**FENTANYL DRUG TEST**

**HOW TO ONBOARD THE LAB  
AT YOUR HOSPITAL**

**Goal**: To increase the engagement of the medical community to mitigate the increase of fatal Fentanyl overdoses in San Diego County. For more information, [here](https://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/cahan/communications_documents/08-21-2020.pdf) is 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.

**The Gold Standard:** Automatically include urine fentanyl in all orders for random urine drug screen.

**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 can a positive urine fentanyl test save lives?**

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

**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.
   * Distributed by
     + Direct from Ark – purchase the ARK Fentanyl II assay
     + Sekisui Diagnostics
     + Seimens
   * [ARK Diagnostics ARK Fentanyl II Assay Quick Overview](https://www.ark-tdm.com/products/urine-drug-tests/fentanyl-II/pdfs/MKT_20-002_FEN_II_Data_Sheet_Web_Rev02_April_2020.pdf)
   * [Sekisui Diagnostics ARK Fentanyl Assay Quick Overview](https://sekisuidiagnostics.com/wp-content/uploads/2019/03/Fentanyl-Assay-Sales-Sheet-5031.pdf)
   * [Siemens Fentanyl Test Information](https://www.siemens-healthineers.com/en-us/laboratory-diagnostics/assays-by-diseases-conditions/drugs-of-abuse-assays/ark-fentanyl-assay)
2. Abbott/ Immunalysis – calibrated to 1 ng fentanyl, does not detected norfentanyl

[SEFRIA reagent information](https://immunalysis.com/products/sefria/)

1. Lin-Zhi – calibrated to 5 ng of norfentnayl, cross reacts with fentanyl at 3 ng
   * MedTest distributes the Point Scientific Fentanyl assay made by Lin-Zhi

* [MedTest Point Scientific Fentanyl Assay Quick Overview](https://medtestdx.com/wp-content/uploads/2020/08/DS-P3111-01.2-Fentanyl-Sell-Sheet.pdf)
* 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.

* [Thermo Fisher DRI Fentanyl Assay Information](https://www.thermofisher.com/order/catalog/product/10016006#/10016006)

**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.

**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.