Effective 1 October 2010

Urine Laboratory Application Form

National Laboratory Certification Program (NLCP)

RTI International
Center for Forensic Sciences
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, North Carolina 27709

NATIONAL LABORATORY CERTIFICATION PROGRAM
URINE LABORATORY APPLICATION FORM

A. Applicant Laboratory

1. Name of Laboratory: _____

   Address: _____

   City, State, ZIP: _____

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

   e-Mail: _____

2. Express delivery address (if different from above)

   Address: _____

   City, State, ZIP: _____

3. Designated Responsible Person (RP): _____

   Title/Position: _____

   Telephone: ___ (____) _____ - _____ Ext. _____

   e-Mail:_____

   If applicable:

   Designated Alternate RP (Alt-RP): _____

   Title/Position: _____

   Telephone: ___ (____) _____ - _____ Ext. _____

   e-Mail:_____

4. **I understand that the answers provided in this application will be used to determine the applicant laboratory's potential eligibility for the National Laboratory Certification Program. To the best of my knowledge and belief, the answers recorded herein are true and complete as of this date.**

   _____

   Signature, Designated RP Date

NOTE: Any false, fictitious, or fraudulent statements or information presented in this application form could subject you to prosecution, monetary penalties, or both. See Sec. 18 U.S.C. 1001; 31 U.S.C. 3801-812.

B. General Laboratory Information

The following table is excerpted from Section 3.4 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010):

Initial Test Analyte	Initial Test Cutoff Concentration	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration
Marijuana metabolites	50 ng/mL	THCA[1]	15 ng/mL
Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL
Opiate metabolites			
Codeine/Morphine[2]	2000 ng/mL	Codeine	2000 ng/mL
		Morphine	2000 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamines[3]			
AMP/MAMP[4]	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine[5]	250 ng/mL
MDMA[6]	500 ng/mL	MDMA	250 ng/mL
		MDA[7]	250 ng/mL
		MDEA[8]	250 ng/mL
[1]Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).			
[2] Morphine is the target analyte for codeine/morphine testing.			
[3] Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.			
[4]Methamphetamine is the target analyte for amphetamine/methamphetamine testing.			
[5]To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.			
[6]Methylenedioxymethamphetamine (MDMA).			
[7]Methylenedioxyamphetamine (MDA).			
[8]Methylenedioxyethylamphetamine (MDEA).			

1. To be eligible for certification, the laboratory must test for all drug analytes and specimen validity test measurands required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs (*Federal Register*, 73 FR 71858, 25 November 2008, effective 1 October 2010). The laboratory must use the test methods specified by the Mandatory Guidelines for screening, differential, initial, and confirmatory tests (i.e., drug tests and specimen validity tests).

   1a. Does the laboratory have validated initial drug test assays for the drug classes required by the Mandatory Guidelines?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

1b. Does the laboratory use an immunoassay method approved, cleared, or otherwise recognized as accurate and reliable by the U.S. Food and Drug Administration (FDA) for the initial drug tests?

___ Yes
___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

1c. Does the laboratory have validated confirmatory test assays for the drug analytes required by the Mandatory Guidelines? *(Note: testing for amphetamine and methamphetamine enantiomers is optional.)*

___ Yes
___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

1d. Does the laboratory use methods combining chromatographic separation and mass spectrometric identification [e.g., gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS)] for the confirmatory drug tests?

___ Yes
___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

1e. Does the laboratory have validated tests to assess specimen validity as required by the Mandatory Guidelines (i.e., at a minimum, tests for creatinine, pH, specific gravity, and one or more oxidizing adulterants)?

___ Yes
___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

1f. Does the laboratory perform testing for amphetamine and methamphetamine enantiomers?

___ Yes → **COMMENT BELOW**
___ No

Briefly describe the procedure for analysis and reporting of the enantiomers:

_____

_____

_____

_____

2. Is the laboratory registered with the U.S. Drug Enforcement Agency (DEA)?

___ Yes → **ATTACH PHOTOCOPY OF REGISTRATION CERTIFICATE**
___ No → **COMMENT BELOW**

If YES, which schedules are covered by the registration?

