OMB No. 0930-0158
Expiration Date: xx/xx/xxxx

ATTACHMENT E

National Laboratory Certification Program

Laboratory Inspection Report

National Laboratory Certification Program
RTI International
Attention: Inspection Department
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions and completing the collection of information, is estimated to average 4 hours per response for an initial certification inspection and 3 hours for subsequent inspections. Federal employees may send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to the SAMHSA Reports Clearance Officer, Paperwork Reduction Project (0930-0158), Room 7-1044, One Choke Cherry Road, Rockville, Maryland 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158.

B. Laboratory Information (completed by the laboratory)

B-1. Name of Laboratory:
Address:

City, State, ZIP:

Telephone: (____) _____ - _____
FAX: (____) _____ - _____
e-Mail:

B-2. Responsible Person's name:
Responsible Person's title:

Or (if more than one RP)

Additional RP's name:
Additional RP's title:

And (if applicable)

Alt-RP's name:
Alt-RP's title:

Additional alt-RP's name:
Additional alt-RP's title:

B-3. ***I certify that the statements and information presented in Sections B and C are true and correct as of this date. I affirm that the key staff have read and are familiar with the current version of the NLCP Guidance Document for Laboratories and Inspectors. I also recognize my responsibility for providing amended Sections B and C to the inspectors at the beginning of the inspection if changes are made between this date and the inspection.***

Note: **Any false, fictitious, or fraudulent statements or information presented in sections B and C or misrepresentations relative thereto may violate Federal Law and could subject you to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).**

_____ _____
Signature, Responsible Person Date

_____ _____
Signature, Additional Responsible Person Date

B-4. Days/hours of operation of the Forensic Urine Drug Testing Laboratory:
_____days per week; _____hours per day

NOTE: If ≤ 6 days, indicate the day(s) that the laboratory is routinely not operational.

Day(s) laboratory routinely not operational:

B-5. Specify the normal days and hours of operations for the following functions:

Accessioning:
Initial Drug Testing:
Initial Specimen Validity Testing:
Confirmatory Specimen Validity Testing:
Extraction:
GC/MS Analysis:
Negative Result Certification:
Non-Negative Result Certification:

B-6. Does the laboratory have a DEA registration?

YES

NO

If YES, for which schedules?

___1 ___2 ___2N ___3 ___3N ___4 ___5

If NO, explain how controlled reference materials are acquired:

B-7. Describe the state licensure requirements for the state in which the laboratory is located:

a. Is the laboratory in compliance?

YES

NO

If NO, explain:

b. Other certifications/licenses for the following:

____ Other States List:
____ CLIA/HCFA List Specialties:
____ CAP List Specialties:
____ Others (Specify):

B-8. List the education and certifications/licenses for the following personnel:

Note: (1) May attach a separate sheet listing key personnel
(2) Indicate (*) individuals new to the positions in the last six months

Position	**Name**	**Education**	**License/ Certification**
RP(s)			
Alt-RP(s)			
Non-Neg CS(s)			
Neg CS(s)			
Supervisor(s)			

Other Key Personnel

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

a. Is licensure and/or certification required for any or all of these positions in the state in which the laboratory is located?

____ YES (Continue with b)

____ NO (Go to Question B-9)

b. Are the key personnel (i.e., RPs, Alt-RPs, Supervisors, and certifying scientists) properly licensed or certified?

____ YES (Go to Question B-9)

____ NO (Continue with c)

c. If **NO**, which individuals are not properly licensed or certified?

_____

B-9. If there is more than one RP, briefly describe how the RPs share the responsibilities for the various laboratory operations/procedures.

B-10. Does the laboratory test any Federal agency specimens for drugs other than the drugs/drug classes specified in the HHS Guidelines because the Federal agency has a waiver from HHS?

YES

NO

If **YES**, list the drug(s) and the Federal agencies for which a waiver applies:

B-11. List the changes made by the laboratory (e.g., new instrumentation, new or revised analytical procedures, new or revised software, etc.), and dates of the changes since ***the last NLCP inspection***:

B-12. Average number of specimens analyzed by the laboratory each day for drugs of abuse ***during the six months preceding submission of Sections B and C (including regulated specimens):***

Specify the months_____
Total specimens/day _____

How was this number derived?

B-13. Average number of specimens analyzed by the laboratory each day under the HHS Guidelines for drugs of abuse ***during the six months preceding submission of Sections B and C:***

Specify the months_____
Regulated specimens/day _____

How was this number derived?

