

Controlled Substance Monitoring Hybrid Drug Profile, 20 Drug Classes, High-Resolution Mass Spectrometry and Immunoassay Screen, Random, Urine

Overview

Useful For

Detecting drug use involving stimulants, barbiturate, benzodiazepines, cocaine, opioids, and tetrahydrocannabinol

This test is not intended for use in employment-related testing.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
LPCM	List Patient's Current	No	Yes
	Medications		
ADULT	Adulterants Survey, U	Yes	Yes
LDPU	Limited Drug Panel, 3, IA, U	No	Yes
TOPSU	Targeted Opioid Screen, U	Yes, (order TOSU)	Yes
TABSU	Targeted Benzodiazepine	Yes, (order TBSU)	Yes
	Screen, U		
TSTIM	Targeted Stimulant Screen,	Yes, (order TSPU)	Yes
	U		

Testing Algorithm

Testing begins with an adulterant survey. If the sample is found to be adulterated, testing will end, and the remaining tests will be canceled.

If the specimen is normal or only diluted, testing will proceed.

If immunoassay screen is positive, confirmation testing **will not be automatically reflexed** but can be requested or ordered separately.

Method Name

ADULT: Spectrophotometry LDPU: Immunoassay TOPSU, TABSU, TSTIM: Liquid Chromatography Tandem Mass Spectrometry, High-Resolution Accurate Mass (LC-MS/MS HRAM)

NY State Available

Yes



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Specimen

Specimen Type

Urine

Ordering Guidance

This test does not screen for drug classes other than those listed in Reference Values.

Specimen Required

Supplies: Urine Tubes, 10 mL (T068)

Collection Container/Tube: Plastic urine container

Submission Container/Tube: Plastic, 10 mL tube

Specimen Volume: 5 mL

Collection Instructions:

- 1. Collect a random urine specimen.
- 2. Submit 5 mL in 1 plastic bottle.
- 3. No preservative

Additional Information:

- 1. No specimen substitutions.
- 2. Submitting less than 5 mL may compromise the ability to perform all necessary testing.
- 3. STAT requests are **not accepted** for this test.

Forms

If not ordering electronically, complete, print, and send a <u>Therapeutics Test Request</u> (T831) with the specimen.

Specimen Minimum Volume

2 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive



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Clinical Information

This test uses the simple screening technique that involves immunoassay testing for drugs by class. All positive immunoassay screening results can be confirmed by either gas chromatography mass spectrometry (GC-MS) or liquid chromatography tandem mass spectrometry (LC-MS/MS) and quantitated if applicable. The targeted opioid, benzodiazepine, and stimulant screen portions are performed by LC-MS/MS high-resolution accurate mass and are completed for all opioids, benzodiazepines, and stimulants.

Opioids are a large class of medications commonly used to relieve acute and chronic pain or help manage opioid abuse and dependence. Medications that fall into this class include buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, tapentadol, tramadol, and others. Opioids work by binding to the opioid receptors that are found in the brain, spinal cord, gastrointestinal tract, and other organs. Common side effects for opiods include drowsiness, confusion, nausea, constipation, and, in severe cases, respiratory depression. These are dose dependant and vary with tolerance. These medications can also produce physical and psychological dependence and have a high risk for abuse and diversion, which is one of the main reasons many professional practice guidelines recommend compliance testing in patients prescribed these medications.

Opioids are readily absorbed from the gastrointestinal tract, nasal mucosa, lungs, and after subcutaneous or intermuscular injection. Opioids are primarily excreted from the kidney in both free and conjugated forms. This assay does not hydrolyze the urine sample and looks for both parent drugs and metabolites (including glucuronide forms). The detection window for most opioids in urine is approximately 1 to 3 days with longer detection times for some compounds (eg, methadone).

Benzodiazepines represent a large family of medications used to treat a wide range of disorders from anxiety to seizures and are also used in pain management. With a high risk for abuse and diversion, professional practice guidelines recommend compliance monitoring for these medications using urine drug tests. However, traditional benzodiazepine immunoassays suffer from a lack of cross-reactivity with all the benzodiazepines, so many compliant patients taking either clonazepam (Klonopin) or lorazepam (Ativan) may screen negative by immunoassay but are positive when confirmatory testing is done. The new targeted benzodiazepine screening test provides a more sensitive and specific test to check for compliance to all the commonly prescribed benzodiazepines and looks for both parent drugs and metabolites in the urine.