___ 1 ___ 2 ___ 2N ___ 3 ___ 3N ___ 4 ___5

If NO, explain how controlled reference materials are acquired: _____

_____

_____

_____

3. Describe the State licensure requirements for urine forensic toxicology for the State in which the laboratory is located.

_____

_____

_____

_____

4. 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)

4a. **ATTACH PHOTOCOPIES OF ALL LICENSES AND CERTIFICATIONS INDICATED ABOVE.**

C. Laboratory Standard Operating Procedures (SOP) Manual

1. For certification, the laboratory must have a complete SOP manual that will apply to testing of regulated specimens under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010).

   Note: Manufacturers' package inserts or instrument manuals are not considered formal procedures. A written SOP manual is required to be eligible to apply for certification and it must be completed before the laboratory is eligible to receive NLCP performance testing (PT) samples.

   1a. Does the laboratory have a complete SOP manual for regulated drug testing?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

LABORATORY SOP MANUAL INDEX

Indicate the location for each of these topics in the laboratory's SOP manual:

TOPIC	***SECTION***	***PAGE NO.***
Security		
Procedure for controlling access to the drug testing facility	_____	_____
Procedure for controlling access to individual secured areas	_____	_____
Procedure for documenting visitor access	_____	_____
Accessioning (Specimen receipt)		
Procedure for receipt and processing of specimens	_____	_____
Procedure for accessioning specimens received from another laboratory	_____	_____
Procedure for problem/rejected specimens	_____	_____
Chain-of-Custody		
Procedure for documenting all transfers of specimens	_____	_____
Procedure for documenting all transfers of aliquots	_____	_____

TOPIC	***SECTION***	***PAGE NO.***

Specimen Validity Tests
Note: Provide the following information for each specimen validity test (Initial, Confirmatory, Screening, Differential)

Creatinine

Principle of analysis	_____	_____
Preparation of reagents, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedures for conducting creatinine tests	_____	_____
QC acceptance/rejection criteria and corrective action for creatinine tests	_____	_____
Procedure for validation of creatinine test methods	_____	_____
Procedure for periodic re-verification of creatinine test methods	_____	_____
Special requirements, etc.	_____	_____
References	_____	_____

Specific Gravity

Principle of analysis	_____	_____
Preparation of calibrators and and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____

D. Chain of Custody, Accessioning, and Security

The laboratory must have chain of custody, accessioning, and security procedures that ensure integrity is maintained for the original specimens and their aliquots. Procedures must address specimens received from collectors, Instrumented Initial Test Facilities (IITFs), and other laboratories. The chain of custody forms and procedures must account for all individuals who handle the specimens and aliquots. The chain of custody forms and procedures should provide a clear picture of the handling/transfers of specimens and aliquots from initial receipt to final disposition. The laboratory must ensure the security of specimens and aliquots during processing and placement in any storage locations.

1. Provide a description of the laboratory's chain of custody 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
-Assignment of laboratory accession numbers
-Handling and resolution of problems with specimen bottles and/or custody and control forms
-Location of temporary storage area(s)

Aliquotting Procedures

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

Initial Drug Tests (First and Second Tests)

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

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

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

Confirmatory Drug Tests

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

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) Insert here.
(2) Do not exceed a total of 4 pages.

2. Attach a flowchart and/or examples of chain of custody documents showing how regulated specimens and aliquots will be processed and their custody documented (chain of custody documents may be referenced and/or provided as examples for clarification).

3. Will regulated specimens be accessioned in a limited access, secure area?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

4. Will regulated specimens be tested in a limited access, secure area?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

5. Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks; location of secured storage areas such as refrigerators or freezers and how they are secured).

6. Will the original specimens be maintained in a limited access, secured area at all times?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

   6a. Where will the original specimens be stored?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

   6b. Who will have access to the specimen storage areas?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

7. When testing is complete, will all positive, adulterated, substituted, and invalid specimens (A and B Bottles) and split specimens be retained in long-term frozen storage in their original containers?

