





Conclusion of Validation Study of Commercially Available Field Test Kits for Common Drugs of Abuse

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Abstract

The National Forensic Science Technology Center (NFSTC), as part of its Field Investigation Drug Officer (FIDO) program, has developed a comprehensive training program and quality assurance system that provides law enforcement with the resources necessary to perform preliminary identification of controlled substances utilizing field test kits. To provide information concerning test kit performance, NFSTC expanded the FIDO project to include a validation study of the tests most frequently employed by law enforcement agencies. The NFSTC previously presented to the Academy preliminary results of this validation study in 2006. This poster presents the results of some additional testing on the NarcoPouch®, NIK®, and NARK® II field test kits as well as the results of the entire validation study performed on the QuickCheck® test kits.

Kits included in this study are those manufactured by:

- ODV, Inc. (NarcoPouch®)
- Sirchie Group (NARK®II)
- Public Safety, Inc. (NIK®)
- Lynn Peavey Company (QuickCheck™)

In particular, the kits designed for presumptive identification of cocaine, methamphetamine, and heroin were assessed.

The results presented here include a narrower limit of detection (LOD) range than what was previously reported as well as test kit inter-day reproducibility, specificity, and environmental exposure performance. Each sample was tested in duplicate with final color assignment occurring after a one minute time interval. Colors were assigned as a numeric designation of hue, value, and chroma within using the Munsell Color Chart System.

The results of this validation study will provide law enforcement agencies with data to enable them to select the test kits best suited to their needs. Information is provided with respect to measured criteria as well as corollary observations regarding test kit quality control, safety, and color. Results of this study will be included in the Best Practices Guide provided by NFSTC to all interested parties.

Introduction

Program Development

The Field Investigator Drug Officer (FIDO) Program was created to aide the criminal justice system by decreasing the overwhelming controlled substance caseload. The concept of a FIDO program was to develop a best practices guide that contains guidance documents and information for fast and effective application to on-scene drug investigation. The development of the FIDO program was managed by the National Forensic Science Technology Center (NFSTC). The NFSTC partnered with the Rural Law Enforcement Technology Center (RULETC) and Eastern Kentucky University (EKU) for program pilot testing and evaluation.

Benefits of the effective implementation of a FIDO program include:

- Immediate on-scene investigative information
- Facilitation of adjudication in the preliminary phase of possession and non-residue cases
- Reduction of laboratory case backlog

The program is comprised of a comprehensive training program and quality assurance system that provides a guide to law enforcement to train personnel to perform presumptive tests on certain controlled substances.

The program is comprised of documents that articulate:

- Program administration
- Guidelines for quality assurance
- Legal issues
- Materials for the development of training and certification programs
 - Lesson plans
- Practical exercises

- Class outlines

- Written examinations and practical assessments
- Recertification lesson plans
- Forms
- Class lecture content and slideshows References







Validation Study

The use of color test kits is the most common method for the presumptive field identification of controlled substances because they are:

- · Easy to use
- Quick to produce results
- · Cost effective

For consideration in the FIDO program, color test kits must provide:

- · Sufficient specificity to minimize false positive or false negative interpretation
- Adequate sensitivity to allow the detection of drugs at concentrations commonly encountered in street samples
- · Accurate results for drugs mixed with a variety of adulterants
- · Reproducible results

The validation study was designed to address the above listed criteria.

Materials and Equipment

Samples were prepared by combining pure drug standards with pure cutting agents in the following ratios (w/w): 5:95, 10:90, 20:80, 30:70, 40:60, 50:50, 60:40. 80:20

The following mixtures of drug-cutting agent were prepared:

- Cocaine HCI Boric Acid, Caffeine, Mannitol, and Procaine
- · Cocaine Base Benzocaine, Caffeine, and Mannitol
- Methamphetamine HCI Caffeine, Dimethylsulfone (DMS), and Niacinamide
- Heroin Caffeine, Procaine, and Quinine

