**Introduction**

**Background**

Three separate homogeneous immunoassays are commercially available for the detection of Morphine/Codeine, Hydrocodone/Hydromorphone and Oxycodone/Oxymorphone. A new High Sensitivity (HS) Opiates Assay for human urine screening has been developed by ARK Diagnostics, Inc. The ARK™ HS Opiates Assay is designed to detect Morphine/Codeine, Hydrocodone/Hydromorphone and Oxycodone/Oxymorphone in a single assay when calibrated with dihydrocodeine at a cutoff level of 300 ng/mL. The benefit provided by this assay is the consolidation of three assays into one, thereby minimizing cost, labor, and eliminating the need for multiple channels on the analyzer. The assay consists of ready-to-use liquid reagents that provide qualitative and semi-quantitative results. The data presented in this study was generated on the Beckman Coulter AU680 System.

**Methods**

The ARK™ HS Opiates Assay is a liquid stable, homogeneous enzyme immunoassay, intended for the qualitative and/or semi-quantitative determination of opiates in human urine at levels that span the assay range (50-4000 ng/mL). The ARK HS Opiates Assay on the Beckman Coulter AU680 System is a sensitive opiates screening method for urine specimens at a cutoff level of 300 ng/mL, providing qualitative and semi-quantitative analysis of morphine, codeine, hydrocodone, hydromorphone, oxycodone, and oxymorphone in a single assay.

**Analytical Recovery and Linearity**

Analytical recovery and linearity were performed by adding concentrated dihydrocodeine into drug-free negative urine. Test sample concentrations were 50, 100, 225, 375, 1500 and 3000 ng/mL. Semi-quantitative percent nominal values ranged from 91.7 % to 103.2 %.

**Specificity – Target Opiate Cross-reactants**

The seven listed opiates were prepared in drug-free negative urine. Their corresponding concentration approximately equivalent to the 300 ng/mL dihydrocodeine cutoff was investigated using a dose-response curve.

**Specificity – Opioid Cross-reactivity**

All opioid compounds tested were added to drug-free negative urine. If 100,000 ng/mL produced a positive result, their corresponding concentration approximately equivalent to the 300 ng/mL dihydrocodeine cutoff was investigated using a dose-response curve.

**Limit of Blank and Detection**

The following characteristics were determined according to CLSI EP17-A2. The LOD and LoQ were evaluated by testing 60 replicates of drug-free negative urine (BLANK) and 60 replicates of 10:00 mg/mL dihydrocodeine. The LOD was determined using the non-parametric method. The LoQ was calculated using the following formula, where μ is the mean of the blank measurement, and SD refers to the standard deviation of the blank measurement. The constant used to calculate the LoQ is 1.645/(1-(1/4*f )), where f is the degrees of freedom of the estimated standard deviation. In this case, a value of 1.673 was used to calculate LoD.

Limit of Detection (LoD) = μ + 1.673*SD

The grand mean, root mean square standard deviation (RMS SD), LoQ, and LoD results are summarized in the table below.

**Conclusions**

The ARK HS Opiate Assay on the Beckman Coulter AU680 System is a sensitive opiates screening method for urine specimens at a cutoff level of 300 ng/mL, providing qualitative and semi-quantitative analysis of morphine, codeine, hydrocodone, hydromorphone, oxycodone, and oxymorphone in a single assay.

**REGULATORY STATUS**

In Development