Wondfo® One Step Multi-Drug Urine Test

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 Panel offers any combination from 2 to 16 drugs of abuse tests for the following drugs: Amphetamine (AMP), Barbiturates (BAR), Barbiturates 200 (BAR200), Benzodiazepines (BZO), Benzodiazepines 100 (BZO100), Cocaine (COC), Marijuana (THC), Marijuana 25 (THC25), 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), Ethyl Glucuronide (EtG), Amphetamine (AMP500), Cocaine (COC150), Methamphetamine (MET500) and Fentanyl (FTY).

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 cut off level.

For healthcare professional use only, For in vitro diagnostic use.

INTENDED USE

Wondfo One Step Multi-Drug Urine Test Panel is consisted of 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
Amphetamine (AMP500)	Amphetamine	500
Barbiturates	Secobarbital	300
Barbiturates (BAR200)	Secobarbital	200
Benzodiazepines	Oxazepam	300
Benzodiazepines (BZO100)	Oxazepam	100
Cocaine	Benzoylecgonine	300
Cocaine (COC150)	Benzoylecgonine	150
Marijuana	11-nor-Δ9-THC-9-COOH	50
Marijuana (THC25)	11-nor-Δ9-THC-9-COOH	25
Methadone	Methadone	300
Methamphetamine	Methamphetamine	1,000
Methamphetamine (MET500)	Methamphetamine	500
Morphine	Morphine	300
Methylenedioxymetham-phetamine	3,4-Methylenedioxymetham-phetamine HCl (MDMA)	500
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	50
Cotinine	Cotinine	100
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500
Fentanyl	Fentanyl	200
	Norfentanyl	20

The assays are intended to verify intoxication in patients. They provides qualitative, preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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

Wondfo One Step Multi-Drug Urine 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.

WARNING 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.
- Do not touch the test area of test.
- Keep out of the reach of children.
- Do not read after 5 minutes.

STORAGE AND STABILITY

1. Store at 4~30ºC in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.

MATERIAL

Material Provided

1. 25 Individual pouches, each containing:
   - 1 test device
   - 1 desiccant pouch (for storage purposes only and not used in thetest procedures)
2. Leaflet with instructions for use

Material Required But Not Provided

1. Timer
2. 25 Urine collection cup

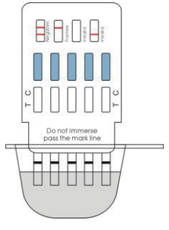
SPECIMEN COLLECTION AND PREPARATION

Collect urine specimen in the urine cup. Urine specimens may be refrigerated (2~8ºC) and stored up to forty-eight hours. For longer storage, freeze the samples (-20ºC 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 (18ºC 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 at least 10 seconds. Make sure immerse about 2/3 of absorbent end, but not above the mark 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 5 minutes.**



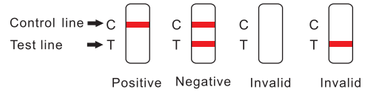
INTERPRATATION OF RESULTS

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 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 OF PROCEDURE

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
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.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using each of the tests and commercially available drug rapid test. 1920 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	BAR 200	BZO	BZO 100	COC	THC
Positive	99%	97.5%	*	95%	*	100%	95%
Negative	99%	99%	*	100%	*	99%	99%
Total	99%	98.6%	*	97.9%	*	99%	97.9%

Specimen	THC 25	MTD	MET	MDMA	MOP 300	OPI 2000	PCP
Positive	*	90%	99%	95%	97.5%	97.5%	97.9%
Negative	*	99%	99%	99%	99%	99%	99%
Total	*	96.4%	99%	97.9%	98.6%	98.6%	98.6%

Specimen	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Positive	95%	97%	99%	96%	95%	97.5%	97%
Negative	99%	97%	99%	99%	100%	99%	97%
Total	97.9%	97%	99%	97.5%	97.9%	98.6%	97%

Specimen	K2	COT	ETG	AMP(500)	COC(150)	MET(500)	FTY
Positive	96%	97%	97%	97%	98%	99%	97%
Negative	97%	97%	97%	98%	98%	98%	97%
Total	96.5%	97%	97%	97.5%	98%	98.5%	97%

* NOTE: Commercial kit unavailable for comparison testing.

