TECHNICAL NOTE

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Evaluation of the Accuracy of On-Site Multi-Analyte Drug Testing Devices in the Determination of the Prevalence of Illicit Drugs in Drivers*

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ABSTRACT: A principal goal of this research was to conduct a field evaluation of "on-site" multi-analyte drug testing devices to determine the most accurate, efficient, and cost-effective device available for the purpose of rapidly detecting drivers under the influence of drugs.

Four on-site kits were selected and evaluated for accuracy and efficiency for the detection of tetrahydrocannabinol (THC), the cocaine metabolites (COC), and opiates (OPI). From 16 December 1995 to 17 March 1996, 303 voluntary urine specimens were collected by law enforcement officers from persons arrested for driving-under-the-influence (DUI). These specimens were tested using the four selected kits and aliquots of the specimens were sent to a DHHS certified lab for "gold standard" comparison testing by immunoassay and Gas Chromatography/Mass Spectrometry.

On-site kit sensivity ranged from 82.9% to 100% for THC, 82.5% to 100% for COC, and all were at 100% for OPI. Specificity, and positive and negative predictive values were also determined. Accuracy ranged from 94.0% to 98.3% for THC, 97.4% to 98.0% for COC, and 99.7% to 100% for OPI. All four kits were in very close agreement on prevalence: 15.5% to 15.8% for THC, all were at 13.2% for COC, and all were at 0.7% for OPI. For law enforcement purposes, sensitivity may be the most important indicator in these kits.

KEYWORDS: forensic science, forensic toxicology, on-site testing, drugs and driving, substance abuse, tetrahydrocannabinol, cocaine, opiates

Drug abuse impacts morbidity and mortality in a variety of ways. The total cost of drug abuse to the United States economy in 1990 was estimated to have been between $100 billion and $180 billion, up from an estimated $47 billion in 1980 (1). And in 1995, an estimated 12.8 million Americans were current illicit drug users, meaning they had used an illicit drug in the month prior to interview (2). The magnitude of the problem of drug abuse is difficult to comprehend but one might say that too often the consequences of drug abuse are fatal, and that the victims are often our youth (1). One of the ways in which drug abuse damages the larger society is by making many existing problems, such as "driving under the influence," worse.

A public health problem gaining the rapid attention of law enforcement, safety officials, and emergency medical services is the increase in the number of dead and injured from vehicular crashes caused by or associated with the use of illegal drugs. It is a major public health problem not well recognized or appreciated by the public health community or the general public.

In comparison with the alcohol literature, relatively little information is available regarding the true incidence and prevalence of illegal drug use in driving accidents. Escalating marijuana use, especially among adolescents, presents serious challenges to the field of Public Health in terms of research, prevention, and treatment. As reported by the Community Epidemiology Work Group (CEWG) at their 39th meeting held in December 1995: indicator data need to include more information on user demographics and drug use patterns, prevention strategies could take advantage of increased public sophistication about health consequences, such as marijuana's adverse pulmonary effects; and the treatment community may need to prepare for increased use of harder drugs to the extent that marijuana is a "gateway" drug that introduces youth to other drugs and dealers (3).

Willette and Walsh pointed out that the full impact of drugs on traffic safety was unknown in 1983 and unfortunately this remains somewhat true today (4). Some data has emerged over the last decade, however, which gives insight as to the extent of the problem. The National Institute on Drug Abuse (NIDA) has estimated that if every worker aged 18–40 were tested for drug use on any given day, 14–25 percent would test positive for marijuana, cocaine, barbiturates, or other controlled substances (5). These same workers are on our roads and highways everyday as they drive to and from work. Driving under the influence of drugs other than alcohol is a growing cause of traffic crashes, injuries and deaths and a major national public health problem that needs to

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be directly and clearly addressed by the public health community. New and easy methods to detect drug impaired drivers is needed.

The goals of this research included a field evaluation of "on-site" multi-analyte drug testing devices to determine their accuracy, efficiency, and cost-effectiveness as a tool to identify drug impaired drivers and to determine the prevalence of illicit drugs in reckless drivers in Hillsborough County, Florida.

