Multi-Drug
One Step
Screen Test Device (Urine)

Package Insert

REF-RT115	English

Package insert for testing of any combination of the following drugs:
Amphetamine, Amphetamine 500, Amphetamine 300, Barbiturates, Benzodiazepines, Tramadol 100, Buprenorphine, Cocaine, Cocaine 150, Marijuana, Methadone, Methamphetamine, Methamphetamine 500, Methamphetamine 300, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For medical and other professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The Multi-Drug One Step Screen Test Device (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC 150)	Benzoylecgonine	150
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Opiate (OPI 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tramadol (TRL)	Tramadol	100
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

PRINCIPLE

The Multi-Drug One Step Screen Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test in the test device contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test devices
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

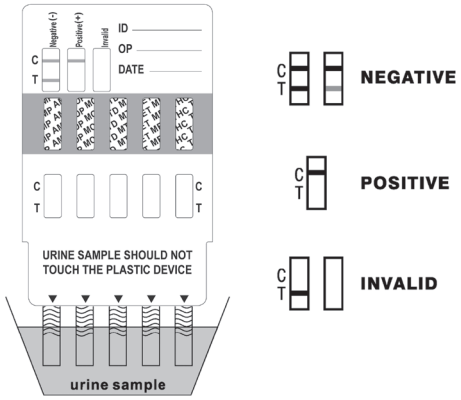
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

Remove the cap from the end of the test device. With arrows pointing toward the urine specimen, immerse the strip(s) of the test device vertically in the urine specimen for at least 10-15 seconds.

Immerse the test device to at least the level of the wavy lines on the strip(s), but not above the arrow(s) on the test device. See the illustration below.

2. Place the test device on a non-absorbent flat surface
3. Wait for the colored lines(s) to appear. **Read results at 5 minutes.** Do not interpret results after 10 minutes.

Note: This illustration shows a 5-drug test device



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

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

Control standards are not supplied with this kit. However, 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.

LIMITATIONS

1. The Multi-Drug One Step Screen Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[2, 3]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug One Step Screen Test Device (Urine) and a commercially available drug rapid test. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. Negative urine specimens were screened initially by Predicate test, 10% negative specimens were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP	AMP 500	AMP 300	BAR	BZO	TRL	BUP**	COC	COC 150	THC	MTD
Positive	>99%	*	>99%	98%	99%	*	88%	>99%	>99%	>99%	87%
Negative	>99%	*	>99%	>99%	>99%	*	>99%	99%	>99%	>99%	>99%
Total	>99%	*	>99%	99%	99%	*	97%	99%	>99%	>99%	94%

Specimen	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA
Positive	>99%	>99%	*	98%	94%	99%	96%	>99%	>99%	92%
Negative	>99%	82%	*	>99%	>99%	>99%	99%	>99%	>99%	>99%
Total	>99%	89%	*	99%	97%	99%	98%	>99%	>99%	98%

*** NOTE:** Commercial kit unavailable for comparison testing.
**** NOTE:** BUP was compared to the self-reported use of Buprenorphine

% Agreement with GC/MS

Specimen	AMP	AMP 500	AMP 300	BAR	BZO	TRL*	BUP*	COC	COC 150	THC	MTD
Positive	94%	95%	>99%	92%	98%	98%	98%	95%	99%	95%	93%
Negative	99%	>99%	99%	99%	98%	99%	99%	>99%	>99%	96%	>99%
Total	97%	98%	99%	96%	98%	99%	99%	98%	99%	95%	97%

Specimen	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA**
Positive	90%	99%	98%	98%	98%	99%	98%	90%	94%	>99%
Negative	>99%	96%	>99%	98%	97%	99%	99%	99%	99%	94%
Total	95%	97%	99%	98%	97%	99%	99%	96%	97%	95%

***NOTE:** BUP,TRL was based on LC/MS data instead of GC/MS.
****NOTE:** TCA was based on HPLC data instead of GC/MS.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		AMP 500		AMP 300		BAR		BZO		TRL 100		BUP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	90	0	90	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	90	0	90	0
-25% Cut-off	30	26	4	24	6	25	5	23	7	24	6	81	9	78	12
Cut-off	30	23	7	16	14	16	14	14	16	15	15	54	36	48	42
+25% Cut-off	30	7	23	4	26	4	26	7	23	6	24	25	65	24	66
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	90	0	90

