Effective 1 October 2010
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URINE LABORATORY

INFORMATION CHECKLIST

NATIONAL LABORATORY CERTIFICATION PROGRAM (NLCP)

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or any other aspect of this collection of information, including suggestions for reducing this burden, to

DATE Rev. No.	CHANGE	QUESTION NO.
November 1, 2015 Rev. 1115	Revisions to instructions as documented in separate file: *Summary of Changes - November 2015, NLCP Urine Laboratory Checklist*	Section A; Section C; C-15; C-16

SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, Maryland, 20857.

NLCP Urine Laboratory Information Checklist: Summary of Changes

NATIONAL LABORATORY CERTIFICATION PROGRAM
URINE LABORATORY CHECKLIST

Table of Contents

I. URINE LABORATORY INFORMATION CHECKLIST

I. URINE LABORATORY INFORMATION CHECKLIST

A. Instructions for the Laboratory

Pre-inspection Materials

Before each scheduled inspection, the NLCP sends instructions to the laboratory listing the required pre-inspection materials with due dates for provision. The required materials depend on the inspection type (e.g., initial inspection, maintenance inspection, records audit, special inspection). The following describes some items that may be required.

1. NLCP Urine Laboratory Information Checklist (Sections B and C)

   The laboratory provides up-to-date information to the NLCP on its drug testing operation (i.e., staffing, facility, and procedures) using the NLCP Urine Laboratory Information Checklist (Sections B and C). The information is maintained in NLCP records and is verified by the inspection team (i.e., inspectors, records auditors) at each NLCP inspection.

2. Laboratory Operation Schedule/Inspection Schedule

   The laboratory provides a schedule of its operations to the NLCP, listing the days and hours for various processes (e.g., receiving, accessioning, initial testing, confirmation aliquotting, confirmatory drug test extractions, certification). Using this schedule, NLCP staff prepare a tentative schedule for the inspection team. The lead inspector determines the final schedule for the inspection team at most NLCP inspections. The lead auditor determines the final schedule for a records audit.

3. Key Staff Interview List

   The laboratory provides a Staff Interviews List to the NLCP, listing key staff, their job titles, and work schedules. NLCP staff select individuals from the list to be interviewed at the inspection and return the list to the laboratory, instructing the laboratory to ensure that the selected individuals are available for interview during the inspection. In addition to interacting with laboratory staff in the course of the inspection, the inspection team conducts formal interviews (i.e., 10 – 15 minutes each) with the selected staff members to evaluate their knowledge and ability to fulfill job duties.

4. Laboratory Computers and Information Systems (Section P)

   To facilitate the inspection of the laboratory's computers and information systems, the NLCP directs the laboratory to perform a self-assessment using Section P, Laboratory Computer Systems. The laboratory provides the completed Section P to the inspection team at the beginning of the inspection.

5. Floor plan of the laboratory

6. Laboratory data packages

   The laboratory provides two data packages to the NLCP: one for a positive specimen and one for a specimen that was reported as adulterated, substituted, or invalid based on specimen validity testing (i.e., invalid-abnormal pH, invalid-inconsistent creatinine and specific gravity results, or invalid-possible <adulterant> activity). These data packages should contain all chain of custody forms, worksheets, initial drug test data, screening/differential specimen validity test data, initial specimen validity test data, confirmatory specimen validity test data, confirmatory drug test data, and reports pertaining to the specimen. The program-required format for data packages is described in Section R of the NLCP Manual for Urine Laboratories. These must be recent specimens, processed since the last NLCP inspection using the laboratory's current procedures. The laboratory must provide test data for all specimens in the confirmatory drug test batch. Note: if the laboratory performs any testing on regulated specimens using LC/MS/MS, the laboratory must also provide LC/MS/MS batch data and associated documents (e.g., CCF, worksheets) for a drug positive specimen.

7. Hotel list

   The laboratory provides a list of several hotels/motels located in close proximity to the laboratory and to the airport. Hotels selected should ensure the safety and welfare of the inspectors during the inspection.

