One Step Multi-Drug Urine Cup

Catalog No. See Pouch Label

One Step Multi-Drug Urine Cup offers any combination from 2 to 12 drugs of abuse tests for 16 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Cannabinoids (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 with integrated cup. 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 healthcare professional use only. For in vitro diagnostic use.

INTENDED USE

One Step Multi-Drug Urine Cup is rapid urine screening test. 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	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 Cup 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 at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

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 pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

WARNINGS 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 expiration date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.

STORAGE AND STABILITY

- Store at 4 ºC ~ 30 ºC up to the expiration date.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- One pouch containing a test cup, a screw key and a desiccant.
- Package insert

Material Required But Not Provided

- Timer
- External controls

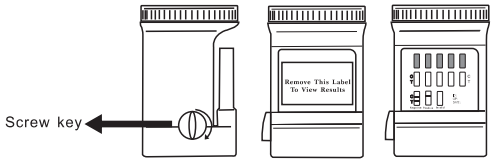
SPECIMEN COLLECTION AND PREPARATION

- Wash your hands with soap and warm water. Open the sealed pouch and remove the urine test cup.
- The donors collect their urine samples. Open the cap of the cup and urinate directly into the test cup. Replace and seal the cap. Check the cap for a tight seal.
  The minimum sample volume is 25mL (See the Minimum Fill Volume scale on the cup label).
- The technician check cap for tight seal and observe the temperature indicator card attached on the cup to see if the donor collect water or liquid other than urine. Normally, the temperature of urine just out of body is approximate to the body temperature. Technician dates and signs the names of the donor and the operator on the cap label.
- Urine specimens should be tested within one hour after collection in the test urine cup.

TEST PROCEDURE

Test must be in room temperature (10ºC to 30ºC). Bring the test cup with the sample to room temperature prior to testing. The test is performed by a technical not the sample donor.

1. After the urine has been collected, place the test cup on a flat surface.
2. Insert the screw key to the key hole, then twists screw key from left to right till to a full position at one time.
3. Wait for 5 minutes, remove the label and read the result. **Do not read results after 5 minutes.**



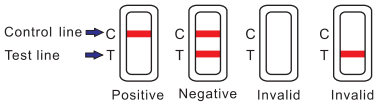
INTERPRETATION OF RESULTS

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. 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.



Results example:

Negative result for the corresponding drug in the test region T1 and T2

Positive result for the corresponding drug in the test region T1 and T2

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

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. The test result 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 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		**Methamphetamine**	
d-Amphetamine	1,000	D(+)-Methamphetamine	1,000
d,1-Amphetamine	3,000	D-Amphetamine	50,000
1-Amphetamine	50,000	Chloroquine	50,000
(+/-) 3,4-methylenedioxyamphetamine	5,000	(+/-)-Ephedrine	50,000
Phentermine	3,000	(-)-Methamphetamine	25,000
Barbiturates		(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
Secobarbital	300	b-Phenylethylamine	50,000
Amobarbital	300	Trimethobenzamide	10,000
Alphenol	150	**Methylenedioxymethamphetamine(MDMA)**	
Aprobarbital	200	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Butabarbital	75	3,4-Methylenedioxyamphetamine HCl	3,000
Butathal	100	3,4-Methylenedioxyethylamphetamine	300
Butalbital	2,500	Morphine	
Cyclopentobarbital	600	Morphine	300
Pentobarbital	300	Codeine	300
Phenobarbital	100	Ethyl Morphine	300
Benzodiazepines		Hydrocodone	5,000
Oxazepam	300	Hydromorphone	5,000
Alprazolam	200	Morphinie-3-b-d-glucuronide	1,000
α-Hydroxyalprazolam	1,500	Thebaine	30,000
Bromazepam	1,500	**Opiate 2000**	
Chlordiazepoxide	1,500	Morphine	2,000
Clonazepam HCl	800	Codeine	2,000
Clobazam	100	Ethylmorphine	5,000
Clonazepam	800	Hydrocodone	12,500
Clorazepate dipotassium	200	Hydromorphine	5,000
Delorazepam	1,500	Levorphanol	75,000
Desalkylflurazepam	400	σ-Monoacetylmorphine	5,000
Diazepam	200	Morphine 3-β-D-glucuronide	2,000
Estazolam	2,500	Norcodeine	12,500
Flunitrazepam	400	Normorphone	50,000
D,L-Lorazepam	1,500	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	Trimipramiine	3,000
Ecgonine	32,000	Amitriptyline	1,500

Promazine	1,500	Codeine	100,000
Desipramine	200	Hydromorphone	100,000
Imipramine	400	Morphine	>100,000
Clomipramine	12,500	Acetylmorphine	>100,000
Doxepine	2,000	Buprenorphine	>100,000
Maprotiline	2,000	Ethylmorphine	>100,000
Promethazine	25,000	**Propoxyphene**	
Marijuana		d-Propoxyphene	300
11-nor-Δ9-THC-9-COOH	50	d-Norpropoxyphene	300
11-nor-Δ8-THC-9-COOH	30	**Buprenorphine**	
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	Buprenorphine 3-D-Glucuronide	15
Δ8- Tetrahydrocannabinol	7,500	Norbuprenorphine	20
Δ9- Tetrahydrocannabinol	10,000	Norbuprenorphine 3-D-Glucuronide	200
Cannabinol	10,000	**Ketamine**	
Cannabidiol	100,000	Methadone	50,000
Methadone		Pethidine	12,500
Methadone	300	Methylamphetamine	12,500
Doxylamine	50,000	Methoxyphenamine	12,500
Oxycodone		Promethazine	25,000
Dihydrocodeine	20,000	Phencyclidine	25,000

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 Cup 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
Benzilic 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 Cup resists well against interference from these substances.

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MEANING OF SYMBOLS ON PACKAGE


Keep away from sunlight

Store between 4°C and 30°C


Keep dry


Do not re-use

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