Drug Conc. (Cut-off range)	n	COC		COC 150		THC		MTD		MET		MET 500		MET 300	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	24	6	26	4	25	5	27	3	27	3
Cut-off	30	20	10	13	17	15	15	13	17	23	7	13	17	15	15
+25% Cut-off	30	5	25	7	23	6	24	5	25	6	24	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA		MOP 300		OPI 2000		OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	20	10	26	4	30	0	26	4	26	4	25	5
Cut-off	30	17	13	18	12	11	19	18	12	19	11	19	11	13	17
+25% Cut-off	30	6	24	7	23	5	25	6	24	5	25	8	22	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Screen Test Device (Urine) at 5 minutes.

AMPHETAMINE	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
Phentermine	3,000
3,4- Methylendioxyamphetamine (MDA)	2,000
AMPHETAMINE 500	
d-Amphetamine	500
d,l-Amphetamine	1,500
β-Phenylethylamine	50,000
3,4-Methylendioxyamphetamine (MDA)	800
Phentermine	1,500
Tryptamine	50,000
Tyramine	25,000
AMPHETAMINE 300	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylendioxyamphetamine (MDA)	1,560
p-Hydroxyamphetamine	1,560
β-Phenylethylamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
Phenylpropanolamine (d,l-Norephedrine)	100,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butethal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
OXYCODONE	
Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Levorphanol	50,000
Naloxone	37,500
Naltrexone	37,500
Oxymorphone	200

METHADONE	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
Mephentermine	50,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
METHAMPHETAMINE 500	
d-Methamphetamine	500
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
l-Phenylephrine	100,000
METHAMPHETAMINE 300	
d-Methamphetamine	300
d,l-Amphetamine	100,000
Chloroquine	25,000
p-Hydroxymethamphetamine	25,000
l-Methamphetamine	3,125
3,4-Methylenedioxymethamphetamine (MDMA)	780
Mephentermine	50,000
(1R,2S)-(-)-Ephedrine	100,000
l-Epinephrine	50,000
Ephedrine	100,000
Fenfluramine	12,500
Trimethobenzamide	25,000
METHYLENEDIOXYMETHAMPHETAMINE	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
BUPRENORPHINE	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200

BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
d,l-Lorazepam	1,562
RS-Lorazepam glucuronide	1,562
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
MORPHINE 300	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2000	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300
BENZODIAZEPINES 200	
Alprazolam	195
α-Hydroxyalprazolam	1,562
Bromazepam	390
Chlordiazepoxide	780
Clobazam	390
Clorazepate	1,562
Desalkylflurazepam	1,000
Diazepam	200
Estazolam	780
Flunitrazepam	12,500
(+) Lorazepam	100,000
Midazolam	6,250
Nitrazepam	100
Norchlordiazepoxide	3,125
Nordiazepam	780
Oxazepam	200
Sertraline	12,500
Temazepam	100
Triazolam	50,000
7-Aminoflunitrazepam	200
7-Aminonitrazepam	5,000
7-Aminoclonazepam	>100,000
COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
TRICYCLIC ANTIDEPRESSANTS	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000
TRAMADOL	
n-Desmethyl-cis-tramadol	195
o-Desmethyl-cis-tramadol	6,250
cis-tramadol	100
Phencyclidine	100,000
Procyclidine	100,000
d,l-O-Desmethyl venlafaxine	25,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Amphetamine 500, Amphetamine 300, Barbiturates, Benzodiazepines, Tramadol 100, Buprenorphine, Cocaine, Cocaine 150, Marijuana, Methadone, Methamphetamine, Methamphetamine 500, Methamphetamine 300, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Screen Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	l-Cotinine	Ketamine	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-Acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloralhydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isoxsuprine	d,l-Propanolol	Zomepirac
Cortisone			

BIBLIOGRAPHY

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Multi-Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

Attention, see instructions for use	Tests per kit	Manufacturer
For *in vitro* diagnostic use only	Use by	Do not reuse
Store between 2-30℃	Lot Number	

ISO, CE, GMP

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