DIAGNOSTIC ACCURACY OF AN IMMUNOMETRIC METHOD FOR TOXICOLOGICAL SCREENING ON URINARY MATRIX ACCORDING TO CLSI EP12-A2 GUIDELINE

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Background: Urine immunoassay screening method is the most common approach to detect the presence of several illicit drugs and potential substance abuse concerns due to its ease and rapid sampling protocol. However, its efficacy is compromised by inherent constraints arising from false-positive (FP) and false-negative (FN) results. The latter can lead to serious medical and social consequences if the results are not confirmed by a reference method such as HPLC-MS/MS. The present study aims to evaluate the sensitivity (SE) and specificity (SP) performances of six toxicology immunoassays in urine samples, using a homogeneous enzyme immunoassay method (Emit® II Plus) applied to Atellica® Solution. **Methods:** Diagnostic SE and SP evaluation was conducted using a total of 170 urine specimens collected by our laboratory to obtain at least 10 positives, and 10 negative samples for each tested analyte: Amphetamine, Ecstasy, Methadone, Cannabinoid, Cocaine, and Opiate. For each test, analytical session acceptability was assessed by internal quality controls, whose maximum acceptable imprecision was ± 15%. Furthermore, all results were confirmed by HPLC-MS/MS method using Chromsystems® MassTox® Drugs of Abuse Testing in Urine kit. **Results:** For all tests, SE was 100% while SP was 100% for Amphetamine, Cocaine and Opiate, except for Cannabinoid (99,3%) due to the presence of 2 FP, Methadone (98,6%) linked to 1 FP, and Ecstasy (SP 99,4%) with 1 FP probably due to the presence of Quetiapine (5107 µg/L) which belong to structurally unrelated compounds of MDMA capable to produce a positive result, as indicated by cross-reactivities manufacturer's document. **Conclusions:** For all immunoassays, the study exhibits good diagnostic accuracy for urine drug screening. Data meet the requirements adopted by the laboratory and for all analytes SE and SP are better than those of the manufacturer except for Cannabinoids because the SP of our study is slightly lower than the manufacturer's SP (100%). In these cases, HPLC-MS/MS technology significantly reduces the number of false positive results. **Key Words:** Drugs of Abuse Testing, Urine Screening.