8. Directions

   The laboratory provides a clear, precise map with directions describing the routes from the airport to the hotels and from the hotels to the laboratory.

Non-Negative Specimen List (NNSL)

Prior to each NLCP inspection that includes a records audit, the NLCP notifies the laboratory of the specified audit period (e.g., the six-month period ending one month prior to the month of the inspection). The laboratory is required to identify all regulated specimens reported during that time period as positive, adulterated, substituted, invalid, rejected, reconfirmed, or failed to reconfirm. In addition, the laboratory must identify all specimens received for testing from an Instrumented Initial Test Facility (IITF), *including specimens reported as negative*. The laboratory must submit to the NLCP a list of these specimens, with specific information for each specimen. The laboratory also provides a monthly summary for the records audit period listing the numbers of regulated specimens reported as positive, adulterated, substituted, invalid, negative, rejected, reconfirmed, or failed to reconfirm.

The NLCP provides instructions for the NNSL to the laboratory prior to the inspection. These instructions include, but are not limited to, the following:

1. Format for NNSL spreadsheet

2. NNSL categories:
   - The laboratory will provide information concerning results reported for the following NNSL categories: amphetamine/methamphetamine/enantiomers, methylenedioxymethamphetamine (MDMA)/methylenedioxyamphetamine (MDA)/ methylenedioxyethylamphetamine (MDEA), benzoylecgonine, opiates, phencyclidine, cannabinoids, adulterated, invalid, substituted, and rejected.
   - If the laboratory has tested a regulated specimen for an additional Schedule I or II drug upon request of a Federal Agency and reported the specimen as positive (i.e., drug present at or above the cutoff used for the test), the laboratory must submit a separate NNSL sheet for that drug.
   - If no specimen is identified for a specific category, the laboratory must submit that sheet indicating "None."

3. Specimens to be included on the NNSL:
   - Specimens reported positive, adulterated, substituted, invalid, rejected, reconfirmed, and failed to reconfirm.
   - Specimens received for testing from an IITF, *including those reported negative*.

   The laboratory must remove all known NLCP performance testing (PT) samples.

4. Requirements for records assembly

   The NLCP selects specimens from the submitted NNSL for review during the inspection and provides the selected list to the laboratory and to the lead auditor. The laboratory must organize and assemble records for each of the selected specimens to facilitate their review by the audit team during the inspection. At a minimum, records must be assembled by NNSL category and in chronological order, to facilitate their location within labeled storage folders/boxes. Auditors must be able to retrieve all records (excluding failed batches) pertaining to a specimen on the selected NNSL with a minimum of assistance from the laboratory staff.

   During the inspection, the lead auditor and the Responsible Person (RP) will prepare an inventory of records for the selected specimens on the NNSL that were not available for review. The RP must forward the missing records to the NLCP for subsequent review and follow-up.

Laboratory Preparation Criteria List

Prior to each inspection, the NLCP sends a Laboratory Preparation Criteria List to the laboratory, listing materials that must be available for the inspection team upon their arrival at the laboratory. Materials include a copy of the standard operating procedures (SOP) manual for each inspection team member, NLCP PT records, personnel files,

quality assurance (QA)/quality control (QC) records, reagent records, validation records, a timeline of any changes in QC criteria and control acceptance limits during the records audit period, and documentation of security procedures (e.g., access rosters and visitor logs for each secured area). Other items may be requested for review prior to or during the inspection.

