachment 3](#).

##### 4.5.3. Sponsor Selected Reassays

There were no Sponsor selected reassays. The procedure for SSR reassays and reporting of reassay results is provided in [Attachment 3](#).

##### 4.5.4. Incurred Sample Reproducibility

The method for the determination of cotinine and *trans*-3'-hydroxycotinine was considered reproducible, 90.9% out of 22 repeat analyses for cotinine and 81.8% out of 22 repeat analyses for *trans*-3'-hydroxycotinine met acceptance criteria as defined in [section 3.2.4](#). Results are presented in [Table 14](#) and [Table 15](#).

## 5. CHROMATOGRAMS

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

## 6. DEVIATIONS

6.1. Deviation DEV-LNK-13-0607 was initiated due to associate not completing documentation for reading the BAM SOP and BSP as LNK SOP.0023 Bioanalytical Method (BAM) Procedures, BAM SOPs, and System Settings prior to creating run lists and regressing analytical runs. The associate read the required documents and corrected the missing documentation. There was no further impact.

## 7. EVENTS

7.1. Event Observation EO-LNK-AA99122-02-13- 630 was initiated due to the following samples failed ISR testing and required investigation:

For both cotinine and *trans*-3'-hydroxycotinine:  
Subject 134, Period 1, Day -1, 0 hr, 0 min

For *trans*-3'-hydroxycotinine only:  
Subject 128, Period 1, Day -1, 0 hr, 0 min  
Subject 140, Period 1, Day -1, 0 hr, 0 min

These samples were selected for VRC (Value Requiring Confirmation) testing with standard VRC criteria applied (ER-LNK-AA99122-02-13-0165). There was no impact on the analytical data as the original measurements for the three samples were confirmed. The original results were reported.

## 8. ANALYTICAL NOTES

8.1 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 possible impacted studies included ZRHM-PK-05-JP (AA99122). A single subject, 0107, discontinued from the clinical phase post-randomization. After verification of the discontinuance of the subject by the Bioanalytical Principal Investigator, the samples for Subject 0107 were analyzed. No notification of a possible consent issue was provided by the Sponsor, Project Management for the central laboratory, or the clinical site.

Through a Sponsor CAPA process the documentation of the subject intent was provided by the Principal Investigator from the clinical site. It was confirmed that Subject 0107 had not removed consent for the analysis of the clinical samples taken prior to subject discontinuance. Documentation from the Principal Investigator was provided to Celerion and is archived with the

study correspondence for this study. The results from the clinical samples taken from Subject 0107 are included within this report.

## 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

## 10. CONCLUSION

In this bioanalytical study the concentration of cotinine and *trans*-3'-hydroxycotinine was determined in a total of 73 human plasma (K<sub>2</sub>EDTA) samples collected in the Philip Morris International Research and Development clinical study ZRHM-PK-05-JP 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 ZRHM-PK-05-JP: "A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco



- Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum”
- [4] Study Plan Bioanalysis: Determination of Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA) Samples from “A Single-center, Open-label, Randomized, Controlled, Crossover Study to Investigate the Nicotine Pharmacokinetic Profile and Safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) Following Single use in Smoking, Healthy Subjects Compared to Menthol Conventional Cigarettes and Nicotine Gum” by LC-MS/MS, Celerion Study AA99122-02
- [5] Validation of an LC-MS/MS Method for the Determination of Nicotine, Cotinine, and *trans*-3'-Hydroxycotinine in Human Plasma (EDTA), Celerion Study AA33664-01
- [6] Bioanalytical Method SOP for the Determination of Nicotine, Cotinine, and *trans*-3'-Hydroxycotinine in Human Plasma (EDTA), Celerion Study AA33664-01

## RESULT TABLES

Table 1 Summary of Analytical Runs Performed

Analyte Name	Run ID	Regression Status	Extraction Date	Assay Date	Description	Comment
Cotinine	1	Accepted	13-Dec-2013	13-Dec-2013	SEE WORKLIST FOR SUBJECT AND TIMEPOINTS	OK
Cotinine	2	Accepted	17-Dec-2013	17-Dec-2013	SEE WORKLIST + REASSAYS	OK
Cotinine	3	Accepted	19-Dec-2013	19-Dec-2013	ISRS + REASSAYS	OK
Cotinine	4	Accepted	27-Dec-2013	28-Dec-2013	VRCs + REASSAY SUB 0140 FOR COT	OK
Trans-3-Hydroxycotinine	1	Accepted	13-Dec-2013	13-Dec-2013	SEE WORKLIST FOR SUBJECT AND TIMEPOINTS	OK
Trans-3-Hydroxycotinine	2	Accepted	17-Dec-2013	17-Dec-2013	SEE WORKLIST + REASSAYS	OK
Trans-3-Hydroxycotinine	3	Accepted	19-Dec-2013	19-Dec-2013	ISRS + REASSAYS	OK
Trans-3-Hydroxycotinine	4	Accepted	27-Dec-2013	28-Dec-2013	VRCs + REASSAY SUB 0140 FOR COT	OK

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

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

Assay Date	Run ID	QC A 3.00 ng/mL	QC G 50.0 ng/mL	QC C 75.0 ng/mL	QC C DF2 75.0 ng/mL	QC D DF10 200 ng/mL	QC D DF5 200 ng/mL
13-Dec-2013	1	3.30	48.8	69.7			
		3.37	49.9	73.6			
17-Dec-2013	2	3.17	50.3	75.5		194	
		3.34	51.8	72.0		213	
						200	
19-Dec-2013	3	3.26	49.6	72.1		196	
		3.31	53.1	72.0		211	
						213	
28-Dec-2013	4	3.27	52.0	73.1	72.2		194
		3.19	51.9	75.6	78.5		192
					78.0		209
Mean		3.28	50.9	73.0	76.2	205	198
S.D.		0.0693	1.48	1.97	3.50	8.83	9.29
%CV		2.1	2.9	2.7	4.6	4.3	4.7
%Theoretical		109.3	101.8	97.3	101.6	102.5	99.0
%Bias		9.3	1.8	-2.7	1.6	2.5	-1.0
n		8	8	8	3	6	3

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

Assay Date	Run ID	QC A 3.00 ng/mL	QC G 50.0 ng/mL	QC C 75.0 ng/mL	QC C DF2 75.0 ng/mL	QC D DF10 200 ng/mL	QC D DF5 200 ng/mL
13-Dec-2013	1	2.92	45.3	67.2			
		3.11	47.5	70.4			
17-Dec-2013	2	3.00	46.0	71.4		190	
		3.10	48.6	69.2		208	
						195	
19-Dec-2013	3	2.97	46.1	69.8		190	
		3.10	47.6	66.7		199	
						202	
28-Dec-2013	4	2.97	45.7	67.7	68.2		185
		3.00	46.0	71.3	73.5		184
					72.9		198
Mean		3.02	46.6	69.2	71.5	197	189
S.D.		0.0724	1.15	1.83	2.90	7.09	7.81
%CV		2.4	2.5	2.6	4.1	3.6	4.1
%Theoretical		100.7	93.2	92.3	95.3	98.5	94.5
%Bias		0.7	-6.8	-7.7	-4.7	-1.5	-5.5
n		8	8	8	3	6	3

Table 4 Back-calculated Calibration Standard Concentrations for Cotinine

Assay Date	Run ID	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 10.0 ng/mL	STD F 25.0 ng/mL	STD G 50.0 ng/mL	STD H 75.0 ng/mL	STD I 90.0 ng/mL	STD J 100 ng/mL
13-Dec-2013	1	0.990	2.03	4.05	9.70	26.3	51.9	74.0	89.6	93.7
17-Dec-2013	2	1.02	1.90	4.09	9.75	26.3	52.8	73.5	93.5	90.8
19-Dec-2013	3	1.01	1.98	4.00	9.44	25.1	50.9	71.3	102	94.8
28-Dec-2013	4	0.998	2.01	4.01	9.82	25.8	52.0	73.5	96.0	89.5
Mean		1.00	1.98	4.04	9.68	25.9	51.9	73.1	95.3	92.2
S.D.		0.0132	0.0572	0.0411	0.166	0.568	0.779	1.21	5.20	2.47
%CV		1.3	2.9	1.0	1.7	2.2	1.5	1.7	5.5	2.7
%Bias		0.0	-1.0	1.0	-3.2	3.6	3.8	-2.5	5.9	-7.8
n		4	4	4	4	4	4	4	4	4



Table 5 Back-calculated Calibration Standard Concentrations for *trans*-3'-Hydroxycotinine

Assay Date	Run ID	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 10.0 ng/mL	STD F 25.0 ng/mL	STD G 50.0 ng/mL	STD H 75.0 ng/mL	STD I 90.0 ng/mL	STD J 100 ng/mL
13-Dec-2013	1	1.01	1.98	3.93	9.49	25.8	52.6	77.7	*74.4	94.8
17-Dec-2013	2	1.02	1.93	3.96	9.75	26.0	51.4	75.3	92.0	95.4
19-Dec-2013	3	0.996	2.06	3.89	9.51	25.2	51.0	73.9	97.4	95.5
28-Dec-2013	4	0.969	2.14	3.99	9.58	25.9	50.8	75.7	90.1	94.4
Mean		0.999	2.03	3.94	9.58	25.7	51.5	75.7	93.2	95.0
S.D.		0.0221	0.0922	0.0427	0.118	0.359	0.806	1.57	3.79	0.519
%CV		2.2	4.5	1.1	1.2	1.4	1.6	2.1	4.1	0.5
%Bias		-0.1	1.5	-1.5	-4.2	2.8	3.0	0.9	3.6	-5.0
n		4	4	4	4	4	4	4	3	4

Reason Deactivated

\* Rejected

Table 6      Standard Curve Parameters for Cotinine

Assay Date	Run ID	Slope	Intercept	R-Squared
13-Dec-2013	1	0.0596712115	-0.00249582189	0.9984
17-Dec-2013	2	0.0584772886	-0.00216556035	0.9967
19-Dec-2013	3	0.0538153010	-0.00451318793	0.9956
28-Dec-2013	4	0.0521799731	-0.00193860849	0.9970
Mean		0.0560359436	-0.00277829467	0.9969
S.D.		0.00360440010	0.00117900547	0.0012
%CV		6.4	-42.4	0.1
n		4	4	4

Table 7 Standard Curve Parameters for *trans*-3'-Hydroxycotinine

Assay Date	Run ID	Slope	Intercept	R-Squared
13-Dec-2013	1	0.0461306544	-0.00483234406	0.9979
17-Dec-2013	2	0.0455110846	-0.00401519192	0.9988
19-Dec-2013	3	0.0462724689	-0.00316570789	0.9978
28-Dec-2013	4	0.0464154703	-0.00453855665	0.9980
Mean		0.0460824196	-0.00413795013	0.9981
S.D.		0.000398242716	0.000730979495	0.0005
%CV		0.9	-17.7	0.1
n		4	4	4

Table 8 Study Sample Concentrations for Cotinine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000001	2	0002	-1	0	0	214	OK		Cotinine
05112010000002	2	0004	-1	0	0	140	OK		Cotinine
05112010000003	2	0005	-1	0	0	215	OK		Cotinine
05112010000004	2	0007	-1	0	0	325	OK		Cotinine
05112010000005	2	0010	-1	0	0	219	OK		Cotinine
05112010000006	2	0013	-1	0	0	424	OK		Cotinine
05112010000007	2	0017	-1	0	0	365	OK		Cotinine
05112010000008	2	0018	-1	0	0	203	OK		Cotinine
05112010000009	2	0022	-1	0	0	242	OK		Cotinine
05112010000010	2	0024	-1	0	0	355	OK		Cotinine
05112010000011	2	0025	-1	0	0	151	OK		Cotinine
05112010000012	2	0027	-1	0	0	184	OK		Cotinine
05112010000026	1	0031	-1	0	0	60.2	OK		Cotinine
05112010000028	2	0035	-1	0	0	102	OK		Cotinine
05112010000030	1	0036	-1	0	0	37.1	OK		Cotinine
05112010000032	2	0039	-1	0	0	109	OK		Cotinine
05112010000034	1	0040	-1	0	0	95.9	OK		Cotinine
05112010000036	2	0043	-1	0	0	246	OK		Cotinine
05112010000038	1	0045	-1	0	0	56.7	OK		Cotinine
05112010000040	2	0047	-1	0	0	136	OK		Cotinine
05112010000042	2	0048	-1	0	0	103	OK		Cotinine
05112010000044	2	0049	-1	0	0	216	OK		Cotinine
05112010000046	2	0050	-1	0	0	195	OK		Cotinine
05112010000048	1	0051	-1	0	0	79.3	OK		Cotinine
05112010000050	2	0052	-1	0	0	209	OK		Cotinine

Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
 Celerion Study AA99122-02

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000052	2	0054	-1	0	0	190	OK		Cotinine
05112010000054	2	0060	-1	0	0	229	OK		Cotinine
05112010000056	2	0061	-1	0	0	120	OK		Cotinine
05112010000058	2	0063	-1	0	0	214	OK		Cotinine
05112010000060	1	0067	-1	0	0	46.7	OK		Cotinine
05112010000062	2	0070	-1	0	0	212	OK		Cotinine
05112010000064	1	0071	-1	0	0	75.9	OK		Cotinine
05112010000066	2	0072	-1	0	0	118	OK		Cotinine
05112010000068	2	0073	-1	0	0	150	OK		Cotinine
05112010000070	2	0074	-1	0	0	139	OK		Cotinine
05112010000072	2	0075	-1	0	0	286	OK		Cotinine
05112010000074	1	0076	-1	0	0	97.8	OK		Cotinine
05112010000076	2	0078	-1	0	0	194	OK		Cotinine
05112010000078	2	0082	-1	0	0	124	OK		Cotinine
05112010000080	1	0083	-1	0	0	93.7	OK		Cotinine
05112010000082	2	0084	-1	0	0	110	OK		Cotinine
05112010000084	2	0066	-1	0	0	189	OK		Cotinine
05112010000086	2	0089	-1	0	0	217	OK		Cotinine
05112010000088	1	0090	-1	0	0	20.7	OK		Cotinine
05112010000090	1	0092	-1	0	0	29.4	OK		Cotinine
05112010000092	2	0093	-1	0	0	193	OK		Cotinine
05112010000094	1	0095	-1	0	0	90.2	OK		Cotinine
05112010000096	2	0097	-1	0	0	191	OK		Cotinine
05112010000098	1	0102	-1	0	0	30.3	OK		Cotinine
05112010000100	2	0105	-1	0	0	238	OK		Cotinine
05112010000102	2	0107	-1	0	0	427	OK		Cotinine
05112010000104	1	0108	-1	0	0	90.5	OK		Cotinine
05112010000106	1	0112	-1	0	0	91.0	OK		Cotinine



Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000108	2	0113	-1	0	0	247	OK		Cotinine
05112010000110	2	0115	-1	0	0	142	OK		Cotinine
05112010000112	1	0116	-1	0	0	48.6	OK		Cotinine
05112010000114	2	0117	-1	0	0	255	OK		Cotinine
05112010000116	2	0119	-1	0	0	176	OK		Cotinine
05112010000118	1	0120	-1	0	0	23.1	OK		Cotinine
05112010000120	2	0122	-1	0	0	345	OK		Cotinine
05112010000122	2	0123	-1	0	0	230	OK		Cotinine
05112010000124	2	0128	-1	0	0	163	OK		Cotinine
05112010000126	1	0129	-1	0	0	68.4	OK		Cotinine
05112010000128	2	0132	-1	0	0	273	OK		Cotinine
05112010000130	2	0134	-1	0	0	167	OK		Cotinine
05112010000132	2	0135	-1	0	0	200	OK		Cotinine
05112010000134	3	0136	-1	0	0	185	OK		Cotinine
05112010000136	3	0139	-1	0	0	279	OK		Cotinine
05112010000138	2	0140	-1	0	0	57.2	OK		Cotinine
05112010000140	3	0141	-1	0	0	154	OK		Cotinine
05112010000142	3	0142	-1	0	0	383	OK		Cotinine
05112010000144	3	0148	-1	0	0	231	OK		Cotinine
05112010000146	3	0152	-1	0	0	344	OK		Cotinine

Table 9 Study Sample Concentrations for *trans*-3'-Hydroxycotinine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000001	2	0002	-1	0	0	119	OK		Trans-3-Hydroxycotinine
05112010000002	1	0004	-1	0	0	85.0	OK		Trans-3-Hydroxycotinine
05112010000003	1	0005	-1	0	0	49.3	OK		Trans-3-Hydroxycotinine
05112010000004	1	0007	-1	0	0	55.6	OK		Trans-3-Hydroxycotinine
05112010000005	1	0010	-1	0	0	80.5	OK		Trans-3-Hydroxycotinine
05112010000006	1	0013	-1	0	0	95.9	OK		Trans-3-Hydroxycotinine
05112010000007	1	0017	-1	0	0	52.0	OK		Trans-3-Hydroxycotinine
05112010000008	1	0018	-1	0	0	39.6	OK		Trans-3-Hydroxycotinine
05112010000009	1	0022	-1	0	0	54.2	OK		Trans-3-Hydroxycotinine
05112010000010	1	0024	-1	0	0	93.4	OK		Trans-3-Hydroxycotinine
05112010000011	1	0025	-1	0	0	37.0	OK		Trans-3-Hydroxycotinine
05112010000012	1	0027	-1	0	0	20.0	OK		Trans-3-Hydroxycotinine
05112010000026	1	0031	-1	0	0	16.8	OK		Trans-3-Hydroxycotinine
05112010000028	1	0035	-1	0	0	64.5	OK		Trans-3-Hydroxycotinine
05112010000030	1	0036	-1	0	0	1.91	OK		Trans-3-Hydroxycotinine
05112010000032	1	0039	-1	0	0	8.26	OK		Trans-3-Hydroxycotinine
05112010000034	1	0040	-1	0	0	9.40	OK		Trans-3-Hydroxycotinine
05112010000036	1	0043	-1	0	0	97.9	OK		Trans-3-Hydroxycotinine
05112010000038	1	0045	-1	0	0	2.59	OK		Trans-3-Hydroxycotinine
05112010000040	1	0047	-1	0	0	60.5	OK		Trans-3-Hydroxycotinine
05112010000042	1	0048	-1	0	0	9.80	OK		Trans-3-Hydroxycotinine
05112010000044	1	0049	-1	0	0	34.2	OK		Trans-3-Hydroxycotinine
05112010000046	1	0050	-1	0	0	53.9	OK		Trans-3-Hydroxycotinine
05112010000048	1	0051	-1	0	0	6.77	OK		Trans-3-Hydroxycotinine
05112010000050	1	0052	-1	0	0	37.6	OK		Trans-3-Hydroxycotinine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000052	2	0054	-1	0	0	143	OK		Trans-3-Hydroxycotinine
05112010000054	1	0060	-1	0	0	46.0	OK		Trans-3-Hydroxycotinine
05112010000056	1	0061	-1	0	0	87.9	OK		Trans-3-Hydroxycotinine
05112010000058	1	0063	-1	0	0	25.3	OK		Trans-3-Hydroxycotinine
05112010000060	1	0067	-1	0	0	2.32	OK		Trans-3-Hydroxycotinine
05112010000062	1	0070	-1	0	0	56.6	OK		Trans-3-Hydroxycotinine
05112010000064	1	0071	-1	0	0	27.8	OK		Trans-3-Hydroxycotinine
05112010000066	1	0072	-1	0	0	49.4	OK		Trans-3-Hydroxycotinine
05112010000068	1	0073	-1	0	0	61.1	OK		Trans-3-Hydroxycotinine
05112010000070	1	0074	-1	0	0	18.7	OK		Trans-3-Hydroxycotinine
05112010000072	1	0075	-1	0	0	29.0	OK		Trans-3-Hydroxycotinine
05112010000074	1	0076	-1	0	0	64.6	OK		Trans-3-Hydroxycotinine
05112010000076	2	0078	-1	0	0	146	OK		Trans-3-Hydroxycotinine
05112010000078	2	0082	-1	0	0	104	OK		Trans-3-Hydroxycotinine
05112010000080	1	0083	-1	0	0	8.06	OK		Trans-3-Hydroxycotinine
05112010000082	1	0084	-1	0	0	10.0	OK		Trans-3-Hydroxycotinine
05112010000084	1	0066	-1	0	0	71.1	OK		Trans-3-Hydroxycotinine
05112010000086	1	0089	-1	0	0	31.6	OK		Trans-3-Hydroxycotinine
05112010000088	1	0090	-1	0	0	8.76	OK		Trans-3-Hydroxycotinine
05112010000090	1	0092	-1	0	0	6.08	OK		Trans-3-Hydroxycotinine
05112010000092	1	0093	-1	0	0	95.1	OK		Trans-3-Hydroxycotinine
05112010000094	1	0095	-1	0	0	15.3	OK		Trans-3-Hydroxycotinine
05112010000096	1	0097	-1	0	0	90.2	OK		Trans-3-Hydroxycotinine
05112010000098	1	0102	-1	0	0	2.03	OK		Trans-3-Hydroxycotinine
05112010000100	2	0105	-1	0	0	103	OK		Trans-3-Hydroxycotinine
05112010000102	1	0107	-1	0	0	87.9	OK		Trans-3-Hydroxycotinine
05112010000104	1	0108	-1	0	0	40.4	OK		Trans-3-Hydroxycotinine
05112010000106	1	0112	-1	0	0	39.6	OK		Trans-3-Hydroxycotinine

Custom ID	Run ID	Subject	Day Nominal	Hour Nominal	Minute Nominal	Concentration (ng/mL)	Sample Condition	Sample Comments	Analyte
05112010000108	2	0113	-1	0	0	186	OK		Trans-3-Hydroxycotinine
05112010000110	1	0115	-1	0	0	16.8	OK		Trans-3-Hydroxycotinine
05112010000112	1	0116	-1	0	0	64.1	OK		Trans-3-Hydroxycotinine
05112010000114	1	0117	-1	0	0	80.0	OK		Trans-3-Hydroxycotinine
05112010000116	1	0119	-1	0	0	60.8	OK		Trans-3-Hydroxycotinine
05112010000118	1	0120	-1	0	0	3.57	OK		Trans-3-Hydroxycotinine
05112010000120	2	0122	-1	0	0	151	OK		Trans-3-Hydroxycotinine
05112010000122	1	0123	-1	0	0	56.7	OK		Trans-3-Hydroxycotinine
05112010000124	1	0128	-1	0	0	13.3	OK		Trans-3-Hydroxycotinine
05112010000126	1	0129	-1	0	0	12.5	OK		Trans-3-Hydroxycotinine
05112010000128	1	0132	-1	0	0	30.4	OK		Trans-3-Hydroxycotinine
05112010000130	1	0134	-1	0	0	26.2	OK		Trans-3-Hydroxycotinine
05112010000132	1	0135	-1	0	0	16.9	OK		Trans-3-Hydroxycotinine
05112010000134	2	0136	-1	0	0	41.2	OK		Trans-3-Hydroxycotinine
05112010000136	2	0139	-1	0	0	43.1	OK		Trans-3-Hydroxycotinine
05112010000138	2	0140	-1	0	0	5.01	OK		Trans-3-Hydroxycotinine
05112010000140	2	0141	-1	0	0	39.8	OK		Trans-3-Hydroxycotinine
05112010000142	2	0142	-1	0	0	49.7	OK		Trans-3-Hydroxycotinine
05112010000144	2	0148	-1	0	0	81.0	OK		Trans-3-Hydroxycotinine
05112010000146	3	0152	-1	0	0	298	OK		Trans-3-Hydroxycotinine

Table 10 Summary of Reassay for Analytical Reasons for Cotinine

Run ID	Reason	Sample Name
1	AAR	AA99122-02 05112010000001 0002 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000002 0004 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000003 0005 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000004 0007 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000005 0010 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000006 0013 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000007 0017 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000008 0018 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000009 0022 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000010 0024 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000011 0025 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000012 0027 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000028 0035 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000032 0039 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000036 0043 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000040 0047 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000042 0048 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000044 0049 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000046 0050 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000050 0052 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000052 0054 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000054 0060 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000056 0061 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000058 0063 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000084 0066 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000062 0070 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000066 0072 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000068 0073 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000070 0074 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000072 0075 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000076 0078 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000078 0082 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000082 0084 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000086 0089 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000092 0093 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000096 0097 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000100 0105 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000102 0107 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000108 0113 N/A P1 Day -1 0h 0m PL-1



Run ID	Reason	Sample Name
1	AAR	AA99122-02 05112010000110 0115 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000114 0117 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000116 0119 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000120 0122 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000122 0123 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000124 0128 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000128 0132 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000130 0134 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000132 0135 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000134 0136 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000136 0139 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000140 0141 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000142 0142 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000144 0148 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000146 0152 N/A P1 Day -1 0h 0m PL-1
3	AAR	AA99122-02 05112010000137 0140 N/A P1 Day -1 0h 0m PL-2

Table 11 Summary of Reassay for Analytical Reasons for *trans*-3'-Hydroxycotinine

Run ID	Reason	Sample Name
1	AAR	AA99122-02 05112010000001 0002 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000052 0054 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000076 0078 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000078 0082 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000100 0105 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000108 0113 N/A P1 Day -1 0h 0m PL-1
1	AAR	AA99122-02 05112010000120 0122 N/A P1 Day -1 0h 0m PL-1
2	AAR	AA99122-02 05112010000146 0152 N/A P1 Day -1 0h 0m PL-1

Table 12. Summary of Reassays for Sample Investigation for Cotinine

Subject	Period	Timepoint	Analyte	Reasons for Reassay	Units	Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat	CV% of Reassays	% Difference	% Difference	% Difference	% Difference	Confirms Original	Reported Concentration
												Reassay 1 and 2	Reassay 2 and 3	Reassay 1 and 3	from Original		
134	1	Day -1	Oh Cotinine	VRC	ng/mL	167.000	162.000	173.000	175.000	170.000	4.118	6.567	1.149	7.715	1.796	Yes	167.000
140	1	Day -1	Oh Cotinine	VRC	ng/mL	57.200	59.000			59.000	#DIV/0!	100.000	#DIV/0!	100.000	3.147	Yes	57.200

Table 13. Summary of Reassays for Sample Investigation for *trans*-3'-Hydroxycotinine

Subject	Period	Timepoint	Analyte	Reasons for Reassay	Units											Confirms Original	Reported Concentration
						Original Value	Reassay Value 1	Reassay Value 2	Reassay Value 3	Mean repeat	CV% of Reassays	% Difference and 2	% Difference and 3	% Difference and 3	% Difference from Original		
128	1	Day -1 Oh	THC	VRC	ng/mL	13.300	13.700	14.000	14.200	13.967	1.802	2.166	1.418	3.584	5.013	Yes	13.300
134	1	Day -1 Oh	THC	VRC	ng/mL	26.200	26.500	27.900	27.400	27.267	2.602	5.147	1.808	3.340	4.071	Yes	26.200
140	1	Day -1 Oh	THC	VRC	ng/mL	5.010	4.680	5.170	4.870	4.907	5.035	9.949	5.976	3.979	2.063	Yes	5.010

Table 14. 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
0002	1	Day -1 0h 0m	Cotinine	ng/mL	214	207	211	3.32	Pass	No	90.9
0007	1	Day -1 0h 0m	Cotinine	ng/mL	325	333	329	2.43	Pass	No	
0017	1	Day -1 0h 0m	Cotinine	ng/mL	365	357	361	2.22	Pass	No	
0024	1	Day -1 0h 0m	Cotinine	ng/mL	355	351	353	1.13	Pass	No	
0031	1	Day -1 0h 0m	Cotinine	ng/mL	60.2	59.5	59.9	1.17	Pass	No	
0040	1	Day -1 0h 0m	Cotinine	ng/mL	95.9	94.2	95.1	1.79	Pass	No	
0048	1	Day -1 0h 0m	Cotinine	ng/mL	103	112	108	8.33	Pass	No	
0051	1	Day -1 0h 0m	Cotinine	ng/mL	79.3	80.6	80.0	1.63	Pass	No	
0060	1	Day -1 0h 0m	Cotinine	ng/mL	229	218	224	4.91	Pass	No	
0072	1	Day -1 0h 0m	Cotinine	ng/mL	118	115	117	2.56	Pass	No	
0075	1	Day -1 0h 0m	Cotinine	ng/mL	286	286	286	0.00	Pass	No	
0082	1	Day -1 0h 0m	Cotinine	ng/mL	124	125	125	0.80	Pass	No	
0066	1	Day -1 0h 0m	Cotinine	ng/mL	189	185	187	2.14	Pass	No	
0089	1	Day -1 0h 0m	Cotinine	ng/mL	217	212	215	2.33	Pass	No	
0093	1	Day -1 0h 0m	Cotinine	ng/mL	193	190	192	1.56	Pass	No	
0105	1	Day -1 0h 0m	Cotinine	ng/mL	238	225	232	5.60	Pass	No	
0112	1	Day -1 0h 0m	Cotinine	ng/mL	91.0	93.3	92.2	2.49	Pass	No	
0116	1	Day -1 0h 0m	Cotinine	ng/mL	48.6	49.0	48.8	0.82	Pass	No	
0120	1	Day -1 0h 0m	Cotinine	ng/mL	23.1	23.7	23.4	2.56	Pass	No	
0128	1	Day -1 0h 0m	Cotinine	ng/mL	163	163	163	0.00	Pass	No	
0134	1	Day -1 0h 0m	Cotinine	ng/mL	167	55.6	111	100.36	Fail	Event	
0140	1	Day -1 0h 0m	Cotinine	ng/mL	57	AAR	N/AP	N/AP	Fail	N/AP	

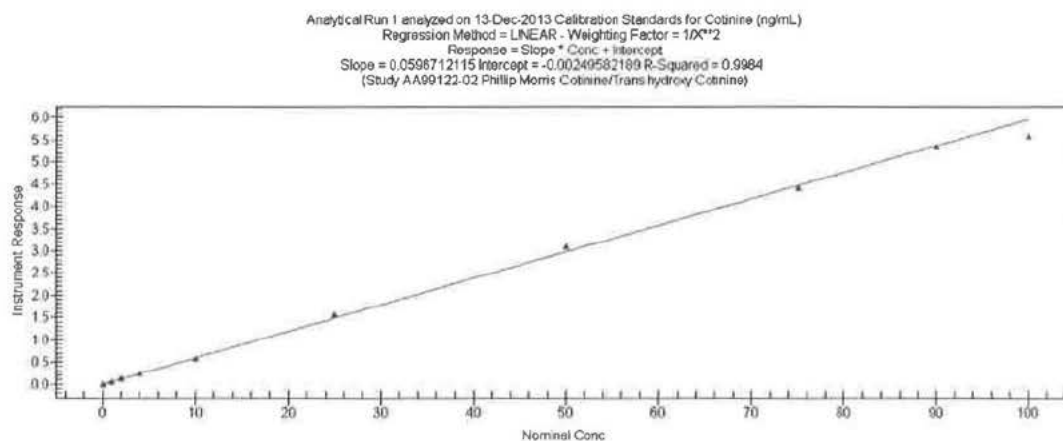


Table 15 Incurred Sample Reproducibility Assessment for *trans*-3'-Hydroxycotinine

Subject	Period	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
0002	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	119	120	120	0.83	Pass	No	81.8
0007	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	55.6	55.5	55.6	0.18	Pass	No	
0017	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	52.0	56.6	54.3	8.47	Pass	No	
0024	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	93.4	93.5	93.5	0.11	Pass	No	
0031	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	16.8	17.0	16.9	1.18	Pass	No	
0040	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	9.40	10.5	9.95	11.06	Pass	No	
0048	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	9.80	13.9	11.9	34.45	Fail	No	
0051	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	6.77	6.90	6.84	1.90	Pass	No	
0060	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	46.0	47.9	47.0	4.04	Pass	No	
0072	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	49.4	49.3	49.4	0.20	Pass	No	
0075	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	29.0	32.4	30.7	11.07	Pass	No	
0082	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	104	104	104	0.00	Pass	No	
0066	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	71.1	72.3	71.7	1.67	Pass	No	
0089	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	31.6	31.7	31.7	0.32	Pass	No	
0093	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	95.1	92.7	93.9	2.56	Pass	No	
0105	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	103	105	104	1.92	Pass	No	
0112	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	39.6	42.1	40.9	6.11	Pass	No	
0116	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	64.1	65.0	64.6	1.39	Pass	No	
0120	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	3.57	3.43	3.50	4.00	Pass	No	
0128	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	13.3	29.3	21.3	75.12	Fail	Event	
0134	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	26.2	4.69	15.4	139.68	Fail	Event	
0140	1	Day -1 0h 0m	Trans-3-Hydroxycotinine	ng/mL	5.01	40.6	22.8	156.10	Fail	Event	

## FIGURES

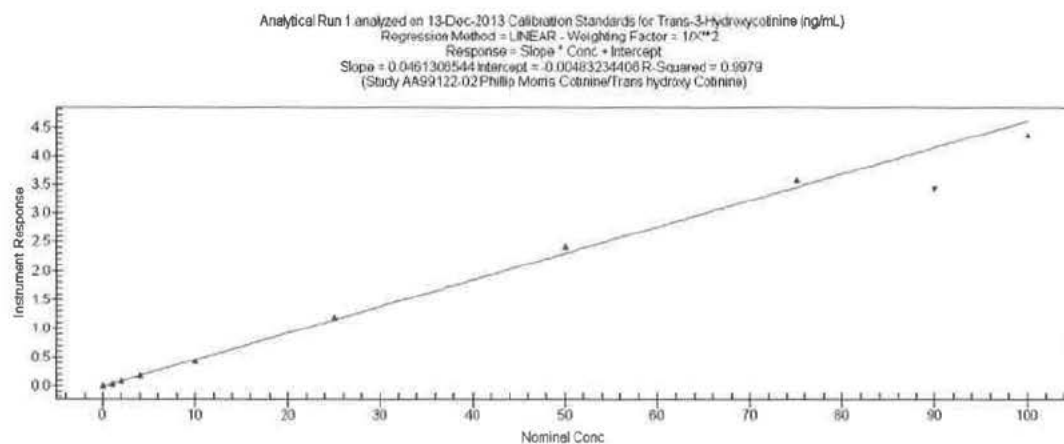
Figure 1 Calibration Curve for Cotinine in Control Matrix, Watson Run ID 1<sup>1</sup>



---

<sup>1</sup> 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.

Figure 2 Calibration Curve for *trans*-3'-Hydroxycotinine in Control Matrix, Watson Run ID 1<sup>2</sup>



<sup>2</sup> 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.

## 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	Stmospheric 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

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

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

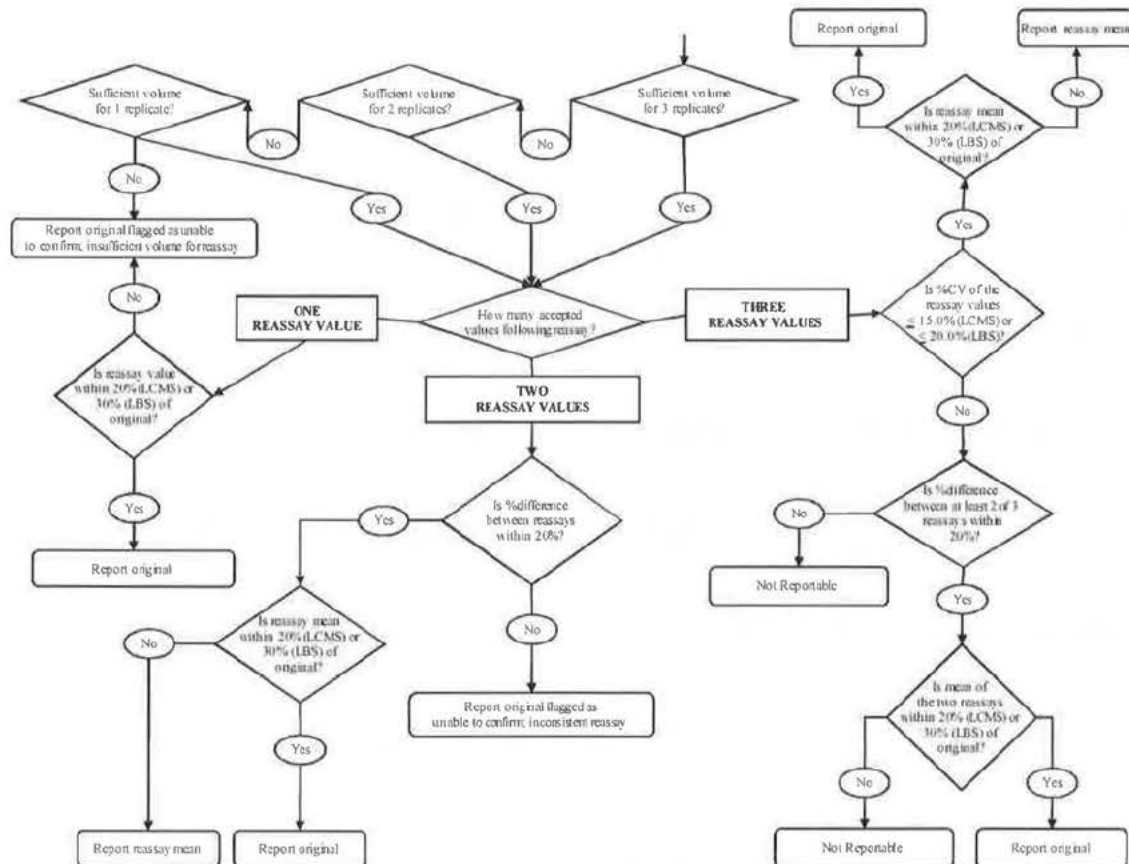


## Attachment 2 Temperature Definitions at Celerion

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

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



To compare reassays:

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

To compare to original:

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

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.

#### Attachment 4 General List of Calculation Formulae

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

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

Precision (RSD, CV): 
$$CV \% = (SD / x_{\text{Mean}}) \cdot 100$$

Accuracy (% Theoretical): 
$$\text{Accuracy \%} = (X / x_{\text{Nominal}}) \cdot 100$$

$$\text{Accuracy of Mean \%} = (x_{\text{Mean}} / x_{\text{Nominal}}) \cdot 100$$

Inaccuracy (% Bias, % RE): 
$$\text{Bias \%} = ((X - x_{\text{nominal}}) / x_{\text{nominal}}) \cdot 100$$

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

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

## 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 <ul style="list-style-type: none"> <li>- 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).</li> <li>- 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).</li> </ul>
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).

Attachment 6 Certificates of Analysis

## Cotinine



RECEIVED  
31 - Oct - 2012

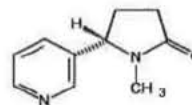
C-016  
FN061710-01  
Revision 1  
Page 1 of 7

AS/006038

### Certificate of Analysis

#### (-)-Cotinine

(S)-1-Methyl-5-(3-pyridinyl)-2-pyrrolidinone



**Catalog Number:** C-016  
**Solution Lot:** FN061710-01  
**Expiration Date:** June 2015  
**Solvent:** Methanol  
**Volume per Ampule:** Not less than 1 mL  
**Storage:** Store in freezer.  
**Intended Use:** For R&D/analytical purposes only. Not suitable for human or animal consumption.  
**Safety:** Flammable, Poison

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

Component	Solution Purity	Concentration
(-)-Cotinine	99.8%	1.047 ± 0.005 mg/mL
• Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of k = 2 and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique.		
• Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics.		

#### Solution Standard Verification and Homogeneity

Standard Solution	Lot Number	Verified Concentration (mg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FN061710-01	1.047	± 5%	0.7	≤ 3%
Previous Lot	FN010909-03	1.000	± 5%	1.5	≤ 3%
• Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration curve.					
• Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot.					
• The % RSD of the Previous Lot represents variability of the analysis performed at the time of release.					

#### Traceability

- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against an independently prepared 4-point calibration curve gravimetrically prepared using balances calibrated to NIST.
- In addition, each neat material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Spectral data is provided on subsequent pages of the COA.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.



*Lara Sparks*  
Lara Sparks, Quality Assurance Director

January 11, 2012  
Date

Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974



Standard Solution Assay Parameters		Calibration Curve	
Analysis Method:	GC/FID	Calibration Curve:	Linear Regression
Column:	DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness	Number of Points:	4
Temp Program:	60°C to 200°C at 40°C/min 200°C to 260°C at 15°C/min (hold 1.5 min)	Linearity (r):	1.000
Injector Temp:	Cool-on-Column		
Detector Temp:	325°C		

Neat Material Data

Compound Name:	(-)-Cotinine	Chemical Formula:	C <sub>10</sub> H <sub>12</sub> N <sub>2</sub> O
Compound Lot:	PN030410-01	CAS Number:	486-56-6
		Molecular Weight:	176.22

Neat Material Characterization Summary

Analytical Test	Method	Results
Primary Chromatographic Purity by GC/FID Analysis	SP10-0101	99.4%
Secondary Chromatographic Purity by HPLC/PDA Analysis	SP10-0102	99.1%
Identity by GC/MS Analysis	SP10-0105	Consistent with Structure
Identity by <sup>1</sup> H-NMR Analysis	USP <761>, SP10-0116	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	AM1087 <sup>1</sup>	None Detected
Residual Water Analysis by Karl Fischer Coulometry	USP <921>, SP10-0103	3.06%
Chiral Purity Analysis by Specific Rotation	SP10-0133	[α] <sub>D</sub> <sup>25</sup> -20.4° (c=0.3134, methanol)
Purity Factor		96.32%

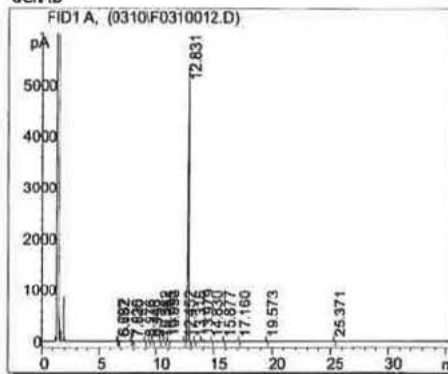
- Primary purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- The primary chromatographic purity value is used to calculate the Purity Factor.
- A secondary chromatographic purity method is utilized as a control.
- Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- Purity factor does not include adjustment for chiral and/or isotopic purity.

<sup>1</sup> Validated analytical method

C-016  
 FN061710-01  
 Revision 1  
 Page 3 of 7

**Spectral and Physical Data**

GC/FTD



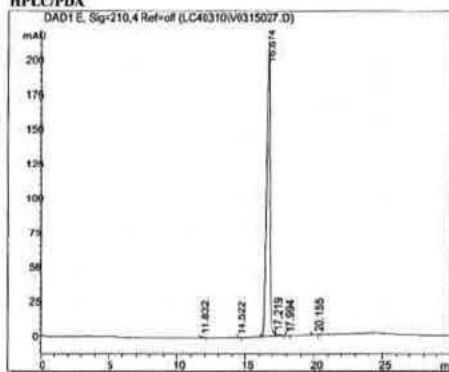
Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness  
 Temp Program: 40°C to 140°C at 40°C/min  
 140°C to 280°C at 5°C/min (hold 5 min)  
 Injector Temp: Cool-on-Column  
 Detector Temp: 325°C  
 Data File Name: S:\GC\GC020100310\F0310012.D  
 Operator: RPC  
 Instrument: GC#6  
 Sample Name: PN030410-01  
 Method File: B01G.M  
 Acquired: March 11, 2010 9:52 AM

Peak #	Ret Time	Area	Height	Area %
1	6.70	0.56	0.21	0.00
2	6.76	33.60	13.52	0.10
3	7.83	8.52	2.98	0.02
4	7.93	5.36	1.77	0.02
5	8.98	3.99	1.29	0.01
6	9.45	5.88	1.91	0.02
7	9.75	0.61	0.19	0.00
8	10.36	1.60	0.42	0.00
9	10.72	1.85	0.54	0.01
10	10.99	45.87	10.54	0.13
11	12.45	2.68	0.58	0.01
12	12.83	34416.40	5342.62	99.38
13	13.32	3.63	1.03	0.01
14	13.98	86.07	22.06	0.25
15	14.83	6.27	1.59	0.02
16	15.88	6.76	1.63	0.02
17	17.16	0.51	0.16	0.00
18	19.57	0.89	0.21	0.00
19	25.37	1.08	0.25	0.00

C-016  
 FN061710-01  
 Revision 1  
 Page 4 of 7

*Spectral and Physical Data (cont.)*

**HPLC/PDA**



Column: Synergi Polar RP, 4.6 x 250 mm  
 Mobile Phase:  
 A: Acetonitrile  
 B: 10 mM Potassium phosphate buffer  
 Gradient:  

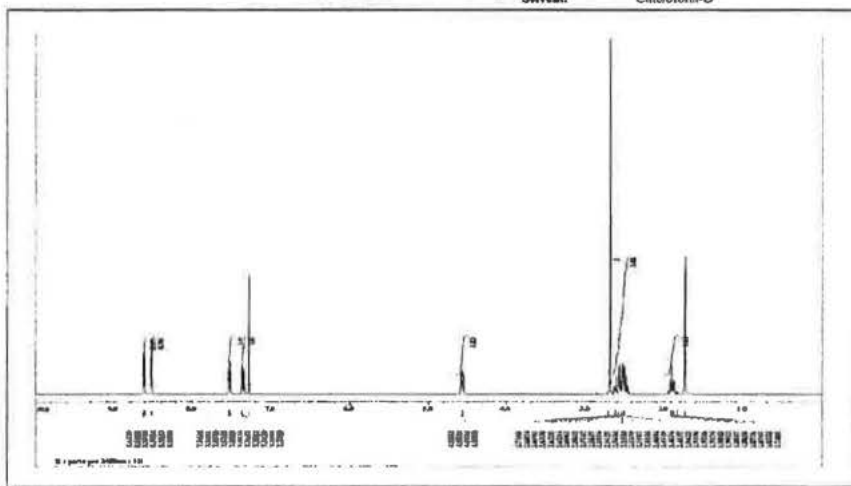
Time (min)	%A	%B
0.0	5	95
20.0	25	75
20.1	5	95

 Program:  
 Flow Rate: 1.0 mL/min  
 Wavelength: 219 nm  
 Data File Name: S:\HPLC\HPLC04\2010\LC0310\V0315027.D  
 Operator: TNT  
 Instrument: LCM  
 Sample Name: PN030410-01  
 Method File: RMC028G1.M  
 Acquired: March 15, 2010 2:36 AM

Peak #	Ret Time	Area	Height	Area %
1	11.83	7.98	0.75	0.21
2	14.52	1.09	0.12	0.03
3	16.67	3727.30	211.28	99.09
4	17.22	20.97	1.65	0.56
5	17.99	0.51	0.06	0.01
6	20.16	3.79	0.25	0.10

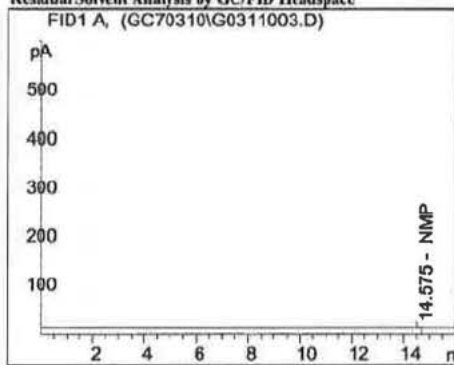
**<sup>1</sup>H NMR**

Instrument: JEOL ECS 400  
 Solvent: Chloroform-D



*Spectral and Physical Data (cont.)*

**Residual Solvent Analysis by GC/FID Headspace**



Column: DB-ALC1 30 m x 0.53 mm, 3 µm film thickness  
Temp Program: 40°C (12 min) to 220°C at 40°C/min (5.5 min)  
Carrier Gas: Helium  
Flow Rate: 2.0 mL/min  
Detector Temp: 250°C  
Injector: Headspace Sampler  
Injector Temp: 200°C  
HS Oven Temp: 60°C  
Incubation Time: 10 minutes  
Data File Name: S:\GC\GC-HS7\GC70310\G0311003.D  
Operator: BD  
Instrument: GC#7  
Sample Name: PN030410-01  
Acquired: March 11, 2010 1:05 PM

Peak	Compound	Area	Weight %
1	NMP	NA	NA
Total			ND

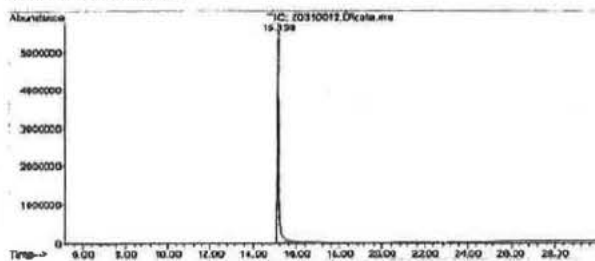
ND - Not Detected

*Spectral and Physical Data (cont.)*

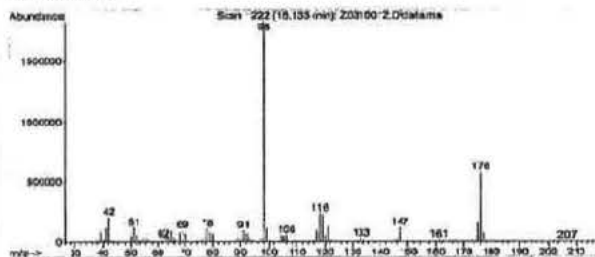
GC/MS

Compound Name : (-)-Cotinine  
Lot Number : 99030413-01  
Instrument : Agilent 5975N MSD/6890N GC  
Operator-Inst II : RFI - C10136  
Date Reported : Thu Mar 11 14:05:52 2010  
Column Type : DB-Sem, 30m x 0.25mm ID, 0.25um film thickness  
Temp. Program : 50°C to 303°C @ 10°C/min, 5min hold  
Injector Temp. : Cool on-column  
Carrier Gas : Helium  
Flow Rate (mL/min) : 0.80 mL/min  
Transfer Line Temp. : 285°C  
Scan Range : 35-400

Total Ion Chromatogram



Mass Spectrum



C-016  
FN061710-01  
Revision 1  
Page 7 of 7

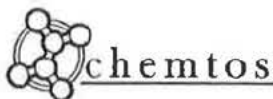
---

***COA Revision History***

Revision No.	Date	Reason for Revision
00	7/26/2010	Initial version
01	1/11/2012	Revised Storage condition from "Refrigerate or freeze" to "Store in freezer."



***trans*-3'-Hydroxycotinine**



**Certificate of Analysis**

Issued: April 2<sup>nd</sup>, 2012

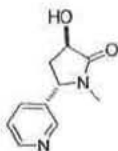
Re-Test: April 2<sup>nd</sup>, 2014

**COPY**

AS/005788

03 Apr 2012

<b>Compound Name</b>	Trans-3'-Hydroxycotinine
<b>Potency</b>	997 µg of Trans-3'-Hydroxycotinine per mg
<b>Physical Description</b>	White Solid
<b>Purchase Order</b>	2021467
<b>Chemtos Lot Number</b>	C8-127-040
<b>Chemical Structure</b>	



<b>Empirical Formula</b>	C <sub>10</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub>
<b>Molecular Weight</b>	192.21
<b>Exact Mass</b>	192.09
<b>Mass Spectrometry</b>	Electrospray MS(ES+): m/z 193.1 (M+H) <sup>+</sup> Data consistent to that of the title compound

**HPLC Purity**

The product was examined by analytical HPLC using a diode array detector. Column: Chromolith Performance C<sub>18</sub> 4.6 mm X 100 mm; Flow Rate: 1 ml/min; Solvents: Water (0.1% TFA) and acetonitrile; Gradient: 5% to 100% acetonitrile over 20 min, return to 95% water over 10 minutes. The chromatogram used for purity and homogeneity assessment was the summed absorbance between 220 nm and 270 nm. Purity was determined as the area percent of the major peak after integration of any impurities judged to be authentic by the analyst. Using this method the purity was determined at 99.9%.

**<sup>1</sup>H NMR**

Proton magnetic resonance spectra were run in deuterio-chloroform at 300 MHz. The NMR data is consistent with the structure.

#### Karl Fischer Water Analysis

Water content was determined via Coulometric titration in accordance with USP<921>. The analysis was performed in duplicate. Prior to performing analysis on the above sample the operation of the apparatus was verified using a potassium citrate monohydrate water standard containing 5.55 ±0.05% water.

Method	Sample	Result	Sample Amount	Date
1c USP<921>	Solid Standard	5.743% Pass	24.5 mg	4/2/2012
1c USP<921>	C8-127-040	0.231%	10.4 mg	4/2/2012
1c USP<921>	C8-127-040 Duplicate	0.182%	13.2 mg	4/2/2012

The water content of the above sample was determined as the summed average of the total number of Karl Fischer titrations. Using this method the water content is determined at **0.207%**.

#### Storage Conditions

Individual variation in chemical stability profiles, do occur and for this reason we recommend adherence to the minimum recommended storage conditions. Because most compounds are custom made and shipped upon completion long-term stability data is not available in most cases. If data is available, a specific recommendation will be provided below. Chemtos cannot provide a guarantee of the long-term chemical stability of any compound.

##### Minimum Recommended Storage Conditions:

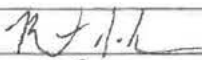
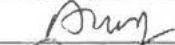
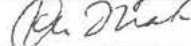
- Samples should be stored in an air tight vial
- Samples should be stored at ≤ 0° Celsius when not in use for a prolonged period of time.
- Samples should be stored in the dark or in an amber vial.

#### Caution

This information is provided as an indication of the quality of the underlying material when examined by a specific technique. The reported values are subject to normal experimental error and should be treated as estimates. The absence of undetected impurities cannot be guaranteed by this or any other general approach and this certificate does not certify the absence of such substances in the sample.

#### Intended Use

This product is intended for investigational use only and should not be used in humans. It is pharmaceutically unrefined, may contain uncharacterized toxic impurities, and is not intended for use in humans. Responsibility for its use and compliance with all federal laws rests solely with the purchaser.

Preparer		4/2/12
Analytical Review and Approval		4/2/12
QA Review		4/2/12

**d<sub>3</sub>-Cotinine (IS)**



Rec'd 03 Oct 2012  
AS/006005

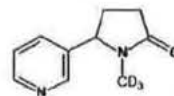
C-017  
FN102110-02  
Revision 1  
Page 1 of 6

*Certificate of Analysis*

**(±)-Cotinine-D<sub>3</sub>**

ISO GUIDE 34  
CERTIFICATE 00100  
ISO/IEC 17025  
CERTIFICATE 00100  
ISO 9001:2008  
CERTIFICATE 00100

**Catalog Number:** C-017  
**Solution Lot:** FN102110-02  
**Expiration Date:** October 2015  
**Solvent:** Methanol  
**Volume per Ampule:** Not less than 1 mL  
**Storage:** Store in freezer.  
**Intended Use:** For R&D/analytical purposes only. Not suitable for human or animal consumption.  
**Safety:** Flammable, Poison



- Expiration Date has been established through real time stability studies.
- Ampoules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

Component	Chromatographic Purity	Certified Concentration
(±)-Cotinine-D <sub>3</sub>	99.7%	100.0 ± 0.6 µg/mL
• Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of k = 2 and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique.		
• Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics.		

**Solution Standard Verification and Homogeneity**

Standard Solution	Lot Number	Verified Concentration (µg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FN102110-02	99.9	± 3%	0.6	≤ 3%
Previous Lot	FN071307-01	100.6	± 3%		
• Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.					
• Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot.					

**Traceability**

- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler-Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler-Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against an independently prepared calibration solution gravimetrically prepared using balances calibrated to NIST.
- In addition, each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Spectral data is provided on subsequent pages of the COA.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.



*Lara Sparks*  
Lara Sparks, Quality Assurance Director

January 12, 2012  
Date

Cerilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974

C-017  
FN102110-02  
Revision 1  
Page 2 of 6

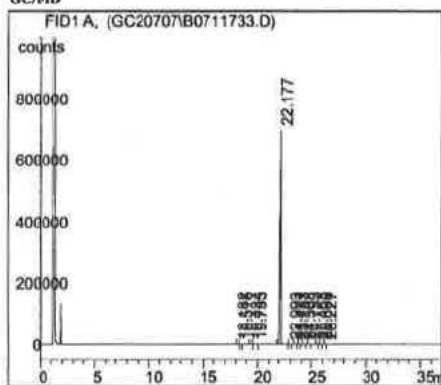
Standard Solution Assay Parameters		Calibration Curve	
Analysis Method:	UV/Vis	Calibration Curve:	Linear Regression
Wavelength:	210 nm	Number of Points:	4
Slit Width:	1.0 nm	Linearity (r):	1.000
Response:	0.5 g		

Neat Material Data		
Compound Name:	(±)-Cotinine-D <sub>3</sub>	Chemical Formula: C <sub>10</sub> H <sub>9</sub> D <sub>3</sub> N <sub>2</sub> O
Compound Lot:	31333-75	CAS Number: 66269-66-7
		Molecular Weight: 179.19
Neat Material Characterization Summary		
Analytical Test	Method	Results
Primary Chromatographic Purity by GC/FID Analysis	SP10-0101	99.7%
Secondary Chromatographic Purity by HPLC/PDA Analysis	SP10-0102	100.0%
Identity by GC/MS Analysis	SP10-0105	Consistent with Structure
Isotopic Purity by GC/MS SIM Analysis	SP10-0105	0.44% D <sub>3</sub> vs D <sub>2</sub>
Identity by <sup>1</sup> H-NMR Analysis	USP <761>, SP10-0116	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	AM1087	None Detected
Residual Water Analysis by Karl Fischer Coulometry	USP <921>, SP10-0103	1.91%
Inorganic Content by Microash Analysis	Outsourced	< 0.1%
Purity Factor		97.82%
<ul style="list-style-type: none"><li>Primary purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.</li><li>The primary chromatographic purity value is used to calculate the Purity Factor.</li><li>A secondary chromatographic purity method is utilized as a control.</li><li>Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].</li><li>Purity factor does not include adjustment for chiral and/or isotopic purity.</li></ul>		

C-017  
FN102110-02  
Revision 1  
Page 3 of 6

# Spectral and Physical Data

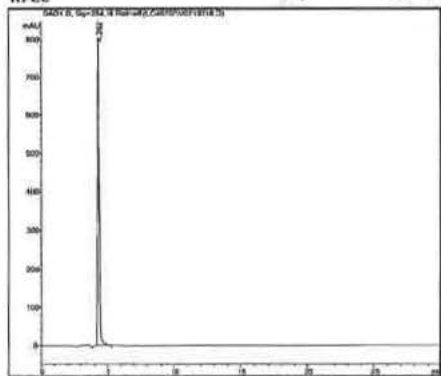
## GC/FID



Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness  
Temp Program: 40°C to 80°C at 40°C/min  
80°C to 200°C at 5°C/min  
200°C to 280°C at 40°C/min hold 10 min  
Injector Temp: Cool-on-Column  
Detector Temp: 325°C  
Data File Name: C:\HPCHEM\1\DATA\GC20707\B0711733.D  
Operator: LMH  
Instrument: GC#2  
Sample Name: RMC029 31333-75  
Method File: B0117.M  
Acquired: July 12, 2007 8:47 AM

Peak #	Ret Time	Area	Height	Area %
1	18.18	132	26	0.00
2	18.52	235	37	0.01
3	19.43	424	82	0.01
4	19.76	569	88	0.02
5	22.18	3782820	699885	99.73
6	22.99	345	60	0.01
7	23.44	5816	1269	0.15
8	23.75	140	27	0.00
9	24.31	374	39	0.01
10	24.75	1161	190	0.03
11	24.46	397	121	0.01
12	25.81	348	91	0.01
13	26.23	120	35	0.00

## HPLC



Column: Betasil Phenyl 4.6 x 150 mm  
Mobile Phase: A: 0.01M Potassium Phosphate Buffer  
B: Acetonitrile  
Gradient Program: Time (min) %A %B  
0 70 30  
27 30 70  
Flow Rate: 0.6 mL/min  
Wavelength: 254 nm

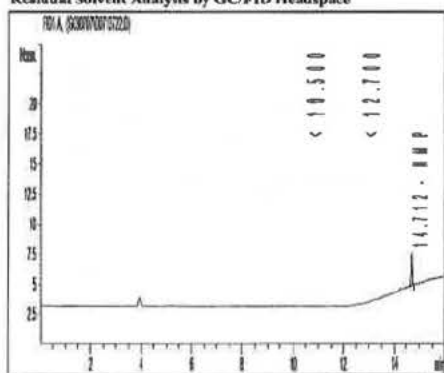
Data File Name: C:\HPCHEM\1\DATA\LC40707\B0718716.D  
Operator: MAM  
Instrument: HPLC#4  
Sample Name: 31333-75  
Method File: RMC029.M  
Acquired: July 18, 2007 7:36 PM

Peak #	Ret Time	Area	Height	Area %
1	4.26	7041.92	804.65	100.00

C-017  
 FN102110-02  
 Revision 1  
 Page 4 of 6

*Spectral and Physical Data (cont.)*

Residual Solvent Analysis by GC/FID Headspace



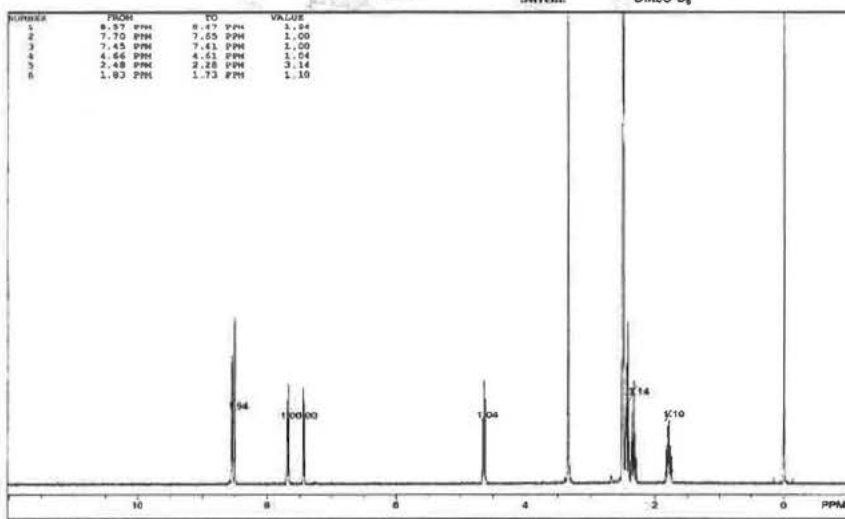
Column: DB-ALC1 30 m x 0.53 mm, 3 µm film thickness  
 Temp Program: 40°C (12 min) to 220°C at 40°C/min (5.5 min)  
 Carrier Gas: Helium  
 Flow Rate: 2.0 mL/min  
 Detector Temp: 250°C  
 Injector: Headspace Sampler  
 Injector Temp: 200°C  
 HS Oven Temp: 200°C  
 Injection Volume: 1.0 mL  
 Incubation Time: 10 minutes

Data File Name: C:\CHEM32\1\DATA\GC90707\00713722.D  
 Operator: KRS  
 Instrument: GC#9  
 Sample Name: 31333-75  
 Acquired: July 13, 2007 11:13 PM

Peak	Compound	Area	Weight %
1	Pressure peak	NA	NA
Total			0.00

<sup>1</sup>H NMR

Instrument: Bruker DRX 400  
 Solvent: DMSO-D<sub>6</sub>

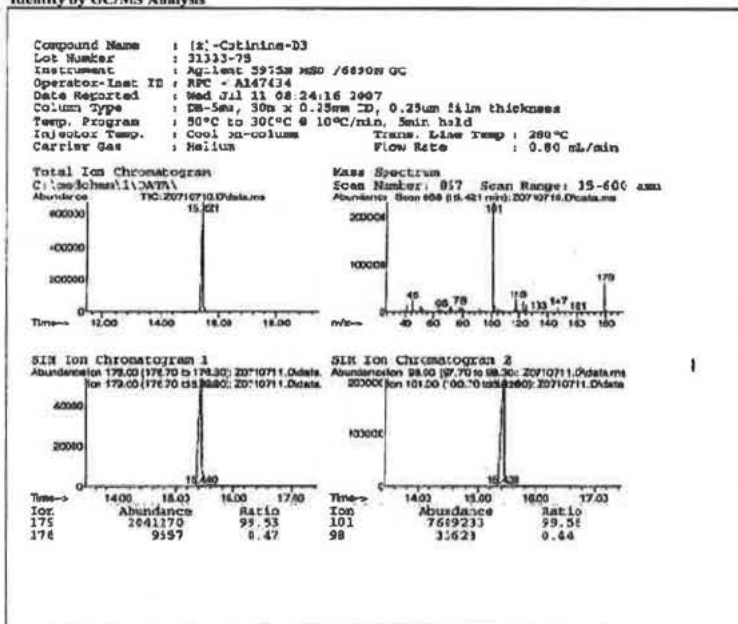


Carilliant Corporation 811 Paloma Drive, Suite A, Round Rock, TX 78665 800-848-7837 / 512-238-9974



*Spectral and Physical Data (cont.)*

Identity by GC/MS Analysis



C-017  
FN102110-02  
Revision 1  
Page 6 of 6

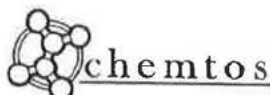
---

***COA Revision History***

Revision No.	Date	Reason for Revision
00	11/4/2010	Initial version
01	1/12/2012	Revised Storage condition from "Refrigerate or freeze" to "Store in freezer."



