Effective 1 October 2017
Revised December 2018
Rev. 1218

URINE LABORATORY

INFORMATION CHECKLIST

NATIONAL LABORATORY CERTIFICATION PROGRAM (NLCP)

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

DATE Rev. No.	CHANGE	QUESTION NO.
December 12, 2018 Rev. 1218	Revisions to the urine laboratory information checklist are documented in separate document: *Summary of Changes - December 2018, NLCP Manual for Urine Laboratories*	multiple sections

NATIONAL LABORATORY CERTIFICATION PROGRAM
URINE LABORATORY CHECKLIST

Table of Contents

I. URINE LABORATORY INFORMATION CHECKLIST

I. URINE LABORATORY INFORMATION CHECKLIST

A. Instructions for the Laboratory

Pre-inspection Materials

Before each scheduled inspection, the NLCP sends instructions to the laboratory 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 Laboratory Information Checklist (Sections B and C)

   The laboratory provides up-to-date information to the NLCP on its drug testing operation (i.e., staffing, facility, and procedures) using the NLCP Urine Laboratory 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. Laboratory Operation Schedule/Inspection Schedule

   The laboratory provides a schedule of its operations to the NLCP, listing the days and hours for various processes (e.g., receiving, accessioning, initial testing, confirmation aliquotting, confirmatory drug test extractions, certification). Using this schedule, NLCP staff prepare a tentative schedule for the inspection team. To adequately assess operations on every shift, inspectors will periodically inspect processes that occur during off-shifts. 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. Inspectors should note any changes to the schedule in their checklist submission.

3. Key Staff Interview List

   The laboratory 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 laboratory, instructing the laboratory to ensure that the selected individuals are available for interview during the inspection. In addition to interacting with laboratory staff in the course of the inspection, the inspection team conducts formal interviews (i.e., 10 – 15 minutes each) with each selected staff member individually to evaluate their knowledge and ability to fulfill job duties.

4. Laboratory Computers and Information Systems (Section P)

   To facilitate the inspection of the laboratory's computers and information systems, the NLCP directs the laboratory to perform a self-assessment using Section P,

Laboratory Computer Systems. The laboratory will answer Section P checklist questions and provide explanatory comments (e.g., describe procedures and records) to support those answers. The laboratory provides the completed Section P to the inspection team at the beginning of the inspection.

5. Floor plan of the laboratory

   The floorplan must clearly identify areas (e.g., accessioning, testing, certification, reporting), clearly indicate how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks; location of secured storage areas such as refrigerators or freezers and how they are secured).

6. Laboratory data packages

   The laboratory provides two data packages to the NLCP: one for a positive specimen and one for a specimen that was reported as adulterated, substituted, or invalid based on specimen validity testing (i.e., invalid-abnormal pH, invalid-inconsistent creatinine and specific gravity results, or invalid-possible <adulterant> activity). These data packages should contain all chain of custody forms, worksheets, initial drug test data, screening/differential specimen validity test data, initial specimen validity test data, confirmatory specimen validity test data, confirmatory drug 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 Laboratories. These must be recent specimens, processed since the last NLCP inspection using the laboratory's current procedures. The laboratory must provide test data for all samples in the confirmatory drug test batch. Note: if the laboratory uses more than one technology for initial drug tests (e.g., immunoassay, LC-MS/MS) or confirmatory drug tests (e.g., GC-MS, GC-MS/MS, LC-MS/MS), the laboratory must also provide drug test batch data and associated documents for a drug positive sample tested using each technology.

7. Hotel list

   The laboratory provides a list of several hotels/motels located in close proximity to the laboratory and to the airport. Hotels selected should ensure the safety and welfare of the inspectors during the inspection. During the inspection, inspectors should notify the RP of alternate hotel suggestions and notify the NLCP of suggestions after the inspection.

8. Directions

   The laboratory provides a clear, precise map with directions describing the routes from the airport to the hotels and from the hotels to the laboratory.

