Specimen Collection, Labeling, Shipping, and Result Reporting

Steps in the Toxicology Testing Process



Specimen Collection & Submission

PROCESS

- Collection
 - Room preparation
 - Materials
 - Donor Information
 - Test Requisition Form Completion
 - Labeling

- Submission
 - Packaging
 - Shipment by FedEx or USPS

Specimen Collection

Specimen Collection

ROOM PREPARATION

MINIMIZE ACCESS TO ADULTERANTS

- A designated single-toilet room with a full-length privacy door is preferable.
- Before the donor enters the collection area, inspect it for substitute urine, adulterants, or any other substances that may be used to alter the specimen.
- Remove or secure soap, disinfectants, cleaning supplies, or other potential adulterants.
- Secure water sources by turning off the valve to the faucet or using tamper-evident tape on the faucet's handles.
- Tape or secure the toilet tank or place a bluing agent in the toilet and its tank.
- Ensure undetected access to the restroom is not possible.



Specimen Collection

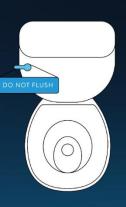
MATERIALS

- Collection Containers Urine containers should have temperature strips.
- Shipping Supplies If using Federal Express to ship specimens from your location to the lab, you will need FedEx clinical paks and FedEx pre-printed air bills.
- Test Requisition Form Must contain specimen seal(s) with bar-coded ID numbers that match IDs on the form.

Specimen Collection

OBSERVED COLLECTION PROCESS

- After the donor's belongings are secured, the collector (not the donor) should complete the top part of the test requisition form. The following procedures should be followed for observed collections:
 - Explain the collection process to the client (donor). Both the collector and donor must keep the specimen in their sight until the collection has been completed.
 - Instruct the donor to wash their hands to remove any potential adulterants from the skin or under the fingernails; they should remain in your presence during this time.
 - Supply the donor with a sealed specimen collection bottle and instruct them to provide at least 30 mL of urine.
 - Instruct the donor that they may not flush the urinal or toilet, wash their hands, or use any other water supply until the collection is completed
 - The collector should personally observe donors void into specimen containers.
 - Collectors must be of the same sex as the donor providing the urine specimen.



Specimen Collection

UNOBSERVED COLLECTION PROCESS

- In some cases, circumstances may prevent the observed collection of a specimen. The following unobserved urine collection procedures should be followed:
 - Only the donor should be present in the room, unless the specimen is being taken using Observed Collection procedures.
 - If a single-toilet restroom is not available, you may use a multi-stall facility that provides substantial visual privacy for each toilet. Allow the donor to provide the specimen in a stall. The collector may wait outside of the multi-stall room, or you may wish to have a monitor of the same gender be present in the non-stall portion of the restroom.
 - If you use a public restroom, no other individuals should be allowed into the restroom during the collection process.
 - Collector may indicate whether the collection was observed in Section 4 of the Non-Clinical Test Requisition Form.



Specimen Collection

TEMPERATURE

- Within the first four minutes after the specimen has been provided, inspect the specimen's temperature, volume, and color. Using the temperature strip on the side of the collection container, measure the temperature—it should be within 90°F and 100°F.
- If the temperature is acceptable, complete the collection and seal the specimen using the security seals from the test requisition form and place the sealed specimen in the specimen baggie. Once the collection has been completed allow the donor to wash their hands.
- If the temperature is outside the acceptable range, you may collect a second specimen or follow your internal collection procedure.

Specimen Collection

Specimen Collection

MATERIALS

- Oral Fluid Collection Kit
- Timer/Watch
- Shipping Supplies If using Federal Express to ship specimens from your location to the lab, you will need FedEx clinical packs and FedEx pre-printed air bills.
- Test Requisition Form Must contain specimen seal(s) with bar-coded ID numbers that match IDs on the form

Specimen Collection

COLLECTION PROCESS

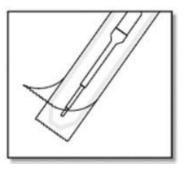
- Ensure donor has refrained from eating, drinking or smoking for 10 minutes prior to specimen collection
- If unsure, collector should wait 10 minutes

Specimen Collection

COLLECTION PROCESS

- Remove the kit contents from the packaging. Save the outer packaging.
- Peel open the collector pad package and remove the collection device. Do not touch the pad.
- Place the collector pad under the donor's tongue and instruct donor to close his/her mouth.

