OMB No. 0930-0158
Expiration Date: xx/xx/xxxx

ATTACHMENT D

National Laboratory Certification Program

Application Form

National Laboratory Certification Program
RTI International
Attention: Inspection Department
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions and completing the collection of information, is estimated to average 4 hours per response for an initial certification inspection and 3 hours for subsequent inspections. Federal employees may send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to the SAMHSA Reports Clearance Officer, Paperwork Reduction Project (0930-0158), Room 7-1044, One Choke Cherry Road, Rockville, Maryland 20857. 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.

NATIONAL LABORATORY CERTIFICATION PROGRAM
APPLICATION FORM

A. APPLICANT LABORATORY

1. Laboratory Name: _____

   Address: _____

   City, State, ZIP: _____

   Country: _____

   Telephone Number: ☐☐☐–☐☐☐–☐☐☐☐

   FAX Number: ☐☐☐–☐☐☐–☐☐☐☐

2. Is your express delivery address the same as listed above?

   ☐ Yes

   ☐ No→ **ENTER YOUR EXPRESS DELIVERY ADDRESS BELOW**

   Name: _____

   Address: _____

   City, State, ZIP: _____

   Country: _____

3. Designated Responsible Person: _____

   Title/Position: _____

   Telephone Number: ☐☐☐–☐☐☐–☐☐☐☐

4. Laboratory Contact Person: _____
   (If different from designated RP)

   Title/Position: _____

   Telephone Number: ☐☐☐–☐☐☐–☐☐☐☐

B. GENERAL LABORATORY INFORMATION

1. In order to be eligible for certification in this program, your laboratory must perform both initial and confirmatory drug testing at the same location. If this is not the case, your laboratory is **not** eligible to apply for this program.

   1a. Does your laboratory perform initial and confirmatory drug testing at the same location?

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

2. In order to be certified, your laboratory must test for all drugs and specimen validity test analytes required by the Mandatory Guidelines. Your laboratory must use different test methods for the initial and confirmatory tests (i.e., for drugs and adulterants).

   2a. Does your laboratory have validated initial test assays for all five drug classes listed in Table 1?

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

   2b. Does your laboratory use an immunoassay method approved by the FDA for the initial dug tests?

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

   2c. Does your laboratory have validated GC/MS assays for the confirmatory testing of required drug analytes listed in Table 3? *(Note: testing for methamphetamine enantiomers is optional.)*

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

   2d. Does your laboratory 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 → **LABORATORY NOT ELIGIBLE TO APPLY**

   2e. Does your laboratory perform enantiomeric analysis of methamphetamine?

   ☐ Yes → **COMMENT BELOW**
   ☐ No

   Briefly describe the procedure for analysis and reporting of methamphetamine enantiomers.

   _____

   _____

   _____

3. Is your laboratory registered with the U.S. Drug Enforcement Administration (DEA)?

   ☐ Yes → **ATTACH PHOTOCOPY OF REGISTRATION CERTIFICATE**
   ☐ No → **COMMENT BELOW, THEN GO TO QUESTION 7**

   If NO, explain how controlled reference materials are acquired: _____

   _____

   _____

   3a. What is your laboratory's DEA registration number? _____

   3b. What type of registration does your laboratory have (e.g., researcher, practitioner)?

   _____

4. In the boxes below, check each schedule covered by your registration.

   ☐ 1 ☐ 2 ☐ 2N ☐ 3 ☐ 3N ☐ 4 ☐ 4N ☐ 5

5. Describe the State licensure requirements for urine forensic toxicology for the State in which your laboratory is located.

   _____

   _____

   _____

   _____

6. Is your laboratory in compliance?

   ☐ Yes
   ☐ No

7. List your laboratory's licenses and certifications (e.g., CLIA/HCFA, CAP). Attach photocopies of all licenses and certifications.

