SureScreen Diagnostics

Multi-Drug Screen Test

For Professional Use Only

The Multi-Drug Screen Test detects multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
AMP300	Amphetamine	300
AMP1000	Amphetamine	1,000
BAR	Barbiturates	300
BAR200	Barbiturates	200
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
BZO200	Benzodiazepines	200
COC	Cocaine	150
COC100	Cocaine	100
COC300	Cocaine	300
COT100	Cotinine	100
COT200	Cotinine	200
EDDP	Methadone Metabolite	300
EDDP	Methadone Metabolite	100
ETG	Ethyl Glucuronide	500
FEN	Norfentanyl	100
K2	SyntheticMarijuana	50
K2+	AB-PINACA	10
KET1000	Ketamine	1,000
MDMA	Ecstasy	500
MET	Methamphetamine	500
MET1000	Methamphetamine	1,000
MPD	Methylphenidate	1000
MTD	Methadone	300
MOP	Morphine	300
OPI	Opiates	2,000
OPI100	Opiates	100
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50
THC25	Marijuana	25
TRA	Tramadol	100

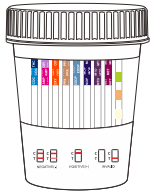
This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognised drug levels for these prescription drugs in urine.

PROCEDURE

Preparation:

1. Allow the test device, and/or controls to reach to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

Cup:



1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.

RESULT INTERPRETATION

Read results after 5 minutes. Do not read results past 60 minutes.

A red or pink line must appear next to the "C"(control) on all of the test strips. The appearance of a red or pink line next to the "C" on each test strip indicates that the test has worked properly.

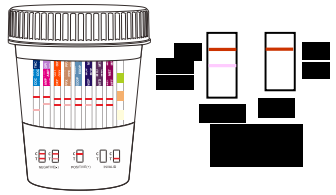
Negative Result:

A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.

Preliminary Positive Result:

If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

The illustration on the right shows preliminary positive results for THC and AMP, but negative for all other drugs.



Invalid Result:

A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter "C" on the first strip (COC, THC) and fourth strip (PPX). The test results for those two test strips are invalid.

SPECIMEN VALIDITY TEST

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The Urine AdulterationTest is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration.

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dL. Values outside this range generally indicate a manipulated test.

Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dL is considered adulterated.

Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may disrupt the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.

Quality control testing should be performed with each new lot, with each new shipment, and every thirty days to check storage conditions. External controls can be purchased from the following vendor: Biomedical Diagnostics, 1-631-595-9200, www.biochemicaldiagnostics.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the Multi-Drug Screen Test was evaluated in comparison to GC/MS and LC/MS. Drug-free urine samples collected from presumed non-user volunteers were tested with the Multi-Drug Screen Test. Of these negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 30 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy results on cassette, dip card, cup and strip formats are shown in the following tables.

Summary of Accuracy Results on the Multi-Drug Screen Test:

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	%Agreement
AMP/300	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	0	52	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
AMP/1000	Neg	40	2	0	0	0	0	97.7%
	Pos	0	0	1	3	2	42	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BAR/200	Neg	40	1	1	0	0	0	95.45%
	Pos	0	0	2	2	3	42	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
BZO/200	Neg	40	0	1	0	0	0	100%
	Pos	0	0	3	2	2	43	94%
COC/100	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	0	40	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	0	3	1	0	0	100%
	Pos	0	0	0	4	1	46	98.0%
COT/100	Neg	145	5	1	2	3	0	97.4%
	Pos	0	2	2	1	6	83	94.7%
COT/200	Neg	146	7	1	2	3	0	97.4%
	Pos	0	2	2	1	7	79	94.6%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
EDDP/100	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	9	0	32	100%
ETG/500	Neg	141	15	8	5	13	65	99.40%
	Pos	0	0	1	2	0	0	97.60%
FEN/100	Neg	40	5	2	0	0	0	97.9%
	Pos	0	0	1	2	1	30	100%
K2/50	Neg	40	3	1	0	0	0	95.7%
	Pos	0	0	2	2	4	22	100%
K2+/10	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	4	0	100%
KET/1000	Neg	40	19	2	0	0	0	95.3%
	Pos	0	0	2	4	2	35	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	2	3	45	100%

MOP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MPD/1000	Neg	40	1	0	1	0	0	97.6%
	Pos	0	0	1	0	1	32	97.1%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/100	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	0	40	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%
THC/25	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	0	40	100%
TRA/100	Neg	40	4	4	1	0	0	100%
	Pos	0	0	0	2	4	27	97.1%

B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the Multi-Drug Screen Test cassette, dip card, cup, and strip.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the Multi-Drug Screen Test. Concentrations are given in ng/ml.

