

Instruction sheet for testing of any combination of the following drugs:

Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cannabis, Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Phencyclidine and Tricyclic Antidepressants.

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

For professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based screen 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 Panel (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of the following drugs without the need of instruments.¹

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

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

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 Panel (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 coated on the particles. The antibody coated particles will then be captured by the immobilised drug conjugate and a visible coloured line will show up in the test line region of the specific drug strip. The coloured line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a coloured line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a coloured 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 line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test panel 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 panel 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 strip is stable through to the expiration date printed on the sealed pouch. The test strip 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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

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

MATERIALS

Materials Provided

- Test panels
- Package Instructions

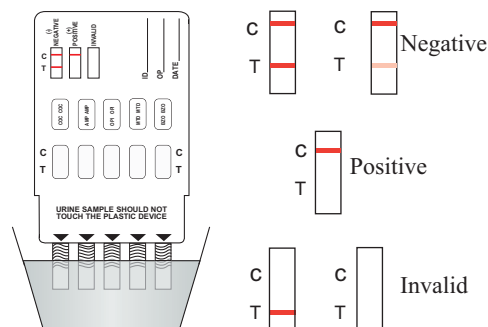
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it as soon as possible.
- Remove the cap that covers the test end. With the arrows pointing towards the urine specimen, immerse the test panel vertically into the urine specimen to at least the wavy lines on the test strip(s), but do not immerse above the level of the arrows. **Hold the test panel in the urine specimen for at least 10-15 seconds.** See the illustration below.
- Place the test panel on a non-absorbent flat surface, start the timer and wait for the coloured line(s) to appear. **Read results at 5 minutes.** Do not interpret results after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A coloured line in the control line region (C) and a coloured 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 colour in the test region (T) may vary, but it should be considered negative even if only a faint coloured line is present.

POSITIVE: A coloured 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 panel. 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 coloured 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

- The Multi-Drug One Step Screen Test Panel (Urine) provides only a preliminary analytical result. A more specific analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{2,3}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- The test does not distinguish between drugs of abuse and certain medications.
- 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 Panel (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presented for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP	BAR	BZO	BUP**	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA
Positive	97%	>99%	90%	88%	95%	98%	>99%	98%	>99%	>99%	>99%	98%	95%
Negative	>99%	99%	97%	>99%	>99%	>99%	>99%	>99%	99%	>99%	>99%	>99%	>99%
Total	98%	99%	94%	97%	98%	99%	>99%	99%	99%	>99%	>99%	99%	99%

**NOTE: BUP was compared to the self-reported use of Buprenorphine.

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	BUP**	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA**
Positive	97%	92%	97%	98%	96%	97%	99%	99%	>99%	>99%	>99%	>99%	>99%
Negative	95%	98%	95%	99%	90%	88%	94%	94%	98%	94%	90%	97%	89%
Total	96%	95%	96%	99%	93%	91%	96%	96%	99%	97%	95%	98%	91%

*NOTE: BUP 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 give concentrations of +/- 25% and +/- 50% of the cut-off level. The results are summarised below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		BUP		COC		THC		MTD	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	90	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	90	0	30	0	30	0	29	1
-25% Cut-off	30	22	8	27	3	27	3	75	15	30	0	12	18	24	6
Cut-off	30	12	18	22	8	11	19	60	30	4	26	1	29	21	9
+25% Cut-off	30	2	28	7	23	5	25	31	59	0	30	1	29	2	28
+50% Cut-off	30	0	30	2	28	0	30	0	90	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MET		MDMA		MOP300		OPI2000		PCP		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	30	0	26	4	25	5	30	0	19	11	22	8
Cut-off	30	18	12	17	13	17	13	13	17	16	14	17	13
+25% Cut-off	30	1	29	4	26	1	29	4	26	6	24	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

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

AMPHETAMINE	BUPRENORPHINE
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
Phentermine	3,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
BARBITURATES	COCAINE
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butethal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	CANNABIS
Oxazepam	300
Alprazolam	196
α-Hydroxylprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clonazepam	781
Clobazam	98
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
d,l Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCOAINE	CANNABIS
Benzoyllecgonine	300
Cocaine	780
Cocacethylene	12,500
Ecgonine	32,000
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
METHAMPHETAMINE	METHYLENEDIOXYMETHAMPHETAMINE
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
Mephentermine	50,000
3,4-Methylenedioxyamphetamine (MDMA)	2,000
3,4-Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
TRICYCLIC ANTIDEPRESSANTS	METHYLENEDIOXYMETHAMPHETAMINE
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

OPIATE 2000	MORPHINE 300
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine	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
300	300
50,000	50,000
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine	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
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cannabis, Methadone, Methamphetamine, Methylenedioxyamphetamine, Morphine 300, Opiate 2000, Phencyclidine, Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Screen Test Panel (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	Nifedipine	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
Chloral hydrate	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	Isosuprine	d,l-Propranolol	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°C		Lot Number		Catalog #

Manufacturer

"Auth. Rep."
acc.to. IVDD 98/79/EC
MDSS
Burckhardtstr. 1
30163 Hannover, Germany