B-14. The total number of staff who have authorized access to the forensic drug testing laboratory:

_____ individuals
_____ FTEs

B-15. The total number of staff who are trained and routinely accession regulated specimens:

_____ individuals
_____ FTEs

B-16. This question deals with ***specimen receiving/accessioning personnel.*** In order to avoid double counting and misrepresentation of multi-tasked or part-time staff, the following definition must be used when answering this question:

Based on an average seven-day (i.e., one calendar week) time interval, divide the **total number of hours** expended by the specimen receiving/accessioning staff *by 40* to arrive at a Receiving Personnel Equivalent unit (**RPE**). RPEs should be reported to two decimal places. For example, if an average of 250 hours are expended, then 250 divided by 40 equals 6.25.

a. Total number of RPEs required for receiving/accessioning ***all specimens*** analyzed by the laboratory for drugs of abuse (regulated specimens and all other specimens received by the laboratory):

_____ RPEs

b. Total number of RPEs required for receiving/accessioning ***only regulated specimens:***

_____ RPEs

B-17. The total number of laboratory staff members who are technically trained and routinely perform initial drug testing:

_____ initial drug testing analysts
_____ FTEs

B-18. The total number of laboratory staff members who are technically trained and routinely perform initial specimen validity testing:

_____ initial specimen validity testing analysts
_____ FTEs

B-19. The total number of laboratory staff members who are technically trained and routinely perform confirmatory specimen validity testing:

_____ confirmatory specimen validity testing analysts
_____ FTEs

B-20. The total number of laboratory staff members who are technically trained and routinely perform extractions:

_____ extractors
_____ FTEs

B-21. The total number of laboratory staff members who are technically trained and routinely perform GC/MS analysis:

_____ GC/MS operators
_____ FTEs

B-22. This question deals with ***certifying scientists***. In order to avoid double counting and misrepresentation of multi-tasked or part-time staff, the following definition must be used when answering this question:

Based on an average seven-day (i.e., one calendar week) time interval, divide the total number of hours expended by the certifying scientist staff by 40 to arrive at a Certifying Scientist Equivalent unit (CSE). CSEs should be reported to two decimal places. For example, if an average of 250 hours are expended, then 250 divided by 40 equals 6.25.

a. ***Total number of individuals*** who are trained to perform the duties of a certifying scientist for the laboratory (either negative or non-negative results):

_____ certifying scientists

b. Total number of CSEs utilized for certifying ***only negative (initial drug test and mandated initial SVT)*** results for

regulated specimens:
_____ CSEs

c. Total number of CSEs utilized for certifying ***non-negative (initial drug test, specimen validity tests and confirmatory drug test)*** results for regulated specimens:
_____ CSEs

B-23. Maximum number of specimens in an accessioning batch:
_____ specimens

B-24. Maximum number of specimens in an initial drug test batch:
_____ specimens

a. Average number of initial drug test batches per day that contain one or more regulated specimens:
_____ batches

B-25. Maximum number of specimens in a confirmatory drug test batch:
_____ specimens

a. Average number of confirmatory drug test batches per day that contain one or more regulated specimens:
_____ batches

B-26. Describe the administrative relationships that exist for the ***key staff*** of the forensic drug testing laboratory:

a. To whom does the RP(s) report?

b. Who rates the performance of the RP(s)?

c. What staff administratively report ***directly*** to the RP(s)?

d. The RP(s) rates the performance of which staff members?

e. What staff do not report to the RP(s)?

C. Laboratory Procedures (completed by the laboratory)

C-1. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Security

- Building
- Department
- Specimens
- Records

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-2. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Specimen Receiving/Accessioning

- Receipt of specimen packages, how they are handled, who reviews the accuracy of the information on the custody and control forms and how discrepancies are documented.
- Handling problems with specimen bottles and/or custody and control forms.
- Assignment of laboratory accession numbers.
- Location of temporary storage area(s).

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-3. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Aliquoting Procedures

- Aliquoting of the original specimen bottles (i.e., who and where).
- The actual aliquoting procedure (pouring or pipetting and amounts) used for preparing aliquots for initial drug tests, specimen validity tests, and confirmatory drug tests.
- Transfer of aliquots from the individuals performing the aliquoting to those who will be testing the aliquots.

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-4. Provide a ***TYPED*** description of the laboratory's quality control program for the following:

Specimen Accessioning

- Introduction and/or aliquoting of blind controls into the test batches by accessioning personnel.
- Content and concentration of each blind control.
- If applicable, preparation and submission of blind samples as donor specimens from external sources.