   _____

   _____

   _____

   _____

Table 1: Initial Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	Cannabinoids	Cocaine Metabolite	Opiates	Phencyclidine
Immunoassay Method					
Kit Manufacturer					
Test Kit Name					
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Cutoff					
Make and Model of Analyzer					
Maximum Batch Size					

Method Abbreviations:

CEDIA - Cloned Enzyme Donor Immunoassay
EIA - Enzyme Immunoassay
FPIA - Fluorescence Polarization Immunoassay
KIMS - Kinetic Interaction of Microparticles in Solution
RIA - Radioimmunoassay

NOTE: Define any abbreviation not listed

Table 2: Secondary Initial Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	Cannabinoids	Cocaine Metabolite	Opiates	Phencyclidine
Immunoassay Method					
Kit Manufacturer					
Test Kit Name					
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Cutoff (ng/ml)					
Make and Model of Analyzer					
Maximum Batch Size					

Method Abbreviations:

CEDIA - Cloned Enzyme Donor Immunoassay
EIA - Enzyme Immunoassay
FPIA - Fluorescence Polarization Immunoassay
KIMS - Kinetic Interaction of Microparticles in Solution
RIA - Radioimmunoassay

NOTE: Define any abbreviation not listed

Table 3: Confirmatory Drug Tests Used by the Laboratory

	Internal Standard	Int. Std. Conc'n (ng/mL)	LOD (ng/mL)	LOQ (ng/mL)	ULOL (ng/mL)	COL (ng/mL)
Amphetamine						
Methamphetamine						
THC Acid						
Benzoylecgonine						
Codeine						
Morphine						
6-Acetylmorphine						
Phencyclidine						
d,l-methamphetamine						

Abbreviations:

Int. Std. - Internal Standard
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity
COL - Carryover Limit

Table 4: Confirmatory Drug Tests Used by the Laboratory

	AMP/MAMP	THCA	BZE	COD/MOR	6-AM	PCP	D,L-MAMP
Volume (mL) Used							
Extraction Method (L/L or SPE)							
Hydrolysis Method (N, Enz, A, B)							
Derivatizing Reagent *							
Concentration of Calibrator(s) (ng/mL)							
Concentration of Controls (ng/mL)**							
Cutoff							

Abbreviations:

L/L - Liquid/Liquid Extraction
SPE - Solid Phase Extraction
N - None
Enz - Enzymatic
A - Acid
B - Base

* For Example: BSTFA, BSA, MSTFA, TFA, PFPA, HFBA, CH3/TMAH, HFIP/PFPA, etc
** Open (O) [and Blind (B) if used]

Table 5: Confirmatory Drug Tests Used by the Laboratory

	AMP	MAMP	THCA	BZE	COD	MOR	6-AM	PCP	D,L-MAMP
Make and Model of GC/MS									
Injection Port Temp (°C)									
Column Initial Temp (°C)									
Interface Temp (°C)									
Isothermal or Temperature Program * (°C)									
Split or Splitless Injection									
Column Type									
Column Length (m)									
Full Scan Mass Range									
Analyte SIM Ions Monitored **									
Int.Std. SIM Ions Monitored **									

* For Example: 100(3)15/230(3) Initial temperature 100 degrees, held for 3 minutes, then ramped at 15 degrees/min to 230 degrees which is held for 3 minutes

** Bold or circle quantitative ion

Table 6: Initial Specimen Validity Tests Used by the Laboratory

	Creatinine	Specific Gravity	pH	Nitrite	Other: ( )	Other: ( )	Other: ( )
Method							
Kit Manufacturer							
Test Kit Name							
Unit of Measurement							
Target Analyte							
Concentration of Calibrator(s)							
Concentration of Controls							
LOD							
LOQ							
ULOL							
COL							

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CLR - Colorimetric

mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption

ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table 7: Confirmatory Specimen Validity Tests Used by the Laboratory

	Creatinine	Specific Gravity	pH	Nitrite	Other: ( )	Other: ( )	Other: ( )
Method							
Kit Manufacturer							
Test Kit Name							
Unit of Measurement							
Target Analyte							
Concentration of Calibrator(s)							
Concentration of Controls							
LOD							
LOQ							
ULOL							
COL							

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CRL - Colorimetric
mREF - Manual Refractometer
DREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption

ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity/Quantitation
COL - Carryover Limit

Table 8: Screening/Differential Specimen Validity Tests Used by the Laboratory

	Other: ( )	Other: ( )	Other: ( )	Other: ( )	Other: ( )
Method					
Kit Manufacturer					
Test Kit Name					
Unit of Measurement					
Target Analyte					
Concentration of Calibrator(s)					
Concentration of Controls					
LOD					
LOQ					
ULOL					
COL					

Method / Characteristic Abbreviations:

NOTE: Define any abbreviation not listed

CLR - Colorimetric
mREF - Manual Refractometer
dREF - Digital Refractometer
PHM - pH Meter
DS - Dipstick
CHRM - Chromatography
AA - Atomic Absorption
ISE - Ion Selective Electrode
CE - Capillary Electrophoresis
LOD - Limit of Detection
LOQ - Limit of Quantitation
ULOL - Upper Limit of Linearity
COL - Carryover Limit

C. STANDARD OPERATING PROCEDURES MANUAL

1. For certification, your laboratory must have a complete drug testing procedures manual that will apply to testing of regulated specimens under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (*Federal Register*, 69 FR 19644, 13 April 2004 effective 1 November 2004).

   Note: manufacturers' package inserts or instrument manuals are not considered formal procedures. A written procedure manual is required in order to be eligible to apply for certification and it must be completed before the laboratory is eligible to receive NLCP PT samples.

1a. Does your laboratory have a written drug testing procedures manual?

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

LABORATORY SOP INDEX

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

TOPIC	***SECTION***	***PAGE NO.***
Accessioning (Specimen receipt)		
Procedure for receipt and processing of specimens	_____	_____
Procedure for accessioning specimens or aliquots received from another laboratory	_____	_____
Procedure for problem/rejected specimens	_____	_____
Chain-of-Custody		
Procedure for documenting all transfers of specimens	_____	_____
Procedure for documenting all transfers of aliquots	_____	_____
Procedure for maintaining security of specimen bottles	_____	_____
Procedure for maintaining security of specimen aliquots	_____	_____
Procedure for sending a specimen or aliquot to another laboratory	_____	_____

TOPIC	SECTION	PAGE NO.

D. CHAIN OF CUSTODY, ACCESSIONING, AND SECURITY

The laboratory must have chain of custody, accessioning, and security procedures to ensure that integrity is maintained for both the original specimens and their aliquots.

The laboratory must have chain of custody forms and procedures to 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 laboratory must ensure the security of specimens and aliquots during processing and placement in any short-term or long-term storage locations.

1. Provide a **TYPED** description of the laboratory'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 laboratory accession numbers
-Handling problems with specimen bottles and/or custody and control forms
-Location of temporary storage area(s)

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, initial specimen validity tests, confirmatory drug tests, and confirmatory specimen validity tests.
-Transfer of aliquots from the individuals performing the aliquotting to those who will be testing the aliquots

Initial Drug Tests (Primary and Secondary)

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

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

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

Confirmatory Drug Tests

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

Disposition of Specimens and Aliquots

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

Note: (1) Do not exceed a total of 4 pages.
(2) Attach pages here.

2. Attach a flowchart and/or examples of chain of custody documents showing how specimens and aliquots are processed and their custody documented (chain of custody documents may be referenced and/or provided as examples for clarification).

3. Are regulated specimens accessioned in a limited access, secure area?

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

4. Are regulated specimens tested in a limited access, secure area?

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

5. Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens 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).

6. During testing, will the original specimens be maintained in a limited access, secured area at all times?

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

   6a. Where will the original specimens be stored? _____

   _____

   _____

   6b. Who will have access to the specimen storage area? _____

   _____

   _____

7. When testing is complete, will all non-negative specimens (A and B Bottles) and retest specimens be retained in long-term frozen storage in their original containers?

   ☐ Yes→ **# of days to be stored:** ☐☐☐
   ☐ No → **LABORATORY NOT ELIGIBLE TO APPLY**

   7a. How will non-negative specimens (A and B Bottles) and retest specimens be stored? _____

   _____

   _____

   _____

   _____

   _____

   _____

E. RECORDS

The laboratory must maintain records to support test results (i.e., including but not limited to all associated QC results, analytical data, chain of custody documents and associated administrative records) for at least two years. The laboratory must also maintain method validation records for past and current procedures, records documenting the standard operating procedures used at any given time period, and records of the education, training, and certification of all employees associated with regulated testing. The laboratory must have security measures in place to limit access to electronic and hardcopy records to essential authorized personnel.

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

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

   1a. Will there be a secured area for the storage of records for reported specimens?

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

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

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

3. Attach two data packages using the format described in the Mandatory Guidelines to support (1) a positive drug test result and (2) a non-negative result based on specimen validity testing.