**d<sub>3</sub>-*trans*-3'-hydroxycotinine (IS)**



**Certificate of Analysis**

Issued: April 11<sup>th</sup>, 2012

Re-Test: April 11<sup>th</sup>, 2014

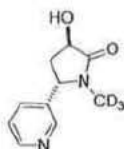
**COPY**

AS/005822

RECEIVED  
APR 19 2012

**Compound Name** Labeled d<sub>3</sub> *Trans*-3'-Hydroxycotinine  
**Potency** 999 µg of Labeled d<sub>3</sub> *Trans*-3'-Hydroxycotinine per mg  
**Physical Description** White Solid  
**Purchase Order** 2021467  
**Chemtos Lot Number** C8-127-047

**Chemical Structure**



**Empirical Formula** C<sub>10</sub>H<sub>9</sub>D<sub>3</sub>N<sub>2</sub>O<sub>2</sub>  
**Molecular Weight** 195.23  
**Exact Mass** 195.11  
**Mass Spectrometry** Electrospray MS(ES+): m/z 196.1 (M+H)<sup>+</sup>  
Data consistent to that of the title compound

**Isotopic Purity** The following table gives the normalized isotopic mass distribution, including the naturally occurring higher isotopic masses.

Abundance	m/z	Abundance	m/z
0.5	193.2 (Unlabeled)	1.1	197.9 (+5)
0.5	194.2 (+1)	0.1	199.2 (+6)
4.2	195.0 (+2)		
100.0	196.1 (+3)		
13.0	197.1 (+4)		

#### HPLC Purity

The product was examined by analytical HPLC using a diode array detector. Column: Chromolith Performance C<sub>18</sub> 4.6 mm X 100 mm; Flow Rate: 1 ml/min; Solvents: Water (0.1% TFA) and acetonitrile; Gradient: 5% to 100% acetonitrile over 20 min, return to 95% water over 10 minutes. The chromatogram used for purity and homogeneity assessment was the summed absorbance between 220 nm and 280 nm. Purity was determined as the area percent of the major peak after integration of any impurities judged to be authentic by the analyst. Using this method the purity was determined at **99.9%**.

#### <sup>1</sup>H NMR

Proton magnetic resonance spectra were run in deuterio-chloroform at 300 MHz. The NMR data is consistent with the structure.

#### Storage Conditions

Individual variation in chemical stability profiles, do occur and for this reason we recommend adherence to the minimum recommended storage conditions. Because most compounds are custom made and shipped upon completion long-term stability data is not available in most cases. If data is available, a specific recommendation will be provided below. Chemtos cannot provide a guarantee of the long-term chemical stability of any compound.

##### Minimum Recommended Storage Conditions:

- Samples should be stored in an air tight vial
- Samples should be stored at ≤ 0° Celsius when not in use for a prolonged period of time.
- Samples should be stored in the dark or in an amber vial.

#### Caution

This information is provided as an indication of the quality of the underlying material when examined by a specific technique. The reported values are subject to normal experimental error and should be treated as estimates. The absence of undetected impurities cannot be guaranteed by this or any other general approach and this certificate does not certify the absence of such substances in the sample.

#### Intended Use

This product is intended for investigational use only and should not be used in humans. It is pharmaceutically unrefined, may contain uncharacterized toxic impurities, and is not intended for use in humans. Responsibility for its use and compliance with all federal laws rests solely with the purchaser.

Preparer	<i>MTL</i>	4/11/2012
Analytical Review and Approval	<i>Ang</i>	4/11/12
QA Review	<i>Amnatulain</i>	4/11/2012

## Attachment 7 Bioanalytical Method Summary



PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM00498 - CR204A2

Version N°: 2.0

Page 1 of 2

<b>Biomarker:</b> Cotinine		<b>Matrix:</b> Plasma	
<b>MVR/SOP no. &amp; date:</b> AA33864-01 / 17-Sep-2012		<b>CRO/Laboratory:</b> Celerion-Lincoln	
<b>LLOQ:</b> 1.00 ng/mL		<b>ULOQ:</b> 100 ng/mL	
<b>Validation</b>	<input checked="" type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Cross <b>Comments (required for Partial/Cross):</b>		
<b>Assay:</b>	<input checked="" type="checkbox"/> Chromatographic <input type="checkbox"/> Ligand binding <input type="checkbox"/> Enzymatic <input type="checkbox"/> Other describe: <input type="checkbox"/> LC/MS <input checked="" type="checkbox"/> LC/MS/MS <input type="checkbox"/> GC/MS <input type="checkbox"/> GC/MS/MS <input type="checkbox"/> ELISA		
<b>Equipment and short description of extraction and analysis:</b> An aliquot of human plasma containing the analyte and internal standard was extracted using a solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 5000™ or QTRAP® 5500 mass spectrometer. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration <sup>2</sup> ) of peak area ratios of each analyte and internal standard.			
<b>Selectivity/Sensitivity/Matrix effect:</b>	No significant matrix effect was observed in 6 of the 6 human plasma (EDTA) lots that were spiked near the concentration of the LLOQ and in any of the 6 human plasma (EDTA) lots that were spiked near the concentration of the high QC sample		
<b>Accuracy:</b>	Intra-batch: -7.2 to 3.3% R.E. Inter-batch: -4.3 to 2.1% R.E.		
<b>Precision:</b>	Intra-batch: 1.1 to 4.3% C.V. Inter-batch: 2.1 to 4.2% C.V.		
<b>Recovery:</b>	91% at 2.00 ng/mL in human plasma 90% at 10.0 ng/mL in human plasma 90% at 75.0 ng/mL in human plasma		
<b>Freeze and thaw stability:</b>	6 freeze/cycles in polypropylene tubes at -20°C under white light 7 freeze/cycles in polypropylene tubes at -20°C under UV-shielded light		
<b>Short-term temperature stability:</b>	27 hours in polypropylene tubes at ambient temperature under white light		
<b>Long-term stability:</b>	194 days in polypropylene tubes at -20°C		
<b>Stock solution stability:</b>	39 days at 200 µg/mL in water in a polypropylene container at -20°C		
<b>Post-preparative stability:</b>	135 hours in a polypropylene 96 well plate at 5°C		
<b>Accreditation/ GLP compliance/ QA statements:</b>	GLP Compliance as Assay Validation conforms to Celerion Standard Operating Procedures which were written in compliance with FDA: Guidance to Industry "Bioanalytical Method Validation"		





PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM000495 – CR204A2

Version N°: 2.0

Page 2 of 2

<b>BMS completed by:</b>		
<u>Name:</u>	<u>Date:</u>	<u>Signature:</u>
Erica Nachi	14-MAY-2013	<i>Erica Nachi</i>



PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM000498 – CH204A2

Version N°: 2.0

Page 1 of 2

<b>Biomarker:</b> <i>trans</i> -3'-hydroxycotinine		<b>Matrix:</b> Plasma
<b>MVR/SOP no. &amp; date:</b> AA33664-01 / 17-Sep-2012		<b>CRO/Laboratory:</b> Celerion-Lincoln
<b>LLOQ:</b> 1.00 ng/mL		<b>ULOQ:</b> 100 ng/mL
<b>Validation</b>	<input checked="" type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Cross <b>Comments (required for Partial/Cross):</b>	
<b>Assay:</b>	<input checked="" type="checkbox"/> Chromatographic <input type="checkbox"/> Ligand binding <input type="checkbox"/> Enzymatic <input type="checkbox"/> Other describe: <input type="checkbox"/> LC/MS <input checked="" type="checkbox"/> LC/MS/MS <input type="checkbox"/> GC/MS <input type="checkbox"/> GC/MS/MS <input type="checkbox"/> ELISA	
<b>Equipment and short description of extraction and analysis:</b> An aliquot of human plasma containing the analyte and internal standard was extracted using a solid-phase extraction procedure. The extracted samples were analyzed by a HPLC equipped with an AB SCIEX API 5000™ or QTRAP® 5500 mass spectrometer. Positive ions were monitored in the multiple reaction monitoring (MRM) mode. Quantitation was determined using a weighted linear regression analysis (1/concentration <sup>2</sup> ) of peak area ratios of each analyte and internal standard.		
<b>Selectivity/Sensitivity/Matrix effect:</b>	No significant matrix effect was observed in 4 of the 6 human plasma (EDTA) lots that were spiked near the concentration of the LLOQ and in any of the 6 human plasma (EDTA) lots that were spiked near the concentration of the high QC sample	
<b>Accuracy:</b>	Intra-batch: -6.6 to 4.0% R.E. Inter-batch: -4.2 to 1.3% R.E.	
<b>Precision:</b>	Intra-batch: 1.7 to 4.7% C.V. Inter-batch: 2.3 to 3.7% C.V.	
<b>Recovery:</b>	75% at 2.00 ng/mL in human plasma 77% at 10.0 ng/mL in human plasma 76% at 75.0 ng/mL in human plasma	
<b>Freeze and thaw stability:</b>	6 freeze/cycles in polypropylene tubes at -20°C under white light 7 freeze/cycles in polypropylene tubes at -20°C under UV-shielded light	
<b>Short-term temperature stability:</b>	27 hours in polypropylene tubes at ambient temperature under white light	
<b>Long-term stability:</b>	194 days in polypropylene tubes at -20°C	
<b>Stock solution stability:</b>	572 days at 1000 µg/mL in water in a polypropylene container at -20°C	
<b>Post-preparative stability:</b>	135 hours in a polypropylene 96 well plate at 5°C	
<b>Accreditation/ GLP compliance/ QA statements:</b>	GLP Compliance as Assay Validation conforms to Celerion Standard Operating Procedures which were written in compliance with FDA: Guidance to Industry "Bioanalytical Method Validation"	



PMI RESEARCH & DEVELOPMENT

BIOANALYTICAL METHOD SUMMARY (BMS)

Doc No: FOR\_QM000468 – CR204A2

Version N°: 2.0

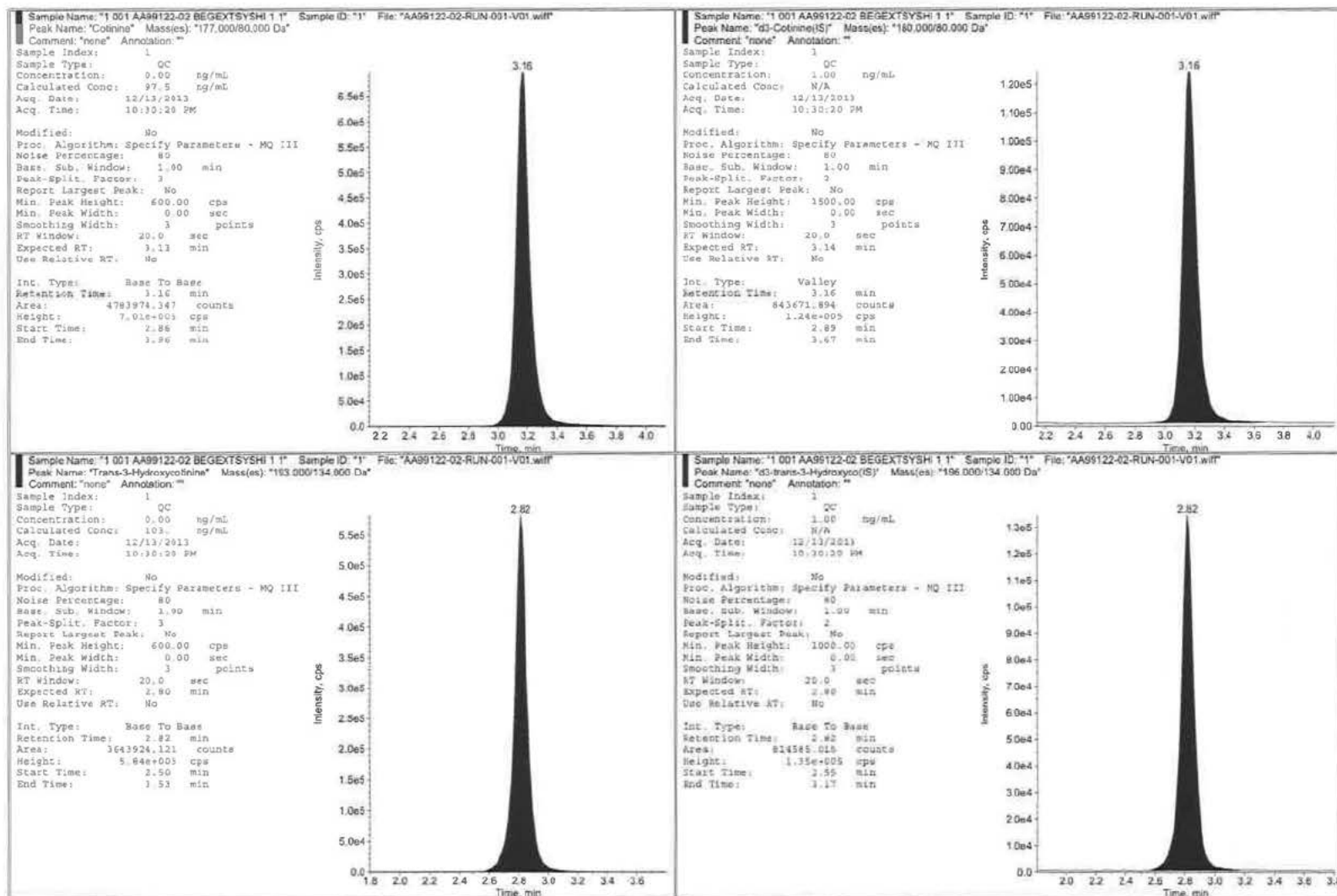
Page 2 of 2

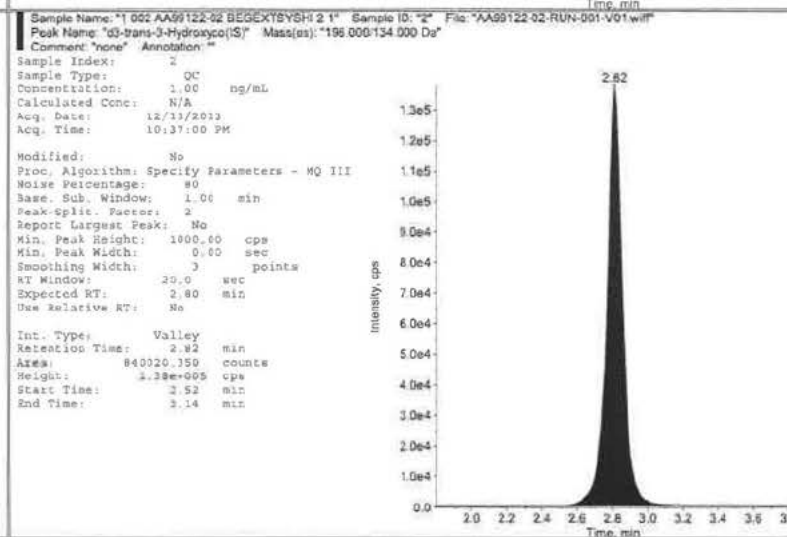
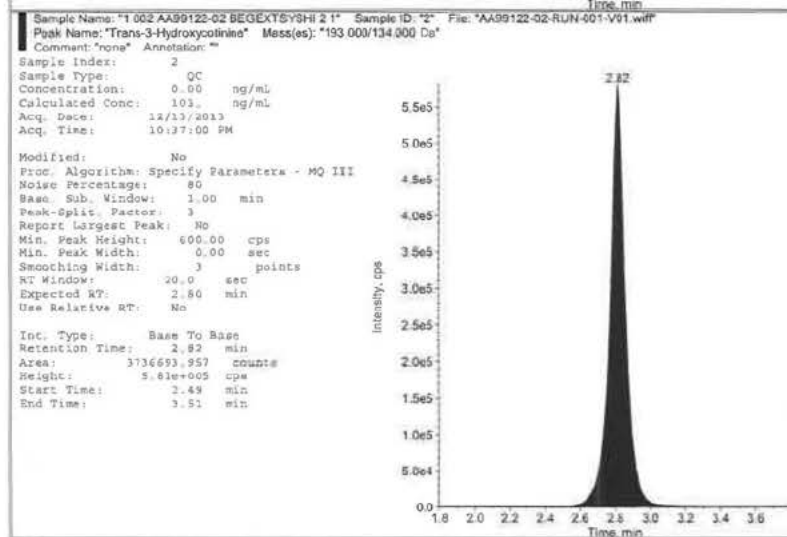
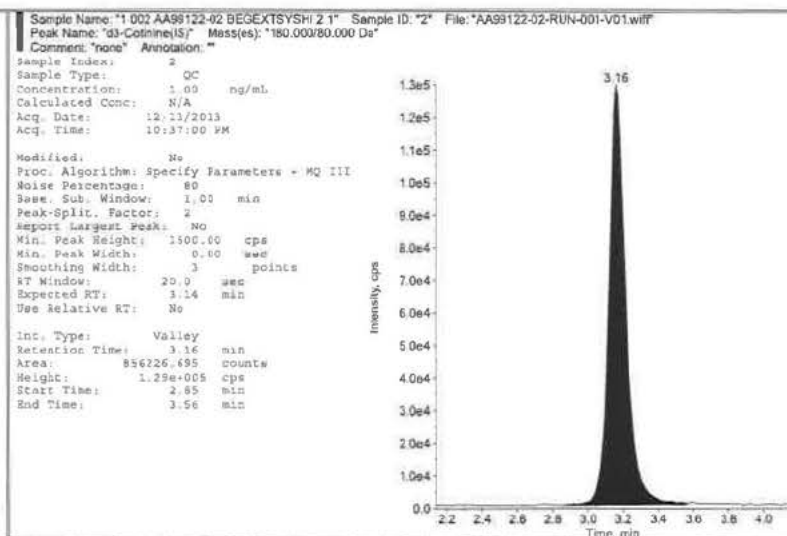
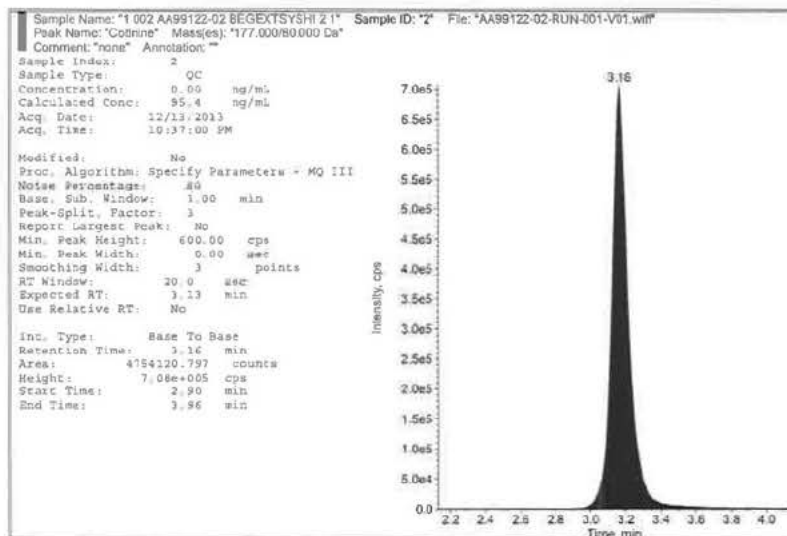
<b>BMS completed by:</b>		
<u>Name:</u>	<u>Date:</u>	<u>Signature:</u>
Erica Nachi	14-MAY-2013	<i>Erica J. Nachi</i>

## Attachment 8 Chromatograms

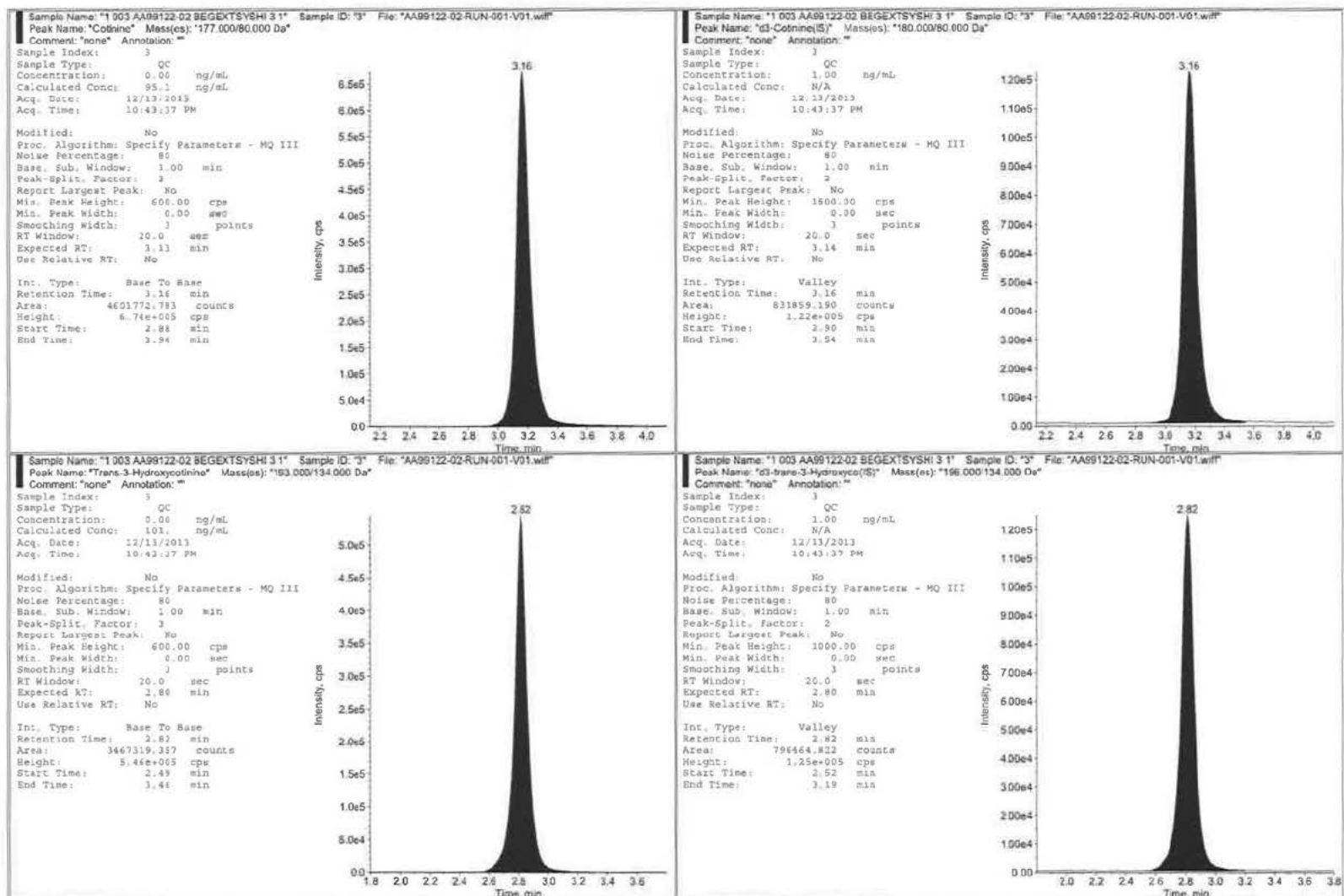
Total number of pages including this page: 97

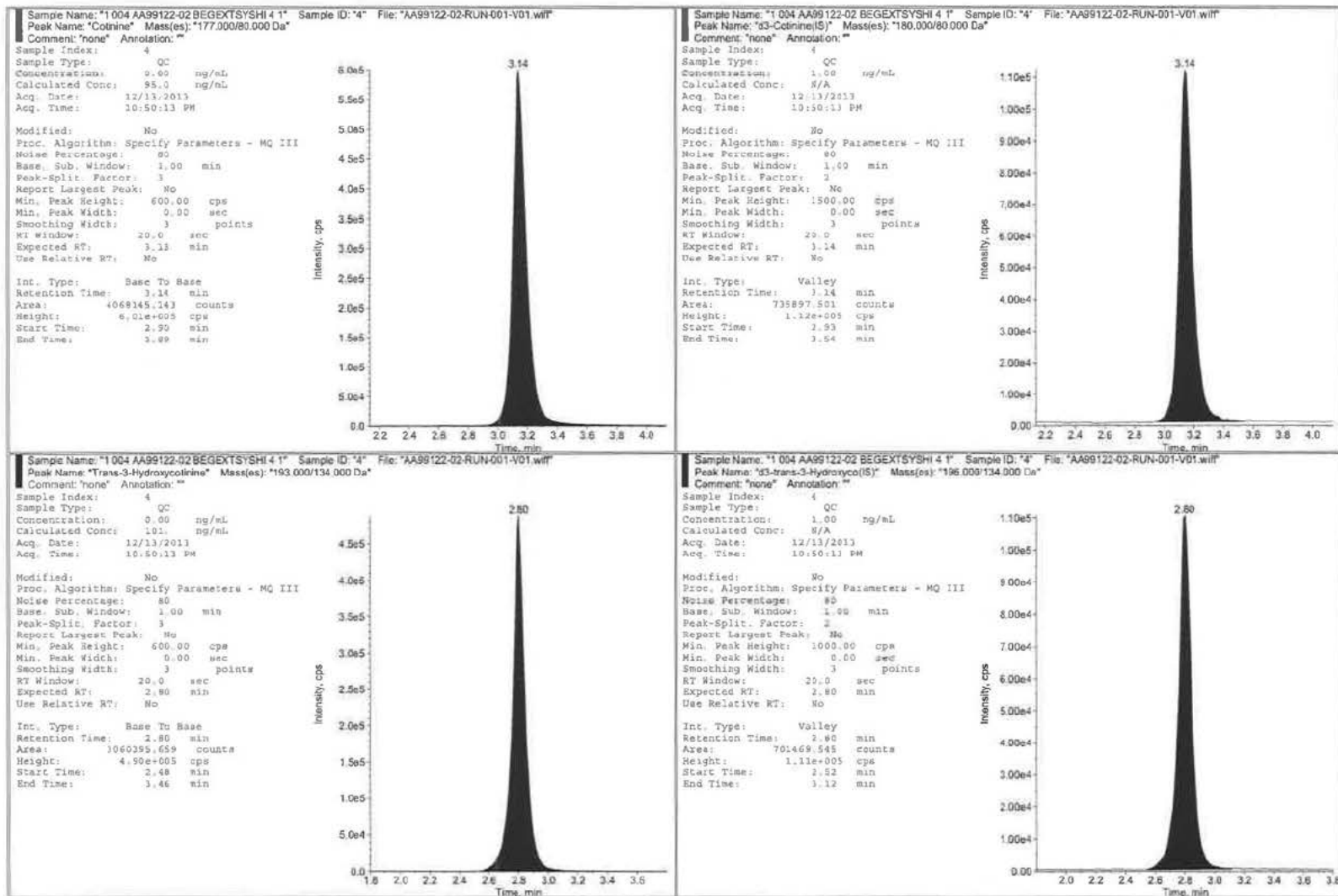
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



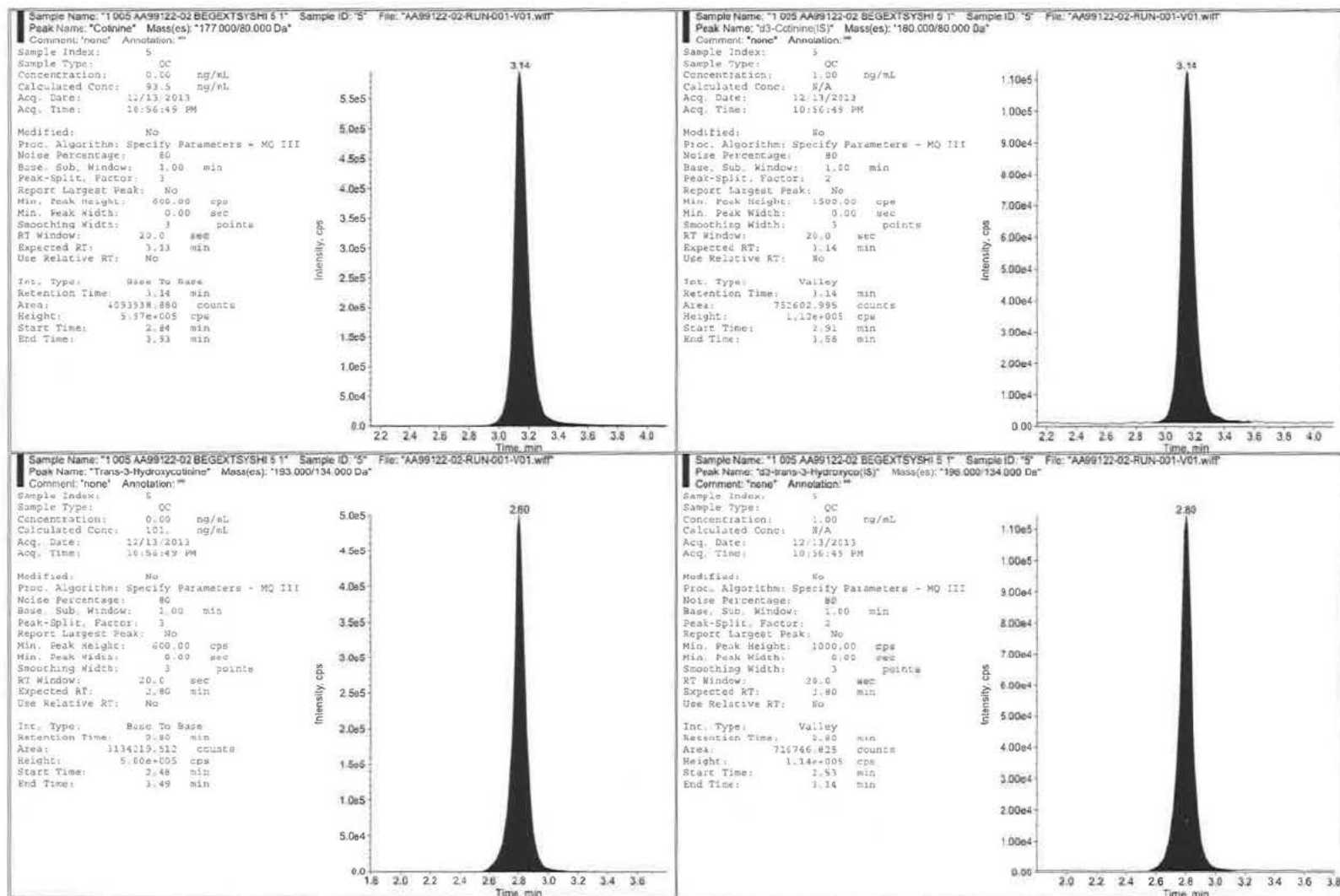


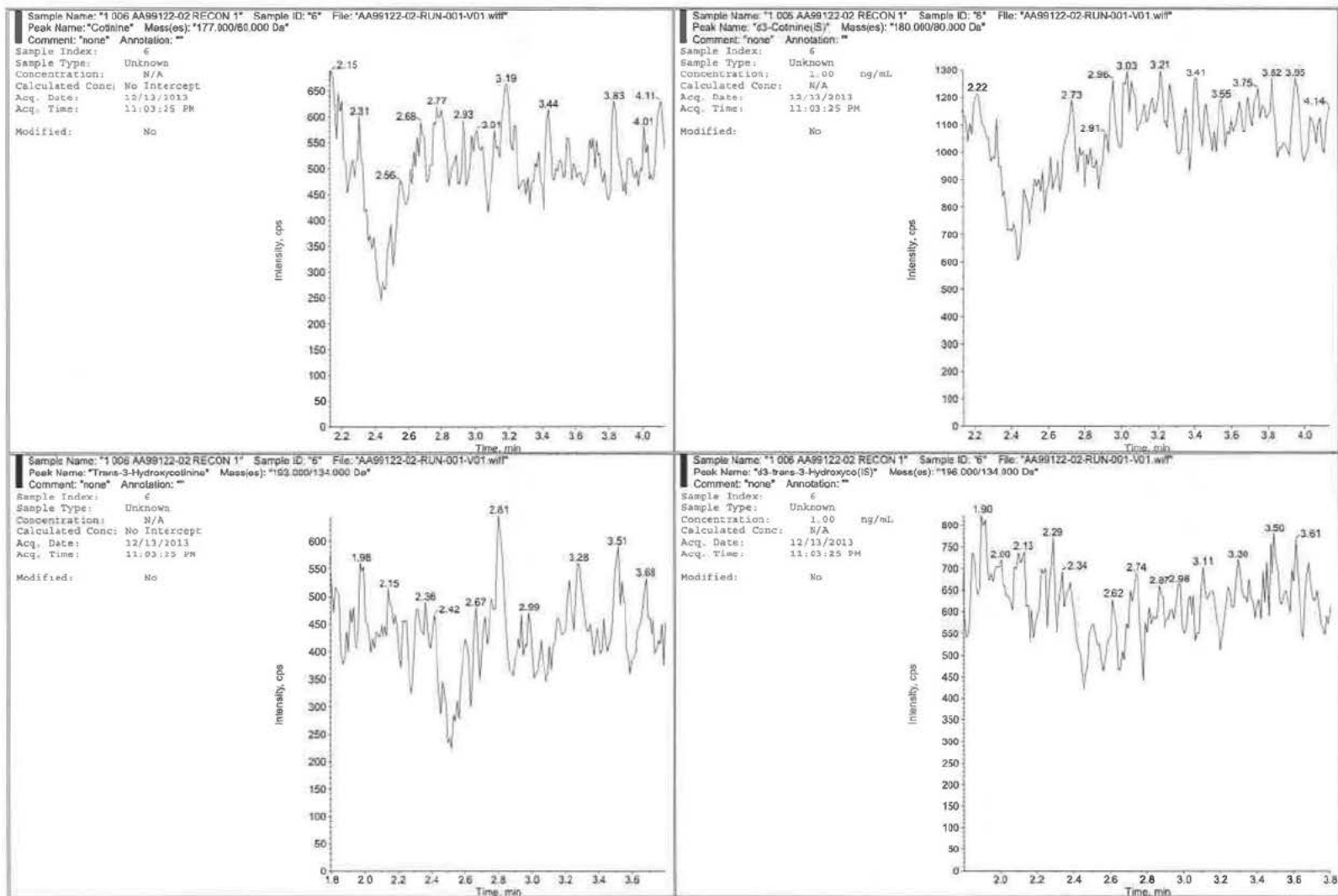




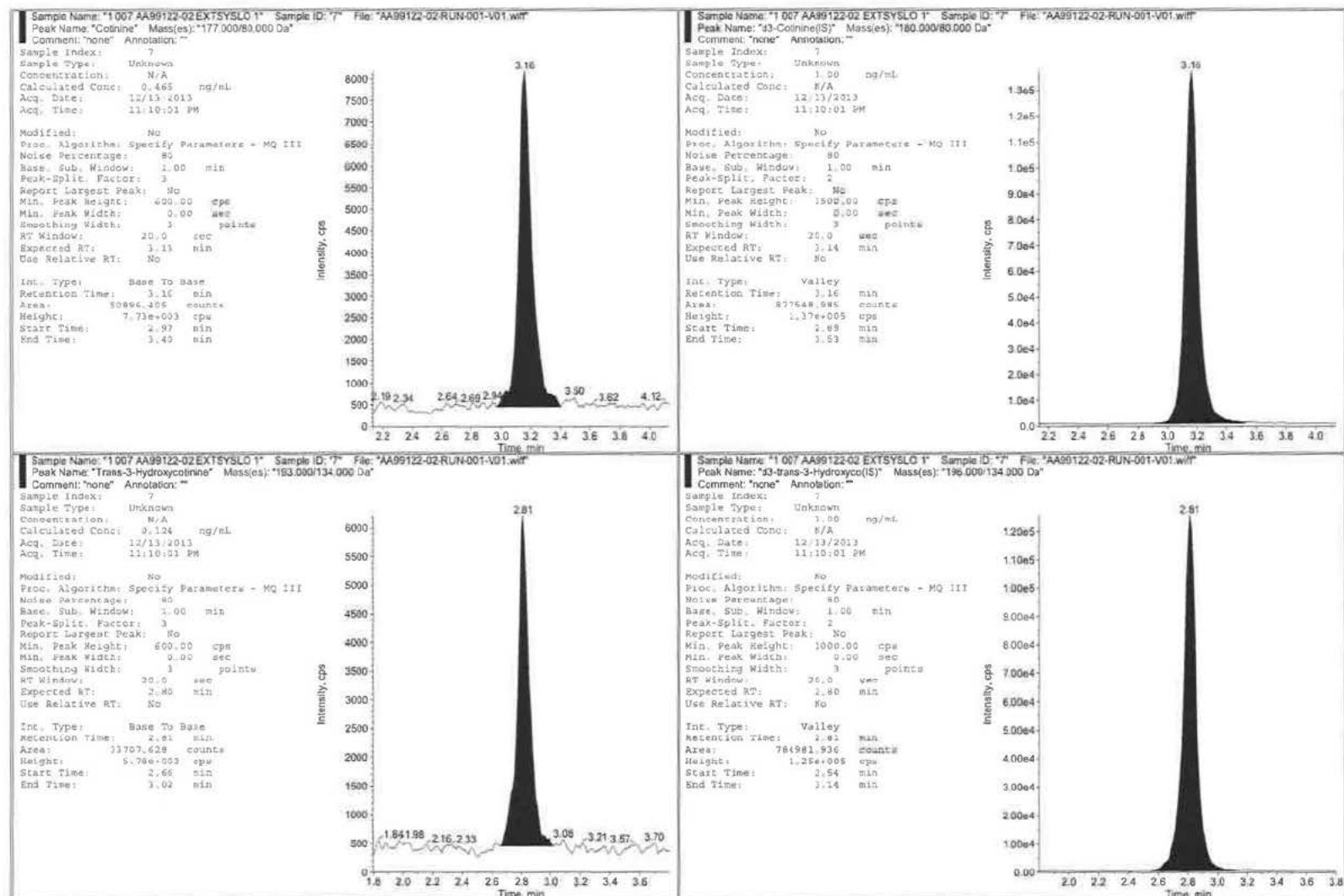


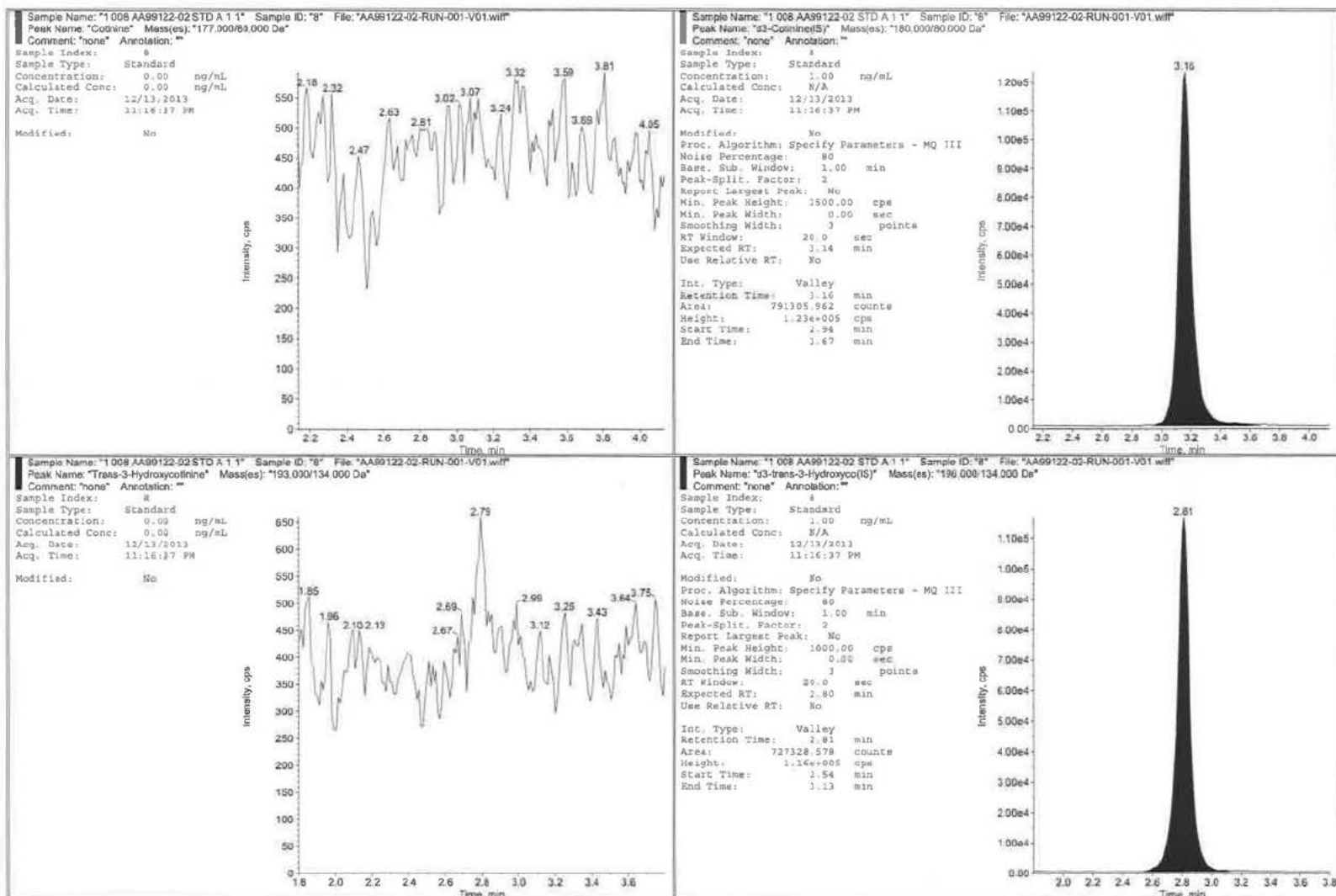
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02





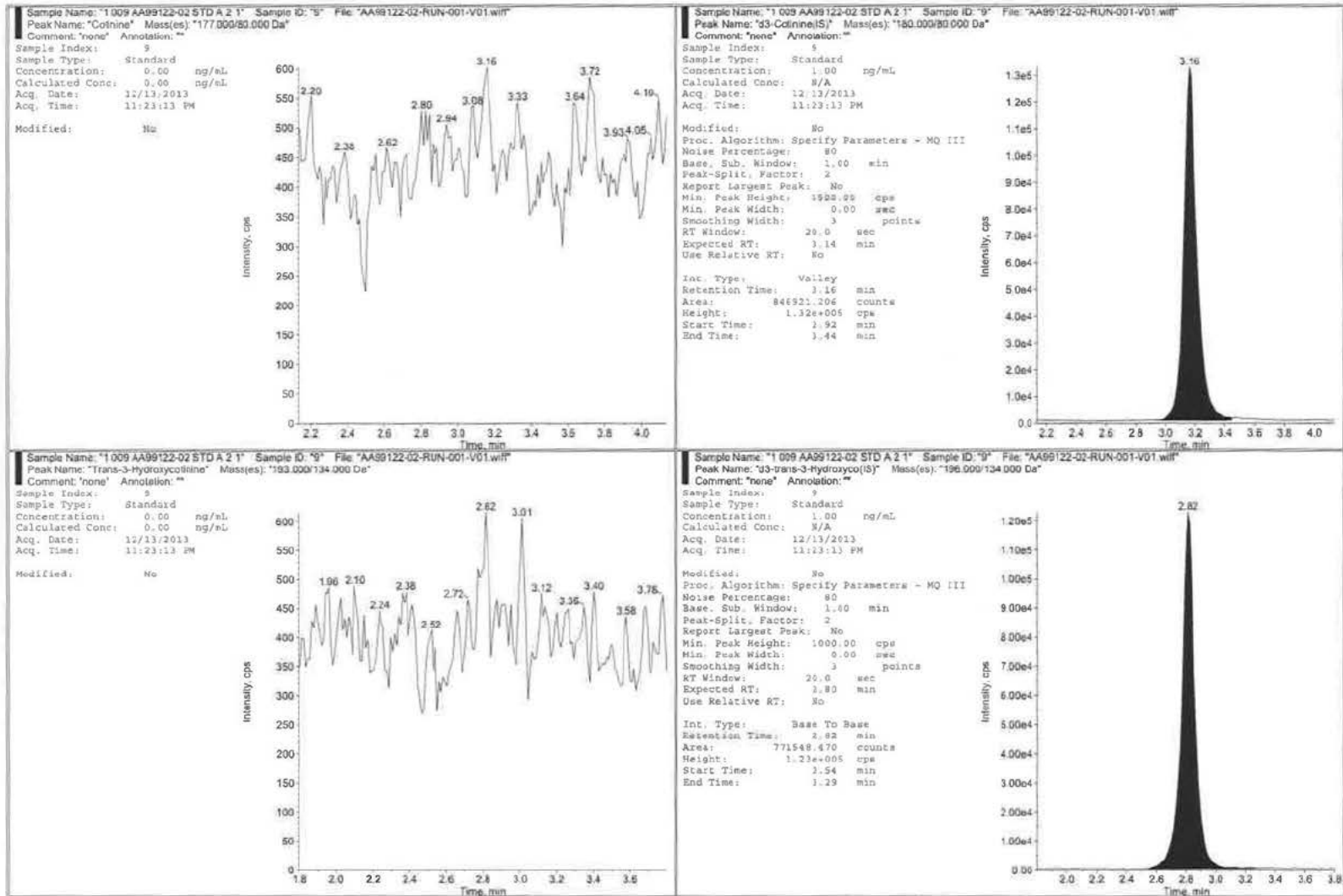
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



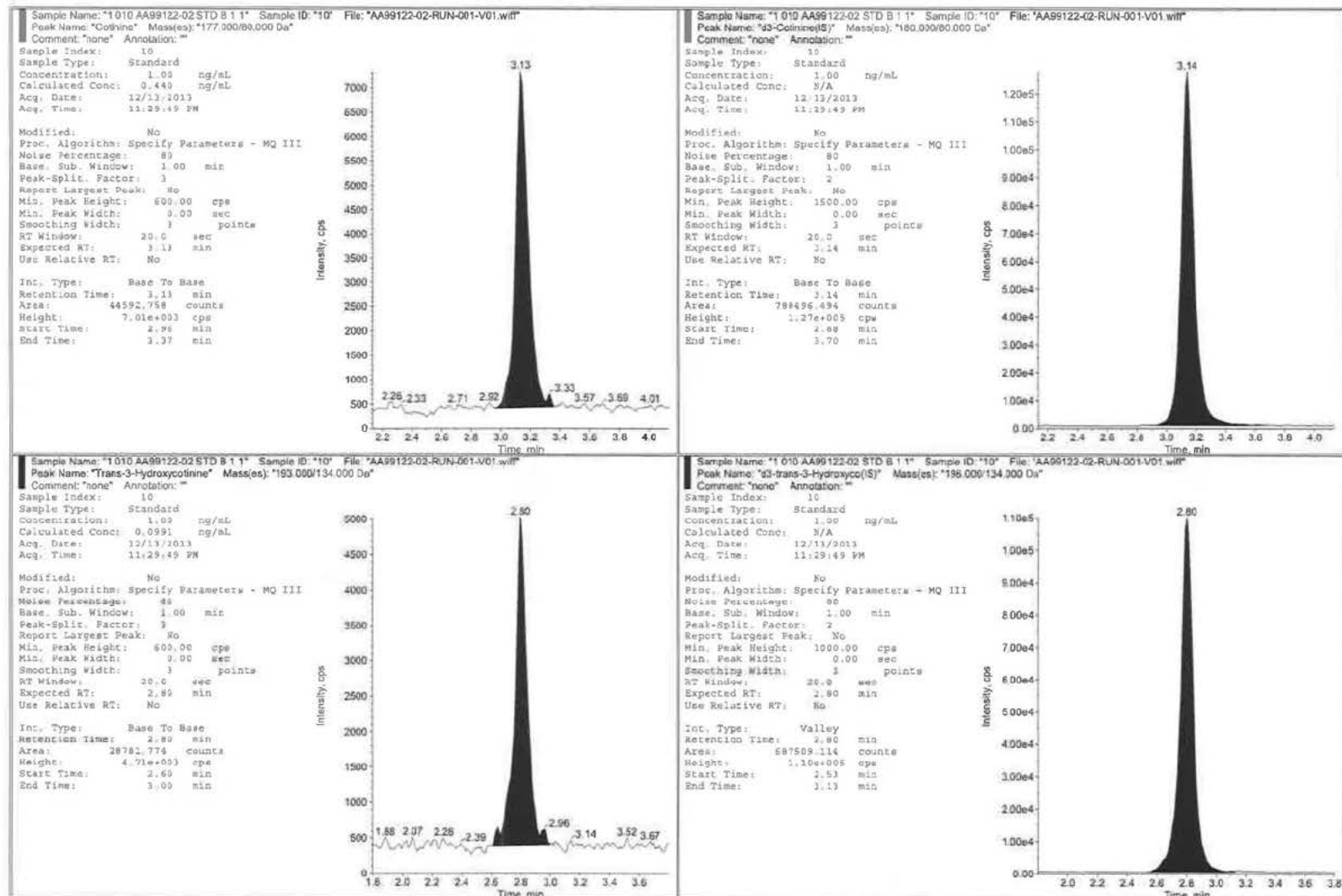




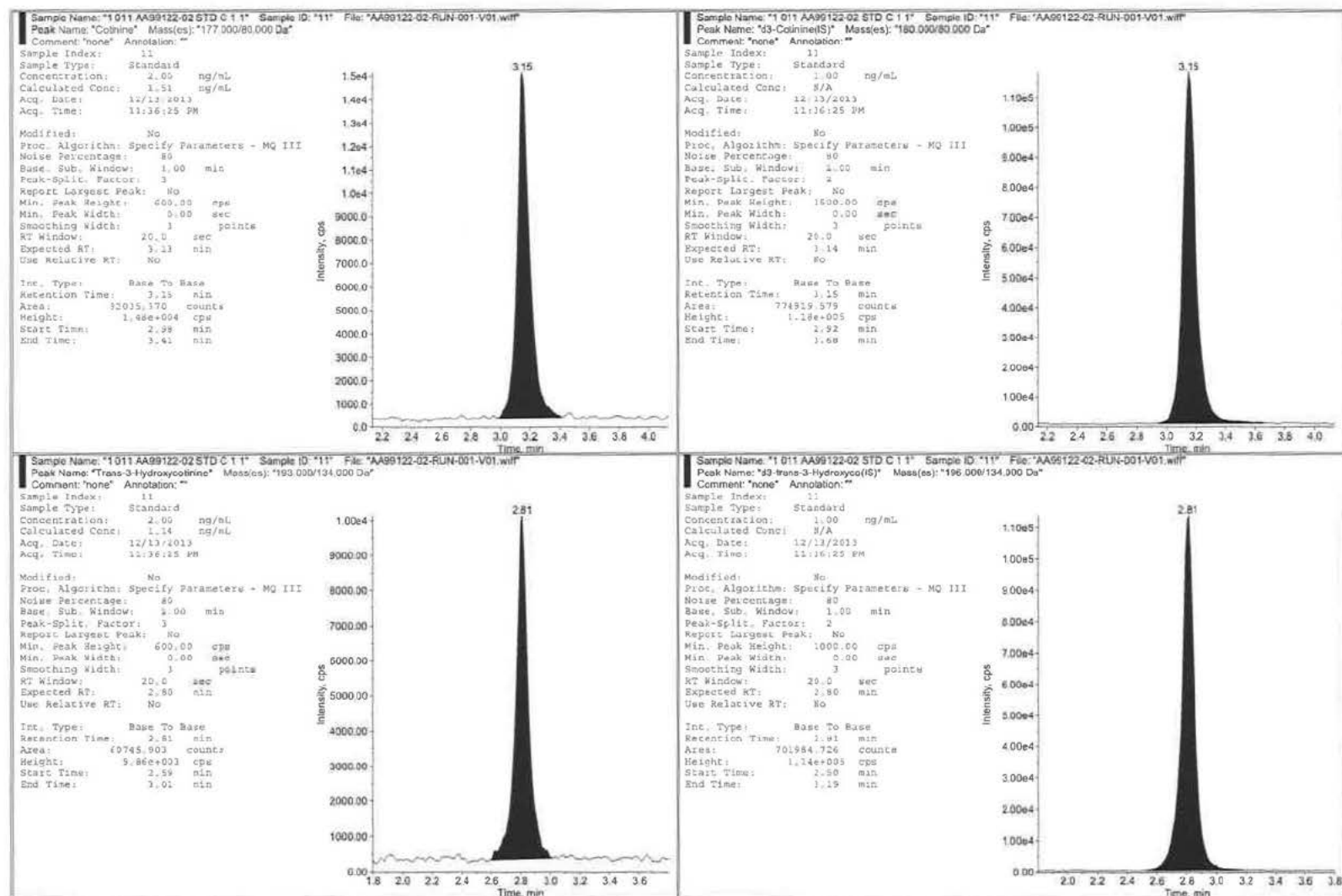
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

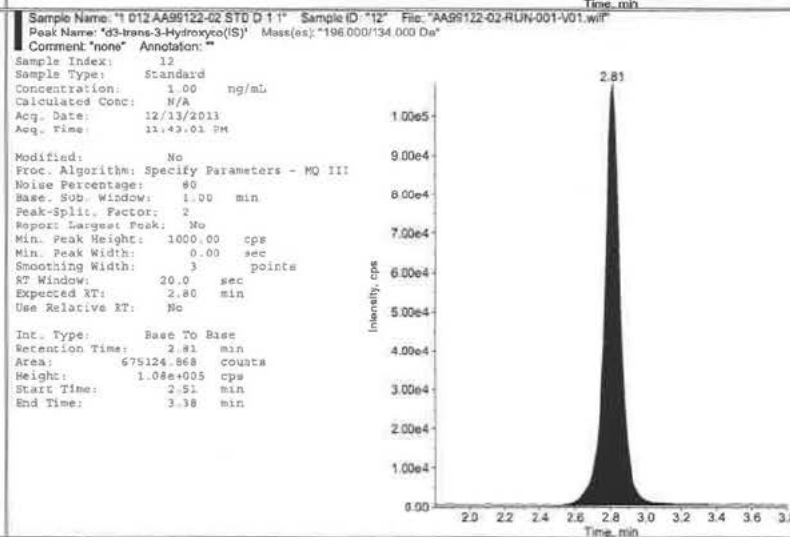
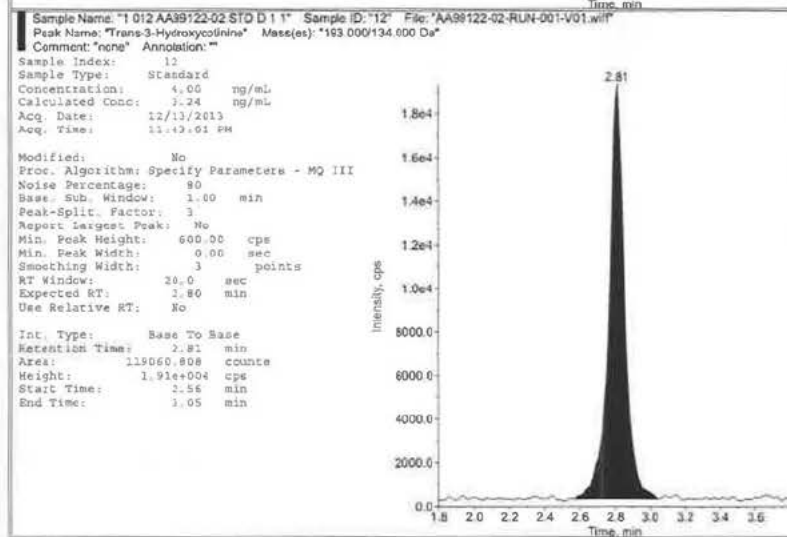
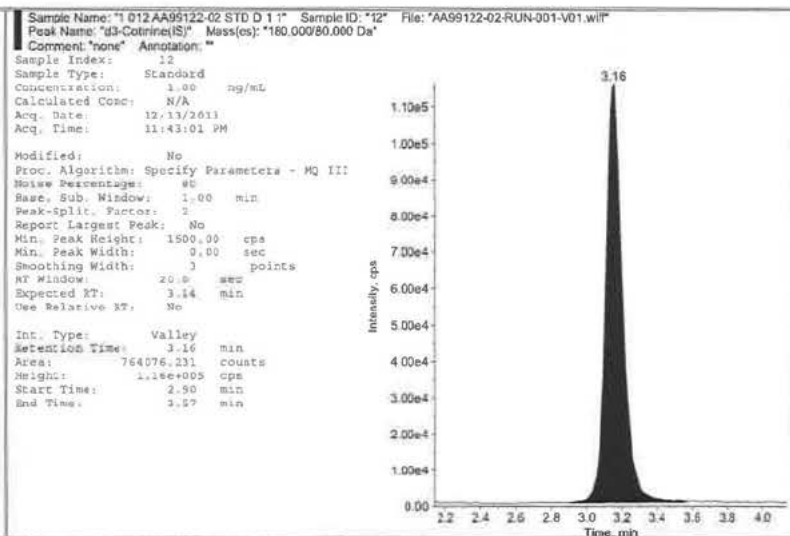
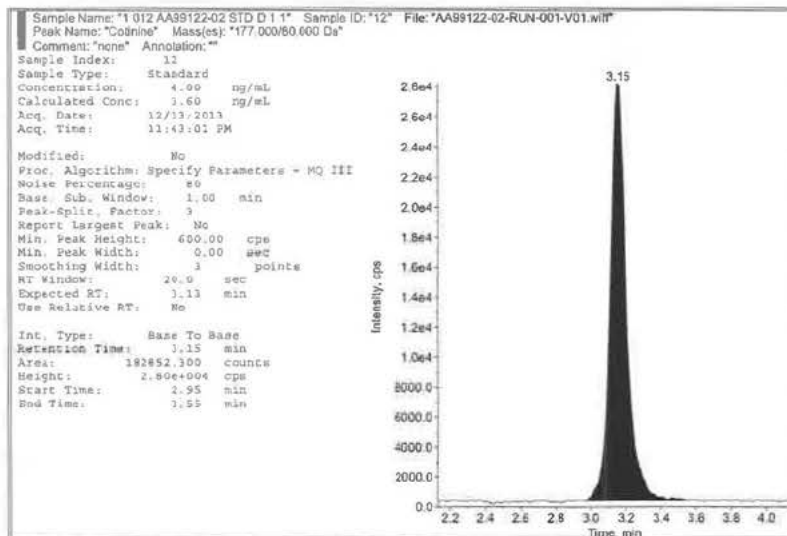


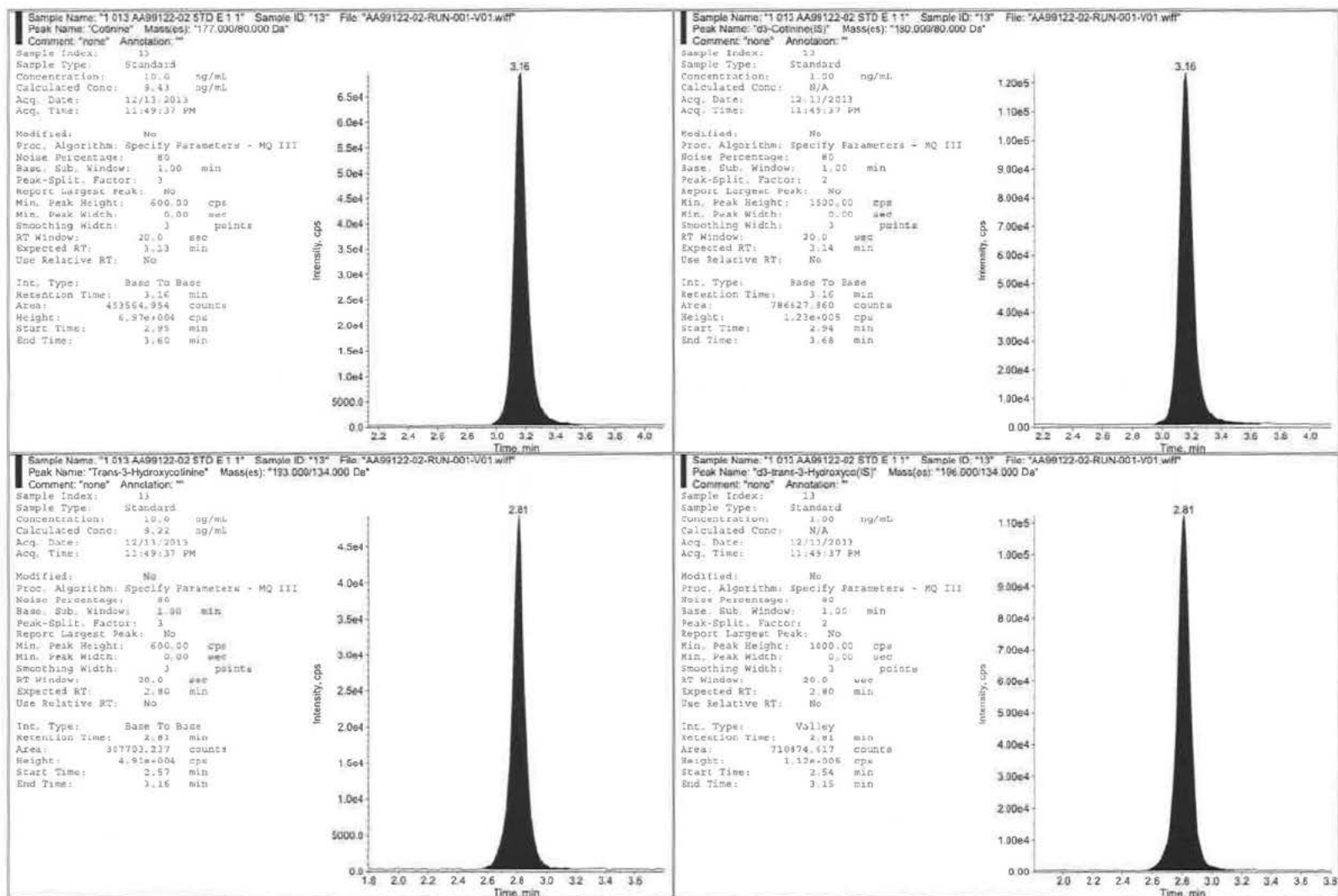
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



