# **Urine Laboratory Application Form**

# National Laboratory Certification Program (NLCP)

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

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# NATIONAL LABORATORY CERTIFICATION PROGRAM URINE LABORATORY APPLICATION FORM

# A. Applicant Laboratory 1. Name of Laboratory: Address: City, State, ZIP: Telephone: (\_\_\_\_) \_\_\_ - \_\_\_ FAX: \_\_\_\_ (\_\_\_) \_\_\_ - \_\_\_ e-Mail: \_\_\_\_\_ 2. Express delivery address (if different from above) Address: City, State, ZIP: 3. Designated Responsible Person (RP): Title/Position: Telephone: \_\_\_\_ (\_\_\_\_) \_\_\_\_ - \_\_\_\_ Ext. \_\_\_\_\_ If applicable: Designated Alternate RP (Alt-RP): Title/Position: Telephone: \_\_\_\_ (\_\_\_\_) \_\_\_ - \_\_\_\_ Ext. \_\_\_\_ e-Mail: 4. 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 as of this date.

**NOTE:** Any false, fictitious, or fraudulent statements or information presented in this application form could subject you to prosecution, monetary penalties, or both. See Sec. 18 U.S.C. 1001; 31 U.S.C. 3801-812.

Date

Signature, Designated RP

## **B.** General Laboratory Information

The following table is excerpted from Section 3.4 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010):

Marijuana metabolites 50 ng/mL THCA¹ 15 ng/mL  Cocaine metabolites 150 ng/mL Benzoylecgonine 100 ng/mL  Opiate metabolites  Codeine/Morphine² 2000 ng/mL Codeine 2000 ng/mL  Morphine 2000 ng/mL  6-Acetylmorphine 10 ng/mL 6-Acetylmorphine 10 ng/mL  Phencyclidine 25 ng/mL Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL Amphetamine 250 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDEA® 250 ng/mL  1 Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  2 Morphine is the target analyte for codeine/morphine testing.  3 Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  4 Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  5 To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  5 Methylenedioxymethamphetamine (MDAA).  5 Methylenedioxyamphetamine (MDAA).  5 Methylenedioxyamphetamine (MDAA).  5 Methylenedioxyamphetamine (MDAA).  5 Methylenedioxyamphetamine (MDEA).	Initial Test Analyte	Initial Test Cutoff Concentration	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration		
Opiate metabolites  Codeine/Morphine² 2000 ng/mL  Morphine 2000 ng/mL  6-Acetylmorphine 10 ng/mL  Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL  Morphine 250 ng/mL  Amphetamine 250 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDEA® 250 ng/mL  1 Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  2 Morphine is the target analyte for codeine/morphine testing.  3 Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  3 Either a period positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  5 Methylenedioxymethamphetamine (MDMA).  5 Methylenedioxymethamphetamine (MDMA).	Marijuana metabolites	50 ng/mL		15 ng/mL		
Opiate metabolites  Codeine/Morphine² 2000 ng/mL  Morphine 2000 ng/mL  6-Acetylmorphine 10 ng/mL  Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL  Morphine 250 ng/mL  Amphetamine 250 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDEA® 250 ng/mL  1 Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  2 Morphine is the target analyte for codeine/morphine testing.  3 Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  3 Either a period positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  5 Methylenedioxymethamphetamine (MDMA).  5 Methylenedioxymethamphetamine (MDMA).		4.50 / 1		100 / 1		
Codeine/Morphine 2000 ng/mL	Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL		
Morphine 2000 ng/mL 6-Acetylmorphine 10 ng/mL 6-Acetylmorphine 10 ng/mL  Phencyclidine 25 ng/mL  Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDA¹ 250 ng/mL  MDEA® 250 ng/mL  ¹Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  ² Morphine is the target analyte for codeine/morphine testing. ³ Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff. ⁴Methamphetamine is the target analyte for amphetamine/methamphetamine testing. ⁵To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL. ⁵Methylenedioxymethamphetamine (MDMA).  *Methylenedioxymethamphetamine (MDMA).	Opiate metabolites					
6-Acetylmorphine 10 ng/mL 6-Acetylmorphine 10 ng/mL  Phencyclidine 25 ng/mL Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL Amphetamine 250 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA 250 ng/mL  MDMA 250 ng/mL  MDA 250 ng/mL  MDEA® 250 ng/mL  Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  Morphine is the target analyte for codeine/morphine testing.  Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDMA).  Methylenedioxyamphetamine (MDMA).	Codeine/Morphine <sup>2</sup>	2000 ng/mL	Codeine	2000 ng/mL		
Phencyclidine 25 ng/mL Phencyclidine 25 ng/mL  Amphetamines³  AMP/MAMP⁴ 500 ng/mL Amphetamine 250 ng/mL  Methamphetamine⁵ 250 ng/mL  MDMA⁶ 500 ng/mL MDMA 250 ng/mL  MDMA 250 ng/mL  MDA⁷ 250 ng/mL  MDEAՑ 250 ng/mL  ¹Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  ² Morphine is the target analyte for codeine/morphine testing.  ³ Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  ⁴Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  ⁵To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  ⁵Methylenedioxymethamphetamine (MDMA).  ¹Methylenedioxyamphetamine (MDMA).			Morphine	2000 ng/mL		
Amphetamines³  AMP/MAMP⁴  500 ng/mL  Amphetamine  250 ng/mL  Methamphetamine⁵  250 ng/mL  MDMA  500 ng/mL  MDMA  250 ng/mL  MDA³  250 ng/mL  MDEA³  250 ng/mL  MDEA³  1Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  Morphine is the target analyte for codeine/morphine testing.  Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDA).  Methylenedioxyamphetamine (MDA).	6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL		
AMP/MAMP <sup>4</sup> 500 ng/mL Amphetamine 250 ng/mL  Methamphetamine <sup>5</sup> 250 ng/mL  MDMA <sup>6</sup> 500 ng/mL MDMA 250 ng/mL  MDA <sup>7</sup> 250 ng/mL  MDEA <sup>8</sup> 250 ng/mL  Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  Morphine is the target analyte for codeine/morphine testing.  Bether a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDMA).  Methylenedioxyamphetamine (MDMA).	Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL		
Methamphetamine 5 250 ng/mL  MDMA 500 ng/mL MDMA 250 ng/mL  MDA 250 ng/mL  MDEA 250 ng/mL  MDEA 250 ng/mL  MDEA 250 ng/mL  MDEA 250 ng/mL  Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  Morphine is the target analyte for codeine/morphine testing.  Bether a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDMA).  Methylenedioxyamphetamine (MDMA).	1 .					
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MDA <sup>7</sup> 250 ng/mL  Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).  Morphine is the target analyte for codeine/morphine testing.  Bither a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.  Methamphetamine is the target analyte for amphetamine/methamphetamine testing.  To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDMA).  Methylenedioxyamphetamine (MDA).			Methamphetamine <sup>5</sup>	250 ng/mL		
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concentration equal to or greater than 100 ng/mL.  Methylenedioxymethamphetamine (MDMA).  Methylenedioxyamphetamine (MDA).						
<sup>6</sup> Methylenedioxymethamphetamine (MDMA). <sup>7</sup> Methylenedioxyamphetamine (MDA).						
<sup>7</sup> Methylenedioxyamphetamine (MDA).						
MELTYIENEULONYELTYIATIPHELAHINE (MDLA).						

