MAYO CLINIC LABORATORIES

Test Definition: BUPR

Buprenorphine Screen with Reflex, Random, Urine

Overview

Useful For

Screening and confirmation for drug abuse or use of buprenorphine

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
BUPS	Buprenorphine Screen, U	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
BUPM	Buprenorphine and Metabolite, U	Yes	No

Testing Algorithm

Testing begins with a screening assay. If the buprenorphine screen is positive, then the liquid chromatography tandem mass spectrometry confirmation with quantification will be performed at an additional charge.

Method Name

Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Urine

Ordering Guidance

For screening buprenorphine alone, order BUPS / Buprenorphine Screen, 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 Aliquot Tube, 5 mL (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	
	Ambient	72 hours	
	Frozen	14 days	

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

If the screen result is negative, buprenorphine concentrations were not detected.

If the screen result is positive, then confirmation by liquid chromatography tandem mass spectrometry will be performed.

A positive interpretation will be given if either the buprenorphine result is greater than or equal to 5.0 ng/mL or the norbuprenorphine result is greater than or equal to 2.5 ng/mL.

The presence of buprenorphine above 5.0 ng/mL or norbuprenorphine above 2.5 ng/mL is a strong indicator that the patient has used buprenorphine.

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;2:489-526
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

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
Mayo Clinic Laboratories - Rochester Superior Drive

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

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LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BUPR	Buprenorphine Screen w/Reflex, U	93494-3

Result ID	Test Result Name	Result LOINC® Value
63119	Buprenorphine Screen, U	93494-3