 Donor must not chew or suck on the pad. When the indicator window turns blue, remove the collection device from the donor's mouth. DO NOT remove the collection device until the indicator turns blue. If the indicator does not turn blue within 15 minutes, remove the collection device and discard. Re-collection with a new device may begin immediately after saliva has accumulated in the donor's mouth.





Specimen Collection

COLLECTION PROCESS

- Holding the transport tube in an upright position, remove the cap, and insert the collector device (pad first) into the tube.
 DO NOT set the transport tube on a table.
 If any of the buffer is spilled, a new transport tube must be used. The amount of liquid in the transport tube is critical to the testing process.
- Push the cap firmly onto the transport tube until you hear the SNAP. Gently shake the tube to mix the saturated collector pad with the buffer.



Specimen Labeling

Specimen Labeling

SPECIMEN CUPS

The 90ml collection bottle comes with a temperature strip.

When closing the bottle, ensure the lid is tightly sealed.

If lid is not properly sealed, the bottle may leak.



Specimen Labeling

COLLECTION KITS

Ensure that the cap was firmly pushed into the transport tube.

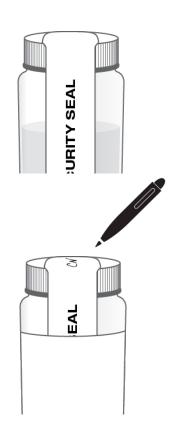
If cap is not secure, the tube may leak.



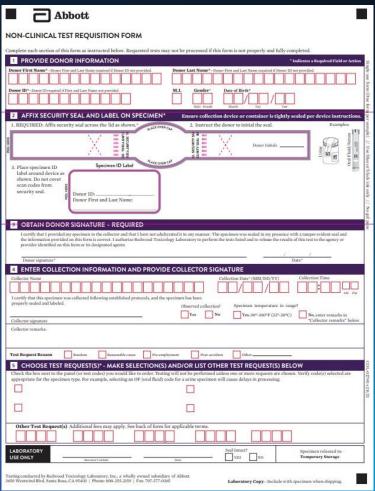
Specimen Labeling SECURITY SEAL

ENSURE NO TAMPERING OCCURS

- Place the specimen security seal label over the top of the device/container, so that it attaches to both sides of the specimen device/container
- Collector should instruct donor to initial the security seal. Collector should verify the information provided by the donor and validate that the specimen was collected correctly.
- Ensure that the security seal has been properly adhered to the specimen device/container and has not been broken.
- The specimen I.D. label (if applicable) can be prepared during or after specimen collection and should be placed on the lower portion of the specimen cup.



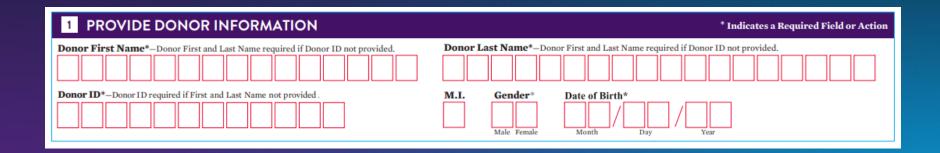
Test Requisition Form



Specimen Labeling

TEST REQUISITION FORM – SECTION 1: PROVIDE DONOR INFORMATION

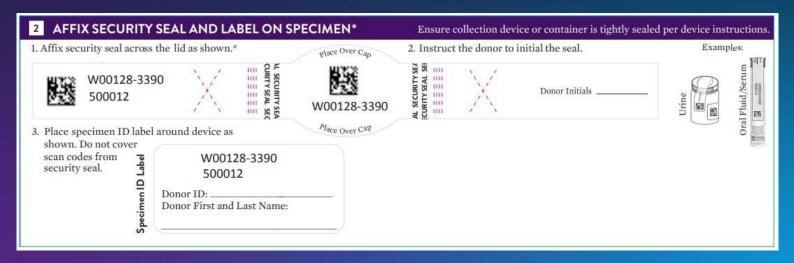
- Collector shall provide the donor's information, including first and last name
 - Alternatively, a Donor ID may be provided (instead of a first and last name)
- Collector shall add the donor's gender and date of birth



