

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), Methylenedioxyamphetamine (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	Benzoylcegonine	300
Cocaine (COC150)	Benzoylcegonine	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

Test	Calibrator	Cut off (ng/mL)
Methylenedioxyamphetamine	3,4-Methylenedioxyamphetamine 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 4~30°C 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 the test procedures)
2. Leaflet with instructions for use

Material Required But Not Provided

1. Timer
2. 25 Urine collection cup

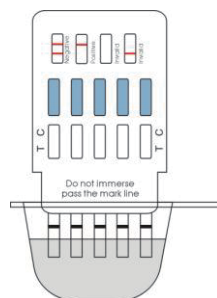
SPECIMEN COLLECTION AND PREPARATION

Collect urine specimen in the urine cup. Urine specimens may be refrigerated (2~8°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 (18°C to 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 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 (-)

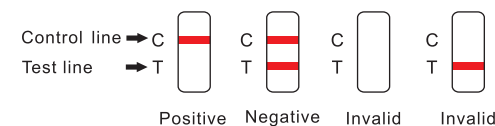
A rose-pink band is visible in each control region and the appropriate test region. It

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:

Specimen	% Agreement with commercial kit							
	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.

Specimen	% Agreement with GC/MS						
	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



物料编码及项目名称: 13009039 毒品尿液多联卡W20xx-P说明书(460x210mm)国际版V02

尺寸规格: 460*210mm

颜色:  K100M40  K20

设计师: 杨晓洁

稿件类型: 风琴五折+再对折

申请人: 林园园

设计时间: 2020.08.03
