Effective 1 January 2020

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

1. To be eligible for certification, the laboratory must test for all drug analytes in the Department of Health and Human Services (HHS) authorized drug test panel. The laboratory must also use the initial and confirmatory drug test methods specified by the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine.

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

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

   1b. 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**

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

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

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

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

   1e. 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 reference materials containing controlled substances are acquired:___
_____
_____
_____
_____
_____
_____
_____
_____

3. Describe the relevant 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): _____

____ NLCP (Specify Matrix): _____

____ 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 using Urine.

   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 urine 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.***
Procedure for each ECCF system (if applicable)	_____	_____
Procedure for maintaining security of specimen bottles	_____	_____
Procedure for maintaining security of specimen aliquots	_____	_____
Procedure for sending a specimen to another laboratory	_____	_____
Procedures for documenting all transfers of specimens received from another laboratory	_____	_____

Aliquot Preparation

Procedure for preparing initial drug test aliquots	_____	_____
Procedure for preparing screening/differential specimen validity test aliquots	_____	_____
Procedure for preparing initial specimen validity test aliquots	_____	_____
Procedure for preparing confirmatory specimen validity test aliquots	_____	_____
Procedure for preparing confirmatory drug test aliquots	_____	_____
Procedure for automated aliquotting equipment	_____	_____

Initial Drug Test (For alternate technology initial drug tests [as applicable], provide the following information for each drug analyte.)

Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____

Specimen Validity Tests

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

Creatinine

Other Specimen Validity Tests

Note: Provide the following information for each specimen validity test

Measurand:_____

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 from other laboratories. The chain of custody forms and procedures must account for all individuals who handle the specimens and aliquots and 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 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
-Description of collection kit to be used
-Location of all temporary storage area(s)
-Procedures for electronic (digital) or combination (electronic and paper) Federal CCF (if applicable)

Aliquotting Procedures

-Aliquotting from the original specimen bottles (i.e., who and where)
-The aliquotting procedure (method and amounts) used for preparing aliquots for initial and confirmatory drug tests, screening/differential specimen validity tests, and for initial 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
-Location of all temporary storage area(s)

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
-Location of all temporary storage area(s)

Confirmatory Drug Tests

-Handling and testing of aliquots by laboratory personnel
-Maintenance of chain of custody and aliquot identity during the testing
-Location of all temporary storage area(s)

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. Will the laboratory use an electronic (digital) or combination (electronic and paper) Federal CCF?

   ___ Yes → Provide the items on the Electronic CCF System Submission List (attached)
   ___ No

3. 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).

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

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

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

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

6. 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).

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

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

   7a. Where will the original specimens be stored?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

   7b. Who will have access to the specimen storage areas?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

8. 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**

8a. 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 calibrator and control 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 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.

4. In addition to the data packages described above: if the laboratory will use more than one technology for initial drug tests (e.g., immunoassay, LC-MS/MS) or confirmatory drug tests (e.g., GC-MS, GC-MS/MS, LC-MS/MS), the laboratory must also provide drug test batch data and associated documents for a drug positive sample tested using each technology.

F. Personnel

To be eligible to apply for certification a laboratory must have a Responsible Person (RP) candidate that meets all eligibility requirements listed in Section 11.3 of the Mandatory Guidelines. A laboratory may not apply for certification unless they can affirmatively answer questions 2 and 3 below regarding the RP Candidate.

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

_____ YEARS

6. Is the RP 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?

   _____
   _____
   _____
   _____

7. If approved as the RP for the certified urine laboratory, how many hours per week would the candidate work in the regulated forensic urine drug testing laboratory?

   _____ HOURS PER WEEK

8. If approved as the RP for the certified urine laboratory, what additional duties (i.e., other than regulated forensic urine drug testing) would the candidate perform for the company? (List here.)

   _____
   _____
   _____

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 alt-RP 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. How long has the alt-RP candidate been associated with the laboratory?

_____ YEARS

6. Is the alt-RP 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?

_____
_____
_____
_____

7. If approved as the alt-RP for the certified urine laboratory, how many hours per week would the candidate work in the regulated forensic urine drug testing laboratory?

_____ HOURS PER WEEK

8. If approved as the alt-RP for the certified urine laboratory, what additional duties (i.e., other than regulated forensic urine drug testing) would the candidate perform for the company? (List here.)

_____
_____
_____
_____

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 calibrators/controls, instrument responses, etc., fail defined acceptance criteria?