Specimen Labeling

TEST REQUISITION FORM – SECTION 2: AFFIX SECURITY SEAL AND LABEL ON SPECIMEN

- A security seal and Specimen ID Label appear in Section 2 of the test requisition form
- The collector uses these labels to seal the specimen and sends the test requisition form with the specimen to the laboratory for analysis. Upon receipt, the laboratory personnel ensure the specimen IDs from the forms and labels match. The lab will reject any specimens with mismatched IDs or if seals are missing.



Specimen Labeling

TEST REQUISITION FORM – SECTION 3: OBTAIN DONOR SIGNATURE

• Collector shall obtain the donor's signature and date

OBTAIN DONOR SIGNATURE - REQUIRED			
certify that I provided my specimen to the collector and that I have not adulterated it in any manner. The specimen was sealed in the information provided on this form is correct. I authorize Redwood Toxicology Laboratory to perform the tests listed and to provider identified on this form or its designated agents.			
	-	1	
Donor signature*	Da	to [®]	

Specimen Labeling

TEST REQUISITION FORM – SECTION 4: ENTER COLLECTION INFORMATION AND PROVIDE COLLECTOR SIGNATURE

- Collector shall enter his/her name and the collection date this is a required field
- Collector shall sign the form
- Collection time, whether or not collection was observed, specimen temperature, collector remarks, and test request reason may be tracked in this section.

4 ENTER COLLECTION INFORMATION AND PROVIDE COLLECTOR SIGNATURE						
Collector Name I certify that this specimen was collected following established protocols, and the speciment properly sealed and labeled. Collector signature	Collection Date* (MM/DD/YY) Collection Time AM PM men has been Observed collection? Specimen temperature in range? Yes No Yes, 90°-100°F (32°-38°C) No, enter remarks in "Collector remarks" below.					
Collector remarks:						
Test Request Reason Random Reasonable cause Pre-employment	nt Post-accident Other:					

Specimen Labeling

TEST REQUISITION FORM – SECTION 5: CHOOSE TEST REQUESTS

- Test codes are pre-printed according to your agency's instructions
- Choose one or more tests to be performed by checking the corresponding box to the left of the test code
 - Verify code selected is appropriate for the specimen type
 - Choose a urine code or oral fluid (OF) code but NOT both
- If the test code is not pre-printed, refer to the list of commonly ordered tests on the back of the form
 - Input the corresponding test code into the section marked "Other Test Requests." (pricing may vary)

5 CHOOSE TEST REQUESTS*	1			
Check the box next to the panel (or test codes) you would like to order. Testing appropriate for the specimen type. For example, selecting an OF (oral fluid) cod	will not be performed unless one or more requests are chosen. Verify code(s) selected are le for a urine specimen will cause delays in processing.			
B35 - Urine 14 panel - ALC, AMP, BUP, BZO, COC, CR, FEN, MTD, OPI, OXY, PCP, PH, SG, THC 9539 - OF 8 Panel - ALC, AMP, BAR, BZO, COC, MTD, OPI Screen Only				
5483 - Tianeptine LC-MS/MS Screen with Confirmation, Urine	9721 - OF 9 Panel - AMP, BAR, BZO, COC, MTD, OPI, PCP, SC, THC; Confirmed			
Other Test Requests Additional fees may apply. See back of form for app	licable terms.			

Specimen Labeling

TEST REQUISITION FORM – LABORATORY USE ONLY SECTION

• Information should <u>not</u> be entered into the area marked "Laboratory Use Only."

