Effective 1 October 2010

URINE
INSTRUMENTED INITIAL TEST FACILITY (IITF)

INFORMATION CHECKLIST

NATIONAL LABORATORY CERTIFICATION PROGRAM (NLCP)

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NATIONAL LABORATORY CERTIFICATION PROGRAM
URINE IITF CHECKLIST

Table of Contents

I. URINE IITF INFORMATION CHECKLIST

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A. Instructions for the IITF

Pre-inspection Materials

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

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

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

2. IITF Operation Schedule/Inspection Schedule

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

3. Key Staff Interview List

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

4. IITF Computer Systems (Section P)

   To facilitate the inspection of the IITF's computer system, the NLCP directs the IITF to perform a self-assessment using Section P, IITF Computer Systems. The IITF provides the completed Section P to the inspection team at the beginning of the inspection.

5. Floor plan of the IITF

6. IITF data packages

   The IITF provides two data packages to the NLCP: one for a specimen forwarded to a laboratory based on initial **drug test** results and one forwarded to a laboratory based on **specimen validity test** results (i.e., pH, creatinine and specific gravity, or oxidant tests). These data packages should contain all chain of custody forms, worksheets, initial drug test data, screening specimen validity test data, initial specimen validity test data, and reports pertaining to the specimen. The program-required format for data packages is described in Section R of the NLCP Manual for Urine IITFs. These must be recent specimens, processed since the last NLCP inspection using the IITF's current procedures. **Note**: the terms "screening specimen validity test" and "initial specimen validity test" are defined in Section J of the NLCP Manual for Urine IITFs.

7. Hotel list

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

8. Directions

   The IITF provides a clear, precise map with directions describing the routes from the airport to the hotels and from the hotels to the IITF. Hotels selected should ensure the safety and welfare of the inspectors during the inspection.

Forwarded and Rejected Specimen List (FRSL)

Prior to each NLCP inspection that includes a records audit, the NLCP notifies the IITF of the specified audit period (e.g., the six-month period ending one month prior to the month of the inspection). The IITF is required to identify all regulated specimens that, during that time, were reported as rejected or were forwarded to a certified laboratory for testing. The IITF must submit to the NLCP a list of these specimens, with specific information for each specimen. The IITF also provides a monthly summary for the records audit period listing the numbers of regulated specimens reported as negative, negative-dilute, and rejected.

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

1. Format for FRSL spreadsheet

2. The IITF will provide information for each specimen (e.g., the reason for rejection, the reason for forwarding to a laboratory and identification of the laboratory to which the specimen was forwarded, receipt date, report date, forwarded date).

3. Specimens to be included on the FRSL:
   - The IITF must list only specimens reported as rejected and specimens forwarded to a certified laboratory for testing.
   - The IITF must remove all known NLCP performance testing (PT) samples.

4. Requirements for records assembly

   The NLCP selects specimens from the submitted FRSL for review during the inspection and provides the selected list to the IITF and to the lead auditor. The IITF must organize and assemble records for each of the selected specimens to facilitate their review by the audit team during the inspection. At a minimum, records must be assembled by reason (see item 2 above) and in chronological order, to facilitate their location within labeled storage folders/boxes. Auditors must be able to retrieve all records (excluding failed batches) pertaining to a specimen on the selected FRSL with a minimum of assistance from the IITF staff.

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

IITF Preparation Criteria List

Prior to each inspection, the NLCP sends an IITF Preparation Criteria List to the IITF, listing materials that must be available for the inspection team upon their arrival at the IITF. Materials include a copy of the standard operating procedures (SOP) manual for each inspection team member, NLCP PT records, personnel files, quality assurance (QA)/quality control (QC) records, reagent records, validation records, a timeline of any changes in QC criteria and control acceptance limits during the records audit period, and documentation of security procedures (e.g., access rosters and visitor logs for each secured area). Other items may be requested for review prior to or during the inspection.

B. IITF Information (completed by the IITF)

B-1. Name of IITF: _____
Address: _____
_____
City, State, ZIP: _____

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

B-2. **Responsible Technician(s)**
RT's name: _____
RT's title: _____

RT's name: _____
RT's title: _____

RT's name: _____
RT's title: _____

Alternate Responsible Technician(s)
Alt-RT's name: _____
Alt-RT's title: _____

Alt-RT's name: _____
Alt-RT's title: _____

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

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

_____
Signature, Responsible Technician Date

_____
Signature, Responsible Technician Date

_____
Signature, Responsible Technician Date

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

_____
_____
_____
_____
_____
_____
_____

B-5. Days/hours of operation of the forensic urine drug testing IITF:
_____days per week; _____hours per day

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

_____

B-6. Does the IITF have a U.S. Drug Enforcement Agency (DEA) registration? YES NO

If **YES**, for which schedules?

___1 ___2 ___2N ___3 ___3N ___4 ___5

If NO, explain how controlled reference materials are acquired:

_____
_____
_____

B-7. Describe the State licensure requirements for urine forensic toxicology for the State in which the IITF is located:

_____
_____
_____

B-8. List IITF certifications/licenses:

____ States (List): _____
____ CLIA/HCFA[1] (List Specialties): _____
____ CAP[2] (List Specialties): _____
____ Others (Specify): _____

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

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

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

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

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

If **YES**, describe requirements:

_____
_____
_____

B-10. If there is more than one RT, briefly describe how the RTs share the responsibilities for the various IITF operations and procedures.

