

Overview

Useful For

Screening for drug abuse or use of buprenorphine

Method Name

Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Urine

Ordering Guidance

For screening with reflex confirmation of positive screening results, order BUPR / Buprenorphine Screen with Reflex, Random, Urine.

For comprehensive opioid screening, order TOSU / Targeted Opioid Screen, Random, Urine.

For situations where chain of custody is required, a Chain of Custody Kit (T282) is available. For chain-of-custody testing, order BUPMX / Buprenorphine and Norbuprenorphine, Chain of Custody, Random, Urine.

Additional Testing Requirements

If urine creatinine is required or adulteration of the sample is suspected, the following test should also be ordered, ADULT / Adulterants Survey, Random, Urine.

Specimen Required

Supplies: Sarstedt 5 mL Aliquot Tube (T914)

Collection Container/Tube: Plastic urine container

Submission Container/Tube: Plastic vial

Specimen Volume: 5 mL

Collection Instructions:

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

Additional Information:

1. **No specimen substitutions.**
2. STAT requests are **not accepted** for this test.

3. Submitting less than 5 mL will compromise the ability to perform all necessary testing.

Forms

If not ordering electronically, complete, print, and send a [Therapeutics Test Request](#) (T831) with the specimen.

Specimen Minimum Volume

2.5 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	
	Ambient	72 hours	

Clinical & Interpretive

Clinical Information

Clinically, buprenorphine is utilized as a substitution therapy for opioid dependence and as an analgesic. Buprenorphine is a partial agonist of the mu-opioid receptor. These mu binding sites are discretely distributed in the human brain, spinal cord, and other tissue. The clinical effects of mu receptor agonists are sedation, euphoria, respiratory depression, and analgesia. As a partial mu receptor agonist, buprenorphine's clinical effects are decreased, giving buprenorphine a wider safety margin.(1) Buprenorphine has a prolonged duration of activity. The combination of decreased clinical effects and prolonged activity gives buprenorphine the added advantage of a delayed and decreased withdrawal syndrome, compared to other opioids.(1) Compared to morphine, buprenorphine is 25 to 40 times more potent.(1) As with any opioid, abuse is always a concern. To reduce illicit use of buprenorphine, it is available mixed with naloxone in a ratio of 4:1. When the combination is taken as prescribed, only small amounts of naloxone will be absorbed. However, if the combination is transformed into the injectable form, naloxone then acts as an opioid receptor antagonist.

Buprenorphine is metabolized through N-dealkylation to norbuprenorphine through cytochrome P450 3A4 (CYP 3A4). Both parent and metabolite then undergo glucuronidation. Norbuprenorphine is an active metabolite possessing one fifth of the potency of its parent. The glucuronide metabolites are inactive.(1)

This procedure uses immunoassay reagents that are designed to produce a negative result when no drugs are present in a natural (ie, unadulterated) specimen of urine; the assay is designed to have a high true-negative rate. Like all immunoassays, it can produce a false-positive result due to cross-reactivity with natural chemicals and drugs other than those they were designed to detect. The immunoassay also can produce a false-negative result due to the antibody's ability to cross-react with different drugs in the target class.

Reference Values

Negative

Screening cutoff concentration:

Buprenorphine: 5 ng/mL

Interpretation

This assay only provides a preliminary analytical test result. A more specific alternative method (ie, liquid chromatography-tandem mass spectrometry: LC-MS/MS) must be used to obtain a confirmed analytical result.

Cautions

Care should be taken when interpreting results since there are many factors (eg, fluid intake and other biologic factors) that may influence a urine test result. It is possible that substances other than those investigated in the specificity study may interfere with the test and cause false-positive or false-negative results.

Clinical Reference

1. Elkader A, Spuroule B: Buprenorphine clinical pharmacokinetics in the treatment of opioid dependence. Clin Pharmacokinet 2005;44(7):661-680
2. 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 Lab Med. 2018 Jan;2(4):489-526. doi: 10.1373/jalm.2017.023341
3. Langman LJ, Bechtel LK, Meier BM, Holstege CP: Clinical Toxicology. In: Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018:832-887

Performance

Method Description

This assay is a homogeneous enzyme immunoassay technique. The assay will be performed semi- quantitatively. The assay is based on competition between free drug in the urine sample, and a drug labeled with the enzyme glucose-6-phosphate dehydrogenase for a fixed amount of specific antibody binding sites. Active enzyme reduces nicotinamide adenine dinucleotide (NAD+) to NADH, which results in an absorbance change that can be measured spectrophotometrically at 340nm. Similar testing is being performed on the Olympus AU680 analyzer and this test would be an addition to the current testing.(Package insert: Buprenorphine Urine Enzyme Immunoassay. Immunalysis Corporation; 04/2021)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BUPS	Buprenorphine Screen, U	3415-7

Result ID	Test Result Name	Result LOINC® Value
63119	Buprenorphine Screen, U	3415-7