

**Core-Clinical Chemistry New Test Notification**

**Fentanyl Screen Urine**

***DMC University Laboratory is pleased to announce that effective March 13, 2024 Fentanyl Screen Urine testing will be available in house.***

**Intended Use:** The Fentanyl assay is a homogeneous Enzyme Immunoassay for Beckman Coulter, Inc. which is intended for the qualitative determination of norfentanyl in human urine at the cutoff value of **5 ng/mL**, when calibrated against norfentanyl. Norfentanyl is the metabolite found and assayed in urine following fentanyl exposures. The assay is designed for prescription use with a number of automated clinical chemistry analyzers. **The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result.** Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

**Results:** The Fentanyl assay is a urine qualitative assay with a cutoff value of **5 ng/mL**, which is used as a reference for distinguishing a preliminary positive from negative. Any result equal to or greater than the cutoff value is considered positive. Anything less than the cutoff value is considered negative.

**\*\*Please remember that the in-house Fentanyl assay is a screening test only and should be followed by confirmation when positive\*\***

- Fentanyl will be offered as:
  - Fentanyl Screen Urine – In-house standalone test
  - Fentanyl Urine Confirmation-NMS Send out (will need to be sent on downtime slip until test is built)
  - Fentanyl Screen with Reflex Confirmation. – In-house screen, if positive a reflex NMS Send out will automatically be ordered.(still in the Build phase)

**Ordering Information:**

Antrim Reporting Title: Fentanyl, Urine  
Antrim unit code:354043

CIS: Fentanyl, Urine  
Antrim Ordering Mnemonics UFEN

Urine Samples: Freshly collected urine specimen (5 mL of Urine sample required).

Transport: Room temperature

Testing schedule: 24/7

Test result: positive/negative

Reference range: Negative

**Technical inquiries:**

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