

Immunoanalysis Receives FDA Clearance for SEFRIA™ Fentanyl Urine Drug Screening Test

First-ever 510(k)-cleared fentanyl enzyme immunoassay brings high-performance qualitative screening to a wide range of healthcare settings

POMONA, Calif., July 31, 2017 – Immunoanalysis Corporation, a division of Alere Inc. (NYSE: ALR), today announced that its SEFRIA™ Fentanyl Urine Enzyme Immunoassay has been granted 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the qualitative detection of fentanyl in urine. The SEFRIA™ Fentanyl Urine Enzyme Immunoassay is the first ever 510(k) cleared fentanyl enzyme immunoassay and is the first analyte utilizing Immunoanalysis' proprietary SEFRIA™ technology.

Previously, fentanyl immunoassay tests were only available for forensic testing. With the clearance of the SEFRIA™ Fentanyl Urine Enzyme Immunoassay, fentanyl drug screening is now available for CLIA (Clinical Laboratory Improvement Amendments) certified reference laboratories, hospitals, physician offices and other healthcare settings that perform moderate complexity testing.

“The availability of an FDA-cleared fentanyl immunoassay enables more reference and hospital laboratories to conduct precise qualitative screening, which is a key strategy in stemming the alarming increase in misuse and abuse of fentanyl,” said Kathy Miller, Vice President, Sales and Marketing, Immunoanalysis Corporation. “The SEFRIA fentanyl urine drug screening test rounds out our offering of technologically advanced assays for detecting prescription and illegal drugs of abuse by providing clinicians and toxicologists with a relevant menu of FDA-cleared opiate and opioid tests.”

The illegal use of fentanyl is a large part of the U.S. opioid abuse epidemic. According to the Centers for Disease Control and Prevention (CDC), death rates from synthetic opioids such as fentanyl increased by 72.2 percent from 2014 to 2015, due in part to its low cost and high potency, which can be up to 50 times greater than heroin and 100 times greater than morphine. Drug overdoses associated with fentanyl are often linked to unintentional ingestion when fentanyl is laced in street-sold heroin or cocaine, which significantly amplifies its potency.¹

About the SEFRIA™ Fentanyl Urine Enzyme Immunoassay

The SEFRIA™ Fentanyl Urine Enzyme Immunoassay detects the presence of fentanyl in urine with a cutoff of 1 ng/mL. In clinical performance studies, testing with the SEFRIA™ Fentanyl Urine Enzyme Immunoassay compared favorably to liquid chromatography-mass spectrometry (LC-MS) analysis in both sensitivity (identification of positive results) and specificity (identification of negative results).

About Immunalysis

Immunalysis Corporation, an Alere group company, is committed to identifying and meeting the demands of the toxicology marketplace. Since 1976, Immunalysis has developed a range of toxicology testing solutions for use in laboratory test facilities, including ELISA kits for forensic laboratories, drug assays, applications for new matrices and new immunoassay formats. For more information on Immunalysis, please visit <https://immunalysis.com/>.

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¹ Centers for Disease Control and Prevention (CDC). Synthetic opioids data.
<https://www.cdc.gov/drugoverdose/data/fentanyl.html>; accessed June 19, 2017.

SEFRIA is a trademark of Advance Immunoassays Inc.