U.S. Department of Transportation
National Highway Traffic Safety Administration

TRAFFIC TECH
Technology Transfer Series

NHTSA

DOT HS 812 859

April 2021

Evaluation of On-Site Oral Fluid Drug Screening Devices

Oral fluid has emerged as a popular alternative matrix for drug detection in criminal justice, workplace, and impaired driving populations. The detection windows for many drugs in oral fluid are similar to those in blood. The advantages of using oral fluid specimens over blood and urine are oral fluid can be collected using non-invasive sample collection techniques that eliminate the need for collection facilities or same-sex observation. They also have minimal potential for adulteration and contamination, which help to save time and resources. Furthermore, oral fluid samples can be collected proximate to the time of driving, allowing for better correlation between signs and symptoms of impairment observed at the time of arrest as compared to any drugs detected in a biological sample collected later. Limitations of oral fluid as a sample matrix include the fact that drug concentrations cannot be related to a specific degree of impairment in the driver, nor can they be used to predict blood drug concentrations, but neither can any other type of test.

The increased popularity of oral fluid as a biological matrix in drug screening has led to the development of an increasing number of portable oral fluid drug-testing devices designed for use in the field, which vary in applicability and quality. There is no program to evaluate the suitability of point-of-contact oral fluid devices for field use in impaired driving cases in the oral fluid drug testing market.

The purpose of this study was to evaluate field oral fluid drug testing devices to assess their accuracy, reliability, performance to manufacturer specification, susceptibility to interference, and resistance of the consumables to extremes of temperature and humidity. The devices were selected based on them having appropriate tests for several drug categories including, at a minimum, cannabinoids, opiates, cocaine/metabolite, methamphetamine/amphetamine, and in some cases methadone or benzodiazepines. Devices were tested in the laboratory using oral fluid samples prepared with target analytes at specified concentrations for each test.

Methods

We selected five currently available devices for our evaluation. The five devices tested were as follows:

- Dräger DrugTest 5000 (DDT5000)
- Dräger DrugCheck 3000 (DDC3000)
- Securetec DrugWipe S 5-Panel (DrugWipe)
- Alere DDS2 Mobile System (DDS2)
- AquilaScan Oral Fluids Testing Detection System

The scope of each device and cutoff concentration for each target analyte is shown in Table 1.

Table 1. Drug category assay and cutoff concentration (ng/mL) for each device

Drug Category/Assay	Oral Fluid Drug Testing Device				
	DDT5000	DDC3000	DrugWipe	DDS2	AquilaScan
THC	5	15‡	5	25	40
Cocaine	20	20	10	30*	20
Amphetamine	50	35	80†	50	50
Methamphetamine	35	35	80†	50	50
Benzodiazepines	15	–	–	20	15
Opiates	20	20	10	40	20
Methadone	20	–	–	–	15

‡ DDC3000 offers a THC cutoff of 15 ng/mL or 25 ng/mL depending on the testing procedure used; the procedure providing the more sensitive cutoff was followed throughout the evaluation.
* DDS2 device targets benzoylecgonine instead of cocaine.
† DrugWipe 5S has a combined amphetamine/methamphetamine panel.

An appropriate scope of testing and cutoff concentrations for this study were based on two important previous studies using oral fluid drug testing devices, the Roadside Testing Assessment (ROSITA), which recommended greater than 90 percent sensitivity and specificity, and greater than 95 percent accuracy; and the Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) project, which recommended greater than 80 percent sensitivity, specificity and accuracy. Performance in each phase of the study was evaluated for individual drug classes and in aggregate for each device.

Results

The overall performance of the five devices when aggregating all the scoreable tests from the cutoff, cross-reactivity, and environmental testing experiments are shown in Table 2. The DDT5000 and the DDC3000 performances, in aggregate, demonstrated performance consistent with the requirements of the ROSITA group. The DDS2 data, in aggregate, met the performance requirements for ROSITA; however, its THC assay

did not. None of the individual assays on the DrugWipe or the AquilaScan met the performance requirement of ROSITA, nor did the performance of either device in aggregate. The DDT5000, DDC3000 and DDS2 met the performance requirements for DRUID.

Chewing tobacco produced frequent false positive and false negative results across all five devices. Coffee, milk, soda, and wintergreen produced intermittent and inconsistent false positive or false negatives on one device or another, but there was no consistent pattern of interference. Incorporation of a 10-minute waiting/deprivation period as recommended by the manufacturers prior to testing eliminated all of the effects of the potential interferents.

There was variability in performance across devices as well as variability across drugs for devices. Each device tested had pros and cons. Detailed desciptions of each device's performance and functionality are provided in the final report. It should be noted that all the devices we tested are screening devices. Results in field use would still require confirmatory testing.

Table 2. Aggregate overall performance data for the five devices evaluated

Device	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
DDT5000	886	8	15	1766	99.1%	99.2%	99.1%	98.3%	99.5%
DDC3000	589	17	0	929	97.2%	100.0%	98.9%	100.0%	98.2%
DrugWipe with DrugRead	289	213	3	489	57.6%	99.4%	78.3%	99.0%	69.7%
DrugWipe with Manual Evaluation	451	73	2	466	86.1%	99.6%	92.4%	99.6%	86.5%
DDS2	635	62	4	1306	91.1%	99.7%	96.7%	99.4%	95.5%
Aquilascan	161	581	5	988	21.7%	99.5%	66.2%	97.0%	63.0%

True Positive (TP): The device indicated a positive result; the lab confirmed the sample as positive.
True Negative (TN): The device indicated a negative result; the lab confirmed the sample as negative.
False Positive (FP): The device indicated a positive result; the lab indicated the sample was negative.
False Negative (FN): The device indicated a negative result; the lab indicated the sample was positive.
Sensitivity: The probability of a positive result for a drug class among drivers confirmed positive for a drug within that class.
Specificity: The probability of a negative result for a drug class among drivers confirmed negative for a drug within that class.
Accuracy: The proportion of true positive and true negative results; an overall measure.
PPV: Percentage of samples with positive results that are true positives.
NPV: Percentage of samples with negative results that are true negatives.

NCREP Notice

In its Moving Ahead for Progress in the 21st Century (MAP-21) Act, Congress directed NHTSA to establish a cooperative program—the National Cooperative Research and Evaluation Program (NCREP)—to conduct research and evaluations of State highway safety countermeasures. This program is administered by NHTSA and managed jointly by NHTSA and the Governors Highway Safety Association (GHSA). Each year, the States (through GHSA) identify potential highway safety research or evaluation topics they believe are important for informing State policy, planning, and programmatic activities. One such topic identified by GHSA, an evaluation of on-site oral fluid drug screening devices, formed the basis for this project.

How to Order

To order the *Evaluation of On-Site Oral Fluid Drug Screening Technology,* prepared by the Center for Forensic Science Research and Education, write to the Office of Behavioral Safety Research, NHTSA, NPD-310, 1200 New Jersey Avenue SE, Washington, DC 20590, fax 202-366-7394, or download from www.nhtsa.gov.

Suggested APA format citation for this report:

Buzby, D., Mohr, A., & Logan, B. (2021, April). *Evaluation of on-site oral fluid drug screening devices* (Traffic Tech, Technology Transfer Series. Report No. DOT HS 812 859). National Highway Traffic Safety Administration.

U.S. Department of Transportation
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14557-040821-v5