Multi-Drug Screen Test

For Forensic 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)
6AM	6-Acetylmorphine	10
AMP	Amphetamine	300
AMP500	Amphetamine	500
AMP1000	Amphetamine	1,000
BAR	Barbiturates	300
BAR200	Barbiturates	200
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
BZO200	Benzodiazepines	200
CLO	Clonazepam	300
COC	Cocaine	150
COC300	Cocaine	300
COT	Cotinine	200
EDDP	Methadone Metabolite	300
ETG	Ethyl Glucuronide	500
FEN 20	Norfentanyl	20
FEN 50	Norfentanyl	50
FEN 100	Norfentanyl	100
K2	Synthetic Marijuana	50
K2 25	Synthetic Marijuana	25
K2+	AB-PINACA	10
KRA	Mitragynine	100
MDMA	Ecstasy	500
MET	Methamphetamine	500
MET1000	Methamphetamine	1,000
MTD	Methadone	300
OPI300	Morphine	300
OPI2000	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000
THC 20	Marijuana	20
THC	Marijuana	50
TRA 100	Tramadol	100
TRA 200	Tramadol	200
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This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricvclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

PROCEDURE

Preparation:

- Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testina.
- 2. Do not open the test device pouch until ready to perform the test. Test must be used within 2 hours of opening the pouch.

Dip Card:

- Remove the dip card from the sealed pouch. Write the donor 1 name or ID on the dip card in the provided space, then remove the cap.
- With the arrows pointing downward, dip the card into the 2. urine specimen for at least 20 seconds. Replace the cap and place the card on a flat surface. Alternatively, the dip card can remain in the specimen throughout the testing process.
- Negative results can be interpreted as soon as the control 3. lines appear and there are visible Test lines which usually occurs within 1 minute. Positive drug screen test results should be read at 5 minutes. All results remain stable for 60

minutes.

Read urine adulteration test results by comparing the color of 4 the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes. Position of adulteration pads may vary based on the drug strip configuration.

Cup:

- Remove cup from the sealed pouch and write the donor 1 name or ID in the provided space.
- 2. Collect urine in the cup.
- 3. Negative results can be interpreted as soon as the control lines appear and there are visible Test lines which usually occurs within 1 minute. Positive drug screen test results should be read at 5 minutes. All results remain stable for 60 minutes
- Read urine adulteration test results by comparing the color of 4. the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.

RESULT INTERPRETATION

Negative results can be interpreted as soon as the control lines appear and there are visible Test lines which usually occurs within 1 minute. Positive drug screen test results should be read at 5 minutes. All results remain stable for 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 AMP, MET and PPX, 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 third strip (EDDP) and sixth strip (OXY). The test results for those two test strips are invalid.

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.

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.

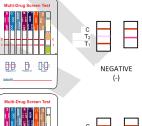
Summary of Accuracy Results on the Multi-Drug Screen Test:

Drug Toot/		-		Ra	ange of GC/M	Drug Screer S Data		
Drug Test/ Cutoff (ng/ml)	Result	Drug-free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	% Agreemen
	Neg	40	<u><-25% C/O</u> 4	1	+25% C/O	+50% C/O	0	>99%
6AM/10	Pos	0	Ö	Ö	Ĭ	4	36	>99%
AMP/300	Neg	40	0	0	0	0	0	100%
AMF/300	Pos	0	0	0	0	0	52	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0 40	0	1	2	2	45 0	100% 97.7%
AMP/1000	Neg Pos	40	0	1	3	2	42	100%
	Neg	40	1	1	ŏ	0	0	95.2%
BAR/300	Pos	0	0	2	5	2	36	100%
BAR/200	Neg	40	1	1	0	0	0	95.45%
DAIV200	Pos	0	0	2	2	3	42	100%
BUP/10	Neg Pos	40 0	1	1	0 8	0	0 32	95.5% 100%
	Neg	40	0	1	0 0	0	0	93.2%
BZO/300	Pos		0	3	1	6	34	100%
D70/000	Neg	40	Ő	Ĩ	Ö	Ő	0	100%
BZO/200	Pos	0	0	3	2	2	43	94%
CLO/300	Neg	40	2	0	0	0	0	97.67%
320,000	Pos	0	0	1	0	1	26	100%
COC/150	Neg Pos	40 0	0	3	0	0	0 53	97.7% 100%
	Neg	40	0	3	4	0	53	100%
COC/300	Pos	40	0	0	4	1	46	98.0%
COT/200	Neg	40	0	0	0	0	0	>99.0%
CO1/200	Pos	0	0	0	0	0	40	>99.0%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
288.7000	Pos	0	0	3	5	2	33	100%
ETG/500	Neg Pos	141 0	15 0	8	5	13 0	65 0	99.40% 97.60%
	Neg	100	3	2	0	0	0	99.06%
FEN/20	Pos	0	Ő	1	3 3	3	46	100%
FEN/50	Nea	42	0	0	0	0	0	100%
FEIN/30	Pos	0	0	0	1	0	17	100%
FEN/100	Neg	40	5	2	0	0	0	97.9%
	Pos	0 40	0	1	2	1	30 0	100% 95.7%
K2/50	Neg Pos	40	0	2	2	4	22	95.7%
	Neg	40	2	1	0	0	0	93.5%
K2/25	Pos	0	0	3	2	3	21	100%
K2+/10	Neg	40	0	0	0	0	0	100%
N21/10	Pos	0	0	0	0	4	0	100%
KRA/100	Neg Pos	40 0	2	0	0	0	0	97.67% >99%
	Neg	40	1	1	0	0	14 0	95.5%
MDMA/500	Pos	40	0	2	5	1	34	100%
NET/500	Neg	40	1	0	ŏ	0	0	93.2%
MET/500	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%
MTD/300	Neg Pos	40	0	2	0 4	0	0	95.5% 100%
	Neg	0 40	0	<u> </u>	4	0	37	93.2%
OPI/300	Pos	0	0	3	4	0	53	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
01-1/2000	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0 40	0	3	7	1	33	100%
PCP/25	Neg Pos	40	0	3	3	8	0 33	97.7% 100%
	Nea	40	0	1	0	0	0	95.3%
PPX/300	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
10/1000	Pos	0	0	2	5	7	28	100%
THC/20	Neg	40	7	4	0	0	0	96.2%
	Pos	0 40	0	2	0	0	14 0	100% 97.7%
THC/50	Neg Pos	40	1	2	0	0	0 44	97.7%
	Neg	40	8	4	4	0	0	>99%
TRA/100	Pos	0	0	0	1	4	62	>99%
TRA/100 TRA/200				0 6	1 1 4	4 0 2	62 0 8	>99% 100% 93.33%

B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by three personnel in-house. Results showed over 99% agreement at +/-50% cutoff levels with the Multi-Drug Screen Test dip card, and cup.

