

## Evaluation of the DrugCheck® 9 On-Site Immunoassay Test Cup According to a Standard Method Validation Protocol

**E. Howard Taylor<sup>1\*</sup>, Pat Pizzo<sup>2</sup>**

<sup>1</sup>National Toxicology Specialists 732 Fesslers Lane, Nashville, TN 37210,

<sup>2</sup>Kroll Laboratory Specialists, 1111 Newton St., Gretna, LA 70053

There is currently no standard method evaluation protocol for “point-of-care” (POC) drug testing devices. We evaluated the DrugCheck® 9 cup, a qualitative visually read, competitive binding, immunoassay cup that measures 9 analytes, amphetamine, methamphetamine, carboxy – THC, cocaine metabolite, PCP, opiates, benzodiazepines, and barbiturates and tricyclic antidepressants. The study was performed according to the recent National Laboratory Certification Program (NLCP) guidelines for validating a laboratory-based immunoassay. The study included a linearity challenge with 5 replicates at concentrations 0, 25%, 50%, 75%, 100%, 125% and 150% of the cutoff and also determination of the limit of detection (LOD). At 75% of the cutoff, all replicates of each analyte were positive with the exception of morphine. At 50% of the cutoff, all replicates for barbiturates, cocaine metabolite, methamphetamine, and tricyclic antidepressants were positive, while all replicates at 50 % of the cutoff for benzodiazepines, opiates, and Carboxy-THC were negative. Amphetamine and PCP were mixed (2 positive and 3 negative) at 50% of the cutoff. Only barbiturates were positive at 25% of the cutoff, while all of the remaining analytes were negative for all 5 replicates. All analytes were negative for all replicates in drug free urine. All replicates above the cutoff were positive. Interference (specificity) studies were included to evaluate the cross reactivity of common structural analogs or others purported to interfere with the assay. Ephedrine, pseudoephedrine, chloroquine, diphenhydramine, phenylpropanolamine methylphenidate. D-methamphetamine and L-methamphetamine, MDMA, MDEA produced no interference with the amphetamine assay, indicating a very specific antibody to amphetamine. Only phentermine and MDA showed a positive result at 1000 ng/mL. The same group of sympathomimetic amines (including phentermine) showed no interference with the methamphetamine assay. MDMA produced a positive at 1000 ng/mL. Oxycodone, oxymorphone, tramadol, meperidine, nor-meperidine, nor-morphine, nor-codeine, and buprenorphine showed no interference at 50,000 ng/mL in the opiate assay. Codeine produced a positive result at 300 ng/mL (the cutoff), while hydromorphone and hydrocodone produced a positive result at 5000 ng/mL.

Out of 136 donor parallel comparisons with the CEDIA® laboratory immunoassay and GC/MS (50 Negatives and 86 Positives) there were 133 out of 136 in agreement (97.8%). There was agreement for all analytes except for 2 opiates which were shown to have very low levels of total morphine by GC/MS at 346 and 351 ng/mL, respectively, and also one specimen that was positive for benzodiazepines which approached the LOD of the GC/MS assay. These results indicate a high degree of correlation, greater sensitivity with extended linearity below the cutoff when compared to the laboratory based immunoassay, and improved specificity over previously evaluated POC testing devices.