 To be eligible for certification, the laboratory must test for all drug analytes and specimen validity test measurands required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs (*Federal Register*, 73 FR 71858, 25 November 2008, effective 1 October 2010). The laboratory must use the test methods specified by the Mandatory Guidelines for screening, differential, initial, and confirmatory tests (i.e., drug tests and specimen validity tests).

test	s).	
1a.		e laboratory have validated initial drug test assays for the drug classes required andatory Guidelines?
		Yes No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY

1b.	Does the laboratory use an immunoassay method approved, cleared, or otherwise recognized as accurate and reliable by the U.S. Food and Drug Administration (FDA) for the initial drug tests?	
	Yes No → LABORATORY NOT ELIGIBLE TO APPLY	
1c.	Does the laboratory have validated confirmatory test assays for the drug analytes required by the Mandatory Guidelines? (Note: testing for amphetamine and methamphetamine enantiomers is optional.)	
	Yes No → LABORATORY NOT ELIGIBLE TO APPLY	
1d.	Does the laboratory use methods combining chromatographic separation and mass spectrometric identification [e.g., gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS)] for the confirmatory drug tests?	
	Yes No → LABORATORY NOT ELIGIBLE TO APPLY	
1e.	Does the 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	
1f.	Does the laboratory perform testing for amphetamine and methamphetamine enantiomers?	
	Yes → COMMENT BELOW No	
	Briefly describe the procedure for analysis and reporting of the enantiomers:	
Is th	e laboratory registered with the U.S. Drug Enforcement Agency (DEA)?  Yes → ATTACH PHOTOCOPY OF REGISTRATION CERTIFICATE	
	No → COMMENT BELOW	

2.

	If YES, which schedules are covered by the registration?
	122N33N45
	If NO, explain how controlled reference materials are acquired:
3.	Describe the State licensure requirements for urine forensic toxicology for the State in which the laboratory is located.
4.	List laboratory certifications/licenses:
	States (List):
	CLIA/HCFA <sup>1</sup> (List Specialties):
	CAP <sup>2</sup> (List Specialties):
	Others (Specify):
	<sup>1</sup> Clinical Laboratory Improvement Amendments(CLIA)/Health Care Financing Administration (HCFA) <sup>2</sup> College of American Pathologists (CAP)

4a. ATTACH PHOTOCOPIES OF ALL LICENSES AND CERTIFICATIONS INDICATED

ABOVE.

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# C. Laboratory Standard Operating Procedures (SOP) Manual

1. For certification, the laboratory must have a complete SOP manual that will apply to testing of regulated specimens under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010).

**Note:** Manufacturers' package inserts or instrument manuals are not considered formal procedures. A written SOP manual is required to be eligible to apply for certification and it must be completed before the laboratory is eligible to receive NLCP performance testing (PT) samples.

