Multi-Drugs Rapid Test 1-Step Cup (Urine)
For professional use

IVD REF

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Instruction Sheet for testing of any combination of the following drugs:
AMP/COC/THC/MTD/MET/MDMA/MOP/TML/KET/CLO/DIA/CNB

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

INTENDED USE AND SUMMARY

The Multi-Drugs Rapid Test 1-Step Cup is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methylenedioxyme-thamphetamine (MDMA)	d,l-Methylenedioxymethampheta mine	1,000
Morphine/Opiate (MOP/OPI)	Morphine	300
Tramadol (TML)	Cis-Tramadol	100
Ketamine (KET)	Ketamine	1,000
Clonazepam (CLO)	Clonazepam	400
Diazepam (DIA)	Diazepam	300
Cannabinol (CNB)	Cannabinol	500

Configurations of the Multi-Drugs Rapid Test 1-Step Cup come with any combination of the above listed drug analytes. 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 indicated.

PRINCIPLES OF DOA TESTS

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. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test Cups
- Package Insert

Materials Required But Not Provided

- Timer

WARNINGS AND PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. The Test 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 should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The Test 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 should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

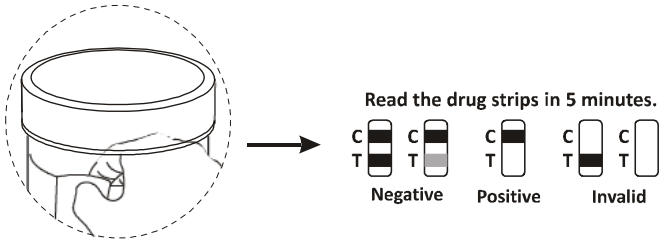
Specimen Storage

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

DIRECTIONS FOR USE

Allow the test and urine specimen to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it within one hour.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 32-38°C (90-100°F).
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off the label on the multi-drug test card to view results.
7. **The drug strip result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the control region (C) and colored line appears in the test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the control region (C) and no line appears in the test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the control 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

1. The Multi-Drugs Rapid Test 1-Step Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. A positive result does not indicate level or intoxication, administration route or concentration in urine.
4. 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.
5. This test does not distinguish between drugs of abuse and certain medications.
6. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

% Agreement with GC/MS

	MET 1,000	AMP 1,000	MDMA 1,000	TML 100	KET 1,000	CLO 400
Positive Agreement	96.2%	98.1%	98.0%	88.2%	97.5%	97.1%
Negative Agreement	97.1%	97.9%	99.3%	92.4%	98.2%	99.3%
Total Results	96.8%	98.0%	98.8%	90.8%	98.0%	98.4%

	DIA 300	COC 300	THC 50	CNB 500	MTD 300	MOP/OPI 300
Positive Agreement	98.4%	98.2%	97.9%	95.8%	98.9%	95.0%
Negative Agreement	99.2%	97.8%	98.1%	97.6%	98.8%	95.3%
Total Results	98.8%	98.0%	98.0%	96.9%	98.8%	95.2%

% Agreement with Commercial Kit

	TML 100	AMP 1,000	KET 1,000	DIA 300	CLO 400	COC 300
Positive Agreement	*	>99.9%	>99.9%	*	*	>99.9%
Negative Agreement	*	>99.9%	>99.9%	*	*	>99.9%
Total Results	*	>99.9%	>99.9%	*	*	>99.9%

	THC 50	MTD 300	MET 1,000	MDMA 1,000	MOP/ OPI 300	CNB 500
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*

*Note: Based on GC/MS data instead of Commercial Kit.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug Concentration Cut-off Range	THC 50		AMP 1,000		MTD 300		MET 1,000		MDMA 1,000		MOP/ OPI 300	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	-	+	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	26	4	30	0	27	3	26	4	25	5
Cut-off	14	16	15	15	27	3	16	14	15	15	15	15
+25% Cut-off	3	27	3	27	14	16	3	27	5	25	3	27
+50% Cut-off	0	30	0	30	3	27	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	TML 100		KET 1,000		CLO 400		DIA 300		COC 300		CNB 500	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	26	4	27	3	26	4	27	3
Cut-off	15	15	16	14	14	16	15	15	13	17	14	16
+25% Cut-off	4	26	3	27	5	25	3	27	3	27	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drugs Rapid Test 1-Step Cup at 5 minutes.

Analytes	conc. (ng/mL)	Analytes	conc. (ng/mL)
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxyamphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
MARIJUANA (THC 50)			
Cannabinol	35,000	Δ^8-THC	17,000
11-nor-Δ^8-THC-9 COOH	30	Δ^9-THC	17,000
11-nor-Δ^9-THC-9 COOH	50		
METHADONE (MTD 300)			
Methadone	300	Doxylamine	100,000
METHAMPHETAMINE (MET 1,000)			
ρ-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 1,000) Ecstasy			
(±) 3,4-Methylenedioxy-methamphetamine HCl	1,000	3,4-Methylenedioxyethyl-amphetamine	600
(±) 3,4-Methylenedioxyamphetamine HCl	6,000		
MORPHINE (MOP/OPI 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
TRAMADOL (TML 100)			
n-Desmethyl-cis-tramadol	200	o-Desmethyl-cis-tramadol	10,000
Cis-tramadol	100	Phencyclidine	100,000
Procyclidine	100,000	d,l-O-Desmethyl venlafaxine	50,000
KETAMINE (KET 1,000)			
Ketamine	1,000	Benzphetamine	25,000
Dextromethorphan	2,000	(+) Chlorpheniramine	25,000
Methoxyphenamine	25,000	Clonidine	100,000
d-Norpropoxyphene	25,000	EDDP	50,000
Promazine	25,000	4-Hydroxyphencyclidine	50,000
Promethazine	25,000	Levorphanol	50,000
Pentazocine	25,000	MDE	50,000
Phencyclidine	25,000	Meperidine	25,000
Tetrahydrozoline	500	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylendioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
CLONAZEPAM (CLO 400)			
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	2,000	RS-Lorazepamglucuronide	250
Bromazepam	1,000	Midazolam	5,000
Chlordiazepoxide	1,000	Nitrazepam	200
Clobazam	250	Norchlordiazepoxide	200
Clorazepatedipotassium	600	Nordiazepam	1,000
Delorazepam	1,000	Oxazepam	350
Desalkylflurazepam	250	Temazepam	150
Diazepam	300	Triazolam	5,000
Estazolam	1,250		
DIAZEPAM (DIA 300)			
Diazepam	300	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepate dipotassium	500	Nordiazepam	900
Alprazolam	100	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepam glucuronide	200
Chlordiazepoxide	900	Triazolam	3,000
Estazolam	6,000	Temazepam	100
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200		
CANNABINOL(CNB 500)			
cannabinol	500	Δ^9 -THC	10,000
11-nor-Δ^9 -THC-9 COOH	300		

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of negative, ±50% and ±25% cut-off level, was labeled, blinded and tested at each site. The results gained ≥75% accuracy in ±25% cut-off level specimen and 100% accuracy in negative and ±50% cut-off level specimen.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing above related calibrator substances. The following compounds show no cross-reactivity when tested with the Multi-Drugs Rapid Test 1-Step Cup at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propanolol	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	Norethindrone	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			

BIBLIOGRAPHY

1. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City,CA 2002.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

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