% Agreement with GC/MS

Specimen	AMP	BAR	BAR 200	BZO	BZO 100	COC	THC
Positive	94%	92%	97.5%	97%	95%	96%	95%
Negative	99%	98%	95%	97%	95%	99%	96%
Total	97%	95%	96.3%	97%	95%	98%	96%

Specimen	THC 25	MTD	MET	MDMA	MOP 300	OPI 2000	PCP
Positive	95%	95%	99%	97%	98%	99%	91%
Negative	97.5%	99%	99%	99%	98%	99%	99%
Total	96.3%	97%	99%	98%	98%	99%	95%

Specimen	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Positive	95%	90%	92.5%	92.5%	90%	95%	95%
Negative	99%	97.5%	97.5%	95%	97.5%	96%	99%
Total	97%	93.8%	95%	93.8%	93.8%	96%	97%

Specimen	K2	COT	ETG	AMP(500)	COC(150)	MET(500)	FTY
Positive	93%	95%	96%	98%	96%	98%	100%
Negative	97%	95%	96%	99%	98%	97%	97.5%
Total	95%	95%	96%	98.5%	97%	97.5%	98.75%

PRECISION AND SENSITIVITY

Standard drugs were spiked into urine samples to the concentration of ± 50% cut off and ± 25% cut off. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BAR200		BZO		BZO100		COC		THC	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	25	5	26	4	26	4	26	4	25	5	25	5	23	7
Cut-off	30	12	18	10	20	10	20	14	16	5	25	15	15	14	16
+25% Cut-off	30	5	25	8	22	0	30	5	25	2	28	6	24	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC25		MTD		MET		MDMA		MOP300		OPI2000		PCP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	23	7	25	5	25	5	23	7	24	6	25	5	26	4
Cut-off	30	3	27	12	18	13	17	10	20	10	20	14	16	15	15
+25% Cut-off	30	1	29	6	24	5	25	4	26	3	27	5	25	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	TCA		BUP		OXY		KET		PPX		EDDP		TRA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	24	6	26	4	26	4	27	3	26	4	23	7	26	4
Cut-off	30	14	16	1	29	3	27	2	28	1	29	12	18	14	16
+25% Cut-off	30	6	24	0	30	0	30	0	30	0	30	2	28	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	K2-JWH-018		K2-WH-073		COT		AMP (500)		COC (150)		MET (500)		FTY		ETG	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	25	5	27	3	28	2	28	2	26	4	24	6
Cut-off	30	6	24	3	27	12	18	4	26	5	25	3	27	14	16	10	20
+25% Cut-off	30	2	28	2	28	6	24	1	29	3	27	3	27	5	25	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

CROSS REACTIVITY

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. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