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)**
RP's name: _____
RP's title: _____

RP's name: _____
RP's title: _____

RP's name: _____
RP's title: _____

Alternate Responsible Person(s)
Alt-RP's name: _____
Alt-RP's title: _____

Alt-RP's name: _____
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 Manual for Urine Laboratories. 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 the date of this submission 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, Responsible Person Date

_____
Signature, Responsible Person Date

B-4. List the changes made by the laboratory (e.g., new instrumentation, new or revised analytical procedures, new or revised software) ***since the last NLCP inspection***, and effective date of each change:

_____
_____
_____
_____
_____
_____

B-5. Days/hours of operation of the forensic urine drug testing laboratory:

_____days per week; _____hours per day

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

_____

B-6. Does the laboratory have a U.S. Drug Enforcement Agency (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 urine forensic toxicology for the State in which the laboratory is located:

_____
_____
_____

B-8. List laboratory certifications/licenses:

____ States (List): _____

____ CLIA/HCFA[1] (List Specialties): _____

____ CAP[2] (List Specialties): _____

____ Others (Specify):_____

[1]Clinical Laboratory Improvement Amendments(CLIA)/Health Care Financing Administration (HCFA)
[2]College of American Pathologists (CAP)

B-9. List name, job title, education, and licenses/certifications for the following key staff:

Note: (1) <u>May attach separate sheet listing additional key staff</u>
(2) <u>Indicate (*) individuals new to the positions in the last 6 months</u>

	Name	Job Title	Education	License/ Certification
RP(s)				
Alt-RP(s)				
Certifying Scientist(s)				
Certifying Technician(s)				
Supervisor(s)				
Other Key Staff				

a. Is licensure and/or certification required for any of the above positions in the State in which the laboratory is located? YES NO

If **YES**, describe requirements:

_____
_____
_____

B-10. If there is more than one RP, briefly describe how the RPs share the responsibilities for the various laboratory operations and procedures.

_____
_____
_____
_____

B-11. Describe the administrative relationships that exist for the ***key staff*** of the forensic drug testing laboratory (see B-9 above):

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

b. Who evaluates the performance of the RP(s)? _____
_____

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

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

e. Which staff members do not report to the RP(s)? _____
_____
_____
_____
_____

B-12. Does the laboratory test any Federal agency specimens for drugs other than those specified in the HHS Guidelines? YES NO

If **YES**, list the drug(s) and answer a and b below:

_____
_____

a. Does the laboratory have a copy of the HHS waiver for a Federal agency to test the additional drug(s) on a routine basis? YES NO

b. Does the laboratory maintain written authorization from Federal agencies to test the additional drug(s) on a case-by-case basis? YES NO

B-13. 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 (both regulated and non-regulated specimens)***:

Specify the months_____

Total specimens/day _____

How was this number derived? _____
_____
_____

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

_____ individuals

B-15. List the total numbers of staff who are trained and routinely perform the following activities ***for regulated specimens***:

Activity	**No. of Individuals**
Accessioning	
Initial drug testing	
Screening/initial specimen validity testing	
Confirmatory specimen validity testing	
Extraction	
Confirmatory drug testing	
Certification	

C. Laboratory Procedures (completed by the laboratory)

NOTE: Before using an electronic Federal Custody and Control Form (ECCF) system for regulated specimens, an HHS-certified test facility must submit a detailed plan and proposed standard operating procedures (SOPs) for the ECCF system to the NLCP for review and authorization, and undergo an onsite inspection.

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

Security

- Building
- Department
- Specimens
- Records

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

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

Specimen Receiving/Accessioning

- Receipt of specimen packages, how they are handled, receipt of specimens received with a paper custody and control form (CCF), receipt of specimens received with an ECCF, 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) Insert here.
(2) Do not exceed a total of one page.

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

Aliquotting Procedures

- Aliquotting of the original specimen bottles (i.e., who and where).
- The actual aliquotting 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 aliquotting to those who will be testing the aliquots.

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

C-4. Provide a description of the laboratory's procedures for the following:

Specimen Accessioning

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

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

C-5. Provide a 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) Insert here.
(2) Do not exceed a total of one page.

C-6. Provide a description of the laboratory's procedures 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 batch?).
- The distribution of specimens and QC samples within each batch.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.
- The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch.