F. PERSONNEL

Qualifications for a Responsible Person Candidate

1. RP Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RP requirements as stated in the Mandatory Guidelines;

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. To be eligible for review as an RP, at least one of the following questions must be answered "yes":

   2a. Is the candidate certified by the State as a Laboratory Director in forensic toxicology or clinical laboratory toxicology?

   ☐ Yes→ **In which State?** _____
   ☐ No

   2b. Does the candidate have a Ph.D. in one of the natural sciences?

   ☐ Yes→ **In which field?** _____. **GO TO QUESTION 3.**

   ☐ No → **GO TO QUESTION 2C.**

   2c. Does the candidate have training and experience equivalent to a Ph.D. in one of the natural sciences, such as a scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ☐ Yes→ **Describe:** _____

   _____

   ☐ No

3. An RP must have extensive experience in analytical toxicology. To be eligible for review as an RP, both of the following questions must be answered "yes":

   3a. Does the candidate have two years or more of postdoctoral experience or at least six years of experience in analytical toxicology beyond any other degree?

   ☐ Yes→ **Describe:** _____

   ☐ No→ **CANDIDATE NOT ELIGIBLE AS RP**

3b. Does the candidate have appropriate training and/or experience in forensic applications of analytical toxicology (e.g., court testimony, research and publications in analytical toxicology of drugs of abuse)?

☐ Yes →**Describe:** _____

_____

☐ No→ **CANDIDATE NOT ELIGIBLE AS RP**

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 laboratory?

☐ Yes
☐ No

If no, what is the relationship between the candidate and the laboratory?

_____
_____
_____
_____

6. How many hours per week will the candidate work in the Forensic Urine Drug Testing Laboratory?

☐☐
HOURS PER WEEK

7. How long has the candidate been employed by the laboratory?

☐☐
YEARS

Qualifications for an Alternate Responsible Person Candidate

1. Alternate RP Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RP requirements as stated in the Mandatory Guidelines;

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. An alt-RP must be capable of fulfilling RP duties for a limited time (i.e., up to 180 days). An alt-RP candidate's qualifications are compared to RP requirements as follow:

   2a. Is the candidate certified by the State as a Laboratory Director in forensic toxicology or clinical laboratory toxicology?

   ☐ Yes→ **In which State?** _____
   ☐ No

   2b. Does the candidate have a Ph.D. in one of the natural sciences?

   ☐ Yes→ **In which field?** _____. **GO TO QUESTION 3.**

   ☐ No → **GO TO QUESTION 2C.**

   2c. Does the candidate have training and experience equivalent to a Ph.D. in one of the natural sciences, such as a scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ☐ Yes→ **Describe:** _____

   _____

   ☐ No

3. An alt-RP candidate must have appropriate experience in analytical toxicology.

   3a. How many years of experience does the candidate have in analytical forensic toxicology (including experience with the analysis of biological material for drugs of abuse) beyond any degree?

   ☐☐
   YEARS

3b. Does the candidate have appropriate training and/or experience in all operations of the forensic drug testing laboratory (i.e., including training and experience as a non-negative certifying scientist)?

☐ Yes

☐ No→ **CANDIDATE NOT ELIGIBLE AS AN ALT-RP**

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 laboratory?

☐ Yes
☐ No

If no, what is the relationship between the candidate and the laboratory?

_____
_____
_____
_____

6. How many hours per week will the candidate work in the Forensic Urine Drug Testing Laboratory?

☐☐
HOURS PER WEEK

7. How long has the candidate been employed by the laboratory?

☐☐
YEARS

Personnel Certifications and Licenses

1. List the education and certifications/licenses for the following:

   NOTE: ATTACH A RÉSUMÉ FOR EACH INDIVIDUAL LISTED BELOW.

Position	Name	Education	License/Certification
Negative Certifying Scientist(s)			
Non-negative Certifying Scientist(s)			
Supervisor(s)			
Other Key Personnel			

Add pages as needed to list all individuals in the job positions in table above.

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

   ☐ Yes
   ☐ No → **GO TO SECTION G**

3. Are the Responsible Person Candidate, Certifying Scientist(s), and Supervisor(s) properly licensed or certified?

   ☐ Yes
   ☐ No

G. QUALITY CONTROL

For certification, the laboratory must have clearly defined quality control 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 controls, instrument responses, etc., exceed defined tolerance limits?