Stimulants are sympathomimetic amines that stimulate the central nervous system activity and, in part, suppress the appetite. Amphetamine and methamphetamine are also prescription drugs used in the treatment of narcolepsy and attention-deficit disorder/attention-deficit hyperactivity disorder (ADHD). Methylphenidate is another stimulant used to treat ADHD. Phentermine is indicated for the management of obesity. All other amphetamines (eg, methylenedioxymethamphetamine: MDMA) are Drug Enforcement Administration-scheduled Class I compounds. Due to their stimulant effects, the drugs are commonly sold illicitly and abused. Physiological symptoms associated with very high amounts of ingested amphetamine or methamphetamine include elevated blood pressure, dilated pupils, hyperthermia, convulsions, and acute amphetamine psychosis.

This test is intended to be used in a setting where the test results can be used to make a definitive diagnosis.



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Reference Values

ADULTERANT SURVEY: Cutoff concentrations Oxidants: 200 mg/L Nitrites: 500 mg/L

LIMITED DRUG PANEL: Negative Screening cutoff concentrations: Barbiturates: 200 ng/mL Cocaine (benzoylecgonine-cocaine metabolite): 150 ng/mL Tetrahydrocannabinol carboxylic acid: 50 ng/mL

This report is intended for use in clinical monitoring or management of patients. It is not intended for use in employment-related testing.

TARGETED OPIOID SCREEN: Not detected

Cutoff concentrations: Codeine: 25 ng/mL Codeine-6-beta-glucuronide: 100 ng/mL Morphine: 25 ng/mL Morphine-6-beta-glucuronide: 100 ng/mL 6-Monoacetylmorphine: 25 ng/mL Hydrocodone: 25 ng/mL Norhydrocodone: 25 ng/mL Dihydrocodeine: 25 ng/mL Hydromorphone: 25 ng/mL Hydromorphone-3-beta-glucuronide: 100 ng/mL Oxycodone: 25 ng/mL Noroxycodone: 25 ng/mL Oxymorphone: 25 ng/mL Oxymorphone-3-beta-glucuronide: 100 ng/mL Noroxymorphone: 25 ng/mL Fentanyl: 2 ng/mL Norfentanyl: 2 ng/mL Meperidine: 25 ng/mL Normeperidine: 25 ng/mL Naloxone: 25 ng/mL Naloxone-3-beta-glucuronide: 100 ng/mL Methadone: 25 ng/mL



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2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 25 ng/mL Propoxyphene: 25 ng/mL Norpropoxyphene: 25 ng/mL Tramadol: 25 ng/mL O-desmethyltramadol: 25 ng/mL Tapentadol: 25 ng/mL N-desmethyltapentadol: 50 ng/mL Tapentadol-beta-glucuronide: 100 ng/mL Buprenorphine: 5 ng/mL Norbuprenorphine: 5 ng/mL Norbuprenorphine: 5 ng/mL

TARGETED BENZODIAZEPINE SCREEN: Not detected

Cutoff concentrations: Alprazolam: 10 ng/mL Alpha-hydroxyalprazolam: 10 ng/mL Alpha-hydroxyalprazolam glucuronide: 50 ng/mL Chlordiazepoxide: 10 ng/mL Clobazam: 10 ng/mL N-desmethylclobazam: 200 ng/mL Clonazepam: 10 ng/mL 7-Aminoclonazepam: 10 ng/mL Diazepam: 10 ng/mL Nordiazepam: 10 ng/mL Flunitrazepam: 10 ng/mL 7-Aminoflunitrazepam: 10 ng/mL Flurazepam: 10 ng/mL 2-Hydroxy ethyl flurazepam: 10 ng/mL Lorazepam: 10 ng/mL Lorazepam glucuronide: 50 ng/mL Midazolam: 10 ng/mL Alpha-hydroxymidazolam: 10 ng/mL Oxazepam: 10 ng/mL Oxazepam glucuronide: 50 ng/mL Prazepam: 10 ng/mL Temazepam: 10 ng/mL Temazepam glucuronide: 50 ng/mL Triazolam: 10 ng/mL Alpha-hydroxytriazolam: 10 ng/mL Zolpidem: 10 ng/mL



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Zolpidem phenyl-4-carboxylic acid: 10 ng/mL