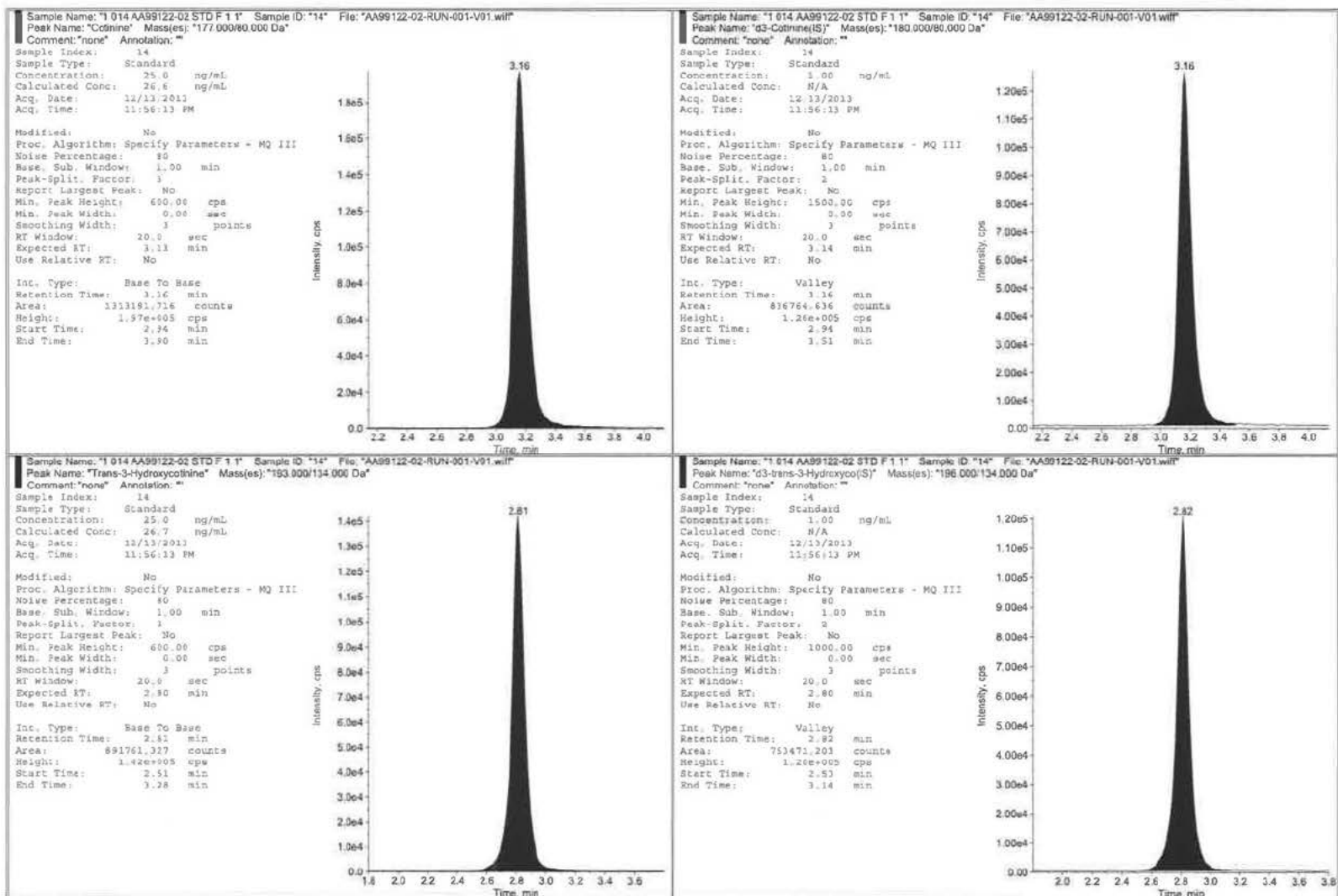
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02





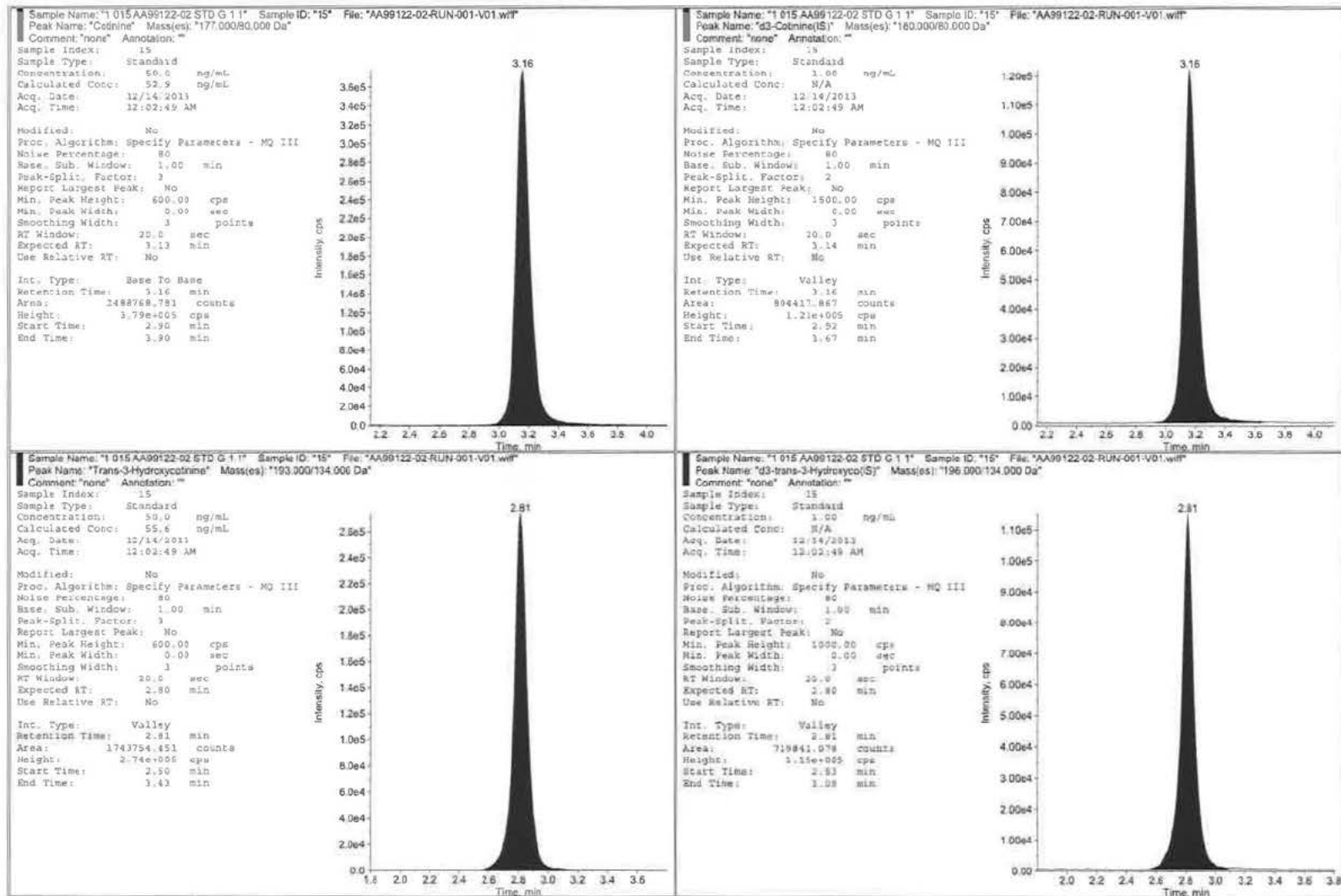


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

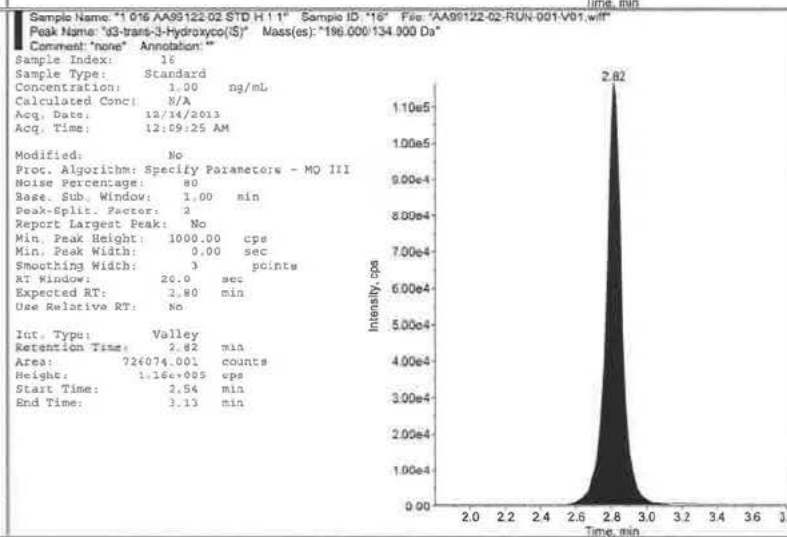
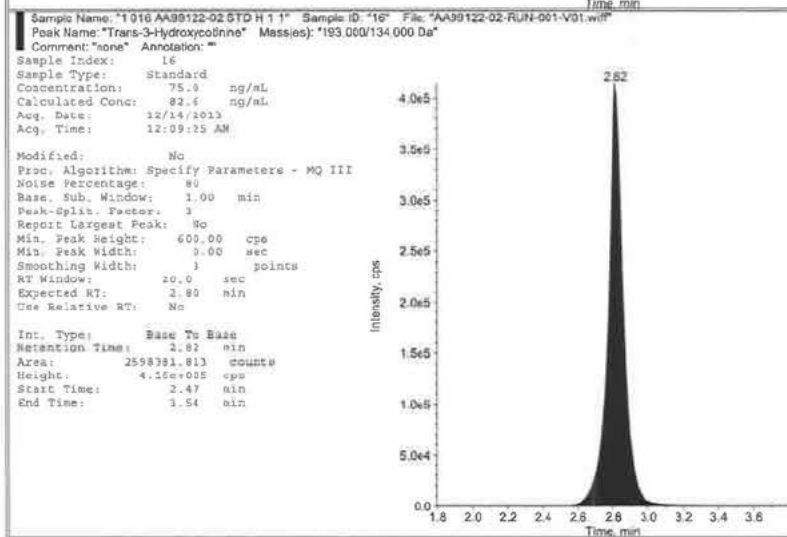
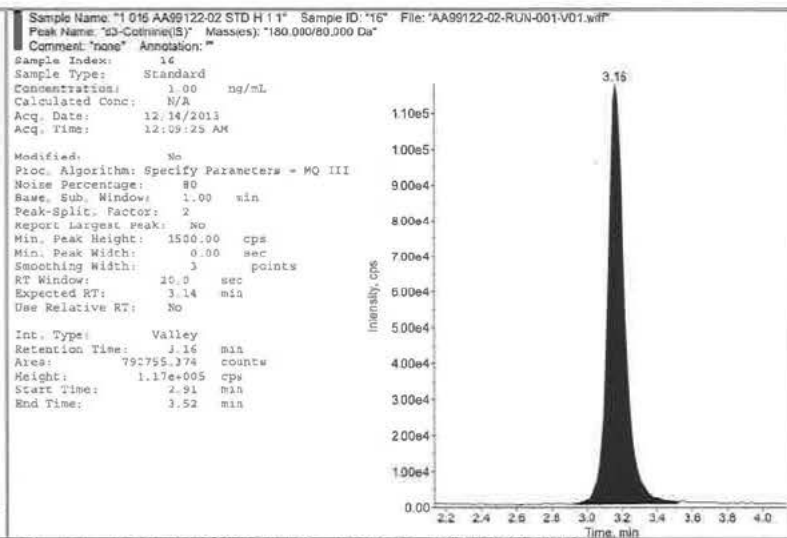
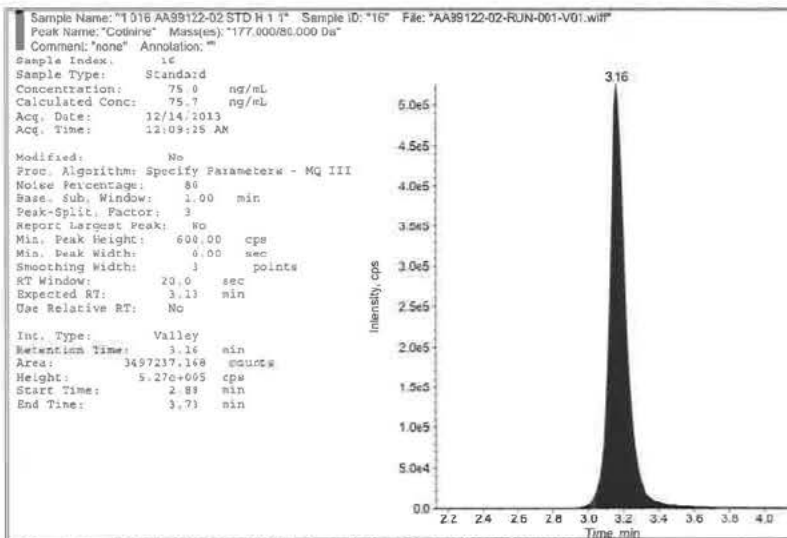




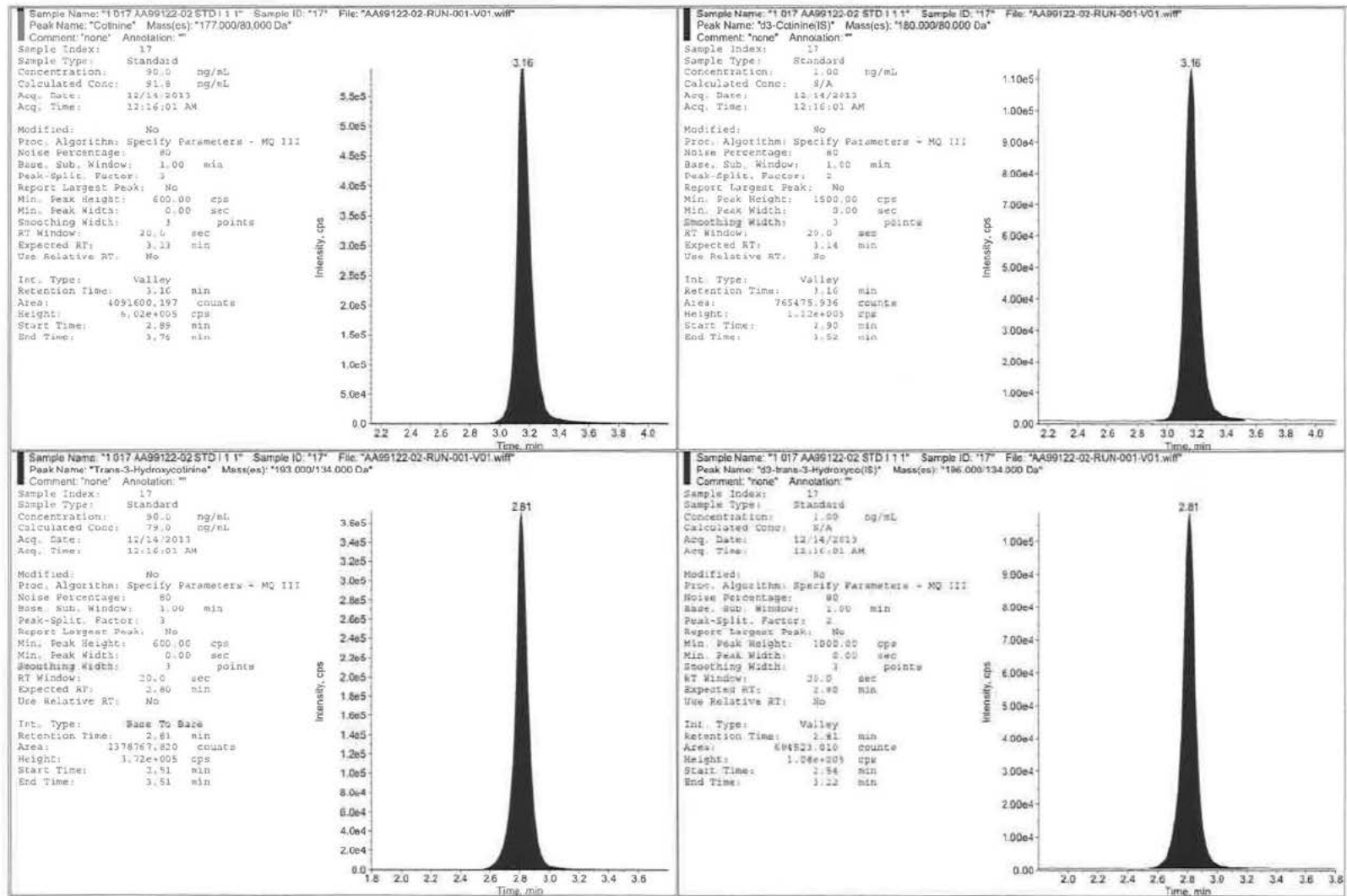
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

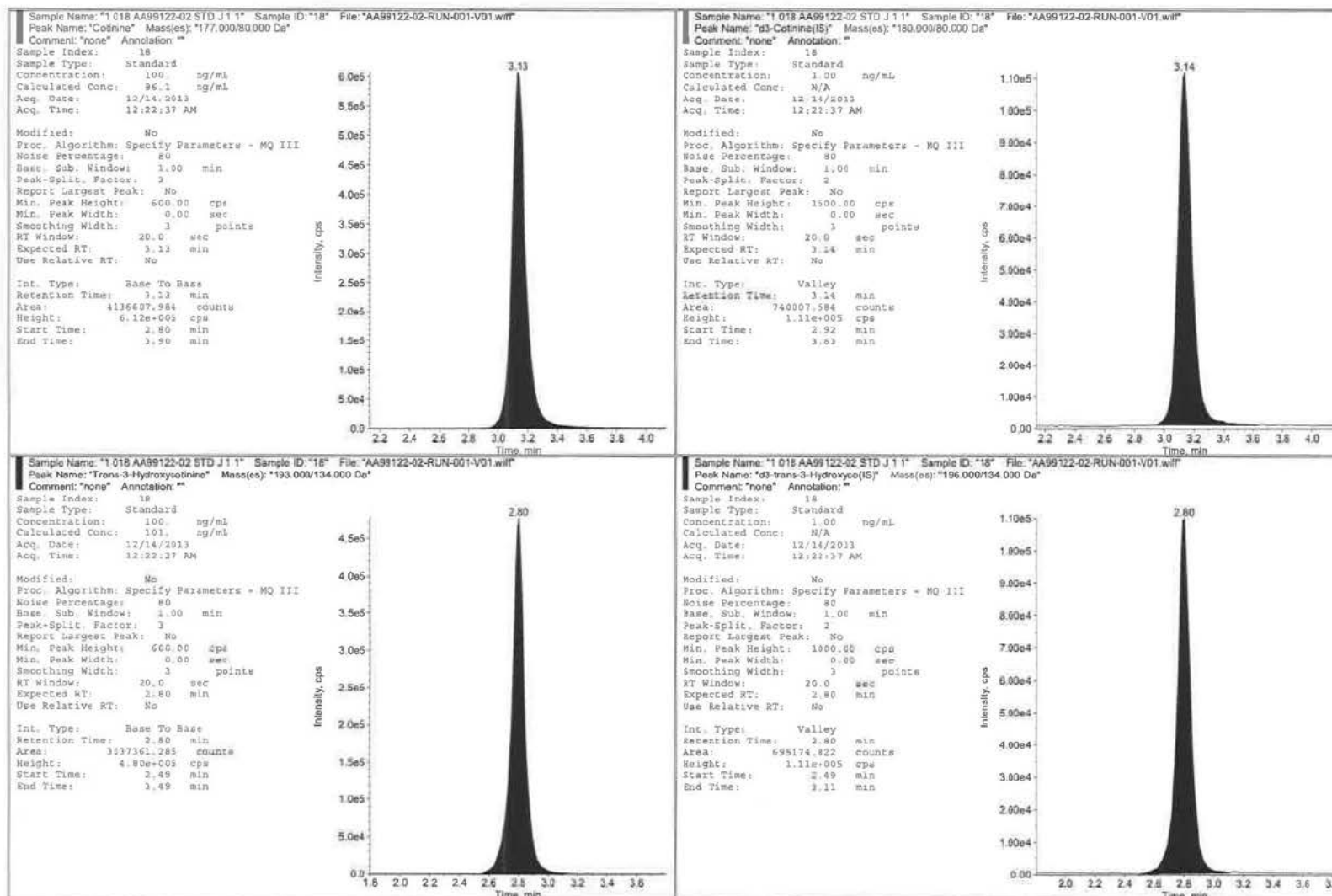


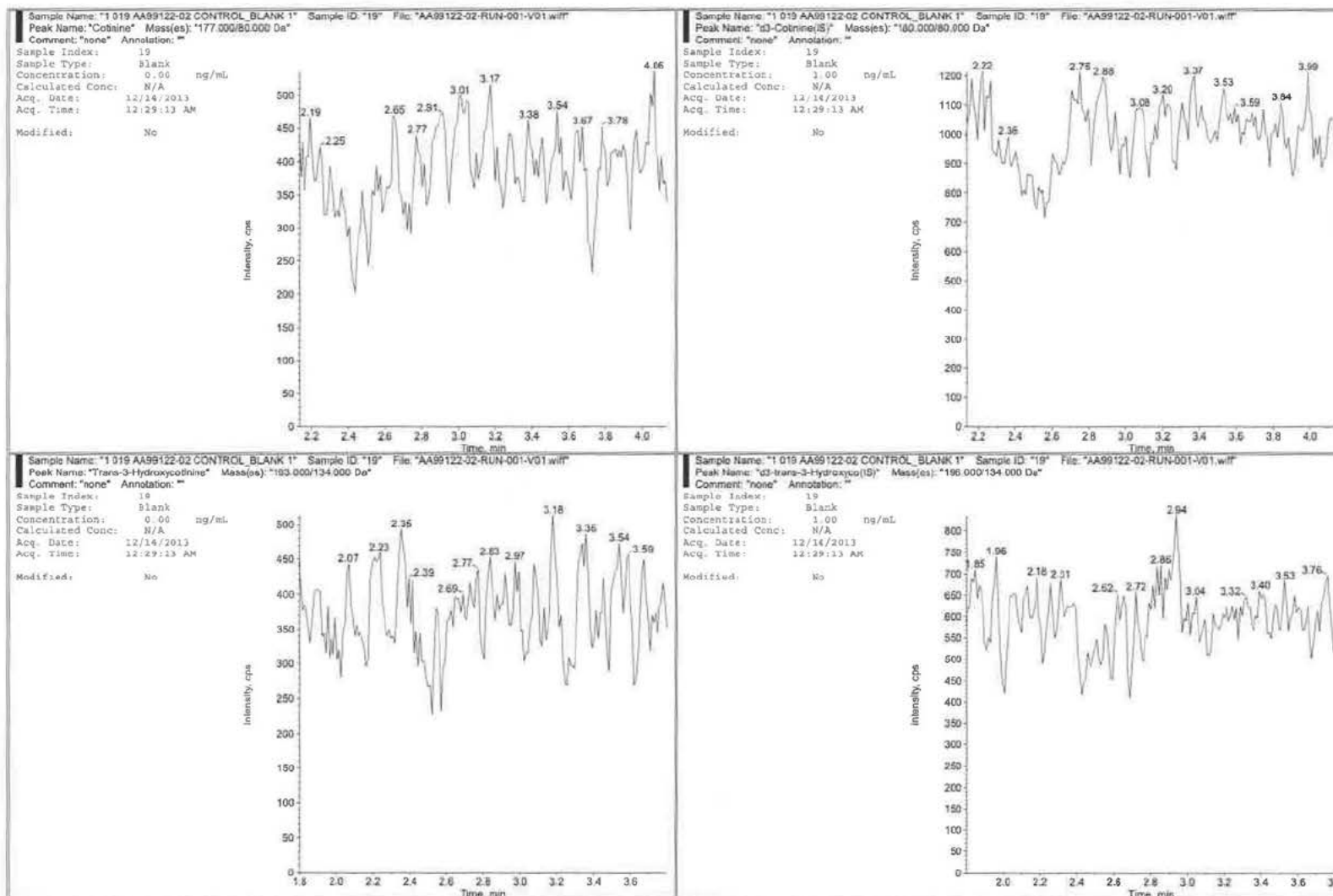
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

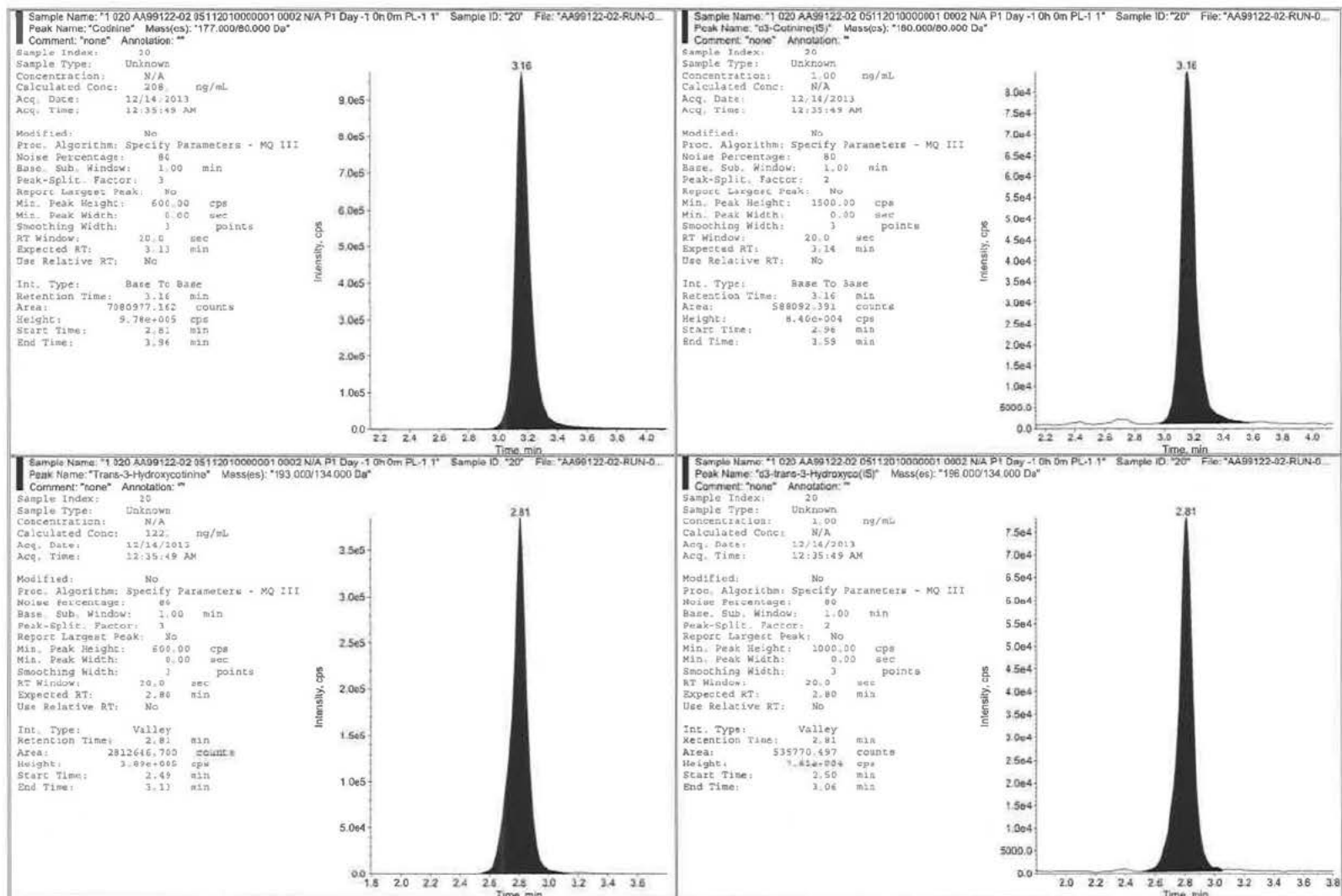


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



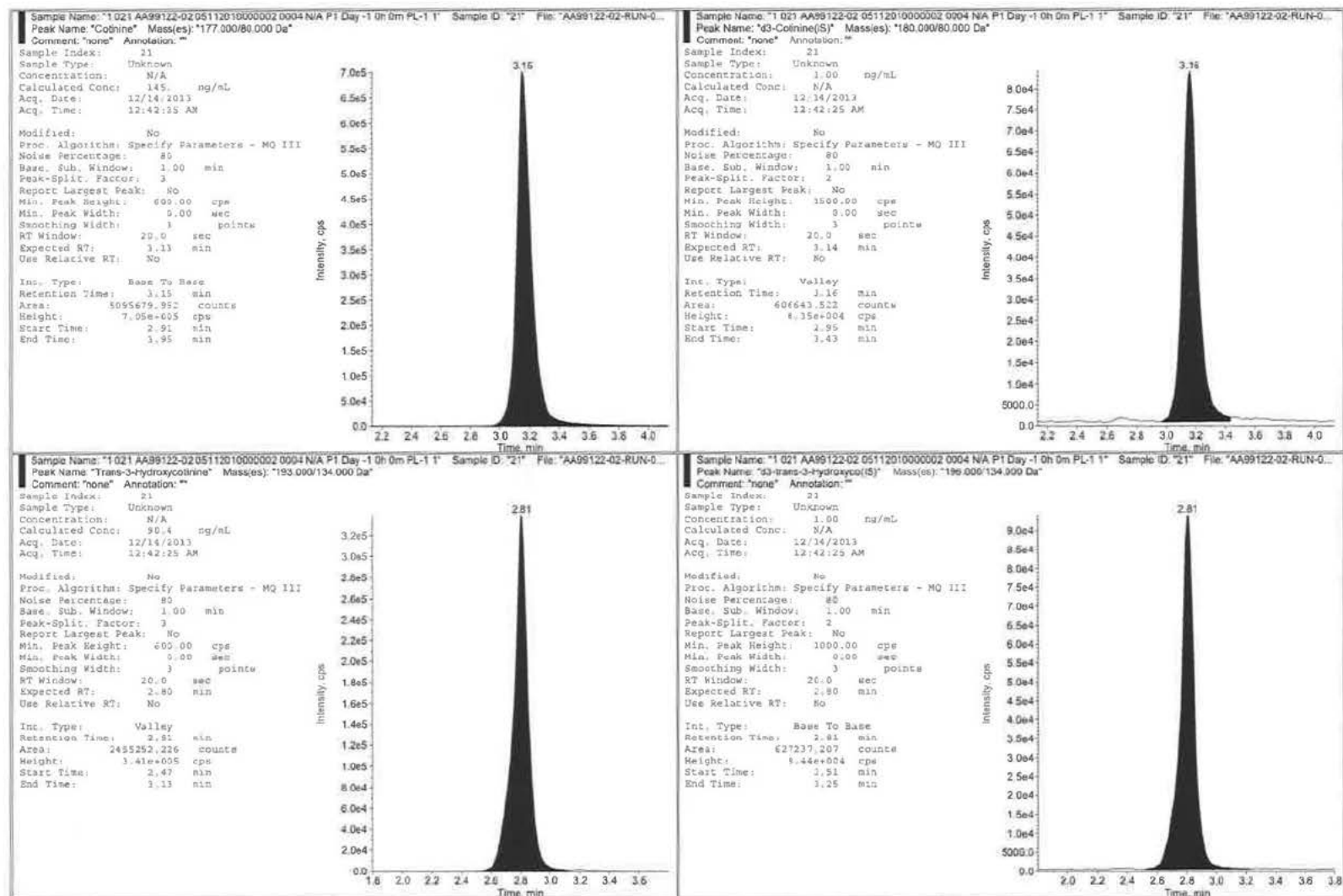




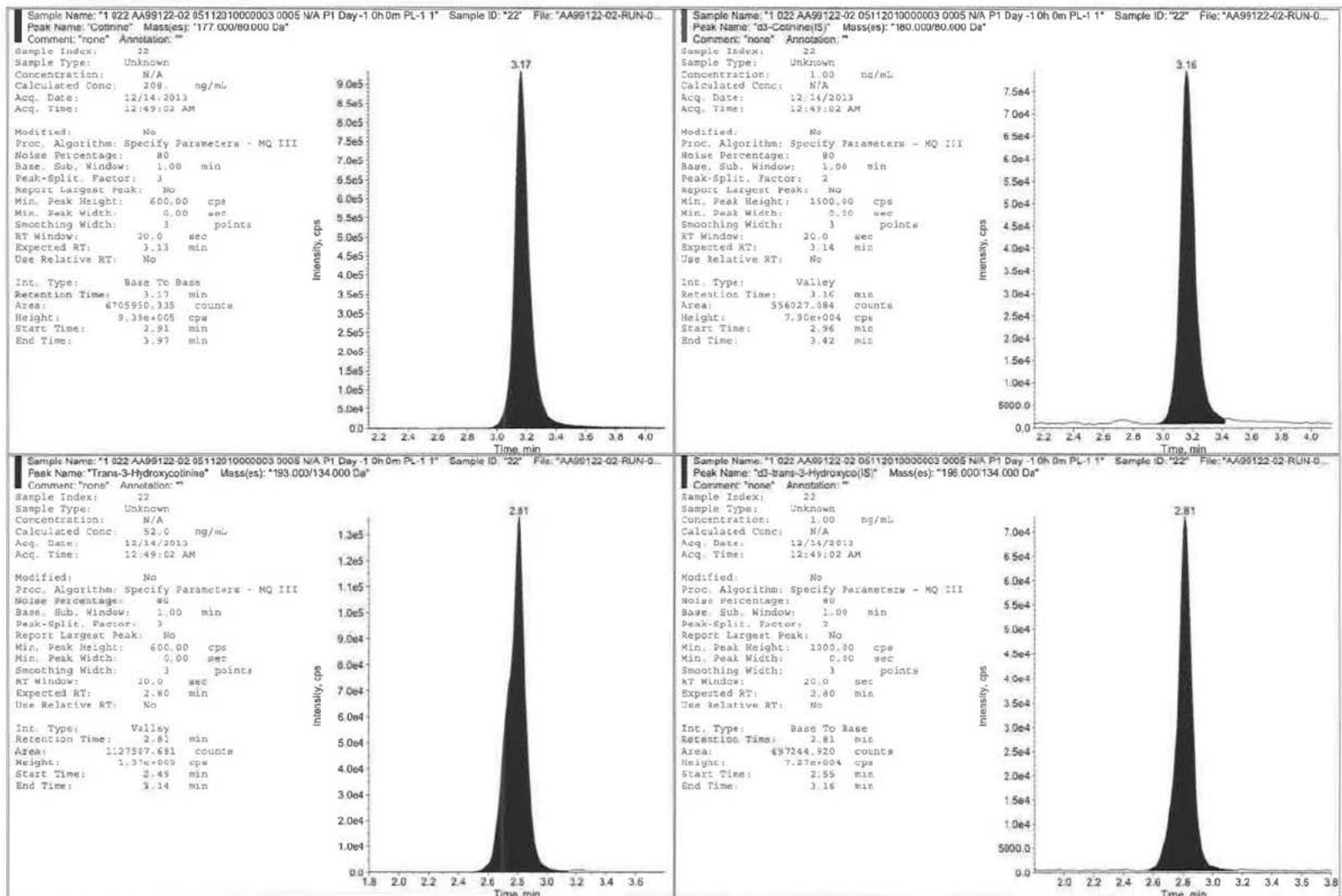


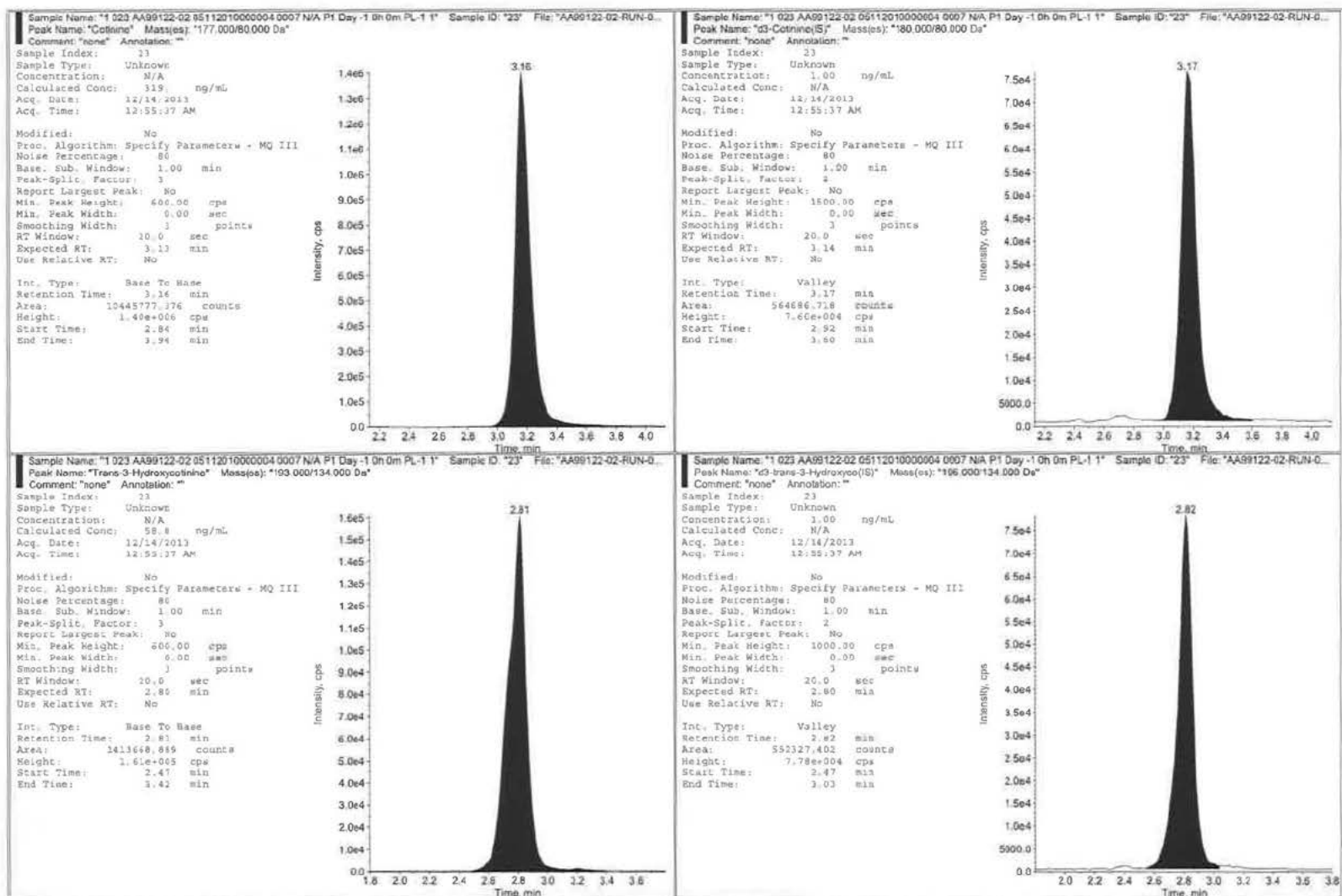


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

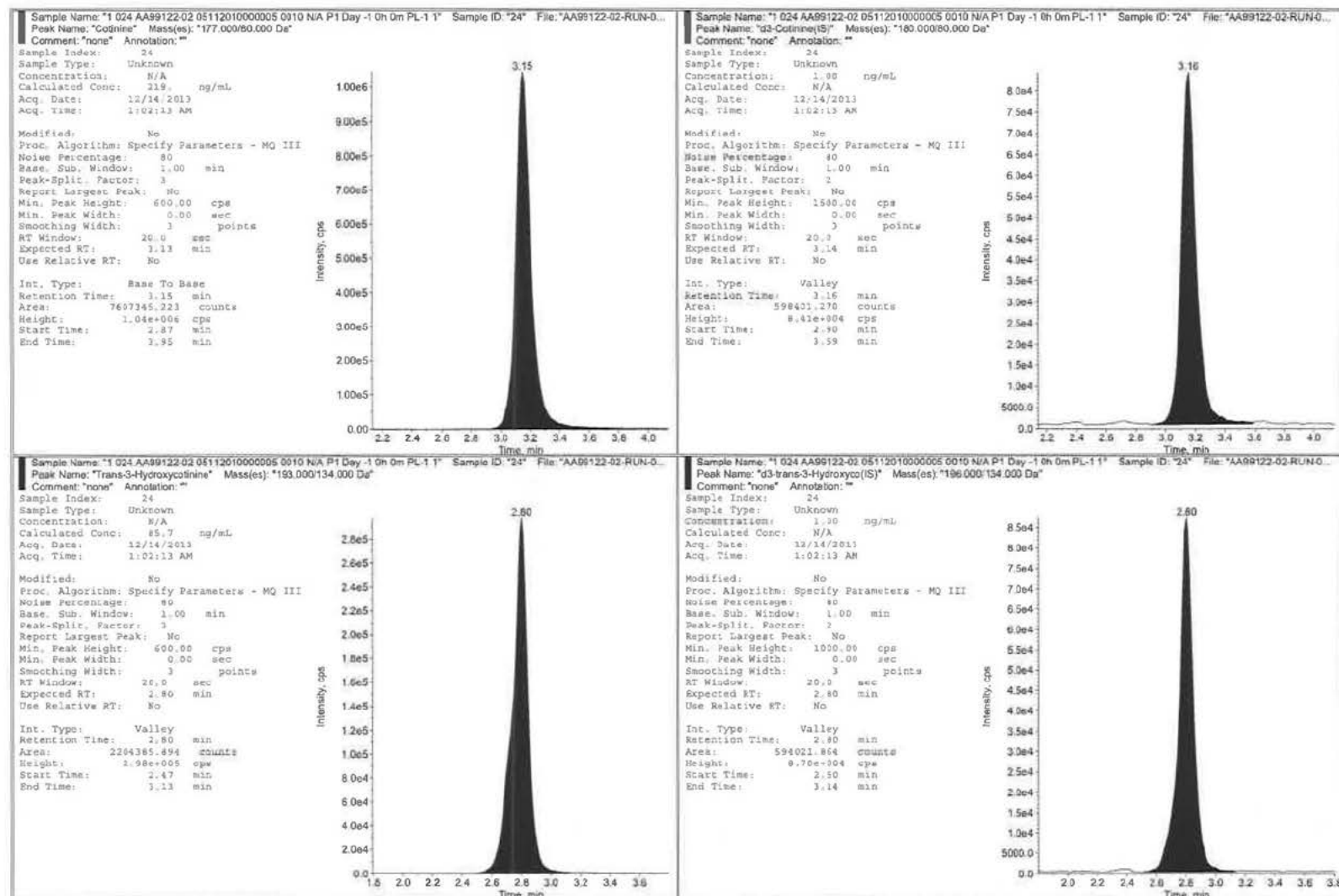


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

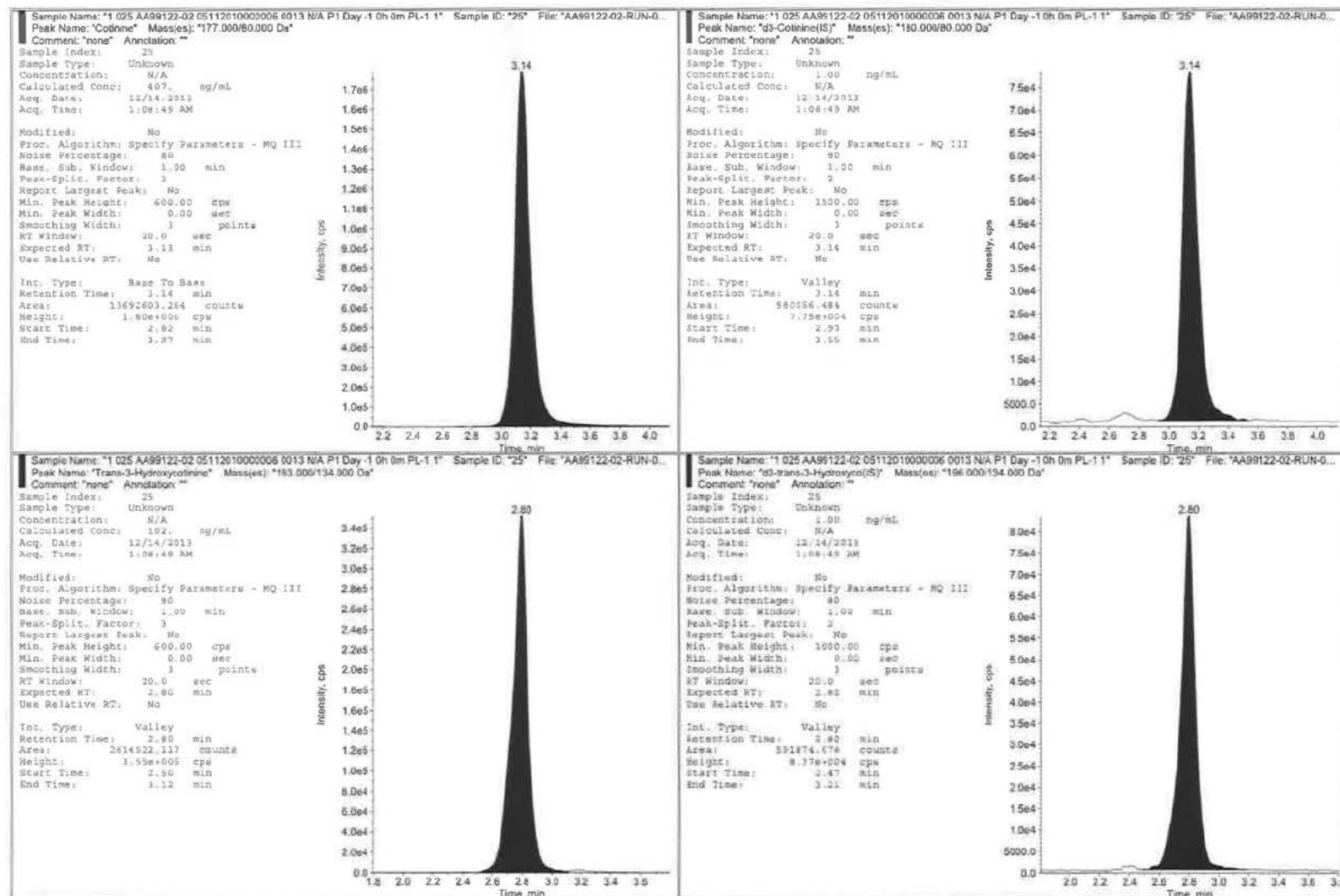


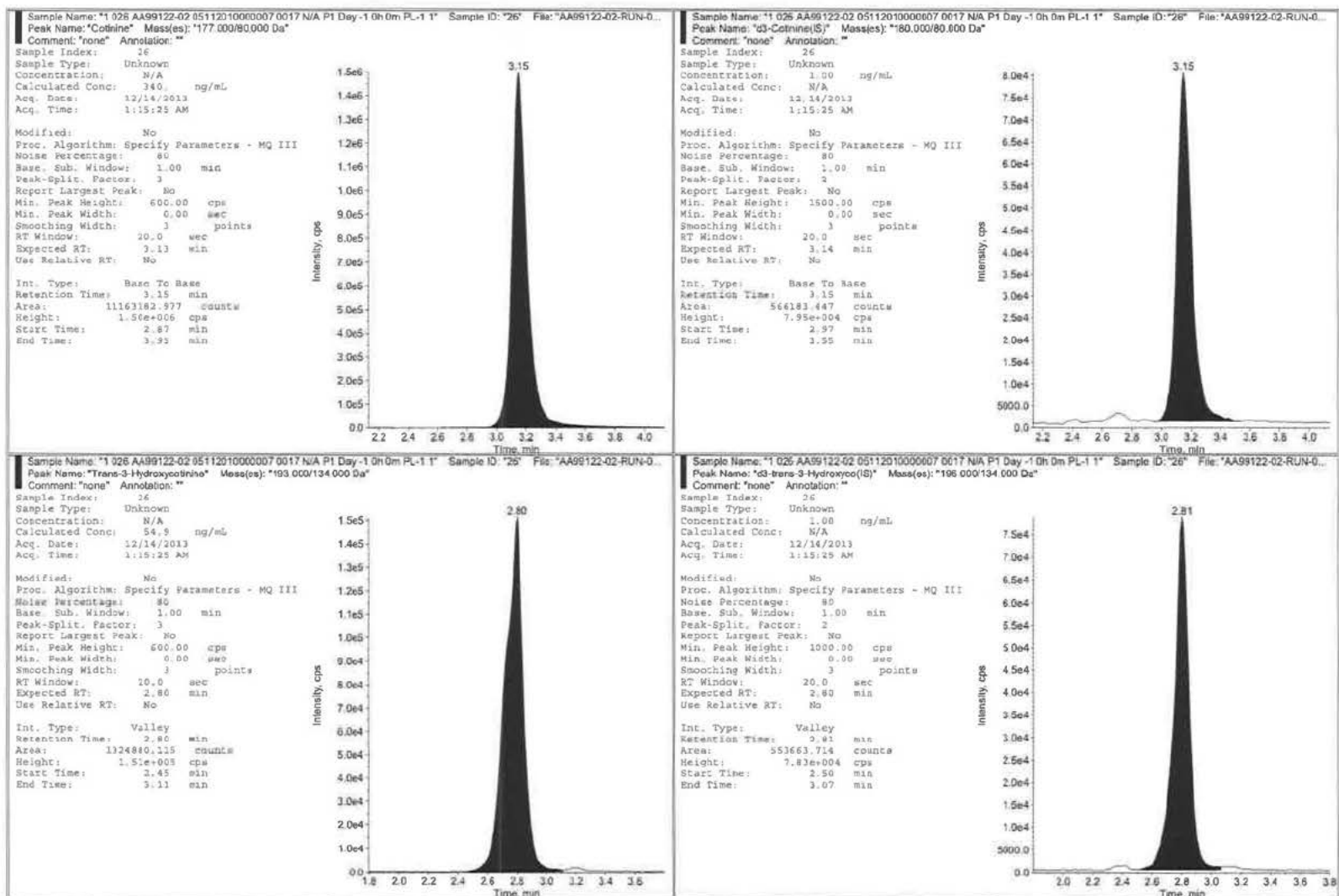


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



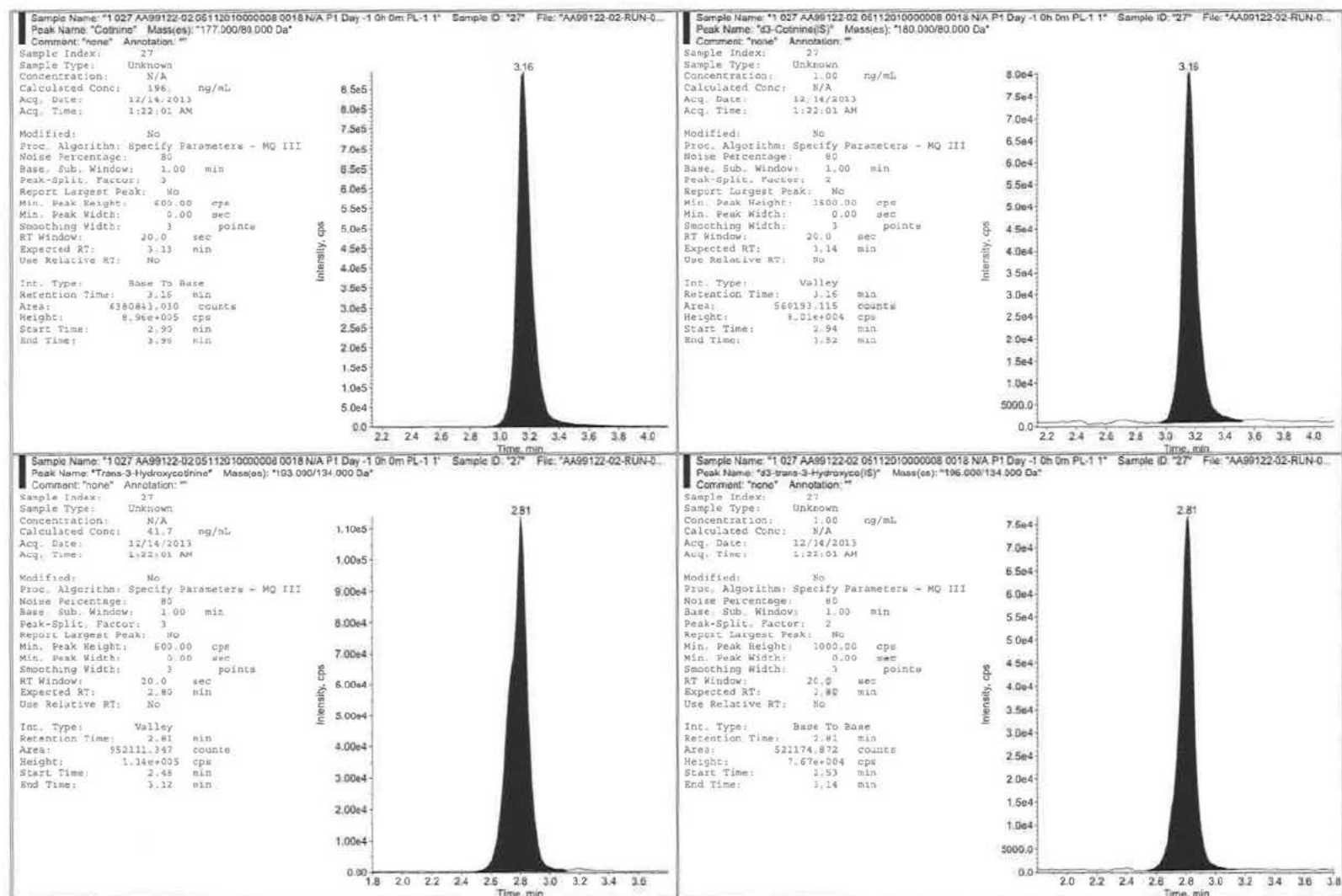
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

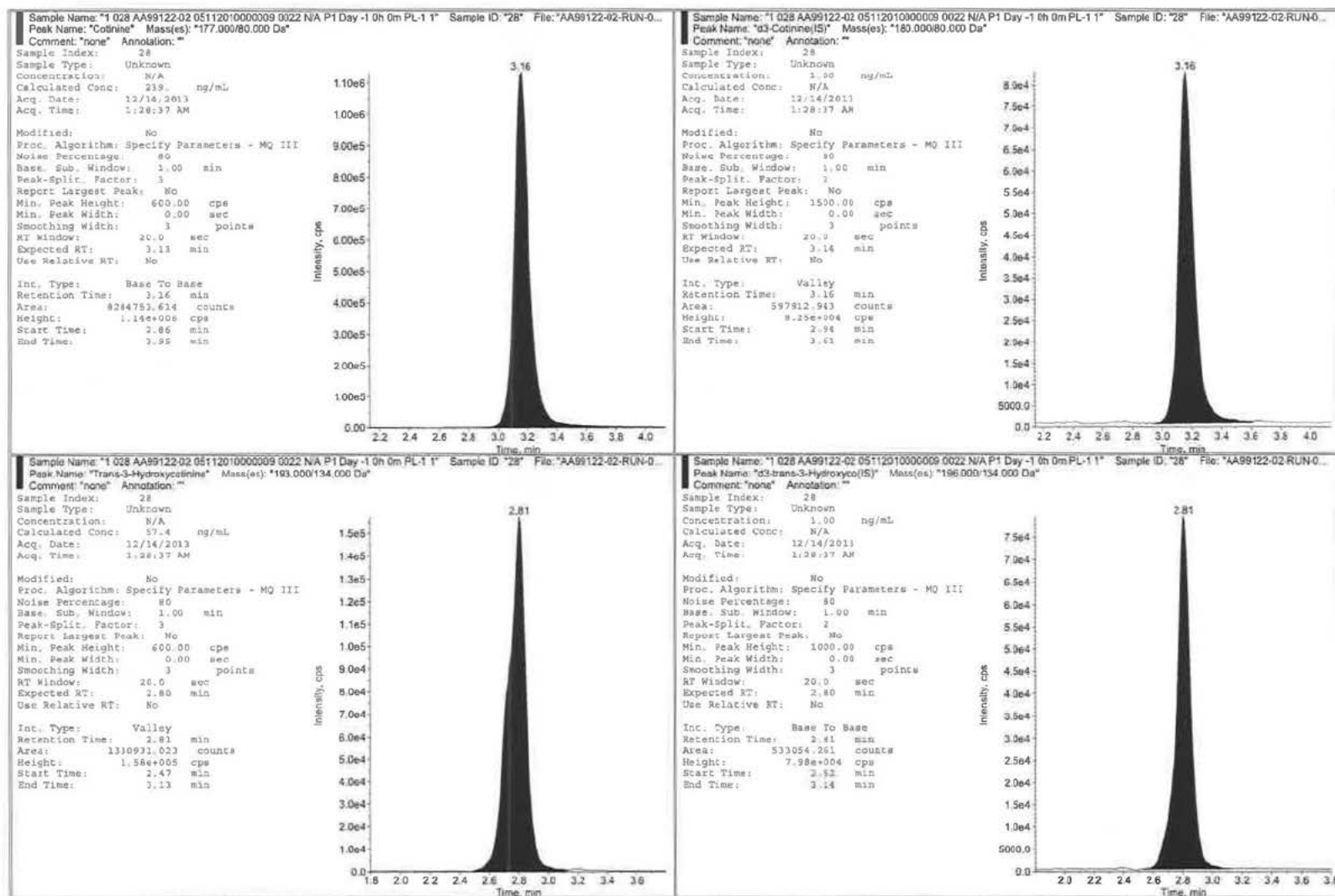




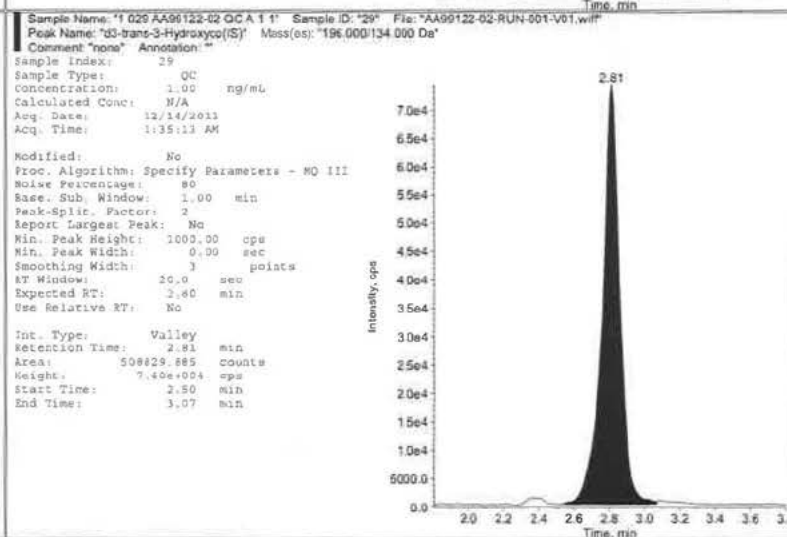
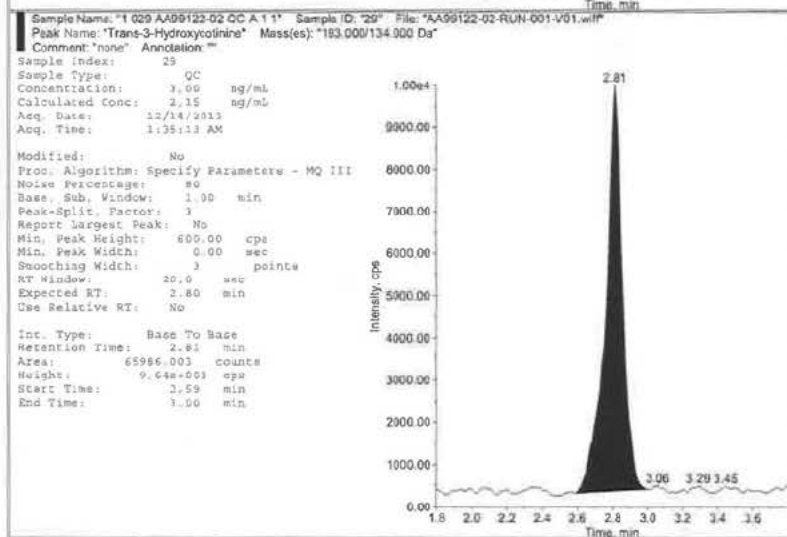
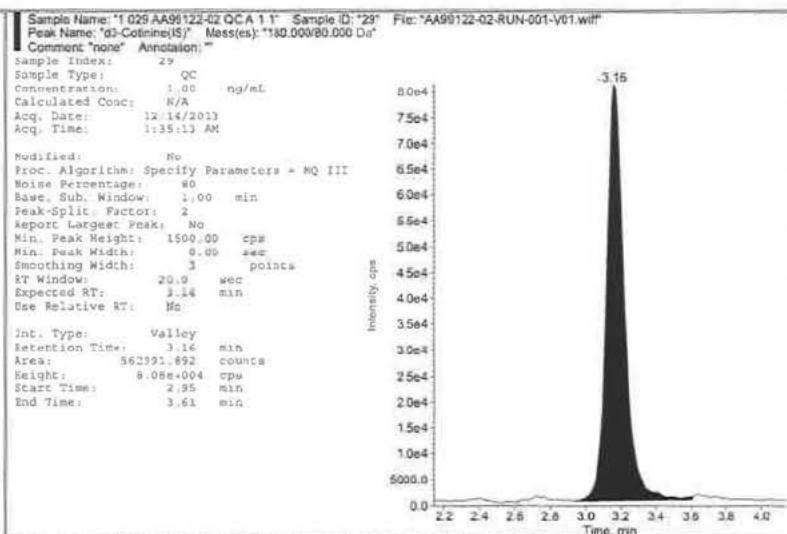
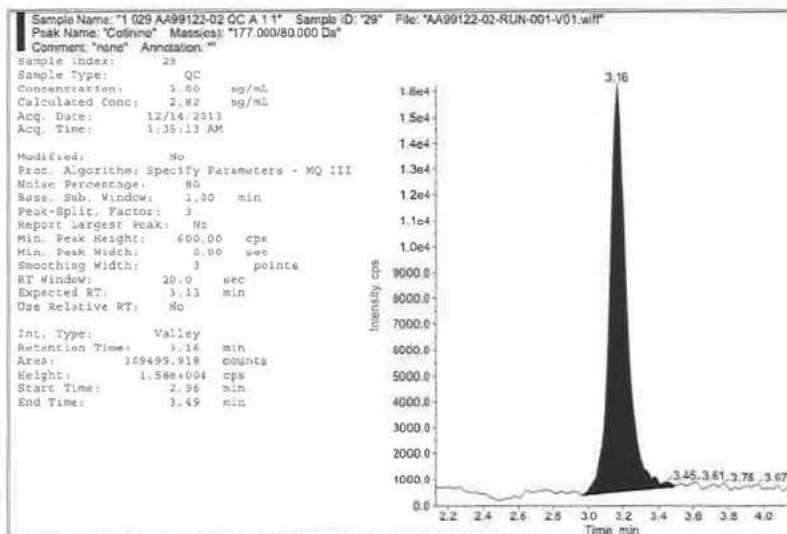