LABORATORY USE ONLY		119	Seal Intact?	Specimen released to: Temporary Storage
	Receiver's initials I Toxicology Laboratory, Inc., a wholly ova, CA 95403 Phone: 800-225-2159 Fa		Laboratory Copy—Inclu	ade with specimen when shipping.

Preparing Specimens for Shipment

Specimen labeling and shipping

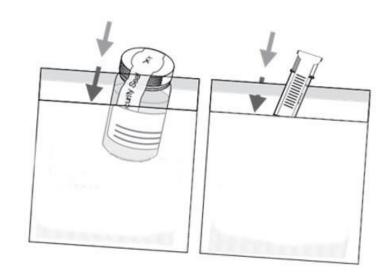
Please ensure the specimen is collected, labeled, and packaged correctly before releasing it to the shipper. Improper labeling and packaging may result in your specimens being rejected by the shipping carrier or excluded from testing at the laboratory.



Specimen Shipping

INTERNAL PACKAGING

- Each specimen will go into its own baggie.
- Place test requisition form into back pouch of baggie.
- Place the specimen into the front pouch (the one with the absorbent material – leave the absorbent pad in the baggie).
- Seal the baggie.
- Store in a secure area until the specimen is ready to be shipped to the laboratory.



FedEx*

PLACE THE SEALED SPECIMEN BAG INSIDE THE FEDEX® CLINICAL PAK.

- Place sealed specimens into the clear Ziploc bag
- Place Ziploc bag into the Clinical Pak and seal.
- IMPORTANT: The sample and its accompanying test requisition form must be shipped in the same Clinical Pak. Sending them in a separate Clinical Pak may result in a delay of processing the specimens.
 - SS SS SS SS Clinical Pak

 Clinical Pak

 Large Zpioc Bag
 posted by PII)

- After sealing the FedEx® Clinical Pak, attach a pre-printed FedEx Express® Return Label for FedEx Standard Overnight® shipping.
- *Those in remote areas may use the U.S. Postal Service (USPS) rather than FedEx.



Specimen Shipping

PACKAGING NOTICE

It is required that all agencies utilize the packaging materials provided by Abbott to ensure the specimen's delivery.

Do not use supplies intended for other laboratories.

Failure to utilize the packaging materials provided by Abbott may result in your specimens being rejected by FedEx® or rejected for testing.



Specimen Shipping

SCHEDULING AND TRACKING

- In most cases, FedEx can provide same day pickup if scheduled prior to that route's cutoff time.
- Should the volume of a location warrant it, you may elect to establish a standing pick up.
- Once the specimen is picked up from a location, it can be tracked through FedEx's system either online or by calling them directly.
- Abbott recommends that the Tracking number from the billable stamp be saved or recorded for each shipment in case the package needs to be researched.
- Unless an issue exists with the labeling of the package, we will receive the specimen within 24 to 48 hours
 of its shipment.
- Customers using FedEx will receive pre-paid/pre-printed peel-and-stick shipping labels and lab paks.
- Abbott will provide those using USPS with corrugated boxes and separate postage-paid, pre-printed USPS return shipping labels. No tracking information is collected for USPS shipments.
- Using the Abbott provided shipping supplies ensures that the courier properly routes specimens.

Specimen Shipping

PACKING THE SHIPMENT

When using FedEx:

- Place as many sealed specimen baggies as possible into the FedEx clinical lab pack.
- Attach the pre-printed billable stamp onto the outside of the lab pack.
- If you do not have a regular pick-up from FedEx, call 1.800GoFedEx (1-800-463-3339) or visit www.fedex.com/us to schedule a pick-up for your location.

When using U.S. Postal Service (USPS)

- Abbott provides shipping boxes to be used to ship specimens via USPS.
- Place the sealed specimen baggies into the shipping box.
- USPS return mailing boxes are pre-printed with the laboratory address where samples need to be mailed.

