Forensic Science International 238 (2014) 120–124

Contents lists available at ScienceDirect

Forensic Science International

journal homepage: www.elsevier.com/locate/forsciint

Performance evaluation of on-site oral fluid drug screening devices in normal police procedure in Germany

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ARTICLE INFO

Article history:
Received 4 March 2013
Received in revised form 24 January 2014
Accepted 9 February 2014
Available online 18 February 2014

Keywords:
Oral fluid
On-site drug testing urine
Blood/serum
Immunoassay
Chromatography
Driving under influence of drugs (DUID)

ABSTRACT

There is a need for quick and reliable methods for rapid screening of drug-influenced drivers on the roadside by police. Because the window of detection in oral fluid is more similar to blood than to urine, this matrix should therefore be appropriate for screening procedures. The performance of the Rapid STAT® (Mavand Solution GmbH, Mössingen, Germany), DrugWipe5/5+® (Securetec Detektions-Systeme AG, Brunnthal, Germany) and Dräger DrugTest® 5000 (Draeger Safety AG & Co. KGaA, Luebeck, Germany) on-site oral fluid devices was evaluated with random oral fluid specimens from car drivers in North Rhine-Westphalia (Germany). Additionally, some drivers were checked using an on-site urine device (DrugScreen®, NAL von Minden, Regensburg, Germany). During a 11-month period, 1.212 drivers were tested. Both OF and urine on-site tests were compared to serum results.

The following sensitivities were obtained by the oral fluid devices: THC 71% (DrugWipe®), 87% (Dräger), 91% (RapidSTAT); opiates 95% (Dräger), 100% (DrugWipe®, RapidSTAT®); amphetamine 84% (DrugTest® 5000), 90% (RapidSTAT®), 100% (DrugTest® 5000); methamphetamine 50% (DrugTest® 5000), 100% (RapidSTAT®); cocaine 76% (DrugTest® 5000), 100% (DrugWipe®, RapidSTAT®); methadone 33–63%, and benzodiazepines 0–33% (both with a low number of positives). THC specificity was especially low (29% [DrugWipe®] and 47% [DrugTest® 5000]) due to low cut-off concentrations. These data were similar to those obtained from the literature (e.g., DRUID project). The urine screening device showed a good sensitivity (THC 93%, opiate 94%, amphetamine 94%, methamphetamine 75% (low number of positives), cocaine 100%) and also an acceptable specificity (39%, 86%, 63%, 77%, 47%, respectively). Although oral fluid may be a useful matrix for on-site testing of drugged drivers, it is evident that oral fluid devices still show a lack of sensitivity (methamphetamine, benzodiazepines) and specificity (THC). Poor results for benzodiazepines may be explained by the small positive test number. Although the sensitivity for THC came out higher than compared to the literature, specificity is not yet satisfactory (only <90%). Furthermore, specificity was poor due to lowered cut-offs resulting in multiple false positive tests.

1. Introduction

Driving under the influence of drugs (DUID) is a common problem in everyday German police work. In most geographic areas, urine is the current sample for on-site drug pre-testing in everyday work of German police officers. Once a urine test comes out positive, a blood sample is taken to confirm and prove possible acute drug effects. As described before, roadside urine testing significantly decreases the number of unnecessary blood analyses in DUID cases [1]. In Germany a detection of any central-nervously active substance in blood/serum in addition to signs of impairment represents a criminal offence. Additionally, there exist so-called "per-se-limits" for illicit drugs and once drugs are found in a driver's blood or serum above the defined cut-off concentrations, he also will get sentenced. Unfortunately the results of urine pre-tests often do not correspond to results compiled by blood/serum sample testing, mostly due to the fact that numerous drugs can be detected for days or even weeks in urine but only for some hours in blood/serum [2]. Additionally, the urine roadside test is not well accepted by tested persons because many look upon this test as an interference to their

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http://dx.doi.org/10.1016/j.forsciint.2014.02.005
0379-0738/

privacy. On the other hand oral fluid (OF) testing offers a non-invasive way of screening at the roadside enabling direct supervising of sampling. Another important advantage is a better correlation between the kinetics of several drugs in blood and OF. Therefore, OF gains more and more importance as a non-invasive drug-screening method being more related to respective blood/serum levels. During recent years, several excellent reviews were published about OF drug testing [3,4]. However, large real-life variations in drug concentration ratios between OF and blood/serum indicate that drug concentration in OF may not be used to estimate accurately drug concentrations in blood [5,6].

There are several providers offering OF tests such as RapidSTAT® (Mavand), Dräger DrugTest® (Dräger Safety), DrugWipe5/5 plus/5 plus neu® (Securetec) and these tests were checked during a 11-months period. For urine pre-testing the DrugScreen® Multi-5 (Nal von Minden) was used.

