

# One Step Multi-Drug Urine Test T-Cup

Catalogue No. See Pouch label

One Step Multi-Drug Urine Test T-Cup offers any combination from 2 to 15 drugs of abuse tests for 15 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), Propoxyphene (PPX).

This package insert applies to all combinations of multi-drug tests panel with integrated T-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 Test T-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	D-Amphetamine	1,000
Barbiturates	Secobarbital	300
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylcegonine	300
Marijuana	11-nor-9-tetrahydrocannabinol-9-carboxylic acid	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
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

### DRUG TESTS

One Step Multi-Drug Urine Test T-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 testing, the urine is absorbed upward 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 °C ~ 30 °C up to the expiration date.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

## MATERIAL

### Material provided

- One pouch containing a test T-Cup and a desiccant.
- Package insert

### Material Required But Not Provided

- Timer

## SPECIMEN COLLECTION AND PREPARATION

- Wash your hands with soap and warm water. Open the sealed pouch and remove the urine test T-Cup.
- The donors collect their urine samples. Open the cap of the T-Cup and urinate directly into the test T-Cup. The sample volume should be higher than the minimum urine level. Re-cap the T-Cup.

## TEST PROCEDURE

Test must be in room temperature (10°C to 30°C).

1. After the urine has been collected, re-cap the T-Cup and place the test T-Cup on a flat surface.
2. Peel the label from right to left and read the result within 5 minutes. **Do not read results after 5 minutes.**



## INTERPRETATION OF RESULTS

### DRUGS

#### 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.

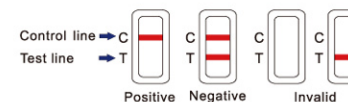
#### Negative (-)

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.



## QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. 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

1200 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding One Step Multi-Drug Urine Test T-Cup. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug	Test Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	%Agreement with GC/MS
AMP	Viewer A	+	0	4	11	29
		-	28	8	0	0
	Viewer B	+	0	1	11	29
		-	28	11	0	0
	Viewer C	+	0	5	11	29
		-	28	7	0	0
BAR	Viewer A	+	0	4	15	20
		-	20	16	5	0
	Viewer B	+	0	2	18	20
		-	20	18	2	0
	Viewer C	+	0	3	18	20
		-	20	17	2	0
BZO	Viewer A	+	0	2	17	20
		-	20	18	3	0
	Viewer B	+	0	1	20	20
		-	20	19	0	0
	Viewer C	+	0	3	18	20
		-	20	17	2	0
COC	Viewer A	+	0	1	11	29
		-	20	19	0	0
	Viewer B	+	0	1	9	29
		-	20	19	2	0
	Viewer C	+	0	2	9	29
		-	20	18	2	0
THC	Viewer A	+	0	4	18	22
		-	22	14	0	0
	Viewer B	+	0	0	17	22
		-	22	18	1	0
	Viewer C	+	0	0	15	22
		-	22	18	3	0
MTD	Viewer A	+	0	0	17	21
		-	22	18	2	0
	Viewer B	+	0	0	18	21
		-	22	18	1	0
	Viewer C	+	0	0	18	21
		-	22	18	1	0

