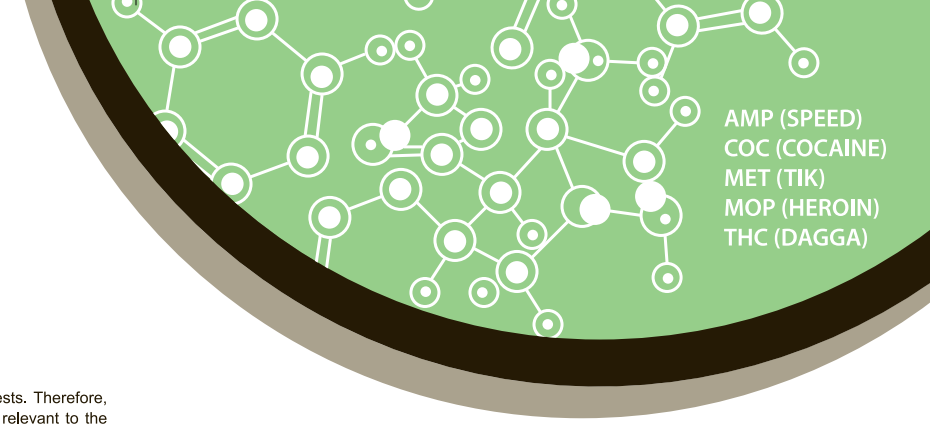
MULTI-PANEL 5 IN 1
URINE DRUG TEST

AMP (Speed)
COC (Cocaine)
MET (Tik)
MOP (Heroin)
THC (Dagga)

Clear I Accurate I One Step



This package insert applies to all combinations of mx™ Multi-panel Urine Drug tests. Therefore, some information on the performance characteristics of the product may not be relevant to the enclosed test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in the enclosed test.

The mx™ Multi-panel Urine Drug Test offers any combination from 2 to 12 drugs of abuse tests for 12 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA).

A rapid one-step test for the qualitative detection of drugs of abuse and their principal metabolites in human urine, at specified cut-off levels. For professional use only/ for in-vitro diagnostic use only.

INTENDED USE

The mx™ Multi-panel Urine Drug Test consists of twelve individual one-step immunoassays. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Test	Calibrator	Cut off (ng/ml)
Amphetamine	Amphetamine	1,000
Barbiturates	Secobarbital	300
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Marijuana	Marijuana	50
Methadone	Methadone	300
Methamphetamine	Methamphetamine	300
Methylenedioxymethamphetamine	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Morphine	Morphine	300
Opiate	Morphine	2000
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Notriptyline	1,000

This assay provides only a preliminary test result. A more specific alternative 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 results are positive.

PRINCIPLE

The mx™ Multi-panel Urine Drug Test Panel is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample, competitively combine to a limited number of antibody-dye conjugate binding sites.
When sample drug levels are at or above the target cut-off, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilised in the Test Region (T) of the device. This prevents the development of a distinct coloured band in the test region, indicating a potentially positive result.
When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate and flows across the pre-coated membrane. When sample drug levels are zero, or below the target cut-off (the detection sensitivity of the test), the antibody-dye conjugate binds to the drug /protein conjugate immobilised in the Test Region (T) of the device. This produces a coloured Test line that, regardless of its intensity, indicates a negative result.
To serve as a procedure control, a coloured line will appear at the Control Region (C), if the test has been performed properly.

WARNING AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Does not use test kit beyond expiry date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Do not read after 15 minutes

STORAGE AND STABILITY

- Store at 4 ~ 25 ºC in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided: • 1 Test • Package insert

Material required but not provided: • Timer • 25ml Urine cup

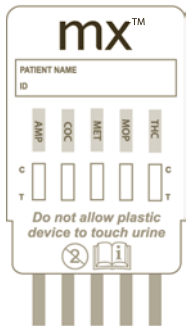
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2-8°C) and stored for up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18ºC to 30ºC)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for about 10 seconds. Ensure that the urine level is not above the “MAX” line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. Do not read after 15 minutes.



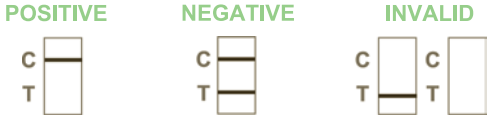
INTERPRATATION OF RESULTS

Positive (+)
A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

Negative (-)
A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid
If a colour band is not visible in each of the control regions or a colour band is only visible in each of the test regions, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store where you bought the product, with the lot number.

Note: There is no meaning attributed to line colour intensity or width.



QUALITY CONTROL

Though there is an internal procedural control line in the test device of the Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen, may cause erroneous results.
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. Test does not distinguish between drugs of abuse and certain medicines.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using each of the tests and commercially available drug rapid test (Acon One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key IM Cup (Urine)). 580 specimens were used in the test. Positive results were confirmed by GC/MS. The results were listed as follows:

% Agreement with commercial kit

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA
Positive	>99%	97.5%	95%	100%	95%	90%	>99%	95%	97.5%	97.5%	97.5%	95%
Negative	>99%	99%	100%	99%	99%	99%	>99%	99%	99%	99%	99%	99%
Total	>99%	98.6%	97.9%	>99%	97.9%	96.4%	>99%	97.9%	98.6%	98.6%	98.6%	97.9%

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA
Positive	94%	92%	97%	96%	95%	95%	99%	97%	98%	99%	91%	95%
Negative	99%	98%	97%	99%	96%	99%	99%	99%	98%	99%	99%	99%
Total	97%	95%	97%	98%	96%	97%	99%	98%	98%	99%	95%	97%

Analytical Sensitivity

Standard drugs were spiked into urine samples to the concentration of ± 50% cut-off and ± 25% Cut-off. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		COC		THC		MTD	
		-	+	-	+	-	+	-	+	-	+	-	+
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	25	5	26	4	26	4	25	5	25	5	23	7
Cut-off	30	12	18	10	20	14	16	12	18	15	15	14	16
25% Cut-off	30	5	25	8	22	5	25	6	24	6	24	3	27
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MET		MDMA		MOP 300		OPI 2000		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	25	5	23	7	24	6	25	5	26	4	24	6
Cut-off	30	13	17	10	20	10	20	14	16	15	15	14	16
25% Cut-off	30	5	25	4	26	3	27	5	25	7	23	6	24
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.

