

Effective 1 April 2019

**Urine
Instrumented Initial Test Facility
(IITF)
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***

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average 3 hours per respondent per year, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, Maryland, 20857.

NATIONAL LABORATORY CERTIFICATION PROGRAM URINE IITF APPLICATION FORM

A. Applicant IITF

1. Name of IITF: _____
Address: _____

City, State, ZIP: _____
Telephone: (____) ____ - _____ FAX: (____) ____ - _____
e-Mail: _____
2. Express delivery address (*if different from above*)
Address: _____

City, State, ZIP: _____
3. Designated Responsible Technician (RT): _____
Title/Position: _____
Telephone: (____) ____ - _____ Ext. _____
e-Mail: _____

If applicable:

- Designated Alternate RT (Alt-RT): _____
Title/Position: _____
Telephone: (____) ____ - _____ Ext. _____
e-Mail: _____
4. **I understand that the answers provided in this application will be used to determine the applicant IITF'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 RT

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 IITF Information

The following table is excerpted from Section 3.4 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 82 FR 7920, 23 January 2017, effective 1 October 2017). **Note:** confirmatory test information is not applicable for IITFs.

Initial Test Analyte	Initial Test Cutoff ¹	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration
Marijuana metabolites (THCA) ²	50 ng/mL ³	THCA	15 ng/mL
Cocaine metabolites (Benzoylecgonine)	150 ng/mL ³	Benzoylecgonine	100 ng/mL
Codeine/Morphine	2000 ng/mL	Codeine Morphine	2000 ng/mL 2000 ng/mL
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone Hydromorphone	100 ng/mL 100 ng/mL
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone Oxymorphone	100 ng/mL 100 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine Methamphetamine	250 ng/mL 250 ng/mL
MDMA ⁴ /MDA ⁵	500 ng/mL	MDMA MDA	250 ng/mL 250 ng/mL
¹ For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff): Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group. Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.			
² An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).			
³ Alternate technology (THCA and benzoylecgonine): The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine).			
⁴ Methylenedioxymethamphetamine (MDMA)			
⁵ Methylenedioxyamphetamine (MDA)			

1. To be eligible for certification, the IITF must test for all initial drug test analytes and initial specimen validity test measurands required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs (*Federal Register*, 82 FR 7920, 23 January 2017, effective 1 October 2017). The IITF must use the test methods specified by the Mandatory

Guidelines for screening and initial tests (i.e., drug tests and specimen validity tests). **Note:** the terms “screening specimen validity test” and “initial specimen validity test” are defined in Section J of the NLCP Manual for Urine IITFs.

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

- Yes
- No → **IITF NOT ELIGIBLE TO APPLY**

1b. Does the IITF 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 → **IITF NOT ELIGIBLE TO APPLY**

2. Is the IITF 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 IITF is located. _____

4. List IITF certifications/licenses:

____ States (List): _____

____ CLIA/HCFA¹ (List Specialties): _____

____ CAP² (List Specialties): _____

____ Others (Specify): _____

¹Clinical Laboratory Improvement Amendments (CLIA)/Health Care Financing Administration (HCFA)

²College of American Pathologists (CAP)

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

5. To be eligible for certification, the IITF must obtain a letter of commitment from one or more HHS-certified laboratories stating that the laboratory will receive, test, and report specimens from the certified IITF. The letter must be signed by each Responsible Person (RP) of the laboratory and by the designated RT of the applicant IITF. The list of currently certified laboratories is published by SAMHSA monthly in the Federal Register and is available on the SAMHSA website, <http://workplace.samhsa.gov/>.

- 5a. Does the IITF have a letter of commitment from one or more HHS-certified laboratories?

____ Yes → **ATTACH PHOTOCOPIES OF ALL LABORATORY COMMITMENT LETTERS**

____ No → **IITF NOT ELIGIBLE TO APPLY**

C. IITF Standard Operating Procedures (SOP) Manual

1. For certification, the IITF 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*, 82 FR 7920, 23 January 2017, effective 1 October 2017).

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 IITF is eligible to receive NLCP performance testing (PT) samples.