MET	Viewer A	+	0	5	19	20	97.50%
		-	26	9	1	0	87.50%
	Viewer B	+	2	3	19	20	97.50%
		-	24	11	1	0	87.50%
	Viewer C	+	1	5	18	20	95%
		-	25	9	2	0	85%
MDMA	Viewer A	+	0	0	19	20	97.50%
		-	20	20	1	0	100%
	Viewer B	+	0	3	19	20	97.50%
		-	20	17	1	0	92.50%
	Viewer C	+	0	2	19	20	97.50%
		-	20	18	1	0	95%
MOP	Viewer A	+	0	3	19	20	97.50%
		-	29	8	1	0	92.50%
	Viewer B	+	0	3	19	20	97.50%
		-	29	8	1	0	92.50%
	Viewer C	+	0	4	19	20	97.50%
		-	29	7	1	0	90%
OPI	Viewer A	+	0	2	16	22	95%
		-	30	8	2	0	95%
	Viewer B	+	0	1	17	22	97.50%
		-	30	9	1	0	97.50%
	Viewer C	+	0	1	16	22	95%
		-	30	9	2	0	97.50%
PCP	Viewer A	+	0	0	15	22	92.50%
		-	23	17	3	0	100%
	Viewer B	+	0	0	17	22	97.50%
		-	23	17	1	0	100%
	Viewer C	+	0	1	15	22	92.50%
		-	23	16	3	0	97.50%
TCA	Viewer A	+	0	0	10	30	100%
		-	29	11	0	0	100%
	Viewer B	+	0	2	10	30	100%
		-	29	9	0	0	95%
	Viewer C	+	0	0	10	30	100%
		-	29	11	0	0	100%

Drug	Test Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	%Agreement with GC/MS
OXY	Viewer A	+	0	0	1	10	28
		-	10	10	19	2	0
	Viewer B	+	0	0	2	9	28
		-	10	10	18	3	0
	Viewer C	+	0	0	0	8	28
		-	10	10	20	4	0
BUP	Viewer A	+	0	0	1	16	20
		-	10	10	19	4	0
	Viewer B	+	0	0	2	16	20
		-	10	10	18	4	0
	Viewer C	+	0	0	0	16	20
		-	10	10	20	4	0
PPX	Viewer A	+	0	0	2	16	20
		-	10	18	10	4	0
	Viewer B	+	0	0	1	17	20
		-	10	18	11	3	0
	Viewer C	+	0	0	0	15	20
		-	10	18	12	5	0



### Precision and Sensitivity

To investigate the precision and sensitivity, for AMP, BAR, BZO, COC, THC, MTD, MET, MDMA, MOP, OPI, PCP and TCA, each drug samples were analyzed at the following concentrations: - 50% cutoff, - 25% cutoff, cutoff, +25% cutoff and + 50% cutoff. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots of the corresponding drug of abuse test. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot of the corresponding drug of abuse test.

For OXY, BUP and PPX, precision and sensitivity was assessed with three lots tested by three individuals over five consecutive days. In the study, seven separate normal urine samples were spiked with each drug to the following concentrations: Zero, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and +100% cutoff. Level of the each drug for these samples was confirmed by GC/MS. Then each sample was divided into 75 aliquots that were further divided into 3 sets of 25 (one set for each lot). Each of the three operators tested 5 aliquots at each concentration for each lot per day. A total of 75 determinations by each operator, at each concentration, were made.