1a.	Does the	e laboratory have a complete SOP manual for regulated drug testing?
		Yes No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY

#### LABORATORY SOP MANUAL INDEX

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

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Security Procedure for controlling access to the drug testing facility		
Procedure for controlling access to individual secured areas		
Procedure for documenting visitor access		
Accessioning (Specimen receipt) Procedure for receipt and processing of specimens		
Procedure for accessioning specimens 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		

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<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedure for maintaining security of specimen bottles		
Procedure for maintaining security of specimen aliquots		
Procedure for sending a specimen to another laboratory		
Procedures for documenting all transfers of specimens received from another laboratory		
Aliquot Preparation Procedure for preparing initial drug test aliquots		
Procedure for preparing screening/differential specimen validity test aliquots	al 	
Procedure for preparing initial specimen validity test aliquots		
Procedure for preparing confirmatory specimen validity test aliquots		
Procedure for preparing confirmatory drug test aliquots		
Procedures for automated aliquotting equipment		
Initial Drug Test Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		
Procedure for instrument maintenance		
Procedure for assay calibration		

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedure for calculating results		
Quality control (QC) procedure and criteria for acceptable results and corrective actions		
Procedure for validation of initial drug test methods		
References		
Second Initial Drug Test Criteria for use		
Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		
Procedure for instrument maintenance		
Procedure for assay calibration		
Procedure for calculating results		
QC procedure and criteria for acceptable results and corrective actions		
Procedure for validation of second initial drug test methods		
References		

# **TOPIC**

#### **SECTION** PAGE NO.

**Specimen Validity Tests**Note: Provide the following information for each specimen validity test (Initial, Confirmatory, Screening, Differential)

Creatinine Principle of analysis	 
Preparation of reagents, calibrators, and controls	 
Procedure for set-up and normal operation of instruments	 
Procedure for instrument maintenance	 
Procedure for assay calibration	 
Procedures for conducting creatinine tests	 
QC acceptance/rejection criteria and corrective action for creatinine tests	 
Procedure for validation of creatinine test methods	 
Procedure for periodic re-verification of creatinine test methods	 
Special requirements, etc.	 
References	 
Specific Gravity Principle of analysis	 
Preparation of calibrators and and controls	 
Procedure for set-up and normal operation of instruments	 
Procedure for instrument maintenance	 

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

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedure for designating reconfirmed results for split specimens as adulterated based on pH		
Procedure for validation of pH test methods		
Special requirements, etc.		
References		
Oxidants Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		
Procedure for instrument maintenance		
Procedure for assay calibration		
Procedures for conducting oxidant tests		
QC acceptance/rejection criteria and corrective action for oxidant tests		
Criteria for identifying acceptable, invalid, and adulterated specimens based on oxidant test results		
Procedure for designating reconfirmed results for split specimens as adulterated with a specific oxidant		
Procedure for validation of oxidant test methods		
Procedure for periodic re-verification of oxidant test methods		
Special requirements, etc.		
References		

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<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Other Adulterants  Adulterant:		
Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		
Procedure for instrument maintenance		
Procedure for assay calibration		
Procedures for conducting the test		
QC acceptance/rejection criteria and corrective action for the test		
Criteria for identifying acceptable, invalid, and adulterated specimens based on the adulterant test results		
Procedure for designating reconfirmed results for split specimens as adulterated		
Procedure for validation of the test methods		
Procedure for periodic re-verification of the test methods		
Special requirements, etc.		
References		
Confirmatory Drug Tests Principle of each analysis THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine		

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Preparation of reagents, calibrators, and THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers	controls	
Extraction procedures THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Procedure for instrument maintenance		
Procedure for tuning instruments		
Procedure for instrument set-up and ope THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers	eration	
Procedure for assay calibration THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine		

<u>TOPIC</u>	SECTION	PAGE NO.
Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Procedure for calculating results THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Procedure when results exceed linearity THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Procedure for designating positive results THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Procedure for designating reconfirmed result THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers	ults for split sp	pecimens

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
QC procedure and QC acceptance criteria THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
Special requirements, etc. THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers		
References THCA Benzoylecgonine Codeine/Morphine 6-Acetylmorphine Phencyclidine Amphetamine/Methamphetamine MDMA/MDA/MDEA Amphetamines enantiomers  Procedure for validation of confirmatory		
drug test methods  Procedure for periodic re-verification of confirmatory drug test methods <b>QC Materials and Reagents</b> Procedures for preparing stock standards, etc.  Procedures for preparing and verifying		
calibrators		

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedures for preparing and verifying controls		
Corrective procedure when QC verification results are out of control limits		
Procedures for preparing and verifying reagents		
Corrective procedure when reagent verification results are unacceptable		
Quality Assurance (QA) Procedures Procedures for monitoring control results		
Corrective procedure when QA review of control results shows problems or potential problems (e.g., trends, shifts, bias)		
Equipment and Maintenance Wash procedure for labware		
Procedure for determining accuracy and precision of pipetting devices		
Procedures for temperature-dependent equipment		
Procedures for centrifuges		
Procedures for analytical balances		
Safety procedures		
Administrative/Reporting Procedures Procedure for reviewing/certifying the test result(s) of a primary specimen		
Procedure for reporting the test result(s) of a primary specimen		
Procedure for reviewing/certifying the test result(s) of a split specimen		

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedure for reporting the test result(s) of a split specimen		
Procedure to detect and correct clerical errors		
Procedure for electronic reporting of results		
Procedure for preparing statistical summary reports		
Procedure for updating the SOP Manual		
Procedure for preparation of data packages		
Procedure for preparation of the Non-Negative Specimen List (NNSL)		
Laboratory Computer System Procedures Computer and Laboratory Information Management System (LIMS) security procedures		
Computer and LIMS maintenance procedures		
Procedure for computer and software validation		
Procedure for requesting, verifying, and implementing software and configuration changes		
Procedure for LIMS records archiving and retrieval		
Procedures for system monitoring, incident response, and disaster recovery		
Procedure for obtaining audit trail reports		

## D. Chain of Custody, Accessioning, and Security

The laboratory must have chain of custody, accessioning, and security procedures that ensure integrity is maintained for the original specimens and their aliquots. Procedures must address specimens received from collectors, Instrumented Initial Test Facilities (IITFs), and other laboratories. The chain of custody forms and procedures must account for all individuals who handle the specimens and aliquots. The chain of custody forms and procedures should provide a clear picture of the handling/transfers of specimens and aliquots from initial receipt to final disposition. The laboratory must ensure the security of specimens and aliquots during processing and placement in any storage locations.

