

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

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.

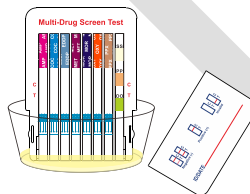
PROCEDURE

Preparation:

- Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
- 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:

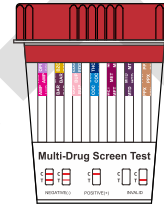
- Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
- With the arrows pointing downward, dip the card into the urine specimen for at least 20 seconds. Replace the cap and place the card on a flat surface. Alternatively, the dip card can remain in the specimen throughout the testing process.
- Negative results can be interpreted as soon as the control 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 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 name or ID in the provided space.
- Collect urine in the cup.
- 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 the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.

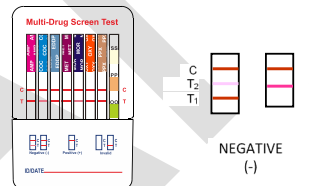


RESULT INTERPRETATION

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:

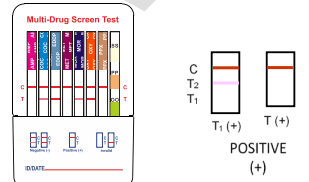
A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



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.

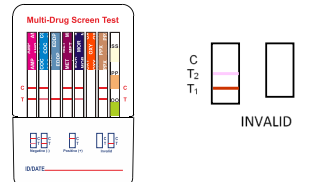
The illustration on the right shows preliminary positive results for AMP, MET and PPX, but negative for all other drugs.



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 Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						% Agreement
		Drug-free	-50% - <-25% C/O	-25% C/O - +25% C/O	+25% C/O - >+25% C/O	>+50% C/O	>+50% C/O	
6AM/10	Neg	40	4	1	0	0	0	>99%
6AM/10	Pos	0	0	0	1	4	36	>99%
AMP/300	Neg	40	0	0	0	0	0	100%
AMP/300	Pos	0	0	0	0	0	52	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
AMP/500	Pos	0	0	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%
BAR/300	Pos	0	0	2	5	2	36	100%
BAR/200	Neg	40	1	1	0	0	0	95.45%
BAR/200	Pos	0	0	2	2	3	42	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
BUP/10	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
BZO/300	Pos	0	0	3	1	6	34	100%
BZO/200	Neg	40	0	1	0	0	0	100%
BZO/200	Pos	0	0	3	2	2	43	94%
CLO/300	Neg	40	2	0	0	0	0	97.67%
CLO/300	Pos	0	0	1	0	1	26	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
COC/150	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	0	3	1	0	0	100%
COC/300	Pos	0	0	0	4	1	46	98.0%
COT/200	Neg	40	0	0	0	0	0	>99.0%
COT/200	Pos	0	0	0	0	0	40	>99.0%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
EDDP/300	Pos	0	0	3	5	2	33	100%
ETG/500	Neg	141	15	8	5	13	65	99.40%
ETG/500	Pos	0	0	1	2	0	0	97.60%
FEN/20	Neg	100	3	2	0	0	0	99.06%
FEN/20	Pos	0	0	1	3	3	46	100%
FEN/50	Neg	42	0	0	0	0	0	100%
FEN/50	Pos	0	0	0	1	0	17	100%
FEN/100	Neg	40	5	2	0	0	0	97.9%
FEN/100	Pos	0	0	1	2	1	30	100%
K2/50	Neg	40	3	1	0	0	0	95.7%
K2/50	Pos	0	0	2	2	4	22	100%
K2/25	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%
K2+/10	Pos	0	0	0	0	4	0	100%
KRA/100	Neg	40	2	0	0	0	0	97.67%
KRA/100	Pos	0	0	1	1	3	14	>99%
MDMA/500	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%
MET/500	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	0	1	0	0	0	95.3%
MET/1000	Pos	0	0	2	2	3	45	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
MTD/300	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
OPI/300	Pos	0	0	3	4	0	53	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
OPI/2000	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
OXY/100	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
PCP/25	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	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%
TCA/1000	Pos	0	0	2	5	7	28	100%
THC/20	Neg	40	7	4	0	0	0	96.2%
THC/20	Pos	0	0	2	0	0	14	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
THC/50	Pos	0	0	1	4	7	44	100%
TRA/100	Neg	40	8	4	0	0	0	>99%
TRA/100	Pos	0	0	0	1	4	62	>99%
TRA/200	Neg	40	5	6	1	0	0	100%
TRA/200	Pos	0	0	0	4	2	8	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.