TARGETED STIMULANT SCREEN: Not detected

Cutoff concentrations: Methamphetamine: 100 ng/mL Amphetamine: 100 ng/mL 3,4-Methylenedioxymethamphetamine (MDMA): 100 ng/mL 3,4-Methylenedioxy-N-ethylamphetamine (MDEA): 100 ng/mL 3,4-Methylenedioxyamphetamine (MDA): 100 ng/mL Ephedrine: 100 ng/mL Pseudoephedrine: 100 ng/mL Phentermine: 100 ng/mL Phencyclidine (PCP): 20 ng/mL Methylphenidate: 20 ng/mL Ritalinic acid: 100 ng/mL

Interpretation

A positive result derived by this testing indicates that the patient has used one of the drugs detected by these techniques in the recent past.

For information about drug testing, including estimated detection times and <u>Result Interpretations</u>, see <u>Controlled</u> <u>Substance Monitoring</u> on MayoClinicLabs.com.

Cautions

No significant cautionary statements

Clinical Reference

1. Physicians' Desk Reference. 60th ed. Medical Economics Company; 2006

2. Bruntman LL Lazo JS, Parker KL, eds. Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 11th ed. McGraw-Hill Book Company; 2006

3. Langman LJ, Bechtel LK, Holstege CP. Clinical toxicology. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:chap 43

4. Gutstein HB, Akil H. Opioid analgesics. In: Brunton LL, Lazo JS, Parker KL, eds. Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 11th ed. McGraw-Hill Companies; 2006:chap 21

5. Rovine T, Ferrero CL, American Pain Society: Chronic Pain in America: Roadblocks to Relief. Roper Starch Worldwide, Inc; 1999. Updated 2001. Accessed July 16, 2024. Available at

http://accurateclinic.com/wp-content/uploads/2016/04/Chronic-Pain-In-America-Roadblocks-To-Relief-1999.pdf 6. Magnani B, Kwong T. Urine drug testing for pain management. Clin Lab Med. 2012;32(3):379-390

7. Jannetto PJ, Bratanow NC, Clark WA, et al. Executive summary: American Association of Clinical Chemistry Laboratory Medicine Practice Guideline-using clinical laboratory tests to monitor drug therapy in pain management patients. J Appl



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Lab Med. 2018;2(4):489-526

 McMillin GA, Marin SJ, Johnson-Davis KL, Lawlor BG, Strathmann FG. A hybrid approach to urine drug testing using high-resolution mass spectrometry and select immunoassays. Am J Clin Pathol. 2015;143(2):234-240
Cone EJ, Caplan YH, Black DL, Robert T, Moser F. Urine drug testing of chronic pain patients: licit and illicit drug patterns. J Anal Toxicol. 2008;32(8):530-543

Performance

Method Description

Adulterant:

All results are measured using spectrophotometry at wavelengths specified by the reagent manufacturer. The use of a refractometer may also be used in the specific gravity measurement. (Package inserts: Specimen Validity Test Creatinine. Roche Diagnostics; V3.0, 08/2015; Specimen Validity Test Nitrite. Roche Diagnostics; V3.0, 08/2018, Specimen Validity Test Oxidant. Roche Diagnostics; V 3.0, 08/2018; Specimen Validity Test pH Roche Diagnostics; V3.0, 02/2019, Specimen Validity Test Specific Gravity. Roche Diagnostics; V4.0, 08/2022)

Drug Panel:

The barbiturate, cocaine metabolite, and tetrahydrocannabinol metabolite assays are based on the kinetic interaction of microparticles in a solution as measured by changes in light transmission. In the absence of sample drug, soluble drug conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases. When a urine sample contains the drug in question, this drug competes with the drug derivative conjugate for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.(Package inserts: BARB. Roche Diagnostics; V 13.0, 09/2021; THC2. Roche Diagnostics; V 13.0, 03/2022; COC2. Roche Diagnostics; V 9.0, 03/2019)

Targeted Screening Panels for opioids, benzodiazepines, and stimulants:

The urine sample is diluted with internal standard and clinical laboratory reagent water and then analyzed by liquid chromatography tandem mass spectrometry using a high-resolution accurate mass orbitrap detector. (Unpublished Mayo method)

