Test Definition: FENR

Fentanyl Screen w/Reflex, U

Overview

Useful For

Screening for drug abuse or use involving fentanyl

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

Specimen Required

Collection Container/Tube: Plastic urine container

Submission Container/Tube: Plastic, 60-mL urine bottle

Specimen Volume: 20 mL

Collection Instructions:

1. Collect a random urine specimen.

2. Submit 20 mL in 1 plastic bottle.

3. No preservative.

Additional Information:

1. 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.

2. If urine creatinine is required or adulteration of the sample is suspected, the following test should be requested, ADULU / Adulterants Survey, Urine or ADULT / Adulterants Survey, Urine.

3. For additional information, refer to ADULU / Adulterants Survey, Urine or ADULT / Adulterants Survey, Urine.

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	
	Frozen	14 days	
	Ambient	72 hours	

Clinical and 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 to the antibodyÃ¢â‚¬â„¢s ability to cross-react with different drugs in the class being screened for.

Reference Values

Negative

Screening cutoff concentration:

Fentanyl: 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: Chapter 21: Opioid analgesics. In Goodman and Gilman's: The Pharmacological Basis of Therapeutics. Vol 11. Edited by LL Hardman, AG Gilman. New York, McGraw-Hill Book Company Inc. 2006

2. Kerrigan S, Goldberger BA: Opioids. In Principles of Forensic Toxicology. Second edition. Edited by ZB Levine. Washington DC, AACC Press, 2003, pp 187-205

Performance

Method Description

This assay is a homogeneous EIA 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 (G6PDH) for a fixed amount of specific antibody binding sites. Active enzyme converts NAD to NADH, which results in an absorbance change that can be measured spectrophotometrically at 340 nm.(Package insert: Fentanyl Enzyme Immunoassay. Immunalysis Corporation. Pomona, CA)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday

Analytic Time

Same day/1 day

Maximum Laboratory Time

2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. 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