Specimen Shipping

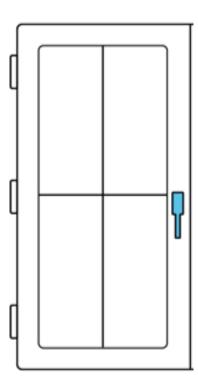
TEMPORARY STORAGE

Upon completion of the collection and test requisition process, specimen should be sealed in the individual specimen baggie immediately.

Several specimens can be collected throughout the day and placed in a single FedEx or USPS package until that package is full.

If packages must be retained at an office or vendor until the following day, the specimens should be refrigerated in a secure area with limited access or in a locked refrigerator.

Specimens should be shipped as soon as possible after collection to reduce degradation.



Specimen Shipping

SHIP TO LABORATORY

The specimen(s) may now be shipped.

Redwood Toxicology Laboratory, Inc. 3650 Westwind Blvd. Santa Rosa, CA 95403

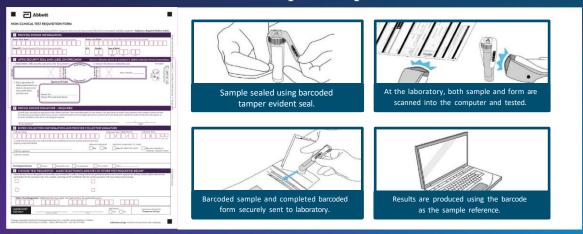
Toxicology Testing Process



Laboratory Receipt

INITIAL RECEIPT AND LOG IN

- Package is scanned, opened and visually inspected
- Receiving staff signs and dates the bottom of the requisition form
- The information is logged into the Laboratory Information Management System (LIMS)
- Items are labeled and move forward to the next step in the process



Specimen Receipt – Fatal Flaws

THE LABORATORY MAY NOT TEST THE SAMPLE IF SECURITY SEAL OR INFORMATION IS MISSING.

FATAL FLAWS INCLUDE:

- No security seal
- Mislabeled specimens
- Unlabeled specimens



Toxicology Testing Process



Review and Certification of Results

- Results are reviewed by a trained, certifying scientist
- Results are certified for accuracy
- Results are released to the client

Toxicology Testing Process



Result Reporting

REPORTING

- The laboratory results are released in the form of a toxicology result report
- The toxicology result report contains all information related to the tested specimen



Laboratory Directors: Jashir S. Arora, Ph.D.: Henry Tsai, M.D.: Ph.D.

Identification: TEST DONOR 6545561D DOB: Sex: Collected By:

Requisition #: C1235122321 Accession #: 210211-12345 SpecimenType:URINE Collected: 02/08/2021 09:36AM Ordering Practitioner: Jane Doe Received: 02/11/2021 11:34 AM

Client: North American Drug Testing, Inc. 454 Mockingbird Way Providence, RI 02940 Phone: (401) 333-1234 Fax: (401) 543-1234

Summary

NPI: 1234567890

Positive for the following drugs:

Codeine (350 ng/mL)

Reported: 02/11/2021

**Please read important information about these results in the Comments section

Tests Ordered

 R08 - Urine 7 Panel AMP.BZO.COC.CR.ETG.OPI.

Drug Tests

	Screen			Confirmation		
Drug or Drug Class	Method	Cutoff	Result	Method	Cutoff	Result
Amphetamines	EIA	1,000 ng/mL	Negative			
Benzodiazepines	EIA	200 ng/mL	Negative			
Cocaine				9	-	
Cocaine (Benzoylecgonine)	EIA	300 ng/mL	Presumptive Positive			
Benzoylecgonine (Cocaine Metabolite)				LC/MS/MS	100 ng/mL	Negative
Ethyl Glucuronide						
Ethyl Glucuronide (EtG)	EIA	500 ng/mL	Presumptive Positive			
Ethyl Glucuronide (EtG)				LC/MS/MS	100 ng/mL	Negative
Ethyl Sulfate (EtS)				LC/MS/MS	25 ng/mL	Negative
Opiates						
Opiates	EIA	300 ng/mL	Presumptive Positive			
Codeine				LC/MS/MS	100 ng/mL	Positive
Hydrocodone				LC/MS/MS	100 ng/mL	Negative
Hydromorphone				LC/MS/MS	100 ng/mL	Negative
Morphine				LC/MS/MS	100 ng/mL	Positive
THC (Marijuana)	EIA	50 ng/mL	Negative			
THC /Creatinine Ratio (EIA)			NA			

