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)
_	AMP	Amphetamine	500
	AMP1000	Amphetamine	1,000
	BAR	Barbiturates	300
	BAR200	Barbiturates	200
	BUP	Buprenorphine	10
	BUP5	Buprenorphine	5
	BZO	Benzodiazepines	300
	BZO200	Benzodiazepines	200
	COC	Cocaine	150
	COC300	Cocaine	300
	COT	Cotinine	200
	EDDP	Methadone Metabolite	300
	ETG	Ethyl Glucuronide	500
	FEN	Norfentanyl	100
	K2	Synthetic Marijuana	50
	MDMA	Ecstasy	500
	MET	Methamphetamine	500
	MET1000	Methamphetamine	1,000
	MTD	Methadone	300
	MOR	Morphine	300
	OPI	Opiates	2,000
	OXY	Oxycodone	100
	PCP	Phencyclidine	25
	PPX	Propoxyphene	300
	TCA	Tricyclic Antidepressants	1,000
	THC	Marijuana	50
	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 recognized drug levels for these prescription drugs in urine.

PROCEDURE

Preparation:

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

Cassette:

- 1. Remove the cassette from the sealed pouch and write the donor name or ID on the device in the provided space.
- 2. Add 3 drops of specimen with the provided dropper to each sample well.
- 3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
- 4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.

ID: DATE: 000000

Dip Card:

- 1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
- 2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface.
- 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.

Position of adulteration pads may vary based on the drug strip configuration.

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

Strip:

- 1. Remove strip from the sealed pouch or bottle.
- 2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 20 seconds. Do not immerse the strip past the maximum line (MAX). Place the test strip on a non-absorbent flat surface.
- 3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.

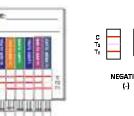
RESULT INTERPRETATION

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.



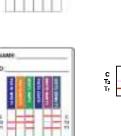
Preliminary Positive Result: If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

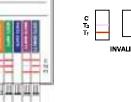
The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.

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 (MTD, TCA) and fourth strip (COC. THC). 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.

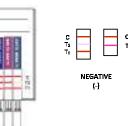
To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from commercial sources. Additional testing may be necessary to comply with 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.



T (+) POSITIVE (+)



NAME



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

Drug Test/		Range of GC/MS 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	3	0	0	0	0	97.7%
AMP/500	Pos	0	Ő	1	2	2	45	100%
AMP/1000	Neg	40	2	0	0	0	0	97.7%
AMP/1000	Pos	0	0	1	3	2	42	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
DAR/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	40	1	1	0	0	0	95.5%
501710	Pos	0	0	2	8	0	32	100%
BUP/5	Neg	40	0	2	1	0	0	97.7%
	Pos	0	0	2	1	1	39	97.6%
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 40	0	3	2	2	43 0	94%
COC/150	Neg	40		3		0		97.7%
	Pos	40	0	3	4	0	53 0	100% 100%
COC/300	Neg Pos	40	0	0	4	1	46	98.0%
	Neg	146	7	1	2	3	40	97.4%
COT/200	Pos	0	2	2	1	7	79	94.6%
	Neg	40	0	1	0	0	0	93.2%
EDDP/300	Pos		0	3	5	2	33	100%
	Neg	141	15	8	5	13	65	99.40%
ETG/500	Pos	0	0	ĭ	ž	0	0	97.60%
FENULAR	Neg	40	5	2	ō	ŏ	ŏ	97.9%
FEN/100	Pos	0	0	1	2	1	30	100%
10/50	Neg	40	3	1	Ō	Ó	0	95.7%
K2/50	Pos	0	0	2	2	4	22	100%
	Neg	40	1	1	0	0	0	95.5%
MDMA/500	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
IVIE 1/500	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%
MOR/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	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 7	0	0 33	93.2%
	Pos	0 40	0	3	0	0		100%
PCP/25	Neg	40	0	3	3	8	0 33	97.7%
	Pos Nea	40	0	1	3	8	33	100% 95.3%
PPX/300	Pos	40	0	2	5	2	33	95.3%
	Neg	40	0	2	0	0	0	95.5%
TCA/1000	Pos	40	0	2	5	7	28	95.5%
	Neg	40	1	2	0	0	0	97.7%
THC/50	Pos	0	0	1	4	7	44	100%
TD 4/400	Neg	40	4	4	1	0	0	100%
TRA/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; percent cross-reactivity is shown in parentheses.

