Overview

Useful For
Monitoring of compliance of buprenorphine therapy
Detection and confirmation of the illicit use of buprenorphine

Chain of custody is required whenever the results of testing could be used in a court of law. Its purpose is to protect the rights of the individual contributing the specimen by demonstrating that it was under the control of personnel involved with testing the specimen at all times; this control implies that the opportunity for specimen tampering would be limited.

Additional Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>COCH</td>
<td>Chain of Custody Processing</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>ADLTX</td>
<td>Adulterants Survey, CoC, U</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Testing Algorithm
Adulterants testing will be performed on all chain-of-custody urine samples as per regulatory requirements.

Method Name
BUPMX: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)
ADLTX: Spectrophotometry (SP)

NY State Available
Yes

Specimen

Specimen Type
Urine

Specimen Required
Supplies: Chain of Custody Kit (T282)

Container/Tube: Chain-of-Custody Kit containing the specimen containers, seals, and documentation required.

Specimen Volume: 20 mL

Collection Instructions: Collect specimen in the provided container, seal, and submit with the associated documentation to satisfy the legal requirements for chain-of-custody testing.

Forms
1. Chain-of-Custody Request is included in the Chain-of-Custody Kit (T282).

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

**Specimen Minimum Volume**
1 mL

**Reject Due To**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross icterus</td>
<td>OK</td>
</tr>
</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
<td></td>
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**Clinical and 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. 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)

The primary clinical utility of quantification of buprenorphine in urine is to identify patients that have strayed from opioid dependence therapy.

Chain of custody is a record of the disposition of a specimen to document the individuals that collected it, handled it, and performed the analysis. When a specimen is submitted in this manner, analysis will be performed in such a way that it will withstand regular court scrutiny.

**Reference Values**

Negative
Test Definition: BUPMX
Buprenorphine w/metabolite, CoC, U

Cutoff concentrations:

Buprenorphine: 5.0 ng/mL
Norbuprenorphine: 2.5 ng/mL

**Interpretation**
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**
Urine concentrations do not correlate well with serum drug levels and are not intended for therapeutic drug management.

**Clinical Reference**

**Performance**

**Method Description**
Buprenorphine and its major metabolite (norbuprenorphine) are liberated from conjugation by enzyme hydrolysis. Acetonitrile is added to the sample and an aliquot of the supernatant is diluted with water. Analysis is performed by liquid chromatography-mass spectrometry/mass spectrometry using multiple reaction monitoring.(Unpublished Mayo method)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Friday

**Analytic Time**
3 days
Maximum Laboratory Time
5 days

Specimen Retention Time
14 days at 2 to 8 degrees C

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
80348
G0480 (if appropriate)

LOINC® Information

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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
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<td>BUPMX</td>
<td>Buprenorphine w/metabolite, CoC, U</td>
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<table>
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<tr>
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<th>Result LOINC Value</th>
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<td>65215</td>
<td>Buprenorphine</td>
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<td>48297</td>
<td>Norbuprenorphine</td>
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<td>Chain of Custody</td>
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