NOTE: (1) Do not exceed a total of one page.
(2) Tables are acceptable.
(3) Insert page here.

C-5. Provide a ***TYPED*** description of the laboratory's procedures for the following:

First and Second Initial Drug Tests

- Handling and testing of aliquots by laboratory personnel.
- Maintenance of chain-of-custody during the testing.

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-6. Provide a ***TYPED*** description of the laboratory's quality control program for the following:

First and Second Initial Drug Tests

- How batches are constituted (e.g., how many specimens are in a batch, is it constituted in one session or are specimens added to the batch throughout the day, are regulated and non-regulated specimens tested in the same batches).
- The distribution of specimens and QC samples within each batch.
- Identify the source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix used for each QC sample.
- The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.

NOTE: (1) Do not exceed a total of one page.
(2) Tables are acceptable.
(3) Insert page here.

C-7. Indicate the following information for the first and second Initial Drug Test instrument(s) used by the laboratory:

a. Manufacturer _____ _____ _____
Model _____ _____ _____
Number of units _____ _____ _____

Calibration Procedure:

Single Point Calibration _____ _____ _____
Multi-Point Calibration _____ _____ _____
Historical Calibration _____ _____ _____
Other (Describe) _____ _____ _____

b. Describe the procedure(s) and acceptance criteria for calibration:

c. Describe the method used to calculate the concentrations/ results of analytes:

d. Describe how the instrumental software analyzes the results:

Table C-1-a: First Initial Drug Tests Used by the Laboratory for the Required Drug Classes

	Amphetamine / Methamphetamine	Cannabinoids	Cocaine Metabolite	Opiates	Phencyclidine
Immunoassay Method					
Kit Manufacturer					
Test Kit Name					
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Average Number of Specimens Tested Daily Under HHS Guidelines					
Average Number of Batches Tested Daily Which Contain Specimens Tested Under HHS Guidelines					
Maximum Batch Size					

Method Abbreviations:

CEDIA - Cloned Enzyme Donor Immunoassay
EIA - Enzyme Immunoassay
FPIA - Fluorescence Polarization Immunoassay
KIMS - Kinetic Interaction of Microparticulates in Solution
RIA - Radioimmunoassay

Table C-1-b: Second Initial Drug Tests Used by the Laboratory for the Required Drug Classes

	Amphetamine / Methamphetamine	Cannabinoids	Cocaine Metabolite	Opiates	Phencyclidine
Immunoassay Method					
Kit Manufacturer					
Test Kit Name					
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Average Number of Specimens Tested Daily Under HHS Guidelines					
Average Number of Batches Tested Daily Which Contain Specimens Tested Under HHS Guidelines					
Maximum Batch Size					

Method Abbreviations:

CEDIA - Cloned Enzyme Donor Immunoassay
EIA - Enzyme Immunoassay
FPIA - Fluorescence Polarization Immunoassay
KIMS - Kinetic Interaction of Microparticulates in Solution
RIA - Radioimmunoassay

C-8. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Specimen Validity Tests (Initial, Confirmatory and Screening/Differential)

- Handling and testing of aliquots by laboratory personnel.
- Maintenance of chain-of-custody during the testing.

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-9. a. Provide a ***typed*** outline or a legible flow chart that comprehensively describes the laboratory's Specimen Validity Testing.

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

b. For the timeframe of the NNSL data audit, provide a list of changes to the Question C-9a outline/flowchart, if any.

Note: (1) Do not exceed a total of one page.
(2) Insert page here.

C-10. Provide a ***TYPED*** description of the laboratory's quality control program for the following:

Specimen Validity Tests

- How batches are constituted.
- The distribution of specimens and QC samples within each batch.
- Identify the source (e.g., in-house, name of supplier), composition, and matrix used for each QC sample.
- The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.

NOTE: (1) Do not exceed a total of 1 page.
(2) Tables are acceptable.
(3) Insert page here.

