K44 Alere™ DDS®2 Mobile Test System Screening for Delta-9-Tetrahydrocannabinol (THC) With Oral Fluid Confirmation by Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)

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After attending this presentation, attendees will understand the use of the Alere™ DDS®2 Mobile Test System as it pertains to field screening for THC in comparison to concentrations determined by confirmation using LC/MS/MS in oral fluid samples collected from human subjects at a music festival.

This presentation will impact the forensic science community by assessing the feasibility of using a field-deployable testing device for the detection of THC. On-site testing devices may be employed for roadside drug screening in subjects suspected of impaired driving; therefore, reliable results are imperative for the employment and use of these devices.

Oral Fluid (OF) is increasingly used as an alternative to blood or urine testing for determination of drug use in impairment cases. OF is advantageous in comparison to blood and urine due to non-invasive collection procedures and the ability for the sample to be collected at the time of incident. The collection and analysis of in the field has become possible with the DDS®2 Mobile Test System.

The objective of this study was to compare the field results for the DDS®2 Mobile Test System to a laboratory-based LC/MS/MS confirmatory analysis with respect to detection of THC in human subjects. As part of a larger Institutional Review Board (IRB) -approved study, two OF samples were collected from participants at a music festival in Miami, FL. One OF sample was field tested using the DDS®2, and a confirmatory OF sample was collected using Quantisal™ oral fluid collection devices. The DDS®2 OF sample was field tested for drugs of abuse including amphetamine, methamphetamine, benzodiazepines, cocaine, opiates, and, specifically with respect to this study, cannabis (THC), at a cutoff of 25ng/mL.

LC/MS/MS confirmatory analysis was performed using an Agilent® 1100 series liquid chromatograph coupled to an Agilent® 6430 tandem mass spectrometer. Calibration and control samples were prepared in pooled, expectorated, THC-free, OF and diluted in Quantisal™ buffer to match the composition of field-collected OF samples. The method was validated according to the Scientific Working Group for Forensic Toxicology (SWGTOX) guidelines for quantitative methods. The LC/MS/MS Limit Of Quantitation (LOQ) was 2ng/mL and the Limit Of Detection (LOD) was 1ng/mL.

Of the 628 participants who provided Quantisal™ OF samples, THC was detected in 231 subjects (36.8%), with THC being over the LOQ (2ng/mL) in 190 subjects (30.3%). The mean and median OF THC concentrations were 57.1 and 10.8 ng/mL, respectively, and ranged from 1.0ng/mL to 1,473ng/mL; 144 (22.9%) samples were positive for THC between 1ng/mL, the LC/MS/MS LOD, and 25ng/mL, the cutoff of the DDS®2; 125 participants provided DDS®2 OF samples that were field tested and the results were as follows: 27 (22.1%) field tested positive for THC, 92 (75.4%) field tested negative for THC, and 6 (2.5%) field tested invalid for THC.

Positive field-test results were confirmed by LC/MS/MS, with 27 (100%) being positive for THC at an LC/MS/MS threshold of 5ng/mL, 23 (85.2%) at 10ng/mL, 21 (77.8%) at 15ng/mL, and 18 (66.7%) at 25ng/mL. Of the 92 DDS®2 THC negative results, 89 (96.7%) were confirmed negative, with THC concentrations less than the DDS®2 cutoff of 25ng/mL. Of the 89 confirmed negatives, 65 (73.0%) were negative below a confirmation threshold of 1ng/mL, while 24 of the screened negative results tested positive for THC between the LOD of 1ng/mL and the DDS®2 cutoff of 25ng/mL. Three samples (3.4%) were determined to be false negatives, with DDS®2 field tests producing a negative result, but with LC/MS/MS confirmation results being greater than 25ng/mL (25.4ng/mL, 26.6ng/mL, and 42.3ng/mL).

For detection of THC in this sample population, the DDS®2 displayed sensitivity, specificity, Positive Predictive Value (PPV), and accuracy as displayed in Table 1 at LC/MS/MS thresholds of 25ng/mL (the DDS®2 published threshold) and 1ng/mL (the LC/MS/MS LOD). Using a cutoff concentration of 25ng/mL resulted in fewer of the cannabis-using subjects being identified (18% positivity vs. 45% positivity at 1ng/mL).

Table 1	25ng/mL LC/MS/MS Cutoff	1ng/mL LC/MS/MS Cutoff
Positivity Rate (n=119)	18% (n=21)	45% (n=54)
DDS®2 Sensitivity	90%	50%
DDS®2 Specificity	100%	100%
DDS®2 PPV	100%	100%
DDS®2 Accuracy	98%	77%

These results from cannabis-using subjects demonstrate the value of field-based OF testing and illustrate the significance of the cutoff concentration with respect to performance evaluation and detection of drug use.

Oral Fluid, THC, Alere™ DDS®2