Non-Negative Specimen List (NNSL)

Prior to each NLCP inspection that includes a records audit, the NLCP notifies the laboratory of the specified audit period (e.g., the six-month period ending one month prior to the month of the inspection). The laboratory is required to identify all regulated specimens reported during that time period as positive, adulterated, substituted, invalid, rejected, reconfirmed, or failed to reconfirm. In addition, the laboratory must identify all specimens received for testing from an Instrumented Initial Test Facility (IITF), *including specimens reported as negative*. The laboratory must submit to the NLCP a list of these specimens, with specific information for each specimen. The laboratory also provides a monthly summary for the records audit period listing the numbers of regulated specimens reported as positive, adulterated, substituted, invalid, negative, rejected, reconfirmed, or failed to reconfirm.

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

1. Format for NNSL spreadsheet

2. NNSL categories:
   - The laboratory will provide information concerning results reported for the following NNSL categories: amphetamine/methamphetamine/enantiomers, methylenedioxymethamphetamine (MDMA)/methylenedioxyamphetamine (MDA), benzoylecgonine, codeine/morphine, 6-acetylmorphine (6-AM), hydrocodone/hydromorphone, oxycodone/oxymorphone, phencyclidine, cannabinoids, adulterated, invalid, substituted, and rejected.
   - If the laboratory has tested a regulated specimen for an additional Schedule I or II drug upon request of a federal agency and reported the specimen as positive (i.e., drug present at or above the cutoff used for the test), the laboratory must submit a separate NNSL sheet for that drug.
   - If no specimen is identified for a specific category, the laboratory must submit that sheet indicating “None.”

3. Specimens to be included on the NNSL:
   - Specimens reported positive, adulterated, substituted, invalid, rejected, reconfirmed, and failed to reconfirm.
   - Specimens received for testing from an IITF, *including those reported negative*.

   The laboratory must remove all known NLCP performance testing (PT) samples.

4. Requirements for records assembly

   The NLCP selects specimens from the submitted NNSL for review during the inspection and provides the selected list to the laboratory and to the lead auditor. The laboratory 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 NNSL category 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 NNSL with a minimum of assistance from the laboratory staff.

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

Laboratory Preparation Criteria List

Prior to each inspection, the NLCP sends a Laboratory Preparation Criteria List to the laboratory, listing materials that must be available for the inspection team upon their arrival at the laboratory. Materials include a copy of the standard operating procedures (SOP) manual for each inspection team member, NLCP PT records, personnel files, quality assurance (QA) records, calibrator and control records, reagent records, validation records, a timeline of any changes in calibrator or control criteria and 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. Laboratory Information (completed by the laboratory)

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

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

B-2. **Responsible Person(s)**
RP's name: _____
RP's title: _____

RP's name: _____
RP's title: _____

RP's name: _____
RP's title: _____

Alternate Responsible Person(s)
Alt-RP's name: _____
Alt-RP's title: _____

Alt-RP's name: _____
Alt-RP'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 Laboratories. 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 Person Date

_____
Signature, Responsible Person Date

_____
Signature, Responsible Person Date

B-4. List the changes made by the laboratory (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 laboratory:

_____days per week; _____hours per day

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

_____

B-6. Does the laboratory 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 laboratory is located:

_____
_____
_____

B-8. List laboratory certifications/licenses:

____ States (List): _____

____ CLIA/HCFA[1] (List Specialties): _____

____ CAP[2] (List Specialties): _____

____ Others (Specify):_____

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

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
RP(s)				
Alt-RP(s)				
Certifying Scientist(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 laboratory is located? YES NO

If **YES**, describe requirements:

_____
_____
_____

B-10. If there is more than one RP, briefly describe how the RPs share the responsibilities for the various laboratory operations and procedures.