   ___ Yes → **# of days to be stored**: _____

   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

   7a. How will specimens (A and B Bottles) and split specimens be stored? _____

   _____

   _____

   _____

E. Records

The laboratory must maintain records to support test results (i.e., including but not limited to all associated QC results, analytical data, chain of custody documents and associated administrative records) for at least two years. The laboratory must also maintain method validation records for past and current procedures, instrument validation records, records documenting the standard operating procedures used at any given time period, and records of the education, training, and certification of all employees associated with regulated testing. The laboratory must have security measures in place to limit access to electronic and hardcopy records to essential authorized personnel.

1. Will the laboratory maintain records supporting specimen test results for at least two years?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

   1a. Will there be a secured area for the storage of records supporting specimen test results?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

2. Will the laboratory limit records access to authorized personnel?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

3. Attach two data packages using the format described in Section R of the NLCP Manual for Urine Laboratories to support (1) a positive drug test result and (2) an adulterated, substituted, or invalid result based on specimen validity testing.

F. Personnel

Qualifications for a Responsible Person Candidate

1. RP Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RP requirements as stated in the Mandatory Guidelines (Section 11.3);

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. To be eligible for review as an RP, at least one of the following questions must be answered "yes":

   2a. Is the candidate certified/licensed by the State in which the laboratory is located and any other State requiring personnel licensure as a Laboratory Director in forensic or clinical laboratory toxicology?

   ___ Yes → **In which State(s)?** _____
   ___ No

   2b. Does the candidate have a Ph.D. in one of the natural sciences?

   ___ Yes → **In which field?** _____
   GO TO QUESTION 3.

   ___ No → **GO TO QUESTION 2C.**

   2c. Does the candidate have training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ___ Yes → **Describe:** _____
   _____
   _____

   ___ No

3. An RP must have extensive experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse. To be eligible for review as an RP, both of the following questions must be answered "yes":

   3a. Does the candidate have two years or more of postdoctoral experience or at least six years of experience in forensic toxicology beyond any other degree?

   ___ Yes → **Describe:** _____
   _____
   _____

   ___ No → **CANDIDATE NOT ELIGIBLE AS RP**

3b. Does the candidate have appropriate experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology?

___ Yes → **Describe:** _____

_____

_____

___ No → **CANDIDATE NOT ELIGIBLE AS RP**

4. In the table below, enter the candidate's education.

Education	**Name of School**	**Major and Minor Fields of Study**	**Diploma, Certificate or Degree Received**
College or University			
Other Schools Attended			

5. Is the candidate a full-time or part-time employee of the laboratory?

___ Full-time (at least 40 hours per week)
___ Part-time _____ hours per week

If not a full- or part-time employee, what is the relationship between the candidate and the laboratory?

_____
_____
_____
_____

6. How many hours per week will the candidate work in the forensic urine drug testing laboratory?

_____ HOURS PER WEEK

7. How long has the candidate been associated with the laboratory?

_____ YEARS

Qualifications for an Alternate Responsible Person Candidate

1. Alt-RP Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RP requirements as stated in the Mandatory Guidelines (Section 11.3);

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. An alt-RP must be capable of fulfilling RP duties for a limited time (i.e., up to 180 days). An alt-RP candidate's qualifications are compared to RP requirements as follows:

   2a. Is the candidate certified/licensed by the State in which the laboratory is located and any other State requiring personnel licensure as a Laboratory Director in forensic or clinical laboratory toxicology?

   ___ Yes → **In which State(s)?** _____
   ___ No

   2b. Does the candidate have a Ph.D. in one of the natural sciences?

   ___ Yes → **In which field?** _____
   GO TO QUESTION 3.

   ___ No → **GO TO QUESTION 2C.**

   2c. Does the candidate have training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ___ Yes → **Describe:** _____

   _____

   ___ No

3. An alt-RP candidate must have appropriate experience in forensic toxicology.

   3a. How many years of experience does the candidate have in forensic toxicology (including experience with the collection and analysis of biological specimens for drugs of abuse) beyond any degree?

   _____ YEARS

   3b. Does the candidate have appropriate training and/or experience in all operations of the forensic drug testing laboratory (i.e., including training and experience as a certifying scientist)?

