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

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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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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

Table 3
Cut-offs for blood/serum testing.

Compound	Cut-off
Tetrahydrocannabinol (THC)	1 ng/ml
Morphine	10 ng/ml
Cocaine	10 ng/ml
Benzoylecgonine	75 ng/ml
Amphetamine	25 ng/ml
Methamphetamine	25 ng/ml
MDMA/MDEA	25 ng/ml

and urine tests were compared to testing serum samples. By this way, it was possible to categorise data into the following parameters: true positives (TP) imply cases with a positive OF screening test matching a positive plasma sample; true negative (TN) = negative OF screening test matching a negative plasma sample; false negative (FN) = negative OF screening test matching a positive plasma sample false positives (FP) = positive OF screening test corresponding to a negative plasma sample. Subsequently, sensitivity (TP/(TP + FN)), specificity (TN/(TN + FP)) and accuracy (TP + TN/(TP + TN + FP + FN)) are calculated. To complete the evaluation, the positive (PPV = TP/(TP + FP)) and negative predictive values (NPV = TN/(TN + FN)) were calculated. The same was performed for urine pre-testing.

3. Results and discussion

In order to make a meaningful statement about all the devices tested it is necessary to highlight that the different cut-offs of on-site test devices may have an impact on sensitivity, specificity and accuracy. At a lower cut-offs a higher number of positive results may appear what has a negative impact on specificity. As a result of high cut-offs more (false) negative results can be detected. This has influence on sensitivity.

Another question arising and also worth discussing is 'when are sensitivity and specificity high enough?' for the aimed purpose. According to the ROSITA 1 study, OF screening devices should have an accuracy higher than 95% with a selectivity and specificity above than 90% [7].

Sensitivity, specificity, accuracy, positive predictive value and negative predictive values of the three tested OF screening devices and the DrugScreen® urine test of this study are shown in Table 4. Additionally, findings from the literature are summarized in Table 5. Not only sensitivities and specificities should be recognized but also corresponding cut-off values in various studies.

In general the findings in the present study fit with what is commonly found by drugged drivers in Germany [14,15]. There is an extreme amount of THC-positive samples compared to other drug classes.

3.1. Cannabinoids

For cannabinoids (labeled THC) a number of samples were taken and evaluated (n = 932). Accordingly, a rather high reliability could be expected. Sensitivity showed good results except for the DrugWipe with 71%, but also the DrugScreen® urine test (93%) revealed acceptable findings. Specificity was non-satisfactory for THC in all four tests (all <50%). The specificity is better for Dräger (cut-off 5 ng/mL) than for DrugWipe (30 ng/mL), while the rapidSTAT has only 9% (cut-off 5 ng/mL) not indicating variation due to cut-off, but more to different devices. A specificity of only 39% for the urine test device can be explained by the fact that the urine test measures THC–COOH which is well known to have a much longer detection window in urine than THC in blood.

Acceptable positive predictive values and poor negative predictive value (NPV) underlined these facts. The relative good

Table 4
Results for sensitivities, specificities, accuracies and Positive and Negative Predictive values. Despite the high number of included subjects, the numbers presented here are lower, probably because in many negative cases, no confirmation in blood was performed.