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

C-7. Provide the following information for the first and second Initial Drug Tests:

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

_____
_____
_____
_____
_____
_____

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

_____
_____
_____
_____
_____
_____
_____
_____

C-8. Provide a 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) Insert here.
(2) Do not exceed a total of one page.

C-9. Provide an outline or a legible flowchart that comprehensively describes the laboratory's Specimen Validity Testing.

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

a. List any changes to the specimen validity testing outline/flowchart during the time period of the NNSL audit, with the effective date of each change.

_____
_____
_____
_____
_____
_____

C-10. Provide a description of the laboratory's procedures for the following:

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

- How batches are constituted.
- The distribution of specimens and QC samples within each batch.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.
- The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch.

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

C-11. Provide the following information for the Specimen Validity Tests (i.e., initial, confirmatory, and screening/differential tests):

Describe the procedures and acceptance criteria for calibration:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Describe the method used to calculate the concentrations/responses of measurands:

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

C-12. Provide a 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) Insert here.
(2) Do not exceed a total of one page.

C-13. Provide a description of the laboratory's procedures 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 batch?).
- The distribution of the donor specimens and QC samples within each batch.
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented.
- The criteria for accepting a donor specimen result, reextracting a specimen, or reinjecting a specimen.

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

C-14. Provide the following information for the Confirmatory Drug Tests:

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

_____
_____
_____
_____

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

_____
_____
_____
_____

C-15. Provide a 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 (i.e., procedures for paper CCFs, combination electronic/paper CCFs, and ECCFs, including use of electronic signatures by certifying technicians and certifying scientists).
- Release/reporting of results.
- Verification of information (e.g., CCF and computer resident result).

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

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

Electronic Reporting Procedures

- Reporting using an ECCF system: ECCF system provider(s) name and address; ECCF reporting procedures (including how ECCF data are secured (e.g., during transmission and storage); reporting methods; how MROs access completed ECCFs
- Web-based reporting: where report data are sent (i.e., website addresses; location and ownership of servers); file formats; external service provider(s) name and address (including cloud-based service providers); how report data are secured (i.e., during transmission and storage); how MROs access reports
- Release of computer-generated electronic reports (i.e., methods other than above).

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

C-17. Provide an example of the laboratory's computer-generated electronic report for each of the following laboratory results:

- Negative
- Negative, Dilute
- Rejected
- Cocaine Metabolite Positive
- 6-AM/Morphine/Codeine Positive
- Amphetamine/ Methamphetamine Positive
- d-Methamphetamine (if applicable)
- MDMA/MDA/MDEA Positive
- Substituted
- Invalid Result
- Specimen Adulterated: pH
- Specimen Adulterated: Others as Pertinent
- Split Specimen: Reconfirmed
- Split Specimen: One or More Primary Specimen Results Not Reconfirmed

C-18. Does the laboratory use an off-site computer information system? YES NO

If **YES**,
Address: _____
_____
City, State, ZIP: _____

C-19. Provide a 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 positive, adulterated, substituted, and invalid specimens to long-term frozen storage.

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

Complete the C Tables:

Table C-1-a. First and Second Initial Drug Test Methods and Instruments

Table C-1-b. First Initial Drug Test QC samples

Table C-1-c. Second Initial Drug Test QC samples

Table C-2-a-1. Initial Specimen Validity Test Methods and Instruments (continued on **Table C-2-a-2** as needed)

Table C-2-b-1. Confirmatory Specimen Validity Test Methods and Instruments (continued on **Table C-2-b-2** as needed)

Table C-2-c-1. Screening/Differential Specimen Validity Test Methods and Instruments (continued on **Table C-2-c-2** as needed)

Table C-2-d-1. Initial Specimen Validity Test QC samples (continued on **Table C-2-d-2** as needed)

Table C-2-d-3. Confirmatory Specimen Validity Test QC samples (continued on **Table C-2-d-4** as needed)