   ___ Yes

   ___ No → **CANDIDATE NOT ELIGIBLE AS AN ALT-RP**

4. In the table below, enter the candidate's education.

Education	Name of School	Major and Minor Fields of Study	Diploma, Certificate or Degree Received
College or University			
Other Schools Attended			

5. Is the candidate a full-time or part-time employee of the laboratory?

___ Full-time (at least 40 hours per week)
___ Part-time _____ hours per week

If not a full- or part-time employee, what is the relationship between the candidate and the laboratory?

_____
_____
_____
_____

6. How many hours per week will the candidate work in the forensic urine drug testing laboratory?

_____ HOURS PER WEEK

7. How long has the candidate been associated with the laboratory?

_____ YEARS

Personnel Certifications and Licenses

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

Note: (1) Attach a résumé for each individual listed below.

(2) Attach a separate sheet as needed to list all individuals in these positions.

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

2. Is licensure and/or certification required for any of the above positions in the State in which the laboratory is located?

___ Yes
___ No → **GO TO SECTION G**

If YES, describe requirements:

_____
_____
_____

G. Quality Control

For certification, the laboratory must have clearly defined QC procedures that are consistently applied, subject to review, and prompt appropriate corrective action upon failure to meet established acceptance criteria.

1. Are instrument function checks reviewed prior to batch analysis?

   ___ Yes → **COMPLETE 1a**
   ___ No

   1a. What is the title and/or position of the person responsible for these checks?

   Title/Position: _____

2. Are corrective actions documented when controls, instrument responses, etc., fail defined acceptance criteria?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

3. Are all QC results reviewed by the Certifying Technician/Scientist prior to the release of the results?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

4. Is the QA/QC program under the direct supervision of a Quality Control Supervisor?

   ___ Yes
   ___ No → **COMPLETE 4a**

   4a. What is the title/position of the person responsible for the QA/QC program?

   Title/Position: _____

5. Is the QA/QC program reviewed periodically by the Responsible Person Candidate?

   ___ Yes
   ___ No → **CANDIDATE NOT ELIGIBLE AS RP**

   5a. What is the title/position of the person responsible for the periodic review?

   Title/Position: _____

6. Are there written procedures that are employed to routinely detect clerical and analytical errors prior to reporting results?

   ___ Yes
   ___ No → **LABORATORY NOT ELIGIBLE TO APPLY**

7. For certification, the laboratory must have a QC program that includes both blind and open QC samples. At a minimum, these must include the number and type of QC samples described in the Mandatory Guidelines for drug and specimen validity tests.

Provide a description of the laboratory's procedures for the following:

Specimen Accessioning
- Introduction and/or aliquotting of blind samples into the test batches by accessioners
- Content and concentration of each blind sample
- If applicable, preparation and submission of blind samples as donor specimens from external sources

Initial Drug Tests (First and Second)
- 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?)
- The distribution of the donor specimens and QC samples within each batch
- The procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented
- 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

Specimen Validity Tests (Initial, Confirmatory, Screening, Differential)
- 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?)
- The distribution of the donor specimens and QC samples within each batch
- The procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented
- 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
- Include an outline or a legible flowchart that comprehensively describes the laboratory's specimen validity testing. The laboratory's submission must identify any "reflex" testing, the use of two separate aliquots, the initial and confirmatory methods for each analytical parameter, and any screening or differential tests.

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 throughout the day?)
- The distribution of the donor specimens and QC samples within each batch
- The procedure and acceptance criteria for calibration, including criteria for exclusion of unsatisfactory calibrators
- 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, re-extracting, or reinjecting a specimen

Note: (1) Insert here.

(2) Do not exceed a total of 3 pages.

H. Review and Reporting

The laboratory must have adequate procedures to ensure the thorough review and accurate reporting of results.

1. Briefly describe the procedures for reviewing initial drug test data and certifying negative results (i.e., title/position of reviewers, electronic/hardcopy documents reviewed, QC review):

2. Briefly describe the procedures for reviewing specimen validity test data/results (i.e., screening, differential, initial and confirmatory tests):

3. Briefly describe the procedures for reviewing confirmatory drug test data and certifying results (i.e., title/position of reviewers, electronic/hardcopy documents reviewed, QC review):

4. Briefly describe the procedures for the reporting of results. If the laboratory will use electronic reporting for any regulated specimens, describe procedures to ensure confidentiality:

5. Is the laboratory's custody and control form (CCF) identical to the OMB-approved Federal CCF to be used for all specimens submitted for testing under the Mandatory Guidelines?

