

FDA-cleared fentanyl enzyme immunoassay, 11/17

November 2017—Immunalysis Corp. announced that its Fentanyl Urine Sefria Drug Screening Kit has been granted FDA 510(k) clearance for the qualitative detection of fentanyl in urine. It is the first analyte on the Sefria diagnostic platform.

The kit detects the presence of fentanyl in urine with a cutoff of 1 ng/mL. In clinical performance studies, testing with the fentanyl urine Sefria kit compared favorably to liquid chromatography-mass spectrometry analysis in both sensitivity and specificity.

[Immunalysis Corp.](#), 909-482-0840