K49 Evaluation of the Lin-Zhi International Opiate Enzyme Immunoassay for the Detection of Opiates in Urine

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After attending this presentation, attendees will learn the performance characteristics of the Lin-Zhi Opiate Assay, as they apply to urine samples and the availability of an alternate vendor for an opiate EIA method.

This presentation will impact the forensic community and/or humanity by reviewing current methods for opiate screening, with the characteristics of an alternate vendor to those currently available. At a minimum, expand the current available information on how robust current opiate methodologies are.

The Opiate Enzyme Immunoassay [OEI] (Lin-Zhi International, Inc., Sunnyvale, CA) for the detection of opiates in urine. The Lin-Zhi assay is based on competitive antibody binding between opiates in urine and glucose-6-phospahate dehydrogenase labeled morphine. The assay is calibrated with morphine.

The Lin-Zhi OEI was evaluated by testing 1212 urine specimens. All specimens were tested on an ADVIA 1200 Chemistry System auto- analyzer (Bayer Health Care, Diagnostics Division, Tarrytown, NY) with calibrators containing 0, and 300 ng/mL (cut-off calibrator) of morphine. Controls containing 0 ng/mL of morphine, 225 ng/mL (negative control) and 375 ng/mL (positive control) of the cut-off calibrator (Bio-Rad Laboratories, Irvine, CA) were analyzed with each batch of samples. All urines were then analyzed by a GC/MS for opiates at a cut-off concentration of 100 ng/mL.

Approximately, 58 % (711) of the 1212 specimens screened positive by the Lin-Zhi assay. GC/MS confirmed the presence of an opiate at >100 ng/mL, in 692 of the 711 specimens, indicating 19 false positive results. However, 88 specimens screening negative were found to contain an opiate above the GC/MS cut-off of 100 ng/mL (78 oxycodone and/or oxymorphone). Opiate concentrations in the specimens as determined by GC/MS, ranged from < 100 - >50,000 ng/mL. From the presented study, the sensitivity of the Lin-Zhi OEI was 0.887 and the selectivity 0.956. Testing at 1,000 mg/mL of other drugs of abuse or their metabolites such amphetamine, benzodiazepines, benzoylecgonine, morphine and phencyclidine, the Lin-Zhi assay demonstrated no cross reactivity. The within-run precision of the Lin- Zhi assay was determined by the absorbance rates of the negative and positive controls was CV£ 5% (n=8); while the between-run precision of the controls was CV=<5% (n=11). The assay was linear from 25% to 150% of cut-off concentration. The Lin-Zhi CBI provides a precise, reliable method for the detection of opiates in urine specimens.

Enzyme Immunoassay, Opiates, Urine Drug Testing

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