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

Yes
 No → **IITF NOT ELIGIBLE TO APPLY**

IITF SOP MANUAL INDEX

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

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
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 problem/rejected specimens	_____	_____
Chain-of-Custody		
Procedure for documenting all transfers of specimens	_____	_____
Procedure for documenting all transfers of aliquots	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Procedure for using an ECCF System (if applicable)	_____	_____
Procedure for maintaining security of specimen bottles	_____	_____
Procedure for maintaining security of specimen aliquots	_____	_____
Procedure for sending a specimen to a laboratory	_____	_____
 <i>Aliquot Preparation</i>		
Procedure for preparing initial drug test aliquots	_____	_____
Procedure for preparing screening specimen validity test aliquots	_____	_____
Procedure for preparing initial specimen validity test aliquots	_____	_____
Procedures for automated aliquotting equipment	_____	_____
 <i>Initial Drug Test</i>		
<i>Note: For alternate technology initial drug tests (as applicable), provide the following information for each drug analyte</i>		
Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedure for calculating results	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Quality control (QC) procedure and criteria for acceptable results and corrective actions	_____	_____
Procedure for validation of initial drug test methods	_____	_____
References	_____	_____
Second Initial Drug Test		
Criteria for use	_____	_____
Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedure for calculating results	_____	_____
QC procedure and criteria for acceptable results and corrective actions	_____	_____
Procedure for validation of second initial drug test methods	_____	_____
References	_____	_____
Specimen Validity Tests		
<i>Note: Provide the following information for each specimen validity test (Screening and Initial tests are defined in Section J of the NLCP Manual for Urine IITFs)</i>		
Creatinine		
Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
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 controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedures for conducting specific gravity tests	_____	_____
QC acceptance/rejection criteria and corrective action for specific gravity tests	_____	_____
Procedure for validation of specific gravity test methods	_____	_____
Special requirements, etc.	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
References	_____	_____
Criteria for identifying acceptable, dilute, and possible invalid or substituted specimens based on creatinine and specific gravity test results	_____	_____
pH		
Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedures for conducting pH tests	_____	_____
QC acceptance/rejection criteria and corrective action for pH tests	_____	_____
Criteria for identifying acceptable and possible invalid or adulterated specimens based on pH test results	_____	_____
Procedure for validation of pH test methods	_____	_____
Special requirements, etc.	_____	_____
References	_____	_____
Oxidants		
Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedures for conducting oxidant tests	_____	_____
QC acceptance/rejection criteria and corrective action for oxidant tests	_____	_____
Criteria for identifying acceptable and possible invalid or adulterated specimens based on oxidant test results	_____	_____
Procedure for validation of oxidant test methods	_____	_____
Procedure for periodic re-verification of oxidant test methods	_____	_____
Special requirements, etc.	_____	_____
References	_____	_____

Other Adulterants

Note: Provide the following information for each adulterant

Adulterant: _____

Principle of analysis	_____	_____
Preparation of test materials, calibrators, and controls	_____	_____
Procedure for set-up and normal operation of instruments	_____	_____
Procedure for instrument maintenance	_____	_____
Procedure for assay calibration	_____	_____
Procedures for conducting the test	_____	_____
QC acceptance/rejection criteria and corrective action for the test	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Criteria for identifying acceptable and possible invalid or adulterated specimens based on the adulterant test results	_____	_____
Procedure for validation of the test methods	_____	_____
Procedure for periodic re-verification of the test methods	_____	_____
Special requirements, etc.	_____	_____
References	_____	_____
QC and Test Materials		
Procedures for preparing stock standards, etc.	_____	_____
Procedures for preparing and verifying calibrators	_____	_____
Procedures for preparing and verifying controls	_____	_____
Corrective procedure when calibrator and control verification results are out of control limits	_____	_____
Procedures for preparing and verifying test materials	_____	_____
Corrective procedure when test materials verification results are unacceptable	_____	_____
Quality Assurance (QA) Procedures		
Procedures for monitoring calibrator and control results	_____	_____
Corrective procedure when QA review of calibrator and control results shows problems or potential problems (e.g., trends, shifts, bias)	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Equipment and Maintenance		
Wash procedure for labware	_____	_____
Procedure for determining accuracy and precision of pipetting devices	_____	_____
Procedures for temperature-dependent equipment	_____	_____
Procedures for centrifuges	_____	_____
Procedures for analytical balances	_____	_____
Safety procedures	_____	_____
Administrative/Reporting Procedures		
Procedure for reviewing/certifying the test result(s) of a specimen	_____	_____
Procedure for reporting the test result(s) of a specimen	_____	_____
Procedure to detect and correct clerical errors	_____	_____
Procedure for electronic reporting of results	_____	_____
Procedure for preparing statistical summary reports	_____	_____
Procedure for updating the SOP Manual	_____	_____
Procedure for preparing data packages	_____	_____
Procedure for preparing the Forwarded and Rejected Specimen List (FRSL)	_____	_____
IITF Computers and Information Systems Procedures		
Computer and Laboratory Information Management System (LIMS) security procedures	_____	_____
Computer and LIMS maintenance procedures	_____	_____

<u>TOPIC</u>	<u>SECTION</u>	<u>PAGE NO.</u>
Procedure for computer and software validation	_____	_____
Procedure for requesting, verifying, and implementing software and configuration changes	_____	_____
Procedure for LIMS records archiving and retrieval	_____	_____
Procedures for system monitoring, incident response, and disaster recovery	_____	_____
Procedure for obtaining audit trail reports	_____	_____
System Security Plan (SSP)	_____	_____

D. Chain of Custody, Accessioning, and Security

The IITF must have chain of custody, accessioning, and security procedures that ensure integrity is maintained for the original specimens and their aliquots. 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 IITF must ensure the security of specimens and aliquots during processing and placement in any storage locations.