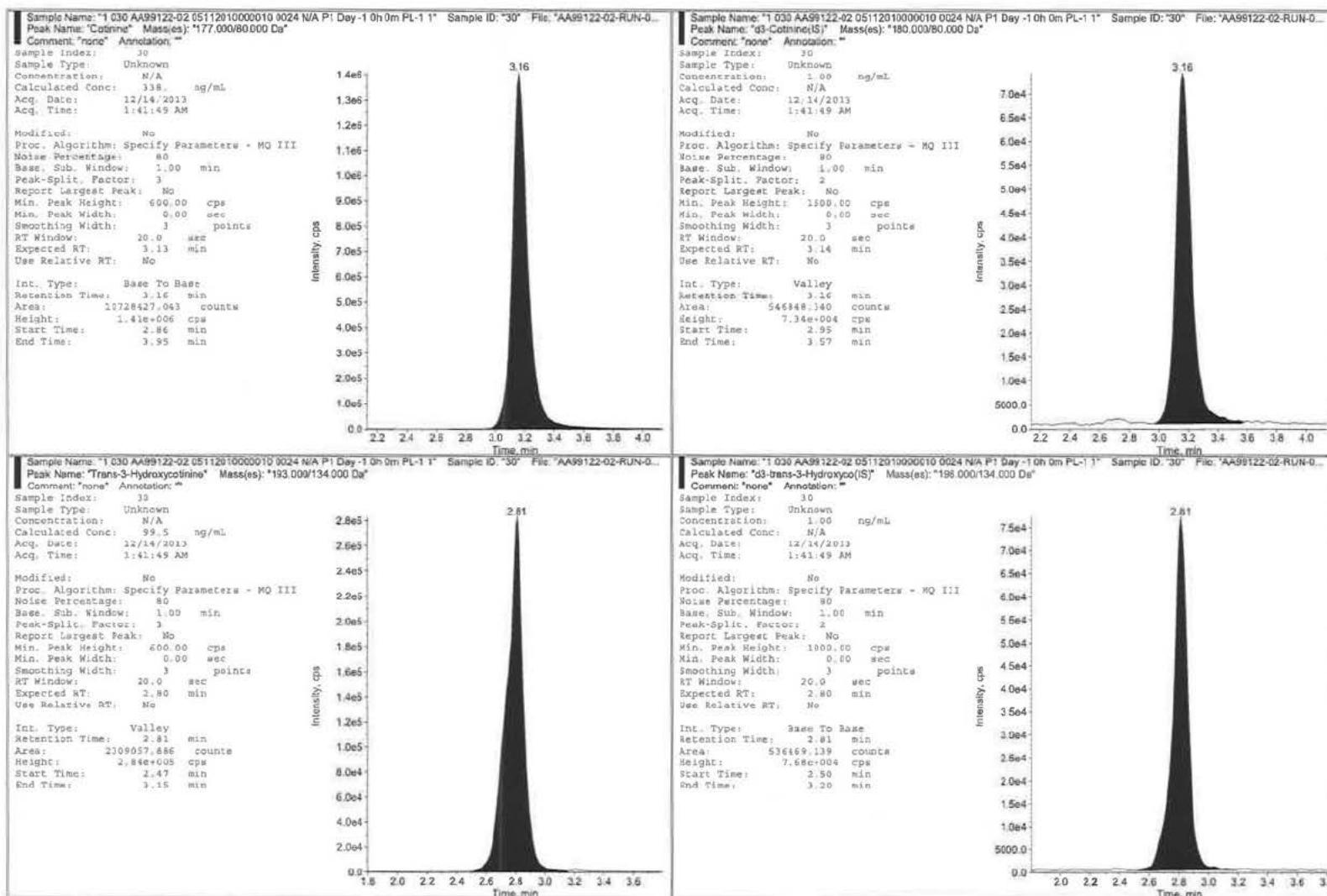
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



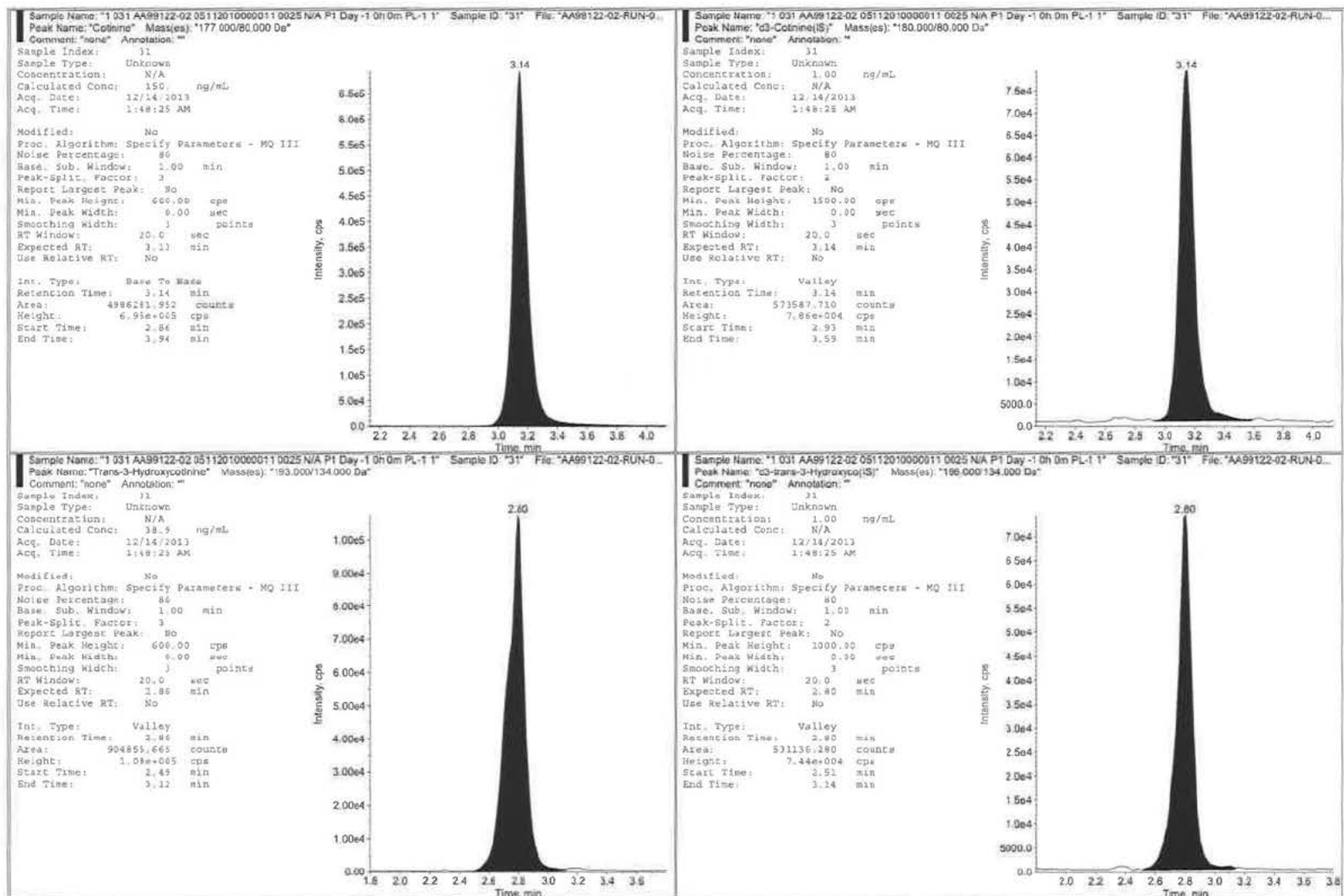


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

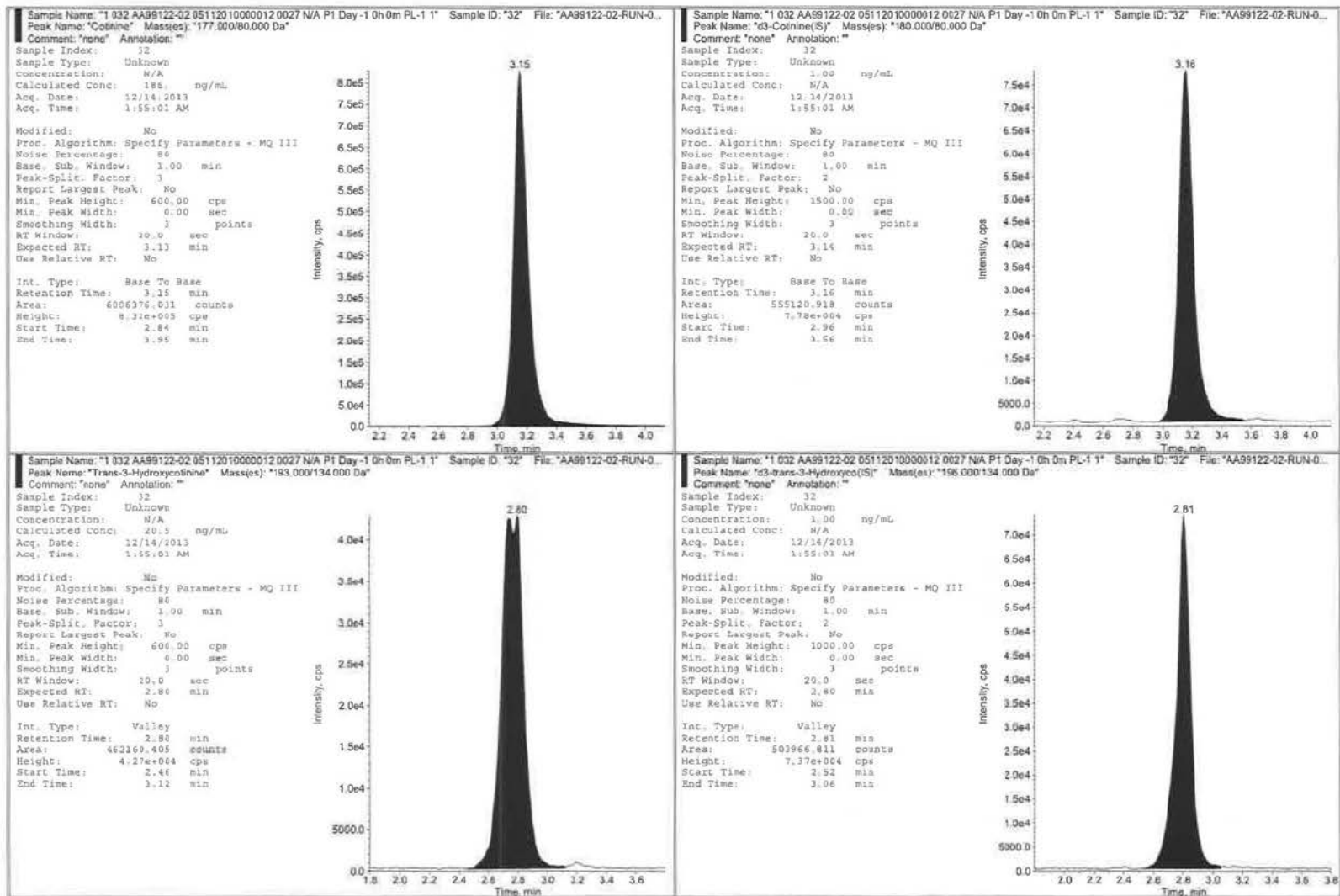




Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

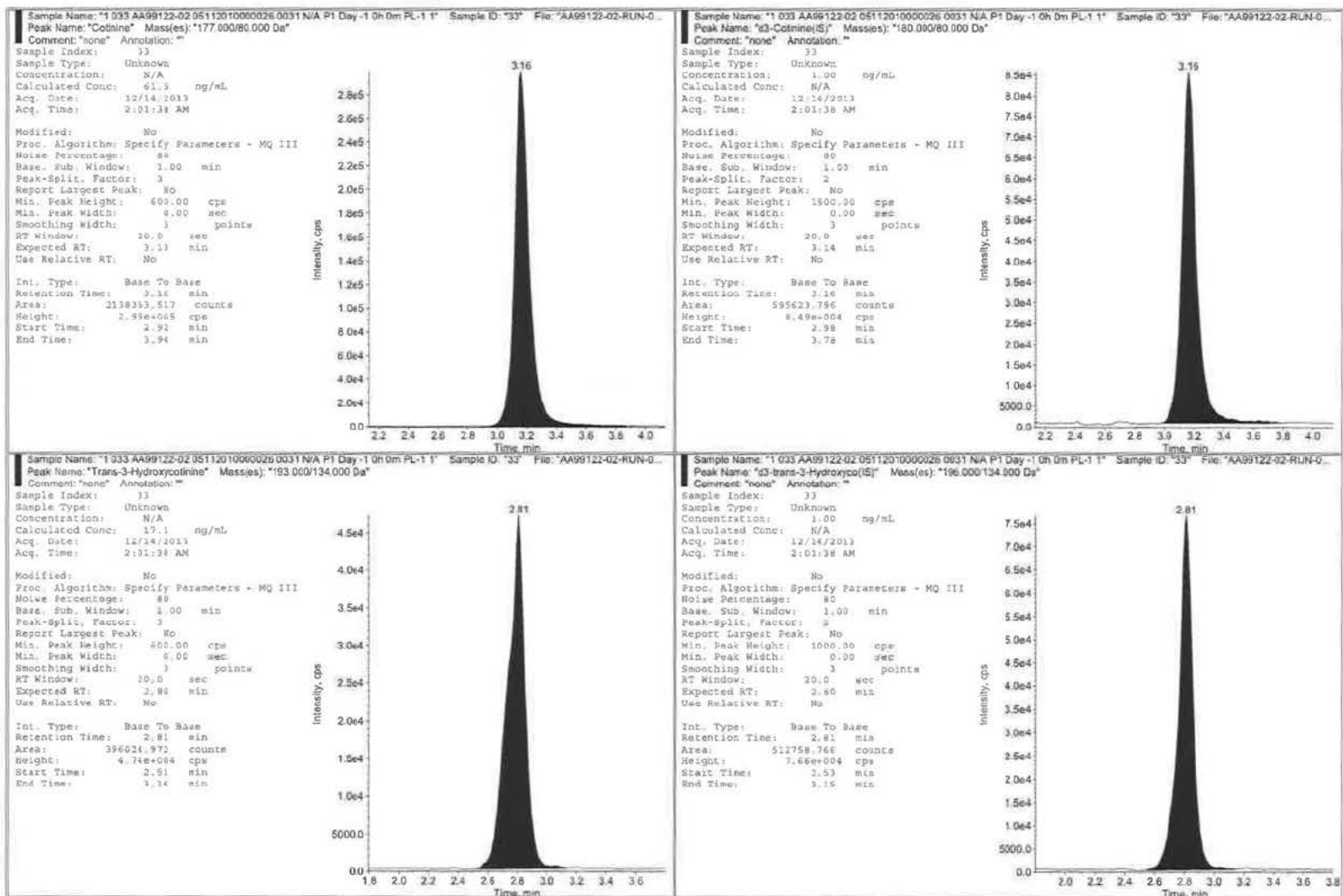


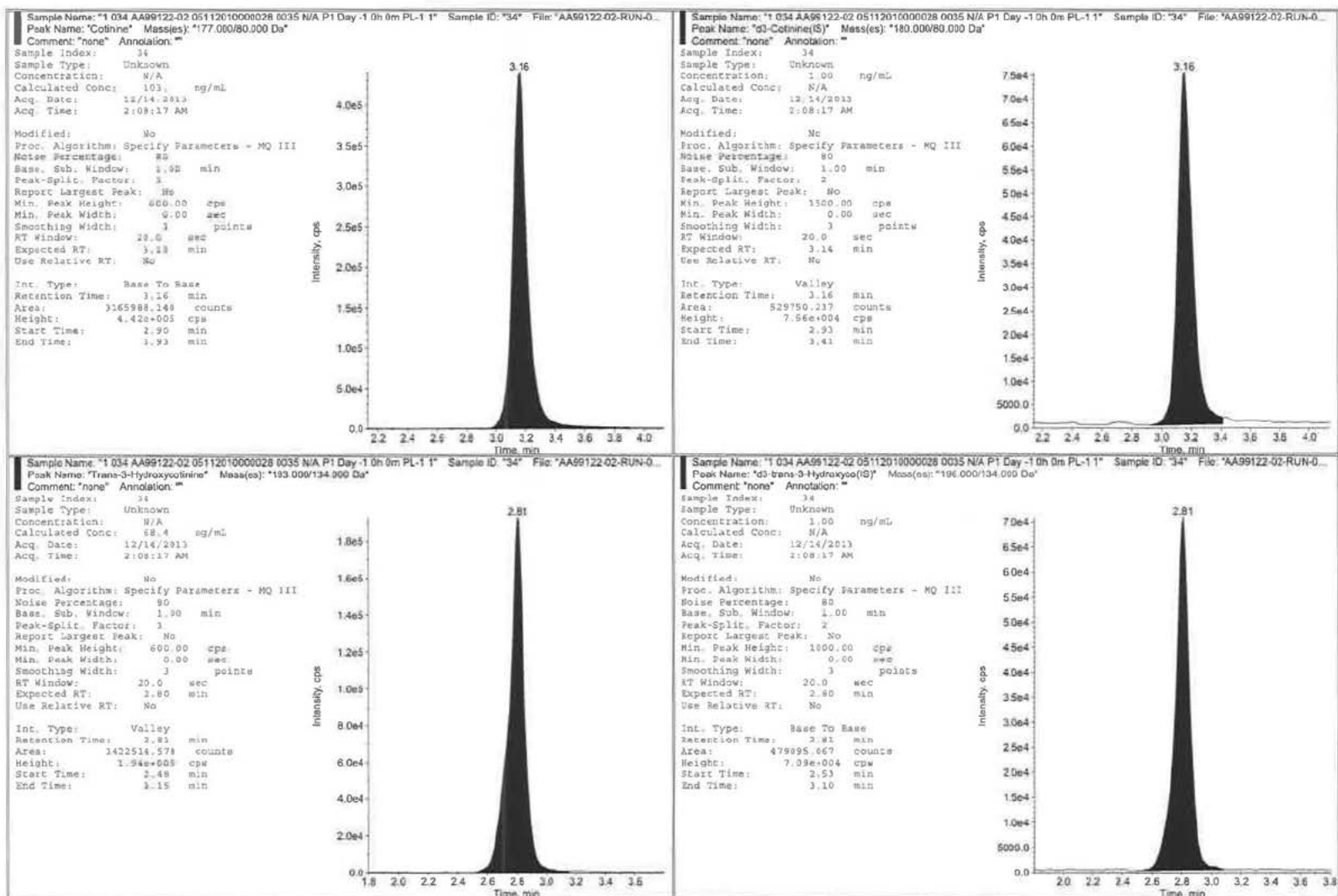
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



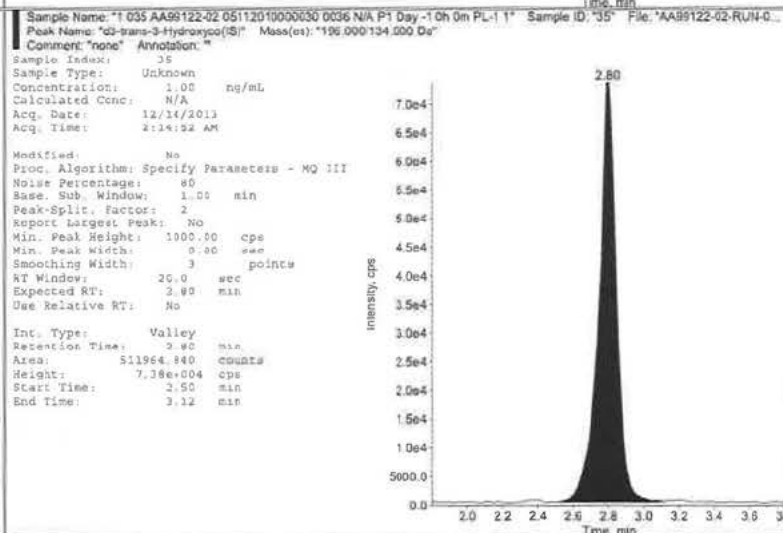
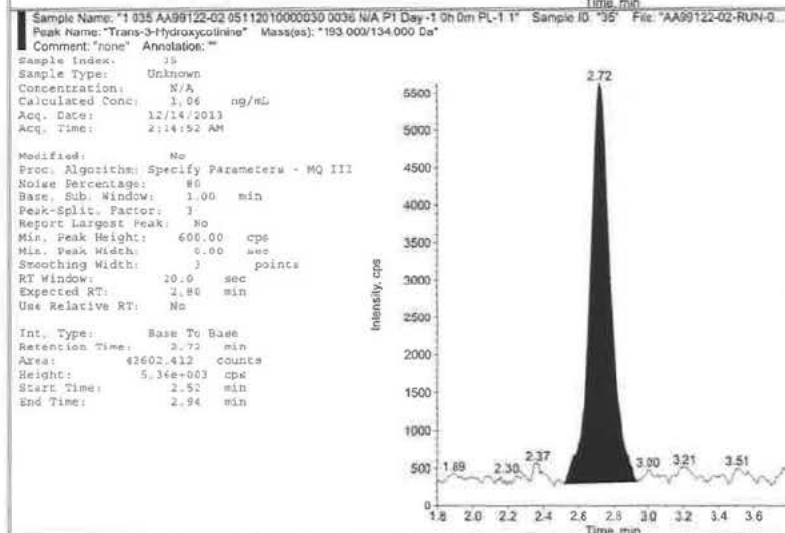
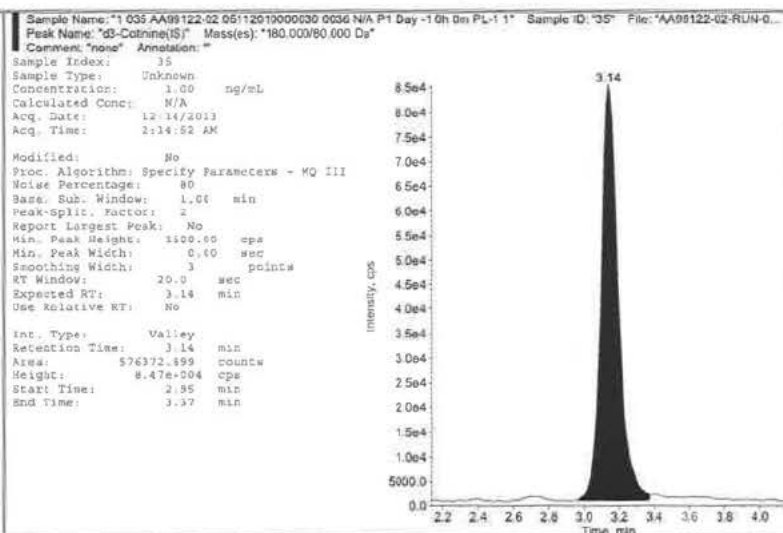
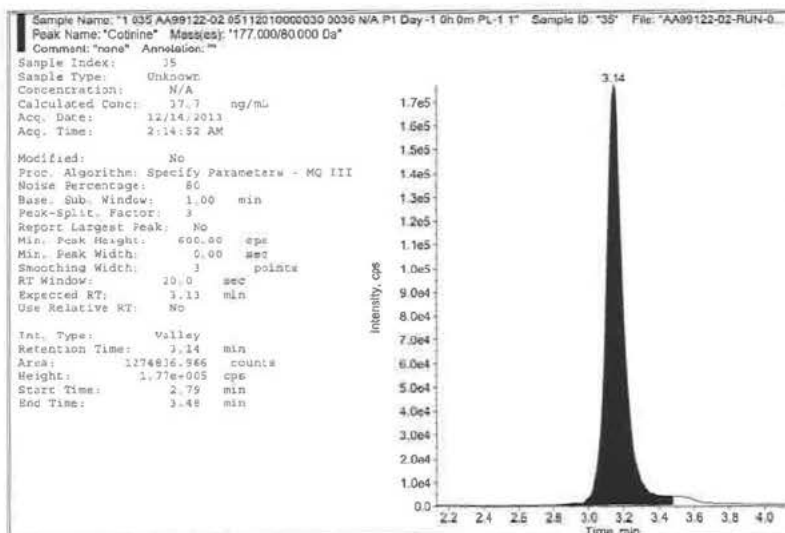


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

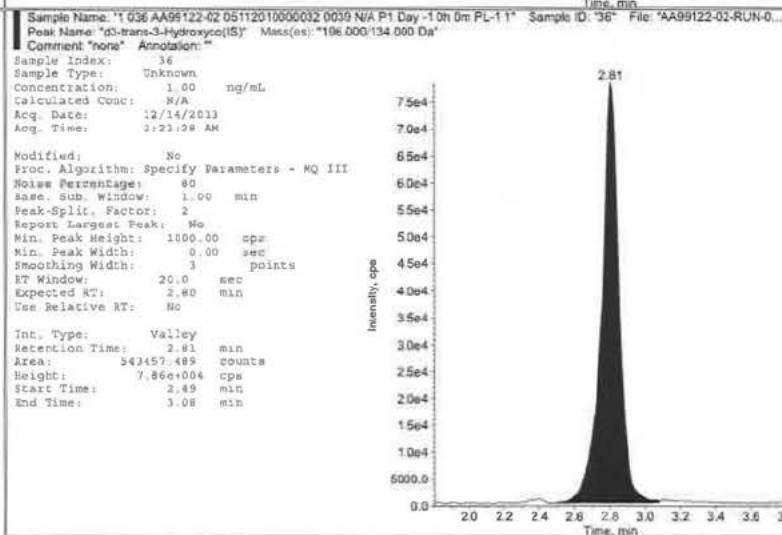
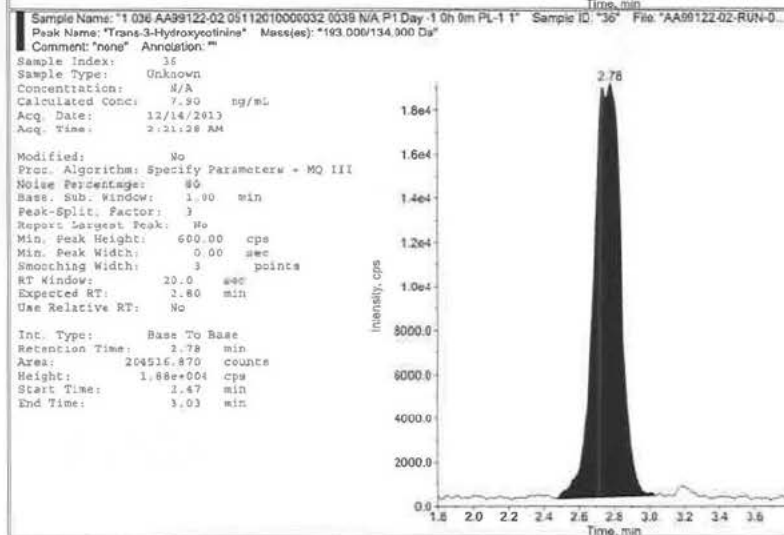
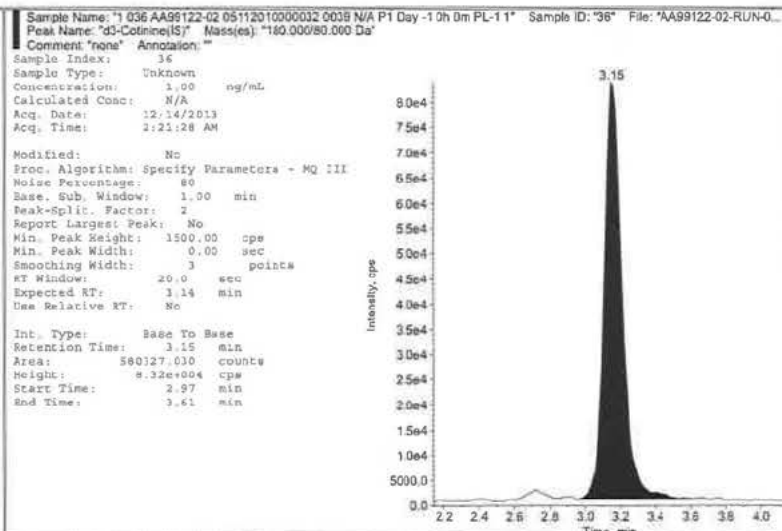
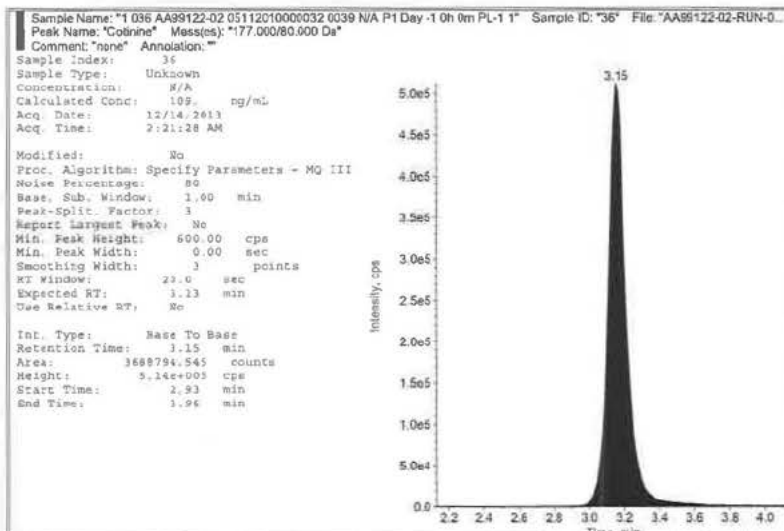




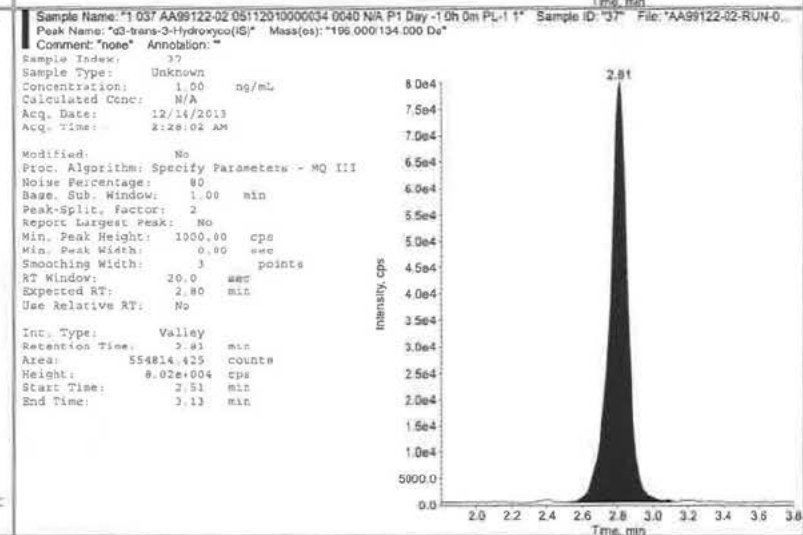
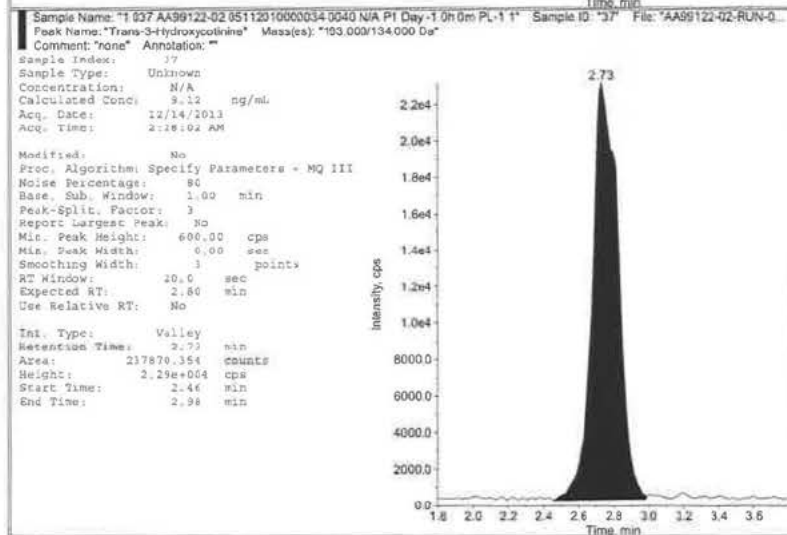
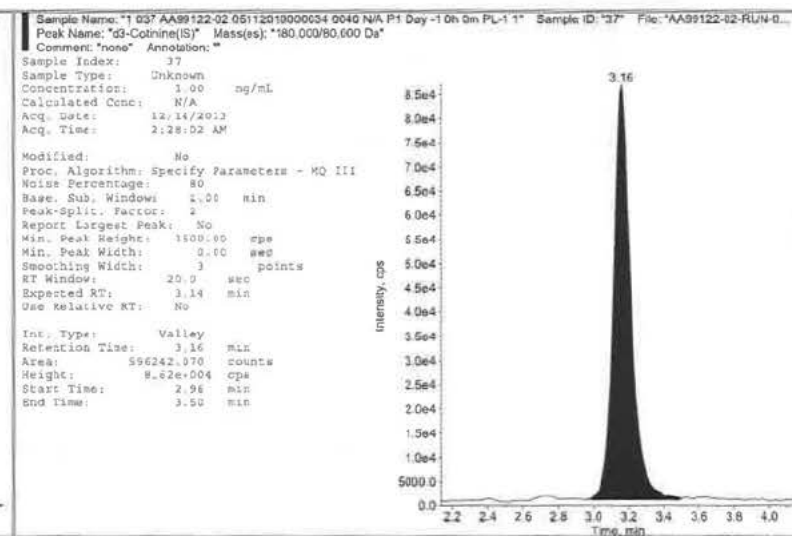
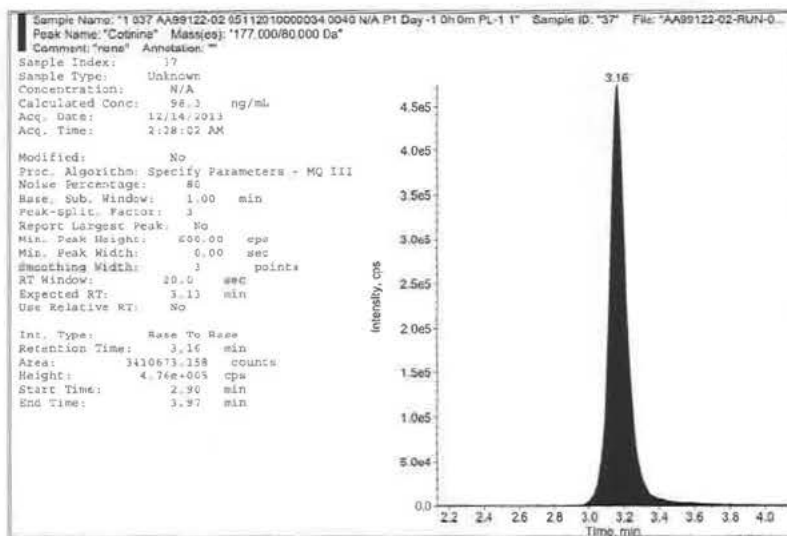
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

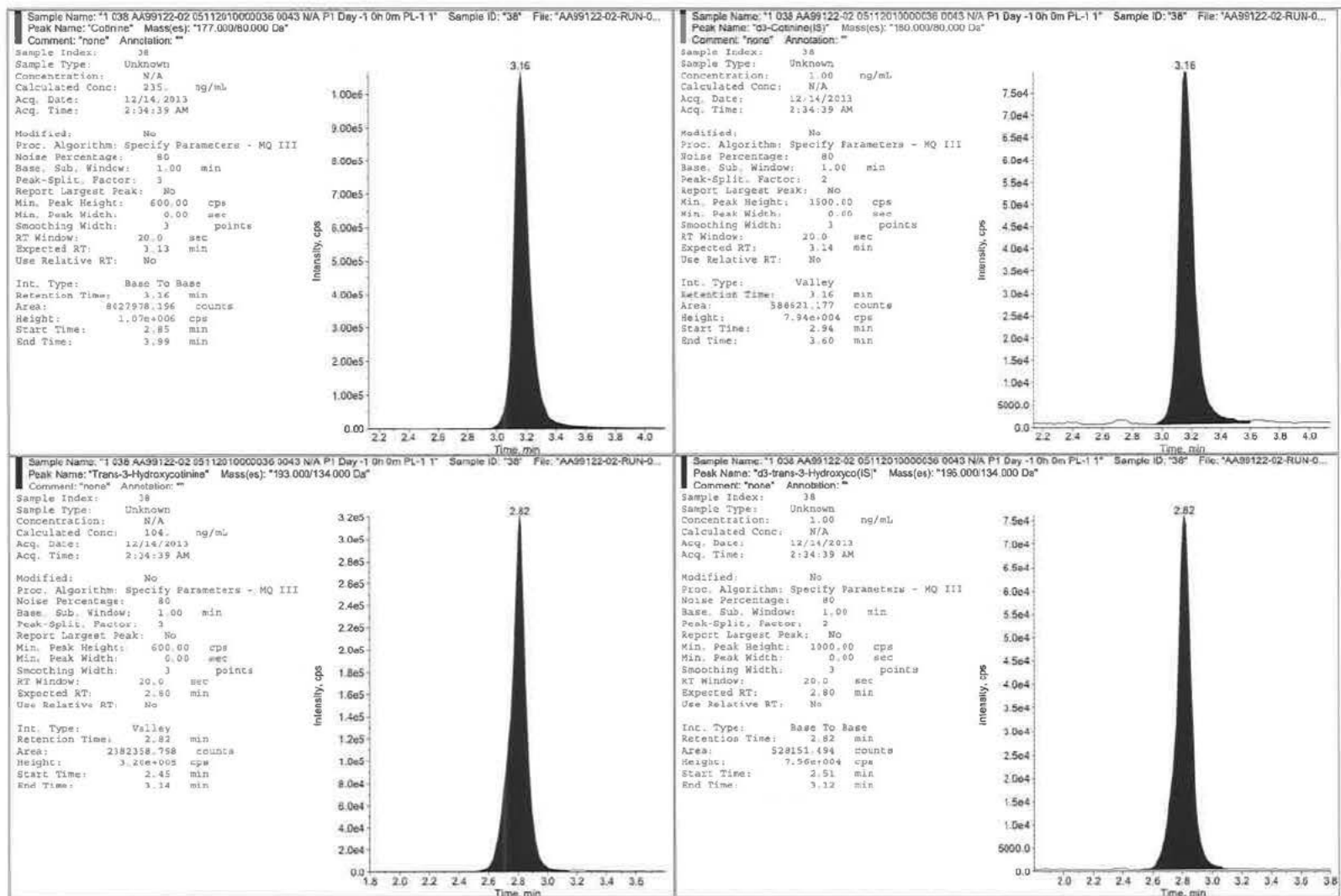


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



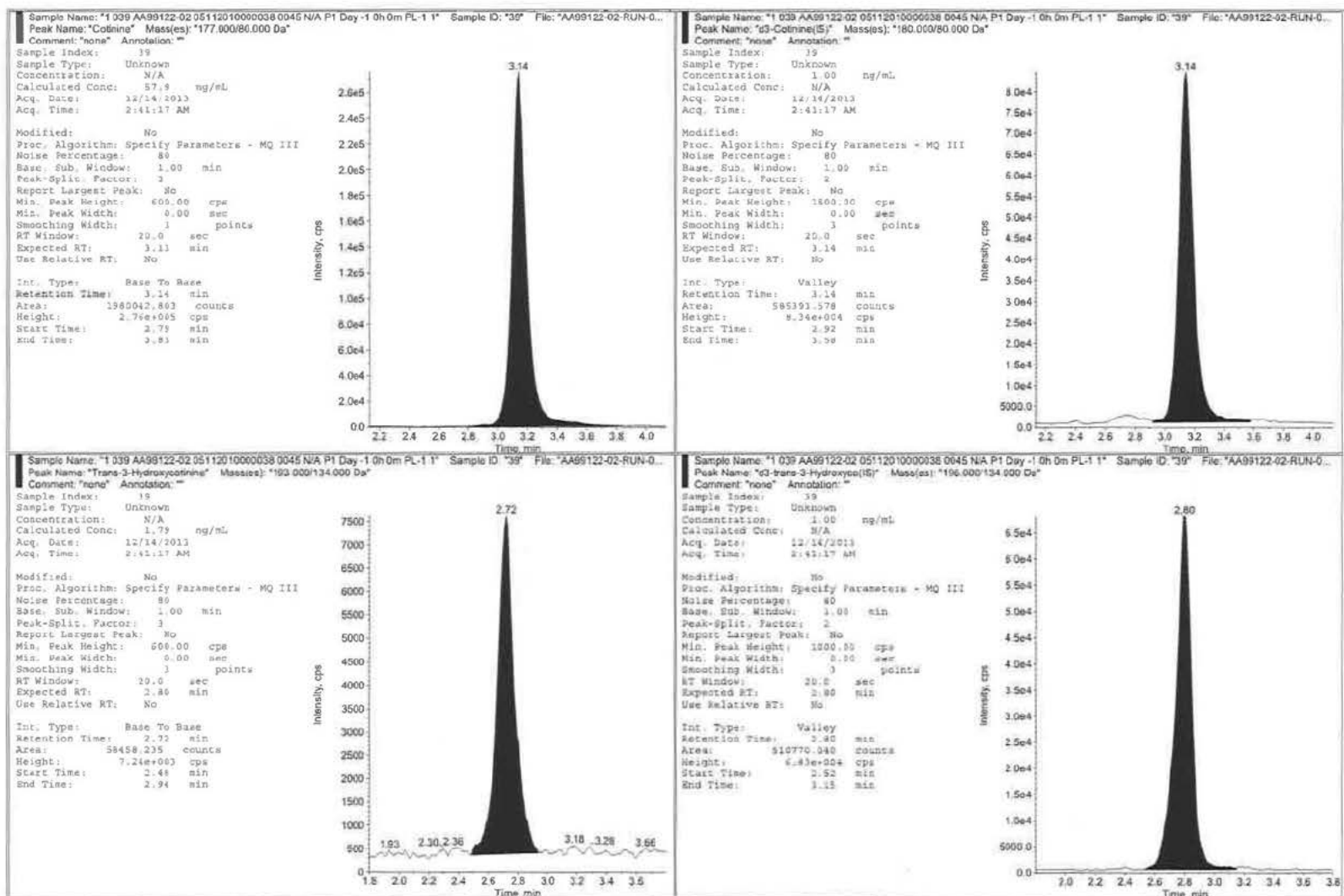
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

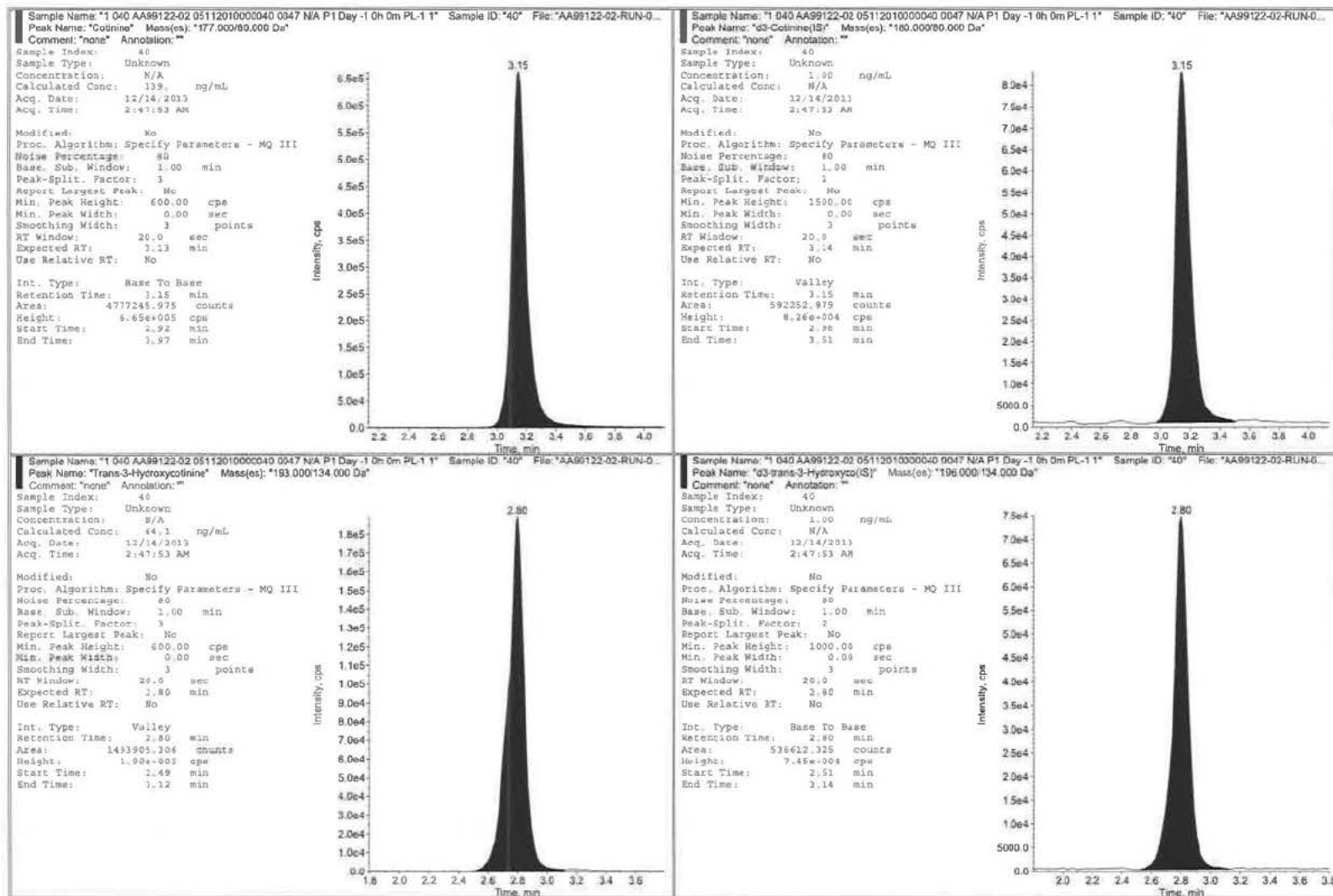




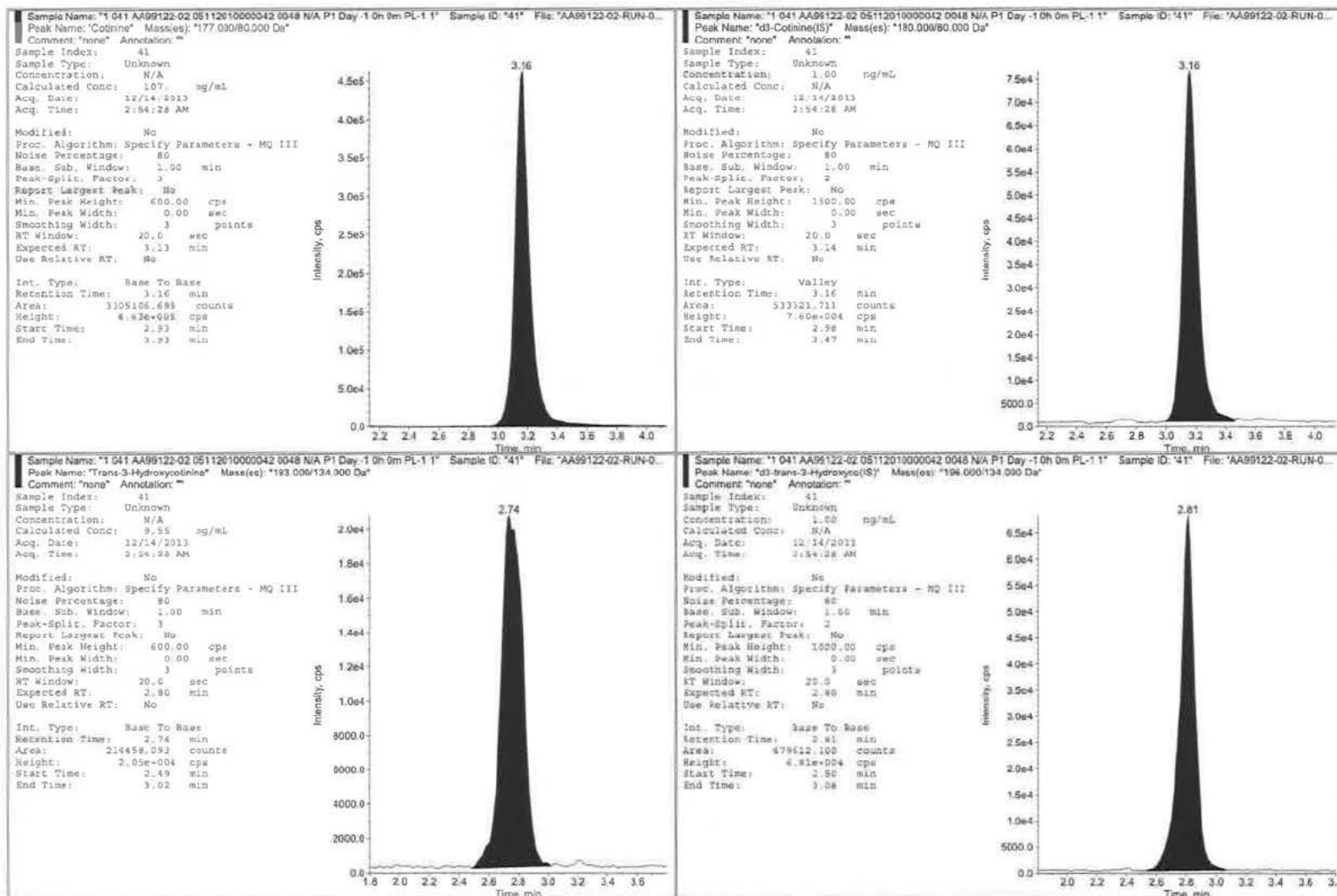


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

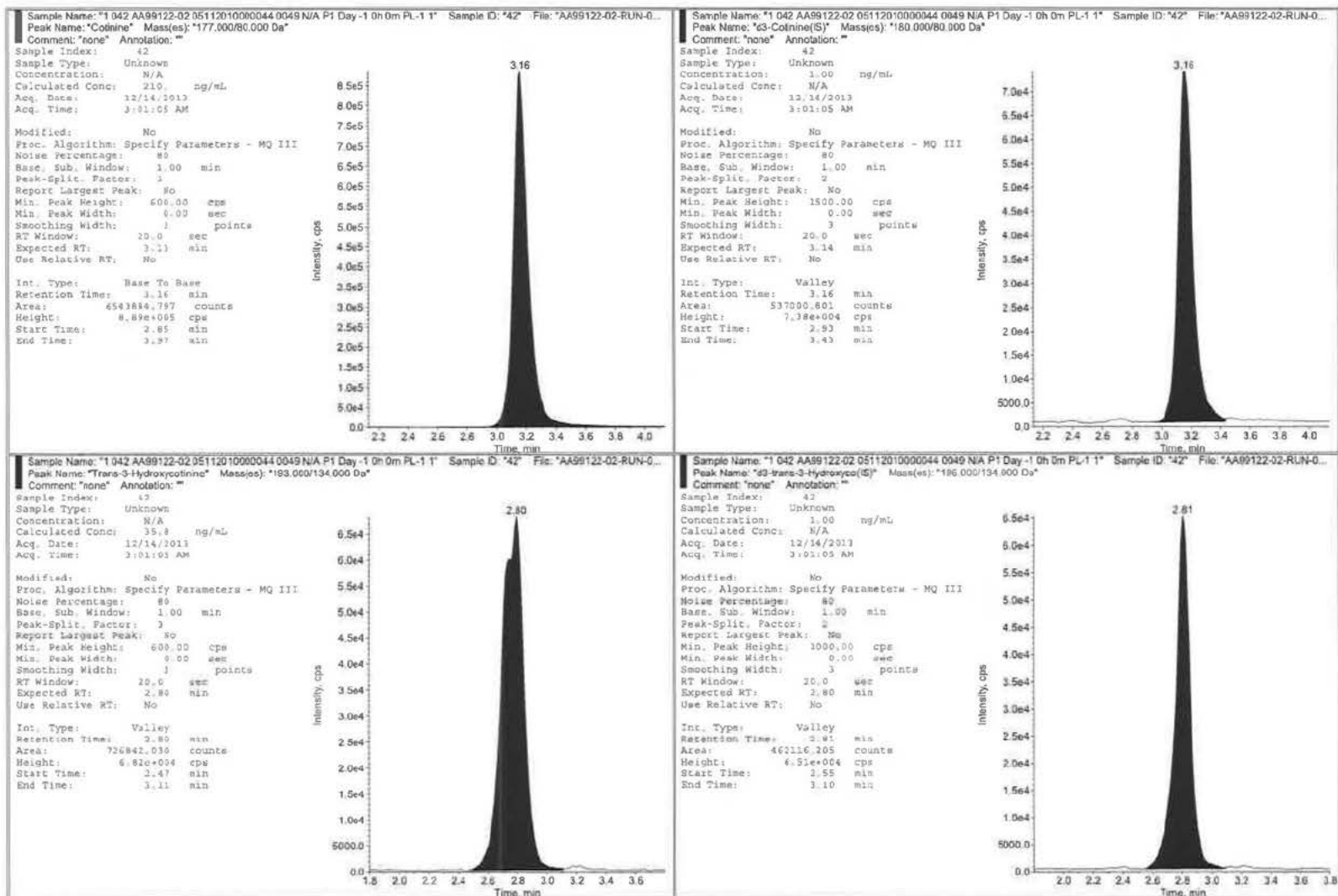




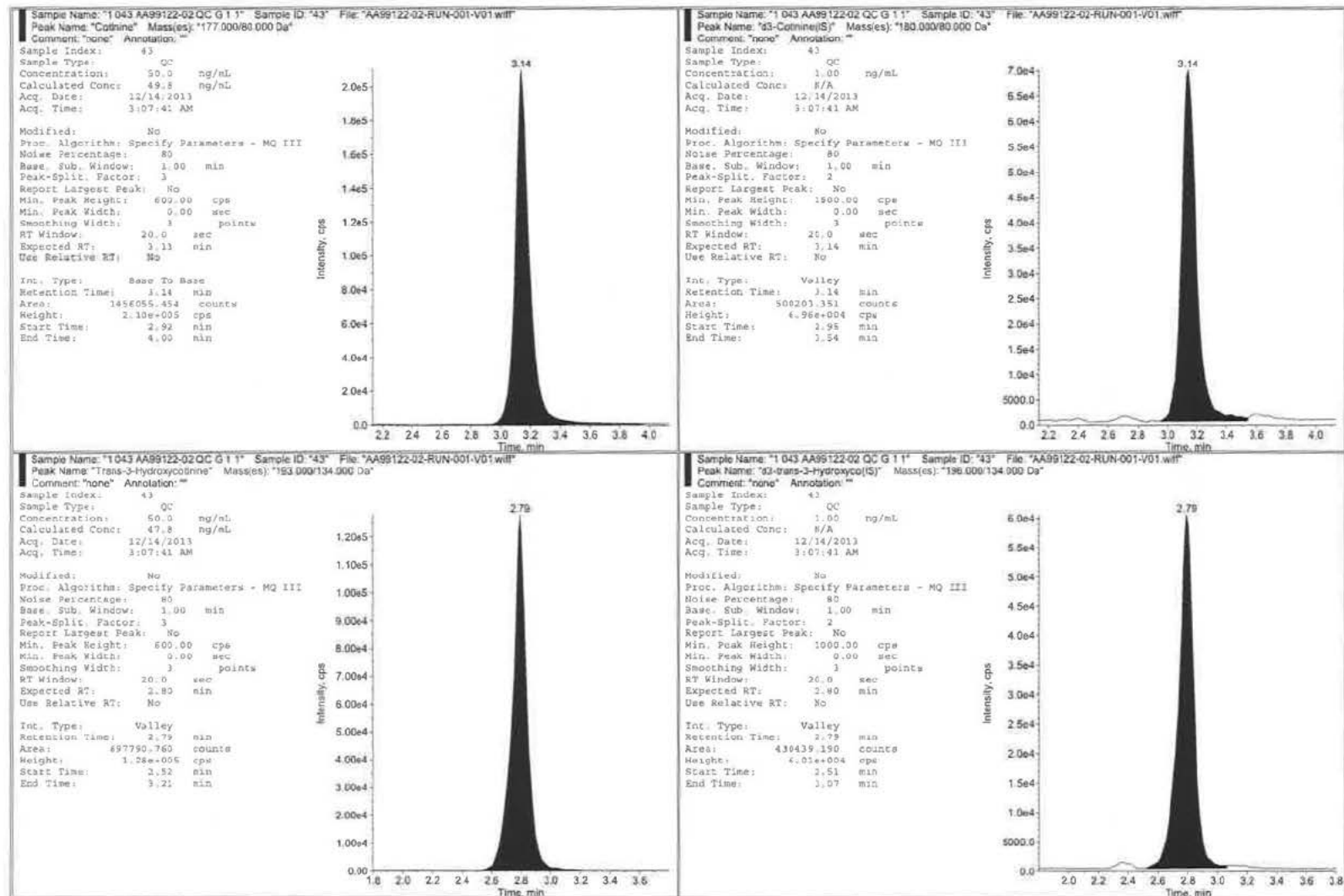
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

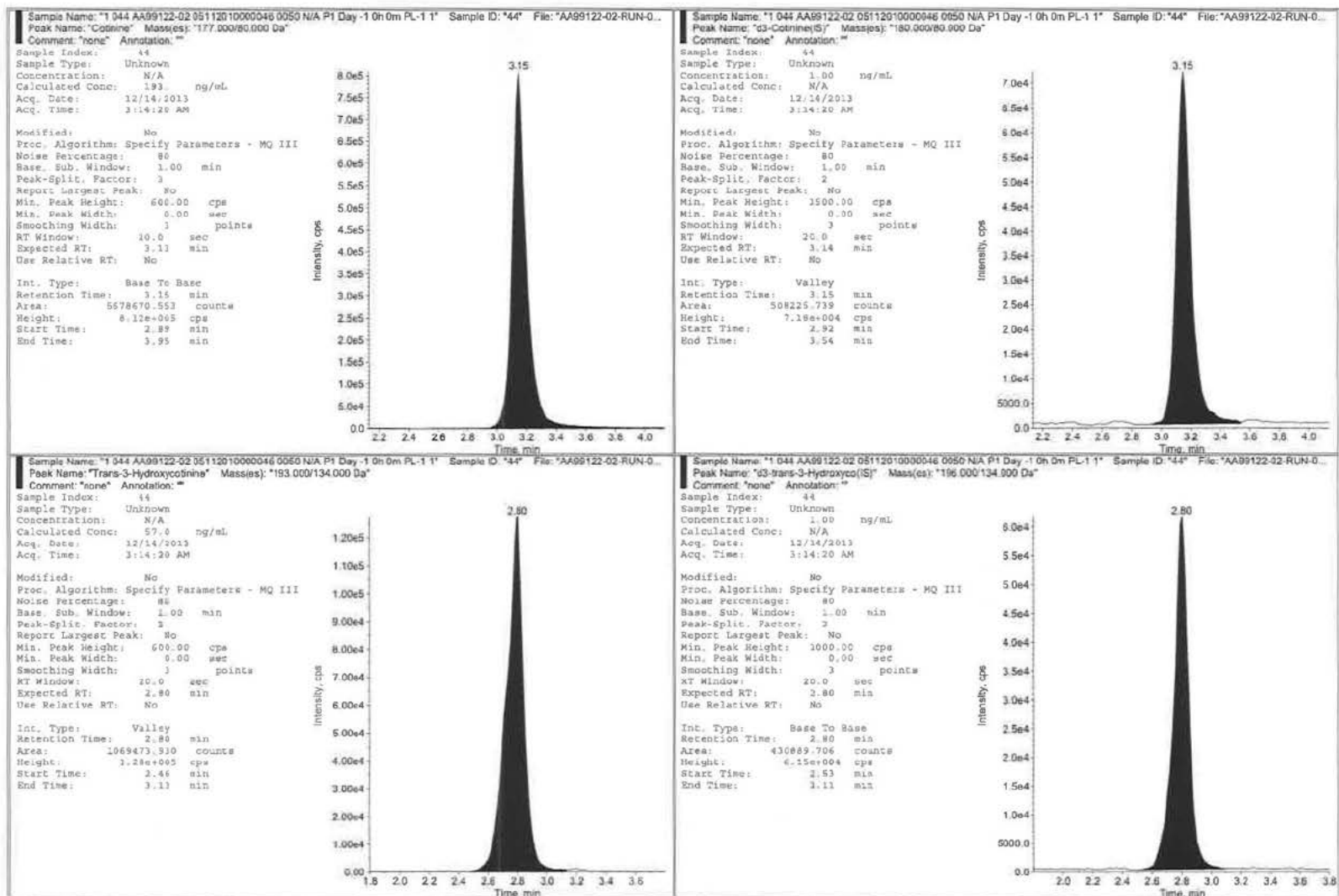


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02





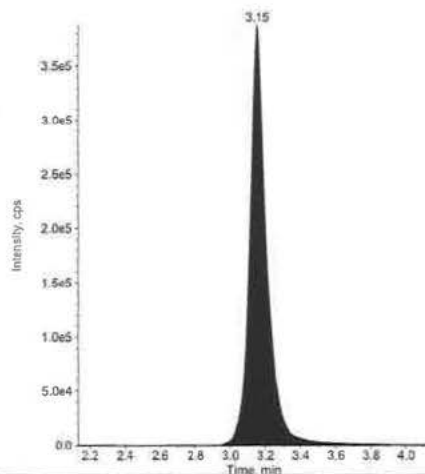


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

Sample Name: "1 045 AA99122-02 0511201000048 0051 N/A P1 Day -1 0h 0m PL-1 1" Sample ID: "45" File: "AA99122-02-RUN-0...  
Peak Name: "Cotinine" Mass(es): "177.000/80.000 Da"  
Comment: "none" Annotation: "  
Sample Index: 45  
Sample Type: Unknown  
Concentration: N/A  
Calculated Conc: 81.2 ng/mL  
Acq. Date: 12/14/2013  
Acq. Time: 3:20:56 AM

Modified: No  
Proc. Algorithm: Specify Parameters - MQ III  
Noise Percentage: 80  
Base, Sub. Window: 1.00 min  
Peak-Split. Factor: 3  
Report Largest Peak: No  
Min. Peak Height: 600.00 cps  
Min. Peak Width: 0.00 sec  
Smoothing Width: 3 points  
RT Window: 20.0 sec  
Expected RT: 3.13 min  
Use Relative RT: No

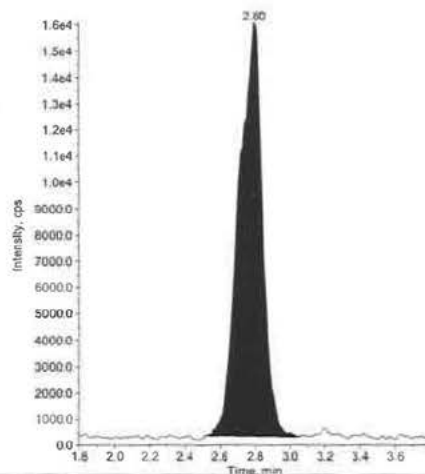
Int. Type: Base To Base  
Retention Time: 3.13 min  
Area: 2690985.137 counts  
Height: 3.90e+005 cps  
Start Time: 2.93 min  
End Time: 3.94 min