AMP(ng/ml)		500	750	1000	1250	1500		
Lot 1	(-/+)	90/0	78/12	32/58	14/76	0/90		
Lot 2		90/0	78/12	32/58	14/76	0/90		
Lot 3		90/0	78/12	32/58	14/76	0/90		
BAR(ng/ml)		150	225	300	375	450		
Lot 1	(-/+)	90/0	79/11	42/48	18/72	0/90		
Lot 2		90/0	79/11	42/48	18/72	0/90		
Lot 3		90/0	79/11	42/48	18/72	0/90		
BZO(ng/ml)		150	225	300	375	450		
Lot 1	(-/+)	90/0	79/11	41/49	9/81	0/90		
Lot 2		90/0	79/11	41/49	11/79	0/90		
Lot 3		90/0	80/10	41/49	11/79	0/90		
COC(ng/ml)		150	225	300	375	450		
Lot 1	(-/+)	90/0	82/8	37/53	13/77	0/90		
Lot 2		90/0	80/10	36/54	13/77	0/90		
Lot 3		90/0	80/10	36/54	13/77	0/90		
THC(ng/ml)		25	38	50	63	75		
Lot 1	(-/+)	90/0	76/14	43/47	12/78	0/90		
Lot 2		90/0	76/14	43/47	12/78	0/90		
Lot 3		90/0	76/14	43/47	12/78	0/90		
MTD(ng/ml)		150	225	300	375	450		
Lot 1	(-/+)	90/0	75/15	41/49	7/83	0/90		
Lot 2		90/0	75/15	41/49	7/83	0/90		
Lot 3		90/0	75/15	41/49	7/83	0/90		
MET(ng/ml)		500	750	1000	1250	1500		
Lot 1	(-/+)	90/0	81/9	34/56	13/77	0/90		
Lot 2		90/0	81/9	34/56	13/77	0/90		
Lot 3		90/0	81/9	34/56	13/77	0/90		
MDMA(ng/ml)		250	375	500	625	750		
Lot 1	(-/+)	90/0	77/13	33/57	9/81	0/90		
Lot 2		90/0	77/13	33/57	9/81	0/90		
Lot 3		90/0	77/13	33/57	9/81	0/90		
MOP(ng/ml)		150	225	300	375	450		
Lot 1	(-/+)	90/0	77/13	28/62	8/82	0/90		
Lot 2		90/0	77/13	28/62	8/82	0/90		
Lot 3		90/0	77/13	28/62	6/84	0/90		
OPI(ng/ml)		1000	1500	2000	2500	3000		
Lot 1	(-/+)	90/0	80/10	44/46	12/78	0/90		
Lot 2		90/0	80/10	44/46	12/78	0/90		
Lot 3		90/0	80/10	44/46	12/78	0/90		
PCP(ng/ml)		13	17	25	32	38		
Lot 1	(-/+)	90/0	83/7	47/43	14/76	0/90		
Lot 2		90/0	83/7	47/43	14/76	0/90		
Lot 3		90/0	83/7	47/43	14/76	0/90		
TCA(ng/ml)		500	750	1000	1250	1500		
Lot 1	(-/+)	90/0	78/12	41/49	13/77	0/90		
Lot 2		90/0	78/12	41/49	13/77	0/90		
Lot 3		90/0	78/12	41/49	13/77	0/90		
OXY(ng/ml)		0	5	75	100	125	150	200
Lot 1	(-/+)	75/0	75/0	63/12	10/65	3/72	0/75	0/75
Lot 2		75/0	75/0	64/11	11/64	4/71	0/75	0/75
Lot 3		75/0	75/0	63/12	9/66	2/73	0/75	0/75

BUP(ng/ml)		0	5	7.5	10	12.5	15	20
Lot 1	(-/+)	75/0	75/0	62/13	9/66	4/71	0/75	0/75
Lot 2		75/0	75/0	63/12	8/67	3/72	0/75	0/75
Lot 3		75/0	75/0	61/14	9/66	2/73	0/75	0/75
PPX(ng/ml)		0	150	225	300	375	450	600
Lot 1	(-/+)	75/0	75/0	65/10	9/66	6/69	0/75	0/75
Lot 2		75/0	75/0	64/11	11/64	4/71	0/75	0/75
Lot 3		75/0	75/0	64/11	9/66	5/70	0/75	0/75