Specimen Validity Tests

- 5	Test	Method	Reference Range	Result	
<u> </u>	Creatinine	Colorimetric	≥20 mg/dL	44 mg/dL	
	Comments: Morphine > 10.0	000 ng/mL			

UNCONFIRMED POSITIVE SCREEN TEST RESULTS (PRESUMPTIVE POSITIVE) ONLY PROVIDE A PRELIMINARY ANALYTICAL RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. CERTAIN SCREENING TEST RESULTS CAN BE IMPACTED BY INTERFERING DRUGS FOODS OR OTHER SUBSTANCES USED OR CONSUMED BY THE SAMPLE DONOR, CAREFUL CONSIDERATION AND APPROPRIATE PROFESSIONAL JUDGMENT SHOULD BE APPLIED WHEN CONSIDERING ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY UNCONFIRMED POSITIVE SCREEN TEST RESULTS.

Method Index

EA - Enzyme Assay GC-FID - Gas Chromatography - Flame Ionization Detector GC-MS - Gas Chromatography / Mass Spectrometry EIA - Enzyme-Immunoassay ELISA - Enzyme-Linked Immunosorbent Assay LC-MS/MS - Liquid Chromatography Tandem Mass Spectrometry

Terminology Index:

Cutoff - The concentration level above which the presence of a drug or drug class in the sample will be reported as Presumptive Positive or Positive.

Presumptive Positive - Preliminary unconfirmed analytical result indicating presence of drug or drug class above the applicable Cutoff Negative - Analytical result indicating drug or drug class not detected above the applicable Cutoff.

Positive - Confirmatory analytical result indicating presence of drug or drug class above the applicable Cutoff.

TEST DONOR 6545561D Printed 2/11/2021 12:54 PM PDT

Result Reporting

SECTION 1: SPECIMEN OVERVIEW

- Specimen identification
- Collection details
- Agency information
- Test type (urine/oral)
- Ordering Practitioner and NPI (for clinical accounts only)



DOB:

Sex: Collected By:

Redwood Toxicology Laboratory, Inc 3650 Westwind Blvd., Santa Rosa, CA 95403 Phone: 707-577-7959 // 800-255-2159 Fax: 707-577-0365 www.redwoodtoxicology.com

Identification: TEST DONOR 6545561D

Collected: 02/08/2021 09:36AM

Received: 02/11/2021 11:34 AM

Reported: 02/11/2021

Account #: Requisition #: Accession #: 500012 C1235122321 210211-12345

SpecimenType:URINE
Ordering Practitioner: Jane Doe

NPI: 1234567890

Laboratory Directors: Jasbir S. Arora, Ph.D.; Henry Tsai, M.D., Ph.D. CLIA License #05D0707588

North American Drug Testing, Inc. 454 Mockingbird Way Providence, RI 02940 Phone: (401) 333-1234 Fax: (401) 543-1234

Toxicology Training | 24-Jan-24

Result Reporting

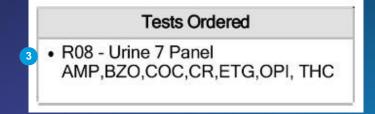
SECTION 2: SUMMARY

Key findings provided here

Summary • Positive for the following drugs: • Codeine (350 ng/mL) • Morphine **Please read important information about these results in the Comments section below.

SECTION 3: TESTS ORDERED

• This section lists the tests that were ordered and performed.



Result Reporting

SECTION 4: DRUG TESTS RESULT SECTION

- This section lists the details regarding the drug, result, cutoff, and method.
- There are separate columns for screen and confirmation results.