	Dräger	RapidSTAT	DrugWipe	DrugScreen (urine)		Dräger	RapidSTAT	DrugWipe	DrugScreen (urine)
THC					Cocaine				
TP	236	91	12	299	TP	16	6	3	24
FP	19	32	5	18	FP	6	0	3	9
TN	17	3	2	12	TN	17	11	2	8
FN	35	9	5	23	FN	5	0	0	0
Sensitivity	87%	91%	71%	93%	Sensitivity	76%	100%	100%	100%
Specificity	47%	9%	29%	39%	Specificity	74%	100%	40%	47%
Accuracy	82%	70%	58%	88%	Accuracy	75%	100%	63%	78%
PPV	92.6%	92.6%	70.6%	94%	PPV	72.7%	100%	50%	72.7%
NPV	32.7%	25%	28.6%	34.3%	NPV	77.3%	100%	100%	100%
Opiates					Benzodiazepines				
TP	21	5	1	16	TP	2	0	0	
FP	2	0	1	2	FP	0	0	0	
TN	21	12	1	12	TN	16	7	1	
FN	1	0	0	1	FN	4	2	0	
Sensitivity	95%	100%	100%	94%	Sensitivity	33%	0%	n.a.	
Specificity	91%	100%	50%	86%	Specificity	100%	100%	100%	
Accuracy	93%	100%	67%	90%	Accuracy	82%	78%	100%	
PPV	91.3%	100%	50%	88.9%	PPV	100%	n.a.	n.a.	
NPV	95.5%	100%	100%	92.3%	NPV	80%	90%	100%	
Amphetamine					Methamphetamine				
TP	95	46	9	107	TP	1	2	0	3
FP	2	8	4	6	FP	1	4	0	3
TN	19	6	2	13	TN	20	10	1	10
FN	18	5	0	7	FN	1	0	0	1
Sensitivity	84%	90%	100%	94%	Sensitivity	50%	100%	n.a.	75%
Specificity	90%	43%	33%	68%	Specificity	95%	71%	100%	77%
Accuracy	85%	80%	73%	90%	Accuracy	91%	75%	100%	76%
PPV	97.9%	85.2%	69.2%	94.7%	PPV	50%	33.3%	n.a.	50%
NPV	51.4%	54.6%	100%	65%	NPV	95.2%	100%	100%	90.9%

Table 5
Data from the literature. Confirmation was made in serum/blood.

	Sensitivity [%]	Specificity [%]	Cut-off [ng/ml]	Lit.
Cannabis				
RapidSTAT	71	55	15	[8]
	84	81	5	[9]
	38	100	15	[10]
	71	60	15	[11]
DrugTest 5000	72	50	25	[8]
	93	71	5	[8]
	35	98		[10]
Drugwipe 5/5plus	71	50	30	[8]
	43	87	200	[10]
	68	88	200	[12]
	43	87	50/200	[13]
Amphetamines				
RapidSTAT	93	75	25	[8]
	100	100	25	[9]
	100	90	25	[11]
DrugTest 5000	92	100	50	[8]
Drugwipe 5plus	100	60	100	[8]
	97	50	200	[10]
	98	87	200	[12]
	97	50	50/200	[13]
Cocaine				
RapidSTAT	71	55	12	[8]
	100	100	10	[9]
DrugTest 5000	67	60	20	[8]
	64	77	20	[8]
Drugwipe 5/5plus	78	100	50	[8]
	99	98	50	[10]
	50	99	50	[12]
	63	99	30/50	[13]
Opiates				
RapidSTAT	100	98	10	[9]
Drugwipe 5/5plus	99	97	20	[10]
	88	97	20	[12]
	10	99	10/20	[13]

sensitivity and low specificity can be explained by the fact that concentrations in OF are with a wide range 20 times higher in OF, so they are detectable for a longer time than in blood.

The Dräger DrugTest® 5000 revealed a sensitivity of 87% and an accuracy of 82%, but a lack of specificity (47%). Wille et al. [8] found a sensitivity of 93% with a specificity of 71%. For RapidSTAT® the sensitivity of 91% calculated in our study appears much better than results compared to literature (summarized in Table 5). On the other hand, with only 9% RapidSTAT® presented a very low specificity for THC compared to other studies. With 71% sensitivity the DrugWipe test corresponds to the sensitivity found by Wille et al. [8]; however, other groups found lower sensitivities. As for RapidSTAT®, DrugWipe® showed a lower specificity (29%) than in the literature. The low observed specificity for the Dräger DrugTest® 5000 (47%), RapidSTAT® (9%), DrugWipe® (29%), and DrugScreen® urine test (39%) is conspicuous. It might be explained by low cut-offs resulting in multiple false-positive tests. Nevertheless, such specificities are unacceptable for THC-screening considering the high prevalence. Contrary to this sensitivities for RapidSTAT® and DrugWipe® were higher than given in the literature. This might be a positive indication of a progress in OF on-site test development. Even although the DrugScreen® urine test also showed low results for specificity, it still revealed the best performance for THC detection compared to OF devices.