Compound	Conc.	Compound	Conc.
AMP			
D-Amphetamine	500	MDA	8,000
L-Amphetamine	50,000	Phentermine	45,000
AMP300			
D-Amphetamine	300	MDA	1,000
L-Amphetamine	27,500	Phentermine	3,000
AMP1000			
D-Amphetamine	1,000	MDA	15,000
L-Amphetamine	100,000	Phentermine	100,000
BAR			
Secobarbital	300	Butalbital	300
Amobarbital	2,500	Cyclopentobarbital	500
Aprobarbital	500	Phenobarbital	300
Butabarbital	100		
BAR200			
Secobarbital	200	Butalbital	200
Amobarbital	1,660	Cyclopentobarbital	330
Aprobarbital	330	Phenobarbital	200
Butabarbital	60		
BUP			
Buprenorphine	10		
BZO			
Oxazepam	300	α-Hydroxyalprazolam	1,900
Alprazolam	200	Lorazepam	3,900
Bromazepam	1,000	Lorazepam-glucuronide	5,000
Clobazam	200	Nitrazepam	250
Clorazepate	750	Norchlordiazepoxide	500
Desalkylflurazepam	1,200	Nordazepam	390
Diazepam	1,000	Temazepam	150
Flunitrazepam	250	Triazolam	2,500

Compound	Conc.	Compound	Conc.
BZO200			
Oxazepam	200	α-Hydroxyalprazolam	1,300
Alprazolam	130	Lorazepam	2,600
Bromazepam	650	Lorazepam-glucuronide	3,500
Clobazam	130	Nitrazepam	160
Clorazepate	500	Norchlordiazepoxide	330
Desalkylflurazepam	800	Nordazepam	260
Diazepam	650	Temazepam	100
Flunitrazepam	160	Triazolam	1,650
COC			
Benzoylecgonine	150	Cocaine	5,000
Cocaethylene	50,000	Ecgonine	50,000
COC100			
Benzoylecgonine	100	Cocaine	5,000
Cocaethylene	45,000	Ecgonine	20,000
COC300			
Benzoylecgonine	300	Cocaine	10,000
Cocaethylene	100,000	Ecgonine	100,000
COT100			
(-)-Cotinine	100	S(-)-Nicotine	>100,000
Trans-3´-hydroxycotinine	700	(R,S)-Norcotine	15,000
COT200			
(-)-Cotinine	200	S(-)-Nicotine	>100,000
Trans-3´-hydroxycotinine	5000	(R,S)-Norcotine	100,000
EDDP			
EDDP	300		
EDDP100			
EDDP	100		
ETG			
Ethyl glucuronide	500		
FEN			
Norfentanyl	100	Fentanyl	750
K2			
JWH-073 N-Butanoic acid metabolite	50	JWH-018 4N-(4-Hydroxypentyl) metabolite	750
JWH-018 5-Pentanoic acid metabolite	50	JWH-018 5-Hydroxypentyl metabolite	1,500
JWH-073 4-Hydroxybutyl metabolite	500	AM2201 N-(4-hydroxypentyl) metabolite	1,500
JWH-019 6-Hydroxyhexyl metabolite	>10,000	JWH 210 N-pentanoic acid metabolite	450
JWH 122 N-(4-hydroxypentyl) metabolite	1,700	MAM2201 N-pentanoic acid metabolite	60
JWH 200 6-hydroxyindole metabolite	700	JWH 073 N-(2-hydroxybutyl) metabolite	1,500
JWH 398 N-pentanoic acid metabolite	300	JWH 018 N-propanoic acid Metabolite	35
RCS-4 N-(5-carboxypentyl) metabolite	5,000	JWH-073 N-(3-hydroxybutyl) JWH-018	700 >10,000
JWH-019 5-Hydroxyhexyl metabolite	3,000	JWH-073	>10,000
JWH-210 5-Hydroxypentyl metabolite	>10,000	BB-22 3-carboxyindole Metabolite	>100,000
5-fluoro PB-22 3-carboxyindole metabolite	>100,000	JWH-210 4-Hydroxypentyl metabolite	>10,000
MDMB-CHMINACA	>100,000	JWH-250 4-Hydroxypentyl metabolite	>10,000
		JWH-122 5-Hydroxypentyl metabolite	>10,000
K2+ 10			
AB-PINACA pentanoic acid metabolite	10	AB-PINACA N-(4-hydroxypentyl) metabolite	10
ADB-PINACA N-(4-hydroxypentyl) metabolite	15	ADB-PINACA N-(5-hydroxypentyl) metabolite	20
5-fluoro AB-PINACA N-(4-hydroxypentyl) metabolite	20	AB-PINACA N-(5-hydroxypentyl) metabolite	30
ADB-PINACA pentanoic acid metabolite	20	AB-PINACA	100
5-fluoro AB-PINACA	50	5-fluoro ADB-PINACA	250
AB-FUBINACA	150	APINACA(AKB-48)	>10,000
5-chloro AB-PINACA	1,000	CUMPY-THPINACA	>100,000
APINACA(AKB-48) 5-Hydroxypentyl metabolite	>10,000	AB-CHMINACA metabolite M2	>100,000
5-fluoro AEB	>100,000	5-fluoro ADB(5-fluoro MDMB-PINACA)	>100,000
PX 1(5-fluoro APP-PICA)	>100,000	MMB-FUBINACA	>100,000
PX 2(5-fluoro APP-PINACA)	>100,000	5-fluoro MN-18	>100,000
4-cyano CUMYL-BUTINACA	>100,000	5-fluoro PB-22 3-carboxyindole metabolite	>100,000
CUMYL-PICA	>100,000	AM2201 N-(4-hydroxypentyl) metabolite	>100,000

