Pocguide

CE

Multi-Drug Test Panel

English

Multi-Drug Test panel offers any combination from 2 to 16 drugs of abuse tests for 25 different drugs:Amphetamine(AMP), Barbiturates(BAR), Buprenorphine(BUP), Benzodiazepines (BZO), Caffeine(CAF), Cocaine(COC), Cotinine(COT), EDDP,Ethyl Glucuronide(ETG), Fentanyl(FTY), Synthetic Cannabis(K2), Ketamine(KET), Methcathinone(MC), Methylenedioxymethamphetamine(MDMA), Methamphetamine(MET), Morphine(MOP), Methaqualone (MQL), Methadone(MTD), Opiate(OPI), Oxycodone(OXY), Phencyclidine(PCP), Propoxyphene(PPX), Tricyclic Antidepressants(TCA), Marijuana(THC), Tramadol(TRA).

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 cutoff level.

For professional use only, For in vitro diagnostic use.

INTENDED USE

Multi-Drug Test Panel 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 cutoff concentrations:

Test	Calibrator	Cutoff(ng/ml)
Amphetamine	Amphetamine	1000
Barbiturates	Secobarbital	300
Buprenorphine	Buprenorphine	10
Benzodiazepines	Oxazepam	300
Caffeine	Caffeine	1000
Cocaine	Benzoylecgonine	300
Cotinine	Cotinine	100
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Ethyl Glucuronide	Ethyl Glucuronide	500
Fentanyl	Norfentanyl	20
Synthetic Cannabis	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	25 25
Ketamine	Ketamine	1000
Methcathinone	Methcathinone	1000
Methylenedioxymethamphetamine	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Methamphetamine	Methamphetamine	1000
Morphine	Morphine	300
Methaqualone	Methaqualone	300
Methadone	Methadone	300
Opiate	Morphine	2000
Oxycodone	Oxycodone	100
Phencyclidine	Phencyclidine	25
Propoxyphene	Propoxyphene	300
Tricyclic Antidepressants	Notriptyline	1000
Marijuana	Marijuana	50
Tramadol	Tramadol	100

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

Multi-Drug 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.

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 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 10 minutes

STORAGE AND STABILITY

- Store at 2 ºC ~ 30 ºC in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIALS

Material Provided

- Test panels
- Package insert

Material Required But Not Provided

• Specimen collection container

• Timer

SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2 ºC -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

Test must be in room temperature (15ºC to 30ºC)

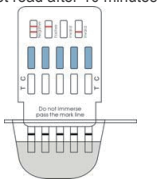
1.Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.

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 about 10 seconds. Make sure 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 10 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 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.

Positive Negative Invalid Invalid

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 cutoff 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. 1920 specimens were used in the test. All the results were confirmed by GC/MS. The results were listed as following:

% Agreement with GC/MS

Specimen	AMP	BAR	BUP	BZO	CAF	COC	COT
Positive	100.00%	100.00%	100.00%	99.20%	99.20%	100.00%	100.00%
Negative	95.80%	99.10%	97.50%	95.80%	97.40%	98.30%	96.70%
Total	97.90%	99.60%	98.80%	97.50%	98.30%	99.20%	98.30%

Specimen	EDDP	ETG	FTY	K2	KET	MC	MDMA
Positive	100.00%	99.10%	100.00%	99.60%	100.00%	100.00%	99.20%
Negative	97.40%	98.40%	99.10%	98.40%	97.50%	98.30%	100.00%
Total	98.80%	98.80%	99.60%	99.00%	98.80%	99.20%	99.60%

Specimen	MET	MOP	MQL	MTD	OPI	OXY	PCP
Positive	100.00%	100.00%	100.00%	100.00%	98.30%	99.20%	100.00%
Negative	99.10%	96.70%	98.30%	99.10%	100.00%	99.10%	98.30%
Total	99.60%	98.30%	99.20%	99.60%	99.20%	99.20%	99.20%