_____
_____
_____
_____

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

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

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

c. What staff administratively report ***directly*** to the RP(s)? ___
_____
_____
_____
_____

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

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

B-12. Does the laboratory 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 laboratory 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 laboratory 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 laboratory 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 laboratory 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	
Confirmatory specimen validity testing	
Extraction	
Confirmatory drug testing	
Certification	

C. Laboratory Procedures (completed by the laboratory)

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 laboratory'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 laboratory'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 laboratory 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 laboratory'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, specimen validity tests, and confirmatory drug 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 laboratory'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-5. Provide a description of the laboratory's procedures for the following:

First and Second Initial Drug Tests

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

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

C-6. Provide a description of the laboratory'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 batch?).
- The distribution of specimens, calibrators, and controls within each batch.
- 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 an alternate technology initial test (as applicable), the criteria for accepting a donor specimen result, reextracting a specimen, or reinjecting a specimen.

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

C-7. 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-8. Provide a description of the laboratory's procedures for the following:

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

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

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

C-9. Provide an outline or a legible flowchart that comprehensively describes the laboratory'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 NNSL audit, with the effective date of each change.

_____
_____
_____
_____
_____
_____

C-10. Provide a description of the laboratory's procedures for the following:

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

- How batches are constituted.
- The distribution of specimens, calibrators, and controls 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-11. Provide the following information for the Specimen Validity Tests (i.e., initial, confirmatory, and screening/differential tests):

Describe the procedures and acceptance criteria for calibration:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

C-12. Provide a description of the laboratory's procedures for the following:

Confirmatory Drug Tests

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

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

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

Confirmatory Drug Tests

- How batches are constituted (e.g., how many specimens are in a batch, is it constituted in one session or are specimens added to the batch, are regulated and non-regulated specimens tested in the same batch?).
- The distribution of the donor specimens, calibrators and controls 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 a donor specimen result, reextracting a specimen, or reinjecting a specimen.

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

C-14. Provide the following information for the Confirmatory Drug Tests:

Describe the requirements for calibration including criteria for exclusion of unsatisfactory calibrators:

_____
_____
_____
_____

Describe the method used to calculate the concentrations of analytes for each calibration procedure used by the laboratory:

_____
_____
_____
_____

C-15. Provide a description of the laboratory's procedures for the following:

Certification/Reporting Procedures

- Review of all calibration 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 and certifying scientists).
- Release/reporting of results.
- Verification of information (e.g., CCF and computer resident result).

Note: (1) Insert here.

(2) Do not exceed a total of one page.

C-16. Provide a description of the laboratory'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-17. Provide an example of the laboratory's computer-generated electronic report for each of the following laboratory results:

- Negative
- Negative, Dilute
- Rejected
- Cocaine Metabolite Positive
- 6-AM/Codeine/Morphine Positive
- Hydrocodone/Hydromorphone Positive
- Oxycodone/Oxymorphone Positive
- Amphetamine/Methamphetamine Positive
- d-Methamphetamine (if applicable)
- MDMA/MDA Positive
- Substituted
- Invalid Result
- Specimen Adulterated: pH
- Specimen Adulterated: Others as Pertinent
- Split Specimen: Reconfirmed
- Split Specimen: One or More Primary Specimen Results Not Reconfirmed

C-18. Does the laboratory use an off-site computer information system? YES NO

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

C-19. Provide a description of the laboratory's procedures for the following:

Disposition of Specimens and Aliquots

- Handling of original specimen bottles and aliquots after testing is completed.
- Procedure for transferring positive, adulterated, substituted, and invalid specimens to long-term frozen storage.

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

Complete the C Tables:

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

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

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

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

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

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

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

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

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

Table C-2-d-1. Initial Specimen Validity Test Calibrators and Controls (continued on **Table C-2-d-2** as needed)

Table C-2-d-3. Confirmatory Specimen Validity Test Calibrators and Controls (continued on **Table C-2-d-4** as needed)

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

Table C-3-a. Confirmatory Drug Test Methods

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