MAYO CLINIC LABORATORIES

Test Definition: FENR

Fentanyl Screen with Reflex, Random, Urine

Overview

Useful For

Screening for drug abuse or use involving fentanyl and confirmation of fentanyl if present in the screen

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
FENS	Fentanyl Screen, U	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
FENTU	Fentanyl w/metabolite Conf, U	Yes	No

Testing Algorithm

Testing begins with a screening assay. If the fentanyl screen is positive, then the liquid chromatography tandem mass spectrometry confirmation with quantification will be performed at an additional charge.

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, Random, 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 ADULT / Adulterants Survey, Random, Urine test should also be ordered.

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.

Forms

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

Specimen Minimum Volume

2.5 mL

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	14 days	
	Ambient	72 hours	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

This test 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 for.

Reference Values

Negative
Screening cutoff concentration: 2 ng/mL

Interpretation

If the screen result is negative, fentanyl concentrations above 0.20 ng/mL were not detected.

If the screen result is positive, then confirmation by liquid chromatography tandem mass spectrometry will be performed.

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

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 either false-positive or false-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 Companies; 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. 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, Holstege CP. Clinical toxicology. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, eds Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:chap 43

Performance

Method Description

This assay is a homogeneous enzyme immunoassay technique. The assay will be performed semiquantitatively. 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

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 2 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

80307

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FENR	Fentanyl Screen w/Reflex, U	59673-4

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