Specimen	PPX	TCA	THC	TRA
Positive	99.20%	100.00%	100.00%	99.20%
Negative	98.30%	99.20%	100.00%	98.30%
Total	98.80%	99.60%	100.00%	98.80%

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.(Cutoff range)	n	AMP		BAR		BUP		BZO		CAF		COC		COT	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cutoff	30	25	5	26	4	25	5	23	7	24	6	26	4	24	6
Cutoff	30	12	18	15	15	14	16	12	18	11	19	13	17	14	16
+25% Cutoff	30	4	26	7	23	5	25	5	25	6	24	5	25	3	27
+50% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.(Cutoff range)	n	EDDP		ETG		FTY		K2		KET		MC		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cutoff	30	25	5	24	6	25	5	23	7	24	6	26	4	24	6
Cutoff	30	13	17	14	16	13	17	14	16	10	20	14	16	11	19
+25% Cutoff	30	3	27	4	36	4	26	3	27	0	30	3	27	5	25
+50% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.(Cutoff range)	n	MET		MOP		MQL		MTD		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cutoff	30	23	7	26	4	25	5	27	3	24	6	26	4	25	5
Cutoff	30	13	17	9	11	12	18	12	18	11	19	12	18	14	16
+25% Cutoff	30	4	26	1	29	4	26	3	27	3	27	4	26	3	27
+50% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.(Cutoff range)	n	PPX		TCA		THC		TRA	
		-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0
-25% Cutoff	30	25	5	26	4	23	7	24	6
Cutoff	30	11	19	13	17	12	18	13	17
+25% Cutoff	30	0	30	5	25	3	27	4	26
+50% Cutoff	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 (AMP)	**ng/mL**
d-Amphetamine	1000
d,l-Amphetamine	3000
l-Amphetamine	50000
(+/-) 3,4-methylenedioxyamphetamine	5000
Phentermine	3000
Barbiturates(BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butathal	100
Butalbital	2500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Buprenorphine(BUP)	
Buprenorphine	10
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-Glucuronide	200
Benzodiazepines (BZO)	
Oxazepam	300
Alprazolam	200
a-Hydroxyalprazolam	1500
Bromazepam	1500
Chlordiazepoxide	1500
Clonazepam HCl	800
Clobazam	100
Clonazepam	800
Clorazepate dipotassium	200
Delorazepam	1500
Desalkylflurazepam	400
Diazepam	200
Estazolam	2500
Flunitrazepam	400
D,L-Lorazepam	1500
Midazolam	12500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Temazepam	100
Trazolam	2500
Caffeine(CAF)	
Caffeine	1000
Cocaine (COC)	
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12500
Ecgonine	32000
Cotinine (COT)	
Cotinine	100
EDDP	
EDDP	100
Methadone	300

EMDP	100000
Ethyl Glucuronide (ETG)	
Ethyl Glucuronide	500
Fentanyl(FTY)	
Norfentanyl	20
Fentanyl	100
Synthetic Cannabis (K2)	
JWH-018 Pentanoic Acid	25
JWH-073 Butanoic Acid	25
JWH-018 N-4-hydroxypentyl	2000
JWH-018 (Spice Cannabinoid)	1000
JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5)	1000
JWH-073 (Spice Cannabinoid)	2000
JWH-073 3-Hydroxybutyl metabolite	1000
JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5)	1000
JWH-019 6-hydroxypentyl	1000
JWH-122 N-4-hydroxypentyl	2000
JWH-210 5-Hydroxypentyl metabolite	5000
AM2201 4-Hydroxypentyl metabolite	1000
Ketamine (KET)	
Ketamine	1000
Methadone	50000
Pethidine	12500
Methylamphetamine	12500
Methoxyphenamine	12500
Promethazine	25000
Phencyclidine	25000
Methcathinone(MC)	
Methcathinone	1000
Methylenedioxymethamphetamine(MDMA)	
3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3000
3,4-Methylenedioxyethylamphetamine (MDE)	300
Methamphetamine (MET)	
D(+)-Methamphetamine	1000