3.2. Opiates

For opiates all of the three OF tests show good results. Only DrugWipe® exhibited some lack of specificity and accuracy (Table 4). For DrugWipe® the number of tests are too small for evaluation. In the literature, DrugWipe® showed different values; in one study Pehrsson et al. [13] demonstrated a sensitivity of only 10%, whereas in another study [12] they reported an acceptable value with 88%, respectively. In the literature, the DrugWipe® gives reasonable results for specificity. Due to a small number of sources the other devices could not be assessed further based on literature.

On the other hand, for opiates a comparison of OF pre-test results with those from chromatographic procedures exhibits very good results for specificity and reasonable values for sensitivity [10,12,16], especially for the RapidSTAT®.

3.3. Amphetamines

Sensitivity for amphetamine was found to be sufficient for RapidSTAT® (90%), DrugWipe® (100%) and DrugScreen® urine test (94%), but the Dräger DrugTest® 5000 with 85% cannot fulfill the requirements for drug screening used in routine traffic checks (>90%). At least in the literature acceptable values were described (see Table 5). However, low specificities are given for RapidSTAT®, DrugWipe® and DrugScreen® urine test, and only the Dräger DrugTest® 5000 revealed acceptable results with 90%.

3.4. Cocaine

For cocaine the DrugTest® 5000 showed nearly similar non-satisfactory values for sensitivity and specificity (76% and 74%) as already given in the literature. Conclusions cannot be drawn for RapidSTAT® and DrugWipe® because of the small numbers of samples examined in this group. DrugScreen® urine test showed 100% sensitivity for cocaine but only 47% specificity.

3.5. Benzodiazepines and methamphetamine

Based on the small number of results for benzodiazepines and methamphetamine, the poor sensitivity and good specificity and accuracy of the DrugTest® 5000 are not reliable in this study. Also in the literature only limited data can be found due to a small number of sources usable for comparison of OF results with those from blood/serum testing. Apparently, also by comparison of OF results of the devices to chromatographic procedures, the sensitivities reported were found not satisfying for both substance classes: methamphetamine with only 30% [16]; benzodiazepines with 64% (DRUID cut off) and 65% [10]. It can be estimated that the Dräger DrugTest® 5000 shows not only a lack regarding the average quantity of benzodiazepines and methamphetamines in blood/serum but also in OF itself. On the other hand, the DrugTest® 5000 showed good values for specificity (methamphetamine: 100% [10], 99.2% [16] benzodiazepines: 99%, 100%, 92% [10]). Additionally, for the RapidSTAT® and the DrugWipe® only a very small number of samples for benzodiazepines and methamphetamine were examined, so that reliability is not given. Otherwise, Blencowe et al. [17] indicated that the DrugWipe® single device was able to detect benzodiazepines in OF even at relatively low levels in corresponding blood samples.

4. Conclusion

None of the test devices assessed in this study fulfilled the ROSITA 1 criteria (accuracy higher than 95% with a selectivity and specificity higher than 90%) [7]. This pertain for all OF devices but also for the urine test. However, the urine on-site test showed the best sensitivity over all substance classes involved. Furthermore, other rapid on-site OF drug tests showed no better results [18]. It has to be taken into consideration that even OF to OF comparison (on-site test results versus results of chromatography) revealed

outcomes which do not fulfill the ROSITA 1 criteria [19–21]. All in all, especially the low specificity of OF devices still is a drawback in the OF-serum comparison due to lowered cut-offs to enhance sensitivities.

In general it has to be taken into consideration that immunoassays will not detect all types of relevant drugs [22]. Furthermore, immunoassays may produce different intensities of response to members of the same drug class and may completely fail to identify important members of drug classes. Due to cross-reactivity and considering interferences false-positive immunoassay results can be obtained and interferences can also reveal false-negatives, no matter what sensitivity and specificity are reported. In our opinion in cases with suspicion of driving while impaired by drugs and especially in traffic fatalities, samples should be subjected to a broad screening for common drugs not only relevant to the patterns of recreational drug use in jurisdiction but also for common CNS-acting prescription and over-the-counter drugs.

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