Clinical Impact of Implementing Urine Fentanyl Testing in A Safety Net Healthcare System

Manar S[1], George B[1], Huang R[1,2]

[1] Department of Pathology and Laboratory Medicine, Harris Health Ben Taub Hospital, Houston, TX, USA

[2] Department of Pathology & Immunology, Baylor College of Medicine, Houston, TX, USA

Background: Given its high potency and prevalence, fentanyl and its analogues pose unique challenges in treatment management of patients with opioid use disorder (OUD). Fentanyl screening has become essential for clinical practice in selecting and initiating appropriate protocol from various treatment options available for OUD. The study aims at evaluating the performance of the LZI assay, and the clinical impact of implementing urine fentanyl screening in a safety net healthcare system.

Methods: The LZI assay was implemented on Beckman AU 5800 analyzer, with a cutoff value of 5 ng/mL for norfentanyl. The SEFRIA assay performed in a reference laboratory has a modified cutoff value of 2 ng/mL for fentanyl. During the initial validation study, a qualitative comparison study was performed using a total of 42 deidentified consecutively collected urine samples. The positive rate and turn-around-time (TAT) between the in-house LZI assay and the send-out SEFRIA assay were also compared for a period of seven months before (2023 Jan. to Jul.) and after (2023 Sep. to 2024 Mar.) the implementation of LZI assay.

Results: LZI and SEFRIA assay agreed on 35 out of 42 samples (10 positive and 25 negative). The seven discrepant results were all negative on SEFRIA but positive on LZI, and later confirmed positive by LC-MS (send-out to a reference laboratory). The false negative results observed on SEFRIA were likely due to a higher cutoff value of 2 ng/mL instead of 1 ng/mL. Overall, there was no false positive result observed by LZI assay in this study and 17 out of 18 positive samples were correctly identified, with a calculated sensitivity of 94%, specificity 100%, positive predictive value 100% and negative predictive value 96%. After implementation, the urine fentanyl screening test volume has increased 1.3 folds, with significantly improved median TAT (2.2 days to 73 minutes). The average positive rate was increased from 9.5% to 15.3%, due to the increased sensitivity.

Conclusions: Overall, the Beckman AU LZI fentanyl assay has shown acceptable performance for clinical screening and the implantation has led to faster and increased detection of fentanyl cases in OUD patients.

Key Words: Fentanyl, Norfentanyl, Immunoassay