PDF Report No

Day(s) Performed Monday through Saturday

Report Available



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3 to 4 days

Specimen Retention Time 14 days

Performing Laboratory Location Rochester

Fees & Codes

Fees

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

80307 80347 80364 80326 G0482 (if appropriate)

LOINC[®] Information

Test ID	Test Order Name	Order LOINC [®] Value
CSMHU	CSM Hybrid Drug Profile,20,HRMS/IA	69739-1

Result ID	Test Result Name	Result LOINC [®] Value
20606	Creatinine, U	2161-8
22312	Specific Gravity	5810-7
23509	рН	2756-5
23511	Oxidants	58714-7
23510	Nitrites	32710-6
30914	Comment	48767-8
42323	Codeine	19411-8
42324	Codeine-6-beta-glucuronide	89310-7



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42325	Morphine	19597-4
42326	Morphine-6-beta-glucuronide	89308-1
42327	6-monoacetylmorphine	19321-9
42328	Hydrocodone	19482-9
42329	Norhydrocodone	89304-0
42330	Dihydrocodeine	19446-4
42331	Hydromorphone	19486-0
42332	Hydromorphone-3-beta-glucuronide	89309-9
42333	Oxycodone	19642-8
42334	Noroxycodone	89303-2
42335	Oxymorphone	19646-9
42336	Oxymorphone-3-beta-glucuronide	89301-6
42337	Noroxymorphone	89302-4
42338	Fentanyl	59673-4
42339	Norfentanyl	43199-9
42340	Meperidine	19532-1
42341	Normeperidine	27920-8
42342	Naloxone	42618-9
42343	Naloxone-3-beta-glucuronide	89307-3
42344	Methadone	19550-3
42345	EDDP	93495-0
42346	Propoxyphene	19429-0
42347	Norpropoxyphene	19632-9
42348	Tramadol	19710-3
42349	O-desmethyltramadol	86453-8
42350	Tapentadol	72485-6
42351	N-desmethyltapentadol	89306-5
42352	Tapentadol-beta-glucuronide	89300-8
42353	Buprenorphine	93494-3
42354	Norbuprenorphine	82371-6
42355	Norbuprenorphine glucuronide	89305-7
65059	Opioid Interpretation	69050-3
604871	Alprazolam	94116-1
604867	Alpha-Hydroxyalprazolam	19325-0
604891	Alpha-Hydroxyalprazolam	94115-3
	Glucuronide	
604872	Chlordiazepoxide	19385-4
604889	Clobazam	94114-6
604890	N-Desmethylclobazam	94113-8
604873	Clonazepam	19399-5
004075	Cionazepani	13332-3



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604267	7-aminoclonazepam	94112-0
604874	Diazepam	19443-1
604880	Nordiazepam	19624-6
604875	Flunitrazepam	19466-2
604866	7-aminoflunitrazepam	94111-2
604876	Flurazepam	19474-6
604868	2-Hydroxy Ethyl Flurazepam	94110-4
604877	Lorazepam	19520-6
604878	Lorazepam Glucuronide	94109-6
604879	Midazolam	19585-9
604869	Alpha-Hydroxy Midazolam	94108-8
604881	Oxazepam	19638-6
604882	Oxazepam Glucuronide	94107-0
604883	Prazepam	19678-2
604884	Temazepam	19698-0
604885	Temazepam Glucuronide	94106-2
604886	Triazolam	19714-5
604870	Alpha-Hydroxy Triazolam	94105-4
604887	Zolpidem	94104-7
604888	Zolpidem Phenyl-4-Carboxylic acid	94103-9
604949	Benzodiazepine Interpretation	69050-3
LPCM	List Patient's Current Medications	66423-5
610273	Methamphetamine	19554-5
610274	Amphetamine	19343-3
610275	3,4-methylenedioxymethamphetami	19568-5
	ne (MDMA)	
610276	3,4-methylenedioxy-N-ethylampheta	59844-1
	mine (MDEA)	
610277	3,4-methylenedioxyamphetamine	19565-1
	(MDA)	
610278	Ephedrine	99108-3
610279	Pseudoephedrine	99109-1
610280	Phentermine	19674-1
610281	Phencyclidine (PCP)	19659-2
610282	Methylphenidate	19577-6
610283	Ritalinic acid	99110-9
610284	Stimulant Interpretation	54247-2
615289	Barbiturates	19270-8
615290	Cocaine	19359-9
615291	Tetrahydrocannabinol	19415-9