Methods

Hillsborough County (Tampa Bay Area, population 870,000) is located in a metropolitan area of over two million people and has a similar socio-demographic profile to the nation. During the time period from 16 December 1995 to 17 March 1996, voluntary and legal urine specimens were collected from 305 persons placed under arrest for suspicion of DUI. This represents approximately 25% of the total number of persons placed under arrest for DUI during this time period. Approximately 90% of the specimens were collected between the hours of 10:00 pm and 6:00 am Thursday, Friday, and Saturday nights. Of those who were asked to provide a specimen, we estimate a 60% participation rate.

Urine specimens were collected using standard acceptable methods and 303 of the specimens contained a sufficient amount of urine for testing and confirmation. Urine specimens were collected in a generic brand sterile 120 mL plastic cup with screw-on lid and were refrigerated immediately upon collection. Specimens were coded by using a specimen control number eliminating any personal identification on the specimen cups. Specimens were transferred to the Epidemiology Laboratory at the USF College of Public Health where they were analyzed within 48 hours of collection.

The following "on-site" kits were evaluated. The respective analytes are listed: (1) Triage (Biosite Diagnostics, San Diego, CA): Phencyclidine (PCP), Benzodiazepines (BZO), Cocaine (COC), Amphetamine (AMP), Marijuana metabolites (THC), Opiates (OPI), and Barbiturates (BAR). (2) Abu-Sign (Princeton BioMeditech, Princeton, NJ): THC, OPI, COC, AMP/MET. (3) OnTraK (Roche Diagnostic Systems, Branchburg, NJ): THC, COC, Morphine (MOR). (4) TestTcup (Roche Diagnostic Systems, Branchburg, NJ): THC, COC, MOR.

Specimens were tested at the Univ. of South Florida College of Public Health Epidemiology laboratory in batches of 6 to 8 specimens and were tested strictly following each kit's manufacturers' guidelines. Testing began with placing a labeled Triage kit and an Abu-Sign kit in front of each urine specimen. Triage testing was begun and while it was processing, the Abu-Sign kit was tested. The Abu-Sign kit results were read and recorded on the Test-Kit Analysis Form, and disposed. The Triage kit was completed testing, read, recorded, and disposed. Next, a labeled Roche On-Track and a labeled TesTcup were placed in front of each urine specimen. On-Track testing was begun and while processing, the remaining urine specimen was poured into a TesTcup for final processing. On-Track and TesTcup results were read, recorded, and disposed.

From the TesTcup, the specimens were poured into individual 30 mL leakproof containers, shipped to CompuChem Labs, Inc. (Research Triangle Park, NC) for immunoassay and Gas Chromatography/Mass Spectrometry (GC/MS) testing. This laboratory is certified by the DHHS/SAMHSA/National Laboratory Certification Program and represented the "gold standard" comparison test. Each specimen was re-analyzed by CompuChem Labs on an Olympus Analyzer by KIMS (Kinetic Immunoassay of Microparticles in Solution, Roche Diagnostic Systems, Online) Immunoassay for a 5-drug panel (marijuana, cocaine, opiates, amphetamines, and phencyclidine) using the DHHS/SAMHSA/NLCP cut-off levels, and if positive, confirmed by GC/MS.

There were some discrepancies between the on-site test kit results and the "gold standard" laboratory results. Discrepant specimens (defined as those specimens which were on-site positive by two or more kits but screened negative at CompuChem Labs) were reconciled by having them re-analyzed by GC/MS with quantitation at CompuChem Labs. A discrepant specimen was considered positive if the drug metabolite was detected by GC/MS and exceeded the limit of detection (LOD defined as 40% of DHHS/SAMHSA/NLCP cutoff level).

Five specimens screened positive for marijuana by 2 or more on-site kits and screened negative at CompuChem Labs. The cut-off level for GC/MS analysis of marijuana at CompuChem Labs is 15 ng/mL, and the LOD is 6 ng/mL. Upon re-analysis, these 5 specimens yielded quantitative values of 13, 32, 20, 8, and 13 ng/mL and were considered positive.

One specimen screened positive for both marijuana and cocaine by 2 or more kits and screened negative for both analytes at CompuChem Labs. The GC/MS cut-off level for cocaine at CompuChem is 150 ng/mL and the LOD is 60 ng/mL. Upon re-analysis, this specimen yielded a quantitative value of 20 ng/mL for marijuana and 126 ng/mL for cocaine and was considered positive.

