Test Definition: FENTX

Fentanyl with Metabolite Confirmation, Chain of Custody, Random, Urine

Overview

Useful For

Detection and confirmation of illicit drug use involving fentanyl

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

Test Id	Reporting Name	Available Separately	Always Performed
COCH	Chain of Custody Processing	No	Yes
ADLTX	Adulterants Survey, CoC, U	Yes	Yes

Testing Algorithm

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

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Urine

Ordering Guidance

This test is for situations that require the chain-of-custody process. For testing **not** requiring chain of custody, order FENTU / Fentanyl with Metabolite Confirmation, Random, Urine

Specimen Required

Supplies: Chain of Custody Kit (T282)
Container/Tube: Chain of Custody Kit (T282) containing the specimen containers, seals, and documentation required.
Specimen Volume: 5 mL
Collection Instructions: Collect urine specimen in the container provided, seal, and submit with the associated

documentation to satisfy the legal requirements for chain-of-custody testing.
Additional Information: Submitting less than 5 mL will compromise the ability to perform all necessary 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

2.1 mL

Reject Due To

Gross hemolysis	OK
Gross icterus	Reject

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

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 are 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 mcg to 200 mcg: 3 to 4 hours
-400 mcg 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.

Chain of custody is a record of the disposition of a specimen to document each individual who collected, handled, 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
Positive results are reported with a quantitative result.

Cutoff concentrations:

Immunoassay screen: 2 ng/mL

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

This screen is a homogeneous enzyme immunoassay technique. The immunoassay will be performed semiquantitatively. The immunoassay method 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 converts nicotinamide adenine dinucleotide (NAD+) to NADH, which results in an absorbance change that can be measured spectrophotometrically at 340nm.(Package insert: Fentanyl Enzyme Immunoassay. Immunalysis Corporation; 10/2016)

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
FENTX	Fentanyl w/metabolite Conf, CoC, U	67822-7

Result ID	Test Result Name	Result LOINC® Value
36190	Norfentanyl by LC-MS/MS	58383-1
36191	Fentanyl by LC-MS/MS	58381-5
36192	Fentanyl Interpretation	69050-3
36193	Chain of Custody	77202-0
36653	Fentanyl Immunoassay Screen	59673-4