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

3. Are all QC results reviewed by the Certifying Scientist prior to the release of the results?

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

4. Is the QA/QC program under the direct supervision of a Quality Control Supervisor?

   ☐ Yes
   ☐ No → **COMPLETE 4a**

   4a. What is the title and/or position of the person responsible for the QA/QC program?
   Title/Position: _____

5. Is the QA/QC program reviewed periodically by the Responsible Person Candidate?

   ☐ Yes
   ☐ No → **CANDIDATE NOT ELIGIBLE AS RP**

   5a. What is the title and/or position of the person responsible for the periodic review?
   Title/Position: _____

6. Are there written procedures that are employed to routinely detect clerical and analytical errors prior to reporting results?

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

4. For certification, the laboratory must have a quality control program that includes both blind and open quality control samples. These must, at a minimum, include the number and type of quality control samples described in the Mandatory Guidelines for drug and specimen validity tests.

Provide a **TYPED** description of the laboratory's quality control program for the following:

Specimen Accessioning

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

Initial Drug Tests (Primary and Secondary)

- 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 and QC samples within each batch
- The source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix for each QC sample
- 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

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

- 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 and QC samples within each batch
- The source (e.g., in-house, name of supplier), composition, and matrix for each QC sample
- 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 flow chart that comprehensively describes the laboratory's specimen validity testing. The laboratory's submission must identify any "reflex" testing, the use of two separate aliquots, the initial and confirmatory methods for each analytical parameter, and any screening or differential tests.

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 throughout the day)
- The distribution of the donor specimens and QC samples within each batch
- The source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix for each QC sample
- The procedure and acceptance criteria for calibration, including criteria for exclusion of unsatisfactory calibrators
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented
- The criteria for accepting a donor specimen result, reextracting the specimen, or reinjecting a specimen

Note: (1) Do not exceed a total of 3 pages.
(2) Insert pages here.

H. REVIEW AND REPORTING

The laboratory must have adequate procedures to ensure the thorough review and accurate reporting of results.

1. Briefly describe the procedures for reviewing initial drug test data and certifying negative results (i.e., title/position of reviewers, electronic/hardcopy documents reviewed, QC review). _____

2. Briefly describe the procedures for reviewing initial and confirmatory specimen validity test data/results: _____

3. Briefly describe the procedures for reviewing confirmatory drug test data and certifying non-negative results: _____

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

5. Is the laboratory's CCF identical to the OMB-approved Federal CCF to be used for all specimens submitted for testing under the Mandatory Guidelines?

   ☐ Yes→ **ENCLOSE EXAMPLE OF LABORATORY'S CUSTODY AND CONTROL FORM**

   ☐ No→→ **LABORATORY NOT ELIGIBLE TO APPLY**

6. Will the laboratory use computer-generated electronic reports for specimens submitted for testing under the Mandatory Guidelines?

   ☐ Yes→ **ENCLOSE EXAMPLES OF THE LABORATORY'S REPORTS FOR (1) A NEGATIVE SPECIMEN, (2) A DRUG POSITIVE SPECIMEN, AND (3) A SUBSTITUTED OR ADULTERATED SPECIMEN**

   ☐ No→

I. LABORATORY COMPUTER SYSTEMS

Laboratory computer systems include any computer system used in processing regulated specimens. Such systems are typically used for accessioning specimens, batch assignment and scheduling, capturing test results, tabulating quality control data, and reporting final results.

1. Give a brief description of the computer system to be utilized by the laboratory. Is it a "Stand Alone" system used solely by the laboratory, part of a local system (e.g., a hospital system), or part of a multi-laboratory corporate system? (If not on-site, provide information on its location and organizational control of the system.)

_____

_____

_____

_____

_____

_____

_____

_____

2. Give a brief description of how the laboratory plans to use the computer system in regulated specimen processing: _____

_____

_____

_____

_____

_____

3. Is the laboratory computer system maintained in a secure area?

☐ Yes
☐ No

Attach a floorplan identifying the laboratory computer system location. Include information to describe how the area is secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks).

3. Does the laboratory limit functional access to the laboratory computer system?

☐ Yes
☐ No

I understand that the answers provided in this application will be used to determine the applicant laboratory's potential eligibility for the National Laboratory Certification Program. To the best of my knowledge and belief, the answers recorded herein are true and complete.

Signature Date

Title

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.