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

3. Are all calibrator and control 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 (for initial testing) and open controls. At a minimum, these must include the number and type of calibrators and controls 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, whether a batch is constituted in one session or specimens are added to the batch throughout the day)
   - The distribution of the donor specimens, calibrators and controls within each batch
   - The procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented and (as applicable for alternate technologies) 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 all donor specimen results or only a partial number of donor specimens in a batch
   - For alternate technologies (as applicable), the criteria for accepting, re-extracting, or reinjecting a specimen

   Specimen Validity Tests (Initial, Confirmatory, Screening, Differential)
   - How batches are constituted (e.g., how many specimens are in a batch, whether a batch is constituted in one session or specimens are added to the batch throughout the day)
   - The distribution of the donor specimens, calibrators, and controls 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 decision points for each test and what constitutes abnormal results
   - 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 specimen validity test measurand, and any screening or differential tests.

   Confirmatory Drug Tests (Primary and Alternate)
   - How batches are constituted (e.g., how many specimens are in a batch, whether a batch is constituted in one session or specimens are added to the batch throughout the day)
   - The distribution of the donor specimens, calibrators, and controls 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-preparing, or reinjecting a batch (including partial batch acceptance criteria)
- The criteria for accepting, re-preparing, or reinjecting a specimen
- Procedures for preventing and detecting carryover
- The criteria for acceptable chromatography

Note: (1) Insert here.

(2) Do not exceed a total of 4 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, criteria for instrument flags):_____

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, integrity, and availability of the data and to limit access to any data transmission, storage, and retrieval system:

5. Is the laboratory's custody and control form (CCF) identical to the OMB-approved Federal CCF to be used for all urine 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 urine 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/Codeine/Morphine Positive
- Hydrocodone/Hydromorphone Positive
- Amphetamine/Methamphetamine Positive
- D-Methamphetamine (if applicable)
- Substituted
- Invalid Result
- Biomarker Result (if applicable)
- Specimen Adulterated: pH
- Specimen Adulterated: Others as Pertinent
- Split Specimen: Reconfirmed
- Split Specimen: One or More Primary Specimen Results Not Reconfirmed

8. Will the laboratory send a data file report in lieu of a formatted electronic report?

___ Yes → **ATTACH EXAMPLE DATA FILE REPORTS** (reflecting what will be sent)
___ No

9. Does the laboratory plan to use an electronic (digital) or combination (electronic and paper) Federal CCF for reporting? Note: Section D of the NLCP Manual for Urine Laboratories describes the allowable formats for the Federal CCF.

___ Yes
___ No

If YES, specify the CCF type(s) and supplier(s):

_____
_____
_____

I. Laboratory Computers and Information 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 (and back-up computer system, if any) to be used 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 onsite, provide information on location and organizational control of each 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

5. Does the laboratory have a System Security Plan (SSP) for each information system used for regulated drug testing, including corporate systems and external service provider systems?

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

6. Will the laboratory use an external service provider (e.g., LIMS provider, software service provider, ECCF provider, report provider) to perform services on the laboratory's behalf related to regulated drug testing?

___ Yes → **List the names of external service providers, and complete 6a**
___ No

_____

_____

6a. Does the laboratory have a signed contract/agreement with each external service provider that includes the priority elements listed in the Priority Elements for Contracts/Agreements with External Service Providers (attached)?

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

7. Does the laboratory use data analysis software (in-house or third party) to process mass spectral results?

___ Yes → **List the software and provide a description of its operation and use in data processing and review**
___ No

_____

_____

_____

_____

Complete the NLCP Application Tables

Table 1-a-1. Immunoassay Initial Drug Test Methods and Instruments

Table 1-a-2. LC-MS/MS Initial Drug Test Methods

Table 1-a-3. Initial Drug Test Methods and Instruments – Liquid Chromatography

Table 1-a-4. Initial Drug Test Methods and Instruments – Tandem Mass Spectrometry

Table 1-b. Immunoassay First Initial Drug Test Calibrators and Controls

Table 1-c. Immunoassay Second Initial Drug Test Calibrators and Controls

Table 1-d. Initial Drug Test Calibrators and Controls – LC-MS/MS

Priority Elements for Contracts/Agreements with External Service Providers

1. Limiting access to regulated specimen information

2. Implementing appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing applicable federal requirements with regard to regulated specimen and drug test information

3. Reporting to the HHS-certified test facility any use or disclosure of the information not provided for by the contract, including incidents that constitute data breaches of unsecured regulated specimen and drug test information