Table C-2-d-5. Screening/Differential Specimen Validity Test QC samples

Table C-3-a. Primary and Alternate Confirmatory Drug Test Methods

Table C-3-b-1. Primary Confirmatory Drug Test Methods and Instruments – Gas Chromatography (GC)

Table C-3-b-2. Alternate Confirmatory Drug Test Methods and Instruments – GC

Table C-3-b-3. Primary Confirmatory Drug Test Methods and Instruments – Liquid Chromatography (LC)

Table C-3-b-4. Alternate Confirmatory Drug Test Methods and Instruments – LC

Table C-3-c-1. Primary Confirmatory Drug Test Methods and Instruments – Mass Spectrometry (MS)

Table C-3-c-2. Alternate Confirmatory Drug Test Methods and Instruments –MS

Table C-1-a

Initial Drug Test
Methods and Instruments

First Initial Drug Test Methods and Instruments							
First Initial Drug Test	THCA (marijuana metabolites)	BZE (cocaine metabolites)	MOR (opiate metabolites)	6-AM	PCP	MAMP (amphetamines)	MDMA
Kit and Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Calibration Method							
Maximum Batch Size							
Average Number of federally regulated specimens tested daily							
Average Number of Batches with federally regulated specimens tested daily							
*If "Other" is selected, please specify:							

Second Initial Drug Test Methods and Instruments							
Second Initial Drug Test	THCA (marijuana metabolites)	BZE (cocaine metabolites)	MOR (opiate metabolites)	6-AM	PCP	MAMP (amphetamines)	MDMA
Kit and Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Calibration Method							
Maximum Batch Size							
*If "Other" is selected, please specify:							

THCA = ∆9-tetrahydrocannabinol-9-carboxylic acid
BZE = benzoylecgonine
MOR = morphine
PCP = phencyclidine
6-AM = 6-acetylmorphine
MAMP = methamphetamine
MDMA = methylenedioxymethamphetamine

Table C-1-b

First Initial Drug Test
QC Samples

1st initial drug test QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
THCA	Conc											
	Matrix											
	Source											
BZE	Conc											
	Matrix											
	Source											
MOR	Conc											
	Matrix											
	Source											
6-AM	Conc											
	Matrix											
	Source											
PCP	Conc											
	Matrix											
	Source											
MAMP	Conc											
	Matrix											
	Source											
MDMA	Conc											
	Matrix											
	Source											
*If "Other" is selected, please specify:												

BQC = blind quality control sample

Table C-1-c

Second Initial Drug Test
QC Samples

2nd initial drug test QC		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
THCA	Conc										
	Matrix										
	Source										
BZE	Conc										
	Matrix										
	Source										
MOR	Conc										
	Matrix										
	Source										
6-AM	Conc										
	Matrix										
	Source										
PCP	Conc										
	Matrix										
	Source										
MAMP	Conc										
	Matrix										
	Source										
MDMA	Conc										
	Matrix										
	Source										
*If "Other" is selected, please specify:											

Table C-2-a-1

Initial Specimen Validity Test Methods and Instruments

Initial SVT	Creatinine	SG	pH	Nitrite	Gen.Oxid.	Other:	Other:
Method		4 dec. place refractometer					
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement	mg/dL			mcg/mL			
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch Size							
*If "Other" is selected, please specify:							

SG = specific gravity
Gen. Oxid. = general oxidant
LOD = limit of detection
LOQ = limit of quantitation
ULOL= upper limit of linearity

Table C-2-a-2

Initial Specimen Validity Test Methods and Instruments

Initial SVT cont.	Other:	Other:	Other:	Other:	Other:	Other:	Other:
Method							
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement							
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch Size							
*If "Other" is selected, please specify:							

Table C-2-b-1

Confirmatory Specimen Validity Test Methods and Instruments

Confirmatory SVT	Creatinine	SG	pH	Nitrite	Other:	Other:	Other:
Method		4 dec. place refractometer					
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement	mg/dL			mcg/mL			
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover limit							
Maximum Batch Size							
*If "Other" is selected, please specify:							