Compound	Conc.	Compound	Conc.
MN-18	>100,000		
BB-22 3-carboxyindole metabolite	>100,000		
KET1000			
Ketamine	1,000		
MDMA			
(+/-)-MDMA	500	(+/-)-MDEA	500
(+/-)-MDA	3,900		
MET			
D-Methamphetamine	500	MDEA	30,000
D-Amphetamine	50,000	MDMA	3,500
L-Amphetamine	50,000	Mephentermine	5,000
1R,2S(-)-Ephedrine	100,000		
MET1000			
D-Methamphetamine	1,000	MDEA	60,000
D-Amphetamine	100,000	MDMA	8,000
L-Amphetamine	100,000	Mephentermine	10,000
1R,2S(-)-Ephedrine	>100,000		
MOP			
Morphine	300	Levorphanol	50,000
Codeine	100	Morphine 3-glucuronide	400
Ethylmorphine	100	Norcodeine	6,000
Heroin	8,000	Oxycodone	75,000
Hydrocodone	1,250	Thebaine	90,000
Hydromorphone	2,500		
MPD			
Methylphenidate	1000		
MTD			
Methadone	300		
OPI			
Morphine	2,000	Hydromorphone	5,000
Codeine	1,800	Morphine-3-glucuronide	2,600
Ethylmorphine	1,500	Oxycodone	70,000
Heroin	11,000	Thebaine	95,000
Hydrocodone	5,000		
OPI100			
Morphine	100	Hydromorphone	350
Codeine	50	Morphine-3-glucuronide	150
Ethylmorphine	70	Oxycodone	15,000
Heroin	1,500	Thebaine	75,000
Hydrocodone	550	Norcodeine	5,000
OXY			
Oxycodone	100	Hydrocodone	5,000
Codeine	50,000	Hydromorphone	25,000
Ethylmorphine	50,000	Oxymorphone	12,500
PCP			
Phencyclidine	25	4-Hydroxy-PCP	1,500
PPX			
Propoxyphene	300	Norpropoxyphene	300
TCA			
Nortriptyline	1,000	Doxepine	1,000
Amitriptyline	4,000	Imipramine	1,000
Clomipramine	2,000	Promethazine	1,000
Desipramine	500	Trimipramine	5,000
THC			
11-nor-Δ9-THC-9-COOH	50	(-)-Δ8-THC	20,000
(+/-)-11-Hydroxy-Δ9-THC	5,000	(-)-Δ9-THC	20,000
THC25			
11-nor-Δ9-THC-9-COOH	25	(-)-Δ8-THC	10,000
(+/-)-11-Hydroxy-Δ9-THC	2,500	(-)-Δ9-THC	10,000
TRA			
Tramadol	100	N-Desmethyl-cis-tramadol	100

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Multi-Drug Screen Test. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the Multi-Drug Screen Test. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/ml when tested with the Multi-Drug Screen Test cassette, dip card, cup, and strip:

Acetaminophen	4-Dimethylaminoantipyrine	Niacinamide
Acetone	Diphenhydramine	(+/-)-Norephedrine
Albumin	Dopamine	Oxalic acid
Ampicillin	(+/-)-Isoproterenol	Penicillin-G
Ascorbic acid	1R,2S(+)-Ephedrine	Pheniramine
Aspartame	Erythromycin	Phenothiazine
Aspirin	Ethanol	L-Phenylephrine

Atropine	Furosemide	B-Phenylethylamine
Benzocaine	Glucose	Procaine
Bilirubin	Guaiacol glyceryl ether	Quinidine
Caffeine	Hemoglobin	Ranitidine
Chloroquine	Ibuprofen	Riboflavin
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	

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Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #

Manufacturer

SureScreen Diagnostics Ltd
1 Prime Parkway
Prime Enterprise Park
Derby. DE1 3QB
United Kingdom

CE

Number: RP5314900
Effective date: 2019-10-31