Amphetamine		**Methamphetamine**	
d-Amphetamine	1,000	D(+)-Methamphetamine	300
d,l-Amphetamine	3,000	D-Amphetamine	15,000
l-Amphetamine	50,000	Chloroquine	15,000
(+/-) 3,4-methylenedioxyamphetamine	5,000	(+/-)-Ephedrine	15,000
Phentermine	3,000	(-)-Methamphetamine	7,500
Barbiturates		(+/-)3,4-methylenedioxumethamphetamine(MDMA)	600
Secobarbital	300	b-Phenylethylamine	15,000
Amobarbital	300	Trimethobenzamide	3,000
Alphenol	150		
Aprobarbital	200	**Methylenedioxymethamphetamine(MDMA)**	
Butabarbital	75	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Butathal	100	3,4-Methylenedioxyamphetamine HCl	3,000
Butalbital	2,500	3,4-Methylenedioxyethylamphetamine	300
Cyclopentobarbital	600	Morphine	
Pentobarbital	300	Morphine	300
Phenobarbital	100	Codeine	300
Benzodiazepines		Ethyl Morphine	300
Oxazepam	300	Hydrocodone	5,000
Alprazolam	200	Hydromorphone	5,000
αHydroxyalprazolam	1,500	Morphinie-3-b-d-glucuronide	1,000
Bromazepam	1,500	Thebaine	30,000
Chlordiazepoxide	1,500	**Opiate 2000**	
Clonazepam HCl	800	Morphine	2,000
Clobazam	100	Codeine	2,000
Clonazepam	800	Ethylmorphine	5,000
Clorazepate dipotassium	200	Hydrocodone	12,500
Delorazepam	1,500	Hydromorphine	5,000
Desalkylflurazepam	400	Levorphanol	75,000
Diazepam	200	σ-Monoacetylmorphine	5,000
Estazolam	2,500	Morphine 3-β-D-glucuronide	2,000
Flunitrazepam	400	Norcodeine	12,500
D,L-Lorazepam	1,500	Normorphone	50,000
		Oxycodone	25,000
Midazolam	12,500	Oxymorphine	25,000
Nitrazepam	100	Procaine	150,000
Norchlordiazepoxide	200	Thebaine	100,000
Nordiazepam	400	**Phencyclidine**	
Temazepam	100	Phencyclidine	25
Trazolam	2,500	4-Hydroxyphencyclidine	12,500
Cocaine		**Tricyclic Antidepressants**	
Benzoylecgonine	300	Notriptyline	1,000
Cocaine HCl	750	Nordoxepine	1,000
Cocaethylene	12,500		
Ecgonine	32,000		
Marijuana		Trimipramiine	3,000
11-nor-D9-THC-9-COOH	50	Amitriptyline	1,500
11-nor-D8-THC-9-COOH	30	Promazine	1,500
11-hydroxy-D9-Tetrahydrocannabinol	2,500	Desipramine	200
D8- Tetrahydrocannabinol	7,500	Imipramine	400
D9- Tetrahydrocannabinol	10,000	Clomipramine	12,500
Cannabinol	10,000	Doxepine	2,000
Cannabidiol	100,000	Maprotiline	2,000
Methadone		Promethazine	25,000
Methadone	300		
Doxylamine	50,000		

Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with the mx™ Multi-panel Drug Urine Test Panels at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

Acetophenetidin
Nalidixic acid
Acetylsalicylic acid
Aminopyrine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Loperamide
Meprobamate
Methoxyphenamine
Nalidixic acid
Quinidine
Quinine
Ranitidine
Salicylic acid
Amoxicillin
Ampicillin
L-Phenylephrine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine
Bilirubin
Deoxycorticosterone
Caffeine
Chloralhydrate
Chloramphenicol
Chlorothiazide
D,L-Chlolrpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Cortisone
L-Cotinine
Diflunisal
Digoxin
Diphenhydramine
L-Ψ-Ephedrine
Ecgonine methylester
Ethyl-p-aminobenzoate
β-Estradiol
Estrone-3-sulfate
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
D,L-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Perphenazine
Phenelzine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisone
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone, 3-Acetate
Tetrahydrocortisone, (β-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D,L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Tyramine
D,L-Tryptophan
Urine acid
Verapamil
Zomepirac

From the results above, it is clear that the mx™ Multi-panel Drug Urine Test resists well against interference from these substances.

BIBLIOGRAPHY OF SUGGESTED READING

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Index of Symbols

	See instruction for use		Tests per kit		Manufacturing date
IVD	For *in vitro* diagnostic use only		Expiry date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch number	REF	Catalog #
0 0 PAN	Test Panel		Urine cup	D	Desiccant
POS	Positive	NEG	Negative	INV	Invalid
	Keep out of sunlight /moisture				

Version 20/07/2007

Specially packaged for Medinox

Medinox Contact details:

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