___ Yes→ **ATTACH EXAMPLE OF LABORATORY'S CUSTODY AND CONTROL FORM**
___ No→**LABORATORY NOT ELIGIBLE TO APPLY**

6. Does the laboratory's report form for split specimens contain all required elements as described in Section U of the NLCP Manual for Urine Laboratories?

___ Yes→ **ATTACH EXAMPLE OF LABORATORY'S SPLIT SPECIMEN REPORT FORM**
___ No

7. Will the laboratory use computer-generated electronic reports for specimens submitted for testing under the Mandatory Guidelines?

___ Yes →**ATTACH EXAMPLE REPORTS (SEE BELOW)**
___ No

If YES, attach 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

I. Laboratory Computer Systems

Laboratory computer systems include any computer system used in processing regulated specimens. Such systems are typically used for accessioning specimens, batch assignment and scheduling, capturing test results, tabulating QC data, and reporting final results. HHS-certified laboratories are prohibited from transmitting data to an IITF through a computer interface. Any computer interface communicating any form of data from an HHS-certified IITF to a laboratory must be approved by the NLCP prior to implementation. The applicant IITF and/or laboratories must submit a detailed plan to the NLCP for review.

1. Give a brief description of the computer system to be utilized by the laboratory. Is it a "stand alone" system used solely by the laboratory, part of a local system (e.g., a hospital system), or part of a multi-laboratory corporate system? (If not on-site, provide information on its location and organizational control of the system.)

   _____
   _____
   _____
   _____
   _____
   _____

2. Give a brief description of how the laboratory plans to use the computer system in regulated specimen processing: _____
   _____
   _____
   _____
   _____
   _____

3. Is the laboratory computer system maintained in a secure area?

   ___ Yes
   ___ No

   Attach a floorplan identifying the laboratory computer system location. Include information to describe how the area is secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks).

4. Does the laboratory limit functional access to the laboratory computer system?

   ___ Yes
   ___ No

Complete the NLCP Application Tables

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

Table 1-b. First Initial Drug Test QC Samples

Table 1-c. Second Initial Drug Test QC Samples

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 3-c-3. Primary Confirmatory Drug Test Methods and Instruments – Tandem Mass Spectrometry

Table 3-c-4. Alternate Confirmatory Drug Test Methods and Instruments – Tandem Mass Spectrometry

Table 3-d-1. Primary Confirmatory Drug Test QC Samples

Table 3-d-2. Alternate Confirmatory Drug Test QC Samples

Table 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							
*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 = Δ9-tetrahydrocannabinol-9-carboxylic acid
BZE = benzoylecgonine
MOR = morphine
PCP = phencyclidine
6-AM = 6-acetylmorphine
MAMP = methamphetamine
MDMA = methylenedioxymethamphetamine

Table 1-b

First Initial Drug Test
QC Samples

1st 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:											

BQC = blind quality control sample

Table 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 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 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 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 2-b-2

Confirmatory Specimen Validity Test Methods and Instruments

Confirmatory SVT cont.	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 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 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 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 2-d-2

Initial Specimen Validity Test
QC Samples

Initial SVT QC cont.		Cal 1	Cal 2	Cal 3	Cal 4	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 2-d-3

Confirmatory Specimen Validity Test
QC Samples

Confirmatory SVT		Cal 1	Cal 2	Cal 3	Cal 4	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 2-d-4

Confirmatory Specimen Validity Test
QC Samples

Confirmatory SVT QC cont.		Cal 1	Cal 2	Cal 3	Cal 4	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 2-d-5

Screening/Differential Specimen Validity Test QC Samples

Screening/Differential SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	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 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											
*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 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 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 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 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 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											

*Minimum required

Table 3-c-2 Alternate Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)

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 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 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 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 3-d-2

Alternate Confirmatory Drug Test QC Samples

Alternate Confirmatory Drug Test QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	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											