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URINE INSTRUMENTED INITIAL TEST FACILITY (IITF)

INFORMATION CHECKLIST

NATIONAL LABORATORY CERTIFICATION PROGRAM (NLCP)

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NATIONAL LABORATORY CERTIFICATION PROGRAM URINE IITF CHECKLIST

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I. URINE IITF INFORMATION CHECKLIST

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 provision. The required materials depend on the inspection type (e.g., initial inspection, maintenance inspection, records audit, special inspection). The following describes some items that may be required.

1. NLCP Urine 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 Computers and Information Systems (Section P)

To facilitate the inspection of the IITF's computer and information systems, 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 ITF 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.

В.	IITF Information (completed by the IITF)	
B-1.		
	Address:	
	City, State, ZIP:	
	Telephone: () FAX: () e-Mail:	<u></u>
B-2.		
	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 S	
	and C are true and correct as of this date. I affirm that the read and are familiar with the current version of the NLCP.	•
	Urine IITFs. I also recognize my responsibility for providing	
	Sections B and C to the inspectors at the beginning of the	inspection if
	changes are made between the date of this submission and	d the
	inspection.	
Note:	Any false, fictitious, or fraudulent statements or information presented	
	sections B and C or misrepresentations relative thereto may violate Fe Law and could subject you to prosecution, monetary penalties, or both	
	<u>U.S.C. 1001; 31 U.S.C. 3801-812)</u> .	1 (Sec 16
	Signature, Responsible Technician Da	ate
	Signature, Responsible Technician Da	ate
	Signature, Responsible Technician Da	ate

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:	
Does the IITF have a U.S. Drug Enforcement Agency (DEA) registration?	YES
If YES, for which schedules?	
122N33N45	
If NO, explain how controlled reference materials are acquired:	
Describe the State licensure requirements for urine forensic toxicology for the State in which the IITF is located:	
List IITF certifications/licenses:	
States (List):	
CLIA/HCFA ¹ (List Specialties): CAP ² (List Specialties):	

- B-9. List name, job title, education, and licenses/certifications for the following key staff:
 - Note: (1) May attach separate sheet listing additional key staff
 - (2) Indicate (*) individuals new to the positions in the last 6 months

	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 YE	S, describe requirements:		

B-10.		e is more than one RT, briefly describe how the RTs share the nsibilities for the various IITF operations and procedures.			
B-11.		be the administrative relationships that exist for the key staff crensic drug testing IITF (see B-9 above):	of		
	a.	To whom does the RT(s) report?			
	b.	Who evaluates the performance of the RT(s)?			
	C.	What staff administratively report <i>directly</i> 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.		the IITF test any Federal agency specimens for drugs other that specified in the HHS Guidelines?	ın	YES	NO
	If YES	s, 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	s?	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 auth forensic drug testing IITF facility:	horize	ed access to the sec	cure				
	individua	als						
B-15.	List the total numbers of staff who are t activities <i>for regulated specimens</i> :	raine	d and routinely perfo	orm the following				
	Activity		No. of Individuals					
	Accessioning							
	Initial drug testing							
	Screening/initial specimen validity test	ing						
	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.

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

C-1. Provide a description of the 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, receipt of specimens received with a paper custody and control form (CCF), receipt of specimens received with an ECCF, who reviews the accuracy of the information on the custody and control forms and how discrepancies are documented.
- Handling problems with specimen bottles and/or custody and control forms.
- Assignment of IITF accession numbers.
- Location of temporary storage area(s).
 - Note: (1) <u>Insert here.</u>
 - (2) <u>Do not exceed a total of one page.</u>
- 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) <u>Insert here.</u>
 - (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-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) <u>Insert here.</u>

(2) <u>Do not exceed a total of one page.</u>

C-10.	Provide an outline or a legible flow chart that comprehensively describes the IITF's Specimen Validity Testing.							
	•	' - *-	<u>Insert here.</u> Do not exceed a total of one page.					
	outline/f	flowch	ges to the specimen validity testing art during the time period of the FRSL audit, with late of each change.					
C-11.	Provide a desc	criptior	n of the IITF's procedures for the following:					
	 How batche The distribution The accept when and the second of donor specific to the second of the sec	es are ution of tance	Tests (Screening and Initial) constituted. If specimens and QC samples within each batch. Criteria for each control (open and blind) in each batch and om these are evaluated and documented. Cocepting all donor specimen results or only a partial number ens in a batch. Insert here. Do not exceed a total of one page.					
C-12.	Provide the fol and initial tests	_	information for the Specimen Validity Tests (i.e., screening					
	Describe the p	oroced	ures and acceptance criteria for calibration:					
	Describe the n		I used to calculate the concentrations/ responses					