Table C-2-b-2

Confirmatory Specimen Validity Test Methods and Instruments

Confirmatory SVT cont.	Other:	Other:	Other:	Other:	Other:	Other:	Other:
Method							
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement							
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch Size							
*If “Other” is selected, please specify:							

Table C-2-c-1

Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential SVT	SG	pH	Other:	Other:	Other:
Method					
Kit Manufacturer					
Analyzer and Manufacturer					
Number of Analyzer Units					
Unit of Measurement					
Target Analyte of Assay					
Target Analyte of Calibrator					
Calibration Method					
LOD					
LOQ					
ULOL					
Carryover Limit					
Maximum Batch Size					
*If “Other” is selected, please specify:					

Table C-2-c-2

Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential SVT cont.	Other:	Other:	Other:	Other:	Other:
Method					
Kit Manufacturer					
Analyzer and Manufacturer					
Number of Analyzer Units					
Unit of Measurement					
Target Analyte of Assay					
Target Analyte of Calibrator					
Calibration Method					
LOD					
LOQ					
ULOL					
Carryover Limit					
Maximum Batch Size					
*If “Other” is selected, please specify:					

Table C-2-d-1

Initial Specimen Validity Test
QC Samples

Initial SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Creatinine	Target value										
	Matrix										
	Source										
SG	Target value										
	Matrix										
	Source										
pH	Target value										
	Matrix										
	Source										
Nitrite	Target value										
	Matrix										
	Source										
Gen Oxid	Target value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-2-d-2

Initial Specimen Validity Test
QC Samples

Initial SVT QC cont.		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-2-d-3

Confirmatory Specimen Validity Test
QC Samples

Confirmatory SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Creatinine	Target Value										
	Matrix										
	Source										
SG	Target Value										
	Matrix										
	Source										
pH	Target Value										
	Matrix										
	Source										
Nitrite	Target Value										
	Matrix										
	Source										
Gen Oxid	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-2-d-4

Confirmatory Specimen Validity Test
QC Samples

Confirmatory SVT QC cont.		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-2-d-5

Screening/Differential Specimen Validity Test
QC Samples

Screening/Differential SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Specific Gravity	Target Value										
	Matrix										
	Source										
pH	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-3-a

Confirmatory Drug Test Methods

Primary Confirmatory Drug Test Methods											
Primary Confirmatory Drug Test	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Method											
Internal Standard											
Int. Std. Isotope Type and Number											
Int. Std. Conc.*											
LOD*											
LOQ*											
ULOL*											
Carryover Limit*											
Maximum Batch Size											
Average Number of Batches with HHS specimens tested daily											
*If “Other” is selected, please specify:											

Alternate Confirmatory Drug Test Methods											
Alternate Confirmatory Drug Test	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Method											
Internal Standard											
Int. Std. Isotope Type and Number											
Int. Std. Conc.*											
LOD*											
LOQ*											
ULOL*											
Carryover Limit*											
Maximum Batch Size											
*If “Other” is selected, please specify:											

* ng/mL

COD = codeine
AMP = amphetamine
MDA = methylenedioxyamphetamine
MDEA = methylenedioxyethylamphetamine

Table C-3-b-1

Primary Confirmatory Drug Test Methods and Instruments - Gas Chromatography

Primary Confirmatory Drug Test Methods and Instruments - Gas Chromatography								
Primary Confirmatory Drug Test - Gas Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMPHETAMINES (select analytes from dropdown lists below)		
Extraction Method								
Volume Used (mL)								
Hydrolysis Method								
Derivatizing Reagent								
Split/Splitless Injection								
Inj. Port Temp (°C)								
Isothermal or Gradient								
Column type								
Column length (m)								
Instrument manufacturer								
Number of units								
GC/GC Methods: provide additional information below								
Cryotrapping (Y/N)								
2nd GC Column Type								
2nd GC Column Length (m)								
*If “Other” is selected, please specify:								