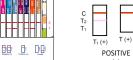




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INVALID

Concentrations are gi	ven in ng/ml; perce	ent cross-reactivity is shown i	in parentheses.
Compound	Conc. (%)	Compound	Conc. (%)
6-AM 6-Acetylmorphine	10 (100%)	Morphine	>100,000 (<0.1%)
Diacetylmorphine (heroin)	300 (3%)	Codeine	>100,000 (<0.1%)
Oxycodone	>100,000 (<0.1%)	Oxymorphone	>100,000 (<0.1%)
AMP 300	000 (1000)	110.4	1 000 (000)
D-Amphetamine L-Amphetamine	300 (100%) 27,500 (1.1%)	MDA Phentermine	1,000 (30%) 3,000 (10%)
AMP500	27,500 (1.170)	Flienderfillite	3,000 (1078)
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
AMP1000 D-Amphetamine	1,000 (100%)	MDA	15,000 (6.7%)
L-Amphetamine	100,000 (1%)	Phentermine	100,000 (1.0%)
BAR	,		
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital Aprobarbital	2,500 (12%) 500 (60%)	Cyclopentobarbital Phenobarbital	500 (60%) 300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250 (120%)
BAR200	()		
Secobarbital	200 (100%)	Butalbital	200 (100%)
Amobarbital	1,660 (12%)	Cyclopentobarbital	330 (66.7%)
Aprobarbital Butabarbital	330 (66.7%) 60 (333%)	Phenobarbital	200 (100%)
BUP	00 (000 /0)		
Buprenorphine	10 (100%)	Norbuprenorphine	7.5 (133%)
Buprenorphine-3-β-D-glucuronide		Norbuprenorphineglucuronide	35 (28%)
BZO300	000 (1000)		1 000 (15 00)
Oxazepam Alprazolam	300 (100%)	α-Hydroxyalprazolam Lorazepam	1,900 (15.8%)
Bromazepam	200 (150%) 1,000 (30%)	Lorazepam-glucuronide	3,900 (7.7%) 5,000 (6%)
Clobazam	200 (150%)	Nitrazepam	250 (120%)
Clorazepate	750 (40%)	Norchlordiazepoxide	500 (60%)
Desalkylflurazepam	1,200 (25%)	Nordazepam	390 (76.9%)
Diazepam Flunitrazepam	1,000 (30%) 250 (120%)	Temazepam Triazolam	150 (200%) 2,500 (12%)
BZO200	200 (12070)	mazolam	2,000 (1270)
Oxazepam	200 (100%)	α-Hydroxyalprazolam	1,300 (15.3%)
Alprazolam	130 (153%)	Lorazepam	2,600 (7.7%)
Bromazepam Clobazam	650 (30.7%)	Lorazepam-glucuronide Nitrazepam	3,500 (5.7%)
Clorazepate	130 (153.8%) 500 (40%)	Norchlordiazepoxide	160 (125%) 330 (60.6%)
Desalkylflurazepam	800 (25%)	Nordazepam	260 (76.9%)
Diazepam	650 (30.7%)	Temazepam	100 (200%)
Flunitrazepam	160 (125%)	Triazolam	1,650 (12.1%)
CLO 7-Amino Clonazepam	300 (100%)	Clonazepam	75,000 (0.4%)
Meclonazepam	>100,000 (<0.3%)	Oxazepam	>100,000 (<0.3%)
Alprazolam	>100,000 (<0.3%)	Bromazepam	>100,000 (<0.3)
Clobazam	>100,000 (<0.3%)	Clorazepate dipotassium	>100,000 (<0.3%)
Desalkylflurazepam Flunitrazepam	100,000 (0.30%) >100,000 (<0.3%)	Diazepam α-Hydroxyalprazolam	>100,000 (<0.3%) >100,000 (<0.3%)
Lorazepam	>100,000 (<0.3)	Lorazepam glucuronide	>100,000 (<0.3%)
Nitrazepam	>100,000 (<0.3%)	Norchlordiazepoxide	>100,000 (<0.3%)
Nordiazepam	>100,000 (<0.3%)	Temazepam	>100,000 (<0.3%)
Triazolam COC150	>100,000 (<0.3%)		
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3 [°] %)	Ecgonine	50,000 (0.3%)
COC300	000 (1000)		10.000 (051)
Benzoylecgonine	300 (100%)	Cocaine	10,000 (3%)
Cocaethylene COT	100,000 (0.3%)	Ecgonine	100,000 (0.3%)
(-)-Cotinine	200 (100%)	(R,S)-Norcotine	100,000 (0.2%)
Trans-3'-hydroxycotinine	5,000 (4%)	S(-)-Nicotine	>100,000 (<0.2%)
	200 (100%)		
EDDP ETG	300 (100%)		
Ethyl glucuronide	500 (100%)		
FEN20			
Norfentanyl(calibrator)	20 (100%)	Fentanyl(parent drug)	1,000 (2%)
Alfentanil	>100,000(>0.02%)	Sufentanil	>10,000(>0.2%)
Carfentanil	>10,000(>0.2%)		
FEN 50			
	50 (100%)	Fentanyl	350 (14.3%)
Norfentanyl	30 (100 %)	1 chianyi	000 (11.070)
Norientanyi FEN 100 Norfentanyi	100 (100%)	Fentanyl	750 (13.3%)

