Overview

Useful For
Detection and confirmation of illicit drug use involving fentanyl

Method Name
Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

NY State Available
Yes

Specimen

Specimen Type
Urine

Advisory Information
For situations where chain of custody is required, a Chain-of-Custody Kit (T282) is available. For chain-of-custody testing, order FENTX / Fentanyl with Metabolite Confirmation, Chain of Custody, Urine.

Additional Testing Requirements
If urine creatinine is required or adulteration of the sample is suspected, the following test should be requested, ADULT / Adulterants Survey, Urine. For additional information, refer to ADULT / Adulterants Survey, Urine.

Specimen Required

Supplies: Plastic, 10-mL urine tube (T068)

Collection Container/Tube: Clean, plastic urine collection container

Submission Container/Tube: Plastic, 10-mL urine tube

Specimen Volume: 3 mL

Collection Instructions:
1. Collect a random urine specimen.
2. No preservative.

Additional Information:
1. No specimen substitutions.
2. No STATS are accepted for this procedure.
3. Submitting less than 3 mL will compromise our 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

2.1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>OK</th>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td></td>
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<tr>
<td>Gross icterus</td>
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Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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Clinical and Interpretive

Clinical Information

Fentanyl is an extremely fast acting synthetic opioid related to the phenylpiperidines.\(^1\,2\) It is available in injectable as well as transdermal formulations.\(^1\) The analgesic effects of fentanyl is similar to those of morphine and other opioids\(^1\): it interacts predominantly with the opioid mu-receptor. These mu-binding sites are discretely distributed in the human brain, spinal cord, and other tissue.\(^1\,3\)

Fentanyl is approximately 80% to 85% protein bound. In plasma, the protein binding capacity of fentanyl decreases with increasing ionization of the drug. Alterations in pH may affect its distribution between plasma and the central nervous system (CNS). The average volume of distribution for fentanyl is 6 L/kg (range 3-8).\(^3\,4\)

In humans, the drug appears to be metabolized primarily by oxidative N-dealkylation to norfentanyl and other inactive metabolites that do not contribute materially to the observed activity of the drug. Within 72 hours of intravenous (IV) administration, approximately 75% of the dose is excreted in urine, mostly as metabolites with less than 10% representing unchanged drug.\(^3\,4\)

The mean elimination half-life is (1-3):

- IV: 2 to 4 hours
- Iontophoretic transdermal system (Ionsys) terminal half-life: 16 hours
- Transdermal patch: 17 hours (13-22 hours, half-life is influenced by absorption rate)
- Transmucosal:
  - Lozenge: 7 hours
  - Buccal tablet
Test Definition: FENTU
Fentanyl w/metabolite Conf, U

- 100 to 200 mcg: 3 to 4 hours
- 400 to 800 mcg: 11 to 12 hours

In clinical settings, fentanyl exerts its principal pharmacologic effects on the CNS. In addition to analgesia, alterations in mood (euphoria, dysphoria) and drowsiness commonly occur.(1,3) Because the biological effects of fentanyl are similar to those of heroin and other opioids, fentanyl has become a popular drug of abuse.

Reference Values
Negative

Interpretation
The presence of fentanyl above 0.20 ng/mL or norfentanyl above 1.0 ng/mL is a strong indicator that the patient has used fentanyl.

Cautions
Urine concentrations do not correlate well to serum drug levels. For therapeutic drug management, monitor serum levels using FENTS / Fentanyl, Serum.

Clinical Reference

Performance

Method Description
Fentanyl is isolated from urine using a liquid-liquid extraction. The solvent is dried and the analytes are reconstituted with mobile phase. Analysis is performed by liquid chromatography-mass spectrometry using selected ion monitoring.(Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Friday; Varies

Analytic Time
2 days

Maximum Laboratory Time
6 days
Specimen Retention Time
14 days

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
80354
G0480 (if appropriate)

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>Fentanyl w/metabolite Conf, U</td>
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<table>
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<td>45532</td>
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