Implementation of an Oral Fluid Drug Testing Program in Alabama: An Evaluation of Draeger DT5000, Alere DDS2, and Randox MultiSTAT with LC/MS/MS Confirmation

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Background/Introduction: Oral fluid (OF) drug testing offers a rapid, non-invasive collection requiring no medical personnel. An OF specimen can be taken in close time proximity to a traffic stop and the presence of parent drugs in OF reflects recent drug use. These advantages make OF testing attractive to DUI/D prevention and roadside drug screening. With the continued evolution of OF testing and drug screening devices, it is important to evaluate this technology and these devices for fit for purpose and use prior to implementation of a statewide OF testing program.

Objective: The Alabama Department of Forensic Sciences (ADFS) and the Alabama Drug Recognition Expert (DRE) program conducted a proof of principle study set forth to validate the use of OF screening in the field by officers and OF confirmation testing at ADFS.

Methods: Approximately 100 drug users from the Clara White Mission in Jacksonville, FL volunteered for this study. The study was conducted in two cohorts: June 2016 and May 2017. The following drugs/drug classes were compared: cocaine, cannabinoids, opioids, methadone, benzodiazepines, methamphetamine, and amphetamine. Randox screens for 21 targets simultaneously, but only the aforementioned targets were assessed. We investigated the accuracy, sensitivity, specificity, positive and negative predictive values, false negative and positive rates of the following OF screening devices/instruments: Draeger DT5000, Alere DDS2, and Randox Evidence MultiSTAT. The MultiSTAT was only evaluated in the May 2017 cohort (n=50). We collected OF, blood, and urine confirmation specimens that were subsequently screened by immunoassay and quantitated by LC/MS/MS. OF samples collected in Quantisal collection devices were extracted using dispersive pipette extraction (DPX) tips and analyzed on an Agilent 6460 Triple Quad. DRE evaluations were performed to assess subject behavior and impairment.

Results: Time to test completion was less than 10, 5, and 17 minutes for Draeger, Alere, and Randox devices, respectively. All instruments demonstrated >90% for accuracy, sensitivity, specificity, positive and negative predictive values for cocaine, opiates, methadone, and cannabinoids with the following exceptions. The Alere DDS2 and Draeger DT5000 had sensitivities less than 90% for opioids and cocaine, respectively. The Randox MultiSTAT had inferior methadone and cannabinoid sensitivity. The devices displayed overall poor sensitivity to the benzodiazepine drug class (50-75%). The MultiSTAT was the exception demonstrating excellent sensitivity (>90%). There were only two methamphetamine positive subjects and no amphetamine positives. Approximately 45% and 40% of participants tested positive for cannabinoids and cocaine, respectively. Median oral/blood (OF:BL) drug concentration ratios were consistent with those published in the literature with low ratios (<1.0) for benzodiazepines and higher ratios (>1.0) for other targets evaluated. However, OF:BL ratios were heavily impacted by recent use and oral cavity contamination.

Conclusion/Discussions: This is the first study to evaluate the Randox Evidence MultiSTAT as an OF screening instrument in the field. The three OF screening instruments evaluated proved to be fit for purpose with comparable performance. However, advantages and potential areas of improvement were noted. The Randox MultiSTAT outperformed other devices in benzodiazepine sensitivity by using two antibodies tailored to this drug class. On the other hand, the MultiSTAT struggled with cannabinoid sensitivity, most likely due to using carboxy-THC as their immunoassay target. However, their software allows for lowering of the cutoff threshold which improves performance for this drug class. The Draeger DT5000 offers the advantage of testing for methadone over the Alere DDS2 (as does the Mult-stat). The Alere DDS2 received excellent officer feedback for ease of use and portability in the field. In summary, the OF drug screening instruments evaluated proved to be fit for purpose with comparable performance. Roadside OF screening combined with OF and/or blood confirmation testing offers law enforcement tools and services to improve DUI/D detection and improve highway safety. In particular, these devices are great tools to complement DRE programs by enhancing the probability of obtaining blood (or OF) search warrants in suspected DUI/D cases, especially in rural areas lacking the presence of DREs.

Keywords: Oral Fluid, Draeger DT500, Alere DDS2, Randox MultiSTAT

PLATFORM