

One Step Multi-Drug Urine Test Panel

Catalog No. See Pouch Label

One Step Multi-Drug Urine Test panel offers any combination from 2 to 12 drugs of abuse tests for 16 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), Buprenorphine (BUP), Oxycodone (OXY), Ketamine (KET), Propoxyphene (PPX).

This package insert applies to all combinations of multi-drug tests panel. Therefore, some information on the performance characteristics of the product may not be relevant to your test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.*

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level.

For professional use only, For in vitro diagnostic use.

INTENDED USE

One Step Multi-Drug Urine Test Panel is consisted 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	Benzoylcegonine	300
Marijuana	Marijuana	50
Methadone	Methadone	300
Methamphetamine	Methamphetamine	1,000
Methylenedioxymethamphetamine	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Morphine	Morphine	300
Opiate	Morphine	2000
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Notriptyline	1,000
Buprenorphine	Buprenorphine	10
Oxycodone	Oxycodone	100
Ketamine	Ketamine	1,000
Propoxyphene	Propoxyphene	300

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

One Step Multi-Drug Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

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 cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug /protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored 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.
- Do 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 5 minutes

STORAGE AND STABILITY

- Store at 4 ~ 30 °C in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- Individual tests
- Package insert

Material Required But Not Provided

- Timer
- Urine cup

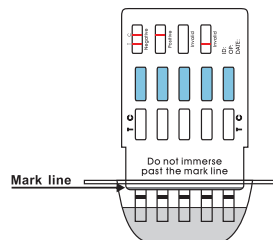
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2-8°C) and stored 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

Allow the test device, urine sample to equilibrate to room temperature (10°C to 30°C) prior to testing.

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 about 10 seconds. Make sure that the urine level is not above the mark 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 5 minutes.**



INTERPRETATION 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.

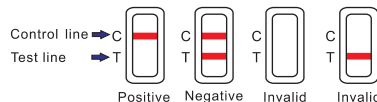
Negative (-)

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 zero or below the detection limit of the test.

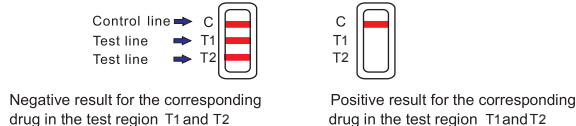
Invalid

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

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



For the multi-line of the test strip, for example:



QUALITY CONTROL

Though there is an internal procedural control line in the test device of 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)). 740 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
Positive	>99%	97.5%	95%	100%	95%	90%	>99%	95%
Negative	>99%	99%	100%	99%	99%	99%	>99%	99%
Total	>99%	98.6%	97.9%	>99%	97.9%	96.4%	>99%	97.9%

Specimen	MOP 300	OPI 2000	PCP	TCA	BUP	OXY	KET	PPX
Positive	97.5%	97.5%	97.5%	95%	97%	>99%	96%	95%
Negative	99%	99%	99%	99%	97%	>99%	99%	100%
Total	98.6%	98.6%	98.6%	97.9%	97%	>99%	97.5%	97.9%

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA
Positive	94%	92%	97%	96%	95%	95%	99%	97%
Negative	99%	98%	97%	99%	96%	99%	99%	99%
Total	97%	95%	97%	98%	96%	97%	99%	98%

Specimen	MOP 300	OPI 2000	PCP	TCA	BUP	OXY	KET	PPX
Positive	98%	99%	91%	95%	90%	92.5%	92.5%	90%
Negative	98%	99%	99%	99%	97.5%	97.5%	95%	97.5%
Total	98%	99%	95%	97%	93.8%	95%	93.8%	93.8%

