Test Definition: FENTU

Fentanyl with Metabolite Confirmation, Random, Urine

Overview

Useful For

Detection and confirmation of illicit drug use involving fentanyl

Special Instructions

- Clinical Toxicology CPT Code Client Guidance

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Urine

Ordering Guidance

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, Random, Urine.

Additional Testing Requirements

If urine creatinine is required or adulteration of the specimen 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: Clean, plastic urine collection container
Submission Container/Tube: Plastic, 5-mL tube
Specimen Volume: 5 mL
Collection Instructions:
1. Collect a random urine specimen.
2. No preservative.
Additional Information:
1. No specimen substitutions.
2. STAT requests are **not accepted** for this procedure.
3. Submitting less than 5 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

Gross hemolysis	OK
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	28 days	
	Ambient	21 days	
	Frozen	28 days	

Clinical & 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

-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
Positive results are reported with a quantitative result.

Cutoff concentrations by liquid chromatography tandem mass spectrometry:
Fentanyl: 0.2 ng/mL
Norfentanyl: 1.0 ng/mL

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.

Very high concentrations of butyl fentanyl (>5 mcg/mL) and acetyl fentanyl (>10 mcg/mL) can potentially interfere and cause a low positive (<0.5 ng/mL) fentanyl concentration, but no interference is noted with norfentanyl.

Clinical Reference

1. Gutstein HB, Akil H. Opioid analgesics. In: Hardman JG LL, Gilman AG, eds. Goodman and Gilman's: The Pharmacological Basis of Therapeutics. 11th ed. McGraw-Hill; 2006:chap 21
2. Kerrigan S, Goldberger BA. Opioids. In: Levine ZB, ed. Principles of Forensic Toxicology. 2nd ed. AACC Press; 2003:187-205
3. DURAGESIC (fentanyl transdermal system). Package insert. Janssen Pharmaceutical Products. LP; 2006
4. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 8th ed. Biomedical Publications; 2008:616-619
5. Langman LJ, Bechtel LK, Meier BM, Holstege C. Clinical toxicology. In: Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 7th ed. Elsevier; 2023:chap 43

Performance

Method Description

The received urine sample is centrifuged, diluted, mixed with internal standard and ammonium hydroxide, and vortexed briefly. It is then extracted using supported liquid extraction, and the extract analyzed by an in-house developed liquid chromatography tandem mass spectrometry method.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
4 to 7 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
G0480
80354 (if appropriate for select payers)
Clinical Toxicology CPT Code Client Guidance

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FENTU	Fentanyl w/metabolite Conf, U	67822-7

Result ID	Test Result Name	Result LOINC® Value
45531	Norfentanyl by LC-MS/MS	58383-1
45530	Fentanyl by LC-MS/MS	58381-5
45532	Fentanyl Interpretation	69050-3