Table C-3-b-2

Alternate Confirmatory Drug Test Methods and Instruments - Gas Chromatography

Alternate Confirmatory Drug Test Methods and Instruments - Gas Chromatography								
Primary Confirmatory Drug Test - Gas Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMPHETAMINES (select analytes from dropdown lists below)		
Extraction Method								
Volume Used (mL)								
Hydrolysis Method								
Derivatizing Reagent								
Split/Splitless Injection								
Inj. Port Temp (°C)								
Isothermal or Gradient								
Column Type								
Column Length (m)								
Instrument Manufacturer								
Number of Units								
GC/GC Methods: provide additional information below								
Cryotrapping (Y/N)								
2nd GC Column Type								
2nd GC Column Length (m)								
*If “Other” is selected, please specify:								

Table C-3-b-3

Primary Confirmatory Drug Test Methods and Instruments - Liquid Chromatography

Primary Confirmatory Drug Test Methods and Instruments- Liquid Chromatography							
Primary Confirmatory Drug Test - Liquid Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMP/MAMP	MDMA/MDA/ MDEA
Extraction Method							
Volume Used (mL)							
Hydrolysis Method							
Injection Volume							
Isocratic or Gradient							
Guard Column (Y/N)							
Flow Rate (mL/min)							
Temperature (°C)							
Column Type							
Column Length (cm)							
Column Diameter							
Column Particle Size							
A Solvent (Buffer)							
Buffer Type							
Molarity							
pH							
B Solvent (Organic)							
Component 1							
Component 2							
Component 3							
Component Ratio (1:2:3)							
Instrument Manufacturer							
Number of Units							
*If “Other” is selected, please specify:							

Table C-3-b-4

Alternate Confirmatory Drug Test Methods and Instruments- Liquid Chromatography

Alternate Confirmatory Drug Test Methods and Instruments- Liquid Chromatography							
Alternate Confirmatory Drug Test - Liquid Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMP/MAMP	MDMA/MDA/ MDEA
Extraction Method							
Volume Used (mL)							
Hydrolysis Method							
Injection Volume							
Isocratic or Gradient							
Guard Column (Y/N)							
Flow Rate (mL/min)							
Temperature (°C)							
Column Type							
Column Length (cm)							
Column Diameter							
Column Particle Size							
A Solvent (Buffer)							
Buffer Type							
Molarity							
pH							
B Solvent (Organic)							
Component 1							
Component 2							
Component 3							
Component Ratio (1:2:3)							
Instrument Manufacturer							
Number of Units							
*If “Other” is selected, please specify:							

Table C-3-c-1

Primary Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)

Primary Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)											
Primary Confirmatory Drug Test - Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Instrument Manufacturer											
Number of Units											
Inlet System											
Ionization											
Ion Focus											
Full Scan Mass Range											
Calibration Type											
Analyte Quantifier Ion											
Analyte Qualifier Ion 1*											
Analyte Qualifier Ion 2*											
Analyte Qualifier Ion 3											
Int. Std. Quantifier Ion											
Int. Std. Qualifier Ion 1*											
Int. Std. Qualifier Ion 2											
*If “Other” is selected, please specify:											

*If “Other” is selected, please specify:

*Minimum required

Table C-3-c-2

Alternate Confirmatory Drug Test Methods and Instruments - Mass Spectrometry

Alternate Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)											
Alternate Confirmatory Drug Test - Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Instrument Manufacturer											
Number of Units											
Inlet System											
Ionization											
Ion Focus											
Full Scan Mass Range											
Calibration Type											
Analyte Quantifier Ion											
Analyte Qualifier Ion 1*											
Analyte Qualifier Ion 2*											
Analyte Qualifier Ion 3											
Int. Std. Quantifier Ion											
Int. Std. Qualifier Ion 1*											
Int. Std. Qualifier ion 2											
*If “Other” is selected, please specify:											

