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INSIGHT

# Clinical Fentanyl Testing

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The opioid crisis in the United States is exacerbated by both the ubiquity and potency of fentanyl, a synthetic opioid that is up to 50 times stronger than heroin and 100 times stronger than morphine. Fentanyl is commonly mixed surreptitiously with other illicit drugs—such as heroin, cocaine, and methamphetamine—and thus is often taken unknowingly, which has driven an increase in opioid overdoses in recent years. The CDC estimates that there were about 110,000 drug overdose deaths in 2022, and of those, roughly 75% were due to fentanyl or other synthetic opioids. Clinical testing for fentanyl plays an important role in identifying individuals who may have unknowingly ingested fentanyl, allowing for adjustments to clinical treatment, as well as arrangement for appropriate supportive interventions. It also facilitates identifying if fentanyl is a causative agent in an active overdose, even if the patient knowingly took fentanyl, but is non-responsive. On a population level, this testing would facilitate monitoring trends of illicit drug use across and within geographic areas, as well as evaluating relevant health outcomes and their correlation with clinical presentation and treatment.

There has been discussion within the public health community about distribution and use of fentanyl test strips, which are touted for their harm reduction potential, to test samples of street drugs for the presence of fentanyl prior to ingestion or use. Test strips for this purpose do not meet the definition of device under the Federal Food, Drug, and Cosmetic Act (FFDCA), and therefore are not regulated by the Food and Drug Administration (FDA). This type of visually-read fentanyl test strip may not currently be used in *clinical* settings, to guide clinical treatment. For a test to be commercialized and used in clinical settings, it generally needs to receive premarket authorization (e.g., 510(k) clearance) from the FDA and be carried out in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory (or CLIA waived setting for waived tests). FDA has stated that it would welcome an opportunity to work with in vitro diagnostic (IVD) developers to bring fentanyl test strips intended for testing human specimens in clinical settings to market, noting that this is an urgent public health gap.

## Regulation of Clinical Fentanyl Tests

Two regulatory oversight mechanisms are relevant for clinical fentanyl testing: FDA regulation of the tests themselves, if they are commercialized; and CLIA certification of laboratories that carry out this testing. CLIA is also relevant for laboratory-developed fentanyl tests (e.g., LDTs)—that is, for LDTs that are developed and carried out within a single clinical laboratory, which have traditionally been regulated

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differently by the FDA than commercially distributed tests. In addition, CLIA is relevant for waived clinical testing carried out in non-laboratory settings holding a CLIA Certificate of Waiver (CoW). These settings may include, for example, primary care settings, nursing homes, urgent care centers, or community health centers, among others. Settings such as an emergency department, or in some cases emergency medical services (EMS), could carry out waived testing under a hospital laboratory's CLIA certificate.

There are several FDA-cleared, moderately complex commercialized tests for use on automated clinical chemistry analyzers to presumptively detect fentanyl. Current FDA-cleared fentanyl tests are usually immunoassays, a type of test which relies on certain proteins to identify target substances (in this case, fentanyl) and which provide presumptive results, requiring confirmation with more sensitive laboratory methods for a definitive result. Automated clinical chemistry analyzers are commonly found in hospital clinical laboratories, and are used to test for many different drugs in toxicology screening panels. Although FDA-cleared fentanyl tests may be available within a hospital, they are generally not point-of-care tests because they must be carried out in the hospital's laboratory with specialized equipment and personnel rather than at the bedside. For this reason, where fentanyl testing is ordered by the provider in a hospital setting (e.g., in a hospital's emergency department), the results may not always be available in real time, which may lessen the clinical utility of the test.

In late 2022, the FDA cleared a point-of-care assay for fentanyl that relies on a portable instrument. However, this test is categorized as a moderate complexity test under CLIA regulations, and therefore must be carried out in compliance with attendant regulatory requirements (e.g., must be carried out by trained laboratorians). Since the test is instrument-based as opposed to visually-read (an example of a visual read test is a home pregnancy test), this may limit its utility as a point-of-care test, as the cost of the test system is generally going to be higher and ease of use lower.

Currently, there are no CLIA-waived fentanyl tests, although such a test could theoretically utilize a visual read strip technology and would be available in decentralized settings, increasing ease of use and likely decreasing cost and improving access to testing. A CLIA-waived test requires FDA marketing authorization, as well as a CLIA waiver (granted by the FDA pursuant to a CLIA waiver by application) to permit its use in point of care settings holding a CLIA CoW.

# Policy Considerations

Testing for fentanyl in clinical settings may be one component of response to the opioid crisis. The decision to include fentanyl testing in drug screening panels is made by an individual hospital absent requirements in state law. There is variability in uptake of testing by hospitals for multiple reasons, including the delay in test results and the cost of the tests, as well as geographic variation in fentanyl in the illicit drug supply. Development and availability of a low-cost CLIA-waived fentanyl test may increase access to fentanyl testing across many clinical settings of care, including emergency departments. Additionally, education about available clinical testing options may impact uptake.

Increased uptake of clinical testing might be balanced against potential use of the test result by non-healthcare entities (e.g., law enforcement), especially as the test result is presumptive, as well as with issues of equity and health disparities, which might act as possible deterrents to seeking needed health care.

## Author Information

Amanda K. Sarata
Specialist in Health Policy

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