1. Provide a 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 and resolution of 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, screening/differential specimen validity 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 (First and Second Tests)

- -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 positive, adulterated, substituted, and invalid specimens to long-term frozen storage

Note: (1)Insert here.

(2) Do not exceed a total of 4 pages.

	Will regulated specimens be accessioned in a limited access, secure area?  Yes No → LABORATORY NOT ELIGIBLE TO APPLY  Will regulated specimens be tested in a limited access, secure area?  Yes No → LABORATORY NOT ELIGIBLE TO APPLY  Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks; location of secured storage
4. \	No → LABORATORY NOT ELIGIBLE TO APPLY  Will regulated specimens be tested in a limited access, secure area?  Yes No → LABORATORY NOT ELIGIBLE TO APPLY  Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security
4. \	Yes No → LABORATORY NOT ELIGIBLE TO APPLY  Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security
	No → LABORATORY NOT ELIGIBLE TO APPLY  Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security
	of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security
( ( (	areas such as refrigerators or freezers and how they are secured).
6. \	Will the original specimens be maintained in a limited access, secured area at all times?
	Yes
	No → LABORATORY NOT ELIGIBLE TO APPLY
6	Sa. Where will the original specimens be stored?
	Before testing?
	During testing?
	After testing is complete?
6	6b. Who will have access to the specimen storage areas?
	Before testing?
	During testing?
	After testing is complete?
á	When testing is complete, will all positive, adulterated, substituted, and invalid specimens (A and B Bottles) and split specimens be retained in long-term frozen storage in their original containers?
	Yes → <b># of days to be stored</b> :
	No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY
7	7a. How will specimens (A and B Bottles) and split 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, instrument validation records, records documenting the standard operating procedures used at any given time period, and records of the education, training, and certification of all employees associated with regulated testing. The 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 supporting specimen test results?
	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 Section R of the NLCP Manual for Urine Laboratories to support (1) a positive drug test result and (2) an adulterated, substituted, or invalid 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 fo	llowing for revie	w of his/her eligibility:	
	(a) A detailed description of the ex requirements as stated in the N	perience and q	ualifications specifically	addressing the RF
	(b) A current résumé or curriculum	vitae; and	, ,,	
	(c) Official copies with raised seal	of all academic	undergraduate and gra	duate transcripts.
2.	<ol><li>To be eligible for review as an RP, "yes":</li></ol>	at least one of	the following questions	must be answered
	2a. Is the candidate certified/licens other State requiring personne laboratory toxicology?			
	Yes → In which Sta	nte(s)?		
	2b. Does the candidate have a Ph.	.D. in one of the	natural sciences?	
	$\underline{\hspace{1cm}}$ Yes $ o$ In which fiel			
	No $\rightarrow$ GO TO QUE	STION 2C.		
	2c. Does the candidate have traini natural sciences, such as a me laboratory/research experience	edical or scientif	ic degree with additiona	l training and
	No			
3.	<ol> <li>An RP must have extensive experi collection and analysis of biologica as an RP, both of the following que</li> </ol>	ıl specimens foi	drugs of abuse. To be	sis on the eligible for review
	3a. Does the candidate have two y years of experience in forensic			e or at least six
	Yes→ Describe: _			
	No → CANDIDATE	NOT ELIGIRI	E AS RP	

toxicology (e	.g., publications, court te	experience in forensic ap stimony, conducting rese rt witness in forensic toxic	arch on the toxicology of
•	, , ,	it withess in foreitsic toxic	
No	D → CANDIDATE NOT	ELIGIBLE AS RP	
4. In the table below	w, enter the candidate's e	education.	
Education	Name of School	Major and Minor Fields of Study	Diploma, Certificate or Degree Received
College or University			
Other Schools Attended			
Fu	a full-time or part-time er Ill-time (at least 40 hours art-time hou		?
If not a full- or pa laboratory?	art-time employee, what i	s the relationship betwee	n the candidate and the
6. How many hours laboratory?	s per week will the candid	date work in the forensic ι	urine drug testing
	HC	OURS PER WEEK	
7. How long has the	e candidate been associa	ated with the laboratory?	
		YEARS	

1.	Alt-RP Candidate's Name:	•		
		LAST	FIRST	MIDDLE
	The candidate must provide the	following for reviev	v of his/her eligibility:	
	(a) A detailed description of the requirements as stated in the			addressing the RP
	(b) A current résumé or curriculu	um vitae; and		
	(c) Official copies with raised se	al of all academic	undergraduate and gra	duate transcripts.
2.	An alt-RP must be capable of ful alt-RP candidate's qualifications			
	2a. Is the candidate certified/lice other State requiring personr laboratory toxicology?			
	Yes → In which S	State(s)?		
	No			
	2b. Does the candidate have a F	h.D. in one of the	natural sciences?	
		ield? JESTION 3.		
	No $ ightarrow$ GO TO QU	JESTION 2C.		
	2c. Does the candidate have trainatural sciences, such as a relaboratory/research experien	medical or scientific	c degree with additiona	I training and
	Yes→ <b>Describe</b> :			
	No			
3.	An alt-RP candidate must have a	appropriate experie	ence in forensic toxicol	ogy.
	3a. How many years of experien experience with the collection beyond any degree?			
		YEA	\RS	
	3b. Does the candidate have appropriate forensic drug testing laborate scientist)?			
	Yes			
	No -> CANDIDATE	NOT ELIGIBLE	AS AN ALT-RP	

**Qualifications for an Alternate Responsible Person Candidate** 

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?
	Full-time (at least 40 hours per week) Part-time hours per week
	If not a full- or part-time employee, what is the relationship between the candidate and the 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 associated with the laboratory?
	YEARS

## **Personnel Certifications and Licenses**

2.