Table 1: Materials and Equipment					
Equipment	Cutting Agents				
Analytical Balance (Mettler Toledo AB104-s/Fisher Scientific accu-124D)	Acetaminophen (Sigma)	Ketamine (Sigma)			
Spatulas	Acetylsalicylic Acid (Aldrich)	Lidocaine (Sigma)			
Weigh Paper	Baking Soda (Arm & Hammer)	Mannitol (Aldrich)			
Munsell Book of Color	Benzphetamine (Sigma)	Mepivacaine (Sigma)			
Drug Standards	Boric Acid (Fisher)	Niacinamide (Sigma)			
Cocaine HCI (Sigma)	Bupivacaine HCI (Sigma)	Parmesan Cheese (Kraft)			
Cocaine Base (secondary standard)	Caffeine anhydrous (Sigma)	Phencyclidine (Sigma)			
Methamphetamine HCI (Sigma)	Chlorpheniramine Maleate Salt (Sigma)	Powdered Milk (Nestle)			
Heroin (secondary standard)	Dextromethorphan (Sigma)	Procaine HCI (Fluka)			
Test Kits	Dimethylsulfone (DMS) (Gaylord)	Psuedoephedrine (Sigma)			
Scott's Reagent (modified)	Diphenhydramine HCI (ICN)	Quinine (Sigma)			
Marquis Reagent	Ephedrine (Aldrich)	Sucrose (Fisher)			
Methamphetamine/MDMA reagent	Inositol (Acros)	Tetracaine (Sigma)			
Mecke's Reagent					

Method

General Procedure

- 1. Three milligram portions of sample were weighed out in duplicate using an analytical balance.
- 2. Each 3mg portion was placed into an appropriately labeled test kit for evaluation. The types of test kits used in this study were:
 - Scott's Reagent (modified) Cocaine HCI and Cocaine Base
 - Marguis Reagent and Methamphetamine/MDMA Reagent for Methamphetamine HCl
 - Marquis Reagent and Mecke's Reagent for Heroin
- 3. Ampoules were broken according to the procedure provided by each manufacturer.
- 4. After 60 seconds, the color (if one developed) was matched to a chip in the Munsell Book of Color. Color chips from the Munsell Book of Color were viewed at angles between 40–50° under General Electric Watt-Miser II F40LW-RS-WMII Lite White 34 Watt fluorescent bulbs. The hue, value, and chroma were recorded.

Deviations from General Procedure

SPECIFICITY:

Test kit specificity was determined using 10mg samples.

Substances producing a false positive at 10mg were then tested at 3mg.

REPRODUCIBILITY:

Inter-day reproducibility was conducted on samples with standard drug to caffeine ratios of 80:20 and 40:60. Reproducibility was evaluated over 10 consecutive working days.

ENVIRONMENTAL:

Test kit performance was assessed after kits were subjected to one of the following environmental conditions for two weeks:

- Frozen (-3°C to -17°C)
- Refrigeration (2°C to 5°C)
- Oven (Dry Heat) (40°C)
- Trunk of vehicle (Moist Heat) (≈20°C to 38°C)

Environmental performance was assessed on samples with drug standard to cutting agent ratios of 80:20 and 40:60.

Results

Table 2: Estimated Limits of Detection (Expressed as % Drug Purity [w/w])						
Drug	Test Kit Type	Cut	NarcoPouch [®]	NIK [®]	NARK [®] II	QuickCheck"
		Boric Acid	40-50%	20-30%	5-10%	5-10%
Cocaine	Scott's	Caffeine	30-40%	20-30%	20-30%	5-10%
Hydrochloride	(modified)	Mannitol	20-30%	30-40%	10-20%	10-20%
		Procaine	30-40%	30-40%	10-20%	10-20%
		Caffeine	30-40%	30-40%	10-20%	10-20%
Cocaine Base	Scott's	Mannitol	30-40%	30-40%	10-20%	5-10%
	(modified)	Benzocaine	30-40%	10-20%	10-20%	10-20%
		Caffeine	5-10%	≤5%	≤5%	≤5%
Methamphetamine	Marquis	DMS	5-10%	5-10%	5-10%	5-10%
		Niacinamide	5-10%	20-30%	5-10%	20-30%
		Caffeine	≤5%	≤5%	≤5%	≤5%
	Methamphetamine	DMS	10-20%	10-20%	≤5%	≤5%
	MDMA	Niacinamide	≤5%	20-30%	≤5%	5-10%
		Caffeine	≤5%	≤5%	5-10%	≤5%
Heroin	Marquis	Procaine	5-10%	5-10%	5-10%	5-10%
		Quinine	5-10%	10-20%	20-30%	20-30%
		Caffeine	5-10%	5-10%	5-10%	5-10%
	Mecke's	Procaine	10-20%	10-20%	30-40%	30-40%
		Quinine	5-10%	5-10%	10-20%	10-20%

Table 4: Inter-day Reproducibility							
Drug	Test	Ratio	NarcoPouch®	NIK®	NARK®II	QuickCheck [™]	
Cocaine HCI	Scott's	40/60	All Positive	All Positive	All Positive	All Positive	
	(modified)	80/20	All Positive	All Positive	All Positive	All Positive	
Cocaine Base	Scott's	40/60	All Positive	All Positive	All Positive	All Positive	
	(modified)	80/20	All Positive	All Positive	All Positive	All Positive	
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Methamphetamine	Marquis	40/60	All Positive	All Positive	All Positive	All Positive	
		80/20	All Positive	All Positive	All Positive	All Positive	
Methamphetamine	Meth/	40/60	All Positive	All Positive	All Positive	All Positive	
	MDMA	80/20	All Positive	All Positive	All Positive	All Positive	
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Heroin	Marquis	40/60	All Positive	All Positive	All Positive	All Positive	
		40/60	All Positive	All Positive	All Positive	All Positive	
Heroin	Mecke's	40/60	All Positive	All Positive	All Positive	All Positive	
		40/60	All Positive	All Positive	All Positive	All Positive	

		mpounds Producing False Positives* Brand				
Test Kit Type	Compound	Mg	NarcoPouch [®]	NIK®	NARK [®] II	QuickCheck™
		3				
Scott's (Modified)	Chlorpheniramine	10				X
		3			X	X
	Dextromethorphan	10	X	X		X
		3	X	X	X	X
	Diphenhydramine	10	X	X	X	X
		3				X
	Quinine	10				X
		3	X	X	X	X
	Bupivacaine	10	X	X	X	X
		3			X	X
	Lidocaine	10	X	X	X	X
		3				X
	Tetracaine	10				X
		3	X	X	X	X
	Phencyclidine	10	X	X	X	X
		3	X	Х	X	X
	Benzphetamine	10	X	X	X	X
		3				X
	Ketamine					X
		3			X	X
Marquis	Diphenhydramine	10	X	X	X	X
	Benzphetamine	3	X	X	X	X
		10	X	X	X	X
				355		
Meth/MDMA	No false positives					
Mecke's	No false positives					
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Table 5: Effects of Environmental Conditions on Test Kit Performance						
Environmental Conditions	Temperature	Duration of Exposure	Results			
Refrigeration	-2°C to -5°C	14 Days	Increase in inconclusive results for Scott's reagent using NarcoPouch [®]			
Dry Heat	40°C	14 Days	Increase in inconclusive results Scott's reagent using NarcoPouch® and NIK®			
Frozen	-10°C to -17°C	14 Days	Increase in inconclusive results for Scott's reagent using NarcoPouch [®]			
Humid Heat	25°C to 38°C (Outside Temp)	14 Days	Increase in inconclusive results for Scott's reagent using NARK®II			

Discussion

This study provides validation data concerning four commercially available field test kits used to presumptively identify controlled substances. The information presented here with respect to test kit sensitivity, specificity, reproducibility, and environmental stress performance confirm that these tests are valuable tools if used as prescribed by the FIDO program guidelines.

Sensitivity

- For Cocaine HCL and Cocaine Base, the QuickCheck™ and NARK®II test kits consistently displayed lower levels of sensitivity than the NarcoPouch® and NIK® test kits.
- All the methamphetamine standard mixtures produced consistently low sensitivity levels across all Marquis test kit brands, with the exception
 of the mixture of methamphetamine and niacinamide. In the NIK® and QuickCheck™ kits, this mixture exhibited reduced sensitivity with a limit of
 detection range of about twice that of the other two kits.
- The NARK®II displayed the lowest and most consistent detection of methamphetamine mixtures using the Sodium Nitro- prusside test. The NARK®II was followed by QuickCheck™, NarcoPouch®, and NIK® in order of decreasing sensitivity.
- The NarcoPouch® and NIK® Marquis and Mecke's test kits produced the lowest limits of detection and the least variation in sensitivity for heroin analysis.
- Within the limit of detection range for each brand of Marquis test kit, samples with low concentrations of heroin to quinine produced an orange-brown color that could be misinterpreted for a positive result for methamphetamine. It is theorized that the yellow color produced by the major component (quinine) in the Marquis kit is blending with the purple color from the minor component (heroin) resulting in the orange-brown color.
 This is a classic example of how a cutting agent can interfere with the color development expected from the drug of interest.

