

Wondfo

One Step Multi-Drug Urine Test Panel

EN

Suitable for the following catalog number:

W2002-P	W2007-P	W2012-P
W2003-P	W2008-P	W2013-P
W2004-P	W2009-P	W2014-P
W2009-P	W2010-P	W2011-P
W2014-P	W2015-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), Phenacyclidine (PCA), Tricyclic Antidepressants (TCA), Buprenorphine (BUP), Oxycodone (OXY), Ketamine (KET), Propoxyphene (PPX), EDDP, Tramadol (TRA), Synthetic Cannabins (K2), Cotinine (COT), Ethyl Glucuronide (EG), Amphetamine (AMP500), Cocaine (COC150), Methamphetamine (MET500) and Fentanyl (FTY).

This package insert applies to all combinations of multi-drug test 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.

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 concentration:

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	Benzoylcofine	300
Cocaine (COC150)	Benzoylcofine	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
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine HCl	500
Opiate	Morphine	2,000

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	Benzoylcofine	300
Cocaine (COC150)	Benzoylcofine	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
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine HCl	500
Opiate	Morphine	2,000

s-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
Phenacyclidine (PCP)	25
Phencyclidine	ng/mL
4-Hydroxyphenacyclidine	12,500
Tricyclic Antidepressants (TCA)	ng/mL
Nortriptyline	1,000
Nordoxepine	3,000
Trimipramine	3,000
Amiripryline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepine	2,000
Promethazine	25,000
Phenothiazine	25,000
Ketamine (KET)	ng/mL
Ketamine	1,000
Methadone	50,000
Pethidine	12,500
Methylphenidate	ng/mL
Methoxyphenamine	12,500
Promethazine	25,000
Phencyclidine	25,000
Buprenorphine (BUP)	ng/mL
Buprenorphine	10
Buprenorphine 3-β-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-β-Glucuronide	200
Oxycodone (OXY)	ng/mL
Oxycodone	100
Hydrocodone	20,000
Cocaine	100,000
Hydromorphone	100,000
Morphine	>100,000
Acetylcholine	>100,000
Buprenorphine	>100,000
Ethylmorphine	>100,000
PRP	ng/mL
4-Propoxyphene	300
4-Norgoxyphene	300
Tramadol	ng/mL
Tramadol	1,000
(-)-Chlorpheniramine	500,000
Diphenhydramine	250,000
Phenamine	>500,000
PCM	>250,000
EDDP	ng/mL

4. Взаимно е технически или процедурни грешки, както и други смущаващи вещества в урината проба, да причинят грешни резултати.

5. Отрицателен резултат не означава непременно убоа на наркотици. Отрицателни резултати могат да се получат, когато наркотиците присъстват, но не прага на теста.

6. Резултатът от теста не прави разлика между наркотици за злоупотреба и определени лекарства.

7. Положителен резултат може да се получи от определени храни или хранителни добавки.

ХАРАКТЕРИСТИКИ НА ИЗПЪЛНЕНИЕ

Точност

Проведено е сравнение между всеки от тестовите и търговски достъпни били тестове за наркотици. В теста са използвани 1920 проби. Положителни резултати са получени чрез LC/MS. Резултатите са добри, като следва:

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	97%	98%	+	95%	+	100%	96%
Отрицателни	99%	98%	+	100%	+	99%	98%
Общо	98%	98%	+	98%	+	99%	97%

% Съответствие с търговския комплект

Проба	THC(25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	+	90%	99%	97%	98%	99%	98%	99%	98%
Отрицателни	+	98%	99%	99%	98%	98%	99%	99%	99%
Общо	+	95%	99%	98%	98%	98%	99%	98%	98%

% Съответствие с търговския комплект

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/MS

Проба	K2	COT	ETG	AMP	AMP (500)	COC	COC (150)	MET	MET (500)	FTY
Положителни	95%	98%	96%	97%	98%	99%	97%	99%	97.6%	97.6%
Отрицателни	98%	98%	96%	98%	98%	98%	98%	98%	97.4%	97.4%
Общо	97%	98%	96%	97.5%	98%	98%	98%	98%	97.5%	97.5%

% Agreement with LC/MS

Проба	AMP	BAR	BAR (200)	BZO	BZO (100)	COC	THC
Положителни	94%	92%	97.5%	97%	95%	96%	95%
Отрицателни	99%	98%	95%	97%	95%	99%	96%
Общо	97%	95%	96.3%	97%	95%	98%	96%

% Agreement with LC/MS

Проба	THC (25)	MTD	MET	MET	MOP	MOP (300)	OPI	OPR	PCP
Положителни	95%	97.3%	97.4%	97.4%	94.9%	95%	95%	95%	95%
Отрицателни	99%	97.7%	97.6%	97.6%	100%	96%	99%	99%	99%
Общо	97%	97.5%	97.5%	97.5%	97.5%	96%	97%	97%	97%

% Agreement with LC/MS

Проба	TCA	BUP	OXY	KET	PPX	EDDP	TRA
Положителни	95%	90%	92.5%	92.5%	90%	95%	95%
Отрицателни	99%	97.5%	97.5%	95%	97.5%	96%	99%
Общо	97%	93.8%	95%	93.8%	93.8%	96%	97%

% Agreement with LC/