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

Note: (1) Attach a résumé for each individual listed below.

(2) Attach a separate sheet as needed to list all individuals in these positions.

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

Is licensure and/or certification required for any of the above positions in the State in which the laboratory is located?										
	Yes No $\rightarrow$ GO TO SECTION	G								
If YES, de	scribe requirements:									

# **G.** Quality Control

For certification, the laboratory must have clearly defined QC procedures that are consistently applied, subject to review, and prompt appropriate corrective action upon failure to meet established acceptance criteria.

1.	Are instrument function checks reviewed prior to batch analysis?
	Yes→ <b>COMPLETE 1a</b> 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., fail defined acceptance criteria?
	Yes
	No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY
3.	Are all QC results reviewed by the Certifying Technician/Scientist prior to the release of the results?
	Yes
	No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY
4.	Is the QA/QC program under the direct supervision of a Quality Control Supervisor?
	Yes No → <b>COMPLETE 4a</b>
	4a. What is the title/position of the person responsible for the QA/QC program?
	Title/Position:
5.	Is the QA/QC program reviewed periodically by the Responsible Person Candidate?
	Yes No → CANDIDATE NOT ELIGIBLE AS RP
	5a. What is the title/position of the person responsible for the periodic review?
	Title/Position:
6.	Are there written procedures that are employed to routinely detect clerical and analytical errors prior to reporting results?
	Yes
	No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY
7.	For certification, the laboratory must have a QC program that includes both blind and open

described in the Mandatory Guidelines for drug and specimen validity tests.

QC samples. At a minimum, these must include the number and type of QC samples

Provide a description of the laboratory's procedures for the following:

## **Specimen Accessioning**

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

#### Initial Drug Tests (First and Second)

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

#### 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 procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented
- The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented
- The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch
- Include an outline or a legible flowchart that comprehensively describes the 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 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, re-extracting, or reinjecting a specimen

Note: (1) Insert here.

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

# 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 specimen validity test data/results (i.e., screening, differential, initial and confirmatory tests):								
3.	Briefly describe the procedures for reviewing confirmatory drug test data and certifying results (i.e., title/position of reviewers, electronic/hardcopy documents reviewed, QC review):								
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 custody and control form (CCF) identical to the OMB-approved Federal CCF to be used for all specimens submitted for testing under the Mandatory Guidelines?
	<ul> <li>Yes→ ATTACH EXAMPLE OF LABORATORY'S CUSTODY AND CONTROL FORM</li> <li>No→LABORATORY NOT ELIGIBLE TO APPLY</li> </ul>
6.	Does the laboratory's report form for split specimens contain all required elements as described in Section U of the NLCP Manual for Urine Laboratories?
	Yes→ ATTACH EXAMPLE OF LABORATORY'S SPLIT SPECIMEN REPORT FORM No
7.	Will the laboratory use computer-generated electronic reports for specimens submitted for testing under the Mandatory Guidelines?  Yes → ATTACH EXAMPLE REPORTS (SEE BELOW)  No
	If YES, attach an example of the laboratory's computer-generated electronic report for each of the following laboratory results:
	<ul> <li>Negative</li> <li>Negative, Dilute</li> <li>Rejected</li> <li>Cocaine Metabolite Positive</li> <li>6-AM/Morphine/Codeine Positive</li> <li>Amphetamine/Methamphetamine Positive</li> <li>d-Methamphetamine (if applicable)</li> <li>MDMA/MDA/MDEA Positive</li> </ul>

- Substituted
- Invalid Result
- Specimen Adulterated: pH
- Specimen Adulterated: Others as Pertinent
- Split Specimen: Reconfirmed
- Split Specimen: One or More Primary Specimen Results Not Reconfirmed

## 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 QC data, and reporting final results. HHS-certified laboratories are prohibited from transmitting data to an IITF through a computer interface. Any computer interface communicating any form of data from an HHS-certified IITF to a laboratory must be approved by the NLCP prior to implementation. The applicant IITF and/or laboratories must submit a detailed plan to the NLCP for review.

