

Multi-Drug Rapid Test Cup (Urine)

For Forensic use

The Multi-Drug Rapid Test Cup with Adulteration Strip (Urine) detects multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Abbreviation	Drug	Calibrator	Cutoff (ng/ml)
AMP	Amphetamine	D-Amphetamine	300
BZO200	Benzodiazepines	Oxazepam	200
COC150	Cocaine	Benzoylcegonine	150
COC300	Cocaine	Benzoylcegonine	300
MET	Methamphetamine	D-Methamphetamine	300
OPI300	Morphine	Morphine	300
THC	Marijuana	11-nor-Δ ⁹ -THC-9-COOH	50

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.

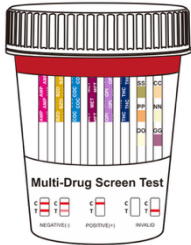
PROCEDURE

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.

Cup:

- Remove cup from the sealed pouch and write the donor name or ID in the provided space.
- Collect urine in the cup.
- Read drug test results at 5 minutes. 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.



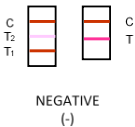
RESULT INTERPRETATION

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.

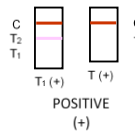
Negative Result:

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.



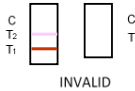
Preliminary Positive Result:

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.



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.



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 Rapid Test Cup with Adulteration Strip (Urine) 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 Rapid Test Cup with Adulteration Strip (Urine). 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 Rapid Test Cup with Adulteration Strip (Urine):

Drug Test	Result	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	11	52	100%
	(-)	40	9	0	0	98%
BZO	(+)	0	3	13	43	100%
	(-)	40	10	0	0	94.3%
COC	(+)	0	0	10	35	100%
	(-)	40	12	0	0	100%

MET	(+)	0	0	9	43	98.1%
	(-)	40	7	1	0	100%
OPI	(+)	0	1	10	46	100%
	(-)	40	8	0	0	98%
THC	(+)	0	1	11	44	100%
	(-)	40	7	0	0	97.9%

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 Rapid Test Cup with Adulteration Strip (Urine) cassette, dip card, cup, and strip.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the Multi-Drug Rapid Test Cup with Adulteration Strip (Urine). Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Conc. (%)	Compound	Conc. (%)
AMP 300		MDA	1,000 (30%)
D-Amphetamine	300 (100%)	Phentermine	3,000 (10%)
L-Amphetamine	27,500 (1.1%)		
BZO200		α-Hydroxyalprazolam	1,300 (15.3%)
Oxazepam	200 (100%)	Lorazepam	2,600 (7.7%)
Alprazolam	130 (153%)	Lorazepam-glucuronide	3,500 (5.7%)
Bromazepam	650 (30.7%)	Nitrazepam	160 (125%)
Clobazam	130 (153.8%)	Norchlordiazepoxide	330 (60.6%)
Clorazepate	500 (40%)	Nordazepam	260 (76.9%)
Desalkylflurazepam	800 (25%)	Temazepam	100 (200%)
Diazepam	650 (30.7%)	Triazolam	1,650 (12.1%)
Flunitrazepam	160 (125%)		
COC150		Cocaine	5,000 (3%)
Benzoylcegonine	150 (100%)	Ecgonine	50,000 (0.3%)
Cocaethylene	50,000 (0.3%)		
COC300		Cocaine	10,000 (3%)
Benzoylcegonine	300 (100%)	Ecgonine	100,000 (0.3%)
Cocaethylene	100,000 (0.3%)		
MET300		MDEA	15,000 (2%)
D-Methamphetamine	300 (100%)	MDMA	1,750 (17.14%)
D-Amphetamine	45,000 (0.67%)	Mephentermine	20,000 (1.5%)
L-Amphetamine	47,500 (0.63%)		
1R,2S(-)-Ephedrine	80,000 (0.38%)		
OPI 300		Levorphanol	10,000 (3%)
Morphine	300 (100%)	Morphine 3-glucuronide	450 (66.7%)
Codeine	100 (300%)	Norcodeine	30,000 (1%)
Ethylmorphine	150 (200%)	Oxycodone	70,000 (0.43%)
Heroin	900 (33.3%)	Thebaine	20,000 (1.5%)
Hydrocodone	500 (60%)	Codein-6-beta-Glucuronide	150 (200%)
Hydromorphone	600 (50%)		
6-Acetylmorphine	400 (75%)		
THC 50		(-)-Δ ⁸ -THC	20,000 (0.3%)
11-nor-Δ ⁸ -THC-9-COOH	50 (100%)	(-)-Δ ⁸ -THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ ⁸ -THC	5,000 (1%)	Cannabinol	>100,000 (0.05%)
Cannabidiol	>100,000 (0.05%)		

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Multi-Drug Rapid Test Cup with Adulteration Strip (Urine). All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the Multi-Drug Rapid Test Cup with Adulteration Strip (Urine). 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 Rapid Test Cup with Adulteration Strip (Urine) 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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