*Minimum required

Table C-3-c-3

Primary Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry

Primary Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry											
Primary Confirmatory Drug Test - Tandem Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Instrument Manufacturer											
Number of Units											
Ionization											
Configuration											
Calibration Type											
Quantifier Transition*	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 1*	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 2	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 3	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Quantifier Transition*	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 1*	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 2	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 3	→	→	→	→	→	→	→	→	→	→	→
*If “Other” is selected, please specify:											

*Minimum required

Table C-3-c-4

Alternate Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry

Alternate Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry											
Alternate Confirmatory Drug Test - Tandem Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Instrument Manufacturer											
Number of Units											
Ionization											
Configuration											
Calibration Type											
Quantifier Transition*	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 1*	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 2	→	→	→	→	→	→	→	→	→	→	→
Qualifier Transition 3	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Quantifier Transition*	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 1*	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 2	→	→	→	→	→	→	→	→	→	→	→
Int. Std. Qualifier Transition 3	→	→	→	→	→	→	→	→	→	→	→
*If “Other” is selected, please specify:											

*Minimum required

Table C-3-d-1

Primary Confirmatory Drug Test QC Samples

Primary Confirmatory Drug Test QC		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
THCA	Concentration									
	Matrix									
	Source									
BZE	Concentration									
	Matrix									
	Source									
COD	Concentration									
	Matrix									
	Source									
MOR	Concentration									
	Matrix									
	Source									
6-AM	Concentration									
	Matrix									
	Source									
PCP	Concentration									
	Matrix									
	Source									
AMP	Concentration									
	Matrix									
	Source									
MAMP	Concentration									
	Matrix									
	Source									
MDMA	Concentration									
	Matrix									
	Source									
MDA	Concentration									
	Matrix									
	Source									
MDEA	Concentration									
	Matrix									
	Source									
*If “Other” is selected, please specify:										

Table C-3-d-2

Alternate Confirmatory Drug Test QC Samples

Alternate Confirmatory Drug Test QC		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
THCA	Concentration									
	Matrix									
	Source									
BZE	Concentration									
	Matrix									
	Source									
COD	Concentration									
	Matrix									
	Source									
MOR	Concentration									
	Matrix									
	Source									
6-AM	Concentration									
	Matrix									
	Source									
PCP	Concentration									
	Matrix									
	Source									
AMP	Concentration									
	Matrix									
	Source									
MAMP	Concentration									
	Matrix									
	Source									
MDMA	Concentration									
	Matrix									
	Source									
MDA	Concentration									
	Matrix									
	Source									
MDEA	Concentration									
	Matrix									
	Source									
*If “Other” is selected, please specify:										

Table C-4-a

AMPS Enantiomer Test Methods

Amphetamines Enantiomer Drug Test	D-AMP	L-AMP	D-MAMP	L-MAMP
Method				
Internal Standard				
Int. Std. Isotope Type and Number				
Int. Std. Conc.*				
LOD*				
LOQ*				
ULOL*				
Carryover Limit*				
*If “Other” is selected, please specify:				
Extraction Method				
Volume Used (mL)				
Derivatizing Reagent				
Enantiomer Calculation				
*If “Other” is selected, please specify:				
Reflex ALL AMPs positive specimens for DL testing?				

* ng/mL

Table C-4-b

AMPS Enantiomer QC Samples

AMPS Enantiomer QCs		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
D-AMP	Concentration									
	Matrix									
	Source									
L-AMP	Concentration									
	Matrix									
	Source									
D-MAMP	Concentration									
	Matrix									
	Source									
L-MAMP	Concentration									
	Matrix									
	Source									
*If “Other” is selected, please specify:										

* ng/mL

AMPS Enantiomer Result Calculation

Describe in detail the method used to calculate the percentages of D- and L-enantiomers (e.g., use of peak abundances, concentrations, use of an internal standard). Indicate if concentrations are calculated that can be compared to the total methamphetamine result obtained in the amphetamines method.

Type description below: