

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

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Berdasarkan :

Peraturan Menteri Kesehatan R.I No.1190/Menkes/Per/VIII/2010 tanggal 23 Agustus 2010 tentang Izin Edar Alat Kesehatan dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 20103714212

Nama : **WONDFO One Step Multi-Drug Urine Test 3 Panel (AMP/MOP/THC)**

Jenis Produk : Multi parameter clinical toxicology test system

Kategori Produk : Peralatan Kimia Klinik dan Toksikologi Klinik

Sub Kategori : Sistem Tes Toksikologi Klinik

Type / Ukuran : Kit

Kemasan : Dus, isi 25 test

Nama Pabrik : GUANGZHOU WONDFO BIOTECH CO.,LTD., China

Nama Pendaftar : PT. EXXEL UTAMA, DKI Jakarta

Atas dasar lisensi dari : -

Ketentuan : 1. Persetujuan izin edar berlaku sampai dengan 13 Februari 2022.
2. Wajib menyampaikan laporan berkala setiap 1 (satu) tahun terhadap jenis dan akibat efek samping dari produk yang diedarkan.

Persyaratan : 1. Apabila dikemudian hari ada pihak lain yang lebih berhak atas nama keagenan diatas, sesuai dengan ketentuan yang berlaku, pendaftar bersedia melepaskan nama keagenan produk tersebut.
2. Apabila dikemudian hari terdapat kekeliruan, maka persetujuan ini akan ditinjau kembali.

07 Agustus 2017

a.n. Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT



drg. Arianti Anaya, MKM
NIP. 19640924 199403 2 001



One Step Multi-Drug Urine Test Panel

Suitable for the following catalogue number:

W2002-P	W2007-P	W2012-P
W2003-P	W2008-P	W2013-P
W2004-P	W2009-P	W2014-P
W2005-P	W2010-P	W2015-P
W2006-P	W2011-P	W2016-P

Wondfo One Step Multi-Drug Urine Test offers any combination from 2 to 16 drugs of abuse tests for 21 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), EDDP, Tramadol (TRA), Synthetic Cannabis (K2), Cotinine (COT) and Ethyl Glucuronide (EtG).

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 recommend the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.

Wondfo One Step Multi-Drug Urine Test Panel is intended for use by healthcare professionals and as qualitative screening *in vitro* diagnostic test for detection of drugs of abuse and their principal metabolites in human urine at specified cut off level.

For in vitro diagnostic use.

INTENDED USE

Wondfo One Step Multi-Drug Urine Test 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
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Tramadol	Tramadol	1000
Synthetic Cannabis (K2).	JWH-018 Pentanoic Acid	50
	WH-073 Butanoic Acid	25
Cotinine	Cotinine	100
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500

The assay is intended to verify an intoxication in patients. It provides a qualitative, preliminary test result. A more specific alternative chemical method must be used 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 each drug of abuse test result, particularly when preliminary results are positive.

PRINCIPLE

Wondfo One Step Multi-Drug Urine Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a 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's drug levels are at zero or below the detection limit 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's drug levels are at or above the detection limit of the test, 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.
- All specimens should be treated as biohazards.
- 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°C~30°C in the sealed pouch up to the expiration date printed on the package.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material Provided

1. Individual pouches, each containing:
 - Test panel
 - Desiccant pouch(The desiccant is for storage purposes only, and is not used in the test procedures.)
2. Leaflet with instructions for use

Material Required But Not Provided

1. Timer
2. Urine Cups


SPECIMEN COLLECTION AND PREPARATION

Collect urine sample with urine cup. Urine sample must be refrigerated at 2°C~8°C and stored up to forty-eight hours if not used immediately. For longer storage, freeze the sample at -20°C or below. Bring frozen or refrigerated samples to room temperature before testing.

TEST PROCEDURE

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

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 under the 'MAX' line printed on the front of the device.

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[illegible]

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	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
(+/-) 3,4-methylenedioxyamphetamine	5,000
Phentermine	3,000
Barbiturates(BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butathal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Benzodiazepines (BZO)	
Oxazepam	300
Alprazolam	200
α -Hydroxyalprazolam	1,500
Bromazepam	1,500
Chlordiazepoxide	1,500
Clonazepam HCl	800
Clobazam	100
Clonazepam	800
Clorazepate dipotassium	200
Delorazepam	1,500
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
D,L-Lorazepam	1,500
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Temazepam	100
Trazolam	2,500
Cocaine (COC)	
Benzoyllecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000
Marijuana (THC)	
11-nor-D9-THC-9-COOH	50
11-nor-D8-THC-9-COOH	30
11-hydroxy-D9-Tetrahydrocannabinol	2,500
D8- Tetrahydrocannabinol	7,500
D9- Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000
Methamphetamine (MET)	
D(+)-Methamphetamine	1,000
D-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
(-)-Methamphetamine	25,000
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	2,000
b-Phenylethylamine	50,000
Trimethobenzamide	10,000