Four specimens screened positive for cocaine by 2 or more kits and screened negative for cocaine at CompuChem Labs. Upon re-analysis, these 4 specimens yielded quantitative values of 131, 142, 93, and 247 ng/mL and were considered positive. Retesting of discrepant specimens yielded an additional 10 positive specimens.

Results

Overall toxicology and demographic findings are described in a companion paper by Walsh, Buchan, and Leaverton. This paper will focus on the evaluation of the accuracy of on-site multi-analyte drug testing devices in the determination of the prevalence of illicit drugs in drivers.

Comparisons of the four on-site kit results have indicated differences in ease of handling, time to conduct the test, specimen handling, reagent mixing, and readability of results. Kits were independently ranked 1 to 4 with the following evaluation designation: 1 = poor, 2 = acceptable, 3 = good, 4 = excellent by three members of the research team who were involved in conducting the on-site evaluations. Evaluators were designated as E-1, E-2, E-3 and the evaluation averages are listed in Table 1.

The kit evaluations clearly indicated the superiority of two kits: Abu-Sign and TesTcup. A major consideration was the fact that these two kits eliminate the need for reagent mixing/handling and significantly simplified the conduct of the test. This is especially important in determining the feasibility of training non-medical personnel in the operation of these diagnostic devices. The Abu-Sign gives a readable result in the shortest amount of time start to finish; about 5 minutes. The OnTrak was the most cumbersome and time consuming because it requires a different track for each analyte investigated and there is considerable reagent handling.

Statistical analysis was performed by placing the on-site test kit results for each analyte per kit in a two-by-two table, also called a contingency table. The Table contains two rows and two columns and is illustrated as an example in Table 2. This creates four cells, labeled a, b, c, and d, each of which represents the number of persons having a particular combination of an on-site test kit results

TABLE 1—*Evaluation of use of "on-site" test kits.*

Ease of Kit Use	Triage			ABU-Sign			Testcup			Ontrak		
	E-1	E-2	E-3	E-1	E-2	E-3	E-1	E-2	E-3	E-1	E-2	E-3
Ease of handling kit	3	3	3	4	3	3	3	4	4	2	1	2
Time to conduct test	4	3	2	4	4	4	4	4	4	1	2	3
Specimen handling	3	3	2	3	3	3	4	4	4	3	3	3
Reagent mixing	3	3	2	N/A	N/A	N/A	N/A	N/A	N/A	1	1	2
Readability of results	4	3	3	4	3	3	3	3	3	4	4	4
Evaluation average	→	→	2.9	→	→	3.4	→	→	3.7	→	→	2.4

TABLE 2—*Example of a two-by-two table for cocaine.*

	CompuChem Labs "Gold Standard" Results		
	Drug Positive	Drug Negative	Total
Abu-Sign Test Result Positive	40 (cell a) (true positive)	6 (cell b) (false positive)	46
Negative	0 (cell c) (false negative)	257 (cell d) (true negative)	257
Total	40	263	303

and the "Gold Standard" result from CompuChem Labs. The cells are defined as follows:

- a = the number of persons who drug test positive with the on-site kit and are confirmed positive by the "Gold Standard" test at CompuChem Labs. This cell represents true positive (TP).
- b = the number of persons who drug test positive with the on-site kit but are confirmed negative by the "Gold Standard" test. This cell represents false positives (FP).
- c = the number of persons who drug test negative with the on-site kit but are confirmed positive by the "Gold Standard" test. This cell represents false negatives (FN).
- d = the number of persons who drug test negative with the on-site kit and are confirmed negative by the "Gold Standard" test. This cell represents true negatives (TN).

The margins of the table represent the total numbers of persons in each row and column and are calculated by adding the relevant cells:

- a + b = the total number of persons who test positive by the on-site kit.
- c + d = the total number of persons who test negative by the on-site kit.
- a + c = the total number of persons who have used the drug in question.
- b + d = the total number of persons who have not used the drug in question.

The sum of all four cells (n = a + b + c + d) is the total sample size of this study (n = 303). Sixteen two-by-two tables were prepared, one table for each analyte per kit. Table 3 provides prevalence data by kit by analyte.

Statistical analysis of the sensitivity, specificity, positive predictive value, and negative predictive value across the various on-site kits is listed in Table 4.