The aim of the study was to compare the results from these onsite-tests obtained by the police in North Rhine-Westphalia (Western part of Germany) during routine traffic checks in urine and OF to the results from serum samples.

2. Materials and methods

2.1. Roadside tests

Data of this paper refers to were taken by police stations in North Rhine-Westphalia during 1.212 on-site tests of drivers suspected of DUID in the period from January to November 2010. At this juncture they used urine or OF tests during routine traffic checks as well. In addition they took blood samples to prove the informational value of rapid pre-testing. In this period the Dräger DrugTest® 5000 was utilised 530 times. RapidSTAT® and DrugWipe® were applied 234 and 47 times, respectively. All in all, 619 urine on-site tests were carried out; in 401 cases only urine samples were tested. Only 239 volunteers took part in both test urine and OF. To prove sensitivity and specificity of the devices blood samples were taken in addition. Table 1 gives an overview of the test quantities. Not all negative tests were confirmed in blood/serum using chromatographic procedures. For more details see Table 4.

2.2. Devices

The three on-site OF drug tests are based on immunological drug detection [2]. The test system of the Dräger DrugTest® (Dräger Safety, Luebeck, Germany) comprises two main components, the Dräger DrugTest® Analyser and a test kit. The test kit consists of a test cassette including an OF collector. OF samples are collected by moving the collection sponge on the cassette within the mouth until an indicator turns blue. This process takes one minute. Afterwards, the test cassette as well as the buffer cartridge, which will trigger the immunological detection, are placed in an analyser. Results of the rapid test are shown in about 8–10 min on a digital screen on the analyser.

Table 1
Numbers of tests.

	Dräger 5000	RapidSTAT	DrugWipe	DrugScreen (urine)
Total number of tests	530	234	47	619
Number of oral fluid/urine + blood samples	404	177	34	473
Number of oral fluid + blood samples + urine	158	65	10	239

The RapidSTAT® (Mavand Solutions, Mössingen, Gemany) consists of a collection device with an aroma field, a buffer solution and a test strip. The collection swab is placed inside the cheek and gums with rotation for at least 30 s. In a next step the samples are washed out by rotary movement into the buffer capsule and mobilized before removal. Subsequently, seven drops of the buffer fluid mixture are pipetted to each well of the incubation device. The lid is closed to the first position, shaken for 10 s and then left for an incubation time of 4 min. This allows the antibodies to react with drugs included in samples. Afterwards, the test is started by pressing down the lid completely so that the buffer runs over the test strips. Within 8 min all lines including the control line should have produced a negative test result. If there is no line detectable after 8 min for a drug the test is positive for this substance group, what is due to the fact that antigens being present in the samples inhibit a reaction of enzyme marked antigens with antibodies. Hence, color change is not possible. The total time needed for testing is 7:40 min for negative results and 12:40 min for positive results.

The DrugWipe® 5 test consists of an OF collector, a detection element and an integrated liquid ampoule. To carry out testing, the OF collector is separated from the test body. The OF sample is collected by advising the client to circle the inside of their mouth with their tongue three times. Then the sample collector can be used to wipe the saliva from the tongue or the inside of the cheek. Afterwards the collector is attached to the test cassette by holding the test accurately vertically. The ampoule is pressed so that it opens and the buffer solution flows onto the test strips. After 15 s, the test has to be positioned horizontally and results are visible within six minutes.

The Nal von Minden DrugScreen® Multi-5 is also known as a multi drop test. Contrary to the preceding tests, the DrugScreen® Multi-5 is based on urine samples and does not detect benzodiazepines. To carry out the test, an urine sample has to be taken from a test person. Afterwards, three drops of urine are pipetted to each well of the incubation device. Five to ten minutes later the results appear as red lines. The test is positive if no line appears for a group of drugs.

The different cut-off-levels for OF on-site tests and the urine test are shown in Table 2.

2.3. Serum samples

Serum analyses were performed in various forensic-toxicological laboratories using routine methods with gas chromatography–mass spectrometry or high performance liquid chromatography–mass spectrometry. All labs belong to Institutes of Forensic Medicine and were accredited according to EN ISO 17025. Cut-offs were set according to the German legal guidelines (Table 3); benzodiazepines cut-offs were set at 10 ng/mL.

2.4. Interpretation of results

In order to make a reliable statement about sensitivity and specificity on the screening devices, the results of OF on-site tests

Table 2
Cut-off-levels (ng/mL) of the OF on-site tests and of the urine test.

	Draeger DrugTest	RapidSTAT	DrugWipe 5/5+	DrugScreen (urine)
THC	5	5	30	150
Opiates	20	10	10	300
Amphetamines	50	25	50	300
Methamphetamine	35	25	25	300
Benzodiazepines	15	25	10	–
Cocaine	20	10	15	300