1.	Give a brief description of the computer system to be utilized by the 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).						
4.	Does the laboratory limit functional access to the laboratory computer system?						
	Yes No						

# Complete the NLCP Application Tables

Table 1-a.	First and Second Initial Drug Test Methods and Instruments
Table 1-b.	First Initial Drug Test QC Samples
Table 1-c.	Second Initial Drug Test QC Samples
Table 2-a-1.	Initial Specimen Validity Test Methods and Instruments (continued on <b>Table 2-a-2</b> as needed)
Table 2-b-1.	Confirmatory Specimen Validity Test Methods and Instruments (continued on <b>Table 2-b-2</b> as needed)
Table 2-c-1.	Screening/Differential Specimen Validity Test Methods and Instruments (continued on <b>Table 2-c-2</b> as needed)
Table 2-d-1.	Initial Specimen Validity Test QC Samples (continued on <b>Table 2-d-2</b> as needed)
Table 2-d-3.	Confirmatory Specimen Validity Test QC Samples (continued on <b>Table 2-d-4</b> as needed)
Table 2-d-5.	Screening/Differential Specimen Validity Test QC Samples
Table 3-a.	Primary and Alternate Confirmatory Drug Test Methods
Table 3-b-1.	Primary Confirmatory Drug Test Methods and Instruments – Gas Chromatography (GC)
Table 3-b-2.	Alternate Confirmatory Drug Test Methods and Instruments – GC
Table 3-b-3.	Primary Confirmatory Drug Test Methods and Instruments – Liquid Chromatography (LC)
Table 3-b-4.	Alternate Confirmatory Drug Test Methods and Instruments – LC
Table 3-c-1.	Primary Confirmatory Drug Test Methods and Instruments – Mass Spectrometry (MS)
Table 3-c-2.	Alternate Confirmatory Drug Test Methods and Instruments –MS
Table 3-c-3.	Primary Confirmatory Drug Test Methods and Instruments – Tandem Mass Spectrometry
Table 3-c-4.	Alternate Confirmatory Drug Test Methods and Instruments – Tandem Mass Spectrometry
Table 3-d-1.	Primary Confirmatory Drug Test QC Samples
Table 3-d-2.	Alternate Confirmatory Drug Test QC Samples

# Table 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											
*If "Other" is	s selected, pleas	e specify:			•	•					
		Second I	nitial Drug Tes	t 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	s selected, pleas		O AM O contidendantino		MDMA and the large discoun						

THCA = Δ9-tetrahydrocannabinol-9-carboxylic acid BZE = benzoylecgonine

MOR = morphine PCP = phencyclidine 6-AM = 6-acetylmorphine MAMP = methamphetamine MDMA = methylenedioxymethamphetamine

# First Initial Drug Test QC Samples

1st initi		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
	Conc.										
THCA	Matrix										
	Source										
BZE	Conc. Matrix										
DZL	Source										
	Conc.										
MOR	Matrix										
	Source										
	Conc.										
6-AM	Matrix										
	Source										
PCP	Conc.										
PCP	Matrix Source										
	Conc.										
MAMP	Matrix										
	Source										
	Conc.										
MDMA	Matrix										
	Source										
*If "	Other" is	s selected, plea	ase specify:								

BQC = blind quality control sample

# Second Initial Drug Test QC Samples

2nd initiatest QC		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										
	Conc.										
MOR	Matrix										
	Source										
	Conc.										
6-AM	Matrix										
	Source										
202	Conc.										
PCP	Matrix										
	Source Conc.										
MAMP	Matrix										
	Source										
	Conc.										
MDMA	Matrix										
	Source										
*If "(	Other" is	s selected, plea	ase specify:			_			_		

# Table 2-a-1

# Initial Specimen Validity Test Methods and Instruments

Initial SVT	Creatinine	SG	рН	Nitrite	Gen.Oxid.	Other:	Other:
IIIIIIai SV I	Creatifile	30	ргі	Millite	Gen.Oxid.		
Method		4 dec. place refractometer					
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" i	s selected, please	specify:					

SG = specific gravity
Gen. Oxid. = general oxidant

LOD = limit of detection

LOQ = limit of quantitation

ULOL= upper limit of linearity

# 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:					

### Confirmatory Specimen Validity Test Methods and Instruments

Confirmatory SVT	Creatinine	SG	рН	Nitrite	Other:	Other:	Other:
Method		4 dec. place refractometer					
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 s	elected, please	e specify:					

### Table 2-b-2

### Confirmatory Specimen Validity Test Methods and Instruments

Confirmatory SVT	Other:	Other:	Other:	Other:	Other:	Other:
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 s	selected, pleas	e specify:				

### Table 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	ed, please specify:				

## Table 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										
*	f "Other" is s	selected, please	specify:								

### Initial Specimen Validity Test QC Samples

Initial SVT C		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
Other (enter name):	Target Value									
outer (enter name).	Matrix									
	Source									
Other (enter name):	Target Value									
	Matrix									
	Source Target Value									
Other (enter name):	Matrix									
	Source									
	Target Value									
Other (enter name):	Matrix									
	Source									
Other (enter name):	Target Value									
Other (enter name):	Matrix									
	Source									
Other (enter name):	Target Value									
	Matrix									
	Source									
Other (enter name):	Target Value									
	Matrix									
	Source									
Other (enter name):	Target Value Matrix									
	Source									
		ease specify:								
ii Other is	selected, pr	ease specify.								