Sample Name: "1 045 AA99122-02 0511201000048 0051 N/A P1 Day -1 0h 0m PL-1 1" Sample ID: "45" File: "AA99122-02-RUN-0...  
Peak Name: "trans-3-Hydroxycotinine" Mass(es): "193.000/134.000 Da"  
Comment: "none" Annotation: "  
Sample Index: 45  
Sample Type: Unknown  
Concentration: N/A  
Calculated Conc: 6.29 ng/mL  
Acq. Date: 12/14/2013  
Acq. Time: 3:20:56 AM

Modified: No  
Proc. Algorithm: Specify Parameters - MQ III  
Noise Percentage: 80  
Base, Sub. Window: 1.00 min  
Peak-Split. Factor: 3  
Report Largest Peak: No  
Min. Peak Height: 600.00 cps  
Min. Peak Width: 0.00 sec  
Smoothing Width: 3 points  
RT Window: 20.0 sec  
Expected RT: 2.80 min  
Use Relative RT: No

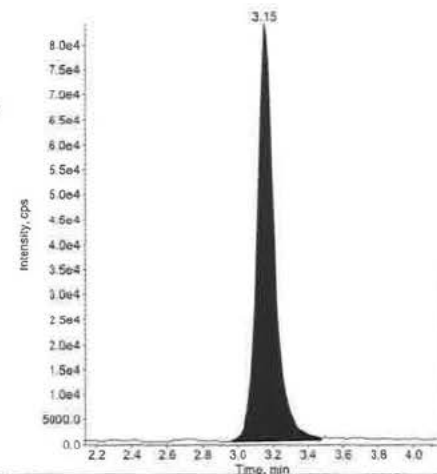
Int. Type: Base To Base  
Retention Time: 2.80 min  
Area: 150237.698 counts  
Height: 1.58e+004 cps  
Start Time: 2.53 min  
End Time: 3.04 min



Sample Name: "1 045 AA99122-02 0511201000048 0051 N/A P1 Day -1 0h 0m PL-1 1" Sample ID: "45" File: "AA99122-02-RUN-0...  
Peak Name: "d3-Cotinine(S)" Mass(es): "180.000/80.000 Da"  
Comment: "none" Annotation: "  
Sample Index: 45  
Sample Type: Unknown  
Concentration: 1.00 ng/mL  
Calculated Conc: N/A  
Acq. Date: 12/14/2013  
Acq. Time: 3:20:56 AM

Modified: No  
Proc. Algorithm: Specify Parameters - MQ III  
Noise Percentage: 80  
Base, Sub. Window: 1.00 min  
Peak-Split. Factor: 2  
Report Largest Peak: No  
Min. Peak Height: 1500.00 cps  
Min. Peak Width: 0.00 sec  
Smoothing Width: 3 points  
RT Window: 20.0 sec  
Expected RT: 3.14 min  
Use Relative RT: No

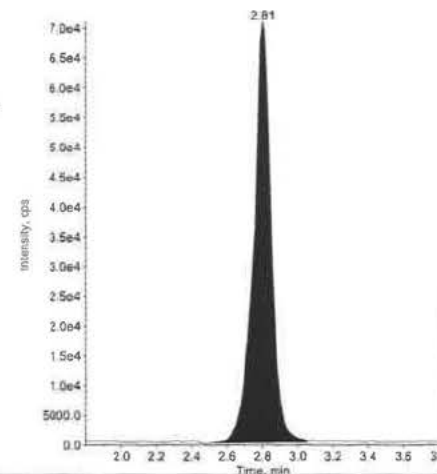
Int. Type: Valley  
Retention Time: 3.15 min  
Area: 568777.825 counts  
Height: 8.40e+004 cps  
Start Time: 2.93 min  
End Time: 3.48 min



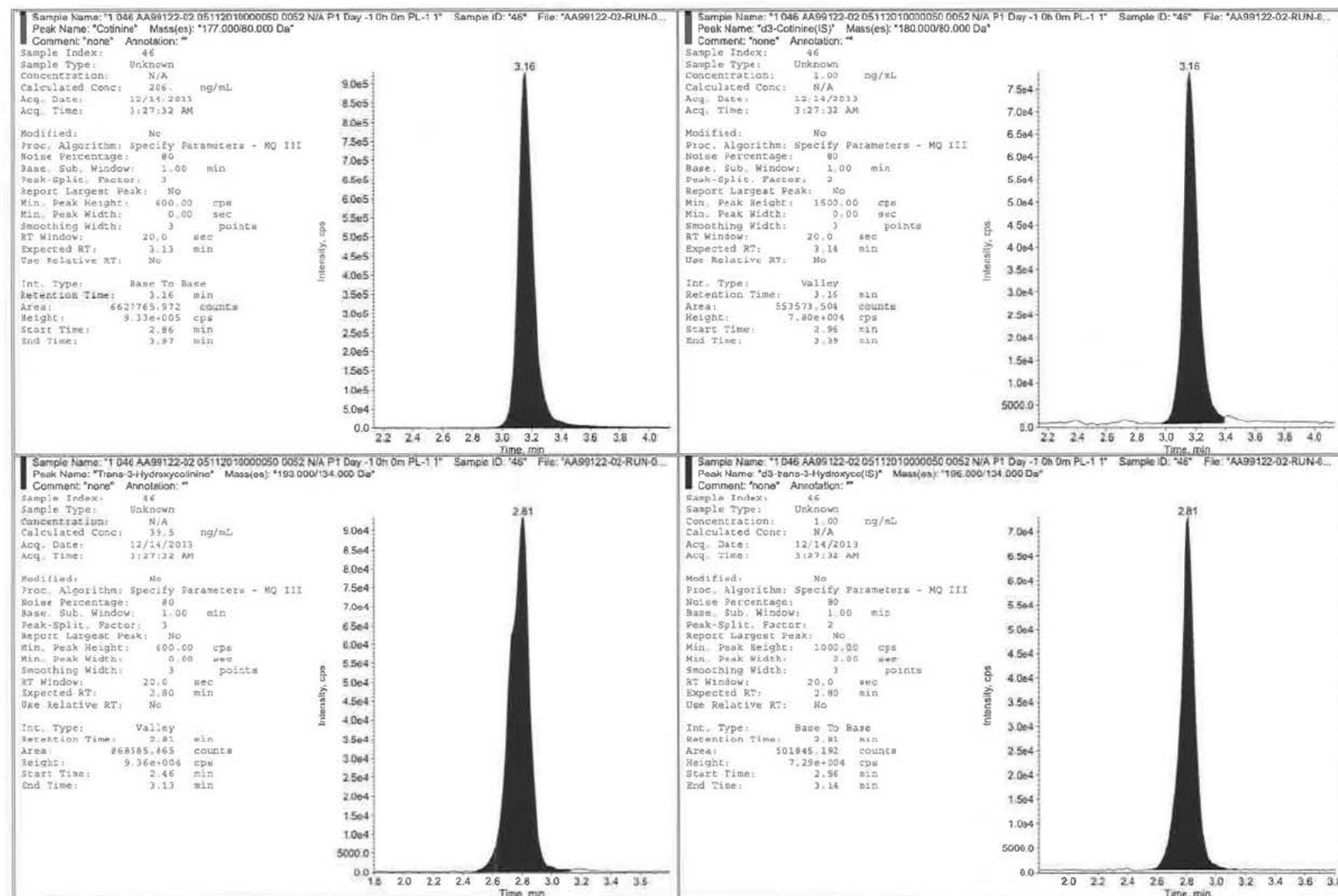
Sample Name: "1 045 AA99122-02 0511201000048 0051 N/A P1 Day -1 0h 0m PL-1 1" Sample ID: "45" File: "AA99122-02-RUN-0...  
Peak Name: "d3-trans-3-Hydroxycotinine(S)" Mass(es): "196.000/134.000 Da"  
Comment: "none" Annotation: "  
Sample Index: 45  
Sample Type: Unknown  
Concentration: 1.00 ng/mL  
Calculated Conc: N/A  
Acq. Date: 12/14/2013  
Acq. Time: 3:20:56 AM

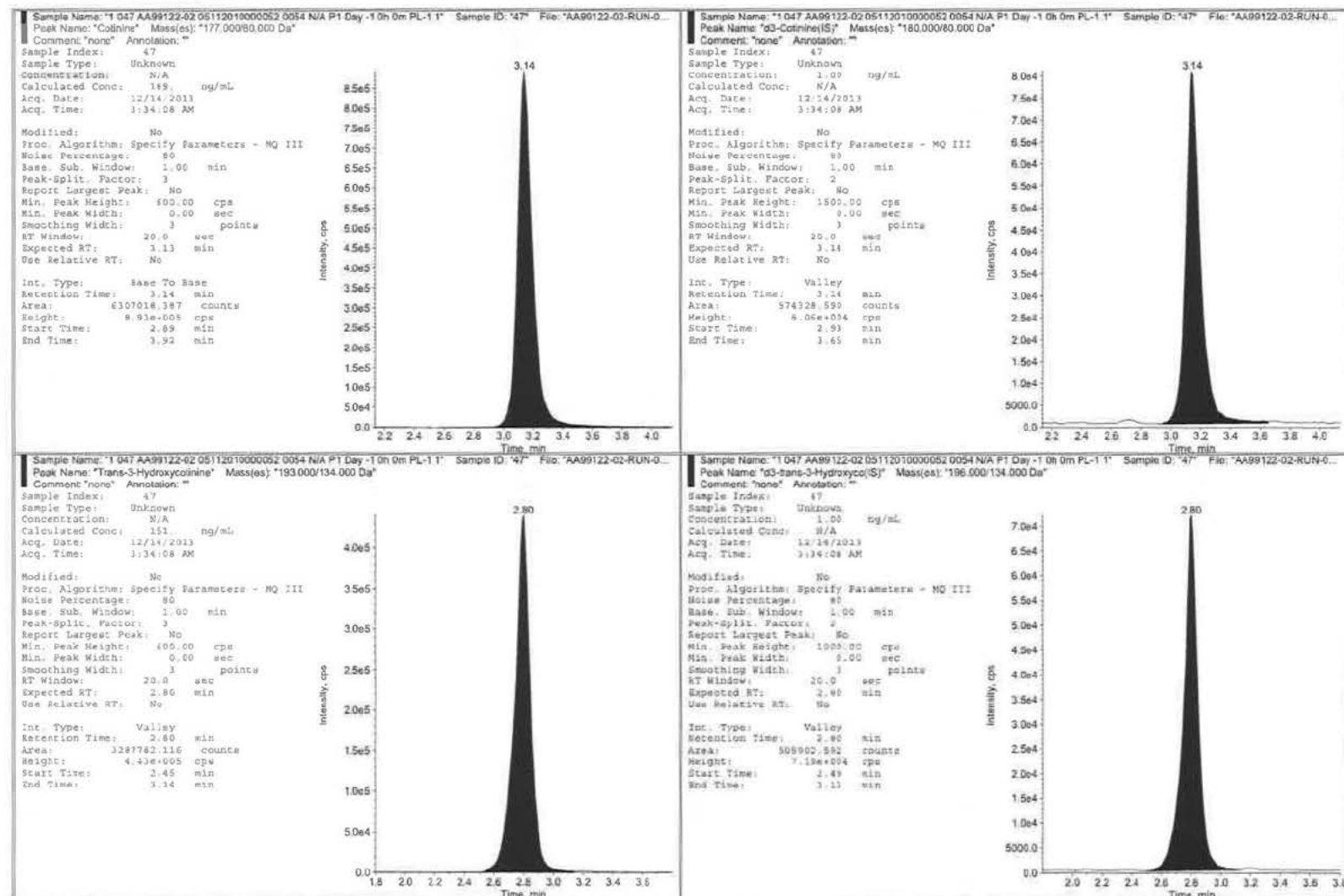
Modified: No  
Proc. Algorithm: Specify Parameters - MQ III  
Noise Percentage: 80  
Base, Sub. Window: 1.00 min  
Peak-Split. Factor: 2  
Report Largest Peak: No  
Min. Peak Height: 1500.00 cps  
Min. Peak Width: 0.00 sec  
Smoothing Width: 3 points  
RT Window: 20.0 sec  
Expected RT: 2.80 min  
Use Relative RT: No

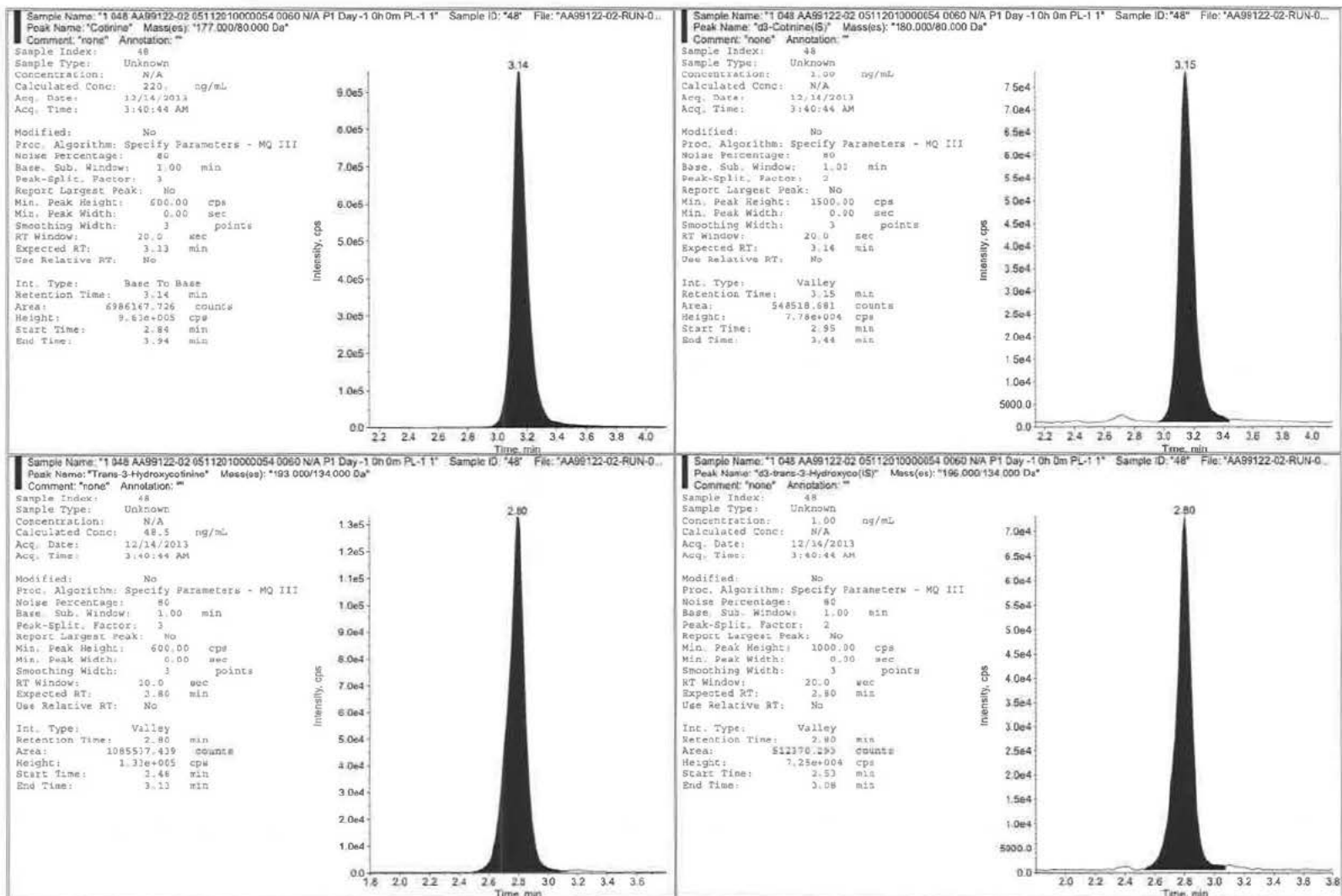
Int. Type: Valley  
Retention Time: 2.81 min  
Area: 488961.115 counts  
Height: 7.07e+004 cps  
Start Time: 2.52 min  
End Time: 3.04 min



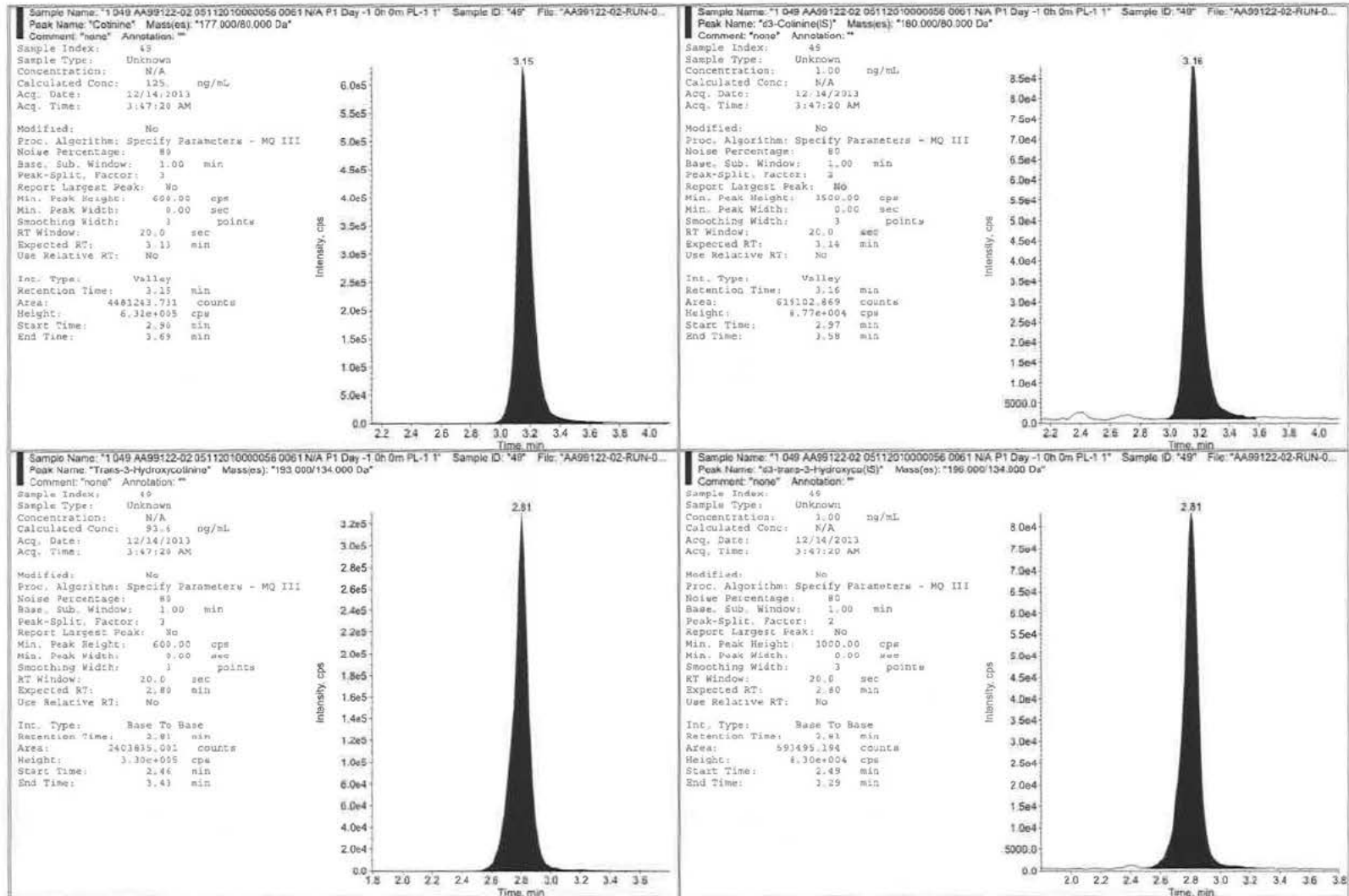
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

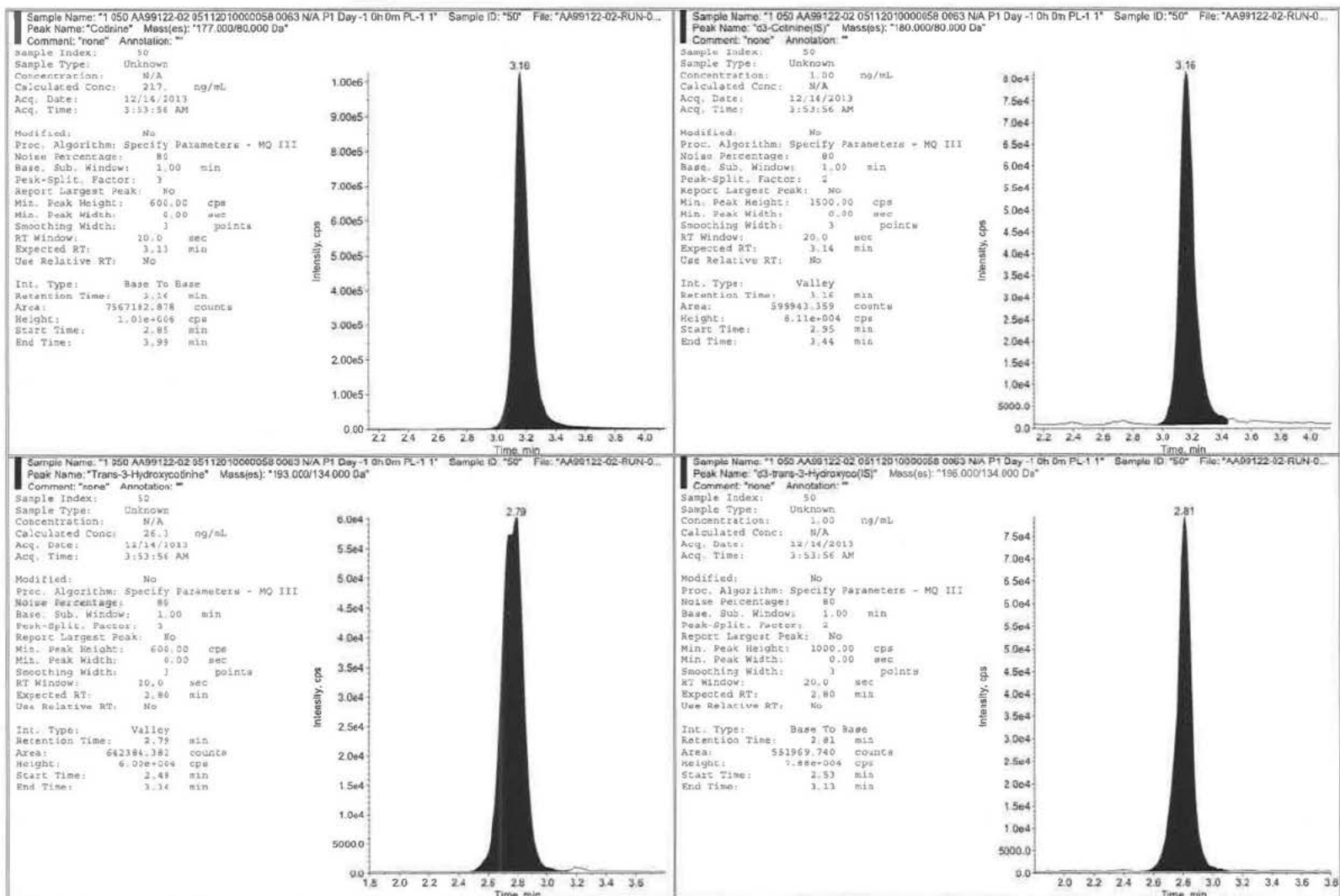






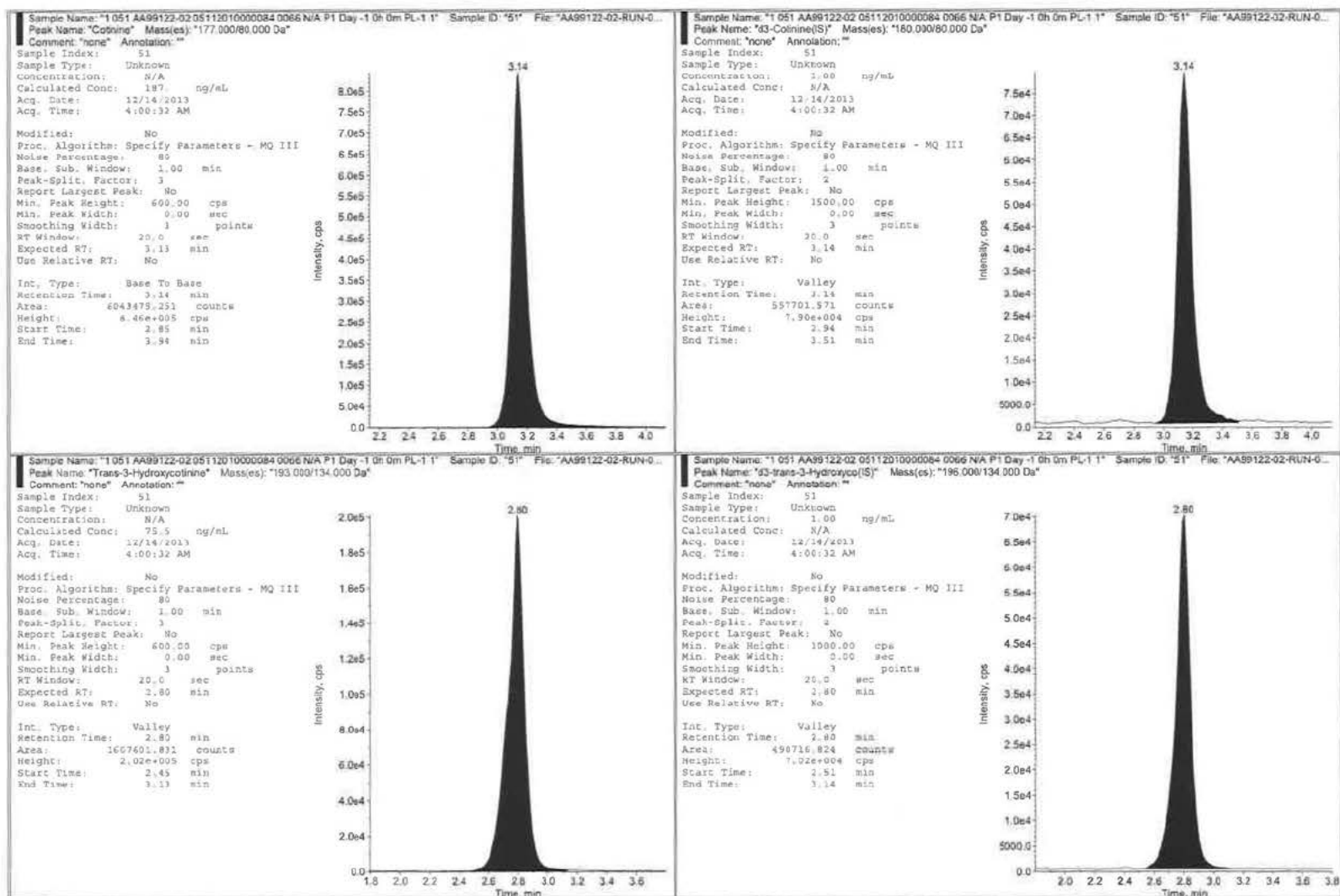
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



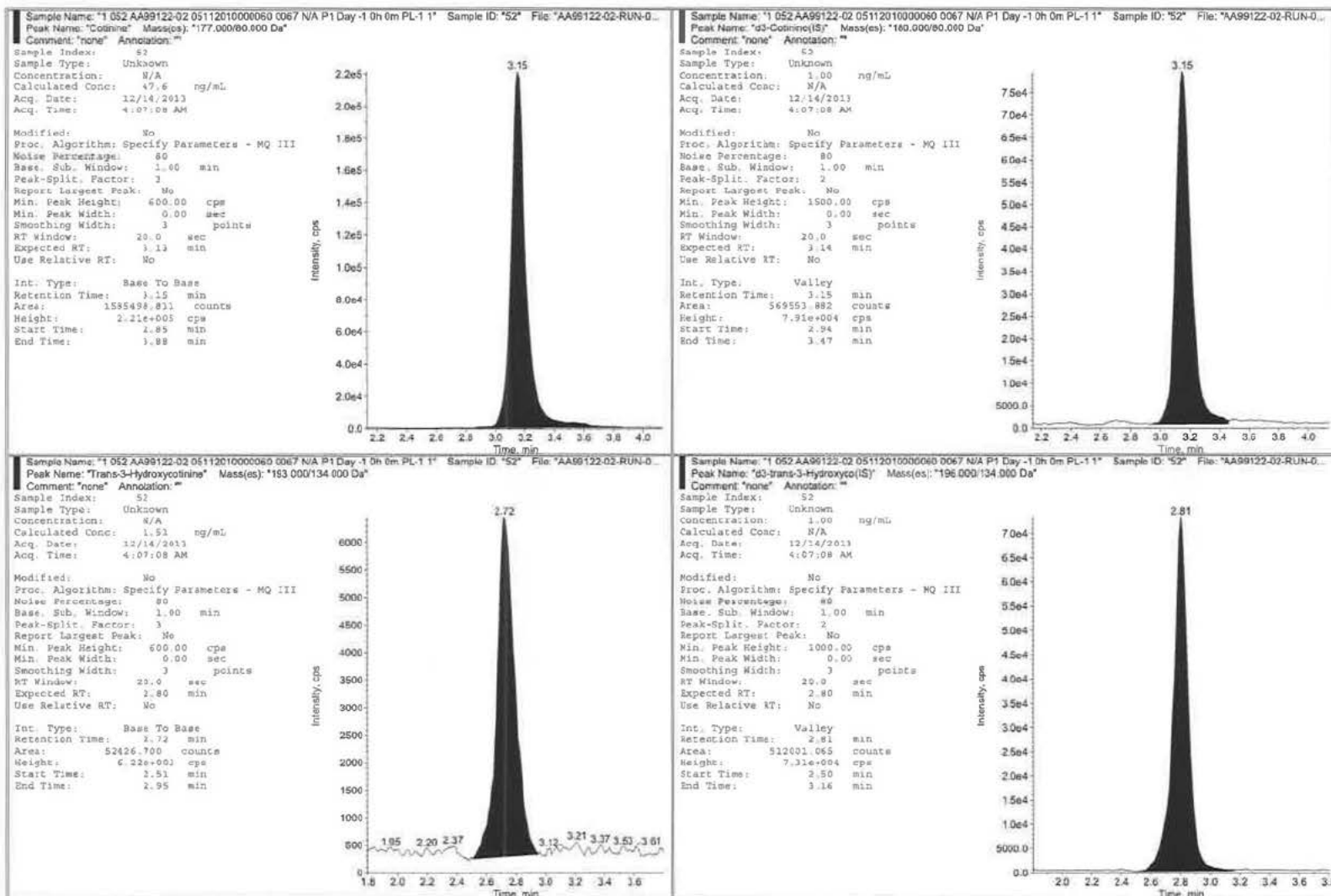




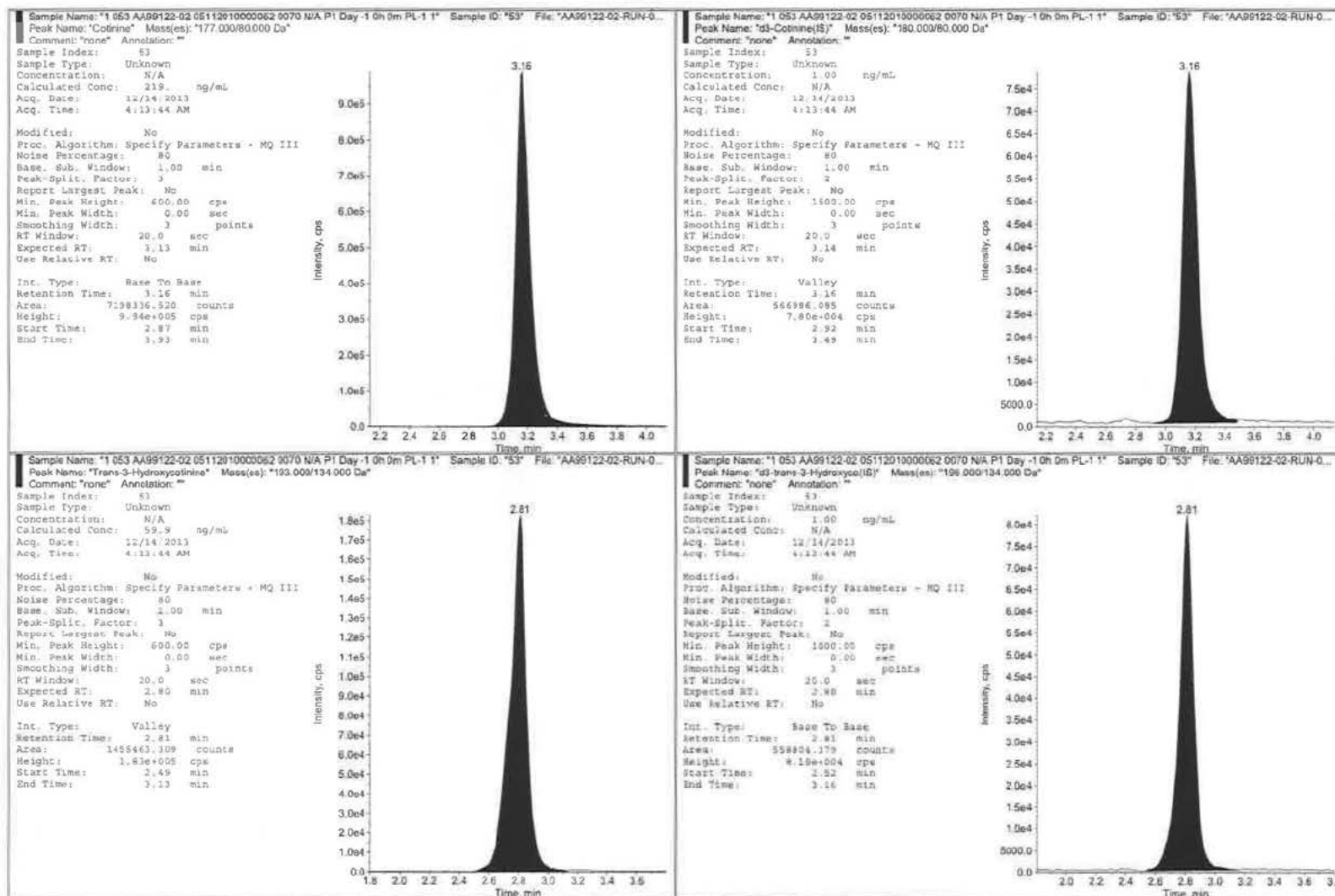
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

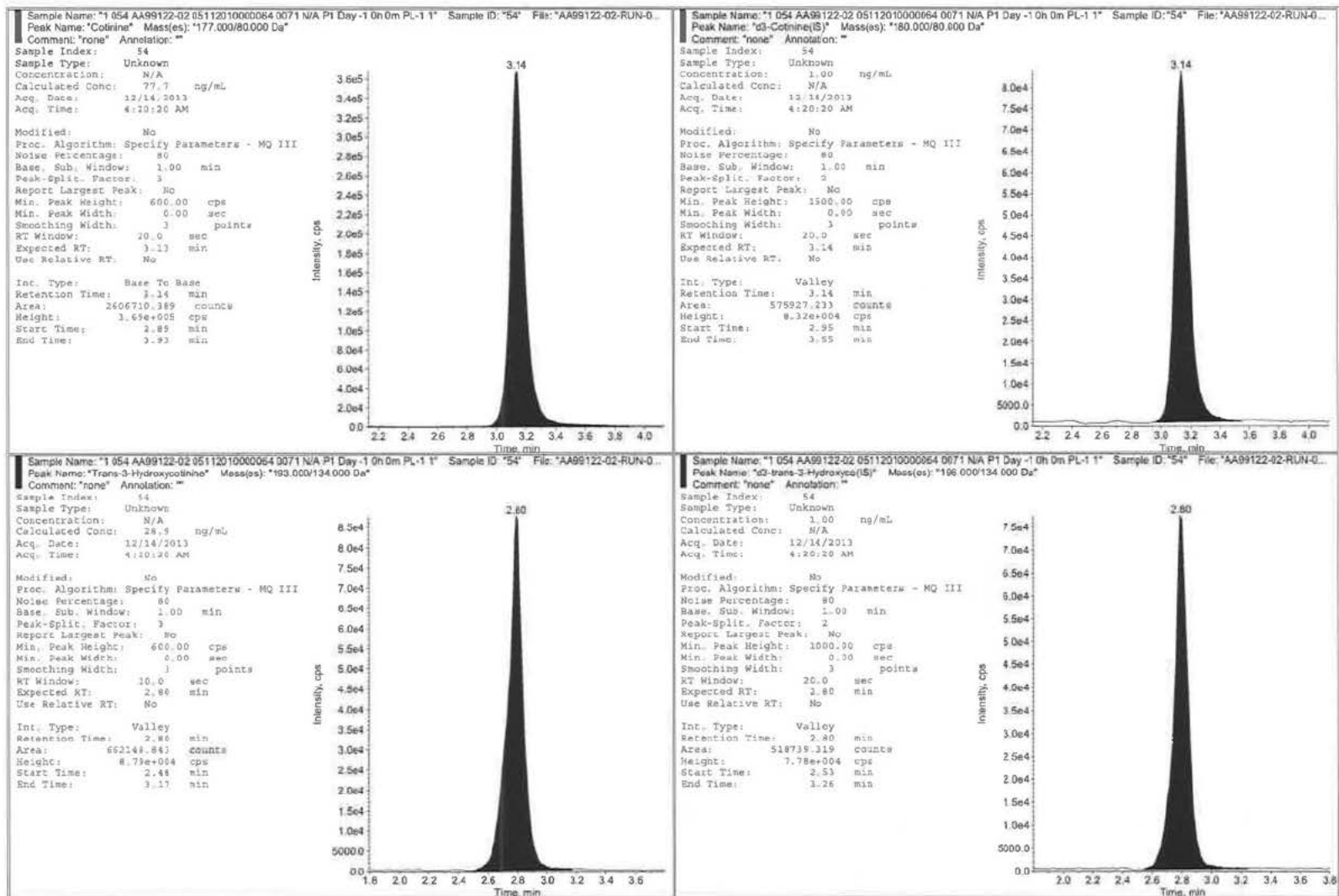


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

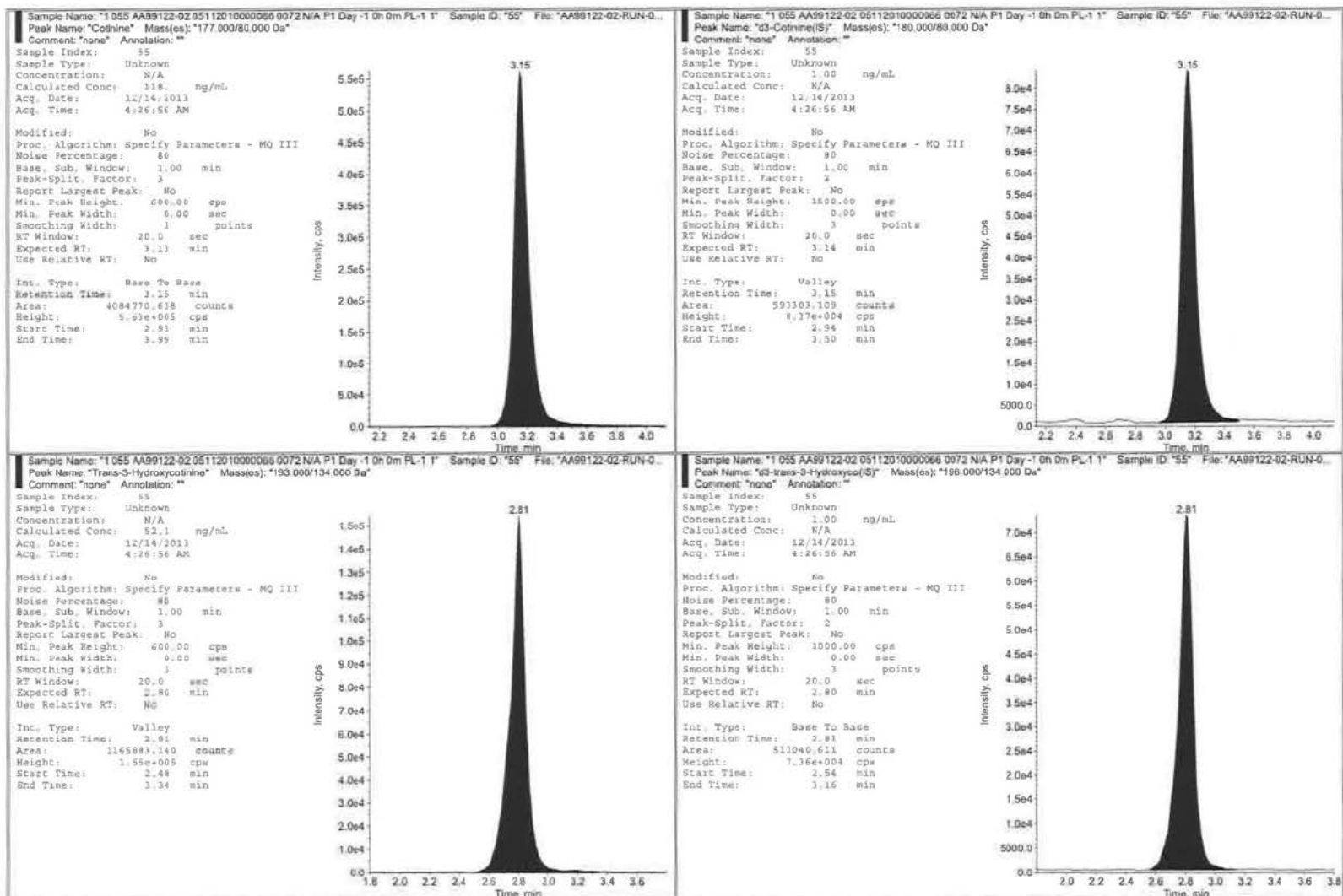


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

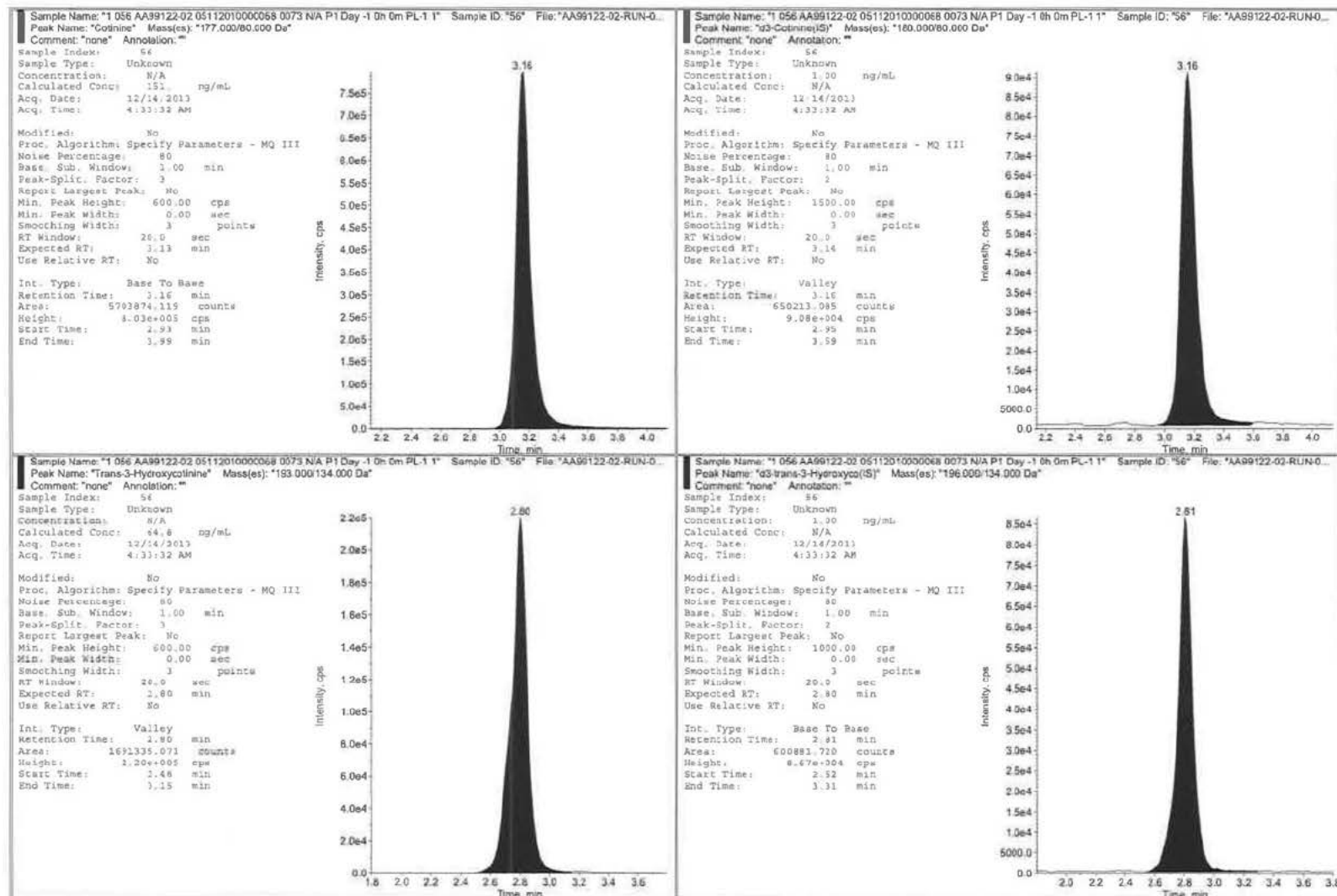




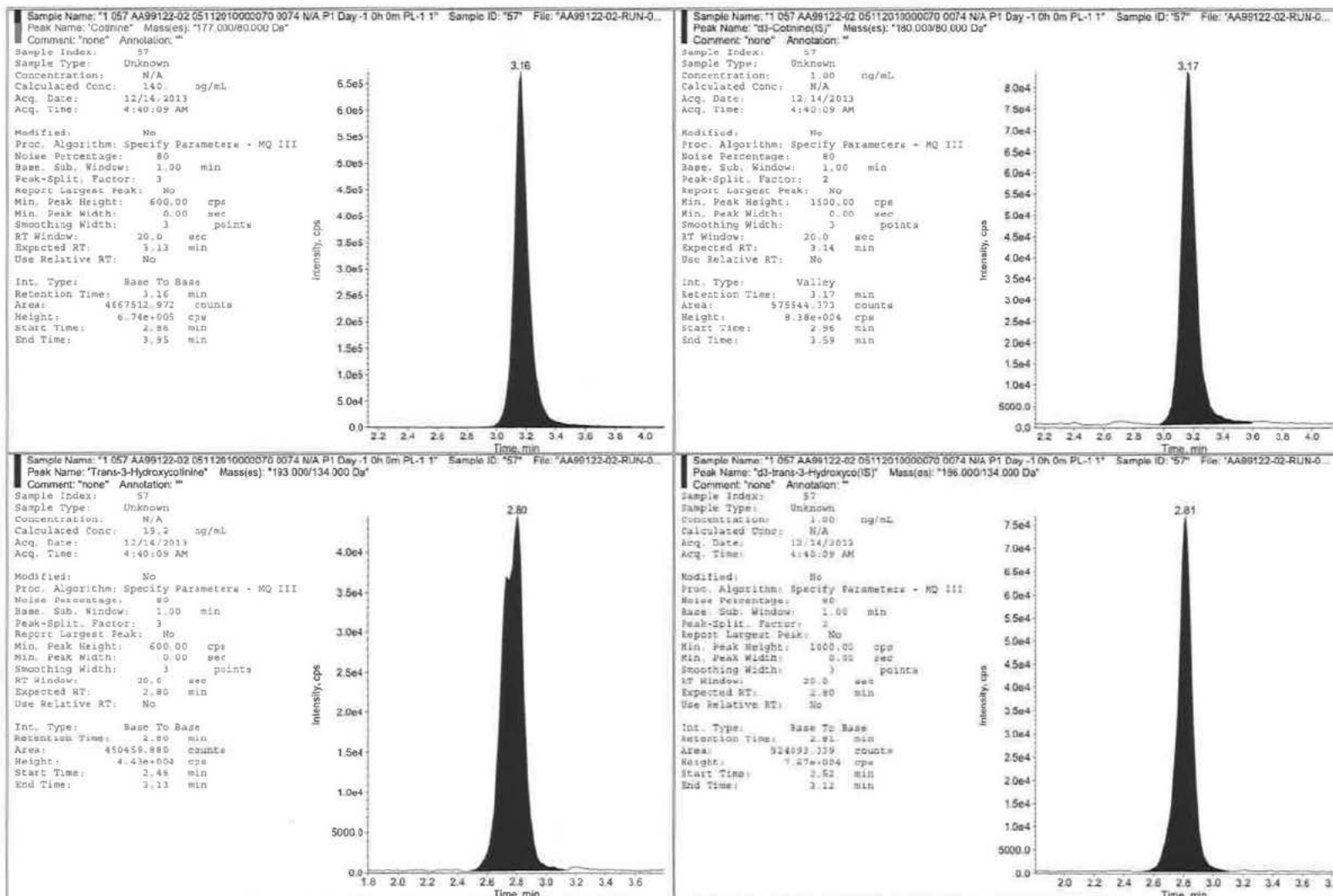
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

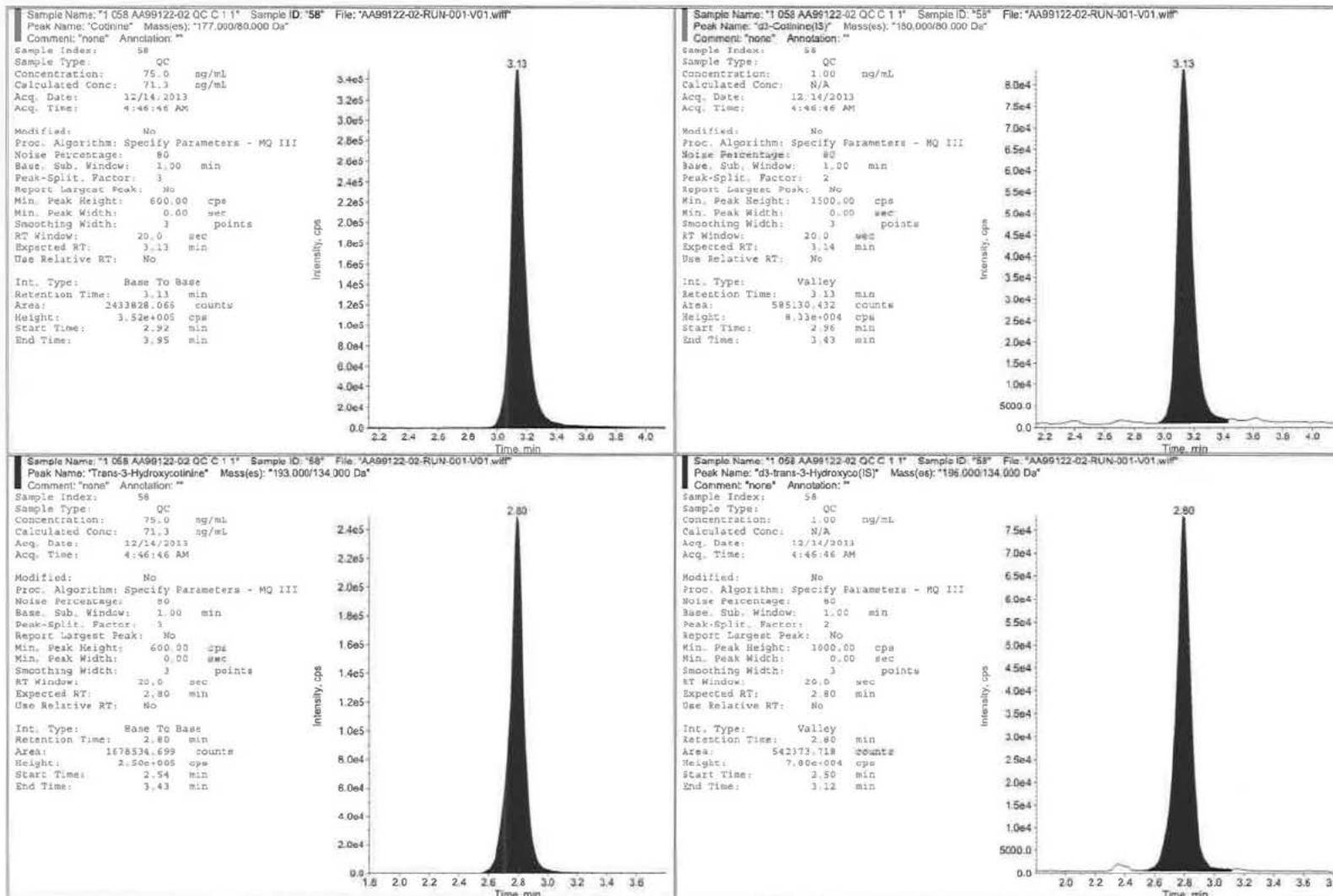


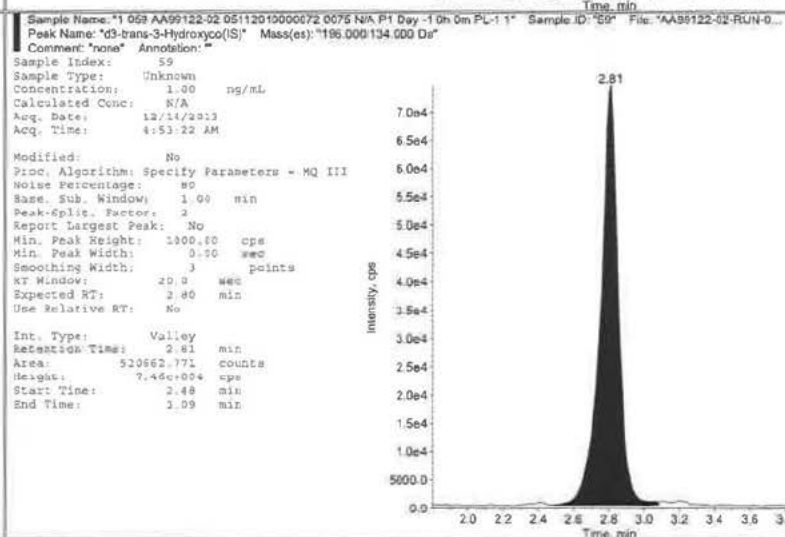
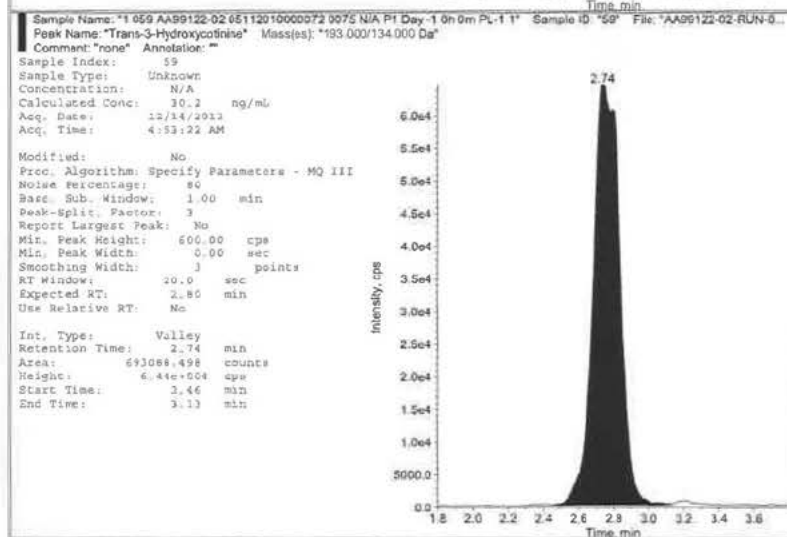
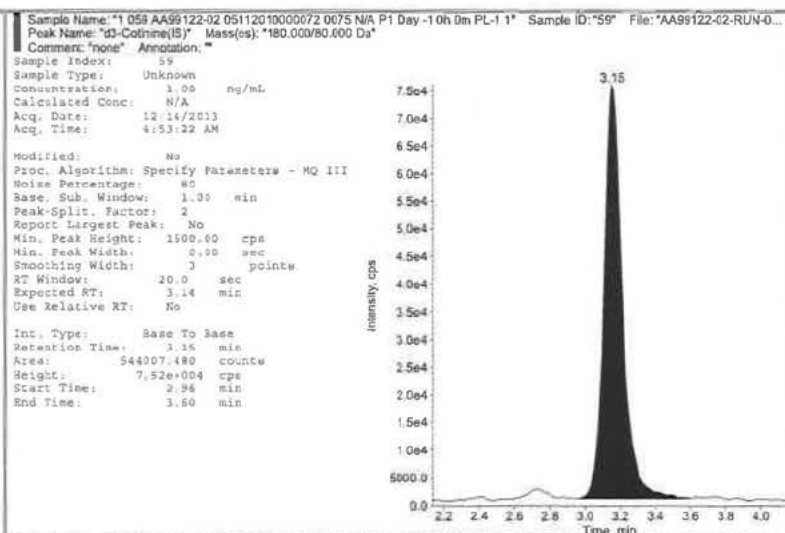
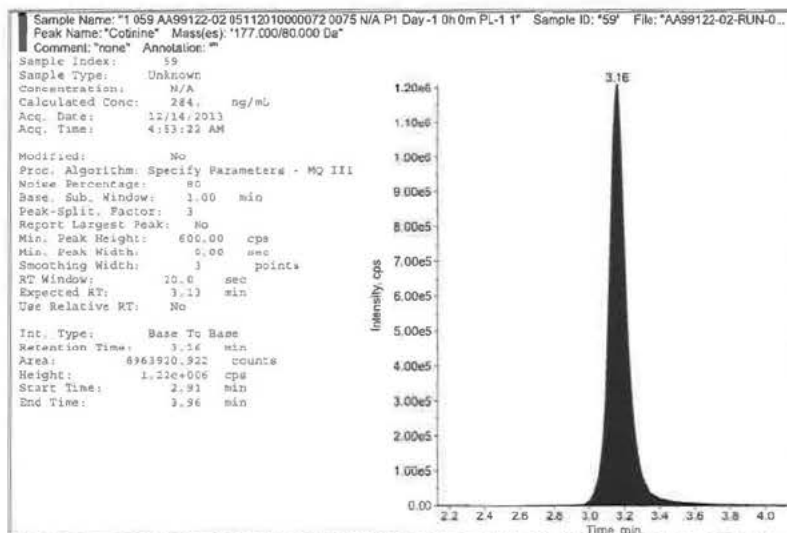
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

