MAYO CLINIC LABORATORIES

Test Definition: FENS

Fentanyl Screen, U

Overview

Useful For
Screening for drug abuse or use involving fentanyl

Method Name
Immunoassay

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, Urine.

For monitoring therapeutic drug levels, order FENTS / Fentanyl, Serum.

Additional Testing Requirements
If urine creatinine is required or adulteration of the sample is suspected, the following test should also be ordered, ADULT / Adulterants Survey, Random, Urine.

Specimen Required
Supplies: Urine Tubes, 10 mL (T068)

Collection Container Tube: Plastic urine container

Submission Container/Tube: 10 mL tube

Specimen Volume: 2 mL

Collection Instructions:

1. Collect a random urine specimen.

2. No preservative.

Forms

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

Reject Due To

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

Specimen Minimum Volume

0.5 mL

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

This procedure uses immunoassay reagents that are designed to produce a negative result when no drugs are present in a natural (ie, unadulterated) specimen of urine; the assay is designed to have a high true-negative rate. Like all immunoassays, it can have a false-positive rate due to cross-reactivity with natural chemicals and drugs other than those they were designed to detect. The immunoassay also has a false-negative rate due to the antibody's ability to cross react with different drugs in the class being screened.

Reference Values

Negative

Screening cutoff concentration: 2 ng/mL

Interpretation

This assay only provides a preliminary analytical test result. A more specific alternative method (ie, liquid chromatography-tandem mass spectrometry: LC-MS/MS) must be used to obtain a confirmed analytical result.

Cautions

Care should be taken when interpreting results since there are many factors (eg, fluid intake and other biologic factors) that may influence a urine test result. It is possible that substances other than those investigated in the specificity study

may interfere with the test and cause false-positive or negative results.

Clinical Reference

1. Gutstein HB, Akil H: Opioid analgesics. In: Brunton LL, Lazo JS, Parker KL, 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, eds. Principles of Forensic Toxicology. 2nd ed. AACC Press; 2003:187-205

3. Baselt RC: Disposition of Toxic Drugs and Chemicals in Man. 8th ed. Biomedical Publications; 2008:616-619

4. 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. 6th ed. Elsevier; 2018:832-887

Performance

Method Description

This assay is a homogeneous enzyme immunoassay technique. The assay will be performed semi-quantitatively. The assay 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 340 nm.(Package insert: Fentanyl Enzyme Immunoassay. Immunalysis Corporation; 10/2016)

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.

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CPT Code Information

80307

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FENS	Fentanyl Screen, U	59673-4

Result ID	Reporting Name	LOINC®
63060	Fentanyl Screen, U	59673-4