Specificity

- Of the 26 different compounds assessed, only the cutting agents producing a positive result (color expected from a target drug) were reported. All cutting agents tested are listed in the Materials Table.
- Generally specificity results were consistent across the test kit brands. It was noted that QuickCheck™ cocaine test kits produced more false
 positives than other brands.
- QuickCheck™ and Nark®II Marquis test kits produced false positives for diphenhydramine and benzphetamine at the 3 and 10 mg level. NarcoPouch® and NIK® Marquis kits did not produce false positives for diphenhydramine at the 3 mg level.

Reproducibility

All 40:60 and 80:20 ratios of drug to caffeine mixtures tested in all kits brands and types exhibited reproducible positive results over the 10 day period.

Environmental

Colors were less readily visible after exposure to some environmental conditions, causing more results to be defined as inconclusive. This occurred in the following circumstances:

- NarcoPouch® Scott's Reagent when exposed to both freezing and refrigerated conditions
- NIK® pouch Scott's Reagent when exposed to refrigeration (though the differences noted were minimal)
- NIK® Scott's Reagent when exposed to dry heat conditions
- QuickCheck™ Methamphetamine/Ecstacy reagent when exposed to freezing temperatures (positive color was slower to develop)
- QuickCheck[™] Marquis Reagent after exposure to dry heat

General Observations

Several observations were made that should be taken into consideration when using field testing kits for controlled substance analysis:

- Large masses of sample have a tendency to interfere with color development if the adulterant interacts with the testing reagent
- · Under dry and humid heat conditions, many of the sealing mechanisms became warped, preventing the pouches from closing properly
- · Glass shards occasionally broke through the pouches under normal and adverse environmental conditions
- Manufacturer's instructions should be followed
- Several kit quality control defects were observed during the study:
 - Ampoules were sometimes cracked or empty
 - Some kit reagents appeared discolored, but this was not found to affect kit performance
 - Spatulas for sample acquisition were missing from some QuickCheck™ kits
 - Some QuickCheck™ kits (primarily Mecke's) appeared to contain debris
 - Some of the NARK® II pouches were found to have deficient bottom seams causing leakage during testing

Conclusions

The results of this study demonstrate that all four brands of test kits are appropriate for use in a FIDO program as presumptive tests for the presence of cocaine, methamphetamine, and heroin with the following limitations:

- Field drug test kits are presumptive in nature. They do not provide any structural information and are subject to false positives. Therefore, all samples producing a negative or ambiguous presumptive result should be sent to a forensic laboratory for a complete analysis.
- Kits should not be used for the analysis of residues.
- · Color interpretation is subjective, especially when analyte concentrations approach the detection limit or when an interfering compound is present.
- Kits should not be used on liquid samples.
- · Kits must be stored in environmental conditions that will not affect the integrity of the test kit or its components.
- Kits should not be utilized past the manufacturers recommended shelf life.
- Use of the Cocaine test kit to distinguish between cocaine salt and base is problematic. It is not recommended to employ field test kits for this
 purpose.

It was noted that new design features introduced by Lynn Peavey in the QuickCheck™ test kits, (i.e., clearer plastic, white background, rounded pouch bottom, zip closure, and instructions) enabled easier handling, test execution, and result interpretation.

The adequacy of these tests for use in a FIDO program lies in their ability to:

- · Display sufficient specificity
- Display adequate sensitivity to allow the detection of drugs at commonly encountered concentrations in street samples
- · Undergo proper color development to indicate the classification of drugs present
- · Produce definitive positives throughout the duration of the reproducibility study

Within a FIDO program, if a result is questionable or a defendant pleads not guilty at pre-trial, the case is submitted to a laboratory for a complete analysis.

All brands appear qualified for application in field analysis, however some are better suited for certain conditions, than others. Minor interferences and anomalies have occurred throughout the study, but none that prohibit the ability of the testing kits to presumptively identify the presence of controlled substances. The variation that occurred between brands is negligible. No brand excelled as the best or performed so poorly as to be considered inadequate.

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