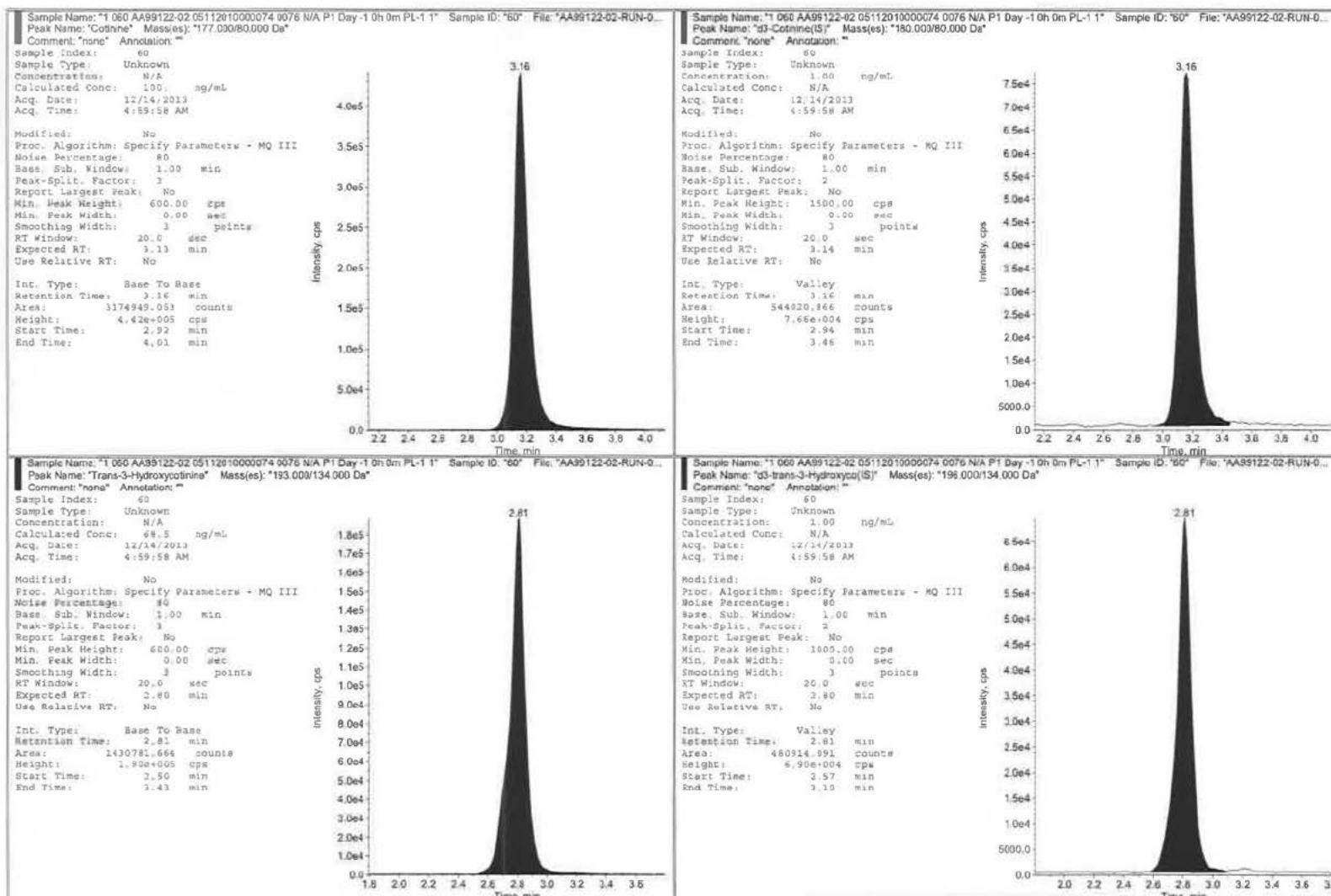


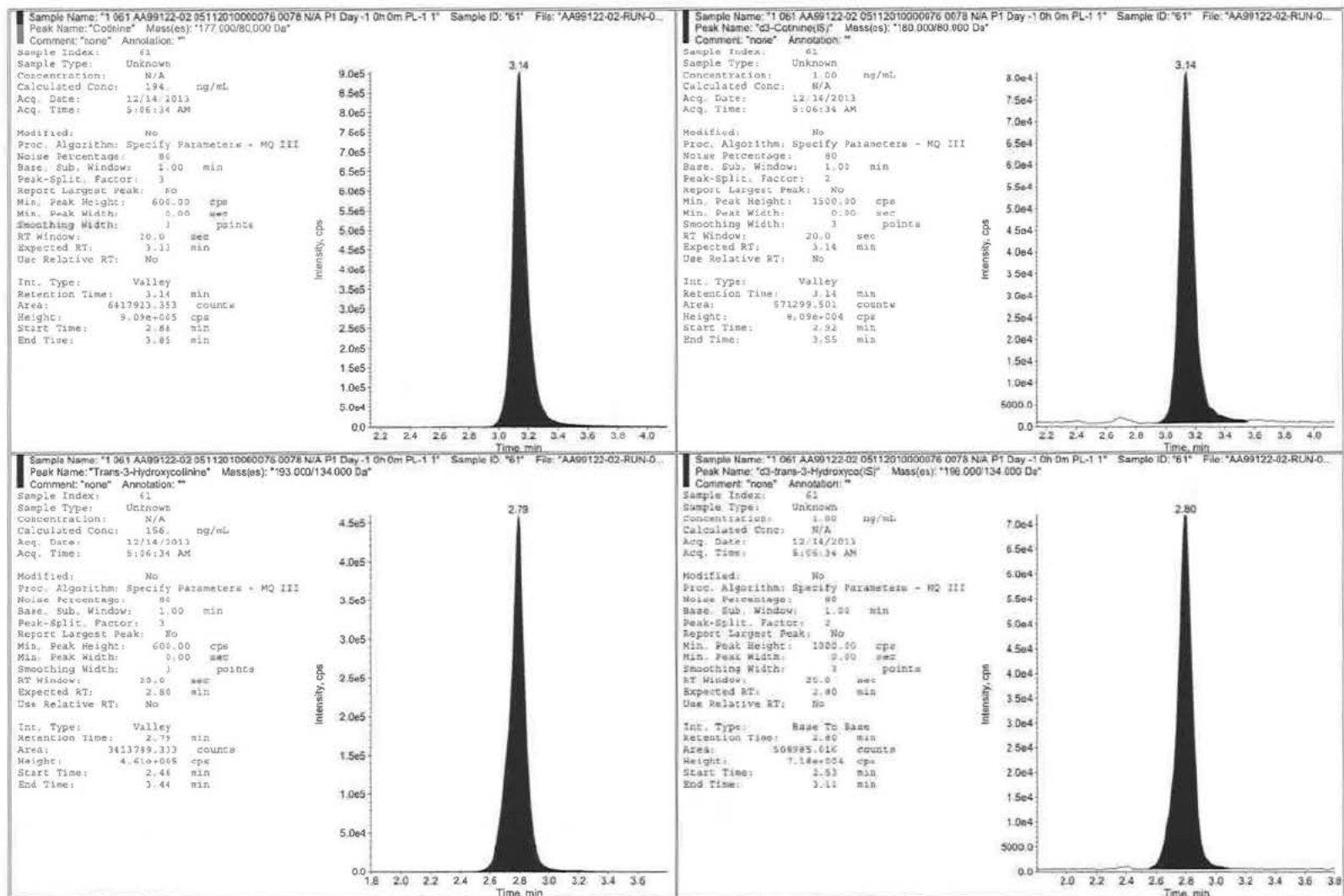


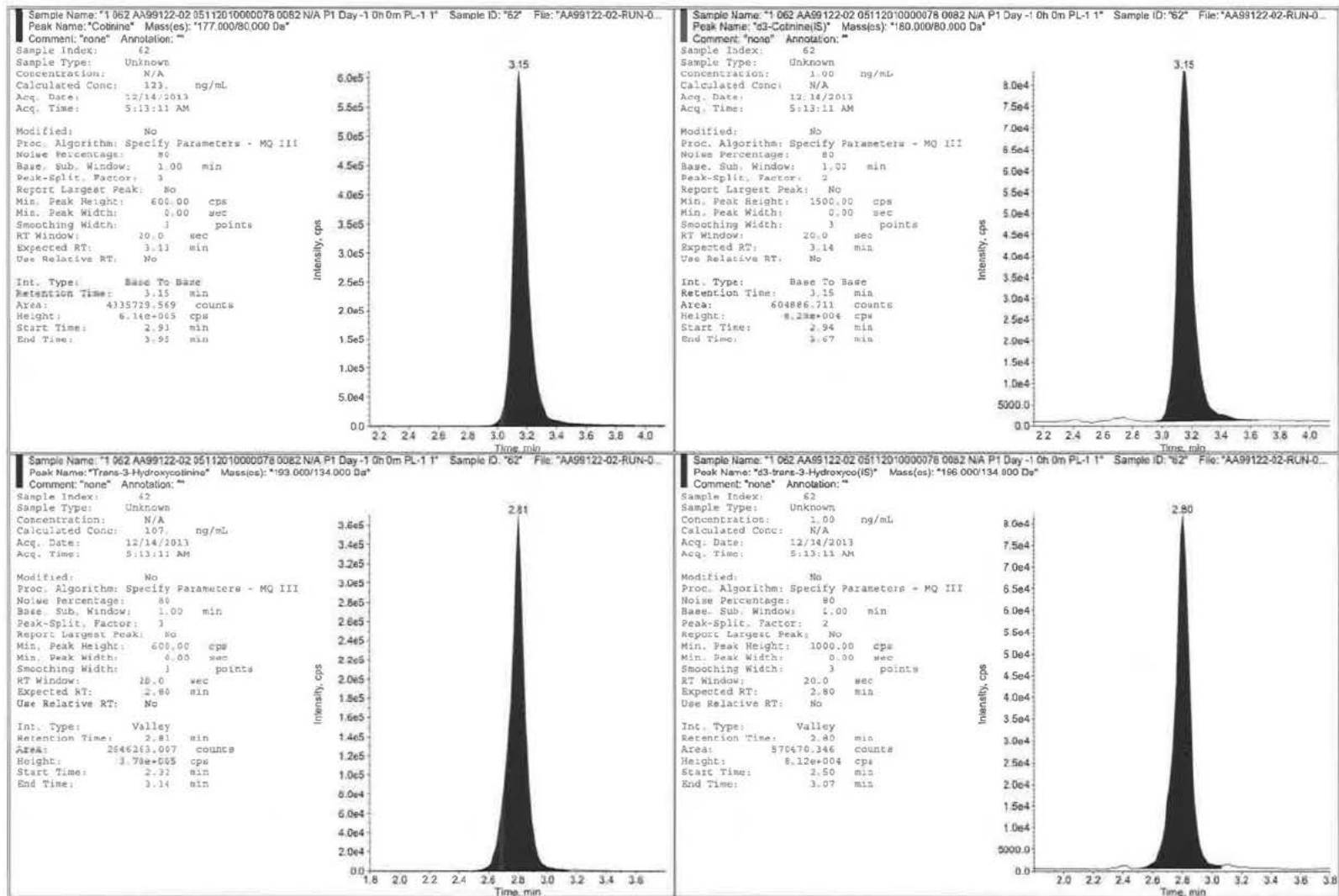






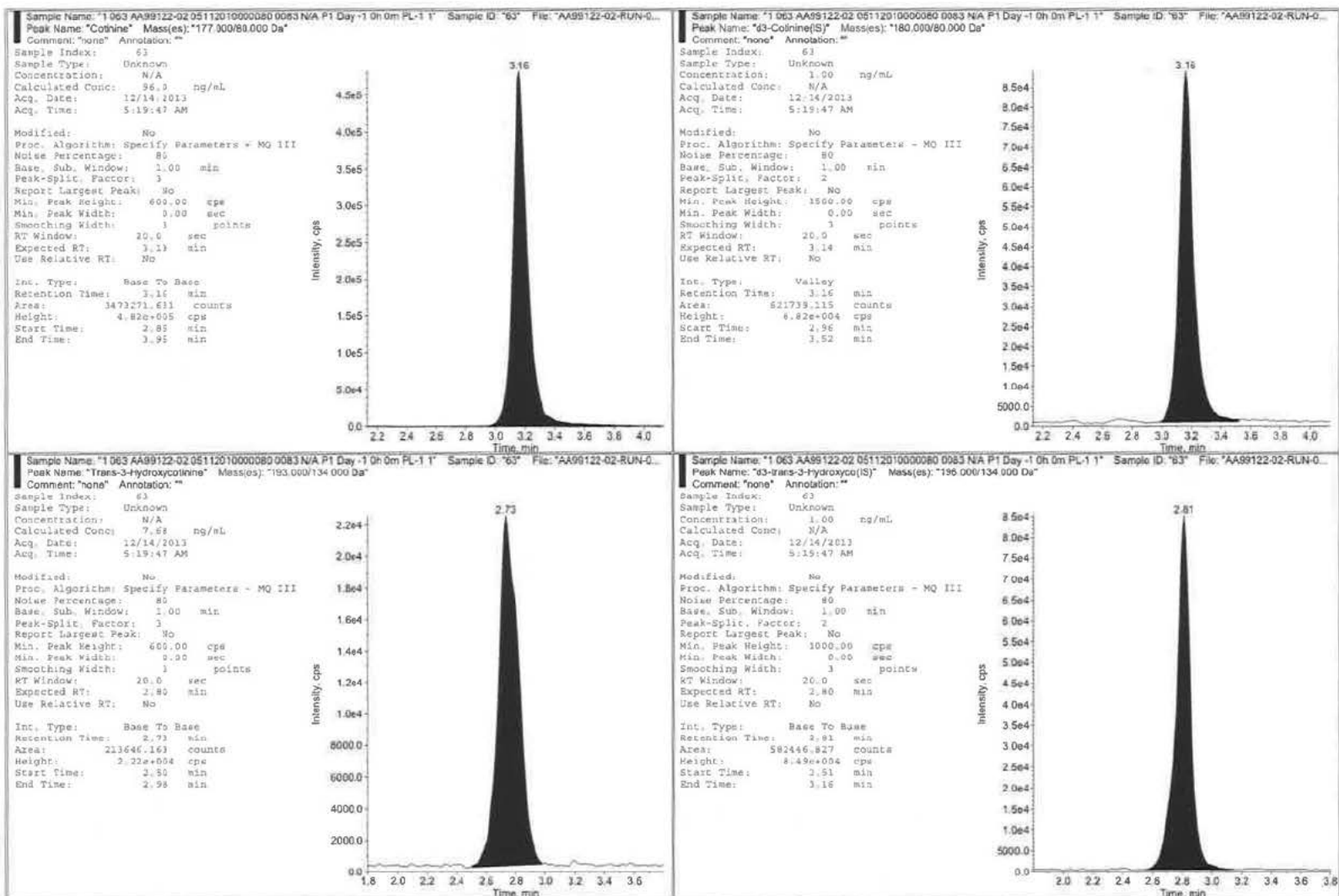




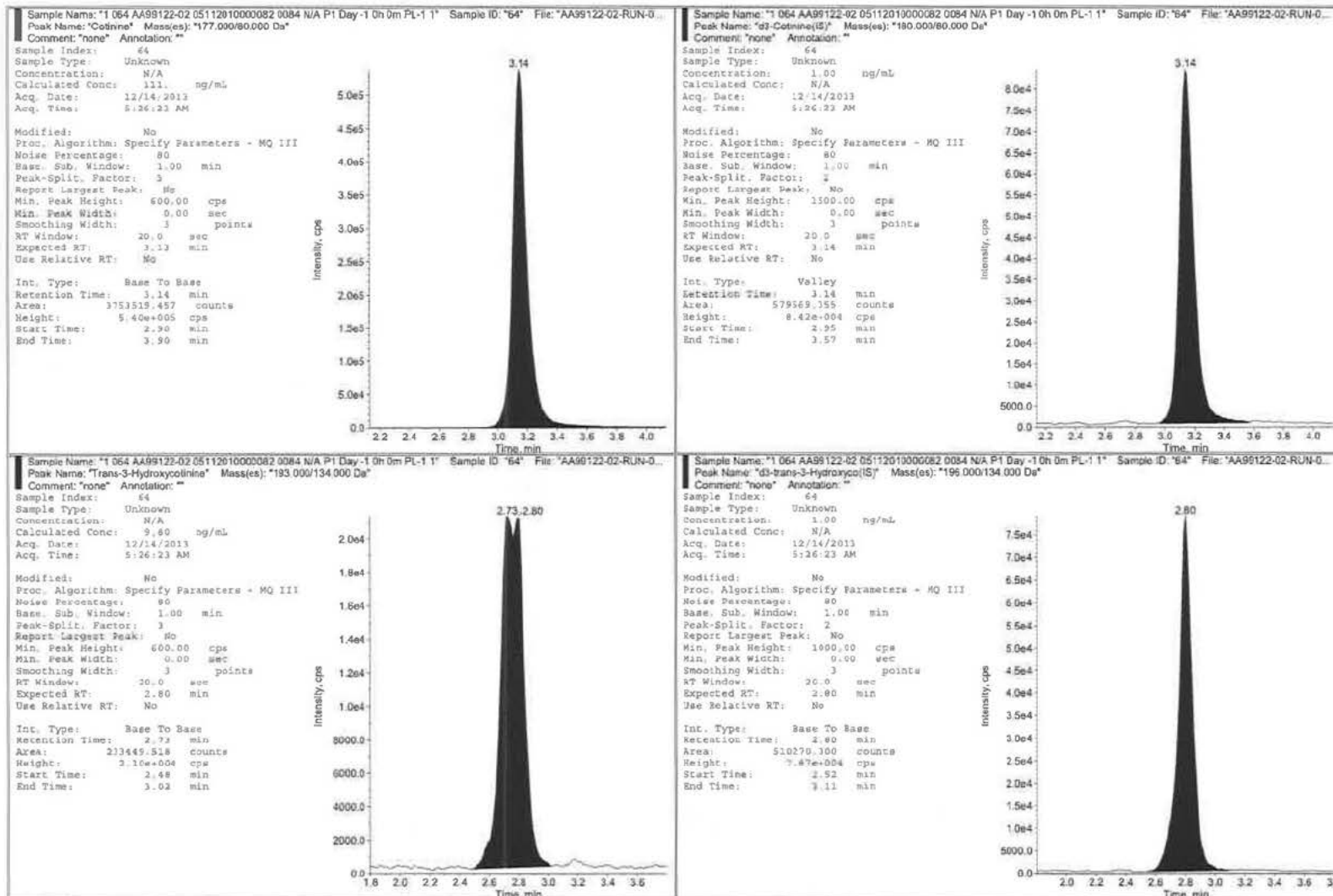




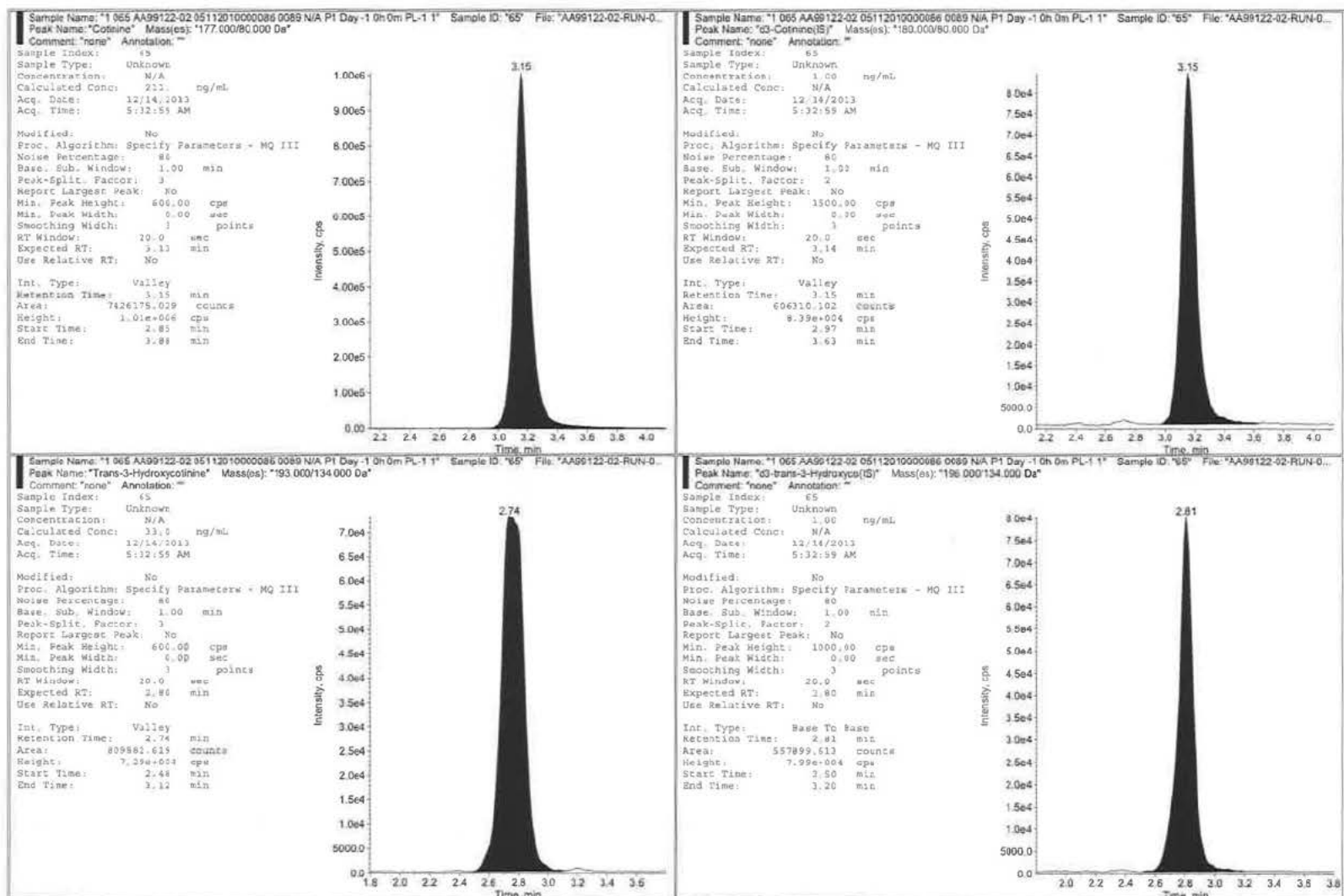
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



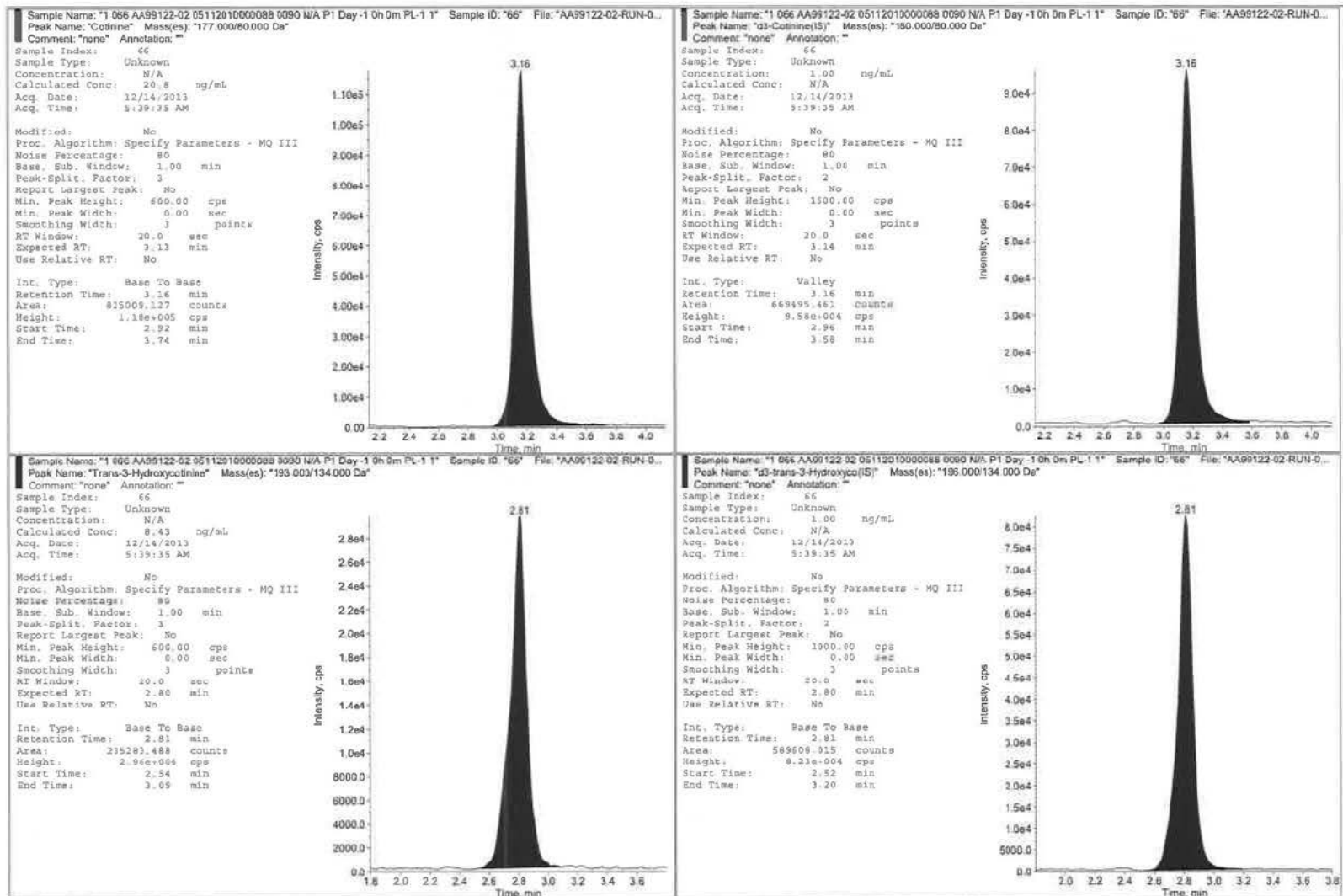
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



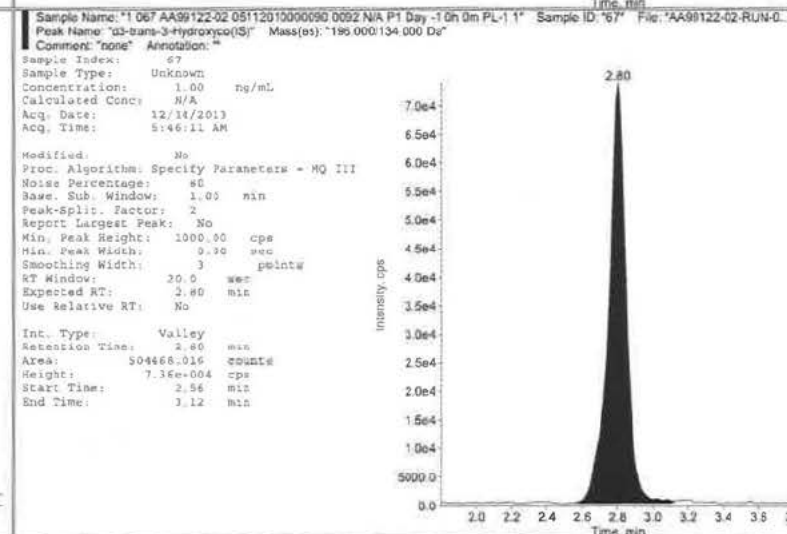
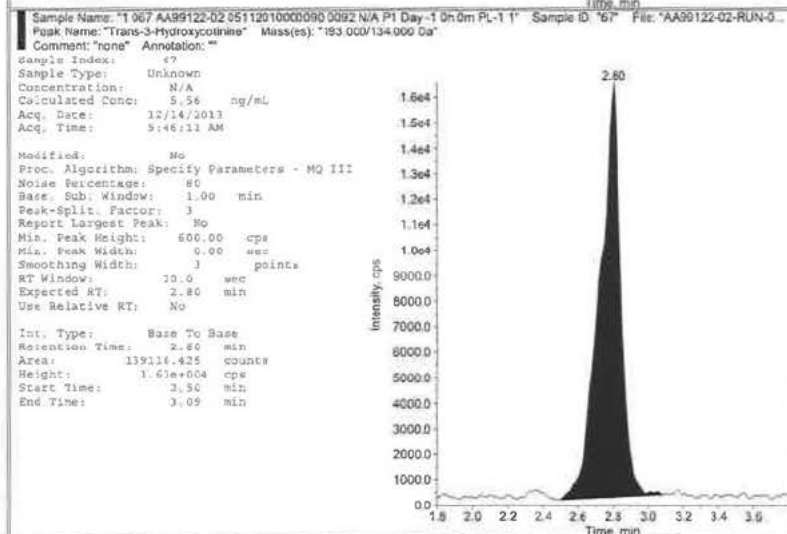
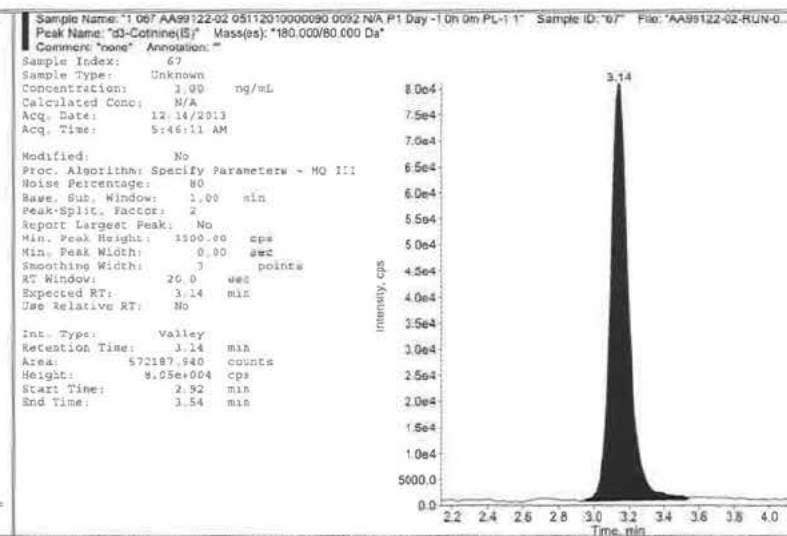
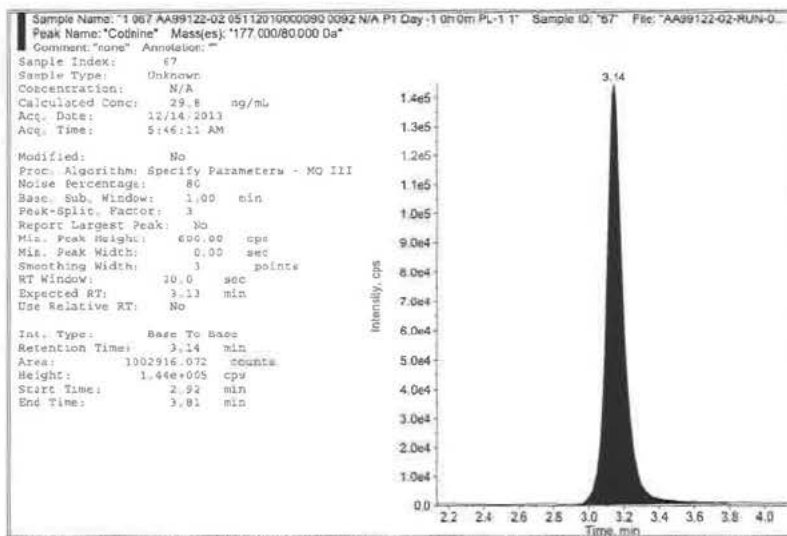
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



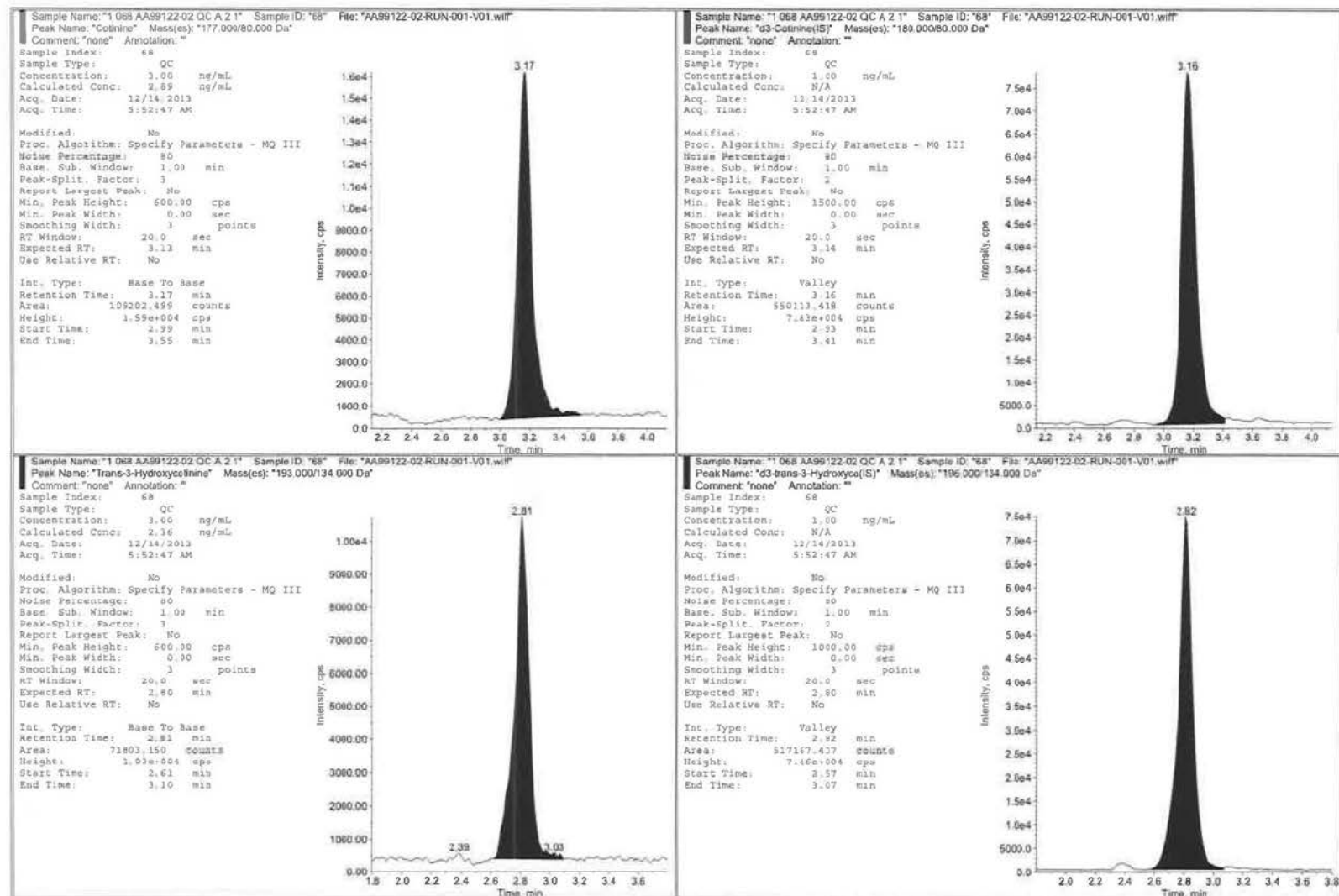
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

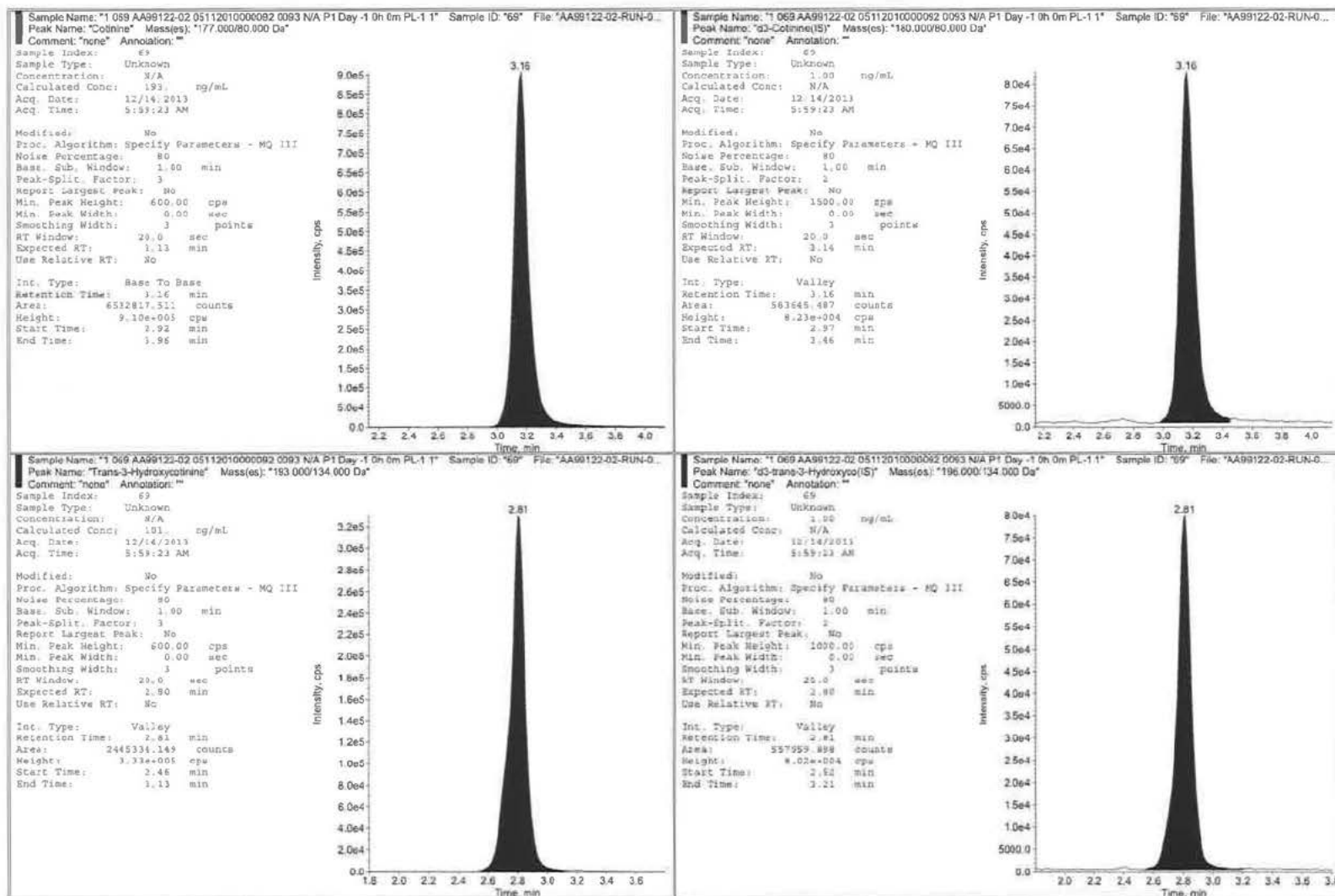


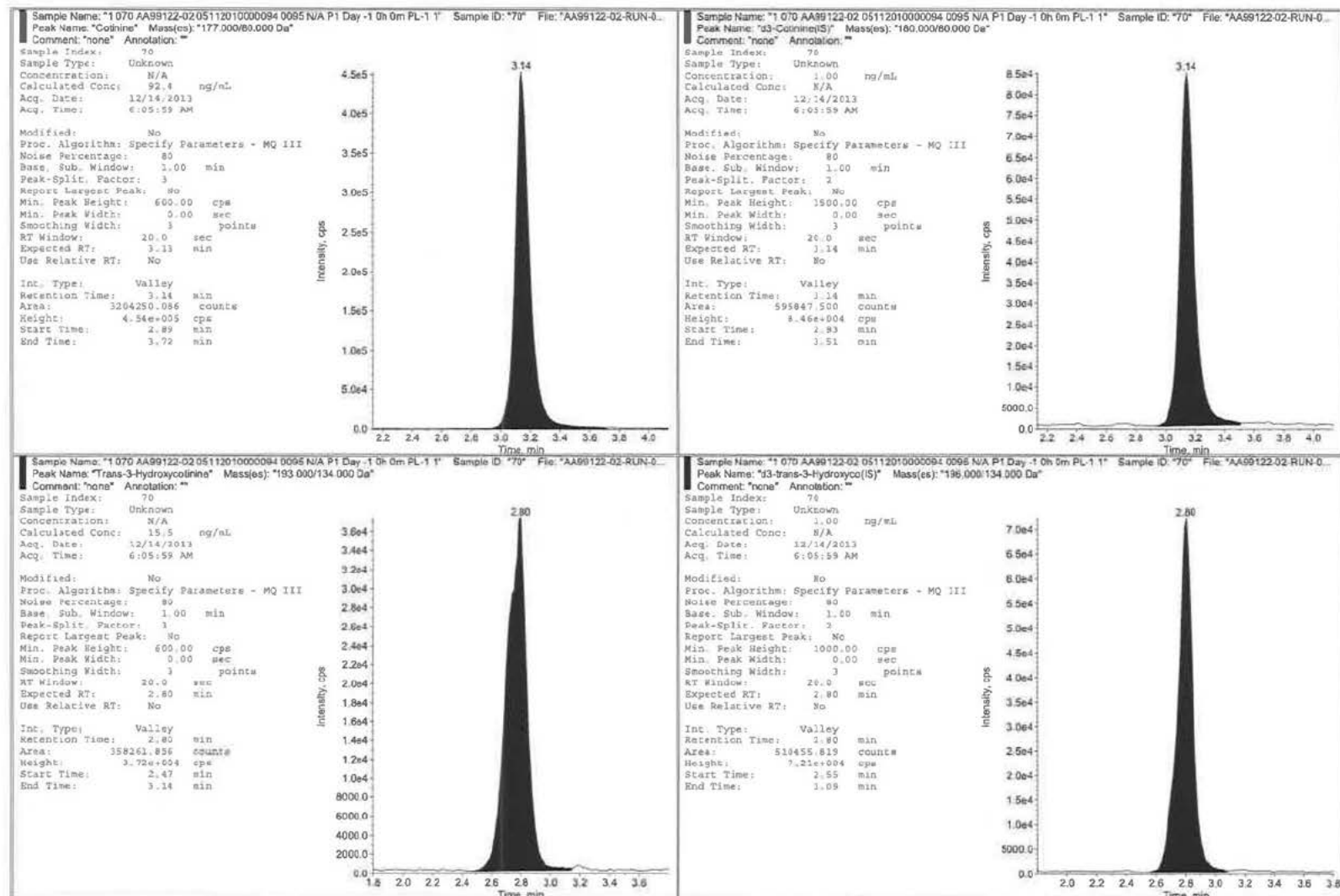
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

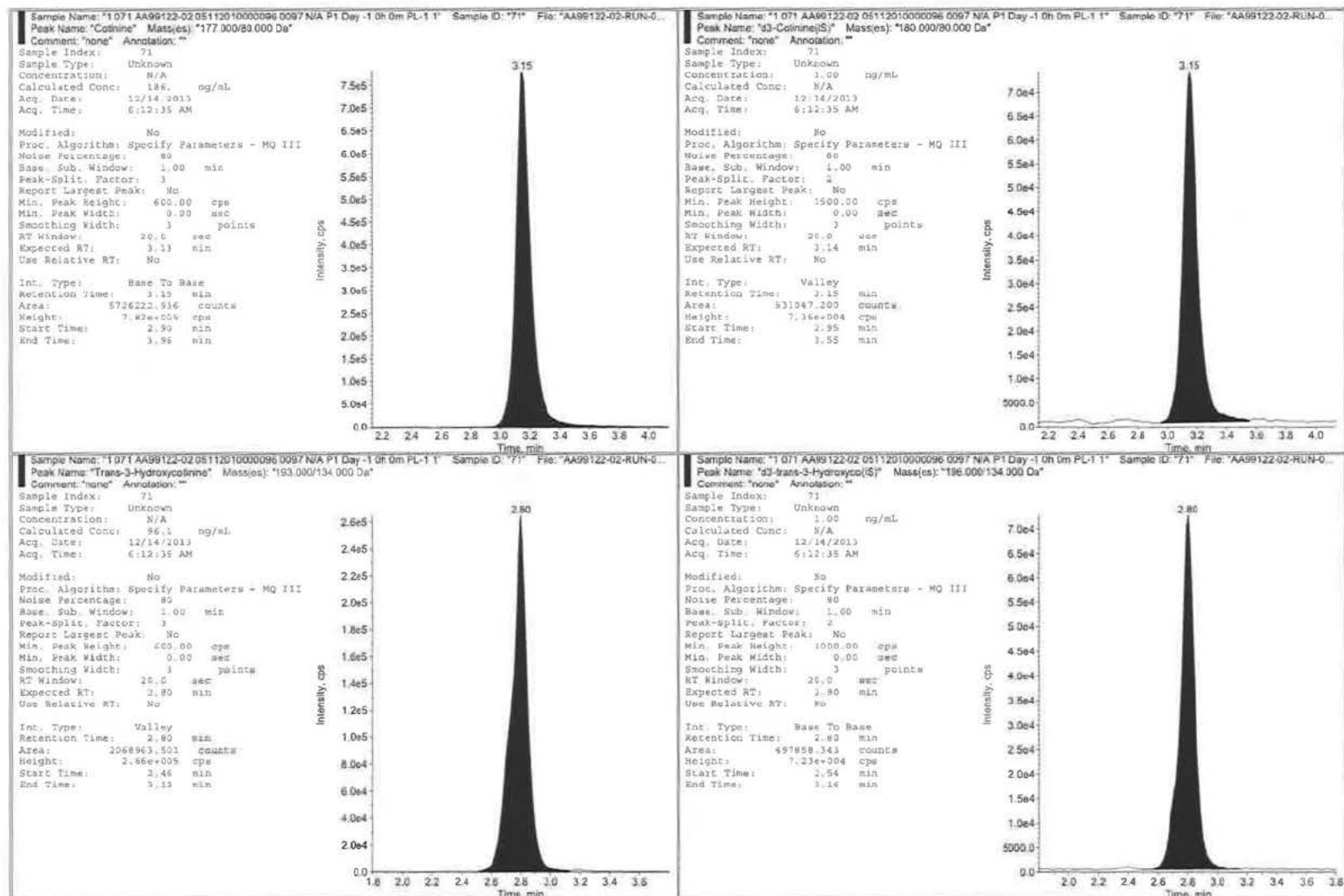




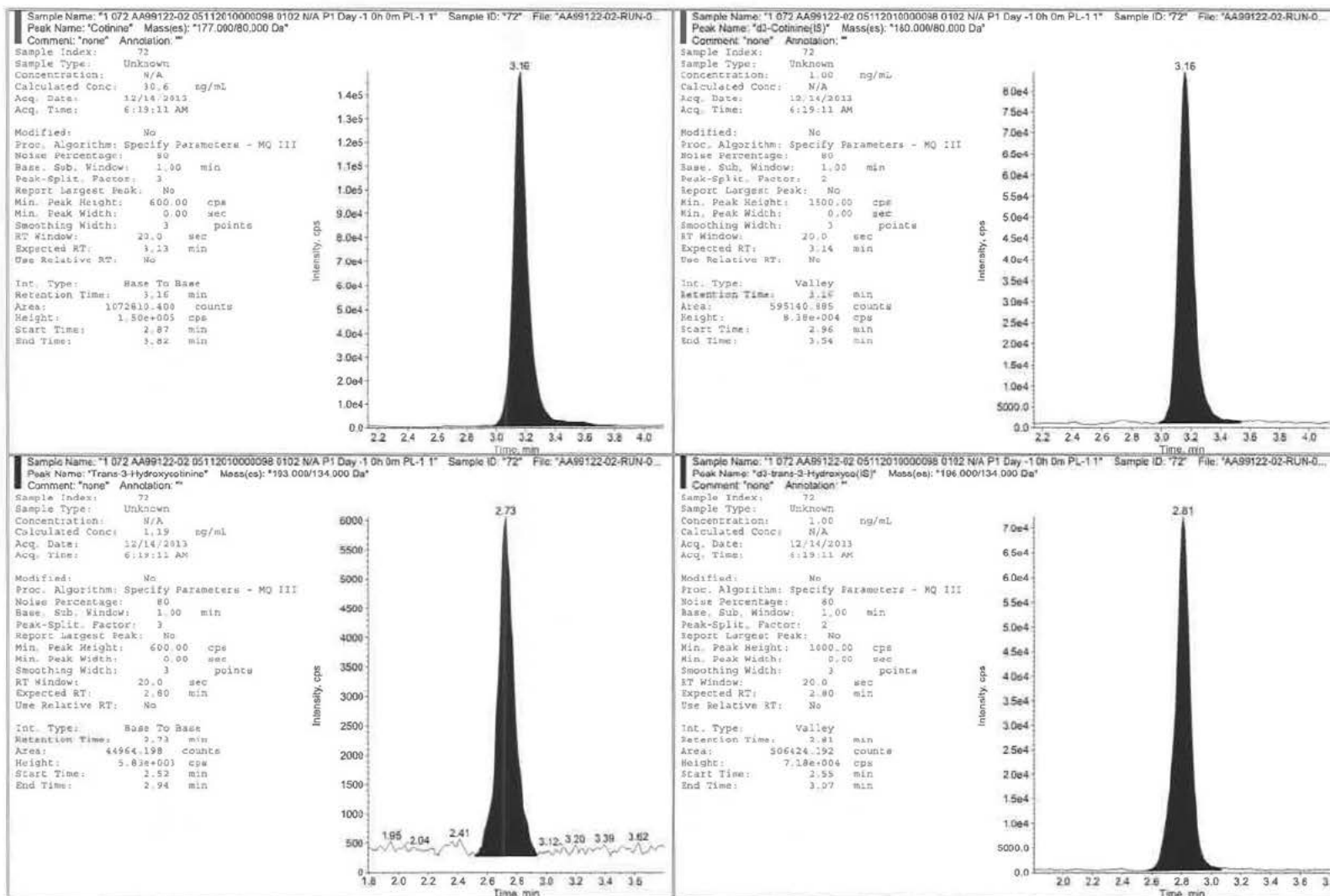
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



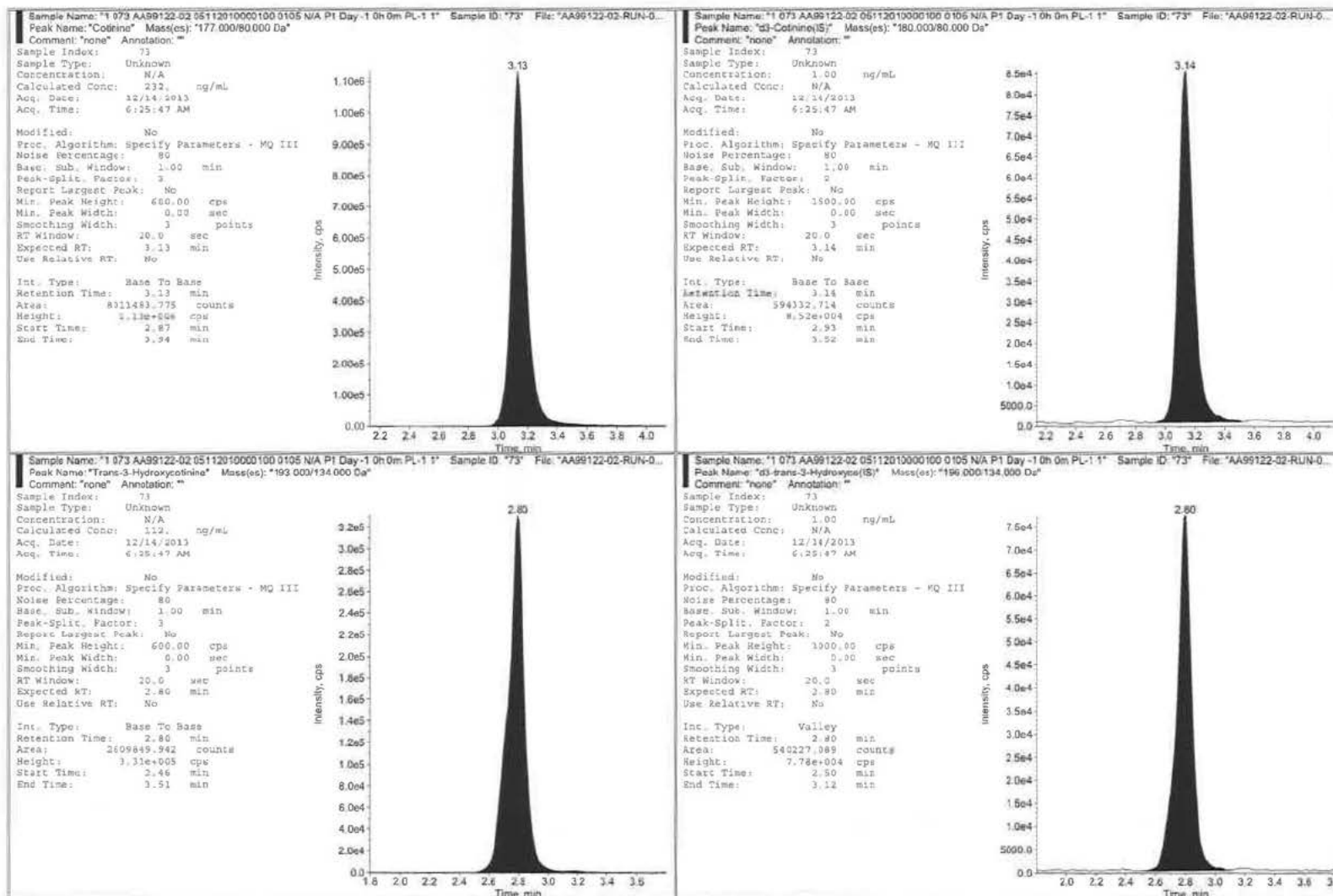


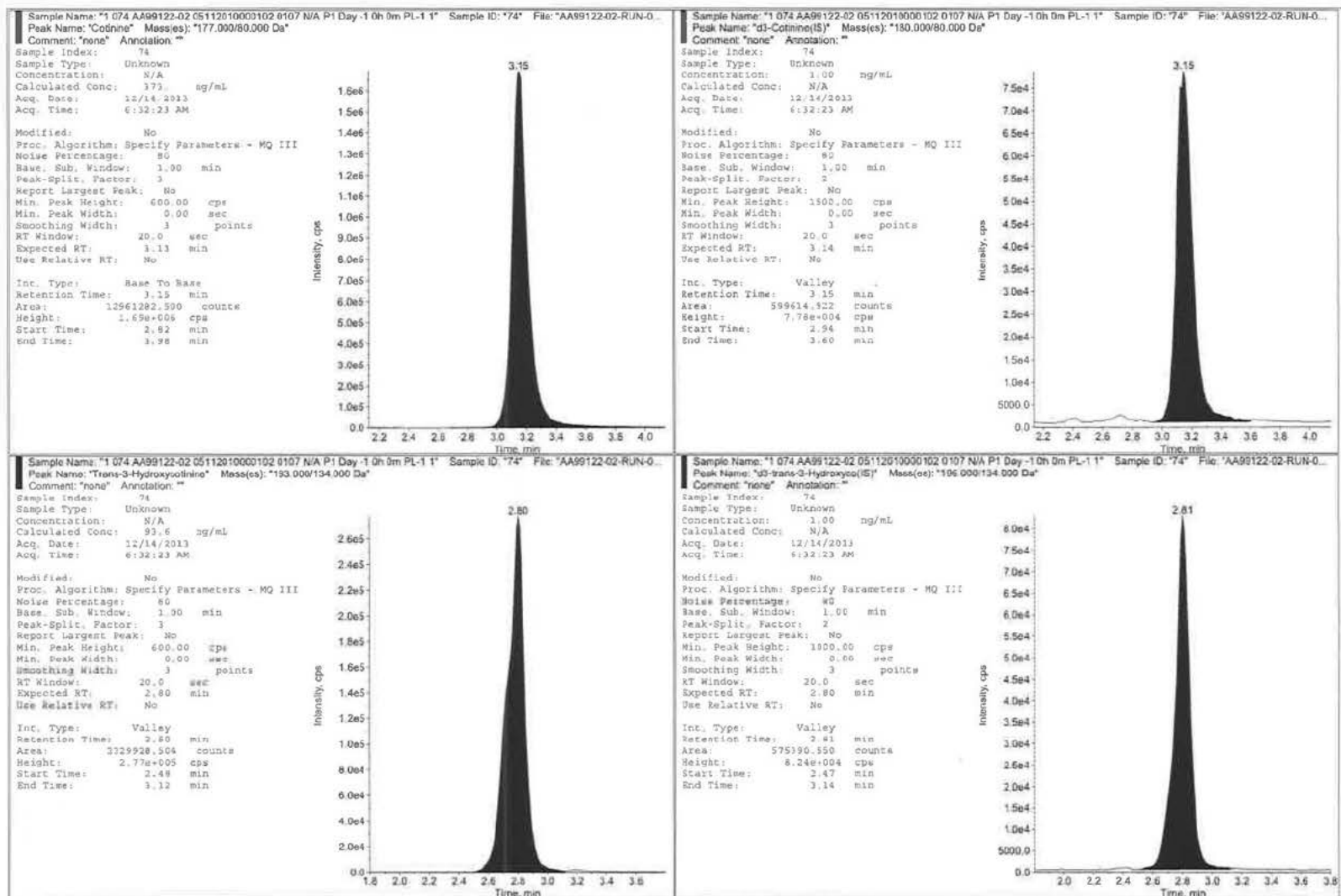


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



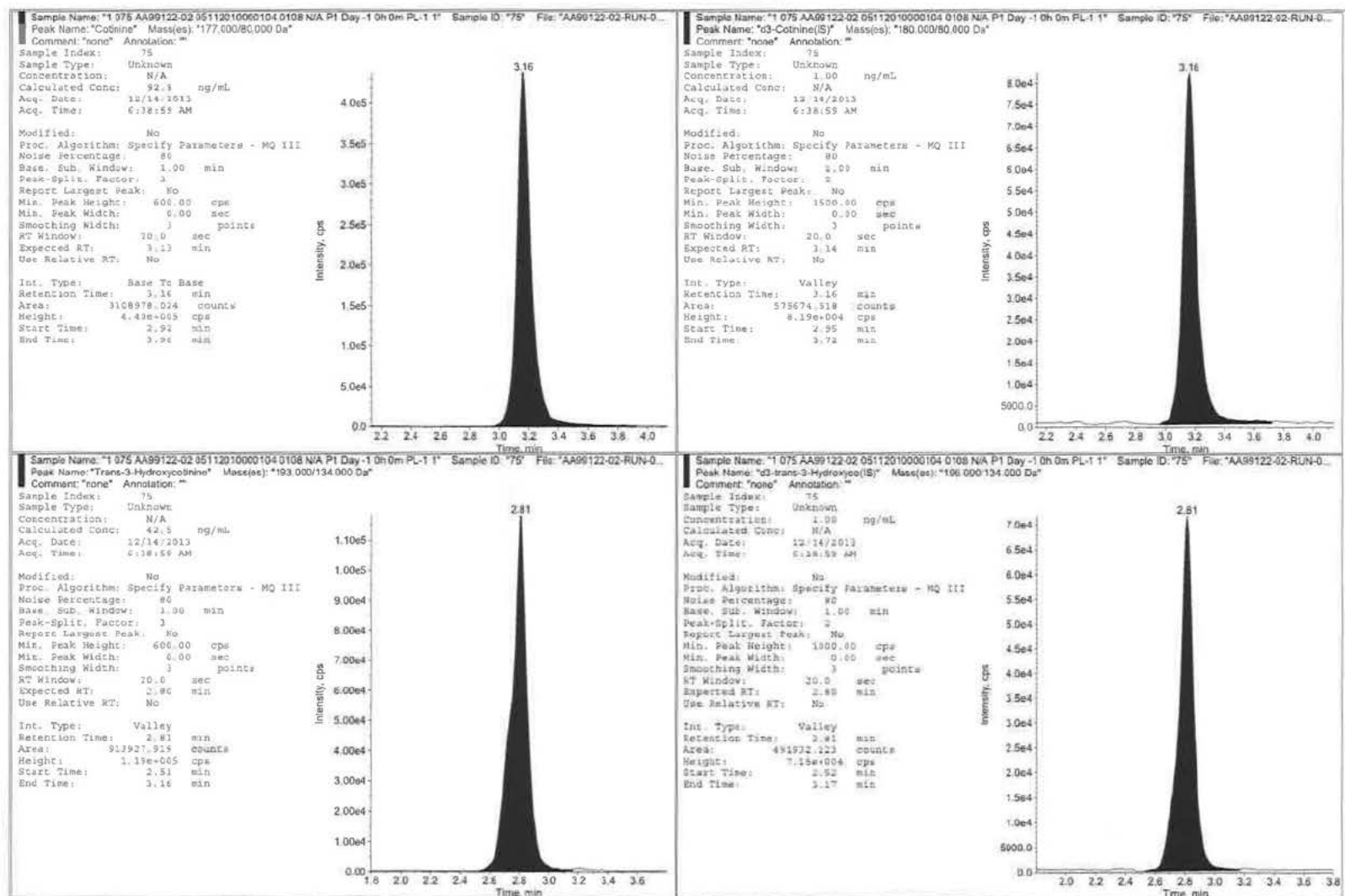
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

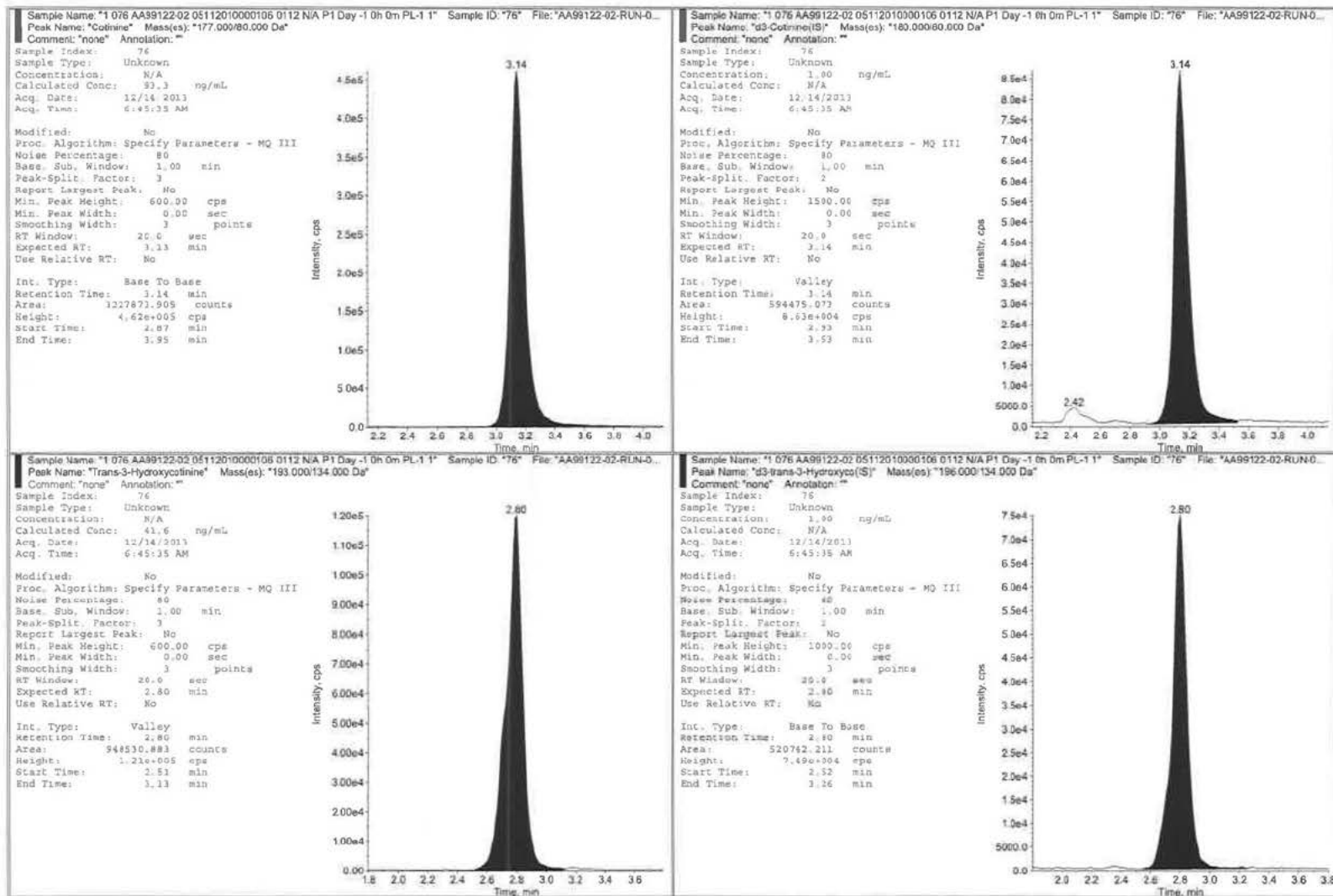




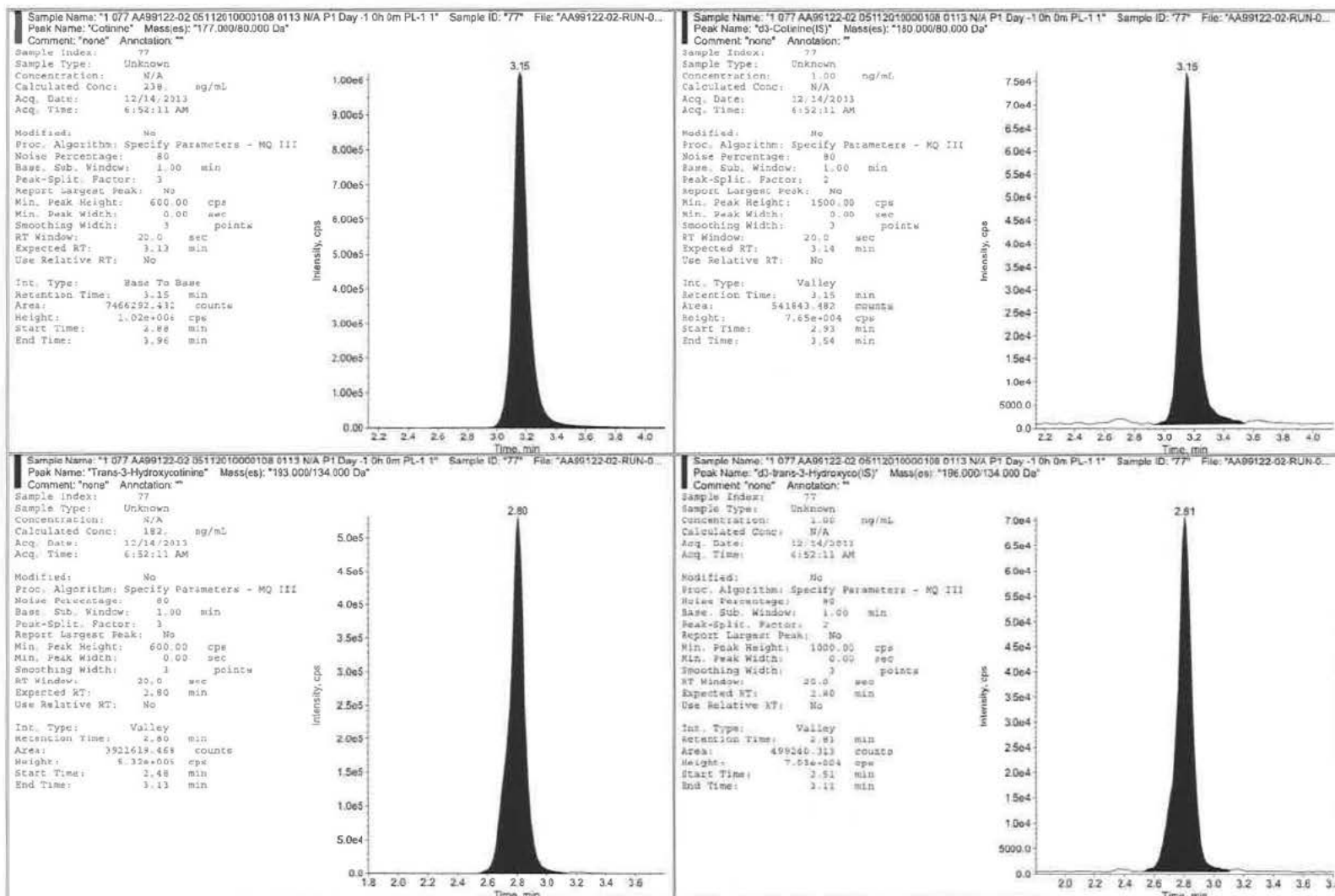


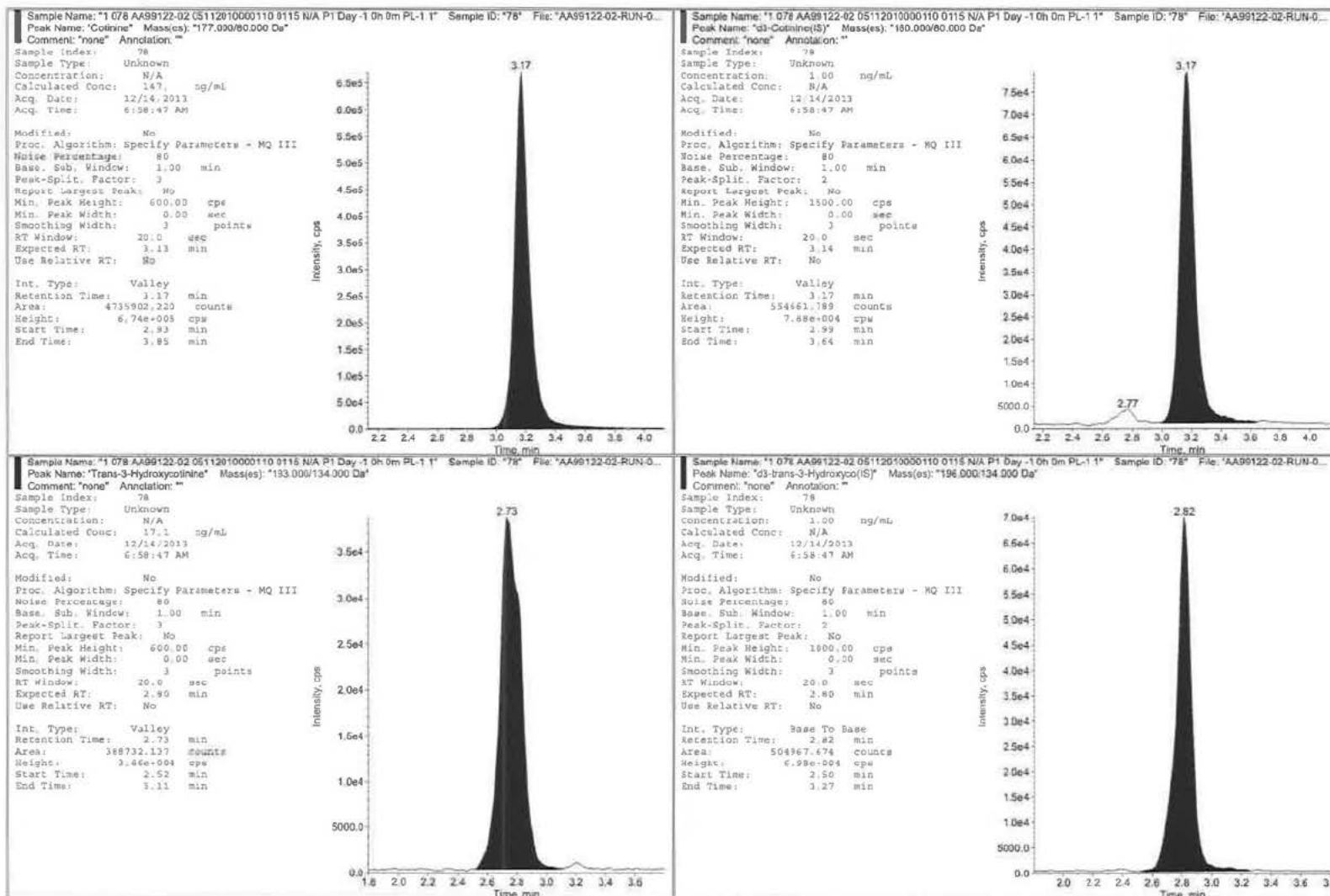
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