Analytical Sensitivity

Standard drugs were spiked into negative urine samples to the concentration of -50% cutoff, -25% cutoff, cutoff, +25% cutoff and +50% cutoff. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		COC		THC		MTD		MET		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
+25% Cut-off	30	25	5	26	4	26	4	25	5	23	7	25	5	25	5	23	7
Cut-off	30	12	18	10	20	14	16	15	15	14	16	12	18	13	17	10	20
+25% Cut-off	30	5	25	8	22	5	25	6	24	3	27	6	24	5	25	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MOP 300		OPI 2000		PCP		TCA		BUP		OXY		KET		PPX	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
-25% Cut-off	30	24	6	25	5	26	4	24	6	26	4	26	4	27	3	26	4
Cut-off	30	10	20	14	16	15	15	14	16	1	29	3	27	2	28	1	29
+25% Cut-off	30	3	27	5	25	7	23	6	24	0	30	0	30	0	30	0	30
+50% Cut-off	30	0	30	0	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		Δ8- Tetrahydrocannabinol	7,500
d-Amphetamine	1,000	Δ9- Tetrahydrocannabinol	10,000
d.1-Amphetamine	3,000	Cannabinol	10,000
1-Amphetamine	50,000	Cannabidiol	100,000
(+/-)	5,000	Methamphetamine	
3,4-methylenedioxyamphetamine		D(+)-Methamphetamine	1,000
Phentermine	3,000	D-Amphetamine	50,000
Barbiturates		Chloroquine	50,000
Secobarbital	300	(+/-)-Ephedrine	50,000
Amobarbital	300	(-)-Methamphetamine	25,000
Alphenol	150	(+/-)3,4-methylenedioxymethamphetamin	2,000
Aprobarbital	200	e(MDMA)	
Butabarbital	75	b-Phenylethylamine	50,000
		Trimethobenzamide	10,000
Butathal	100	Methylenedioxymethamphetamine(MDMA)	
Butalbital	2,500	3,4-Methylenedioxymethamphetamine	500
Cyclopentobarbital	600	HCl(MDMA)	
Pentobarbital	300	3,4-Methylenedioxyamphetamine HCl	3,000
Phenobarbital	10,000	3,4-Methylenedioxyethylamphetamine	300
Benzodiazepines		Morphine	
Oxazepam	300	Morphine	300
Alprazolam	200	Codeine	300
α-Hydroxyalprazolam	1,500	Ethyl Morphine	300
Bromazepam	1,500	Hydrocodone	5,000
Chlordiazepoxide	1,500	Hydromorphone	5,000
Clonazepam HCl	800	Morphinie-3-b-d-glucuronide	1,000
Clobazam	100	Thebaine	30,000
Clonazepam	800	Opiate 2000	
Clorazepate dipotassium	200	Morphine	2,000
Delorazepam	1,500	Codeine	2,000
Desalkylflurazepam	400	Ethylmorphine	5,000
Diazepam	200	Hydrocodone	12,500
Estazolam	2,500	Hydromorphone	5,000
Flunitrazepam	400	Levorphanol	75,000
D,L-Lorazepam	1,500	σ-Monoacetyl Morphine	5,000
Midazolam	12,500	Morphine 3-β-D-glucuronide	2,000
Nitrazepam	100	Norcodeine	12,500
Norchlordiazepoxide	200	Normorphone	50,000
Nordiazepam	400	Oxycodone	25,000
Temazepam	100	Oxymorphone	25,000
Trazolam	2,500	Procaine	150,000
Cocaine		Thebaine	100,000
Benzoylcegonine	300	Phencyclidine	
Cocaine HCl	750	Phencyclidine	25
Cocaethylene	12,500	4-Hydroxyphencyclidine	12,500
Ecgonine	32,000	Tricyclic Antidepressants	
Marijuana		Notriptyline	1,000
11-nor-Δ9-THC-9-COOH	50	Nordoxepine	1,000
11-nor-Δ8-THC-9-COOH	30	Trimipramine	3,000
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	Amitriptyline	1,500

Promazine	1,500	Propoxyphene	
Desipramine	200	d-Propoxyphene	300
Imipramine	400	d-Norpropoxyphene	300
Clomipramine	12,500	Buprenorphine	
Doxepine	2,000	Buprenorphine 3-D-Glucuronide	15
Maprotiline	2,000	Norbuprenorphine	20
Promethazine	25,000	Norbuprenorphine 3-D-Glucuronide	200
Methadone		Ketamine	
Methadone	300	Methadone	50,000
Doxylamine	50,000	Pethidine	12,500
Oxycodone		Methylamphetamine	12,500
Dihydrocodeine	20,000	Methoxyphenamine	12,500
Codeine	100,000	Promethazine	25,000
Hydromorphone	100,000	Phencyclidine	25,000
Morphine	>100,000		
Acetylmorphine	>100,000		
Buprenorphine	>100,000		
Ethylmorphine	>100,000		

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 One Step Multi-Drug Urine Test Panel at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

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

From the results above, it is clear that One Step Multi-Drug Urine Test Panel resists well against interference from these substances.

BIBLIGRAPHY OF SUGGESTED READING

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INDEX OF SYMBOLS



Keep away from sunlight



Store between 4°C and 30°C



Keep dry



Do not re-use