_____
_____
_____
_____

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

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

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

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

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

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

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

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

_____
_____

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

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

B-13. Average number of specimens analyzed by the IITF each day for drugs of abuse ***during the six months preceding submission of Sections B and C (both regulated and non-regulated specimens)***:

Specify the months_____

Total specimens/day _____

How was this number derived? _____
_____
_____

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

_____ individuals

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

Activity	**No. of Individuals**
Accessioning	
Initial drug testing	
Screening/initial specimen validity testing	
Certification	
Specimen sendout to laboratory	

B-16. List the name and location of each HHS-certified laboratory that has a legally binding arrangement to receive, test, and report regulated specimens from the IITF. The documentation of the arrangement (e.g., contract, written agreement between corporate IITFs and laboratories) must outline the responsibilities of each party and be signed by each Responsible Person (RP) of the laboratory and by each RT of the ITF.

Laboratory Name	**Location (City, State)**

C. IITF Procedures (completed by the IITF)

Any computer interface communicating any form of data from an HHS-certified IITF to an HHS-certified laboratory must be approved by the NLCP prior to implementation. The IITF and/or laboratories must submit a detailed plan to the NLCP for review. Affected test facilities will be subject to inspection to verify compliance with NLCP requirements. HHS-certified laboratories are prohibited from transmitting data to an HHS-certified IITF through a computer interface.

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

Security

- Building
- Department
- Specimens
- Records

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

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

Specimen Receiving/Accessioning

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

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

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

Aliquotting Procedures

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

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

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

Specimen Sendout to Laboratory

- Retrieval of the original specimen bottles from storage and how they are handled, including chain of custody documentation.
- Resealing the primary specimen bottle.
- Packaging the primary and split specimen bottles and the Federal Custody and Control Form (CCF) for shipment.
- Maintaining records of forwarded specimens.

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

C-5. Provide a description of the IITF's procedures for the following:

Specimen Accessioning

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

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

C-6. Provide a description of the IITF's procedures for the following:

First and Second Initial Drug Tests

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

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

C-7. Provide a description of the IITF's procedures for the following:

First and Second Initial Drug Tests

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

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

C-8. Provide the following information for the first and second Initial Drug Tests:

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

_____
_____
_____
_____
_____
_____
_____
_____

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

_____
_____
_____
_____
_____
_____
_____
_____

C-9. Provide a description of the IITF's procedures for the following:

Specimen Validity Tests (Screening and Initial)

- Handling and testing of aliquots by IITF personnel.
- Maintenance of chain of custody 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.*

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

C-10. Provide an outline or a legible flow chart that comprehensively describes the IITF's Specimen Validity Testing.

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

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

_____
_____
_____
_____
_____

C-11. Provide a description of the IITF's procedures for the following:

Specimen Validity Tests (Screening and Initial)

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

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

C-12. Provide the following information for the Specimen Validity Tests (i.e., screening and initial tests):

Describe the procedures and acceptance criteria for calibration:

_____
_____
_____
_____
_____
_____
_____
_____

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

_____
_____
_____
_____
_____
_____
_____
_____

C-13. Provide a description of the IITF's procedures for the following:

Certification/Reporting Procedures

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

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

C-14. Provide a description of the IITF's procedures for the following:

Electronic Reporting Procedures

- Release of computer-generated electronic reports.

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

C-15. Provide an example of the IITF's computer-generated electronic report for each of the following IITF results:

- Negative
- Negative, Dilute
- Rejected

C-16. Does the IITF use an off-site computer information system? YES NO

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

C-17. Provide a description of the IITF's procedures for the following:

Disposition of Specimens and Aliquots

- Handling of original specimen bottles and aliquots after testing is completed.

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

Complete the C Tables:

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

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

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

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

Table C-2-b-1 and C-2-b-2. *not applicable for an IITF*

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

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

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

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

Table C-1-a

Initial Drug Test
Methods and Instruments

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

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

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

Table C-1-b

First Initial Drug Test QC Samples

1st initial drug		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 C-1-c

Second Initial Drug Test QC Samples

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

Table C-2-a-1

Initial Specimen Validity Test Methods and Instruments

Initial SVT	Creatinine	pH meter*	Nitrite	Gen.Oxid.	Other:	Other:
Method						
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
*also applies to a colorimetric pH test with dynamic range of at least 2.0 to

Table C-2-a-2

Initial Specimen Validity Test
Methods and Instruments

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

Table C-2-c-1

Screening
Specimen Validity Test
Methods and Instruments

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

Table C-2-c-2

Screening
Specimen Validity Test
Methods and Instruments

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

Table C-2-d-1

Initial Specimen Validity Test
QC Samples

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

*also applies to a colorimetric pH test with dynamic range of at least 2.0 to 12.0

Table C-2-d-2

Initial Specimen Validity Test
QC Samples

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

Table C-2-d-5

Screening
Specimen Validity Test
QC Samples

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