# Confirmatory Specimen Validity Test QC Samples

Confirma	atory SVT	Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
	Target Value									
Creatinine	Matrix									
	Source									
	Target Value									
SG	Matrix									
	Source									
	Target Value									
	Matrix									
	Source									
	Target Value									
Nitrite	Matrix									
	Source									
	Target Value									
Gen Oxid	Matrix									
	Source									
*If	"Other" is	selected, please	specify:			_			_	`

# Confirmatory Specimen Validity Test QC Samples

Confirmatory SV		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
	Target Value Matrix									
Other (enter nema).	Source Target Value Matrix									
	Source Target Value									
	Matrix Source									
	Target Value Matrix									
Other (enter name):	Source Target Value Matrix									
	Source Target Value									
	Matrix Source									
	Target Value Matrix									
Other (enter name):	Source Target Value Matrix									
	Source	se specify:								

### Screening/Differential Specimen Validity Test QC Samples

Screening/Differ QC	rential SVT	Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
	Target Value									
Specific Gravity	Matrix									
	Source									
	Target Value									
рН	Matrix									
	Source									
Other (enter name):	Target Value									
outer (ortion right).	Matrix									
	Source									
Other (enter name):	Target Value									
outer (ortion right).	Matrix									
	Source									
Other (enter name):	Target Value									
outor (ortion riamo).	Matrix									
	Source									
Other (enter name):	Target Value									
outor (ortion riamo).	Matrix									
	Source									
Other (enter name):	Target Value									
outor (ortion riamo).	Matrix									
	Source									
Other (enter name):	Target Value			·						
	Matrix									
	Source									
*If "Other" is	selected, ple	ase specify:	·	·	·	·		·		

			Prim	ary Confir	matory Dr	ug Test M	lethods				
Primary Confirmatory Drug Test	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Method											
Internal Standard											
Int. Std. Isotope											
Type and Number											
Int. Std. Conc.*											
LOD*											
LOQ*											
ULOL*											
Carryover Limit*											
Maximum Batch											
Size		.,									
*If "Other" is sele	cted, pleas	e specify:									
			Alter	nate Conf	irmatory D	rug Test I	Methods				
Alternate											
Confirmatory Drug Test	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Method											
Internal Standard											
Internal Standard Int. Std. Isotope											
Int. Std. Isotope											
Int. Std. Isotope Type and Number											
Int. Std. Isotope Type and Number Int. Std. Conc.* LOD* LOQ*											
Int. Std. Isotope Type and Number Int. Std. Conc.* LOD* LOQ* ULOL*											
Int. Std. Isotope Type and Number Int. Std. Conc.* LOD* LOQ* ULOL* Carryover Limit*											
Int. Std. Isotope Type and Number Int. Std. Conc.* LOD* LOQ* ULOL* Carryover Limit* Maximum Batch											
Int. Std. Isotope Type and Number Int. Std. Conc.* LOD* LOQ* ULOL* Carryover Limit*											

<sup>\*</sup> ng/mL

 $\begin{tabular}{ll} COD = code ine & MDA = methylenedioxyamphetamine \\ AMP = amphetamine & MDEA = methylenedioxyethylamphetamine \\ \end{tabular}$ 

### Primary Confirmatory Drug Test Methods and Instruments - Gas Chromatography

	Primary Confirmatory Drug Test Methods and Instruments - Gas Chromatography										
Primary Confirmatory Drug Test - Gas Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMPHETAMINE	S (select analytes from dr	ropdown lists below)			
Extraction Method											
Volume Used (mL)											
Hydrolysis Method											
Derivatizing Reagent											
Split/Splitless Injection											
Inj. Port Temp (°C)											
Isothermal or Gradient											
Column Type											
Column Length (m)											
Instrument Manufacturer											
Number of Units											
			GC/GC Method	s: provide additior	al information bel	OW					
Cryotrapping (Y/N)											
2nd GC Column Type											
2nd GC Column Length											
(m)											
*If "Other" is s	*If "Other" is selected, please specify										

#### Table 3-b-2

### Alternate Confirmatory Drug Test Methods and Instruments - Gas Chromatography

	Alternate Confirmatory Drug Test Methods and Instruments - Gas Chromatography										
Primary Confirmatory Drug	THCA	BZE	COD/MOR	6-AM	PCP	AMPHETAMINE	S (select analytes from dr	opdown lists below)			
Test - Gas Chromatography	1110/1	DZL	CODIMOR	0 7 tivi	1 01						
Extraction Method											
Volume Used (mL)											
Hydrolysis Method											
Derivatizing Reagent											
Split/Splitless Injection											
Inj. Port Temp (°C)											
Isothermal or Gradient											
Column Type											
Column Length (m)											
Instrument Manufacturer											
Number of Units											
			GC/GC Method	s: provide addition	al information belo	)W					
Cryotrapping (Y/N)											
2nd GC Column Type											
2nd GC Column Length											
(m)											
*If "Other" is se	elected, please	specify			·	<u> </u>		_			

Table 3-b-3
Primary Confirmatory Drug Test Methods and Instruments - Liquid Chromatography

Primary Confirmatory Drug Test Methods and Instruments - Liquid Chromatography												
Primary Confirmatory Drug Test - Liquid Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMP/MAMP	MDMA/MDA/ MDEA					
Extraction Method												
Volume Used (mL)												
Hydrolysis Method												
Injection Volume												
Isocratic or Gradient												
Guard Column (Y/N)												
Flow Rate (mL/min)												
Temperature (°C)												
Column Type												
Column Length (cm)												
Column Diameter												
Column Particle Size												
A Solvent (Buffer)												
Buffer Type												
Molarity												
P. Salvant (Organia)												
B Solvent (Organic) Component 1												
Component 2												
Component 3												
Component Ratio (1:2:3)												
Instrument Manufacturer												
Number of Units												
*If "Other" is selected, ple	ease specify											

Table 3-b-4
Alternate Confirmatory Drug Test Methods and Instruments - Liquid Chromatography