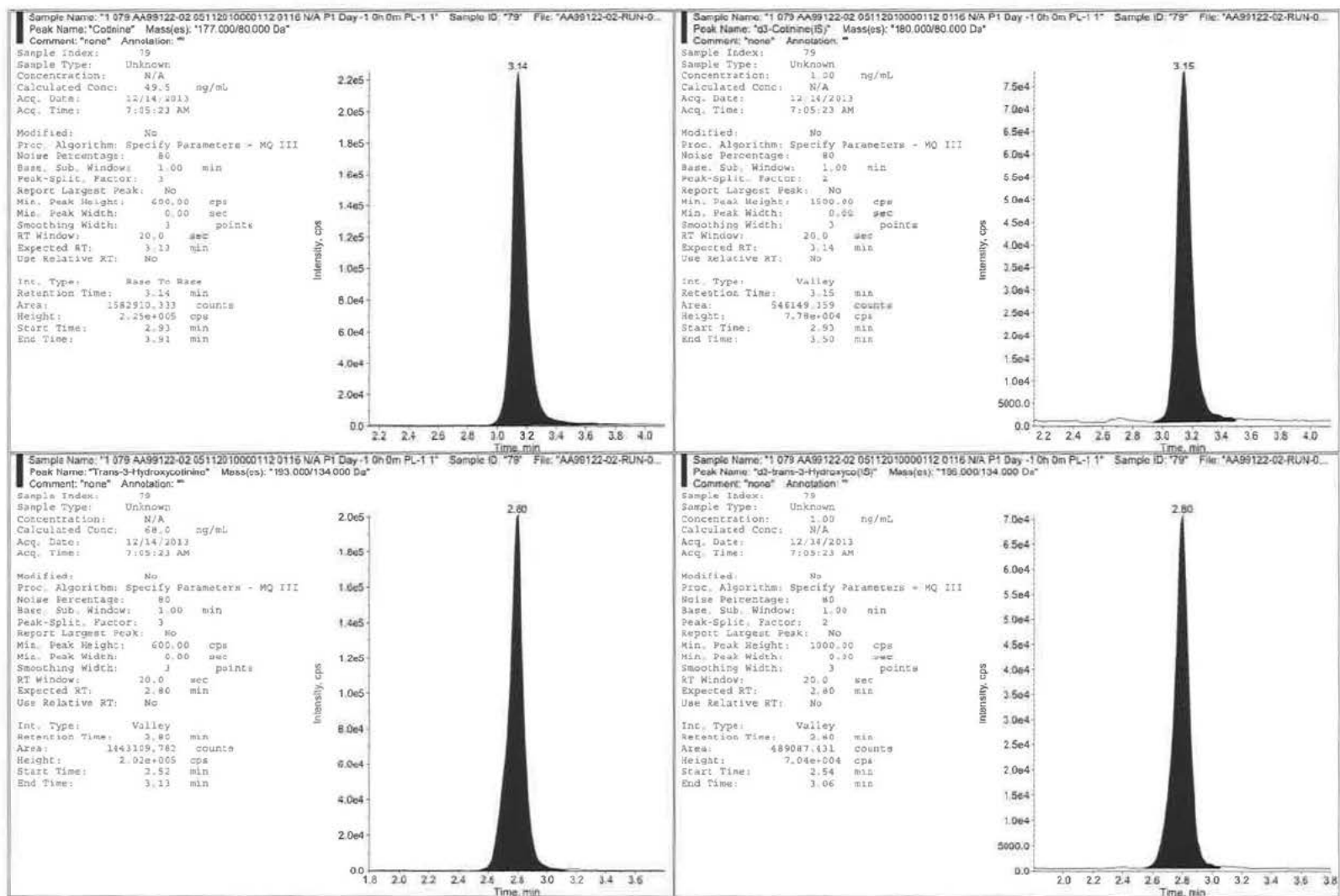


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

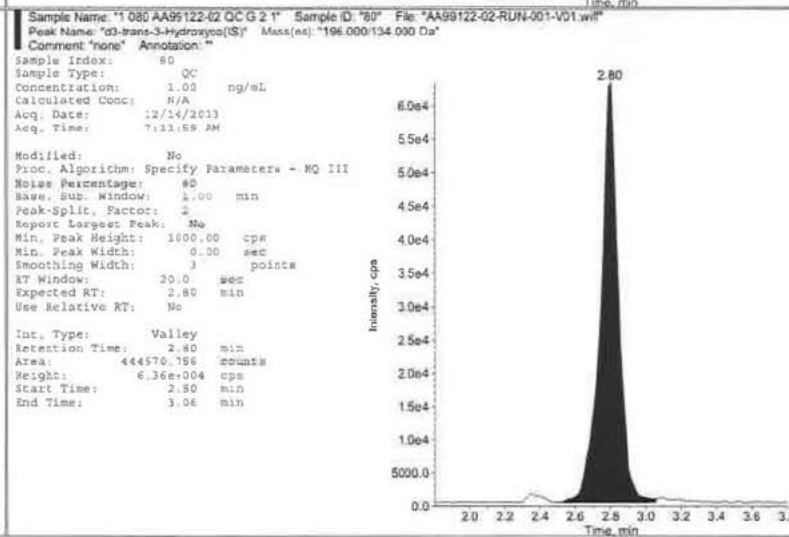
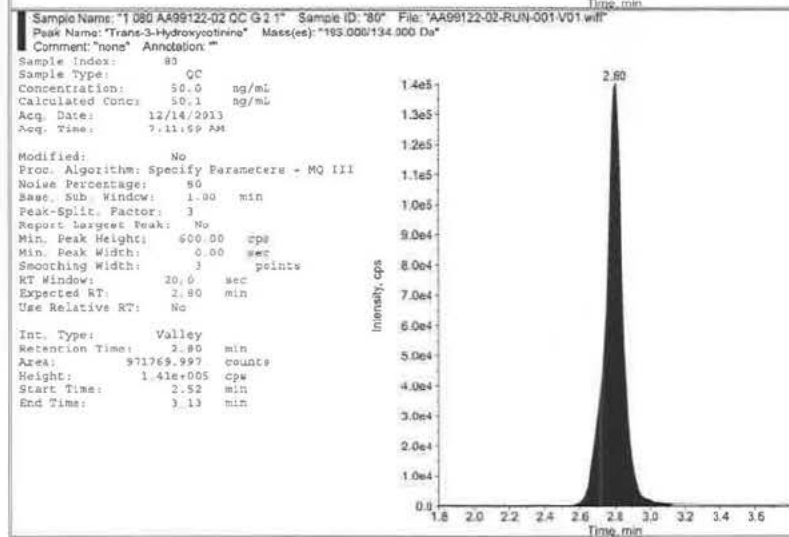
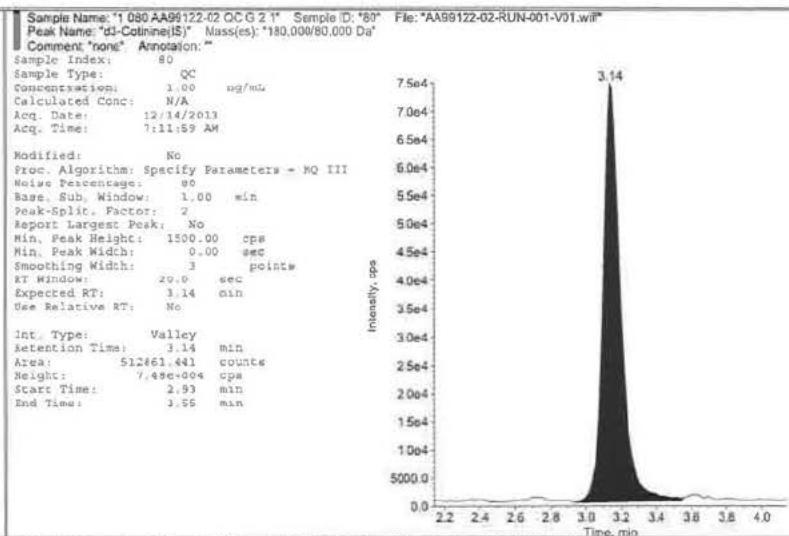
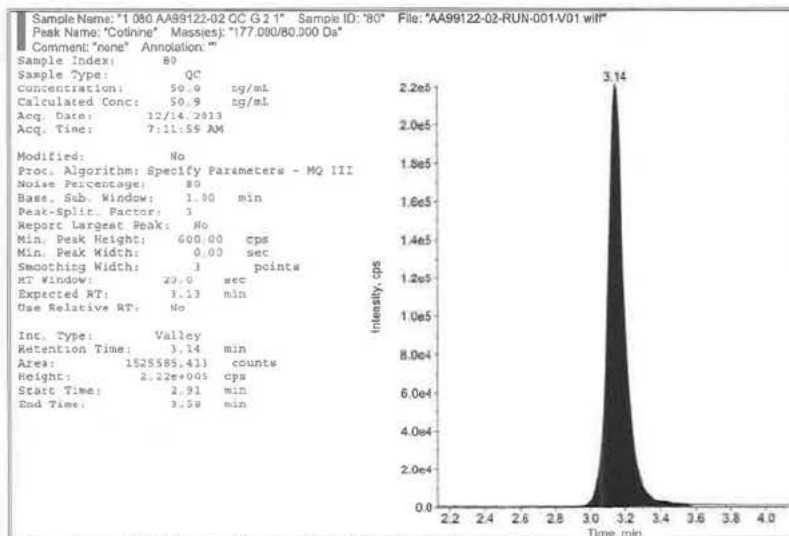




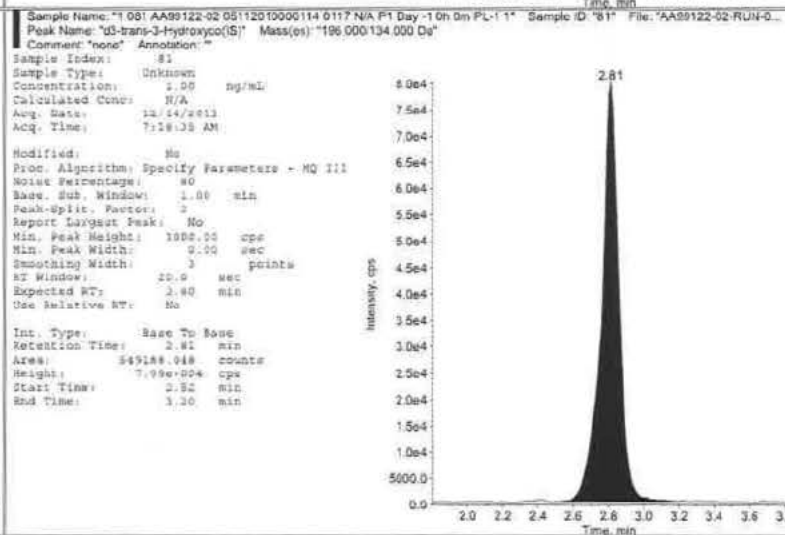
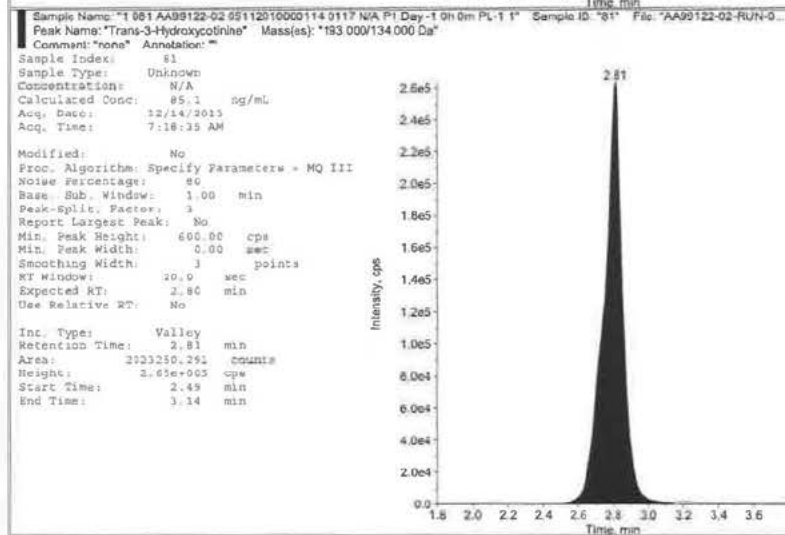
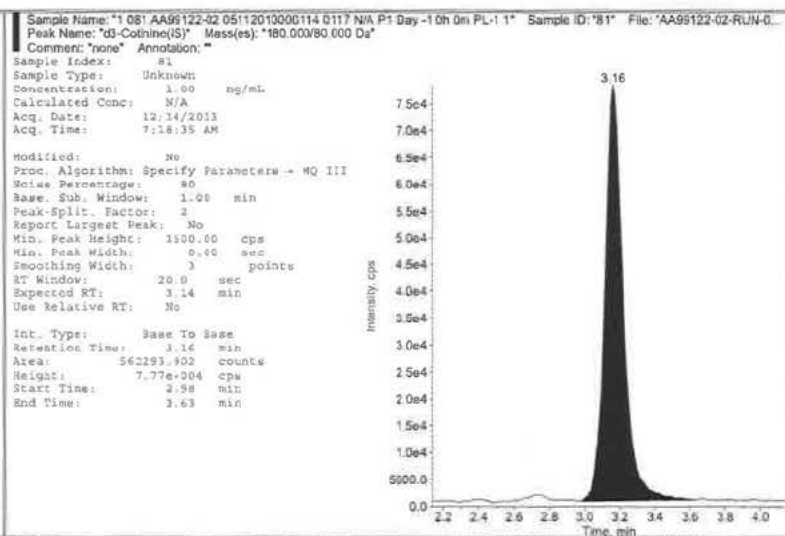
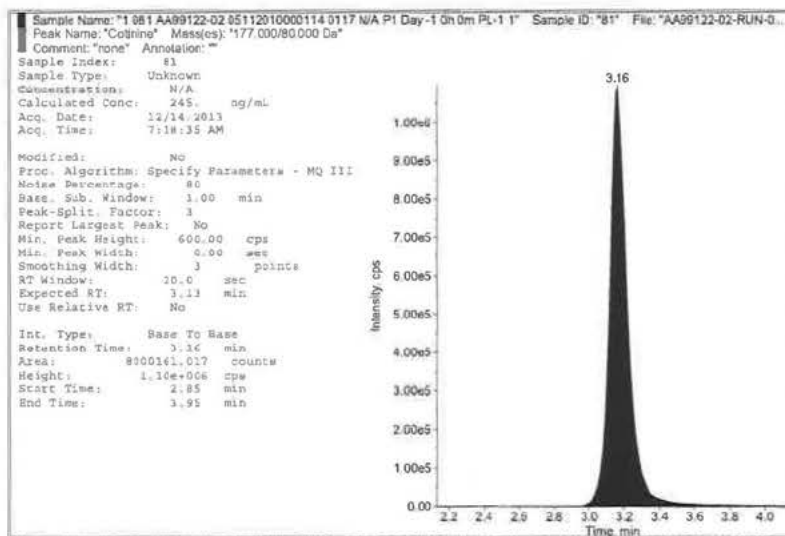
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



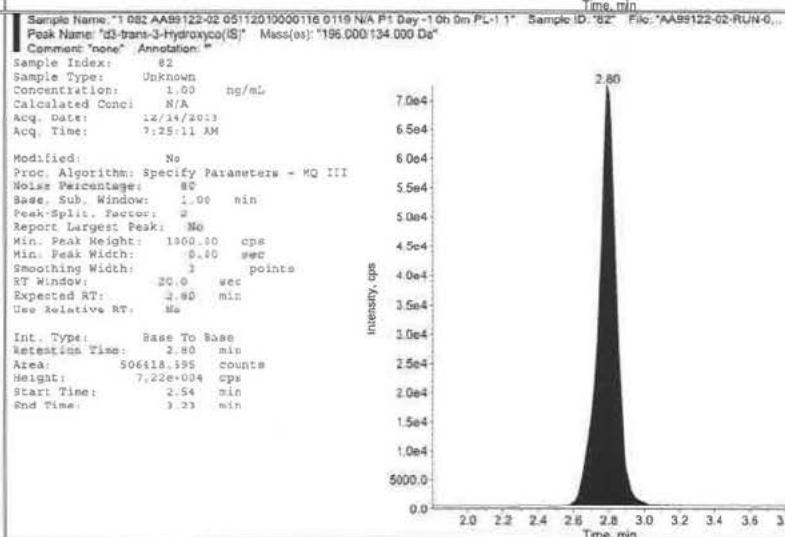
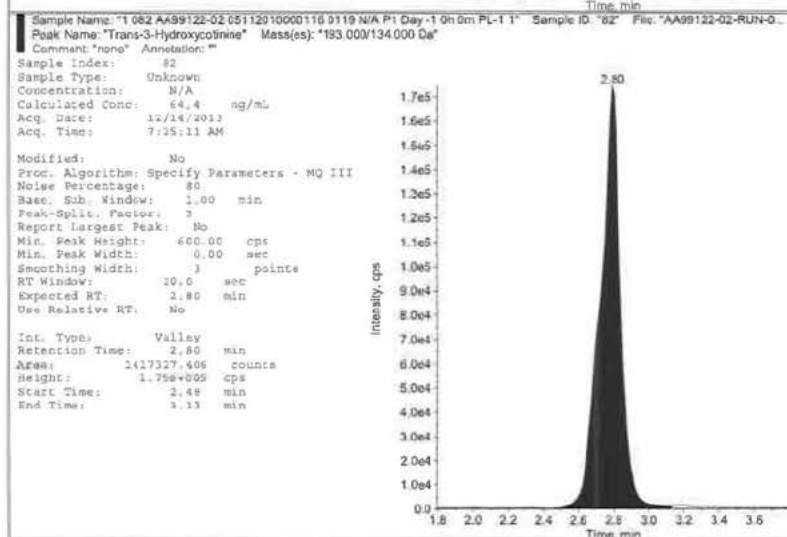
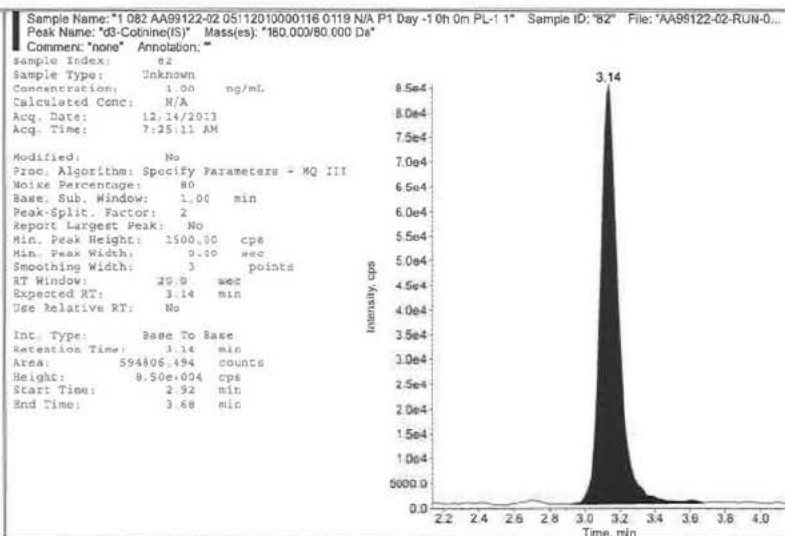
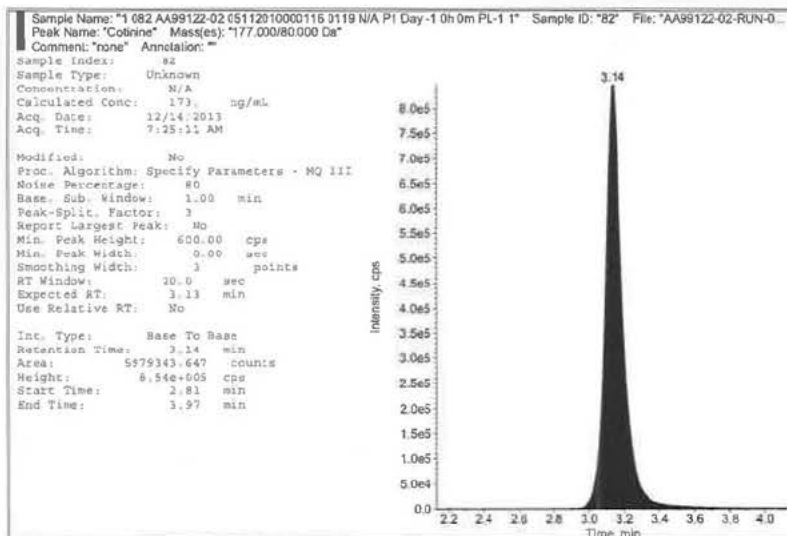
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



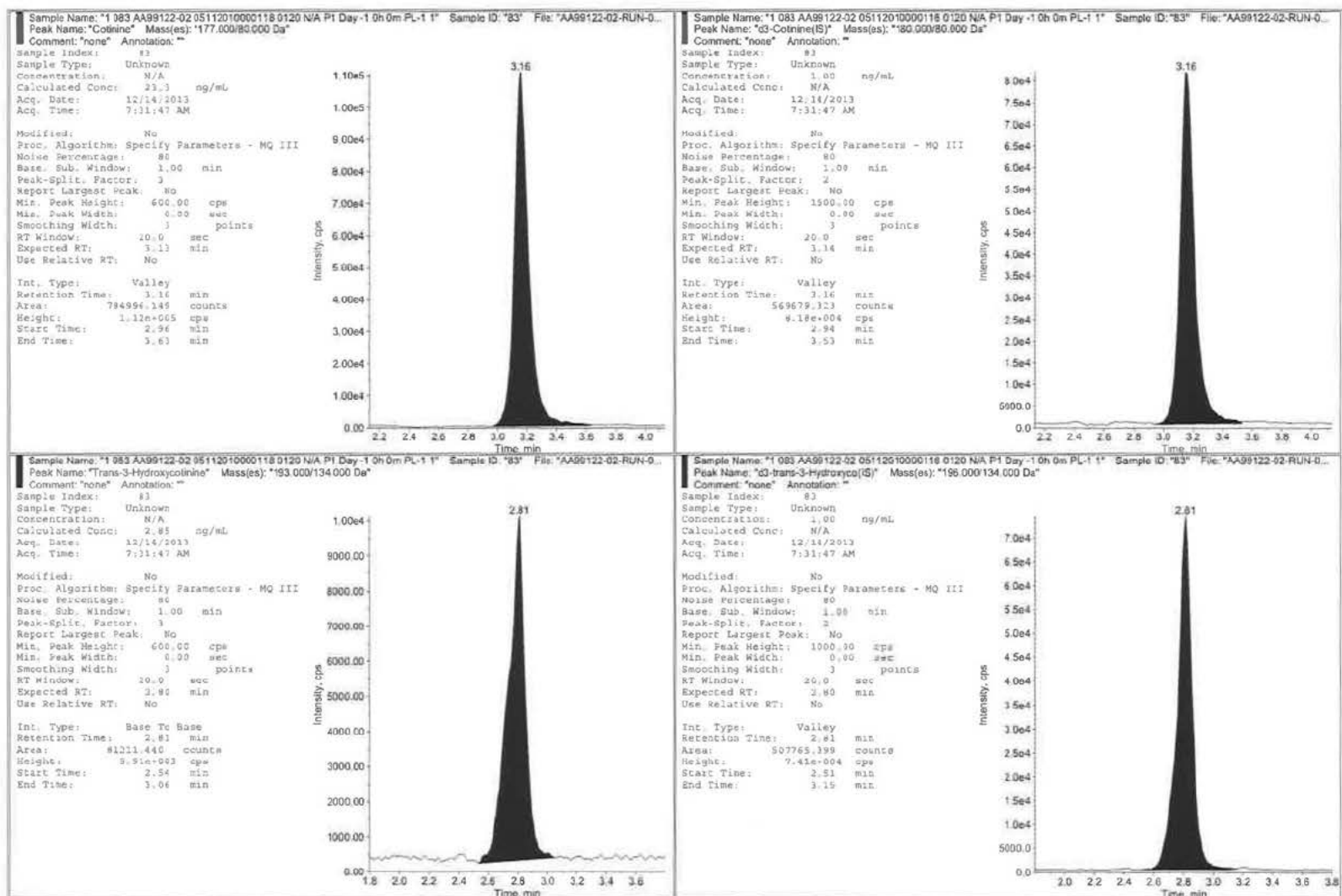


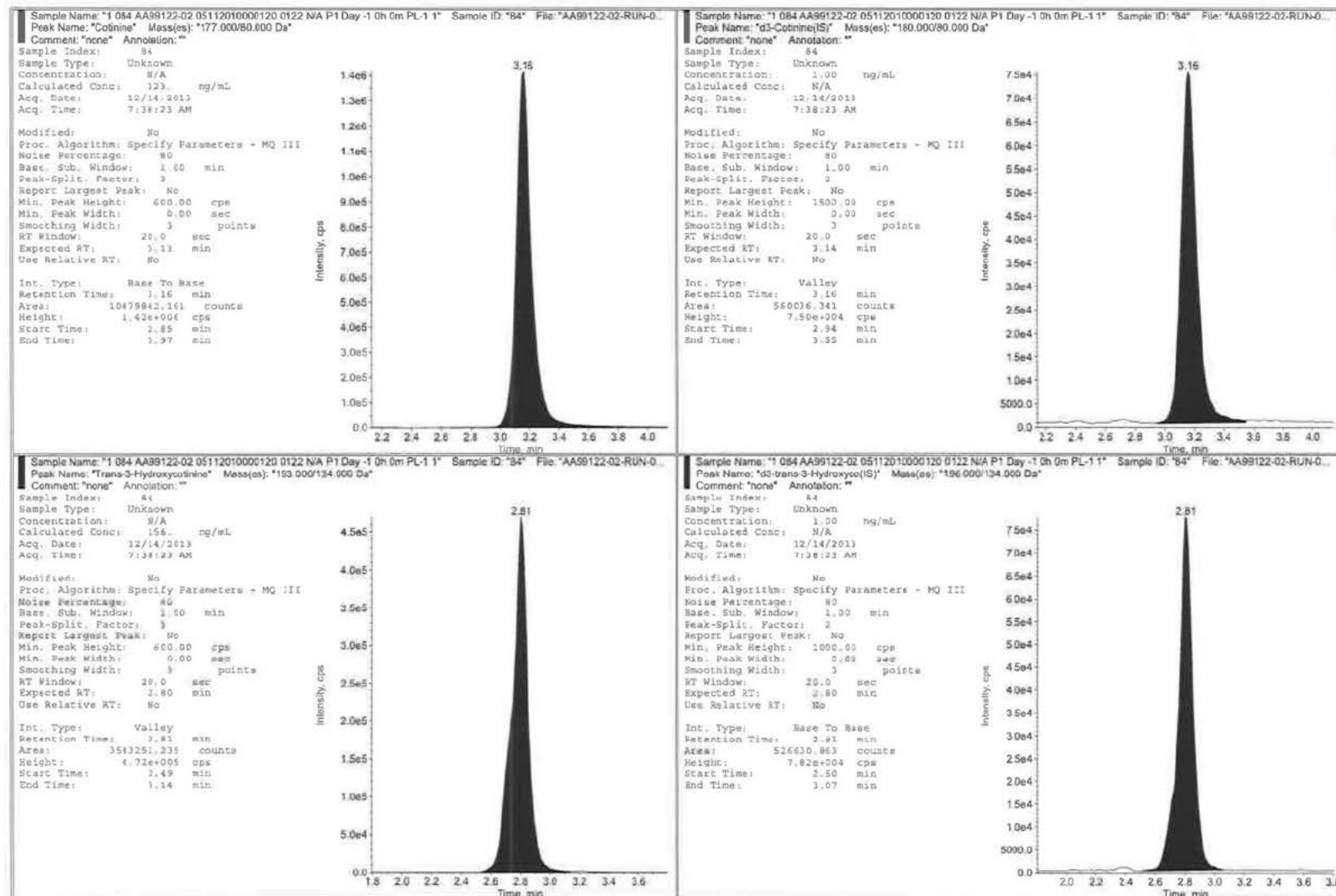


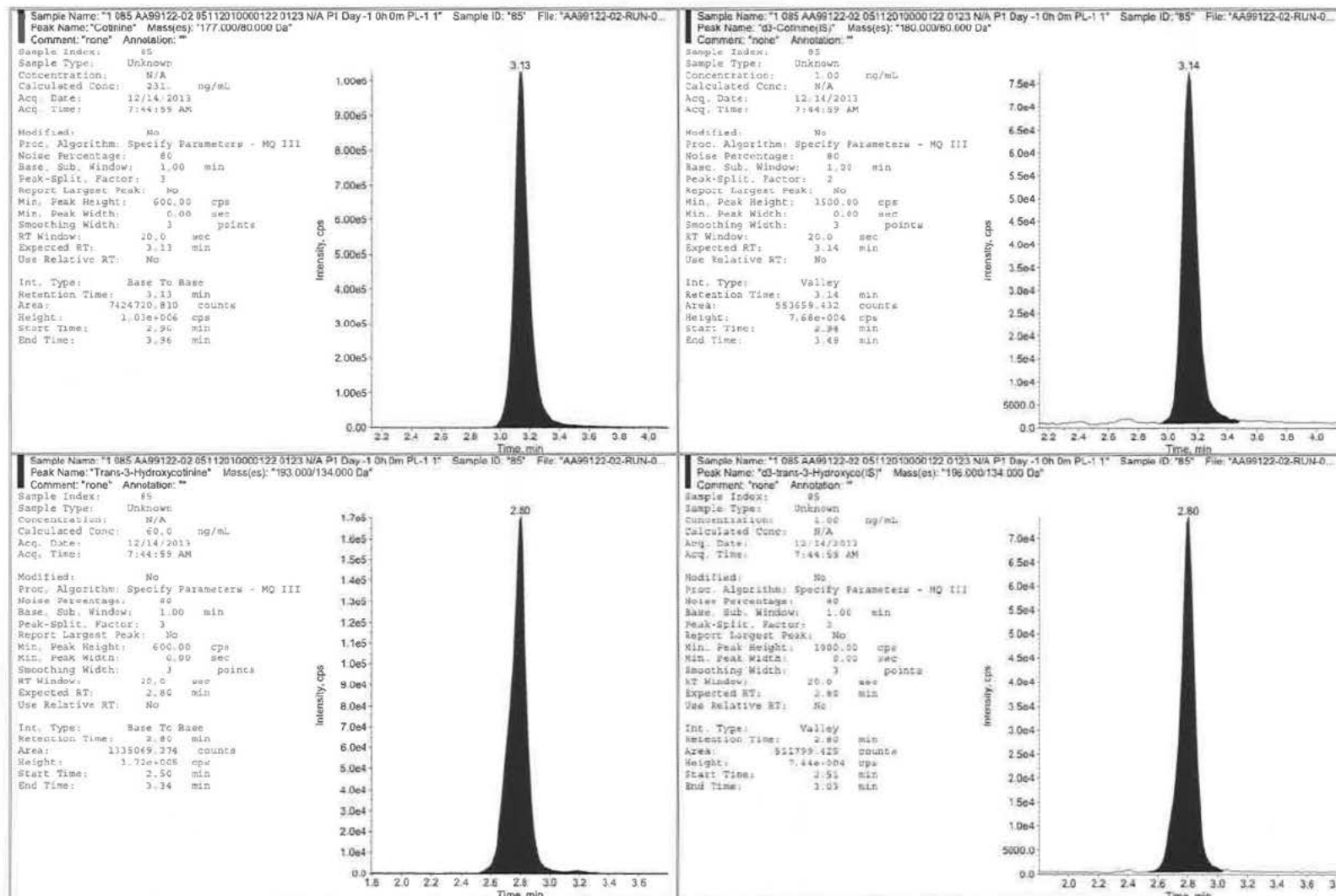
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



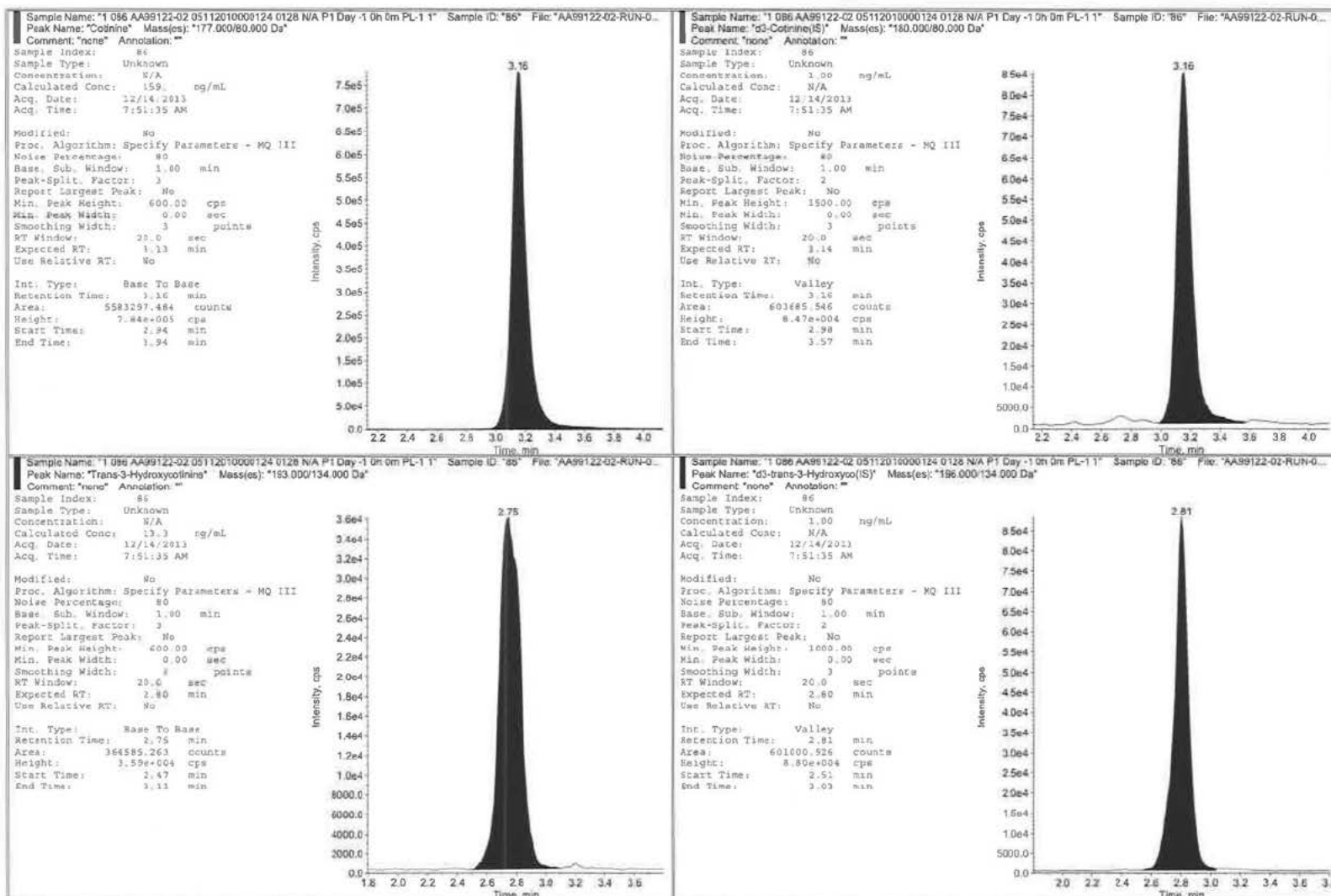
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02





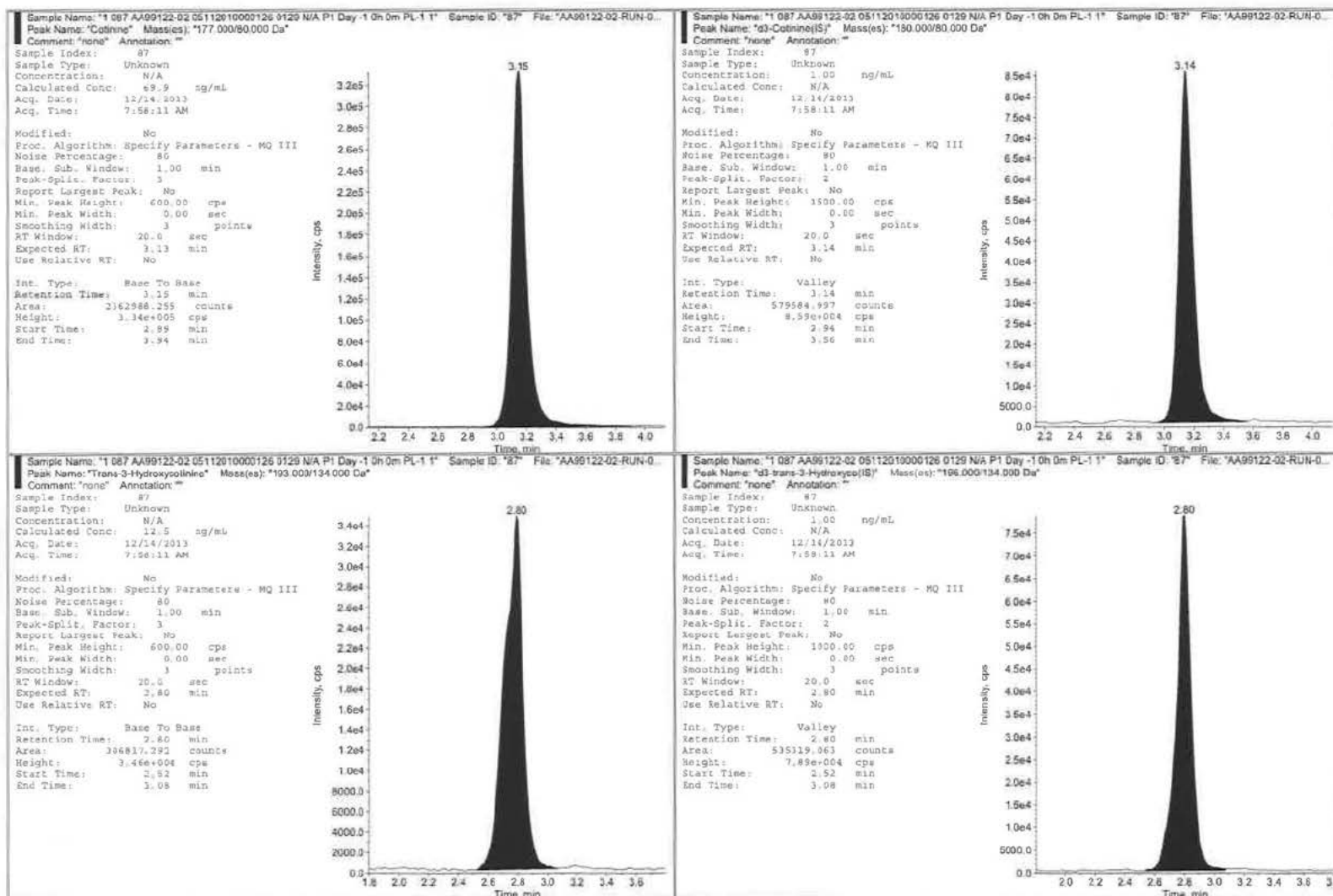


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

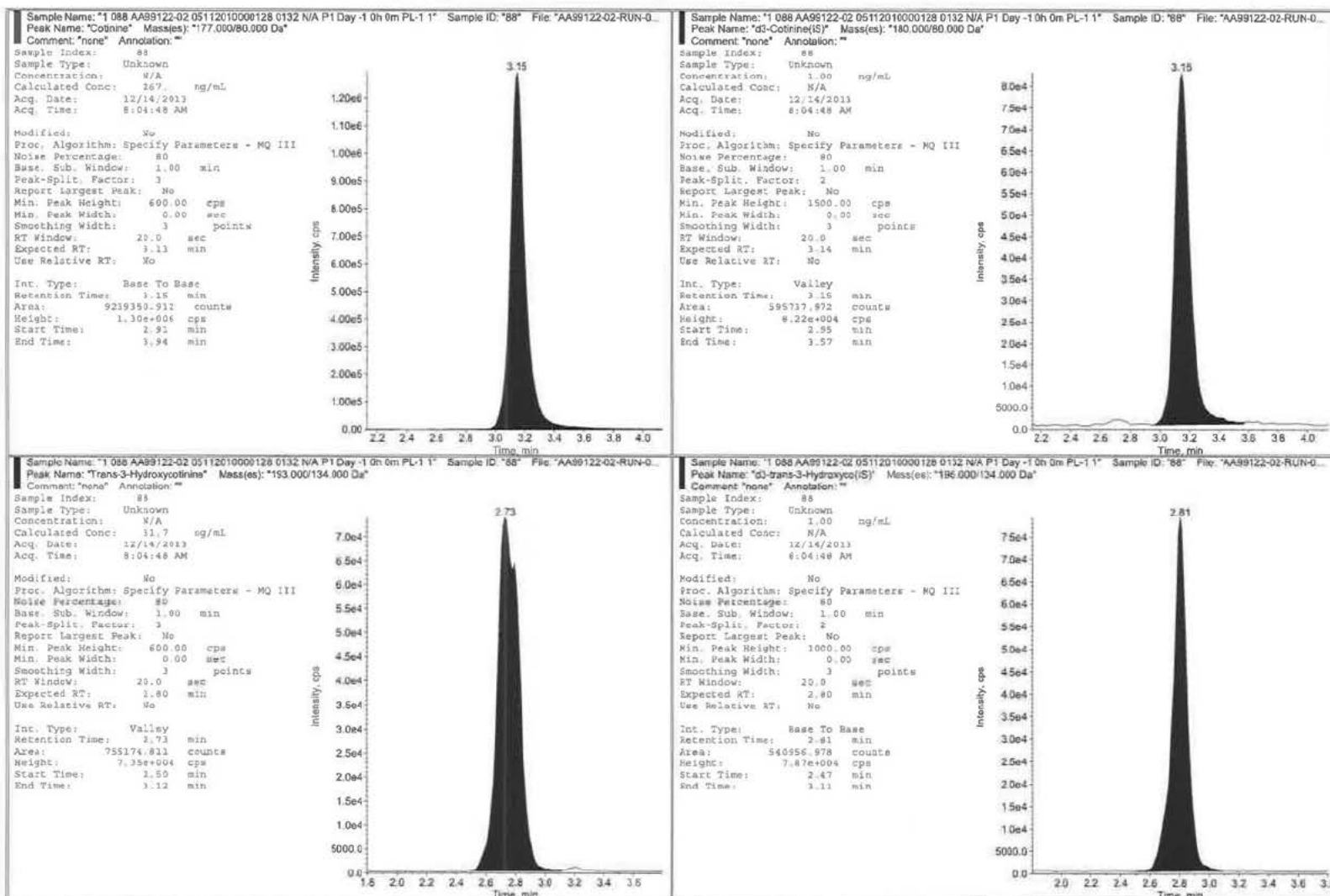




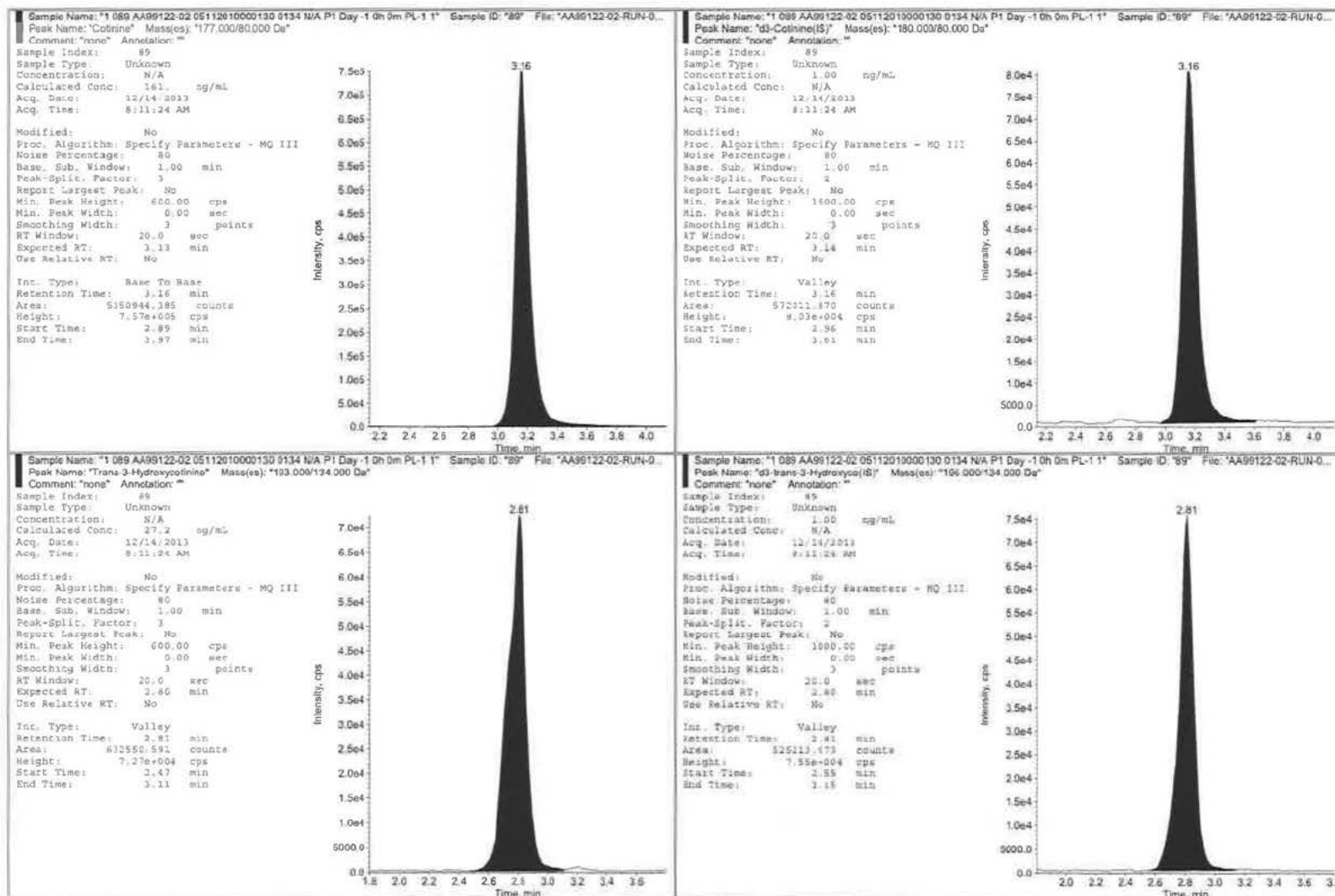
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



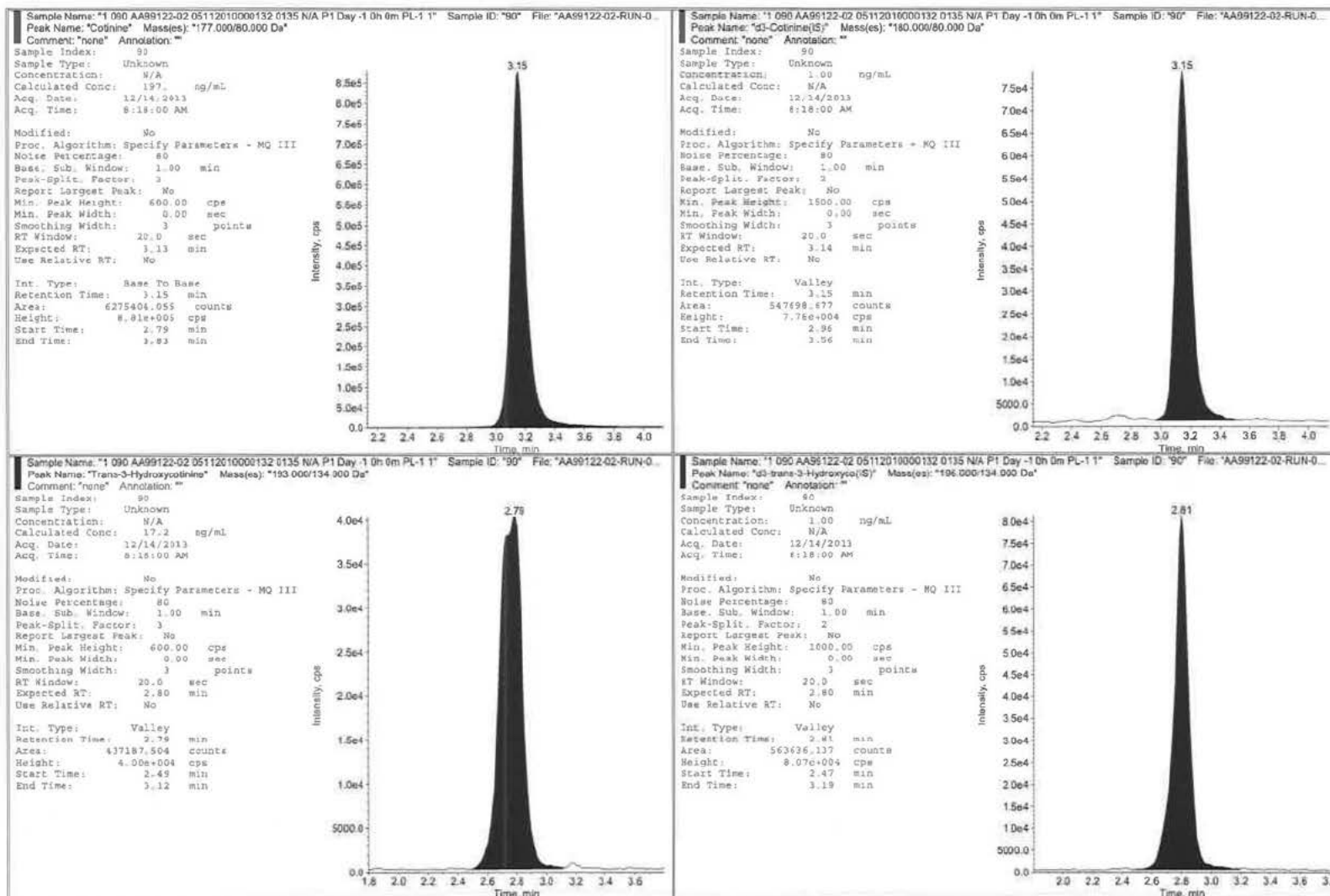
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



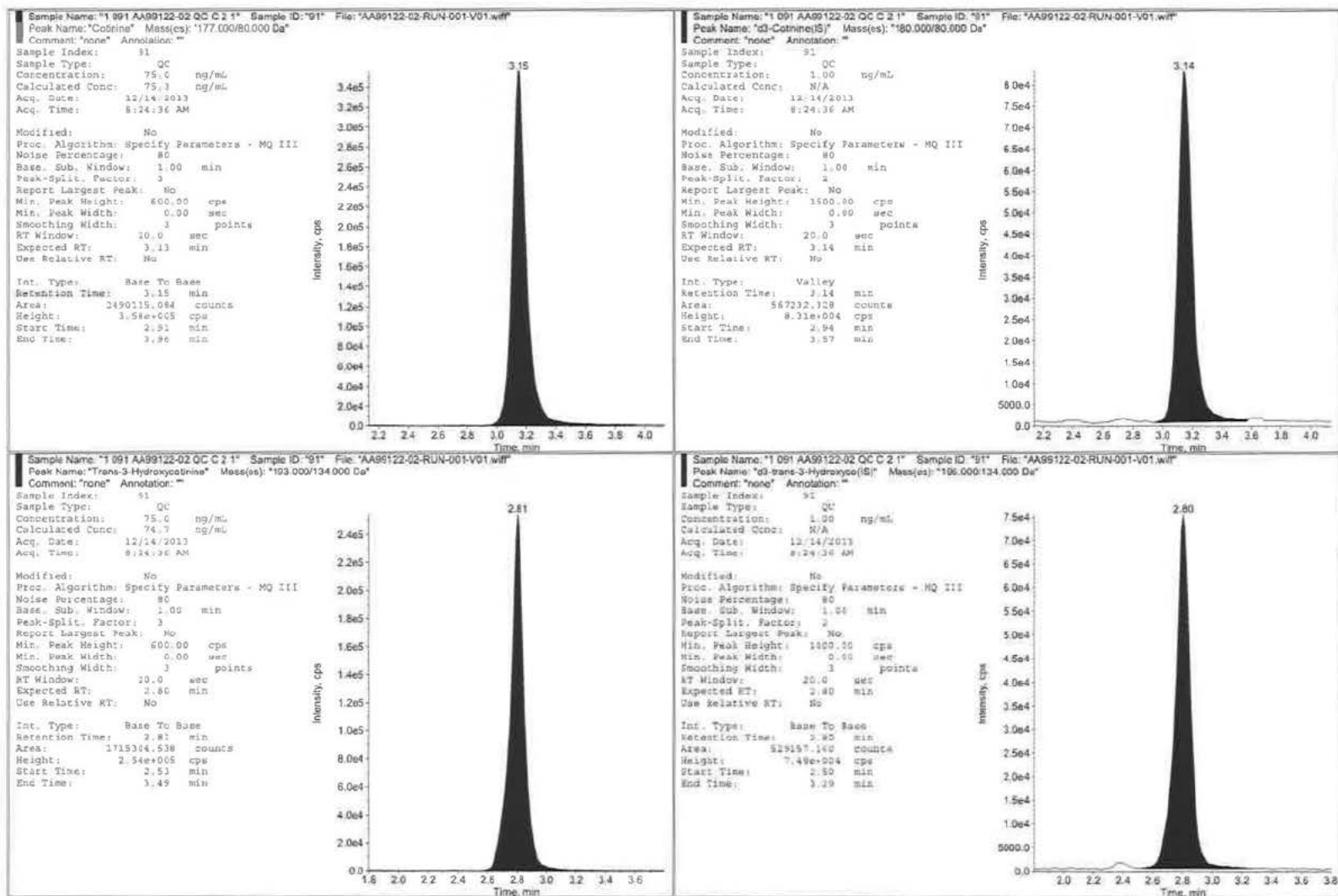
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

