

DrugSmartCup & DrugSmartDip Accuracy Report as produced by Ameditech, Inc.

Accuracy

The accuracy of the DrugSmart™ Drugs of Abuse Tests was evaluated in comparison to commercially available drug screen tests. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested by both DrugSmart™ Drugs of Abuse Cup, Card and commercially available drug screen tests. Of these negative urine samples tested, all were found negatives by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (TCA concentrations were determined by HPLC), were tested by DrugSmart™ Drugs of Abuse Cup, Card and commercial drug screen tests. The results of accuracy study are presented below:

Drug Test		GC/MS (<-50% C/O)	GC/MS (-50% C/O to C/O)	GC/MS (C/O to +50% C/O)	GC/MS (>+50% C/O)	% Agreement with GC/MS
AMP	(+)	0	1	8	62	100
	(-)	15	6	0	0	95.5
BAR	(+)	0	1	4	83	96.7
	(-)	15	7	3	0	95.7
BZO	(+)	0	2	10	49	98.3
	(-)	15	10	1	0	92.6
COC	(+)	0	2	8	70	100
	(-)	15	6	0	0	91.3
MDMA	(+)	0	1	6	37	100
	(-)	24	6	0	0	96.8
MET 300	(+)	0	1	6	68	100
	(-)	15	5	0	0	95.2
MET1000	(+)	0	1	6	58	100
	(-)	20	7	0	0	96.4
MTD	(+)	0	0	6	65	98.6
	(-)	15	5	1	0	100
OPI300	(+)	0	1	6	77	100
	(-)	16	6	0	0	95.7
OPI 2000	(+)	0	2	9	45	100
	(-)	15	6	0	0	91.3
OXY	(+)	0	1	6	47	100
	(-)	15	7	0	0	95.7
PCP	(+)	0	1	5	36	100
	(-)	15	3	0	0	94.7
TCA	(+)	0	1	12	9	100
	(-)	23	11	0	0	97.1
THC	(+)	0	4	24	32	100
	(-)	15	5	0	0	83.3

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Precision

The precision of the DrugSmart™ Drugs of Abuse Tests was evaluated by testing three lots of the test devices at four study sites with spiked drug sample solutions on three consecutive days. Sample concentrations were confirmed by GC/MS.

AMP (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	32/103	72/63	103/32	135/0
BAR (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	30/105	70/65	99/36	135/0
BZO (ng/ml)	0	100	150	200	250	300
(+/-)	0/135	0/135	31/104	74/61	100/35	135/0
COC (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	35/100	72/63	102/33	135/0
MDMA (ng/ml)	0	250	375	500	625	750
(+/-)	0/135	0/135	29/106	74/61	103/32	135/0
MET300 (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	32/103	77/58	99/36	135/0
MET1000 (ng/ml)	0	500	750	1000	1250	1500
(+/-)	0/135	0/135	30/105	74/61	96/39	135/0
MTD (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	32/103	73/62	102/33	135/0
OPI300 (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	33/102	70/65	95/40	135/0
OPI2000 (ng/ml)	0	1000	1500	2000	2500	3000
(+/-)	0/135	0/135	34/101	72/63	100/35	135/0
OXY (ng/ml)	0	50	75	100	125	150
(+/-)	0/135	0/135	29/106	71/64	99/36	135/0
PCP (ng/ml)	0	12.5	18.75	25	31.25	37.5
(+/-)	0/135	0/135	31/104	73/62	99/36	135/0
TCA (ng/ml)	0	500	750	1000	1250	1500
(+/-)	0/135	0/135	24/111	60/75	99/36	135/0
THC (ng/ml)	0	25	37.5	50	62.5	75
(+/-)	0/135	0/135	33/102	67/68	99/36	135/0

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Specificity

The specificity for the DrugSmart™ Drugs of Abuse Cup and Card was determined by testing various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
Amphetamine			
d-Amphetamine	300	d-Methamphetamine	20,000
dl-Amphetamine	750	(+/-)3,4-MDMA	20,000
(+/-)3,4-MDA	400		
Barbiturates			
Secobarbital	300	Butabarbital	400
Allobarbital	600	Butalbital	300
Alphenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Phenobarbital	450
Barbital	1500		
Benzodiazepines			
Oxazepam	200	Flunitrazepam	200
Alprazolam	250	Flurazepam	200
Bromazepam	150	Lorazepam	300
Chlordiazepoxide	250	Medazepam	250
Clobazam	700	Nitrazepam	150
Clonazepam	350	Nordiazepam	100
Clorazepate	100	Prazepam	350
Desalkylflurazepam	150	Temazepam	150
Diazepam	300	Triazolam	300
Estazolam	200		
Cocaine			
Benzoyllecgonine	300	Cocaine	300
Methamphetamine (300)			
d-Methamphetamine	300	(+/-)3,4-MDMA	1,200
d-Amphetamine	30,000	l-Methamphetamine	6,000
l-Amphetamine	60,000	Ephedrine	100,000
(+/-)3,4-MDEA	30,000	Mephentermine	25,000
(+/-)3,4-MDA	50,000		
Methamphetamine (1000)			
d-Methamphetamine	1000	(+/-)3,4-MDMA	3,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4-MDEA	50,000	Mephentermine	75,000
(+/-)3,4-MDA	100,000		
MDMA			
(+/-)3,4-MDMA	500	(+/-)3,4-MDA	4,000
(+/-)3,4-MDEA	450		
Methadone			
(+/-) Methadone	300	Methadol	1,500

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Opiates (300)

Morphine	300	Hydrocodone	500
Codeine	300	Hydromorphone	500
Ethylmorphine	300	Morphine-3-glucuronide	300
Heroin	750	Nalorphine	5,000

Opiates (2000)

Morphine	2,000	Hydrocodone	4,000
Codeine	2,000	Hydromorphone	5,000
Ethylmorphine	1,000	Morphine-3-glucuronide	2,500
Heroin	5,000	Nalorphine	5,000

Oxycodone

Oxycodone	100	Morphine	>100,000
Hydrocodone	5000	Codeine	50,000
Hydromorphone	50,000	Heroin	>100,000

PCP

Phencyclidine	25	Tenocyclidine	2,000
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THC

11-nor- Δ^9 -THC-9-COOH	50	Δ^9 -tetrahydrocannabinol	5,000
11-hydroxy- Δ^9 -THC	1,000	Cannabinol	10,000
Δ^8 -tetrahydrocannabinol	5,000	Cannabidiol	>100,000

Tricyclic Antidepressant

Nortriptyline	1,000	Promazine	1,500
Nordoxepin	2,000	Desipramine	400
Trimipramine	2,000	Doxepin	3,000
Amitriptyline	1,500	Maprotiline	2,000

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Interference

Two pools of drug-free urine were spiked with drug standards to 50% below and 50% above cutoff concentrations. The drug concentrations were confirmed by GC/MS. The following compounds were evaluated for potential positive and/or negative interference with the DrugSmart™ Drugs of Abuse Cup and Card. All compounds were dissolved in the spiked sample solutions and tested with DrugSmart™ Drugs of Abuse Cup and Card. An unaltered sample was used as a control.

No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 µg/ml.

Acetaminophen	Diphenhydramine	(+/-)-Norephedrine
Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	l-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Theophylline
Creatine	(+)-Naproxen	Tyramine
Dexbrompheniramine	Niacinamide	4-Dimethylaminoantipyrine
Dextromethorphan	Nicotine	(1R,2S)-(-)-N-Methyl-Ephedrine