1. Provide a description of the IITF'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 IITF 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 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 (pouring or pipetting and amounts) used for preparing aliquots for initial drug tests, screening specimen validity tests, and initial 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 IITF personnel
- Maintenance of chain of custody and aliquot identity during the testing

Specimen Validity Tests (Screening, Initial)

- Handling and testing of aliquots by IITF personnel
 - Maintenance of chain of custody and aliquot identity during the testing
- Note:** the terms "screening specimen validity test" and "initial specimen validity test" are defined in Section J of the NLCP Manual for Urine IITFs.

Disposition of Specimens and Aliquots

- Handling of original specimen bottles and aliquots after testing is completed
- Procedure for transferring specimens to an HHS-certified laboratory

Note: (1) Insert here.

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

2. Will the IITF 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 → **IITF NOT ELIGIBLE TO APPLY**

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

- Yes
- No → **IITF NOT ELIGIBLE TO APPLY**

6. Attach a floorplan of the IITF 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 → **IITF 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? _____

E. Records

The IITF 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 IITF 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 IITF must have security measures in place to limit access to electronic and hardcopy records to essential authorized personnel.

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

- Yes
 No → **IITF NOT ELIGIBLE TO APPLY**

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

- Yes
 No → **IITF NOT ELIGIBLE TO APPLY**

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

- Yes
 No → **IITF NOT ELIGIBLE TO APPLY**

3. Attach two data packages using the format described in Section R of the NLCP Manual for Urine Instrumented Initial Test Facilities to support (1) a specimen forwarded to a laboratory based on initial drug test results and (2) a specimen forwarded to a laboratory based on specimen validity test results.

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, GC-MS, GC-MS/MS, LC-MS/MS) the laboratory must also provide drug test batch data and associated documents for a sample tested using each technology.

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

4. Does the candidate have appropriate training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise?

___ Yes → **Describe:** _____

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

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 IITF?

___ 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 IITF?

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

_____ HOURS PER WEEK

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

_____ YEARS

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 IITF?

- ___ 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 IITF?

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

_____ HOURS PER WEEK

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

_____ 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)				
Supervisor(s)				
Other Key Staff				

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

- Yes
- No → **GO TO SECTION G**

If YES, describe requirements:

G. Quality Control

For certification, the IITF 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 → **IITF NOT ELIGIBLE TO APPLY**

3. Are all calibrator and control results reviewed by the Certifying Technician prior to the release of the results?

- Yes
 No → **IITF 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 Technician Candidate?

- Yes
 No → **CANDIDATE NOT ELIGIBLE AS RT**

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 → **IITF NOT ELIGIBLE TO APPLY**

7. For certification, the IITF must have a QC program that includes both blind 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 IITF'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, 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 calibration and 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 (Screening, Initial)

- 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, 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 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 IITF's specimen validity testing. The IITF's submission must identify any "reflex" testing, the initial test methods for each specimen validity test measurand, and any screening tests.

Note: (1) Insert here.

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

H. Review and Reporting

The IITF 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 and initial tests):

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

4. Is the IITF'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 IITF'S CUSTODY AND CONTROL FORM**
 No → **IITF NOT ELIGIBLE TO APPLY**

5. Will the IITF 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 IITF's computer-generated electronic report for each of the following IITF results:

- Negative
- Negative, Dilute
- Rejected

6. Will the IITF send a data file report in lieu of a formatted electronic report?

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

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

- Yes
- No

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

I. IITF Computers and Information Systems

IITF 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 IITF. Is it a “stand alone” system used solely by the IITF, part of a local system (e.g., a hospital system), or part of a multi-facility 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 IITF plans to use the computer system in regulated specimen processing: _____

3. Is the IITF computer system maintained in a secure area?
 Yes
 No

Attach a floorplan identifying the IITF 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 IITF limit functional access to the computer system?
 Yes
 No

5. Does the IITF 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 → **IITF NOT ELIGIBLE TO APPLY**

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

- Yes → **List the names of external service providers, and Complete 6a**
 No

6a. Does the IITF 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?

- Yes
 No → **IITF NOT ELIGIBLE TO APPLY**

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
- Table 2-a-1.** Initial Specimen Validity Test Methods and Instruments (continued on **Table 2-a-2** as needed)
- Table 2-b-1.** *not applicable for an IITF*
- 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 Calibrators and Controls (continued on **Table 2-d-2** as needed)

**Tables 2-d-3
and 2-d-4.** *not applicable for an IITF*

Table 2-d-5. Screening/Differential Specimen Validity Test Calibrators and Controls

C-3 Tables. *not applicable for an IITF*

**Tables C-4-a
through C-4-c.** *not applicable for an IITF*

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 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

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: RT 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

Electronic CCF System Submission List

- Servers
 - Workstations
 - Primary routers/switches
 - Remote access devices
 - 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.
- 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)
 - Protection of records to enable accurate and ready retrieval through the records retention period
 - Limiting system access to authorized individuals
 - 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)
 - 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
- Periodic records checks
 - Independent security monitoring by IITF/laboratory IT staff
 - 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

Electronic CCF System Submission List

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.