Compound AMP	Conc. (%)	Compound	Conc. (%)
D-Amphetamine L-Amphetamine	500 (100%) 50,000 (1%)	MDA Phentermine	8,000 (6.5%) 45,000 (1.1%)
AMP1000 D-Amphetamine L-Amphetamine	1,000 (100%) 100,000 (1%)	MDA Phentermine	15,000 (6.7%) 100,000 (1.0%)

0 d	0	0 - market	0
Compound BAR	Conc. (%)	Compound	Conc. (%)
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital Butabarbital	500 (60%) 100 (300%)	Phenobarbital	300 (100%)
	100 (300 %)		
BAR200 Secobarbital	200 (100%)	Butalbital	200 (100%)
Amobarbital	1,660 (12%)	Cyclopentobarbital	330 (66.7%)
Aprobarbital	330 (66.7%)	Phenobarbital	200 (100%)
Butabarbital	60 (333%)		
BUP Buprenorphine	10 (100%)		
BUP5			
Buprenorphine	5 (100%)		
BZO Oxazepam	300 (100%)	α-Hydroxyalprazolam	1,900 (15.8%)
Alprazolam	200 (150%)	Lorazepam	3,900 (7.7%)
Bromazepam	1,000 (30%)	Lorazepam-glucuronide	5,000 (6%)
Clobazam	200 (150%)	Nitrazepam	250 (120%)
Clorazepate Desalkylflurazepam	750 (40%) 1,200 (25%)	Norchlordiazepoxide Nordazepam	500 (60%) 390 (76.9%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
BZO200	200 (100%)	a Hydroxyalprazolam	1 300 (15 3%)
Oxazepam Alprazolam	200 (100%) 130 (153%)	α-Hydroxyalprazolam Lorazepam	1,300 (15.3%) 2,600 (7.7%)
Bromazepam	650 (30.7%)	Lorazepam-glucuronide	3,500 (5.7%)
Clobazam	130 (153.8%)	Nitrazepam	160 (125%)
Clorazepate Desalkylflurazepam	500 (40%) 800 (25%)	Norchlordiazepoxide Nordazepam	330 (60.6%) 260 (76.9%)
Diazepam	650 (30.7%)	Temazepam	100 (200%)
Flunitrazepam	160 (125%)	Triazolam	1,650 (12.1%)
COC Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
COC300		-	
Benzoylecgonine Cocaethylene	300 (100%)	Cocaine	10,000 (3%)
COT	100,000 (0.3%)	Ecgonine	100,000 (0.3%)
(-)-Cotinine	200 (100%)	(-)-Nicotine	3,000 (6.7%)
EDDP EDDP	300 (100%)		
ETG	500 (10070)		
Ethyl glucuronide	500 (100%)		
FEN Norfentanyl	100 (100%)	Fentanyl	750 (13.3%)
K2	100 (10070)	i chianyi	100 (10.070)
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 metabolite	1500 (3.3%)
metabolite	00 (100 %)		1000 (0.070)
MDMA			
(+/-)-MDMA (+/-)-MDA	500 (100%) 3,900 (12.8%)	(+/-)-MDEA	500 (100%)
MET	5,500 (12.078)		
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%) 50,000 (1%)	MDMA Monhontormino	3,500 (14.3%)
L-Amphetamine 1R,2S(-)-Ephedrine	100,000 (0.5%)	Mephentermine	5,000 (0.7%)
MET1000	100,000 (0.070)		
D-Methamphetamine	1,000 (100%)	MDEA	60,000 (1.7%)
D-Amphetamine L-Amphetamine	100,000 (1%) 100,000 (1%)	MDMA Mephentermine	8,000 (12.5%) 10,000 (0.7%)
1R,2S(-)-Ephedrine	>100,000 (1%)	mepromernine	10,000 (0.7 /0)
MOR			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine Ethylmorphine	100 (300%) 100 (300%)	Morphine 3-glucuronide Norcodeine	400 (75%) 6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone MTD	2,500 (12%)		
Methadone	300 (100%)		

Compound OPI	Conc. (%)	Compound	Conc. (%)	
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)	
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)	
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)	
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)	
Hydrocodone OXY	5,000 (40%)			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)	
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)	
Ethylmorphine PCP	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)	
Phencyclidine PPX	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)	
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	500 (200%)	Trimipramine	5,000 (20%)	
11-nor-∆9-THC-9-COOH	50 (100%)	(-)-∆8-THC	20,000 (0.3%)	
(+/-)-11-Hydroxy-∆9-THC TRA	5,000 (1%)	(-)-∆9-THC	20,000 (0.3%)	
Tramadol	100 (100%)	N-Desmethyl-cis-tramadol	100 (100%)	
D. INTERFERENCE	E			
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	(+/-)-lsoproterenol	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	

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