K53 Laboratory Based Evaluation of Commercially Available Oral Fluid Testing Devices

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After attending this presentation, attendees will be able to assess sensitivity and specificity, and detection thresholds of several commercially available oral fluid testing devices designed for use in the field, as well as issues with respect to their readability, robustness, and ease of use.

This presentation will impact the forensic science community by highlighting factors to be considered when selecting field-based testing devices for the presence of drugs in oral fluid.

Oral fluid is increasing in popularity as a biological matrix for drug testing in the workplace, probations and parole, and traffic law enforcement.

Three devices were selected for comparison with the Drager® DT5000 7-panel, based on their price, general availability, and advertised ease of use. The devices evaluated were the Oral Fluid 6 Drug Test (Oral Q®), Alere iScreen®, and Xalex™. Nine blind controls containing a total of 12 drugs representing the classes of amphetamines, MDMA, opiates, benzodiazepines, PCP, cocaine, THC, methadone, oxycodone, and dextromethorphan were prepared in synthetic oral fluid. An open positive (100ng/mL) and drug-free oral fluid negative control were also used.

The concentrations of the target analyte were selected so evaluations could be made below the listed cutoff concentration, near the cutoff concentration, and significantly above the advertised cutoff of the device.

Each device was evaluated in triplicate for each control group with the results being independently verified by two different individuals. The testing protocol used was specific to the device, following a protocol based on the device instructions. In devices with a sorbent sponge, the sponge was saturated with the oral fluid control mixture and subsequently tested as directed. After the verification of the results, the performance of each device was evaluated by drug class and how the device performed around its stated cutoff concentration. For each device, the sensitivity, specificity, and accuracy were assessed.

Positive results were scored as true positives if the analyte was present in the control, irrespective of its concentration. With all negative results, the concentration in the control was compared to the manufacturer's cutoff concentrations and determined if the result was a true positive or true negative relative to that cutoff.

The Drager® DT5000 was an instrumented test with an electronic analyzer generating a printed result. The remaining devices were visually read. These three had cannabinoid tests that were targeted to carboxyTHC which is known to be excreted at very low concentrations in oral fluid. The Xalex™ and Alere iScreen6 did not give a positive cannabinoid result at 100ng/mL of THC. The OralQ gave false positive results for cannabinoids in every negative control. The Drager® DT5000 did not detect the presence of THC at the positive control concentration of 7ng/mL, in spite of its published cutoff of 5ng/mL. Controls at 15ng/mL all tested positive.

The Drager® DT5000 had lower cutoffs for benzodiazepines, methamphetamine, and opiates. The OralQ® had an elevated cutoff for benzodiazepines at 50ng/mL. The Xalex™ and Alere iScreen6® devices did not include a benzodiazepine test. The Drager® DT5000 gave positive results for benzodiazepines at its advertised cutoff of 15ng/mL.

The sensitivity and specificity results for the Xalex™ and iScreen6® did not include scoring from the THC panel because the target analytes were THC metabolites, which would not be expected at the advertised cutoff in oral fluid. Absent this consideration, the Xalex™ device had sensitivity, specificity, and accuracy of 100%, and the Alere iScreen6® had 95% sensitivity, 93% sensitivity, and 94% accuracy. The OralQ® had the lowest sensitivity at 65%, specificity of 86%, and accuracy of 75%. It generated 16 false negative results relative to its advertised cutoffs across several drug classes. The Drager® DT5000 had 97% sensitivity, 100% specificity, and 98% accuracy.

Based on this initial evaluation, it was concluded that the Drager DT5000 gave the best overall performance and lacked the issue of subjectivity in reading the test strips. This laboratory-based assessment, however, indicated it had higher sensitivity for THC than advertised. Additional devices are in the process of being evaluated.

DUID, Oral Fluid, Field Test

 ** Presenting Author*