MAYO CLINIC LABORATORIES

Test Definition: FNTSX

Fentanyl and metabolite, CoC, S

Overview

Useful For

Monitoring fentanyl therapy

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

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Supplies: Chain-of-Custody Kit (T282)

Collection Container/Tube: Red top (Serum gel/SST **are not** acceptable); Chain-of-Custody Kit containing the specimen seals and documentation required.

Submission Container/Tube: Plastic vial

Specimen Volume: 2.3 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial within 2 hours of collection.

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.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Icterus	Reject

Specimen Minimum Volume

1.25 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum Red	Frozen (preferred)	14 days	
	Refrigerated	14 days	
	Ambient		

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 tissues.(1,3)

Fentanyl is approximately 80% to 85% protein bound.(1) Fentanyl plasma protein binding capacity decreases with increasing ionization of the drug. Alterations in pH may affect its distribution between plasma and the central nervous system. 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 <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 (range 103-22 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 central nervous system. In additions 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

Not applicable

Interpretation

Both fentanyl and norfentanyl are reported.

Tolerant individuals may require many-fold increases in dose to achieve the same level of analgesia, which can greatly complicate interpretation of therapeutic drug monitoring results and establishment of a therapeutic window.

Concentration at which toxicity occurs varies and should be interpreted in light of clinical situation.

Clinical Reference

1. Gutstein HB, Akil H: Opioid analgesics. In: Hardman JG LL, Gilman AG, eds. Goodman and Gilmans' The Pharmacological Basis of Therapeutics. Vol. 11. McGraw-Hill Book Company; 2006:chap 21

2. Kerrigan S, Goldberger BA: Opioids. In: Levine B, ed. Principles of Forensic Toxicology. 2nd ed. AACC Press; 2003:187-205

3. DURAGESIC (fentanyl transdermal system. Package insert: Pharmaceutica Products, LP; 2006

4. Baselt RC: Disposition of Toxic Drugs and Chemicals in Man. 10th ed. Biochemical Publications; 2014

Performance

Method Description

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

PDF Report

No

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

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 US Food and Drug Administration.

CPT Code Information

80354

G0480 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FNTSX	Fentanyl and metabolite, CoC, S	81275-0

Result ID	Reporting Name	LOINC®
36302	Norfentanyl	11074-2
36303	Fentanyl	3636-8
36304	Chain of Custody	77202-0