LABQUALITY DAYS

Development and Evaluation of Drug Testing in Urine Using LC-MS/MS in a Clinical Laboratory

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Introduction

The rising prevalence of drug use in South Korea has led to an increased demand for accurate and efficient drug testing in clinical and forensic laboratories. Liquid chromatography-tandem mass spectrometry (LC-MS/MS) has become a gold standard for drug testing due to its high sensitivity, specificity, and ability to detect a wide range of substances. This study focuses on the development and evaluation of an LC-MS/MS-based method using Waters Acquity UPLC and Xevo TQ-XS systems, alongside Chromsystems' MassChrom® Drugs of Abuse Testing in Urine reagent kit, to ensure reliable detection of 21 commonly abused substances. The method's clinical utility in routine testing was evaluated through comprehensive performance assessments.

Approach

Urine samples were analyzed using a Waters Acquity UPLC system coupled with the Xevo TQ-XS tandem mass spectrometer and Chromsystems' MassChrom® Drugs of Abuse Testing in Urine reagent kit. The test targeted 21 substances across categories, including amphetamines (methamphetamine, amphetamine), ecstasy derivatives (MDMA, phencyclidine, MDA), ketamines (ketamine, norketamine), cocaine derivatives (cocaine, benzoylecgonine), opioids (morphine, fentanyl, codeine, hydrocodone, oxycodone, dihydrocodeine, hydromorphone, oxymorphone, LSD, 6-MAM), and cannabis derivatives (11-hydroxy-THC, 11-nor-9-carboxy-THC). Chromsystems' MassCheck® Drugs of Abuse Testing Urine Controls were employed for accuracy and precision assessment. Separation was achieved on an ACQUITY UPLC HSS PFP column (2.1 × 50 mm, 1.8 µm) with a binary gradient of 0.1% formic acid in water and acetonitrile. The Xevo TQ-XS was operated in MRM mode using electrospray ionization. The evaluation included assessments of accuracy, precision, carryover, linearity, recovery, LOD, and LOQ.

Outcome and Conclusions

The method demonstrated high specificity and sensitivity across the 21 targeted substances. Calibration curves for all analytes were linear over the tested concentration ranges, with correlation coefficients (R^2) exceeding 0.99. The limits of detection (LOD) ranged from 0.02 to 2.80 µg/L, while the limits of quantification (LOQ) ranged from 0.17 to 20.81 ng/mL, depending on the substance. Precision, evaluated through intra- and inter-day variability, was within acceptable limits (RSD ≤ 15%), with relative standard deviations below 4% for all analytes.

Accuracy, assessed using Chromsystems' MassCheck® Drugs of Abuse Testing Urine Controls, was consistently within ±10% of the nominal concentrations. Carryover was found to be below 0.1% for all substances. The method demonstrated robust performance in detecting amphetamines, ecstasy derivatives, ketamines, cocaine derivatives, opioids, and cannabis derivatives in random urine samples. The method's comprehensive evaluation ensured reliable performance for forensic and clinical toxicology applications.

LC-MS/MS-based drug confirmation testing in clinical laboratories offers excellent sensitivity and specificity, enabling rapid detection of multiple drugs. This method shows high clinical potential for accurate and timely drug abuse diagnosis, contributing to more effective monitoring of drug use in South Korea.