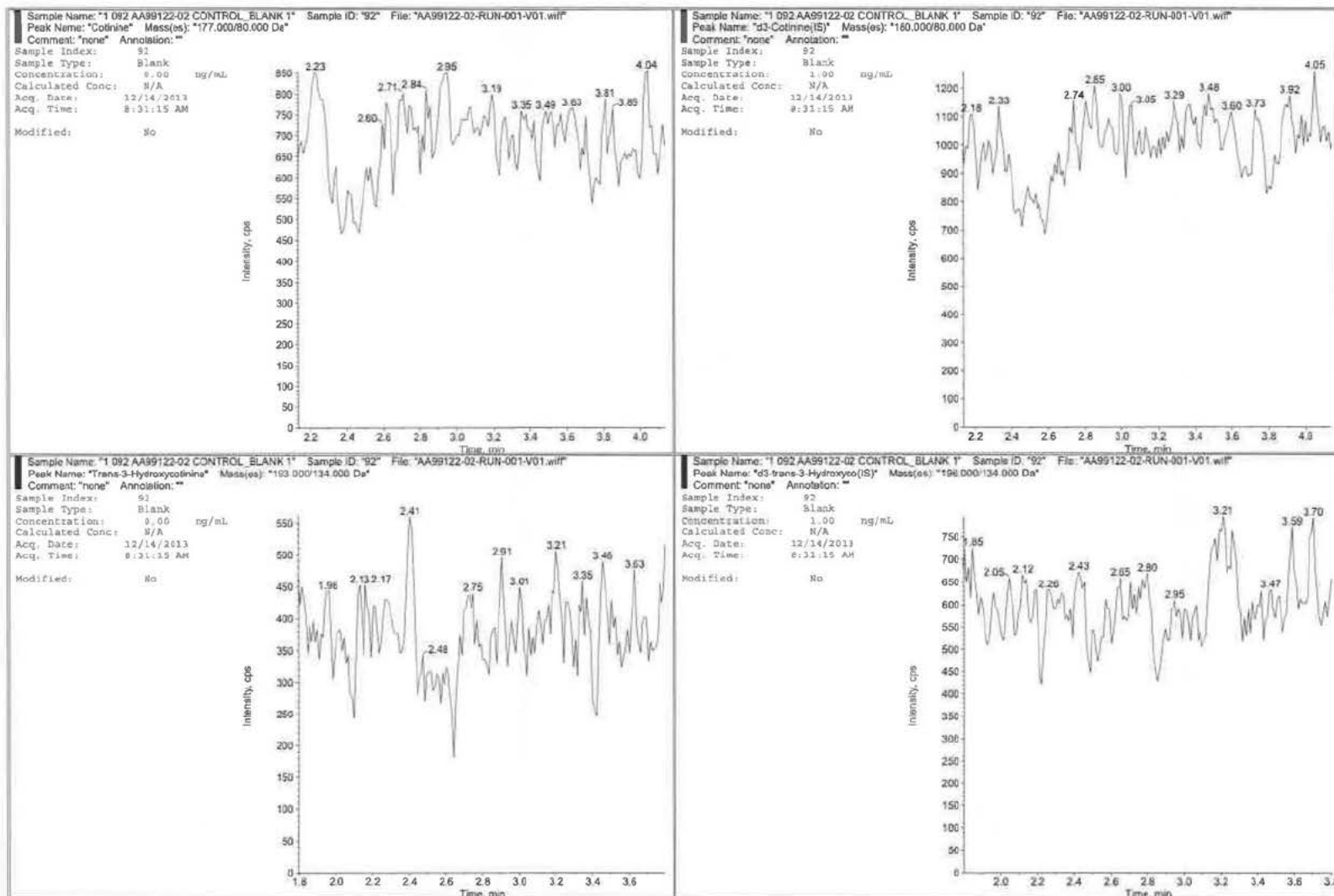


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

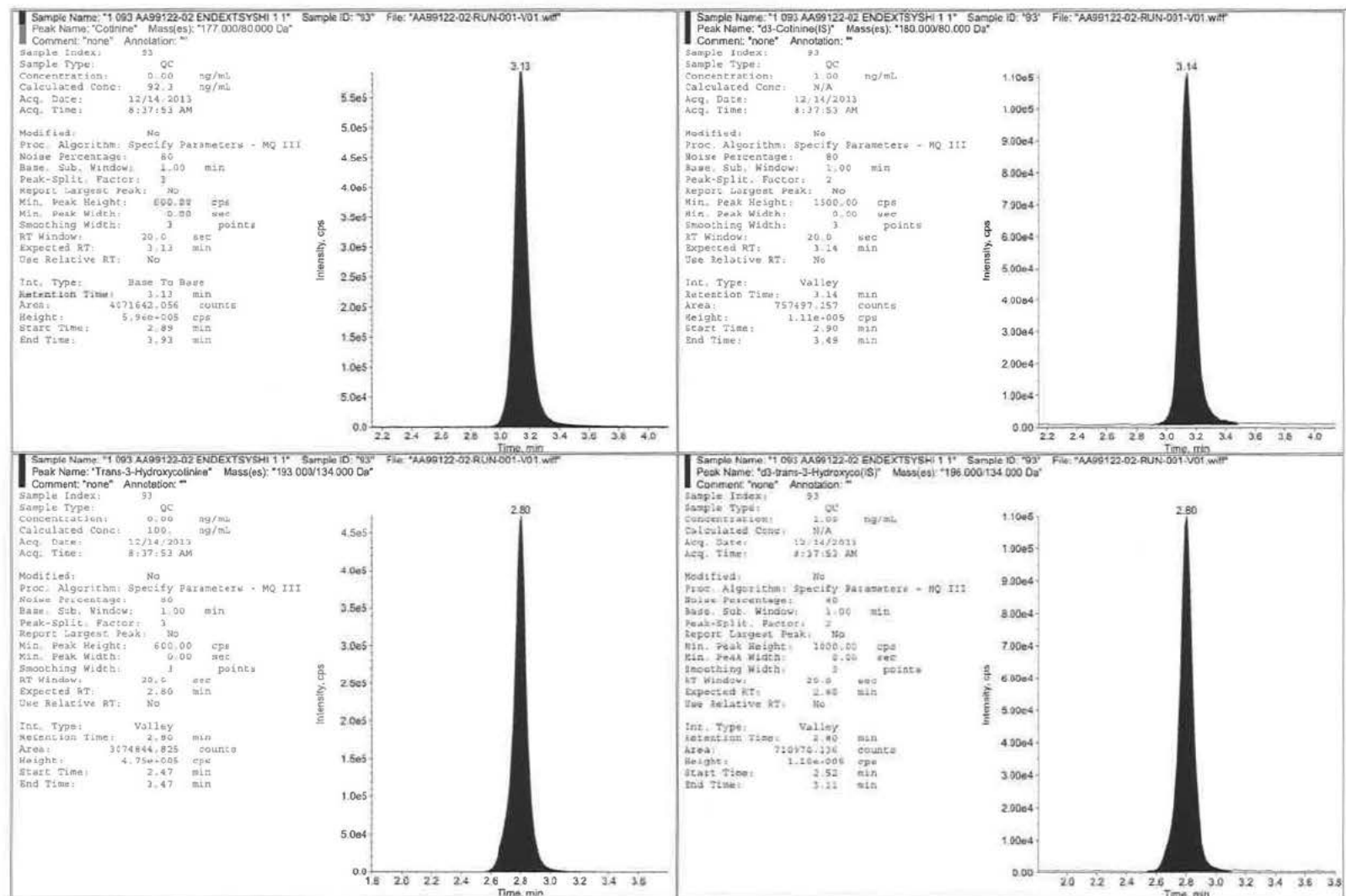


Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02

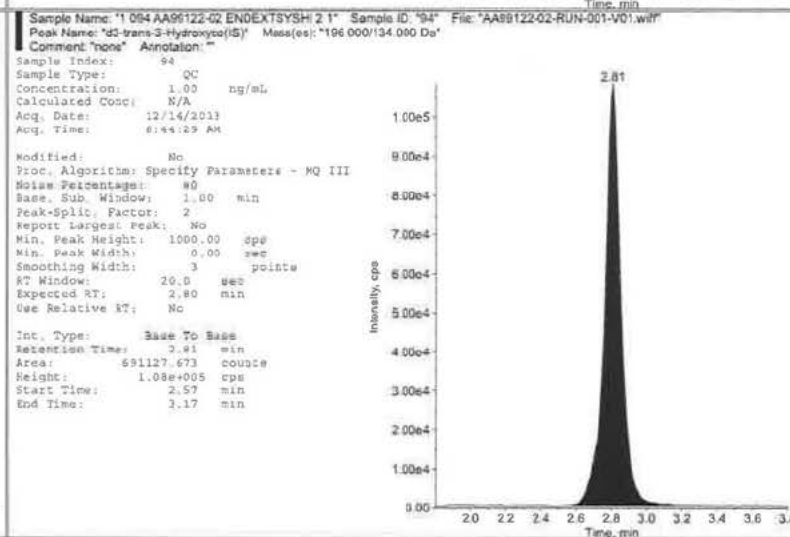
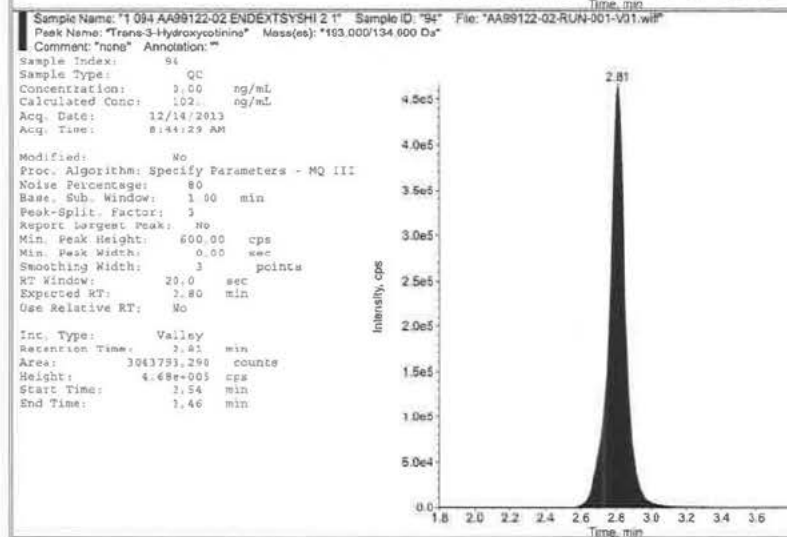
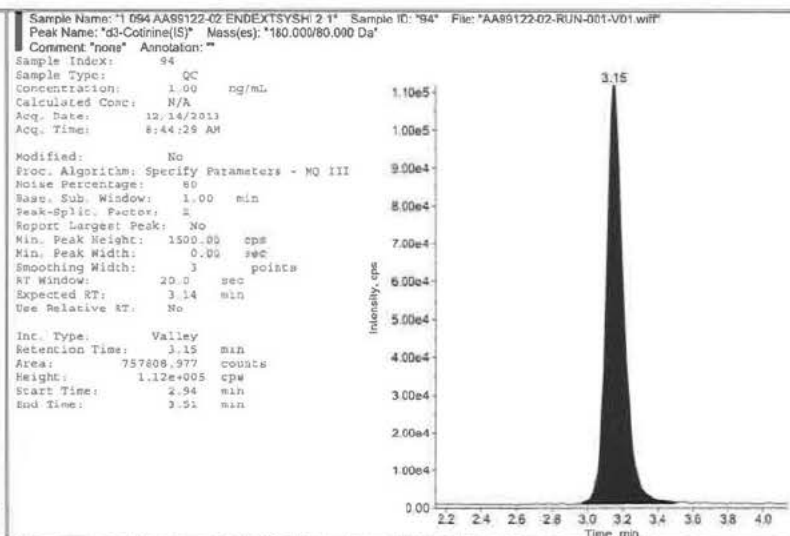
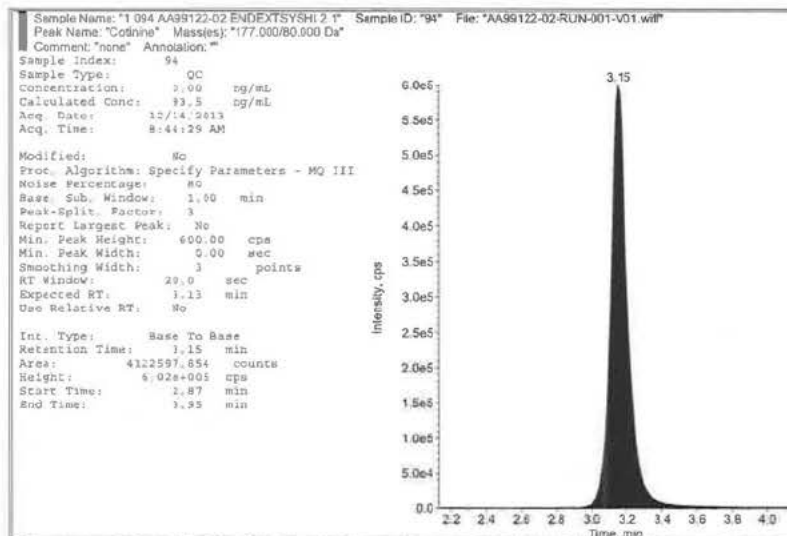




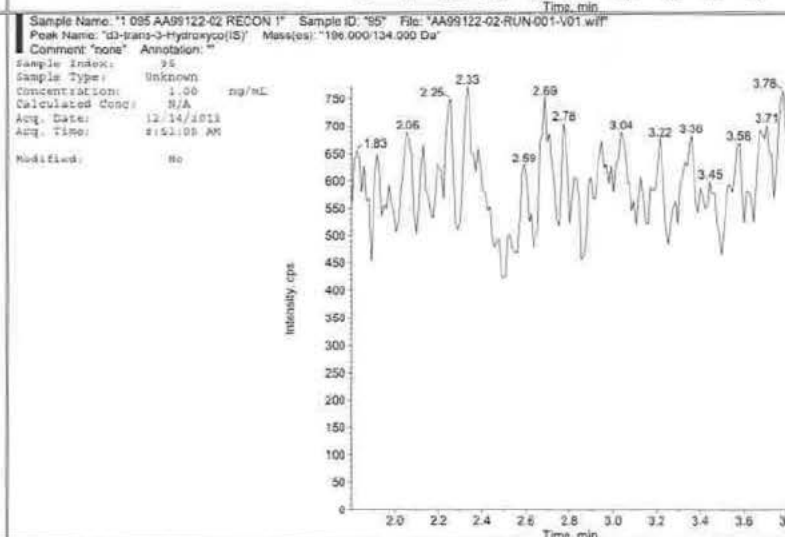
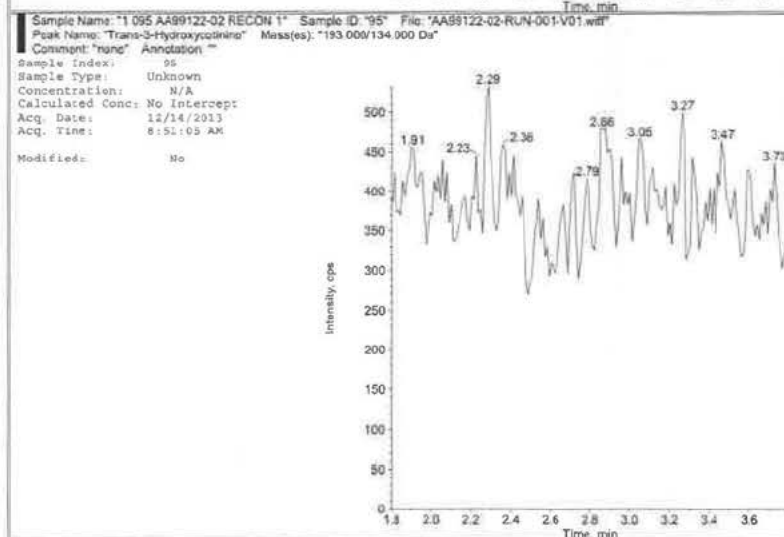
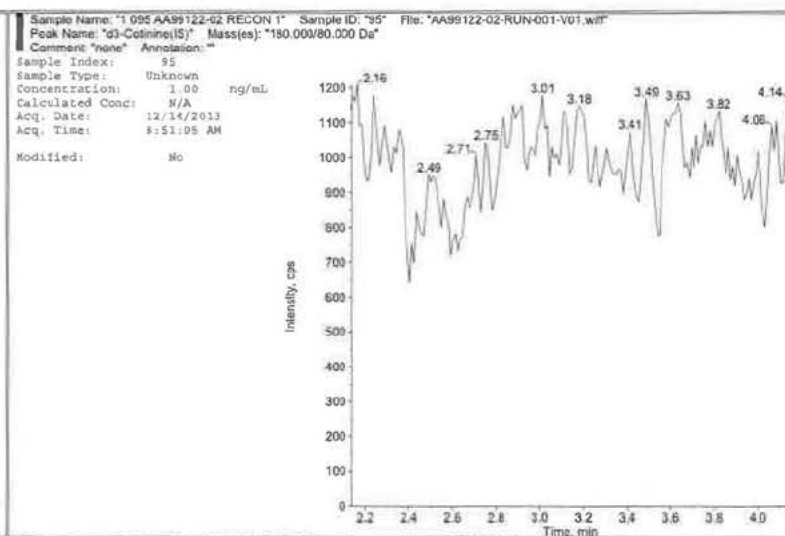
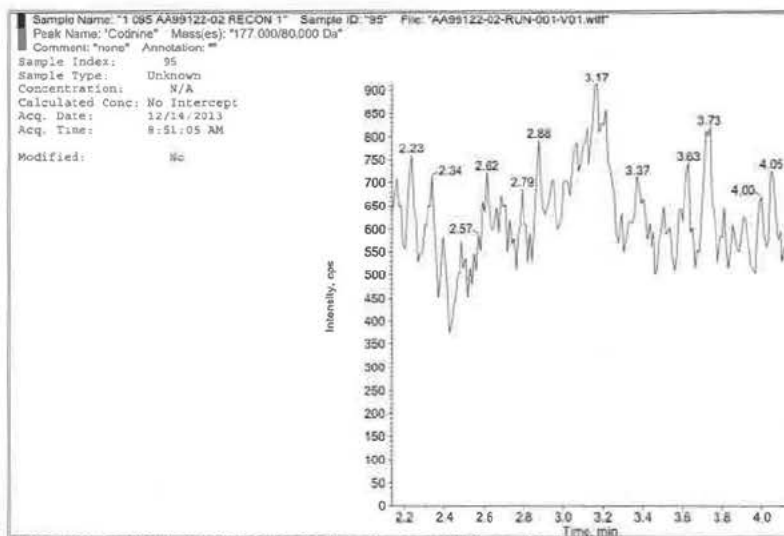




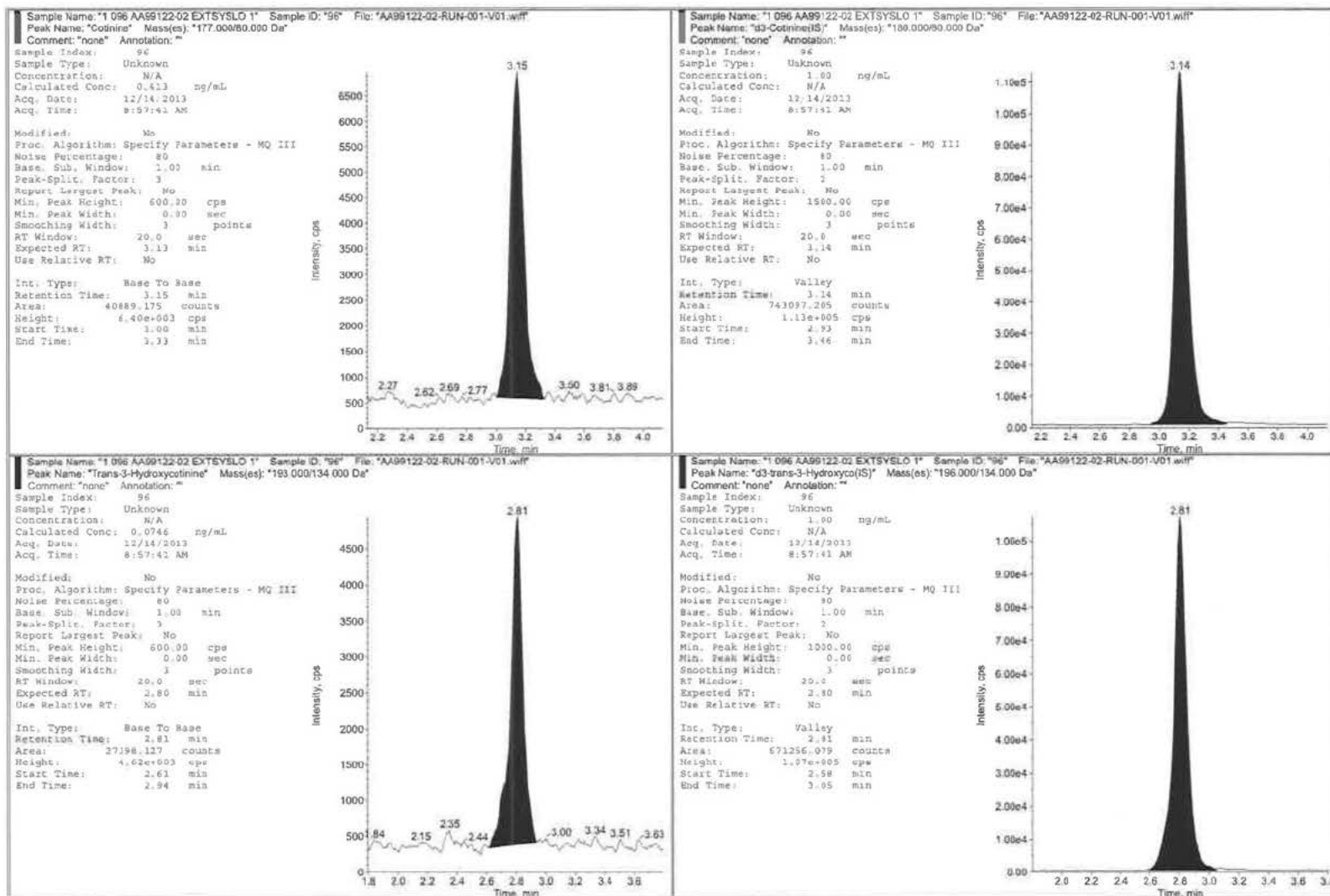
Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K<sub>2</sub>EDTA)  
Celerion Study AA99122-02



### Final Report

Bioanalysis of COHb in Human Whole Blood  
In Support of Clinical Study Protocol (ZRHM-PK-05-JP)

Title of the clinical trial: A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum	
Sponsor:	Philip Morris Products S.A. Quai Jeanrenaud 5 2000 Neuchâtel Switzerland
Study number:	ZRHM-PK-05-JP
Analyte:	Carboxyhaemoglobin (COHb)
Matrix	Human Whole Blood
Anticoagulant:	Sodium Heparin
Method:	CO-oximetry
Testing facility:	Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd. 4-16-22, Kami-ikebukuro, Toshima-ku, Tokyo, 170-0012, Japan
Beginning of the analysis	22/08/2013
Termination of the analysis	11/11/2013

### Confidentiality Statement

---

Contents may not be used, divulged, published, or otherwise disclosed without the written consent of Philip Morris Products S.A.

---

Sponsor: Philip Morris Products S.A.  
STATUS: FINAL      VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
DATE: 31 March 2014

Statement

Statement

The requested clinical tests for the trial listed below were conducted in strict observance of the SOP created by our company, and based on the Clinical Laboratory Technicians Law (the enforcement regulation No.24, 21 July 1958, Ministry of Health and Welfare, Japan).

#### Description

Sponsor: (b) (4)

Study title: Bioanalysis of COHb in Human Whole Blood  
In Support of Clinical Study Protocol (ZRHM-PK-05-JP)

Study number: ZRHM-PK-05-JP

Analyte: Carboxyhemoglobin (COHb)

Period of the analysis: 22/08/2013 to 11/11/2013

Testing facility: Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd.  
4-16-22, Kami-ikebukuro, Toshima-ku, Tokyo, 170-0012, Japan

Concluded

Mitsuaki Kameko *M. Kameko*  
Responsible for accuracy management  
Tokiwa Chemical Industries Co., Ltd.

Date *04-Apr-2014*

Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

Commission

Title	Bioanalysis of COHb in Human Whole Blood In Support of Clinical Study Protocol (ZRHM-PK-05-JP)		
Study Number	ZRHM-PK-05-JP		
Objective	The purpose of this study is to investigate Carbon Monoxide (CO) exposure by measuring COHb in blood, which is one of the biomarker of exposure (BoExp).		
Regulatory compliance	Clinical Laboratory Technicians Law (The enforcement regulation No.24, 21 July 1958, Ministry of Health and Welfare, Japan)		
Coverage for Quality Assurance Unit inspection	Not applicable Raw data was not inspected by Quality Assurance Unit (QAU).		
CoHb analysis service providing facility	Name	(b) (4)	
	Address	(b) (4)	
		(b) (4)	
	Representative	(b) (4)	(b) (4)
	Responsible person	(b) (4)	(b) (4) (b) (4)
	Contact information	TEL : (b) (4)	FAX : (b) (4)
Contractor	Name	Tokiwa Chemical Industries Co., Ltd.	
	Address	4-16-22, Kami-ikebukuro, Toshima-ku, Tokyo, 170-0012, Japan	
Testing facility	Name	Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd.	
	Address	4-16-22, Kami-ikebukuro, Toshima-ku, Tokyo, 170-0012, Japan	
	Study director	Kiyotaka Ishikawa	Leader of Study Test Group
	Contact information	TEL : 03-3940-7768	FAX : 03-3940-7689
	Study staff	Takako Hayashi et al	Study Test Group
Duration of study	Date of study initiation	06-Jun-2013	
	Date of sample reception	22-Aug-2013 to 11-Nov-2013	
	Analysis period	22-Aug-2013 to 11-Nov-2013	
	Date of study completion	31-Mar-2014	



Sponsor: Philip Morris Products S.A.  
STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
DATE: 31 March 2014

Documents submitted to the sponsor

Document	Number	Remarks
SAMPLE ANALYSIS PLAN	1	Original
Final report	1(Original), 1(Copy)	Original, Copy
All of the raw data and records	-	-

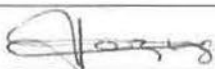
Data storage

Coverage for storage	<ul style="list-style-type: none"><li>• SAMPLE ANALYSIS PLAN (copy)</li><li>• Final report (copy)</li></ul>
Storage period	15 years after completion of the study
Archives	Data storage room in Tokiwa Chemical Industries Co., Ltd.

Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

Signatures of Study Director and Responsible for accuracy management

Title	Bioanalysis of COHb in Human Whole Blood In Support of Clinical Study Protocol (ZRHM-PK-05-JP)	
Study Number	ZRHM-PK-05-JP	
Sponsor		25 06 2014
	Christelle Haziza, PhD (Date) Manager Clinical Science Philip Morris Products S.A.	
Study director	K. Ishikawa	31-Mar-2014
	Kiyotaka Ishikawa (Date) Leader of Study Test Group Tokiwa Chemical Industries Co., Ltd.	
Responsible for accuracy management	M. Kameko	04-Apr-2014
	Mitsuaki Kameko (Date) Responsible for accuracy management Tokiwa Chemical Industries Co., Ltd	
Test facility manager	T. HIRASAWA	04-APR-2014
	Tamiyoshi Hirasawa (Date) Representative director Tokiwa Chemical Industries Co., Ltd	

List of abbreviations

Abbreviation	Definition
COHb	Carboxyhemoglobin
CO	Carbon Monoxide
BoExp	Biomarker of Exposure
(b)	(b) (4)
TCI	Tokiwa Chemical Industries Co., Ltd.
SAP	Sample Analysis Plan
IL	Instrumentation Laboratory
tHb	Total Hemoglobin concentration
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

Sponsor: Philip Morris Products S.A.  
STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
DATE: 31 March 2014

List of acceptable range and actual range for temperature

Name	Acceptable range	Actual range	Conclusion
Analytical sample	1-10°C	3-7°C	conform
IL Cal Dye (Calibrator)	17-28°C	21-25°C	conform
QC samples	1-10°C	3-8°C	conform

Signature of Study Director

Study director	<i>K. Ishikawa</i>	<i>31-Mar-2014</i>
	Kiyotaka Ishikawa Leader of Study Test Group Tokiwa Chemical Industries Co., Ltd.	(Date)

## Contents

Statement .....	2
I. Summary .....	9
II. Materials and method .....	9
1. Analytical samples .....	9
2. Analytes .....	9
3. Reagents .....	9
3.1. Purchased reagents .....	9
4. QC samples .....	10
5. Main instruments .....	10
6. Quality control .....	10
7. Re-analysis and criteria for adoption .....	10
7.1. Re-analysis .....	10
III. Results .....	11
1. Accuracy control .....	11
2. Raw data .....	11
IV. Discussion .....	11
V. Conclusion .....	12
VI. References .....	12
VII. ANNEXES .....	12
Table 1    Calibration results .....	13
Table 2    QCs results of COHb ZRHM-PK-05-JP samples .....	13
Table 3    COHb results of ZRHM-PK-05-JP samples .....	14

## I. Summary

This report describes the determination results of COHb in human whole blood as a part of Study Number: ZRHM-PK-05-JP requested by (b) (4). Measurement was performed by the method that was previously validated in the final report of "Validation for the determination of COHb in human whole blood containing sodium heparin" (Data of Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd., June 22, 2007), and consequently it was performed based on SOP No. 30-B-020-03 of Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd.

## II. Materials and method

### 1. Analytical samples

Title of the clinical trial	A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum
Clinical trial No.	ZRHM-PK-05-JP
Operation protocol No.	CLS2013-033
Matrix	Human Whole Blood
Anticoagulant	Sodium Heparin
Sampling point	5 points (PRIOR TO PRODUCT, 15 MINUTES, 60 MINUTES, 4 HOURS, 12 HOURS) each Day1 and Day3
Condition at reception	1-10°C , with cold pack
Number of subjects	62
Number of received samples	614
Number of analyzed samples	614
Storage condition	1-10°C
Term of validity	Analyzed within 3 weeks after collection <sup>1)</sup>
Handling after analysis	Residual samples were destroyed at TCI after analysis without delay.

### 2. Analytes

COHb in Human Whole Blood

### 3. Reagents

#### 3.1. Purchased reagents

Name	Manufacturer	Storage condition
IL Cal Dye	Instrumentation Laboratory	17-28°C
IL Multi-4 <sup>TM</sup> CO-Oximeter Control Solution	Instrumentation Laboratory	1-10°C
Zeroing Solution	Instrumentation Laboratory	17-28°C
Diluent	Instrumentation Laboratory	17-28°C
Cleaning Agent	Instrumentation Laboratory	17-28°C

#### 4. QC samples

QC samples	Level #1		Level #2		Level #3	
Lot No.	N0820706	N0132447	N0820705	N0132446	N0820707	N0233014
Expiry date	2013.11	2014.04	2013.11	2014.04	2013.11	2014.04
Storage condition	1-10°C					
Concentration	COHb is indicated as a %. tHb is indicated as g/dL. The first decimal place					
Remarks	IL Multi-4™ CO-Oximeter Control Solutions is used for the QC samples.					

#### 5. Main instruments

Name	Model	Manufacturer
CO-Oximeter	IL 682	Instrumentation Laboratory

#### 6. Quality control

QC samples	Criteria
	The Level #1, Level #2, and Level #3 of COHb (%) and tHb (g/dL) must be within the control range designated by the Instrumentation Laboratory.

#### 7. Re-analysis and criteria for adoption

##### 7.1. Re-analysis

In the following cases, the re-analysis should be conducted.

(1)	The acceptance criteria for QC samples are not satisfied.
(2)	A problem on the analytical equipment or instrument occurs. a. Clogging of a nozzle or cell, or similar problem, occurred.
(3)	A technical error is recognized on the determination such as; a. Analytical sample is lost by tubes broken. b. A fibrin clot was aspirated, preventing a correct measurement value from being obtained.
(4)	The study director or study staff judges the re-analysis is necessary. a. It was confirmed that a little fibrin clot was sucked at the tip of the nozzle after analysis etc.



### III. Results

#### 1. Accuracy control

QC samples	Lot No.	Analyte		Conclusion
		COHb		
		Acceptable range (%)	Measured values (%)	
Level #1	N0820706	55.0-65.0	60.2	conform
	N0132447	57.7-61.1	60.3-60.4	conform
Level #2	N0820705	1.0-7.0	3.7	conform
	N0132446	1.5-4.9	3.5-3.7	conform
Level #3	N0820707	20.0-26.0	24.0	conform
	N0233014	19.7-23.1	21.7-21.9	conform

Reference of table 2 QCs results of COHb ZRHM-PK-05-JP samples (COHb)

QC samples	Lot No.	Analyte		Conclusion
		tHb		
		Acceptable range (g/dL)	Measured values (g/dL)	
Level #1	N0820706	15.9-18.0	17.3	conform
	N0132447	15.9-17.3	16.7-17.0	conform
Level #2	N0820705	12.5-14.5	13.7	conform
	N0132446	12.3-13.5	13.1-13.3	conform
Level #3	N0820707	5.5-8.0	6.7	conform
	N0233014	6.8-7.8	7.3-7.4	conform

Reference of table 2 QCs results of COHb ZRHM-PK-05-JP samples (tHb)

#### 2. Raw data

The raw data obtained in this study are shown in [Tables 1 to 3](#).

The results ([Table 1](#)) of calibration (tests were performed within 1 month of the most recent calibration) and the measurement results ([Table 2](#)) from the measured QC samples on each measurement day were within the control range designated by the Instrumentation Laboratory. Fibrin precipitation was observed in the sample from Subject ID 0140, at Visit Day 1 (Time Point: 4 HOURS). A reference comment was added for this sample due to fibrin precipitation. ("Data could be affected by fibrin" was entered in the Supplementary Comment 1 space ([Table 3](#)).)

### IV. Discussion

The results in accuracy control satisfied the acceptance criteria.

The determination was conducted within the period of storage (3 weeks after collection) in which the stability was confirmed. No unrealistic data was noted in the assay.

The Raw data measured this study were obtained in the expected and acceptable experimental conditions regarding the study plan and the purpose of the study.

#### V. Conclusion

No unforeseeable events that may have adversely affected the reliability of the study and deviations from the analytical protocol was noted in this study.

The data obtained in this study can be judged reliable and can be used as “Blood biomarker of exposure” in the main study ZRHM-PK-05-JP.

#### VI. References

(1)	Final Report of “Validation for the determination of COHb in human whole blood (Data of Tokiwa Analytical Laboratory in Tokiwa Chemical Industries Co., Ltd., June 22, 2007)
(2)	SOP No. 30-B-020-03 of Tokiwa Analytical Laboratory (June 30, 2011)
(3)	SAMPLE ANALYSIS PLAN
(4)	Instruction manual of IL 682 CO-Oximeter

#### VII. ANNEXES

(1)	Table 1	Calibration results
(2)	Table 2	QCs results of COHb ZRHM-PK-05-JP samples
(3)	Table 3	COHb results of ZRHM-PK-05-JP samples

Table 1 Calibration results

No.	Date of performance	IL Cal Dye		Remarks
		Lot No.	Actual measurement	
			tHb (g/dL)	
1	2013/8/15	N0921069	15.3	
2	2013/9/9	N0921069	15.3	
3	2013/10/4	N0921069	15.4	
4	2013/10/17	N0921069	15.3	Due to a power outage (57 minutes: 8:49 – 9:46) caused by a typhoon on 10/16, calibration was performed on 10/17 to be certain of reliability.
5	2013/11/8	N0921069	15.3	

**Lot No. and Exp. date of IL Cal Dye**

Lot No.	Exp. date
N0921069	2016.01

Table 2 QCs results of COHb ZRHM-PK-05-JP samples

No	Date of sample reception	Number of received samples	Date of analysis	Number of analyzed samples	IL Multi-4™ CO-Oximeter control solutions								
					Level #1			Level #2			Level #3		
					Lot No.	Actual measurement	unit	Lot No.	Actual measurement	unit	Lot No.	Actual measurement	unit
1	2013/8/22	110	2013/8/22	110	N0820706	tHb 17.3 (g/dL)		N0820705	tHb 13.7 (g/dL)		N0820707	tHb 6.7 (g/dL)	
						COHb 60.2 (%)			COHb 3.7 (%)			COHb 24.0 (%)	
2	2013/9/12	120	2013/9/12	120	N0132447	tHb 16.7 (g/dL)		N0132446	tHb 13.2 (g/dL)		N0233014	tHb 7.3 (g/dL)	
						COHb 60.3 (%)			COHb 3.7 (%)			COHb 21.7 (%)	
3	2013/9/27	160	2013/9/28	160	N0132447	tHb 17.0 (g/dL)		N0132446	tHb 13.3 (g/dL)		N0233014	tHb 7.4 (g/dL)	
						COHb 60.3 (%)			COHb 3.5 (%)			COHb 21.9 (%)	
4	2013/10/17	94	2013/10/17	94	N0132447	tHb 16.9 (g/dL)		N0132446	tHb 13.2 (g/dL)		N0233014	tHb 7.4 (g/dL)	
						COHb 60.3 (%)			COHb 3.7 (%)			COHb 21.8 (%)	
5	2013/11/11	130	2013/11/11	130	N0132447	tHb 16.9 (g/dL)		N0132446	tHb 13.1 (g/dL)		N0233014	tHb 7.4 (g/dL)	
						COHb 60.3 (%)			COHb 3.7 (%)			COHb 21.9 (%)	

**Acceptable range of IL Multi-4™ CO-Oximeter control solutions (N0821071, Exp. date 2013.11)**

Level #1			Level #2			Level #3		
Lot No.	Acceptable range	unit	Lot No.	Acceptable range	unit	Lot No.	Acceptable range	unit
N0820706	tHb 15.9-18.0 (g/dL)		N0820705	tHb 12.5-14.5 (g/dL)		N0820707	tHb 5.5-8.0 (g/dL)	
	COHb 55.0-65.0 (%)			COHb 1.0-7.0 (%)			COHb 20.0-26.0 (%)	

**Acceptable range of IL Multi-4™ CO-Oximeter control solutions (N0132817, Exp. date 2014.04)**

Level #1			Level #2			Level #3		
Lot No.	Acceptable range	unit	Lot No.	Acceptable range	unit	Lot No.	Acceptable range	unit
N0132447	tHb 15.9-17.3 (g/dL)		N0132446	tHb 12.3-13.5 (g/dL)		N0233014	tHb 6.8-7.8 (g/dL)	
	COHb 57.7-61.1 (%)			COHb 1.5-4.9 (%)			COHb 19.7-23.1 (%)	

Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

Table 3 COHb results of ZRHM-PK-05-JP samples

Study ID	Site	Visit	Time Point	Subject ID	Site ID	Sampling Date	Blood Sampling Time	Analyte Name	Result	Unit	Supplementary Comment 1
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0002	AGE	2013/08/18	07:27	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0002	AGE	2013/08/18	07:45	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0002	AGE	2013/08/18	08:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0002	AGE	2013/08/18	11:30	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0002	AGE	2013/08/18	19:30	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0002	AGE	2013/08/20	07:27	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0002	AGE	2013/08/20	07:45	COHb	4.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0002	AGE	2013/08/20	08:30	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0002	AGE	2013/08/20	11:30	COHb	3.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0002	AGE	2013/08/20	19:30	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0004	AGE	2013/08/18	08:35	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0004	AGE	2013/08/18	08:53	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0004	AGE	2013/08/18	09:38	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0004	AGE	2013/08/18	12:38	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0004	AGE	2013/08/18	20:38	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0004	AGE	2013/08/20	08:52	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0004	AGE	2013/08/20	09:10	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0004	AGE	2013/08/20	09:55	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0004	AGE	2013/08/20	12:55	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0004	AGE	2013/08/20	20:55	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0005	AGE	2013/08/18	08:01	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0005	AGE	2013/08/18	08:19	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0005	AGE	2013/08/18	09:04	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0005	AGE	2013/08/18	12:04	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0005	AGE	2013/08/18	20:04	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0005	AGE	2013/08/20	08:01	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0005	AGE	2013/08/20	08:19	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0005	AGE	2013/08/20	09:04	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0005	AGE	2013/08/20	12:04	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0005	AGE	2013/08/20	20:04	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0010	AGE	2013/08/18	08:01	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0010	AGE	2013/08/18	08:19	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0010	AGE	2013/08/18	09:04	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0010	AGE	2013/08/18	12:04	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0010	AGE	2013/08/18	20:04	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0010	AGE	2013/08/20	08:01	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0010	AGE	2013/08/20	08:19	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0010	AGE	2013/08/20	09:04	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0010	AGE	2013/08/20	12:04	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0010	AGE	2013/08/20	20:04	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0013	AGE	2013/08/18	07:27	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0013	AGE	2013/08/18	07:45	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0013	AGE	2013/08/18	08:30	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0013	AGE	2013/08/18	11:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0013	AGE	2013/08/18	19:30	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0013	AGE	2013/08/20	07:27	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0013	AGE	2013/08/20	07:45	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0013	AGE	2013/08/20	08:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0013	AGE	2013/08/20	11:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0013	AGE	2013/08/20	19:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0017	AGE	2013/08/18	08:52	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0017	AGE	2013/08/18	09:10	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0017	AGE	2013/08/18	09:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0017	AGE	2013/08/18	12:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0017	AGE	2013/08/18	20:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0017	AGE	2013/08/20	08:35	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0017	AGE	2013/08/20	08:53	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0017	AGE	2013/08/20	09:38	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0017	AGE	2013/08/20	12:38	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0017	AGE	2013/08/20	20:38	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0018	AGE	2013/08/18	08:52	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0018	AGE	2013/08/18	09:10	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0018	AGE	2013/08/18	09:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0018	AGE	2013/08/18	12:55	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0018	AGE	2013/08/18	20:55	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0018	AGE	2013/08/20	08:52	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0018	AGE	2013/08/20	09:10	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0018	AGE	2013/08/20	09:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0018	AGE	2013/08/20	12:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0018	AGE	2013/08/20	20:55	COHb	2.6	%	



Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0022	AGE	2013/08/18	08:52	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0022	AGE	2013/08/18	09:10	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0022	AGE	2013/08/18	09:55	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0022	AGE	2013/08/18	12:55	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0022	AGE	2013/08/18	20:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0022	AGE	2013/08/20	08:52	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0022	AGE	2013/08/20	09:10	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0022	AGE	2013/08/20	09:55	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0022	AGE	2013/08/20	12:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0022	AGE	2013/08/20	20:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0024	AGE	2013/08/18	07:44	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0024	AGE	2013/08/18	08:02	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0024	AGE	2013/08/18	08:47	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0024	AGE	2013/08/18	11:47	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0024	AGE	2013/08/18	19:47	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0024	AGE	2013/08/20	07:44	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0024	AGE	2013/08/20	08:02	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0024	AGE	2013/08/20	08:47	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0024	AGE	2013/08/20	11:47	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0024	AGE	2013/08/20	19:47	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0025	AGE	2013/08/18	08:18	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0025	AGE	2013/08/18	08:36	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0025	AGE	2013/08/18	09:21	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0025	AGE	2013/08/18	12:21	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0025	AGE	2013/08/18	20:21	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0025	AGE	2013/08/20	08:18	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0025	AGE	2013/08/20	08:36	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0025	AGE	2013/08/20	09:21	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0025	AGE	2013/08/20	12:21	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0025	AGE	2013/08/20	20:21	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0027	AGE	2013/08/18	08:18	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0027	AGE	2013/08/18	08:36	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0027	AGE	2013/08/18	09:21	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0027	AGE	2013/08/18	12:21	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0027	AGE	2013/08/18	20:21	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0027	AGE	2013/08/20	08:18	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0027	AGE	2013/08/20	08:36	COHb	4.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0027	AGE	2013/08/20	09:21	COHb	4.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0027	AGE	2013/08/20	12:21	COHb	3.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0027	AGE	2013/08/20	20:21	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0031	AGE	2013/09/08	07:27	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0031	AGE	2013/09/08	07:45	COHb	4.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0031	AGE	2013/09/08	08:30	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0031	AGE	2013/09/08	11:30	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0031	AGE	2013/09/08	19:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0031	AGE	2013/09/10	07:27	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0031	AGE	2013/09/10	07:45	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0031	AGE	2013/09/10	08:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0031	AGE	2013/09/10	11:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0031	AGE	2013/09/10	19:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0035	AGE	2013/09/08	08:52	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0035	AGE	2013/09/08	09:10	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0035	AGE	2013/09/08	09:55	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0035	AGE	2013/09/08	12:55	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0035	AGE	2013/09/08	20:55	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0035	AGE	2013/09/10	07:44	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0035	AGE	2013/09/10	08:02	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0035	AGE	2013/09/10	08:47	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0035	AGE	2013/09/10	11:47	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0035	AGE	2013/09/10	19:47	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0036	AGE	2013/09/08	07:27	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0036	AGE	2013/09/08	07:45	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0036	AGE	2013/09/08	08:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0036	AGE	2013/09/08	11:30	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0036	AGE	2013/09/08	19:30	COHb	1.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0036	AGE	2013/09/10	08:35	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0036	AGE	2013/09/10	08:53	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0036	AGE	2013/09/10	09:38	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0036	AGE	2013/09/10	12:38	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0036	AGE	2013/09/10	20:38	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0039	AGE	2013/09/08	07:44	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0039	AGE	2013/09/08	08:02	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0039	AGE	2013/09/08	08:47	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0039	AGE	2013/09/08	11:47	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0039	AGE	2013/09/08	19:47	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0039	AGE	2013/09/10	07:27	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0039	AGE	2013/09/10	07:45	COHb	3.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0039	AGE	2013/09/10	08:30	COHb	3.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0039	AGE	2013/09/10	11:30	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0039	AGE	2013/09/10	19:30	COHb	2.8	%	

Study Number: ZRHM-PK-05-JP

DATE:31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0040	AGE	2013/09/08	07:44	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0040	AGE	2013/09/08	08:02	COHB	3.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0040	AGE	2013/09/08	08:47	COHB	3.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0040	AGE	2013/09/08	11:47	COHB	3.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0040	AGE	2013/09/08	19:47	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0040	AGE	2013/09/10	08:01	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0040	AGE	2013/09/10	08:19	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0040	AGE	2013/09/10	09:04	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0040	AGE	2013/09/10	12:04	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0040	AGE	2013/09/10	20:04	COHB	2.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0043	AGE	2013/09/08	08:01	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0043	AGE	2013/09/08	08:19	COHB	3.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0043	AGE	2013/09/08	09:04	COHB	3.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0043	AGE	2013/09/08	12:04	COHB	3.0	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0043	AGE	2013/09/08	20:04	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0043	AGE	2013/09/10	08:18	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0043	AGE	2013/09/10	08:36	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0043	AGE	2013/09/10	09:21	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0043	AGE	2013/09/10	12:21	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0043	AGE	2013/09/10	20:21	COHB	2.0	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0045	AGE	2013/09/08	08:01	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0045	AGE	2013/09/08	08:19	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0045	AGE	2013/09/08	09:04	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0045	AGE	2013/09/08	12:04	COHB	2.6	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0045	AGE	2013/09/08	20:04	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0045	AGE	2013/09/10	07:44	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0045	AGE	2013/09/10	08:02	COHB	3.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0045	AGE	2013/09/10	08:47	COHB	3.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0045	AGE	2013/09/10	11:47	COHB	3.0	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0045	AGE	2013/09/10	19:47	COHB	2.6	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0049	AGE	2013/09/08	08:18	COHB	2.6	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0049	AGE	2013/09/08	08:36	COHB	2.6	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0049	AGE	2013/09/08	09:21	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0049	AGE	2013/09/08	12:21	COHB	2.7	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0049	AGE	2013/09/08	20:21	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0049	AGE	2013/09/10	08:01	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0049	AGE	2013/09/10	08:19	COHB	4.6	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0049	AGE	2013/09/10	09:04	COHB	3.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0049	AGE	2013/09/10	12:04	COHB	3.8	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0049	AGE	2013/09/10	20:04	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0050	AGE	2013/09/08	08:18	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0050	AGE	2013/09/08	08:36	COHB	3.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0050	AGE	2013/09/08	09:21	COHB	3.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0050	AGE	2013/09/08	12:21	COHB	3.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0050	AGE	2013/09/08	20:21	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0050	AGE	2013/09/10	08:35	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0050	AGE	2013/09/10	08:53	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0050	AGE	2013/09/10	09:38	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0050	AGE	2013/09/10	12:38	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0050	AGE	2013/09/10	20:38	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0051	AGE	2013/09/08	08:35	COHB	2.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0051	AGE	2013/09/08	08:53	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0051	AGE	2013/09/08	09:38	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0051	AGE	2013/09/08	12:38	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0051	AGE	2013/09/08	20:38	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0051	AGE	2013/09/10	08:52	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0051	AGE	2013/09/10	09:10	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0051	AGE	2013/09/10	09:55	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0051	AGE	2013/09/10	12:55	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0051	AGE	2013/09/10	20:55	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0052	AGE	2013/09/08	08:52	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0052	AGE	2013/09/08	09:10	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0052	AGE	2013/09/08	09:55	COHB	2.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0052	AGE	2013/09/08	12:55	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0052	AGE	2013/09/08	20:55	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0052	AGE	2013/09/10	08:18	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0052	AGE	2013/09/10	08:36	COHB	3.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0052	AGE	2013/09/10	09:21	COHB	2.8	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0052	AGE	2013/09/10	12:21	COHB	2.9	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0052	AGE	2013/09/10	20:21	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0054	AGE	2013/09/08	08:35	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0054	AGE	2013/09/08	08:53	COHB	3.5	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0054	AGE	2013/09/08	09:38	COHB	3.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0054	AGE	2013/09/08	12:38	COHB	2.8	%
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0054	AGE	2013/09/08	20:38	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0054	AGE	2013/09/10	08:52	COHB	2.1	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0054	AGE	2013/09/10	09:10	COHB	2.4	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0054	AGE	2013/09/10	09:55	COHB	2.3	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0054	AGE	2013/09/10	12:55	COHB	2.2	%
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0054	AGE	2013/09/10	20:55	COHB	2.2	%

Sponsor: Philip Morris Products S.A.  
STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0060	AGE	2013/09/23	08:16	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0060	AGE	2013/09/23	08:34	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0060	AGE	2013/09/23	09:19	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0060	AGE	2013/09/23	12:19	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0060	AGE	2013/09/23	20:19	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0060	AGE	2013/09/25	07:24	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0060	AGE	2013/09/25	07:42	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0060	AGE	2013/09/25	08:27	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0060	AGE	2013/09/25	11:27	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0060	AGE	2013/09/25	19:27	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0061	AGE	2013/09/23	07:24	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0061	AGE	2013/09/23	07:42	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0061	AGE	2013/09/23	08:27	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0061	AGE	2013/09/23	11:27	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0061	AGE	2013/09/23	19:27	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0061	AGE	2013/09/25	08:42	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0061	AGE	2013/09/25	09:00	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0061	AGE	2013/09/25	09:45	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0061	AGE	2013/09/25	12:45	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0061	AGE	2013/09/25	20:45	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0063	AGE	2013/09/23	08:29	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0063	AGE	2013/09/23	08:47	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0063	AGE	2013/09/23	09:32	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0063	AGE	2013/09/23	12:32	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0063	AGE	2013/09/23	20:32	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0063	AGE	2013/09/25	07:37	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0063	AGE	2013/09/25	07:55	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0063	AGE	2013/09/25	08:40	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0063	AGE	2013/09/25	11:40	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0063	AGE	2013/09/25	19:40	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0066	AGE	2013/09/23	07:37	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0066	AGE	2013/09/23	07:55	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0066	AGE	2013/09/23	08:40	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0066	AGE	2013/09/23	11:40	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0066	AGE	2013/09/23	19:40	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0066	AGE	2013/09/25	07:24	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0066	AGE	2013/09/25	07:42	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0066	AGE	2013/09/25	08:27	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0066	AGE	2013/09/25	11:27	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0066	AGE	2013/09/25	19:27	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0067	AGE	2013/09/23	07:24	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0067	AGE	2013/09/23	07:42	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0067	AGE	2013/09/23	08:27	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0067	AGE	2013/09/23	11:27	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0067	AGE	2013/09/23	19:27	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0067	AGE	2013/09/25	07:50	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0067	AGE	2013/09/25	08:08	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0067	AGE	2013/09/25	08:53	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0067	AGE	2013/09/25	11:53	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0067	AGE	2013/09/25	19:53	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0070	AGE	2013/09/23	07:37	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0070	AGE	2013/09/23	07:55	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0070	AGE	2013/09/23	08:40	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0070	AGE	2013/09/23	11:40	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0070	AGE	2013/09/23	19:40	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0070	AGE	2013/09/25	08:03	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0070	AGE	2013/09/25	08:21	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0070	AGE	2013/09/25	09:06	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0070	AGE	2013/09/25	12:06	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0070	AGE	2013/09/25	20:06	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0071	AGE	2013/09/23	07:50	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0071	AGE	2013/09/23	08:08	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0071	AGE	2013/09/23	08:53	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0071	AGE	2013/09/23	11:53	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0071	AGE	2013/09/23	19:53	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0071	AGE	2013/09/25	07:37	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0071	AGE	2013/09/25	07:55	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0071	AGE	2013/09/25	08:40	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0071	AGE	2013/09/25	11:40	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0071	AGE	2013/09/25	19:40	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0072	AGE	2013/09/23	08:42	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0072	AGE	2013/09/23	09:00	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0072	AGE	2013/09/23	09:45	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0072	AGE	2013/09/23	12:45	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0072	AGE	2013/09/23	20:45	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0072	AGE	2013/09/25	08:16	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0072	AGE	2013/09/25	08:34	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0072	AGE	2013/09/25	09:19	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0072	AGE	2013/09/25	12:19	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0072	AGE	2013/09/25	20:19	COHb	2.5	%	



Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0073	AGE	2013/09/23	07:50	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0073	AGE	2013/09/23	08:08	COHb	4.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0073	AGE	2013/09/23	08:53	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0073	AGE	2013/09/23	11:53	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0073	AGE	2013/09/23	19:53	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0073	AGE	2013/09/25	08:29	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0073	AGE	2013/09/25	08:47	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0073	AGE	2013/09/25	09:32	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0073	AGE	2013/09/25	12:32	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0073	AGE	2013/09/25	20:32	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0074	AGE	2013/09/23	08:03	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0074	AGE	2013/09/23	08:21	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0074	AGE	2013/09/23	09:06	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0074	AGE	2013/09/23	12:06	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0074	AGE	2013/09/23	20:06	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0074	AGE	2013/09/25	07:50	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0074	AGE	2013/09/25	08:08	COHb	3.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0074	AGE	2013/09/25	08:53	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0074	AGE	2013/09/25	11:53	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0074	AGE	2013/09/25	19:53	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0075	AGE	2013/09/23	08:03	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0075	AGE	2013/09/23	08:21	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0075	AGE	2013/09/23	09:06	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0075	AGE	2013/09/23	12:06	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0075	AGE	2013/09/23	20:06	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0075	AGE	2013/09/25	08:42	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0075	AGE	2013/09/25	09:00	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0075	AGE	2013/09/25	09:45	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0075	AGE	2013/09/25	12:45	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0075	AGE	2013/09/25	20:45	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0076	AGE	2013/09/23	08:16	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0076	AGE	2013/09/23	08:34	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0076	AGE	2013/09/23	09:19	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0076	AGE	2013/09/23	12:19	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0076	AGE	2013/09/23	20:19	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0076	AGE	2013/09/25	08:03	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0076	AGE	2013/09/25	08:21	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0076	AGE	2013/09/25	09:06	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0076	AGE	2013/09/25	12:06	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0076	AGE	2013/09/25	20:06	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0078	AGE	2013/09/23	08:29	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0078	AGE	2013/09/23	08:47	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0078	AGE	2013/09/23	09:32	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0078	AGE	2013/09/23	12:32	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0078	AGE	2013/09/23	20:32	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0078	AGE	2013/09/25	08:55	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0078	AGE	2013/09/25	09:13	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0078	AGE	2013/09/25	09:58	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0078	AGE	2013/09/25	12:58	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0078	AGE	2013/09/25	20:58	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0082	AGE	2013/09/23	08:42	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0082	AGE	2013/09/23	09:00	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0082	AGE	2013/09/23	09:45	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0082	AGE	2013/09/23	12:45	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0082	AGE	2013/09/23	20:45	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0082	AGE	2013/09/25	08:16	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0082	AGE	2013/09/25	08:34	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0082	AGE	2013/09/25	09:19	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0082	AGE	2013/09/25	12:19	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0082	AGE	2013/09/25	20:19	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0083	AGE	2013/09/23	08:55	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0083	AGE	2013/09/23	09:13	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0083	AGE	2013/09/23	09:58	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0083	AGE	2013/09/23	12:58	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0083	AGE	2013/09/23	20:58	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0083	AGE	2013/09/25	08:55	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0083	AGE	2013/09/25	09:13	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0083	AGE	2013/09/25	09:58	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0083	AGE	2013/09/25	12:58	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0083	AGE	2013/09/25	20:58	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0084	AGE	2013/09/23	08:55	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0084	AGE	2013/09/23	09:13	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0084	AGE	2013/09/23	09:58	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0084	AGE	2013/09/23	12:58	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0084	AGE	2013/09/23	20:58	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0084	AGE	2013/09/25	08:29	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0084	AGE	2013/09/25	08:47	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0084	AGE	2013/09/25	09:32	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0084	AGE	2013/09/25	12:32	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0084	AGE	2013/09/25	20:32	COHb	2.7	%	

Sponsor: Philip Morris Products S.A.  
STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0089	AGE	2013/10/13	07:27	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0089	AGE	2013/10/13	07:45	COHb	4.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0089	AGE	2013/10/13	08:30	COHb	4.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0089	AGE	2013/10/13	11:30	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0089	AGE	2013/10/13	19:30	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0089	AGE	2013/10/15	07:27	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0089	AGE	2013/10/15	07:45	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0089	AGE	2013/10/15	08:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0089	AGE	2013/10/15	11:30	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0089	AGE	2013/10/15	19:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0090	AGE	2013/10/13	07:40	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0090	AGE	2013/10/13	07:58	COHb	3.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0090	AGE	2013/10/13	08:43	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0090	AGE	2013/10/13	11:43	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0090	AGE	2013/10/13	19:43	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0090	AGE	2013/10/15	07:40	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0090	AGE	2013/10/15	07:58	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0090	AGE	2013/10/15	08:43	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0090	AGE	2013/10/15	11:43	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0090	AGE	2013/10/15	19:43	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0093	AGE	2013/10/13	07:53	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0093	AGE	2013/10/13	08:11	COHb	3.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0093	AGE	2013/10/13	08:56	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0093	AGE	2013/10/13	11:56	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0093	AGE	2013/10/13	19:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0093	AGE	2013/10/15	07:53	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0093	AGE	2013/10/15	08:11	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0093	AGE	2013/10/15	08:56	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0093	AGE	2013/10/15	11:56	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0093	AGE	2013/10/15	19:56	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0095	AGE	2013/10/13	07:27	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0095	AGE	2013/10/13	07:45	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0095	AGE	2013/10/13	08:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0095	AGE	2013/10/13	11:30	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0095	AGE	2013/10/13	19:30	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0095	AGE	2013/10/15	08:06	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0095	AGE	2013/10/15	08:24	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0095	AGE	2013/10/15	09:09	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0095	AGE	2013/10/15	12:09	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0095	AGE	2013/10/15	20:09	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0097	AGE	2013/10/13	07:40	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0097	AGE	2013/10/13	07:58	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0097	AGE	2013/10/13	08:43	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0097	AGE	2013/10/13	11:43	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0097	AGE	2013/10/13	19:43	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0097	AGE	2013/10/15	07:27	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0097	AGE	2013/10/15	07:45	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0097	AGE	2013/10/15	08:30	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0097	AGE	2013/10/15	11:30	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0097	AGE	2013/10/15	19:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0102	AGE	2013/10/13	08:06	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0102	AGE	2013/10/13	08:24	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0102	AGE	2013/10/13	09:09	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0102	AGE	2013/10/13	12:09	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0102	AGE	2013/10/13	20:09	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0102	AGE	2013/10/15	08:06	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0102	AGE	2013/10/15	08:24	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0102	AGE	2013/10/15	09:09	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0102	AGE	2013/10/15	12:09	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0102	AGE	2013/10/15	20:09	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0105	AGE	2013/10/13	08:19	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0105	AGE	2013/10/13	08:37	COHb	3.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0105	AGE	2013/10/13	09:22	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0105	AGE	2013/10/13	12:22	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0105	AGE	2013/10/13	20:22	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0105	AGE	2013/10/15	08:19	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0105	AGE	2013/10/15	08:37	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0105	AGE	2013/10/15	09:22	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0105	AGE	2013/10/15	12:22	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0105	AGE	2013/10/15	20:22	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0107	AGE	2013/10/13	07:53	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0107	AGE	2013/10/13	08:11	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0107	AGE	2013/10/13	08:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0107	AGE	2013/10/13	11:56	COHb	2.7	%	

Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0113	AGE	2013/10/13	08:06	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0113	AGE	2013/10/13	08:24	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0113	AGE	2013/10/13	09:09	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0113	AGE	2013/10/13	12:09	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0113	AGE	2013/10/13	20:09	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0113	AGE	2013/10/15	07:40	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0113	AGE	2013/10/15	07:58	COHb	4.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0113	AGE	2013/10/15	08:43	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0113	AGE	2013/10/15	11:43	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0113	AGE	2013/10/15	19:43	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0119	AGE	2013/10/13	08:19	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0119	AGE	2013/10/13	08:37	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0119	AGE	2013/10/13	09:22	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0119	AGE	2013/10/13	12:22	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0119	AGE	2013/10/13	20:22	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0119	AGE	2013/10/15	08:19	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0119	AGE	2013/10/15	08:37	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0119	AGE	2013/10/15	09:22	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0119	AGE	2013/10/15	12:22	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0119	AGE	2013/10/15	20:22	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0120	AGE	2013/11/06	08:32	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0120	AGE	2013/11/06	08:50	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0120	AGE	2013/11/06	09:35	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0120	AGE	2013/11/06	12:35	COHb	2.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0120	AGE	2013/11/06	20:35	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0120	AGE	2013/11/08	07:27	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0120	AGE	2013/11/08	07:45	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0120	AGE	2013/11/08	08:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0120	AGE	2013/11/08	11:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0120	AGE	2013/11/08	19:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0123	AGE	2013/11/06	07:27	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0123	AGE	2013/11/06	07:45	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0123	AGE	2013/11/06	08:30	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0123	AGE	2013/11/06	11:30	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0123	AGE	2013/11/06	19:30	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0123	AGE	2013/11/08	08:32	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0123	AGE	2013/11/08	08:50	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0123	AGE	2013/11/08	09:35	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0123	AGE	2013/11/08	12:35	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0123	AGE	2013/11/08	20:35	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0128	AGE	2013/11/06	07:40	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0128	AGE	2013/11/06	07:58	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0128	AGE	2013/11/06	08:43	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0128	AGE	2013/11/06	11:43	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0128	AGE	2013/11/06	19:43	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0128	AGE	2013/11/08	07:27	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0128	AGE	2013/11/08	07:45	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0128	AGE	2013/11/08	08:30	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0128	AGE	2013/11/08	11:30	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0128	AGE	2013/11/08	19:30	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0129	AGE	2013/11/06	07:27	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0129	AGE	2013/11/06	07:45	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0129	AGE	2013/11/06	08:30	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0129	AGE	2013/11/06	11:30	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0129	AGE	2013/11/06	19:30	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0129	AGE	2013/11/08	07:40	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0129	AGE	2013/11/08	07:58	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0129	AGE	2013/11/08	08:43	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0129	AGE	2013/11/08	11:43	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0129	AGE	2013/11/08	19:43	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0132	AGE	2013/11/06	08:35	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0132	AGE	2013/11/06	08:53	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0132	AGE	2013/11/06	09:38	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0132	AGE	2013/11/06	12:38	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0132	AGE	2013/11/06	20:38	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0132	AGE	2013/11/08	07:53	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0132	AGE	2013/11/08	08:11	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0132	AGE	2013/11/08	08:56	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0132	AGE	2013/11/08	11:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0132	AGE	2013/11/08	19:56	COHb	3.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0134	AGE	2013/11/06	07:53	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0134	AGE	2013/11/06	08:11	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0134	AGE	2013/11/06	08:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0134	AGE	2013/11/06	11:56	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0134	AGE	2013/11/06	19:56	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0134	AGE	2013/11/08	07:40	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0134	AGE	2013/11/08	07:58	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0134	AGE	2013/11/08	08:43	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0134	AGE	2013/11/08	11:43	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0134	AGE	2013/11/08	19:43	COHb	2.3	%	



Sponsor: Philip Morris Products S.A.  
 STATUS: FINAL

VERSION: 1.0

Study Number: ZRHM-PK-05-JP  
 DATE: 31 March 2014

ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0135	AGE	2013/11/06	07:40	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0135	AGE	2013/11/06	07:58	COHb	4.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0135	AGE	2013/11/06	08:43	COHb	3.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0135	AGE	2013/11/06	11:43	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0135	AGE	2013/11/06	19:43	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0135	AGE	2013/11/08	08:06	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0135	AGE	2013/11/08	08:24	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0135	AGE	2013/11/08	09:09	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0135	AGE	2013/11/08	12:09	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0135	AGE	2013/11/08	20:09	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0136	AGE	2013/11/06	08:06	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0136	AGE	2013/11/06	08:24	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0136	AGE	2013/11/06	09:09	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0136	AGE	2013/11/06	12:09	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0136	AGE	2013/11/06	20:09	COHb	2.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0136	AGE	2013/11/08	07:53	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0136	AGE	2013/11/08	08:11	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0136	AGE	2013/11/08	08:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0136	AGE	2013/11/08	11:56	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0136	AGE	2013/11/08	19:56	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0139	AGE	2013/11/06	07:53	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0139	AGE	2013/11/06	08:11	COHb	3.2	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0139	AGE	2013/11/06	08:56	COHb	3.0	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0139	AGE	2013/11/06	11:56	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0139	AGE	2013/11/06	19:56	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0139	AGE	2013/11/08	08:19	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0139	AGE	2013/11/08	08:37	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0139	AGE	2013/11/08	09:22	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0139	AGE	2013/11/08	12:22	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0139	AGE	2013/11/08	20:22	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0140	AGE	2013/11/06	08:06	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0140	AGE	2013/11/06	08:24	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0140	AGE	2013/11/06	09:09	COHb	3.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0140	AGE	2013/11/06	12:09	COHb	2.8	%	Data could be affected by fibrin.
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0140	AGE	2013/11/06	20:09	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0140	AGE	2013/11/08	08:32	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0140	AGE	2013/11/08	08:50	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0140	AGE	2013/11/08	09:35	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0140	AGE	2013/11/08	12:35	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0140	AGE	2013/11/08	20:35	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0142	AGE	2013/11/06	08:19	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0142	AGE	2013/11/06	08:37	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0142	AGE	2013/11/06	09:22	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0142	AGE	2013/11/06	12:22	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0142	AGE	2013/11/06	20:22	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0142	AGE	2013/11/08	08:06	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0142	AGE	2013/11/08	08:24	COHb	3.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0142	AGE	2013/11/08	09:09	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0142	AGE	2013/11/08	12:09	COHb	3.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0142	AGE	2013/11/08	20:09	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0148	AGE	2013/11/06	08:32	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0148	AGE	2013/11/06	08:50	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0148	AGE	2013/11/06	09:35	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0148	AGE	2013/11/06	12:35	COHb	2.5	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0148	AGE	2013/11/06	20:35	COHb	2.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0148	AGE	2013/11/08	08:19	COHb	2.3	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0148	AGE	2013/11/08	08:37	COHb	3.1	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0148	AGE	2013/11/08	09:22	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0148	AGE	2013/11/08	12:22	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	PRIOR TO PRODUCT	0152	AGE	2013/11/06	08:19	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	15 MINUTES	0152	AGE	2013/11/06	08:37	COHb	2.9	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	60 MINUTES	0152	AGE	2013/11/06	09:22	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	4 HOURS	0152	AGE	2013/11/06	12:22	COHb	2.8	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day1	12 HOURS	0152	AGE	2013/11/06	20:22	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	PRIOR TO PRODUCT	0152	AGE	2013/11/08	08:45	COHb	2.7	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	15 MINUTES	0152	AGE	2013/11/08	09:03	COHb	2.4	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	60 MINUTES	0152	AGE	2013/11/08	09:48	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	4 HOURS	0152	AGE	2013/11/08	12:48	COHb	2.6	%	
ZRHM-PK-05-JP	Ageo Medical CL	Day3	12 HOURS	0152	AGE	2013/11/08	20:48	COHb	2.5	%	



#### **16.1.9.4 BIOANALYTICAL REFERENCES**

Please refer to Section 14 of the CSR for all publications referenced in the report. Copies of these publications are available upon request.