### 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 (AMP)		Methamphetamine (MET)	
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
d-methamphetamine	1,000	(+/-)3,4-methylenedioxymethamphetamine(MDMA)	2,000
l-methamphetamine	3,000	b-Phenylethylamine	50,000
3,4-Methylenedioxyethylamphetamine (MDE)	2,000	Trimethobenzamide	10,000
(+/-)3,4-methylenedioxymethamphetamine (MDMA)	300	l-Methamphetamine	8,000
Barbiturates (BAR)		3,4-Methylenedioxyamphetamine (MDA)	3,000
Secobarbital	300	3,4-Methylenedioxyethylamphetamine (MDE)	600
Amobarbital	300	l-Amphetamine	50,000
Alphenol	150	Methylenedioxymethamphetamine (MDMA)	
Aprobarbital	200	3,4-Methylenedioxyamphetamine HCl(MDMA)	500
Butabarbital	75	3,4-Methylenedioxyamphetamine HCl	3,000
Butathal	100	3,4-Methylenedioxyethylamphetamine	300
Butalbital	2,500	D-Amphetamine	50,000
Cyclopentobarbital	600	L-Amphetamine	60,000
Pentobarbital	300	D-Methamphetamine	8,000
Phenobarbital	100	L-Methamphetamine	10,000
Benzodiazepines (BZO)		Morphine (MOP)	
Oxazepam	300	Morphine	300
Alprazolam	200	Codeine	300
α-Hydroxylprazolam	1,500	Ethyl Morphine	300
Bromazepam	1,500	Hydrocodone	5,000
Chlordiazepoxide	1,500	Hydromorphone	5,000
Clonazepam HCl	800	Morphine 3-β-D-glucuronide	1,000
Clobazam	100	Thebaine	30,000
Clonazepam	800	Heroin	300
Clorazepate dipotassium	200	σ-Monoacetylmorphine	400
Delorazepam	1,500	Oxycodone	30,000
Desalkylfurazepam	400	Opiate 2000 (OPI)	
Diazepam	200	Morphine	2,000
Estazolam	2,500	Codeine	2,000
Flunitrazepam	400	Ethylmorphine	5,000
D,L-Lorazepam	1,500	Hydrocodone	12,500
Midazolam	12,500	Hydromorphone	5,000
Nitrazepam	100	Levorphanol	75,000
Norchlordiazepoxide	200	σ-Monoacetylmorphine	5,000
Nordiazepam	400	Morphine 3-β-D-glucuronide	2,000
Temazepam	100	Norcodeine	12,500
Trazolam	2,500	Normorphine	50,000
Cocaine		Oxycodone	25,000
Benzoylcegonine	300	Oxymorphone	25,000
Cocaine HCl	750	Procaine	150,000
Cocaethylene	12,500	Thebaine	100,000
Ecgonine	32,000	Heroin	2,000

<b>Marijuana (THC)</b>			
11-nor-Δ9-THC-9-COOH	50	<b>Phencyclidine (PCP)</b>	
11-nor-Δ8-THC-9-COOH	30	Phencyclidine	25
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	4-Hydroxyphencyclidine	12,500
Δ8-Tetrahydrocannabinol	7,500	Phencyclidine morpholine	50
Δ9-Tetrahydrocannabinol	10,000		
Cannabinol	10,000	<b>Methadone (MTD)</b>	
Cannabidiol	100,000	Methadone	300
<b>Oxycodone (OXY)</b>		Doxylamine	50,000
Oxycodone	100		
Dihydrocodeine	20,000	<b>Tricyclic Antidepressants (TCA)</b>	
Codeine	100,000	Notriptyline	1,000
Hydromorphone	100,000	Nordoxepine	1,000
Morphine	>100,000	Trimipramine	3,000
Acetylmorphine	>100,000	Amitriptyline	1,500
Buprenorphine	>100,000	Promazine	1,500
Ethylmorphine	>100,000	Desipramine	200
Hydrocodone	1,000	Imipramine	400
<b>Buprenorphine (BUP)</b>		Clomipramine	12,500
Buprenorphine 3-D-Glucuronide	15	Doxepine	2,000
Norbuprenorphine	20	Maprotiline	2,000
Norbuprenorphine 3-D-Glucuronide	200	Promethazine	25,000
<b>Propoxyphene (PPX)</b>			
d-Norpropoxyphene	300		

#### 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 T-Cup at a concentration of 100 µg/ml.

#### Non Crossing-Reacting Compounds

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

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

#### Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with each drug at 50% below and 50% above cutoff level. One Step Multi-Drug Urine Test T-Cup was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

#### Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with morphine at 50% below and 50% above cutoff levels. One Step Multi-Drug Urine Test T-Cup was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

#### BIBLIOGRAPHY OF SUGGESTED READING

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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