**URINE FENTANYL QUICK BENCH GUIDE**

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| **Reagent:** | IMMUNALYSIS Sefria Fentanyl Urine Ref. no. 618UR-002:  Compartment A: **EA** (Enzyme Acceptor) & Compartment B: **ED** (Enzyme Donor) | |
| **Onboard stability:** | 28 Days | |
| **Calibrator:** | * Fentanyl Negative Calibrator REF# NEG-600-5 * Fentanyl Urine Calibrator 2 (2ng/mL) REF# 10020-5 * Unopened stability: Until printed expiration if stored at 2-8°C * Opened stability: 60 days if stored at 2-8°C | |
| **Calibration Frequency:** | * **At least every 7 days** * If reagent is a new lot * If QC is out of range or shows unusual trend or shift | * After major preventative maintenance or change of critical instrument component |
| **Controls:** | * **Fentanyl Urine Calibrator 1** (1ng/mL) REF# 10019-5 **(NEGATIVE QC)** * ***(Result must be <2.0 to indicate instrument is correctly producing a NEGATIVE result)*** * **Fentanyl Urine Calibrator 3** (4ng/mL) REF# 10021-5 **(POSITIVE QC)** * ***(Result must be >2.0 to indicate instrument is correctly producing a POSITIVE result)*** * Unopened stability: Until printed expiration if stored at 2-8°C * Opened stability: 60 days if stored at 2-8°C | |
| **Control Frequency:** | * **Every 12 hours included in SET B** * After performing calibration | * To verify instrument operation |
| **Specimen type:** | * Urine – mix well in primary sterile container, then aliquot and centrifuge to remove gross particulate matter. | |
| **Expected results:** | * If result is <2.0 ng/mL: **NEGATIVE** * If result is >2.0 ng/mL: **POSITIVE** | |
| **Result Interpretation by Cerner** | |  |  |  | | --- | --- | --- | | If result is... | And… | Then report result as... | | < 2.0 | Any patient | Negative | | ≥ 2.0 | Patient is < 14 years old  OR  \*Patient is a new mother | Preliminary Positive. Pending Confirmation  **Note:** OPIOID CONFIRMATION [254043] will automatically be reflexed after result verification. Send sample to RRL for confirmatory testing. | | Patient is ≥ 14 years old  AND  \*Patient is not a new mother | POSITIVE. Confirmation upon request only. | | |

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