D-Amphetamine	50000
Chloroquine	50000
(+/-)-Ephedrine	50000
(-)-Methamphetamine	25000
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2000
b-Phenylethylamine	50000
Trimethobenzamide	10000
Morphine (MOP)	
Morphine	300
Codeine	300
Ethyl Morphine	300
Hydrocodone	5000
Hydromorphone	5000
Morphinie-3-b-d-glucuronide	1000
Thebaine	30000
Methaqualone(MQL)	
Methaqualone	300
Methadone(MTD)	
Methadone	300
Doxylamine	50000
Opiate (OPI)	
Morphine	2000
Codeine	2000
Ethylmorphine	5000
Hydrocodone	12500
Hydromorphine	5000
Levorphanol	75000
s-Monoacetylmorphine	5000
Morphine 3-b-D-glucuronide	2000
Norcodeine	12500
Normorphone	50000
Oxycodone	25000
Oxymorphine	25000
Thebaine	100000
Oxycodone(OXY)	
Oxycodone	100
Dihydrocodeine	20000

Codeine	100000
Hydromorphone	100000
Morphine	>100,000
Acetylmorphine	>100,000
Buprenorphine	>100,000
Ethylmorphine	>100,000
Phencyclidine(PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12500
Propoxyphene(PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
Tricyclic Antidepressants (TCA)	
Notriptyline	1000
Nordoxepine	1000
Trimipramiine	3000
Amitriptyline	1500
Promazine	1500
Desipramine	200
Imipramine	400
Clomipramine	12500
Doxepine	2000
Maprotiline	2000
Promethazine	25000
Marijuana (THC)	
11-nor-D9-THC-9-COOH	50
11-nor-D8-THC-9-COOH	30
11-hydroxy-D9-Tetrahydrocannabinol	2500
D8- Tetrahydrocannabinol	7500
D9- Tetrahydrocannabinol	10000
Cannabinol	10000
Cannabidiol	100000
Tramadol(TRA)	
Tramadol	100
(+/-) Chlorpheniramine	500000
Dipehnhydramine	250000
Pheniramine	>500,000
PCM	>250,000

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 Test Panel at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

Acetaminophen	Epinephrine HCl	Metoprolol tartrate
Aciclovir	Esomeprazole	Mifepristone
Afrin	Estroven	Montelukast
Aleve	Fenofibrate	Mosapride Citrate
Amiodarone HCl	Fluvoxamine	Narcotine
Amlodipine Mesylate	Fuel	Nifedipine
Amoxicillin	Gabapentin	Nikethamide
Ampicillin	Glibenclamide	Nimodipine
Aripiprazole	Gliclazide	Omeprazole
Aspirin	Glipizide	Penfluridol
Atorvastatin	Glucosamine Chondroitin	Penicillin V Potassium
Atropine	Glucose	Pioglitazone HCl
Captopril	Haloperidol	Piracetam
Carbamazepine	Heartburn Relief	Pravastatin sodium
Cefaclor	Hydrochlorothiazide	Propylthiouracil
Cefradine	I Caps	Rifampicin
Cephalexin	Isosorbide dinitrate	Sildenafil citrate
Ciprofloxacin	Ketoconazole	Simvastatin
Clarithromycin	Levofloxacin	Spironolactone
Clopidogrel bisulfate	Levonorgestrel	Tetracycline
Clozapine	Levothyroxine sodium	Trazodone HCl
Cortisone	Lidocaine HCl	Triamterene
CVS	Lisinopril	Vitamin B1
Dextromethorphan HBr	Lithium carbonate	Vitamin B2
Diclofenac sodium	Loratadine	Vitamin C
Domperidone	Magnesium	Zencore Plus2
Enalapril maleate	Mega-T Plus	

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

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MEANING OF SYMBOLS ON PACKAGE

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number		Do not use if package is damaged
	Manufacturer		Keep dry		Keep away from sunlight

	Hangzhou Aichek Medical Technology CO.,Ltd. Jinxing Cun, Yuhang Community, Yuhang District (Future Sci-Tech City), Hangzhou, Zhejiang, P.R. China
EC REP	SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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