Methylenedioxyamphetamine(MDMA)	
3,4-Methylenedioxyamphetamine HCl(MDMA)	500
3,4-Methylenedioxyamphetamine HCl	3,000
3,4-Methylenedioxyethylamphetamine	300
Morphine (MOP)	
Morphine	300
Codeine	300
Ethyl Morphine	300
Hydrocodone	5,000
Hydromorphone	5,000
Morphine-3-b-d-glucuronide	1,000
Thebaine	30,000
Methadone(MTD)	
Methadone	300
Doxylamine	50,000
Opiate (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
σ -Monoacetylmorphine	5,000
Morphine 3- β -D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
Phencyclidine(PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
Tricyclic Antidepressants (TCA)	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepine	2,000
Maprotiline	2,000
Promethazine	25,000
Ketamine (KET)	
Ketamine	1000
Methadone	50,000
Pethidine	12,500
Methylamphetamine	12,500
Methoxyphenamine	12,500
Promethazine	25,000
Phencyclidine	25,000
Buprenorphine(BUP)	
Buprenorphine	10
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-Glucuronide	200
Oxycodone(OXY)	
Oxycodone	100
Dihydrocodeine	20,000
Codeine	100,000
Hydromorphone	100,000
Morphine	>100,000
Acetylmorphine	>100,000

Buprenorphine	>100,000
Ethylmorphine	>100,000
Propoxyphene(PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
Tramadol	
Tramadol	1,000
(+/-) Chlorpheniramine	500,000
Dipehnhydramine	250,000
Pheniramine	>500,000
PCM	>250,000
EDDP	
2-Ethylidene -1,5-Dimethyl-3,3-Diphenylpyrrolidine	100
Methadone	100,000
EMDP	100,000
Synthetic Cannabis (K2).	
JWH-018 Pentanoic Acid	50
JWH-073 Butanoic Acid	25
JWH-018 N-4-hydroxypentyl	2,000
JWH-018 (Spice Cannabinoid)	1,000
JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5)	1,000
JWH-073 (Spice Cannabinoid)	2,000
JWH-073 3-Hydroxybutyl metabolite	1,000
JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5)	1,000
JWH-019 6-hydroxypentyl	1,000
JWH-122 N-4-hydroxypentyl	2,000
JWH-210 5-Hydroxypentyl metabolite	5,000
AM2201 4-Hydroxypentyl metabolite	1,000
Cotinine (COT)	
Cotinine	100
Ethyl Glucuronide (EtG)	
Ethyl Glucuronide	500

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

Acetaminophen	Epinephrine HCl	Mifepristone
Aciclovir	Esomeprazole	Montelukast
Afrin	Estroven	Mosapride Citrate
Aleve	Fenofibrate	Narcotine
Amiodarone HCl	Fluvoxamine	Nifedipine
Amlodipine Mesylate	Fuel	Nikethamide
Amoxicillin	Gabapentin	Nimodipine
Ampicillin	Glibenclamide	Omeprazole
Aripiprazole	Gliclazide	Papaverine
Aspirin	Glipizide	Penfluridol
Atorvastatin	Glucosamine Chondroitin	Penicillin V Potassium
Atropine	Glucose	Pioglitazone HCl
Caffeine	Haloperidol	Piracetam
Captopril	Heartburn Relief	Pravastatin sodium
Carbamazepine	Hydrochlorothiazide	Propylthiouracil
Cefaclor	I Caps	Rifampicin
Cefradine	Isosorbide dinitrate	Sildenafil citrate
Cephalexin	Ketoconazole	Simvastatin
Ciprofloxacin	Levofloxacin	Spironolactone














Clarithromycin	Levonorgestrel	Tetracycline
Clopidogrel bisulfate	Levothyroxine sodium	Trazodone HCl
Clozapine	Lidocaine HCl	Triamterene
Cortisone	Lisinopril	Vitamin B1
CVS	Lithium carbonate	Vitamin B2
Dextromethorphan HBr	Loratadine	Vitamin C
Diclofenac sodium	Magnesium	Zencore Plus2
Domperidone	Mega-T Plus	
Enalapril maleate	Metoprolol tartrate	

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

BIBLIOGRAPHY OF SUGGESTED READING

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3. Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR (ed.): Drug Addiction I, New York, Spring – Verlag. 1977.
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5. Hawks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
6. Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press. 1983.
7. McBay, A. J. Dr7. ug-analysis technology--pitfalls and problems of drug testing. Clin. Chem. 33,33B-40B, 1987.

Index of Symbols

 In Vitro Diagnostic Use	 See Instruction for Use	 Expiry Date
 Tests per Kit	 Manufacturing Date	 Keep Dry
 Batch Number	 Authorized Representative	 Keep away from Sunlight
 Manufacturer	 Do not reuse	 Catalog #
 Store between 4~30 °C		



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