Field Study Summary Report for

ulti med SalivaScreen®

Parameter

(AMP/OPI/THC) (MTD/MET/COC) **Item number: 008S804**
(AMP/OPI/THC) (PCP/MET/COC) **Item number: 008S805**

The ulti med SalivaScreen® 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 SalivaScreen®. The study used saliva samples of known drug users and drug free volunteers in combination with self-disclosure about drug consumption. Samples testing positive using a rapid test were verified using gas chromatography/mass spectrometry (GC/MS) at a SAMHSA certified laboratory.
In addition to the saliva samples, the subjects supplied urine samples, which were then tested using immuno-chromatographic rapid tests. Again, positive results were verified with GC/MS testing.

Clinical Samples

A total of 25 saliva samples and 25 urine samples were taken and analyzed for the purpose of this study. Saliva samples were taken using the ulti med SalivaScreen®. Urine samples were collected in sterile urine containers by Andwin Scientific.

Screening methods

The ulti med SalivaScreen® system was used for all saliva samples. The system consisted of an ulti med Handheld Reader with Software Version 2.2 and SalivaScreen® single use tests of lot number PD 061213A for detection of THC, opiates, 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-metabolites, opiates, amphetamine, methamphetamine and cocaine metabolites.

Item number: 008M600

Verification methods

Supposed positive saliva samples were tested using GC/MS/MS by Bendiner and Schlesinger Inc. Brooklyn, New York. The samples were extracted from the Sampling tips of the cartridge using organic solvents, and reconstituted in a liquid prior to analysis.

Supposed positive urine samples were tested by National Toxicology Laboratories, Bakersfield, California, USA, using GC/MS.

Test Results

The test results compared to the subjects' self-disclosure are listed in the following tables.

COCAINE

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

METHAMPHETAMINE

SalivaScreen® Test	Self-disclosur positive	negative
positive	4	0
negative	1	20

Sensitivity 5/(5+0)x100% = >80% [1]
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = 96%

AMPHETAMINE

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

Sensitivity 5/(5+0)x100% = >0% [2]
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = 80%

OPIATES

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

THC

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

Sensitivity 3/(3+2)x100% = >60% [3]
Specificity 20/(20+0)x100% = >99%
Accuracy (3+20)/(3+2+20+0)x100% = 92%

(1) Later comparison results confirmed the presence of methamphetamine in the ambiguous sample.

(2) Later comparison results confirmed the absence of amphetamine in all ambiguous samples. This brought forward proof of the correct function of the test cartridges and that the use of methamphetamine does not necessarily result in detectable amounts of amphetamine in the saliva.

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

Test results SalivaScreen® – GC/MS

SalivaScreen® positive	GC/MS positive	Consistency percentage
Methamphetamine	>40ng/ml	Consistency
4	5	80%
Amphetamine	>25ng/ml	Consistency
0	0	>99%
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 – GC/MS

COCAINE

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

METHAMPHETAMINE

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

AMPHETAMINE

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

OPIATES

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

Sensitivity 5/(5+0)x100% = >99%
Specificity 20/(20+0)x100% = >99%
Accuracy (5+20)/5+0+20+0)x100% = >99%

THC

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

Sensitivity 5/(5+1)x100% = 83% [4]
Specificity 18/(18+1)x100% = 95% [5]
Accuracy (5+18)/5+1+118+1)x100% = 92%

(4) One subject disclosed marijuana consumption within 24 hours prior to the test, yet saliva samples and urine tests were negative, the GC/MS-test on urine samples was also negative for Δ^9-THC metabolites.

(5) Another subject disclosed non-use of marijuana, yet the urine test and the GC/MS-test were positive for THC-metabolites. The saliva 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 can accurately detect drugs in saliva samples, provided the drugs are present in sufficient quantity following consumption. Just as with other saliva tests, the detection of THC is associated with certain requirements due to the lipophilic characters of THC and its metabolites in the saliva matrix.

The correlation between the results of urine and saliva samples of drug consuming subjects demonstrated the effectiveness of ulti med SalivaScreen® and the DrugControl test strips.

The general consistency of test results between the ulti med SalivaScreen® and GC/MS/MS in saliva samples is 85%.

The general consistency of test results between ulti med DrugControl test strips and GC/MS in 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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