

ARK™ Fentanyl Assay for the Siemens Viva-E® Automated Clinical Chemistry Analyzer

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Background: Fentanyl is an addictive potent synthetic opioid widely used for chronic pain management and surgical anesthesia. The drug, 50-100 times more potent than heroin, is available as injectable solution for surgical anesthesia and transdermal patches at concentrations of 25, 50, 75, 100 mg/h for chronic pain management. Fentanyl has been sold to drug users and resulted in thousands of overdoses. Since fentanyl is present in biological samples at very low concentrations, administration and monitoring of fentanyl present a great challenge in clinical and forensic laboratories. There is an urgent need for a high throughput screening method for the detection of fentanyl in human urine.

Methods: The ARK™ Fentanyl Assay is a liquid stable, homogeneous enzyme immunoassay, intended for the qualitative and/or semi-quantitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL on automated clinical chemistry analyzers. Two reagents, calibrators (0.0, 1.0, 2.0, 4.0, and 10.0 ng/mL) and controls (0.5 and 1.5 ng/mL) compose the test system. The 1.0 ng/mL Calibrator is the Cutoff for distinguishing “positive” from “negative” samples. Precision over 5 days, histogram overlap analysis of Control and Cutoff concentrations, recovery and specificity were evaluated on the Siemens Viva-E® benchtop analyzer.

Results: Semi-quantitative precision was determined for 0.5 (8.3%CV), 1.0 (5.7%CV) and 1.5 (5.8%CV) ng/mL. Qualitative determination of fentanyl in Low and High controls did not overlap with the Cutoff by histogram analysis. Recovery of fentanyl ranged from 94.2% (1.75 ng/mL) to 111.5% (4.0 ng/mL). Norfentanyl metabolite tested positive at 300.0 ng/mL. Other nonanalogous opiates were not crossreactive. The sensitivity (true positive, 100 samples) and specificity (true negative, 50 samples) was 97.1% and 96.2%, respectively, versus LC-MS/MS (fentanyl cutoff 0.2 ng/mL).

Conclusions: ARK Fentanyl Assay determines fentanyl in human urine accurately and sensitively in either semi-quantitative or qualitative modes with fast turn-around times. Detection of fentanyl use in pain management, compliance or misuse/abuse with a superior cutoff concentration for a screening assay is an important new addition to clinical chemistry.