The sensitivity (%) of a kit is the ability of the assay to identify those drivers using the drug in question among all drivers who are truly using the drug (true positives) and is calculated as the proportion of drug-using persons with a positive on-site test kit result (a ÷ a + c or TP ÷ TP + FN). For marijuana users, Abu-Sign showed the greatest sensitivity at 100% (48 out of the 48 drug users identified) and OnTrak had the least sensitivity at 82.9% (39 out of 47 drug users identified). This wide range of % sensitivity held true for cocaine users as well. Sensitivity at 100% indicates that the assay was able to correctly identify all persons truly on the drug in question. All kits showed 100% sensitivity on opiate detection (2 out of the 2 drug users identified) but since the sample size is small (only 2 persons using opiates), the point estimate should be viewed with caution.

The specificity (%) of a kit is the ability of the assay to identify those drivers not using the drug in question among all drivers truly not using drugs and is calculated as the proportion of drug-free persons with a negative on-site test kit result (d ÷ b + d or TN ÷ TN + FP). All kits showed excellent sensitivity with a range of 92.9% (237 out of the 255 drug-free persons identified, Abu-Sign) to 99.6% (254 out of the 255 drug-free persons identified, Triage) for marijuana and 97.7% (257 out of the 263 drug-free persons identified, Abu-Sign) to 99.6% (262 out of the 263 drug-free persons identified, Triage) for cocaine.

The Positive Predictive Value (PPV) is the probability (%) that a positive test result is a true positive and it is calculated as the proportion of subjects with a positive drug test who are on drugs (a ÷ a + b or TP ÷ TP + FP). For marijuana, Abu-Sign had the lowest PPV at 72.7% probability (48 TP out of 66 positive drug tests, 18 FP) and Triage had the highest PPV at 97.8% probability (44 TP out of 45 positive drug tests, 1 FP). For cocaine, the range of PPV values was 86.4% probability for TesTcup (38 TP out of 44 positive drug tests, 6 FP) to 97.1% probability for Triage (34 TP out of 35 positive drug tests, 1 FP).

The Negative Predictive Value is the probability (%) that a negative test result is a true negative and it is calculated as the proportion of subjects with a negative drug test who are drug-free (d ÷ d + c or TN ÷ TN + FN). All four kits performed well on negative predictive value (NPV). The marijuana assay ranged from 96.9% (251 TN out of 259 negative drug tests, 8 FN, On-Track) to 100% and the cocaine assay ranged from 97.4% (261 TN out of 268 negative drug tests, 7 FN, On-Track) to 100%. It may be important in some law enforcement applications to know that a negative test result is, indeed, a true negative.

TABLE 3—*Prevalence data by kit by analyte.*

Test Kit/Analyte		TP	FP	TN	FN	n
Triage	THC	44	1	254	4	303
	COC	34	1	262	6	303
	OPI	2	1	300	0	303
	PCP	0	0	303	0	303
	AMP	1	7	295	0	303
Abu-Sign	THC	48	18	237	0	303
	COC	40	6	257	0	303
	OPI	2	0	301	0	303
	AMP	1	2	134	0	137*
	MET	0	1	165	0	166*
On-Track	THC	39	5	251	8	303
	COC	33	1	261	7	302†
	MOR	2	0	300	0	302†
TesTcup	THC	43	4	251	4	302†
	COC	38	6	256	2	302‡
	MOR	2	0	300	0	302‡

*Two Abu-Sign kits were used: 137 specimens were processed with kit THC, COC, OPI, AMP, and 166 specimens were processed with kit THC, COC, OPI, MET for a total sample size of n = 303.

†n = 303 for THC but specimen #300 was insufficient amount for all 3 analyte tracks so specimen was run only on THC track.

‡Specimen #300 was insufficient amount for TesTcup analysis.

TABLE 4—*Sensitivity, specificity, positive and negative predictive values of "on-site" test kits.*

	Marijuana				Cocaine				Opiates			
On-Site Kit	SEN*	SPE†	PPV†	NPV§	SEN*	SPE†	PPV†	NPV§	SEN*	SPE†	PPV†	NPV§
Triage	91.7	99.6	97.8	98.4	85.0	99.6	97.1	97.8	100	99.7	66.7	100
Abu-Sign	100	92.9	72.7	100	100	97.7	86.9	100	100	100	100	100
TesTcup	91.5	98.4	91.5	98.4	95.0	97.7	86.4	99.2	100	100	100	100
OnTrak	82.9	98.0	88.6	96.9	82.5	99.6	97.0	97.4	100	100	100	100

*Sensitivity.
†Specificity.
‡Positive Predictive Value.
§Negative Predictive Value.