	Screen			Confirmation		
Drug or Drug Class	Method	Cutoff	Result	Method	Cutoff	Result
Amphetamines	EIA	1,000 ng/mL	Negative			
Benzodiazepines	EIA	200 ng/mL	Negative			
Cocaine		-				•
Cocaine (Benzoylecgonine)	EIA	300 ng/mL	Presumptive Positive			
Benzoylecgonine (Cocaine Metabolite)				LC/MS/MS	100 ng/mL	Negative
Ethyl Glucuronide		- 100 - 100				
Ethyl Glucuronide (EtG)	EIA	500 ng/mL	Presumptive Positive			
Ethyl Glucuronide (EtG)				LC/MS/MS	100 ng/mL	Negative
Ethyl Sulfate (EtS)				LC/MS/MS	25 ng/mL	Negative
Opiates						
Opiates	EIA	300 ng/mL	Presumptive Positive			
Codeine				LC/MS/MS	100 ng/mL	Positive
Hydrocodone				LC/MS/MS	100 ng/mL	Negative
Hydromorphone				LC/MS/MS	100 ng/mL	Negative
Morphine				LC/MS/MS	100 ng/mL	Positive
THC (Marijuana)	EIA	50 ng/mL	Negative			
THC /Creatinine Ratio (EIA)			NA			

Result Reporting

SECTION 5: SPECIMEN VALIDITY TESTS

• This section includes details on the specimen validity test(s) performed.

5		Specimen	Validity Tests	
	Test	Method	Reference Range	Result
	Creatinine	Colorimetric	≥20 mg/dL	44 mg/dL

SECTION 5A: COMMENTS

• This section includes additional comments as indicated in the Summary (Section 2).

		cimen Validity Tests	
Test	Method	Reference Range	Result
Creatinine	Colorimetric	≥20 mg/dL	44 mg/dL

Result Reporting

SECTION 6: COMMENT/NOTE

Special Note

UNCONFIRMED POSITIVE SCREEN TEST RESULTS (PRESUMPTIVE POSITIVE) ONLY PROVIDE A PRELIMINARY ANALYTICAL RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. CERTAIN SCREENING TEST RESULTS CAN BE IMPACTED BY INTERFERING DRUGS, FOODS OR OTHER SUBSTANCES USED OR CONSUMED BY THE SAMPLE DONOR. CAREFUL CONSIDERATION AND APPROPRIATE PROFESSIONAL JUDGMENT SHOULD BE APPLIED WHEN CONSIDERING ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY UNCONFIRMED POSITIVE SCREEN TEST RESULTS.

SECTION 7: METHOD INDEX

• This section provides information about the method abbreviations used in the report.

Method Index

EA - Enzyme Assay
EIA - Enzyme-Immunoassay
ELISA - Enzyme-Linked Immunosorbent Assay

GC-FID - Gas Chromatography - Flame Ionization Detector GC-MS - Gas Chromatography / Mass Spectrometry LC-MS/MS - Liquid Chromatography Tandem Mass Spectrometry

Result Reporting

SECTION 8: TERMINOLOGY INDEX

• This section defines key terms used throughout the report.

Terminology Index:

Cutoff - The concentration level above which the presence of a drug or drug class in the sample will be reported as Presumptive Positive or Positive.

Presumptive Positive - Preliminary unconfirmed analytical result indicating presence of drug or drug class above the applicable Cutoff.

Negative - Analytical result indicating drug or drug class not detected above the applicable Cutoff.

Positive - Confirmatory analytical result indicating presence of drug or drug class above the applicable Cutoff.

Additional Requests

COURT SERVICES

INTERPRETATION LETTERS

• Interpretations are generally used to establish whether the result of a subsequent collection is from residual elimination or new use in reference to another collection. They can also be used to interpret whether medications or prescriptions may have caused a positive or whether exposures such as through air, skin, or diet may have led to positives.

LITIGATION PACKAGES

• Litigation packages are produced when testimony is required or when counsel subpoenas this information to review internal documents generated in the normal course of business.

AFFIDAVITS

 Affidavits are used to certify that the laboratory report is accurate and was produced according to certified and approved procedures.