4. Disclosing information to HHS related to regulated specimens and drug tests

5. Arranging for disposition of regulated specimen data (i.e., disposal in accordance with specified record retention periods; transfer of records to the HHS-certified test facility upon termination of the agreement)

6. Notifying the HHS-certified test facility prior to allowing any subcontractors to have access to regulated specimen and drug test information

7. Ensuring that any subcontractors agree to the same restrictions and conditions that apply to the external service provider with respect to regulated specimen and drug test information

Electronic CCF System Submission List

Items to be submitted for review:

1. **Process Overview**. A detailed overview of all processes involving the Federal ECCF from initiation until final disposition, including:

    - Assigning unique specimen identification numbers
    - Initiation of the ECCF
    - Collection
    - Specimen shipment (labels/seals for specimen bottles/tubes, boxes, and bags)
    - CCF distribution at the end of collection
    - Collector/collection site records storage and disposal
    - Specimen tracking
    - Test facility accessioning
    - Test facility reporting
    - Test facility records storage and disposal
    - Medical Review Officer review and completion of the CCF
    - MRO reporting
    - MRO records storage and disposal
    - ECCF system provider records storage and disposal

2. **Topic Outline of Proposed SOPs.** An outline of topics to be addressed in:

    - HHS-certified test facility standard operating procedures (SOPs) for accessioning, certification, reporting
    - Procedures/Instructions for other Federal ECCF users including collectors, MROs, and MRO staff

    Note: Proposed Federal ECCF instructions or proposed SOP Table of Contents may be submitted
    Examples: Screenshots, tables of contents

3. **Training Plans.** Training for Federal ECCF system users, including:

    - Federal ECCF system users (IITF staff, laboratory staff, collectors, MROs, MRO staff as applicable)
    - Other individuals given access to regulated specimen data (e.g., IT staff)
        - Security awareness training must address forensic records and regulated specimen donor PII

    Note: RP must document review and approval of training plans and materials

4. **System/Network Diagram.** Logical network diagram including, at a minimum:

    - Firewalls
    - Network security devices

- o Servers
- o Workstations
- o Primary routers/switches
- o Remote access devices
- o Internet connection(s)

5. **System Security Plan (SSP).** Plan that reflects NIST 800-53 or other recognized security standard, and provides an overview of the security requirements of the system, describes the controls in place or planned for meeting those requirements, and delineates responsibilities and expected behavior of all individuals who access the system.

    - o The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, federal agency, or SAMHSA)
    - o Protection of records to enable accurate and ready retrieval through the records retention period
    - o Limiting system access to authorized individuals
    - o Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record)
    - o Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand

6. **System Validation Plan.** Plan for testing and evaluating information system security controls to ensure effective implementation.

    Note: The HHS-certified test facility must provide documentation of security control testing and evaluation at NLCP inspections.
    Examples of records to be provided include
    - o Periodic records checks
    - o Independent security monitoring by IITF/laboratory IT staff
    - o A report from an independent auditor regarding compliance with relevant industry standards

7. **External ECCF Provider Agreement with HHS-Certified Test Facility.** An HHS-certified test facility that plans to use an external ECCF system must have a contract/ agreement signed by each laboratory Responsible Person (RP)/IITF Responsible Technician (RT) and an authorized representative of the ECCF provider that:

- Specifies the responsibilities of the ECCF provider and states restrictions and conditions that apply to the ECCF provider with respect to regulated specimen and drug test information
- Establishes the permitted and required uses and disclosures of regulated specimen and drug test information by the ECCF provider
- Addresses, at a minimum, these **priority elements**:
    - Limiting access to regulated specimen information
    - Implementing appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing applicable federal requirements with regard to regulated specimen and drug test information
    - Reporting to the HHS-certified test facility any use or disclosure of the information not provided for by the contract, including incidents that constitute data breaches of unsecured regulated specimen and drug test information
    - Disclosing information to HHS related to regulated specimens and drug tests
    - Arranging for disposition of regulated specimen data (i.e., disposal in accordance with specified record retention periods; transfer of records to the HHS-certified test facility upon termination of the agreement)
    - Notifying the HHS-certified test facility prior to allowing any subcontractors to have access to regulated specimen and drug test information
    - Ensuring that any subcontractors agree to the same restrictions and conditions that apply to the ECCF provider with respect to regulated specimen and drug test information.

Note: The agreement/contract must be provided for NLCP review with the initial ECCF submission and with other ECCF system documentation at each inspection.