C-11. Indicate the following information for the Specimen Validity Test instrument(s) used by the laboratory:

a. **Assay: Creatinine**	Initial Test	Confirmatory Test
Manufacturer		
Model		
Number of units		
Calibration Procedure:		
Single Point Calibration		
Multi-Point Calibration		
Historical Calibration		
Other (Describe)		

b. **Assay: Specific Gravity**	Initial Test	Confirmatory Test
Manufacturer		
Model		
Number of units		
Calibration Procedure:		
Single Point Calibration		
Multi-Point Calibration		
Historical Calibration		
Other (Describe)		

c. **Assay: pH**	Screening Test	Initial Meter Test	Confirmatory Meter Test
Manufacturer			
Model			
Number of units			
Calibration Procedure:			
Single Point Calibration			
Multi-Point Calibration			
Historical Calibration			
Other (Describe)			

d. **Assay** _____

	Screening/ Differential Test	Initial Test	Confirmatory Test
Manufacturer			
Model			
Number of units			
Calibration Procedure:			
Single Point Calibration			
Multi-Point Calibration			
Historical Calibration			
Other (Describe)			

e. **Assay** _____

	Screening/ Differential Test	Initial Test	Confirmatory Test
Manufacturer			
Model			
Number of units			
Calibration Procedure:			
Single Point Calibration			
Multi-Point Calibration			
Historical Calibration			
Other (Describe)			

f. **Assay** _____

	Screening/ Differential Test	Initial Test	Confirmatory Test
Manufacturer			
Model			
Number of units			
Calibration Procedure:			
Single Point Calibration			
Multi-Point Calibration			
Historical Calibration			
Other (Describe)			

NOTE: Add additional pages as needed.

For each specimen validity test method:

g. Describe the procedures and acceptance criteria for calibration:

h. Describe the method used to calculate the concentrations/ responses of analytes:

i. Describe how the instrumental software analyzes the results:

j. Describe the procedure used to determine the LOD and LOQ if applicable:

Table C-2-a-1: Initial Specimen Validity Tests Used by the Laboratory

	Creatinine	Specific Gravity	pH	Nitrite	Other: ( )	Other: ( )	Other: ( )
Method							
Kit Manufacturer							
Test Kit Name							
Unit of Measurement							
Target Analyte							
Concentration of Calibrator(s)							
Concentration of Controls							
LOD							
LOQ							
ULOL							
COL							

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CLR - Colorimetric
mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption
ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table C-2-a-2: Initial Specimen Validity Tests Used by the Laboratory

	Other: ( )	Other: ( )	Other: ( )	Other: ( )	Other: ( )
Method					
Kit Manufacturer					
Test Kit Name					
Unit of Measurement					
Target Analyte					
Concentration of Calibrator(s)					
Concentration of Controls					
LOD					
LOQ					
ULOL					
COL					

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CLR - Colorimetric
mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter

DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption

ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation

ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table C-2-b-1: Confirmatory Specimen Validity Tests Used by the Laboratory

	Creatinine	Specific Gravity	pH	Nitrite	Other: ( )	Other: ( )	Other: ( )
Method							
Kit Manufacturer							
Test Kit Name							
Unit of Measurement							
Target Analyte							
Concentration of Calibrator(s)							
Concentration of Controls							
LOD							
LOQ							
ULOL							
COL							

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CRL - Colorimetric
mREF - Manual Refractometer
DREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption
ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table C-2-b-2: Confirmatory Specimen Validity Tests Used by the Laboratory

	Other: ( )	Other: ( )	Other: ( )	Other: ( )	Other: ( )
Method					
Kit Manufacturer					
Test Kit Name					
Unit of Measurement					
Target Analyte					
Concentration of Calibrator(s)					
Concentration of Controls					
LOD					
LOQ					
ULOL					
COL					

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CRL - Colorimetric
mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter

DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption

ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation

ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table C-2-c-1: Screening/Differential Specimen Validity Tests Used by the Laboratory

	Other: ( )	Other: ( )	Other: ( )	Other: ( )	Other: ( )
Method					
Kit Manufacturer					
Test Kit Name					
Unit of Measurement					
Target Analyte					
Concentration of Calibrator(s)					
Concentration of Controls					
LOD					
LOQ					
ULOL					
COL					

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CLR - Colorimetric
mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption
ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

C-12. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Confirmatory Drug Tests

- Handling and testing of aliquots by laboratory personnel.
- Maintenance of chain-of-custody during the testing.

Note: (1) Do not exceed a total of one(1) page.
(2) Insert page here.

C-13. Provide a ***TYPED*** description of the laboratory's quality control program for the following:

Confirmatory Drug Tests

- How batches are constituted (e.g., how many specimens are in a batch, is it constituted in one session or are specimens added to the batch, are regulated and non-regulated specimens tested in the same batches).
- The distribution of the donor specimens and QC samples within each batch.
- Identify the source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix used for each QC sample.
- The criteria for accepting a donor specimen result, reextracting a specimen, or reinjecting a specimen.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.

