

Field Study Summary Report for *ulti med* Sweat/Surface Drug Screening System



Parameter

(AMP/OPI/THC) (MTD/MET/COC)
(AMP/OPI/THC) (PCP/MET/COC)

Item number: 008S804
Item number: 008S805

The ulti med sweat/surface drug screening system study was performed by a clinical toxicologist in San Bernardino County, California, USA in December 2006 and January 2007.

The field study was performed to examine the effectiveness of the ulti med sweat/surface drug screening system. The study used sweat and surface samples of known drug users and drug free volunteers in combination with drug consumption self-disclosure. Samples testing positive in a visual analysis were verified using gas chromatography/mass spectrometry (GC/MS) at a SAMHSA certified laboratory. In addition to the sweat/body surface sampling, the subjects supplied urine samples, which were then tested using immuno-chromatographic urine tests. Again, positive results were verified with GC/MS testing.

Clinical Samples

A total of 25 each sweat/body surface and 25 urine samples were collected in line with the investigation and analyzed. Based on the subjects' self-disclosure it was assumed 20 of the combined samples would test positive for at least one, 5 combined samples should be drug free. Sweat/body surface samples were taken during sampling by wiping hands and the forehead. Afterwards, subjects wore powder-free latex gloves to stimulate sweating. After 10-15 minutes, the gloves were removed and the hands were once again wiped with the same screen test. The chromatography was performed with a diluted buffer solution containing less than 10% isopropyl alcohol. All lab results were corrected by this dilution factor.

Screening Methods

The ulti med test was used for all sweat/body surface samples. The system consisted of an ulti med Handheld Reader with Software Version 2.2 and single-use SalivaScreen tests with lot number PD 061213A for detection of THC, opiate, amphetamine, methadone, methamphetamine and cocaine. The results determined by the Handheld Reader were printed out via Brother MPrint MW-140BT Bluetooth printer. Urine samples were tested using DrugControl Multi 5 dip tests (lot 008A434-29) for detection of THC metabolite, opiate, amphetamine, methamphetamine and cocaine metabolites.



Item number: 008M600

Verification method

Supposed positive sweat/body surface samples were tested using GC/MS at National Toxicology Laboratories, Bakersfield, CA, USA. The samples were extracted from the sampling of the test cartridge using organic solvents, and reconstituted in a solution prior to analysis.

Supposed positive urine samples were tested by before mentioned lab using GC/MS.

Test Results

The following tables show the visual interpretations of the test results in comparison with the subjects' self-disclosure.

COCAINE

SalivaScreen® Test	Self-disclosure	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

METHAMPHETAMINE

SalivaScreen® Test	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

AMPHETAMINE

SalivaScreen® Test	Self-disclosur	
	positive	negative
positive	2	0
negative	3	20

Sensitivity $2/(2+3) \times 100\% = 40\%$ (1)
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(2+20)/(2+3+20+0) \times 100\% = 88\%$

OPIATES

SalivaScreen® Test	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

THC

SalivaScreen® Test	Self-disclosur	
	positive	negative
positive	3	0
negative	2	20

Sensitivity $3/(3+2) \times 100\% = >60\%$ (2)
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(3+20)/(3+2+20+0) \times 100\% = 92\%$

(1) Later comparison results confirmed the absence of amphetamine in 2 of 3 ambiguous samples.

(2) Later comparison results confirmed the presence of Δ^9 -THC in both ambiguous samples.

Test results SalivaScreen® – GC/MS

SalivaScreen® positive	GC/MS positive	Consistency percentage
Methamphetamine	>25ng/ml	Consistency
5	5	>99%
Amphetamine	>25ng/ml	Consistency
2	3	67%
Opiates	>25ng/ml	Consistency
5	5	>99%
Cocaine	>25ng/ml	Consistency
5	5	>99%
Δ^9 -THC	>2ng/ml	Consistency
3	5	60%

Test results DrugControl (urine sample) – GC/MS

COCAINE

DrugControl Multi 5	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$

Specificity $20/(20+0) \times 100\% = >99\%$

Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$



METHAMPHETAMINE

DrugControl Multi 5	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

AMPHETAMINE

DrugControl Multi 5	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

OPIATES

DrugControl Multi 5	Self-disclosur	
	positive	negative
positive	5	0
negative	0	20

Sensitivity $5/(5+0) \times 100\% = >99\%$
 Specificity $20/(20+0) \times 100\% = >99\%$
 Accuracy $(5+20)/(5+0+20+0) \times 100\% = >99\%$

THC

DrugControl Multi 5	Self-disclosur	
	positive	negative
positive	5	1
negative	1	18

Sensitivity $5/(5+1) \times 100\% = 83\%$ (3)
 Specificity $18/(18+1) \times 100\% = 95\%$ (4)
 Accuracy $(5+18)/(5+1+18+1) \times 100\% = 92\%$

(3) One subject disclosed marijuana consumption within 24 hours prior to the test, yet sweat/body surface and urine rapid tests were negative.

(4) One subject disclosed non-use of marijuana, yet the urine rapid test was positive for THC metabolites, the sweat/body surface test was negative.

Test results DrugControl – GC/MS

DrugControl Multi Dip 5 positive	GC/MS positive	Consistency percentage
Methamphetamine	>500ng/ml	Consistency
5	5	>99%
Amphetamine	>200ng/ml	Consistency
5	5	>99%
Opiates	>150ng/ml	Consistency
5	5	>99%
Cocaine	>150ng/ml	Consistency
5	5	>99%
Δ^9 -THC	>15ng/ml	Consistency
6	6	>99% %

Summary

The ulti med SalivaScreen test cartridges are reliable in detecting drugs in sweat/body surface samples, provided the drugs are present in sufficient quantity following consumption. This becomes evident when comparing the test results with the subjects' self-disclosure. The drug concentration in the sample is particularly vital, since a puffer is required to ensure the specimen flow onto the test strip.

The correlation between the results of urine and sweat/body surface samples of drug consuming subjects demonstrated the effectiveness of the ulti med drug test system and the DrugControl test strips.

The general consistency in test results between the ulti med drug test system and GC/MS for sweat/body surface samples is 80%.

The general consistency of test results between the ulti med DrugControl test strips and GC/MS for urine samples is >99%.



Your first choice... *...a safe decision*

Virtually all ulti med products are CE labelled for professional use

- Meets EU guideline 98/79 EG IVD (In-vitro Diagnostics)
- Detection limit per SAMHSA and NIDA Standard (USA)
- Certified production per DIN EN ISO 13485:2003
- Matches >98% of GC/MS lab results



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