The prevalence of illicit drugs in reckless drivers in this study population is the proportion of individuals in the study population who are drug positive when arrested for reckless driving. Sensitivity and specificity start from subjects that are on drugs and those who are drug-free and determine how often the test is either positive or negative respectively. They are not dependent on prevalence. However, positive and negative predictive value depend on prevalence because they depend on the relative proportions of drug positive and drug-free persons being tested (6). This study population is a random sample of the target population of reckless drivers, therefore positive and negative predictive values determined in this study are appropriate indexes of the target population. If the prevalence of drug positive persons is high in the population of interest, follow-up laboratory testing is not routine, and greater emphasis must be placed on the results of the on-site kit, then an on-site kit with a high PPV value may be a primary factor in choosing an appropriate kit.

PCP was not detected in any specimens. Only one specimen contained amphetamine and it was correctly identified by the only two kits which screened for amphetamines (Triage and Abu-Sign), however, Triage also identified 7 additional specimens as positive for amphetamine but these were false positives. Abu-Sign produced no false positives for amphetamines. The Triage on-site kit identified 2 specimens as positive for barbiturates and 10 specimens as positive for benzodiazepines, but these analytes were not on the confirmation panel at CompuChem Labs, and therefore, were not confirmed. The other on-site kits did not screen for barbiturates or benzodiazepines.

Overall each of the on-site immunoassay products worked well, and can serve as good screening devices. We believe non-medical persons are quite capable of learning to use these test kits in a very skilled manner when properly trained. A summary of the chemistry evaluation, ease of use of kit, and cost are provided in Table 5. All four factors are important and should enter into the decision of which kit is most suitable for a particular application.

TABLE 5—*Summary of "on-site" test kit evaluation.*

Evaluation of Kits	Sensitivity*	Specificity*	Ease of Use†	Cost‡
Triage	92.2	99.6	2.9	$18–25/7-drug
Abu-Sign	100	96.9	3.4	$12–18/5-drug
TesTcup	95.5	98.7	3.7	$10–15/3-drug
OnTrak	88.5	99.2	2.4	$1.50–3.50/drug

*Overall sensitivity (%) averaged across the three drug classes tested. Overall specificity (%) averaged across the three drug classes tested.

†Ease of kit use from Table 1.

‡Cost-Range of average retail price per kit. The number of drug classes detected per kit varies.

Discussion

The purpose of using an on-site screening kit in a law enforcement application such as this study is to identify an individual who may be driving-under-the-influence of drugs (DUID). It must be kept in mind that this is a presumptive screening technique and that positive test results should be confirmed by laboratory immunoassay screening and GC/MS confirmation. In this regard, sensitivity (the ability of the assay to identify those using the drug in question) is our most important predictor of the success of the kit of choice. The Abu-sign kit was the most successful at 100% sensitivity. This kit identified all persons using marijuana, cocaine, and opiates. Although the positive predictive value (the probability that a positive test result is a true positive) of the Abu-sign kit was the lowest among all kits (72.7% for marijuana), this reflects fewer than 7% false positives and these are easily resolved upon follow-up laboratory screening. The false positive rate in these kits, used for law enforcement purposes, is not a critical measure as long as legal action is not taken based on these presumptive results alone.

If an agency using these kits does not have easy access to laboratory screening and confirmation, specificity (the ability of the assay to identify those not using the drug in question) may be a more important predictor of successful drug testing. The higher % specificity, the less false positives. It provides a higher comfort level or greater probability that a drug-free person will, indeed, have a negative test result. Using specificity as an indicator for choosing a particular kit will readily identify those persons not on drugs. Even though this may cause some persons who are on drugs to be missed, the highest false negative rate was just 8% (TesTcup). If an agency does not have means to submit the urine specimens to a laboratory for follow-up testing, then it is always safer to err in favor of the DUID suspect by choosing a kit with a high specificity.

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