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)	**ng/mL**
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butathal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Barbiturates (BAR200)	**ng/mL**
Secobarbital	200
Amobarbital	200
Alphenol	100
Aprobarbital	150
Butabarbital	50
Butathal	75
Butalbital	1,700
Cyclopentobarbital	400
Pentobarbital	200
Phenobarbital	75
Benzodiazepines (BZO)	**ng/mL**
Oxazepam	300
Alprazolam	200
a-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
Benzodiazepines (BZO100)	**ng/mL**
Oxazepam	100
Alprazolam	75
a-Hydroxyalprazolam	500
Bromazepam	500
Chlordiazepoxide	500
Clonazepam HCl	300
Clobazam	35
Clonazepam	300
Clorazepate dipotassium	75
Delorazepam	500
Desalkylflurazepam	150
Diazepam	75
Estazolam	800
Flunitrazepam	150
D,L-Lorazepam	500
Midazolam	4200
Nitrazepam	35
Norchlordiazepoxide	75
Nordiazepam	150
Temazepam	35
Trazolam	800
Cocaine (COC)	**ng/mL**
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000
Marijuana(THC)	**ng/mL**
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	30
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500
Δ8- Tetrahydrocannabinol	7,500
Δ9- Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000
Marijuana (THC25)	**ng/mL**
11-nor-Δ9-THC-9-COOH	25
11-nor-Δ8-THC-9-COOH	15
11-hydroxy-Δ9-Tetrahydrocannabinol	1,250
Δ8- Tetrahydrocannabinol	3,750
Δ9- Tetrahydrocannabinol	5,000
Cannabinol	5,000
Cannabidiol	50,000
Methamphetamine (MET)	**ng/mL**
D(+)-Methamphetamine	1,000
D-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
(-)-Methamphetamine	25,000
(+/-) 3,4-methylenedioxumethamphetamine (MDMA)	2,000
b-Phenylethylamine	50,000
Trimethobenzamide	10,000
Methylenedioxymethamphetamine (MDMA)	**ng/mL**
3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl	3,000
3,4-Methylenedioxyethylamphetamine	300
Morphine (MOP)	**ng/mL**
Morphine	300
Codeine	300
Ethyl Morphine	300
Hydrocodone	5,000
Hydromorphone	5,000
Morphinie-3-b-d-glucuronide	1,000
Thebaine	30,000
Methadone (MTD)	**ng/mL**
Methadone	300
Doxylamine	50,000
Opiate (OPI)	**ng/mL**
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphine	5,000
Levorphanol	75,000
s-Monoacetylmorphine	5,000
Morphine 3-b-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphine	25,000
Procaine	150,000
Thebaine	100,000
Phencyclidine (PCP)	**ng/mL**
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
Tricyclic Antidepressants (TCA)	**ng/mL**
Notriptyline	1,000
Nordoxepine	1,000
Trimipramiine	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)	**ng/mL**
Ketamine	1,000
Methadone	50,000
Pethidine	12,500
Methylamphetamine	12,500
Methoxyphenamine	12,500
Promethazine	25,000
Phencyclidine	25,000
Buprenorphine (BUP)	**ng/mL**
Buprenorphine	10
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-Glucuronide	200
Oxycodone (OXY)	**ng/mL**
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)	**ng/mL**
d-Propoxyphene	300
d-Norpropoxyphene	300
Tramadol	**ng/mL**
Tramadol	1,000
(+/-) Chlorpheniramine	500,000
Dipehnhydramine	250,000
Pheniramine	>500,000
PCM	>250,000
EDDP	**ng/mL**
2-Ethylidene -1,5-Dimethyl-3,3-Diphenylpyrrolidine	100
Methadone	100,000
EMDP	100,000
Synthetic Cannabis (K2)	**ng/mL**
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)	**ng/mL**
Cotinine	100
Ethyl Glucuronide (EtG)	**ng/mL**
Ethyl Glucuronide	500
Amphetamine (AMP500)	**ng/mL**
d-Amphetamine	500
l-Amphetamine	25,000
dl-Amphetamine	1,500
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,500
Phentermine	1,500
Cocaine (150)	**ng/mL**
Benzoylecgonine	150
Cocaine HCl	375
Cocaethylene	6,250
Ecgonine	16,000
Methamphetamine (500)	**ng/mL**
D(+)-Methamphetamine	500
D-Amphetamine	25,000
Chloroquine	10,000
(+/-)-Ephedrine	25,000
L-Methamphetamine	10,000
(+/-) 3,4-methylenedioxumethamphetamine (MDMA)	1,000
β-Phenylethylamine	25,000
Trimethobenzamide	5,000
Fentanyl (FTY)	**ng/mL**
Norfentanyl	20
Fentanyl	200
Acetyl fentanyl	200
Acetyl norfentanyl	200

Effect of Urinary Specific Gravity

Urinary specific gravity ranges of 1.000~1.035 does not affect the test result.

Effect of Urinary pH

Urinary pH ranging from 4 to 9 does not interfere with the performance of the test.

INTERFERING SUBSTANCE

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for each drug. All potential interferents were added at a concentration of 100 μg/mL.
None of the urine samples tested showed any deviation from the expected results.

Acetaminophen	Epinephrine HCl	Mifepristone
Acyclovir	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	

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Wondfo 万孚

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