NOTE: (1) Do not exceed a total of one page.
(2) Tables are acceptable.
(3) Insert page here.

C-14. Provide the following information for the GC/MS instrument(s) used by the laboratory:

a. Manufacturer _____
Model _____
Number of units _____

Inlet system:	*Ionization:*	*Ion focus:*
____ Capillary	____ Chemical	____ Quadrupole
____ Megabore	____ EI	____ Ion trap
____ Packed		____ Magnetic sector
____ Other:_____		

b. Manufacturer _____
Model _____
Number of units _____

Inlet system:
____ Capillary
____ Megabore
____ Packed
____ Other:_____

Ionization:
____ Chemical
____ EI

Ion focus:
____ Quadrupole
____ Ion trap
____ Magnetic sector

c. Manufacturer _____
Model _____
Number of units _____

Inlet system:
____ Capillary
____ Megabore
____ Packed
____ Other:_____

Ionization:
____ Chemical
____ EI

Ion focus:
____ Quadrupole
____ Ion trap
____ Magnetic sector

C-15. Provide the following information for each confirmatory drug analysis:

a. Calibration Procedure:

	Amp/ MAmp	d-MAmp	Bze	Cod/ Mor	6-AM	PCP	THCA
Single Point Calibration	____	____	____	____	____	____	____
Multi-Point Calibration	____	____	____	____	____	____	____
Historical Calibration	____	____	____	____	____	____	____
Other (Describe)	____	____	____	____	____	____	____

b. Describe the requirements for calibration including criteria for exclusion of unsatisfactory calibrators:

c. Describe the method and criteria used to establish the identities of analytes and internal standards (e.g., SIM, number of ions, ion ratio acceptance criteria):

d. Describe the method used to calculate the concentrations of analytes for each calibration procedure used by the laboratory:

e. Describe how the GC/MS software analyzes the results:

f. Describe the procedure used to determine the LOD, LOQ, ULOL, and carryover limit:

Table C-3-a: Confirmatory Drug Tests Used by the Laboratory for the Required Analytes

	Primary Confirmatory Techniques					
	Internal Standard	I.S. Conc (ng/mL)	LOD (ng/mL)	LOQ (ng/mL)	ULOL (ng/mL)	COL (ng/mL)
Amphetamine						
Methamphetamine						
THC Acid						
Benzoylecgonine						
Codeine						
Morphine						
6-Acetylmorphine						
Phencyclidine						

	Alternate Confirmatory Techniques					
	Internal Standard	I.S. Conc (ng/mL)	LOD (ng/mL)	LOQ (ng/mL)	ULOL (ng/mL)	COL (ng/mL)
Amphetamine						
Methamphetamine						
THC Acid						
Benzoylecgonine						
Codeine						
Morphine						
6-Acetylmorphine						
Phencyclidine						

Abbreviations:
I.S. - Internal Standard
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table C-3-b-1: Confirmatory Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	THC Acid	Benzoylecgonine	Codeine/Morphine	6-Acetylmorphine	Phencyclidine
Volume (mL) Used						
Extraction Method (L/L or SPE)						
Hydrolysis Method (N, Enz, A, B)						
Derivatizing Reagent *						
Concentration of Calibrator(s) (ng/mL)						
Concentration of Controls (ng/mL)**						

Abbreviations:

L/L - Liquid/Liquid Extraction
SPE - Solid Phase Extraction
N - None
Enz - Enzymatic
A - Acid
B - Base

* For Example: BSTFA, BSA, MSTFA, TFA, PFPA, HFBA, CH3/TMAH, HFIP/PFPA, etc.
** Open (O) [and Blind (B) if used]

Table C-3-b-2: Confirmatory Drug Tests Used by the Laboratory

	Amphetamine	Meth-amphetamine	THC Acid	Benzoyl-ecgonine	Codeine	Morphine	6-Acetyl-morphine	Phencyclidine
Injection Port Temperature (°C)								
Column Initial Temperature (°C)								
Interface Temperature (°C)								
Isothermal or Temperature Program * (°C)								
Split or Splitless Injection								
Column Type								
Column Length (m)								
Full Scan Mass Range								
Analyte SIM Ions Monitored **								
I.S. SIM Ions Monitored **								

* For Example: 100(3)15/230(3) Initial temperature 100 degrees, held for 3 minutes, then ramped at 15 degrees/min to 230 degrees which is held for 3 minutes

