FENTANYL DRUG TESTING
HOW TO ONBOARD THE LAB AT YOUR HOSPITAL

How can a positive urine fentanyl test save lives?

1. Alert the provider.
2. Alert the patient.
3. Warn friends that they may be exposed and an opportunity to inform them about naloxone.
4. Naloxone Rx given to patient as a prevention measure for repeat overdose.

Goal
To increase the engagement of the medical community to mitigate the increase of fatal Fentanyl overdoses in San Diego County. For more information, click here to view a CAHAN report detailing the statistics and background.

If a clinician is ordering a urine drug test for THC, PCP, Cocaine, Methamphetamine, or Opioids - then the same clinician should be just as interested in a result for Fentanyl because Fentanyl overdose has become a serious public health threat.

How We Will Accomplish This Goal
Include fentanyl testing in conjunction with every Urine Drug Screen test performed by all hospital laboratories in San Diego and Imperial Counties. Fentanyl is a synthetic opioid that does not test positive in standard drug screen. It requires a separate reagent and test.

How to Obtain Rapid Fentanyl Urine Drug Screen
As of December 2020, there is NO FDA 510(k) cleared point of care rapid urine strip test for fentanyl that is part of a drug panel. San Diego leaders sent a letter to FDA requesting emergency use of rapid urine drug tests.

All hospital laboratories with a chemical analyzer can run FDA c510(k) cleared rapid immunoassay fentanyl test. A fentanyl test is not typically included in routine urine drug screen (UDS) and fentanyl is a synthetic opioid that is not detected as part of the opiate urine drug test. The opiate urine drug test is targeted as morphine and codeine.

There are 3 Manufacturers of Fentanyl Immunoassay that are FDA 510K cleared for clinical use.

1. ARK—calibrated to 1 ng fentanyl, cross reacts with norfentanyl metabolite.
   Note: ARK has developed a second-generation assay called the Fentanyl II assay which is replacing the first-generation Fentanyl assay.

Linked resources to distributors and additional information:
Direct from Ark: Fentanyl II Assay Quick Overview
Sekisui Diagnostics: Fentanyl Assay Quick Overview
Seimens: Fentanyl Test Information

The Gold Standard
Fentanyl Testing should be Automatic and Universal. Any time a urine drug test is requested, it should automatically include fentanyl.
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About the San Diego CReDO Committee

The San Diego Community Response to Drug Overdose (CReDO) is a sub-committee of the San Diego County Prescription Drug Abuse Task Force. The CReDO Committee was started to develop a coordinated response to drug overdoses between public health, public safety, and the medical community.

CReDO Committee 2021 Goals

1. Increase utilization of fentanyl testing at San Diego County Hospitals.
2. Implement OD Maps to inform community response to overdoses.
3. Increase community awareness of fentanyl overdoses.

How to obtain rapid Fentanyl urine drug screen (continued)

2. Immunalysis – calibrated to 2 ng fentanyl, does not detect norfentanyl

Linked resources to distributors and additional information:

HEIA Fentanyl Information

3. Lin-Zhi – calibrated to 5 ng of norfentanyl, cross reacts with fentanyl at 3 ng

Linked resources to distributors and additional information:

MedTest Point Scientific Fentanyl Assay Quick Overview

Additional Testing Resource

Thermo Fisher Scientific DRI Fentanyl Assay: Thermos makes an open channel Fentanyl immunoassay for forensic purposes calibrated to 2 mg fentanyl. It is not FDA 501K cleared for clinical use. Link to Thermo Fisher DRI Fentanyl Assay Information.

Specimen Collection

- Collect freshly voided urine in a clean dry container.
- Minimum volume: 2 mL
- Both UDS and Fentanyl tests can be performed using the same urine sample.
- Results for both tests should be available within one hour of receipt in the laboratory.

Information Technology

Moving forward, the development of a gold standard IT solution would allow for a single order by the clinician that would include both random urine drug screen and urine fentanyl as standard of care.