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Short Communication

Field Testing of the Alere DDS2 Mobile Test System for Drugs in Oral Fluid

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A preliminary field evaluation of a second-generation handheld oral fluid testing device, the Alere DDS2 Mobile Test System (DDS2), is described. As part of a larger study, drivers were randomly stopped at various locations across California (in 2012) and asked to submit voluntarily to a questionnaire regarding their drug and alcohol use, a breath alcohol test and collection of oral fluid with the Quantisal device. The Quantisal-collected oral fluid samples were sent for laboratory-based analyses. At one location, 50 drivers were asked to submit an additional oral fluid sample using the DDS2 collection device; these samples were analyzed by using the DDS2 mobile test system. Thirty-eight donors (76%) provided specimens that were successfully run on the mobile system; in 12 cases (24%), the device failed to provide a valid result. Thirty-two of the 38 collected samples were negative for all drugs; five were positive for tetrahydrocannabinol and one was positive for methamphetamine using the mobile device. These results corresponded exactly with the laboratory-based results from the Quantisal oral fluid collection.

Introduction

In 2011, the Obama administration identified drug-involved driving as one of its top three policy priorities in its National Drug Control Strategy (1). The administration set a 2015 target of reducing driving under the influence of drugs by 10% through a combination of interventions, which include raising public awareness of the risks of drugged driving, assisting states in establishing drug *per se* laws and improving testing methods for impaired drivers.

Improving testing methods has attracted increasing interest in the utility of oral fluid collection and testing at the roadside because of the quick results and ease of collection compared to blood.

Over the last few years, many studies have been published regarding systems for testing oral fluid at the roadside (2). For the most part, these devices have been limited in their usefulness in the field because they failed to meet the criteria for acceptable performance. Many of these devices are visually read tests (e.g., test-strip color comparisons) that can be problematic to interpret at night, are somewhat subjective and do not provide a result that can be stored for future use. Devices that incorporate physical readers and printers tend to be somewhat cumbersome. Further, some devices do not yet achieve the sensitivity required to identify recent drug use, particularly for cocaine, benzodiazepines and marijuana (3, 4).

Recently, four commercial on-site oral fluid drug screening devices were evaluated: DDS Mobile Test System, Drugtest 5000, Drugwipe 5+ and RapidSTAT. Of the four tested products, only the Drugtest 5000 had an acceptable sensitivity for on-site application. The authors concluded that to ensure adequate reliability, mass spectrometric confirmation of on-site screening tests was always necessary due to the presence of a significant number of false positive results, even when using the commercial kit with the best performance (5). However, the increasing numbers of robust devices and improvements in technology, which help to overcome issues of sensitivity and specificity, have positioned oral fluid roadside testing as viable, reliable and useful in law enforcement. In fact, in 2007, Lacey *et al.* (6) conducted the 2007 National Roadside Survey (NRS; funded by the National Highway Traffic Safety Administration) in which they used oral fluid to assess the prevalence of drugs America's highways on Friday and Saturday nights from 10 p.m. and midnight, then again from 1 a.m. to 3 a.m. The results revealed 16% of the drivers were positive for potentially impairing drugs. Oral fluid is a reflection of the active drug circulating in blood, and thus provides information similar to blood tests, which has been traditionally considered the gold standard of drug testing in drivers.

A similar NRS study was conducted in 2010 in the state of California, for which oral fluid samples were collected from 900 randomly selected drivers on Friday and Saturday evenings. Of those drivers tested, 14.4% were positive for illegal drugs and 8.5% were positive for tetrahydrocannabinol (THC) (7). Using this roadside survey as a model, the study was repeated in the summer of 2012. In addition to standard laboratory testing using the Quantisal device, 50 drivers were recruited for additional specimen donation.

Materials and Methods

Supplies and reagents

The second generation of the DDS system, the Alere Mobile Test System DDS2, was obtained from Concateno (Abingdon, UK), including handheld device, test cartridges, DDS2 oral fluid collection devices, positive and negative control cartridges, printer, power charger and car battery charger. Quantisal devices for the collection of oral fluid specimens were obtained from Immunalysis Corporation (Pomona, CA). The Quantisal devices contain a collection pad with a volume adequacy indicator, which turns blue when 1 mL of oral fluid ($\pm$ 10%) has been collected. The pad is placed into a transport buffer (3 mL), allowing a total specimen volume available for analysis of 4 mL (3 mL buffer + 1 mL oral fluid). Because the oral fluid concentration is diluted 1:3 when using Quantisal collection devices, detected drug concentrations were adjusted accordingly.

Sample collection

In the summer of 2012, more than 1,300 drivers were stopped randomly across nine California locations including Anaheim (Orange County), Chula Vista (San Diego County), Ontario (San

Bernardino County), Gardena (Los Angeles County), Fresno (Fresno County), Modesto (Stanislaus County), Eureka (Humboldt County), Redding (Shasta County) and San Rafael (Marin County). Drivers were asked to consent to a questionnaire, a breath alcohol test (BAC) and a Quantisal oral fluid collection device that was sent directly to the laboratory for analysis. In Gardena (Los Angeles County), 50 randomly selected drivers were asked to provide an additional oral fluid sample using the DDS2 collection device, which was immediately analyzed on-site and the results were stored. Manufacturers' representatives for the DDS2 or the Quantisal collection device were not present at the roadside collection site. Those results were not shared with the laboratory or the manufacturer. The analytic results from the laboratory-based collection were reported to the research team conducting the project and compared with the DDS2 results by the research team before any results were shared with either the laboratory or the device manufacturer.