** Bold or circle quantitative ion

Table C-3-c-1: Alternate Confirmatory Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	THC Acid	Benzoylecgonine	Codeine / Morphine	6-Acetylmorphine	Phencyclidine
Volume (mL) Used						
Extraction Method (L/L or SPE)						
Hydrolysis Method (N, Enz, A, B)						
Derivative *						
Concentration of Calibrator(s) (ng/mL)						
Concentration of Controls (ng/mL)**						

Abbreviations:

L/L - Liquid/Liquid Extraction
SPE - Solid Phase Extraction
N - None
Enz - Enzymatic
A - Acid
B - Base

* For Example: BSTFA, BSA, MSTFA, TFA, PFPA, HFBA, CH3/TMAH, HFIP/PFPA, etc.
** Open (O) [and Blind (B) if used]

Table C-3-c-2: Alternate Drug Confirmatory Tests Used by the Laboratory

	Amphetamine	Meth-amphetamine	THC Acid	Benzoyl-ecgonine	Codeine	Morphine	6-Acetyl-morphine	Phencyclidine
Injection Port Temperature (°C)								
Column Initial Temperature (°C)								
Interface Temperature (°C)								
Isothermal or Temperature Program * (°C)								
Split or Splitless Injection								
Column Type								
Column Length (m)								
Full Scan Mass Range								
Analyte SIM Ions Monitored **								
I.S. SIM Ions Monitored **								

* For Example: 100(3)15/230(3) Initial temperature 100 degrees, held for 3 minutes, then ramped at 15 degrees/min to 230 degrees which is held for 3 minutes

** Bold or circle quantitative ion

C-16. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Certification/Reporting Procedures

- Review of all calibration data and control data.
- Review of chain-of-custody forms.
- Review of specimen data.
- Documentation and certification of results.
- Release/reporting of results.
- Verification of information (e.g., CCF and computer resident result)

Note: (1) Do not exceed a total of one page.
(2) Insert pages here.

C-17. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Electronic Reporting Procedures

- Release of computer-generated electronic reports.

Note: (1) Do not exceed a total of one page.
(2) Insert pages here.

C-18. Provide an example of the laboratory's computer-generated electronic report for each of the following laboratory results:

- Negative
- Negative, Dilute
- Rejected for Testing
- Cocaine Metabolite Drug Positive
- 6-AM/Morphine/Codeine Opiate Drug Positive
- d-Methamphetamine/ Amphetamine/ Methamphetamine Drug Positive
- Substituted
- Invalid Result
- Specimen Adulterated: pH Too Low (or pH Too High)
- Specimen Adulterated: Others as Pertinent

C-19. Provide a ***TYPED or Diagrammatic*** (as applicable) description of the laboratory's computer and information system(s) procedures for the following:

- Network, workstation, and fileserver organization (physical and functional) related to specimen records and specimen handling.
- External network connections.
- Network and workstations operating systems.
- The number of systems (e.g., secondary or back-up systems, reporting

systems)
- Software used by the laboratory.
- All data input methods (e.g., human, instrument, device) used in processing regulated specimens.
- Basic specimen process flow.
- System security (e.g., monitoring, firewall, intrusion detection, user access, security reports).
- Physical security (e.g., security to computer room, access log, access card, cipher lock)
- Incident response and disaster protection/recovery.
- Procedures for maintaining and monitoring system records.
- Each reporting method used (for NLCP regulated specimen testing) and how security is ensured for each reporting method.
- Procedures used for obtaining an audit trail and the time period required for generating an audit trail in a human readable format.
- Significant changes or new technologies implemented since the last inspection or planned for implementation prior to the next inspection.
- The general validation process for software and configuration changes.
- Organization chart(s), indicating job functions for key computer staff (e.g., LIMS, IS, or IT managers and supervisors) with duties associated with the data storage, processing, and transmission of data relative to the operations of the forensic drug testing laboratory.

C-20. If the laboratory uses an off-site computer and information system(s), provide the location:

Address:

City, State, ZIP:

Address:

City, State, ZIP:

C-21. Provide a ***TYPED*** description of the laboratory's procedures for the following:

Disposition of Specimens and Aliquots
- Handling of original specimen bottles and aliquots after testing is completed.
- Procedure for transferring non-negative specimens to long-term frozen storage.

Note: (1) <u>Do not exceed a total of one page.</u>
(2) <u>Insert page here.</u>