Alterna	Alternate Confirmatory Drug Test Methods and Instruments - Liquid Chromatography													
Alternate Confirmatory Drug Test - Liquid Chromatography	THCA	BZE	COD/MOR	6-AM	PCP	AMP/MAMP	MDMA/MDA/ MDEA							
Extraction Method														
Volume Used (mL)														
Hydrolysis Method														
Injection Volume														
Isocratic or Gradient														
Guard Column (Y/N)														
Flow Rate (mL/min)														
Temperature (°C)														
Column Type														
Column Length (cm)														
Column Diameter														
Column Particle Size														
A Solvent (Buffer)														
Buffer Type														
Molarity														
pH														
B Solvent (Organic)														
Component 1 Component 2														
Component 3														
Component Ratio (1:2:3)														
Instrument Manufacturer														
Number of Units														
*If "Other" is selected, ple	ease specify					•								

	Primary Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)														
Primary Confirmatory Drug Test - Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA				
Instrument Manufacturer															
Number of Units															
Inlet System															
Ionization															
Ion Focus															
Full Scan Mass Range															
Calibration Type															
Analyte Quantifier Ion															
Analyte Qualifier Ion 1*															
Analyte Qualifier Ion 2*															
Analyte Qualifier Ion 3															
Int. Std. Quantifier Ion															
Int. Std. Qualifier Ion 1*															
Int. Std. Qualifier Ion 2															
*If "Other" is sele	ected, please	e specify													

<sup>\*</sup>Minimum required

	Alternate Confirmatory Drug Test Methods and Instruments - Mass Spectrometry (MS)													
Alternate Confirmatory Drug Test - Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA			
Instrument Manufacturer														
Number of Units														
Inlet System														
Ionization														
Ion Focus														
Full Scan Mass Range														
Calibration Type														
Analyte Quantifier Ion														
Analyte Qualifier Ion 1*														
Analyte Qualifier Ion 2*														
Analyte Qualifier Ion 3														
Int. Std. Quantifier Ion														
Int. Std. Qualifier Ion 1*														
Int. Std. Qualifier ion 2														
*If "Other" is se	elected, please	specify												

<sup>\*</sup>Minimum required

#### Primary Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry

	Р	rimary Conf	irmatory Dru	ug Test Meth	nods and Ins	struments -	Tandem Ma	ss Spectron	netry		
Primary Confirmatory Drug Test - Tandem Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA
Instrument Manufacturer											
Number of Units Ionization											
Configuration											
Calibration Type											
Quantifier Transition*	$\rightarrow$	<b>→</b>	$\rightarrow$	<b>→</b>	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	<b>→</b>	$\rightarrow$
Qualifier Transition 1*	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$
Qualifier Transition 2	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$
Qualifier Transition 3	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$
Int. Std. Quantifier Transition*	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>
Int. Std. Qualifier Transition 1*	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>
Int. Std. Qualifier Transition 2	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>
Int. Std. Qualifier Transition 3	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>
*If "Other" is sele	cted, please s	specify									

<sup>\*</sup>Minimum required

#### Alternate Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry

	Alternate Confirmatory Drug Test Methods and Instruments - Tandem Mass Spectrometry													
Alternate Confirmatory Drug Test - Tandem Mass Spectrometry	THCA	BZE	COD	MOR	6-AM	PCP	AMP	MAMP	MDMA	MDA	MDEA			
Instrument Manufacturer														
Number of Units Ionization														
Configuration														
Calibration Type														
Quantifier Transition*	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$			
Qualifier Transition 1*	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$			
Qualifier Transition 2	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$			
Qualifier Transition 3	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$	$\rightarrow$			
Int. Std. Quantifier Transition*	÷	<b>→</b>	÷	<b>→</b>	<b>→</b>	$\rightarrow$	<b>→</b>	$\rightarrow$	<b>→</b>	<b>→</b>	<b>→</b>			
Int. Std. Qualifier Transition 1*	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>			
Int. Std. Qualifier Transition 2	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>			
Int. Std. Qualifier Transition 3	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>	<b>→</b>			
*If "Other" is sele	cted, please s	specify												

<sup>\*</sup>Minimum required

### Primary Confirmatory Drug Test QC Samples

Primary Confi	rmatory Drug Test QC	Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	Control 5
	Concentration									
THCA	Matrix									
	Source									
	Concentration									
BZE	Matrix									
	Source									
	Concentration									
COD	Matrix									
	Source									
	Concentration									
MOR	Matrix									
	Source									
6-AM	Concentration									
	Matrix									
	Source									
	Concentration									
PCP	Matrix									
	Source									
	Concentration									
AMP	Matrix									
	Source									
	Concentration									
MAMP	Matrix									
	Source									
	Concentration									
MDMA	Matrix									
	Source									
	Concentration									
MDA	Matrix									
	Source									
	Concentration									
MDEA	Matrix									
	Source									
*If "Othe	r" is selected, plea	se specify					•			

# Alternate Confirmatory Drug Test QC Samples

Alternate Confirr	matory Drug Test QC	Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
	Concentration										
THCA	Matrix										
	Source										
	Concentration										
BZE	Matrix										
	Source										
	Concentration Matrix										
COD	Matrix										
	Source										
	Concentration										
MOR	Matrix										
	Source										
6-AM	Concentration										
	Matrix										
	Source										
	Concentration										
PCP	Matrix										
	Source										
	Concentration										
AMP	Matrix										
	Source										
	Concentration										
MAMP	Matrix										
	Source										
	Concentration										
MDMA	Matrix										
	Source										
	Concentration										
MDA	Matrix										
	Source										
	Concentration										
MDEA	Matrix										
	Source										
*If "Othe	r" is selected, please	specify		-			-	-	-		