Roadside analysis

As noted, 50 drivers were asked to give an additional oral fluid specimen after the interview and after the BAC and Quantisal collections. The DDS2 device performs rapidly and has a collection time of less than 1 min to collect approximately 600 μL of oral fluid; there is also a blue dye indication of when adequate oral fluid has been collected (Figure 1). After the mobile test system has been checked with positive and negative cartridges, a test cassette is inserted into the device. When the specimen has been collected, the pad is pushed into the test cartridge that is already in the device (Figure 2). The oral fluid from the pad mixes with the buffer and flows along the test strips in the unit.

Figure 1. DDS2 oral fluid collection device.

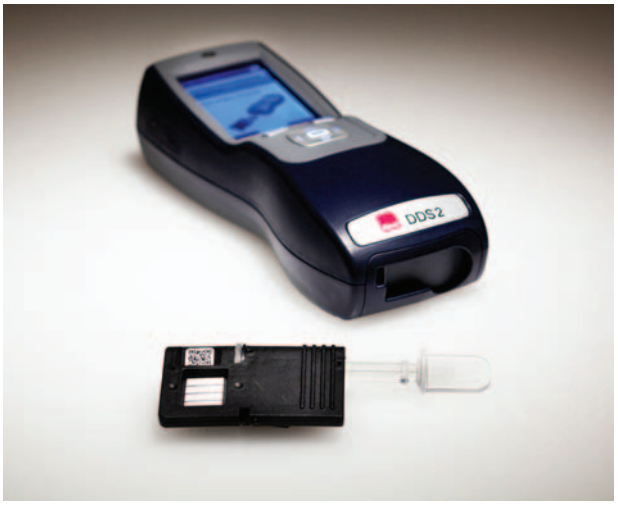

Figure 2. Placement of collected sample into the test unit.

The mobile test unit analyzes for five drug classes (THC, cocaine, opiates, amphetamine and methamphetamine) within 5 min; the cutoff concentrations are shown in Table I. The amphetamine and methamphetamine assays are separate antibodies, targeted at the *d*-isomer in each case.

Laboratory analysis

All oral fluid specimens collected using the Quantisal device and sent for laboratory-based testing were screened using enzyme linked immunosorbent assay (ELISA) and, if positive, confirmed using gas chromatography–mass spectrometry (GC–MS) or liquid chromatography with tandem mass spectral detection (LC–MS-MS) at concentrations shown in Table I. All procedures were fully validated and most have been previously published (8–10).

All positive immunoassay results must be confirmed by using a technique based on a separate chemical principle for identification, usually MS analysis. In this preliminary test, there is insufficient original specimen remaining for analysis, so a separate oral fluid sample must be collected for laboratory analysis if a presumptive positive is obtained.

Results and Discussion

Oral fluid compliance

All 50 drivers who were asked to give an additional specimen after the interview and BAC and Quantisal tests agreed to the DDS2 collections. However, only 38 (76%) results were obtained from the test unit. In nine cases, a code associated with a barcode reading error of the cartridge was observed before the test began to run; in three cases, the cartridge itself caused an error: one before the test began and two at the end.

Comparison to Quantisal results

Thirty-two of the 38 oral fluid specimens that ran on the mobile test system DDS2 were negative for all drugs; all 32 corresponding laboratory-tested specimens were also negative for all drugs. Six specimens were positive at the roadside using the mobile test system DDS2: five for THC and one for methamphetamine. The corresponding results from the Quantisal laboratory-based sample analyses are shown in Table II.

For the specimens from the same donors run on both a roadside test device and in the laboratory, 100% agreement occurred. All 32 negative donors at the roadside were also negative in the laboratory-based test; five THC roadside positive results and one methamphetamine positive were confirmed using the Quantisal device. The amphetamine immunoassay test on the handheld device did not show as a positive result, although the specimen confirmed positively for methamphetamine (2,255 ng/mL) and

Table I
Cutoff Concentrations for Drugs in Oral Fluid

Drug class	DDS2 (ng/mL)	Laboratory screening (ng/mL)	Laboratory confirmation (ng/mL)
THC	25	4	2
Cocaine/benzoylecgonine	30	20	8
Opiates (morphine)	40	20	10
d-Amphetamine	50	25	10
d-Methamphetamine	50	25	10

Table II
Comparison of DDS2 Roadside Results with Laboratory-Based Quantisal Analysis

Specimen	DDS2 result	Laboratory confirmation result (ng/mL)
1	THC +	THC 5
2	THC +	THC 10
3	THC +	THC 10
4	THC +	THC 33
5	THC +	THC 288
6	Methamphetamine +	Methamphetamine 2,255; amphetamine 86

amphetamine (86 ng/mL); this should be considered a false negative for amphetamine on the handheld device because the cutoff for *d*-amphetamine is 50 ng/mL. The cutoff concentration claimed for the handheld device for THC is 25 ng/mL, however, three of the five positive donors were confirmed in the laboratory at concentrations lower than 25 ng/mL. Because the roadside device did not distinguish between THC and its metabolites, this disparity was possibly due to the presence of other cannabinoids in the oral cavity helping to display positive at the roadside, whereas the laboratory test was specific for THC.

Further research

This preliminary study provided encouraging information on the utility of the mobile test system in the field. A larger-scale study is in the planning stages, but this study indicates that the use of oral fluid testing devices for roadside analysis has become a viable alternative or an addition to blood collection.

Acknowledgments

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Conflict of Interest

Christine Moore is employed by Immunalysis Corporation, which manufactures the Quantisal oral fluid collection device. Immunalysis is a subsidiary of Alere, Inc., manufacturers of the DDS2 Mobile Test System described in this publication.

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