

**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	Ambient	72 hours	
	Refrigerated (preferred)	14 days	
	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. AACCC 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**

Rochester

**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