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 (i.e., procedures for paper CCFs, combination electronic/paper CCFs, and ECCFs, including use of electronic signatures by certifying technicians)
- Release of specimens for sendout to a laboratory.
- Release/reporting of results.
- Verification of information (e.g., CCF and computer resident result).
 - Note: (1) Insert here.
 - (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

- Reporting using an ECCF system: ECCF system provider(s) name and address; ECCF reporting procedures (including how ECCF data are secured (e.g., during transmission and storage); reporting methods; how MROs access completed ECCFs
- Web-based reporting: where report data are sent (i.e., website addresses; location and ownership of servers); file formats; external service provider(s) name and address (including cloud-based service providers); how report data are secured (i.e., during transmission and storage); how MROs access reports
- Release of computer-generated electronic reports (i.e., methods other than above).
 - Note: (1) Insert here.
 - (2) Do not exceed a total of one page.
- 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) Insert here.
 - (2) Do not exceed a total of one page.

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

C-3 Tables. not applicable for an IITF

Tables C-4-a

through C-4-c. not applicable for an IITF

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	s selected, pleas	e specify:			1	1			
		Second Init	ial Drug Test M	lethods and Ir	struments				
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	s selected, pleas	e specify:							
THCA = Δ9-tetrahydrocanna	binol-9-carboxylic acid	•	6-AM = 6-acetylmorphine		MDMA = methylenedic	xymethamphetamine			

MAMP = methamphetamine

PCP = phencyclidine

BZE = benzoylecgonine

First Initial Drug Test QC Samples

1st initi test	al drug QC	Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
	Conc											
THCA	Matrix											
	Source											
	Conc											
BZE	Matrix											
	Source											
	Conc											
MOR	Matrix											
	Source											
	Conc											
6-AM	Matrix											
	Source											
	Conc											
PCP	Matrix											
	Source											
	Conc											
MAMP												
	Source											
	Conc											
MDMA												
	Source											
	*If "C	Other" is select	ted, please spe	ecify:								

BQC = blind quality control sample

Second Initial Drug Test QC Samples

2nd initi		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										
O-Alvi	Matrix Source										
DOD	Conc										
PCP	Matrix Source										
	Conc										
MAMP	Matrix Source										
	Conc										
MDMA	Matrix										
	Source		ad places are	oif							
	(Jiner" is select	ted, please spe	сіту:							

Table C-2-a-1

Initial Specimen Validity Test Methods and Instruments

Initial SVT	Creatinine	SG	рН	Nitrite	Gen.Oxid.	Other:	Other:
	Oroammio		ρ	ranto	Join Januar		
Method		4 dec. place refractometer					
Kit Manufacturer							
Analyzer and							
Manufacturer							
Number of							
Analyzer Units							
Unit of	mg/dL			mcg/mL			
Measurement	mg/aL			IIICg/IIIL			
Target Analyte of							
Assay							
Target Analyte of							
Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch							
Size							
*If "Other" is se	lected, pleas	e specify:					

SG = specific gravity
Gen. Oxid. = general oxidant

LOD = limit of detection

ULOL= upper limit of linearity

LOQ = limit of quantitation

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, pleas	se specify:					

Table C-2-c-1

Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential SVT	SG	рН	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 selecte	d, please specify:				

Table C-2-c-2 Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential	Other:	Other:	Other:	Other:	Other:
SVT cont. 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	d, please specify:				

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
	Target value										
Creatinine											
	Source										
	Target value										
SG	Matrix										
	Source										
	Target value										
pН	Matrix										
	Source										
	Target value										
Nitrite	Matrix										
	Source										
	Target value										
Gen Oxid	Matrix										
	Source										
*	lf "Other" is s	selected, please	specify:								

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	Target Value										
name):	Matrix										
	Source										
Other (enter	Target Value										
name):	Matrix										
	Source										
	Target Value										
name):	Matrix										
	Source										
	Target Value										
Other (enter name): Other (enter name): Other (enter name):	Matrix										
04 /	Source										
Otner (enter	Target Value										
namo).	Matrix Source				Cal 4 Cal 5 Control 1 Control 2 Control 3 Control 4						
Other (enter											
name):	Target Value Matrix										
,	Source										
Other (enter											
name):	Target Value Matrix										
	Source										
* f "	Other" is sel	<mark>ected, please s</mark>	pecify:				•	•	•	•	

Screening/Differential Specimen Validity Test QC Samples

		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Specific Gravity	Target Value										
ml l											
рн											
	Target Value										
Other (enter name):	Matrix										
	Target Value										
Other (enter name): MS	Matrix										
	Source										
Other (enter name):	Target Value										
other (enter name).											
Other (enter name):	Target Value										
	pH pH Matrix Source Target Value Matrix Source										
Other (enter name):											
Other (enter name):	Matrix										
		ease specify:			J						