Compound	Conc. (%)	Compound	Conc. (%)
K2 50 JWH-073 N-Butanoic acid	50 (100%)	JWH-018 4N-(4-Hydroxypentyl)	750 (6%)
metabolite JWH-018 5-Pentanoic acid	50 (100%)	metabolite JWH-018 5-Hydroxypentyl	1500 (3.3%)
metabolite K2 25		metabolite	
JWH-018 5- Pentanoic acid metabolite	25 (100%)	JWH-018 4N-(4-Hydroxypentyl) metabolite	2000 (1%)
JWH-073 N- Butanoic acid metabolite	40 (62%)	JWH-018 5-Hydroxypentyl metabolite	1250 (2%)
K2+ AB-PINACA pentanoic acid	10 (100%)	AB-PINACA N-(4-hydroxypentyl)	10 (100%)
metabolite ADB-PINACA N-(4-hydroxypentyl)	15 (66.7%)	metabolite ADB-PINACA N-(5-hydroxypentyl)	20 (50%)
metabolite 5-fluoro AB-PINACA N-(4-	20 (50%)	metabolite AB-PINACA N-(5-hydroxypentyl)	30 (33.3%)
hydroxypentyl) metabolite ADB-PINACA pentanoic acid	20 (50%)	Metabolite AB-PINACA	100 (10%)
metabolite 5-fluoro AB-PINACA	50 (20%)	5-fluoro ADB-PINACA APINACA(AKB-48)	250 (40%) >10,000 (<0.1%)
AB-FUBINACA	150 (6.67%)		>100,000 (<0.01%)
5-chloro AB-PINACA APINACA(AKB-48) 5-	1,000 (1%) >10,000 (<0.1%)	AB-CHMINACA metabolite M2 5-fluoro ADB(5-fluoro MDMB-	>100,000 (<0.01%) >100,000 (<0.01%)
Hydroxypentyl metabolite 5-fluoro AEB	>100,000 (<0.01%)	PINACA) MMB-FUBINACA	>100,000 (<0.01%)
PX 1(5-fluoro APP-PICA)	>100,000 (<0.01%)	5-fluoro MN-18	>100,000 (<0.01%)
PX 2(5-fluoro APP-PINACA)	>100,000 (<0.01%)	5-fluoro PB-22 3-carboxyindole	>100,000 (<0.01%)
4-cyano CUMYL-BUTINACA CUMYL-PICA	>100,000 (<0.01%) >100,000 (<0.01%)	metabolite AM2201 N-(4-hydroxypentyl)	>100,000 (<0.01%)
MN-18	>100,000 (<0.01%)	metabolite	100,000 (10.0170)
BB-22 3-carboxyindole metabolite	>100,000 (<0.01%)		
KRA 100 Mitragynine	100 (100%)	Olanzapine	50,000 (0.02%)
7-Hydroxymitragynine	125 (80%)		
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		. ,
MET500 D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine MET1000	100,000 (0.5%)		
D-Methamphetamine	1,000 (100%)	MDEA	60,000 (1.7%)
D-Amphetamine	100,000 (1%)	MDMA	8,000 (12.5%)
L-Amphetamine 1R,2S(-)-Ephedrine	100,000 (1%) >100,000 (<0.5%)	Mephentermine	100,000 (1%)
MTD			
OPI 300	300 (100%)		
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine Ethylmorphine	100 (300%)	Morphine 3-glucuronide Norcodeine	400 (75%) 6,000 (1.9%)
Heroin	100 (300%) 8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone OPI 2000	2,500 (12%)		
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide Oxycodone	2,600 (76.9%)
Ethylmorphine Heroin	1,500 (133.3%) 11,000 (18.2%)	Thebaine	70,000 (2.9%) 95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
TCA Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine THC 20	500 (200%)	Trimipramine	5,000 (20%)
11-nor-∆9-THC-9-COOH	20 (100%)	(-)-∆8-THC	4,500 (0.44%)
(+/-)-11-Hydroxy-∆9-THC	8,000 (0.25%)	(-)-Δ9-THC	7,000 (0.29%)
Cannabinol THC 50	20,000(0.1%)	Cannabidiol	100,000(0.02%)
11-nor-∆9-THC-9-COOH	50 (100%)	(-)-∆8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-∆9-THC	5,000 (1%)	(-)-∆9-THC	20,000 (0.3%)

Conc. (%)	Compound	Conc. (%)
100 (100%)	N-Desmethyl-cis-tramadol	700 (14.28%)
9,000 (1.11%)		
200 (100%)	N-Desmethyl-cis-Tramadol	800 (25%)
15,000 (1.33%)	O-Desmethylvenlafaxine	>10,000 (<2%)
>100,000 (<0.2%)		
	100 (100%) 9,000 (1.11%) 200 (100%) 15,000 (1.33%)	100 (100%) N-Desmethyl-cis-tramadol 9,000 (1.11%) 200 (100%) 200 (100%) N-Desmethyl-cis-Tramadol 15,000 (1.33%) O-Desmethylvenlafaxine

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	(+)-Naproxen	Sulindac			
Creatine	Lidocaine	Theophylline			
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine			
Dextromethorphan					

*Consumption of ethanol may produce positive EtG test results as the assay is designed but does not interfere with the other tests.

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