

# 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.

 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 Renilaian 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 (MTD), (THC). Methadone 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 |
|---------------------------|---|---------|
| A                         | A   | (ng/mL) |
| Amphetamine               | Amphetamine   | 1,000   |
| Barbiturates              | Secobarbital  | 300     |
| Benzodiazepines           | Oxazepam  | 300     |
| Cocaine                   | Benzoylecgonine                                       | 300     |
| Marijuana                 | Marijuana   | 50      |
| Methadone                 | Methadone   | 300     |
| Methamphetamine           | Methamphetamine                                       | 1,000   |
| Methylenedioxymethamph    | 3,4-Methylenedioxymethamp                             | 500     |
| etamine                   | hetamine HCI(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<br>-diphenylpyrrolidine | 100     |
| Tramadol                  | Tramadol  | 1000    |
| Counth atia Cannahia (KO) | JWH-018 Pentanoic Acid                                | 50      |
| Synthetic Cannabis (K2).  | 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.

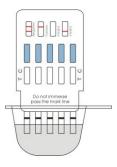
Bring frozen or refrigerated samples to room temperature before testing.

#### **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.
- Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
- 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.

- 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.

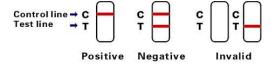
## Negative (-)

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 colored band is not visible in each of the control region or a colored 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 with line color intensity or width.



#### **QUALITY CONTROL**

Though there is an internal procedural control line in the control region of test device, 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 controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted.

#### LIMITATIONS OF PROCEDURE

- 1. This test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
- 3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses.
- 4. If a sample is suspected of being adulterated, obtain a new sample. This test is a qualitative screening assay. It is not designed to determine
- the quantitative concentration of drugs or the level of intoxication 5. It is possible that technical or procedural errors, as well as other
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 6. A negative result may not necessarily indicate drug-free urine.
- 7. Negative results can be obtained when drug is present but below the cut-off level of the test.
- 8. Test does not distinguish between drugs of abuse and certain medicines.
- A positive result might be caused by certain foods or food supplements.
   Do not mix reagent of different lots.

#### PERFORMANCE CHARACTERISTICS

#### Accuracy

(DrugCheck® NxStep Onsite Urinalysis Test Cup). A total number of 1680 specimens were used in the tests. Positive results were confirmed by GC/MS. The results were listed as following:

% Agreement with commercial kit

| Specimen | AMP      | BAR      | BZO      | COC   | THC   | MTD   | MET  |     |     |  |
|----------|----------|----------|----------|-------|-------|-------|------|-----|-----|--|
| Positive | >99%     | 97.5%    | 95%      | 100%  | 95%   | 90%   | >99% |     |     |  |
| Negative | >99%     | 99%      | 100%     | 99%   | 99%   | 99%   | >99% |     |     |  |
| Total    | >99%     | 98.6%    | 97.9%    | >99%  | 97.9% | 96.4% | >99% |     |     |  |
|          |          |          |          |       |       |       |      |     |     |  |
| Specimen | MDMA     | MOP      | OPI      | PCP   | TCA   | BUP   | OXY  |     |     |  |
| Specimen | IVIDIVIA | IVIDIVIA | IVIDIVIA | 300   | 2000  | FCF   | TCA  | БОР | OAT |  |
| Positive | 95%      | 97.5%    | 97.5%    | 97.5% | 95%   | 97%   | >99% |     |     |  |
| Negative | 99%      | 99%      | 99%      | 99%   | 99%   | 97%   | >99% |     |     |  |
| Total    | 97.9%    | 98.6%    | 98.6%    | 98.6% | 97.9% | 97%   | >99% |     |     |  |
|          |          |          |          |       |       |       |      |     |     |  |
| Specimen | KET      | PPX      | EDDP     | TRA   | K2    | COT   | ETG  |     |     |  |
| Positive | 96%      | 95%      | 97.5%    | 97%   | 96%   | 97%   | 97%  |     |     |  |
| Negative | 99%      | 100%     | 99%      | 97%   | 96%   | 97%   | 97%  |     |     |  |
|          |          |          |          |       |       |       |      |     |     |  |

#### % Agreement with GC/MS

97%

96%

97%

97%

98.6%

97.5% 97.9%

Total

| MP BA<br>1% 92°<br>9% 98°<br>7% 95° | % 979<br>% 979  | % 96%<br>% 99%  | 6 95%<br>6 96%  | 95%<br>99%   | 99%<br>99%  |
|-------------------------------------|---|---|---|--|---|
| 989                                 | % 979   | % 99%   | 6 96%   | 99%  |   |
|                                     |   |   |   |  | 99%   |
| 7% 959                              | % 979   | % 98%   | 060/  |  |   |
|                                     |   |   | 0 90%   | 97%  | 99%   |
|                                     |   |   |   |  |   |
| MA MC                               |   | : I PCI   | TCA   | BUP  | OXY   |
| 7% 98°                              | % 999   | % 91%   | 6 95%   | 90%  | 92.5%   |
| 989                                 | % 999   | % 99%   | 6 99%   | 97.5%  | 97.5%   |
| 3% 989                              | % 999   | % 95%   | 6 97%   | 93.8%  | 95%   |
|                                     |   |   |   |  |   |
| ET PP                               | X EDI   | P TRA   | A K2  | COT  | ETG   |
| 5% 909                              | % 959   | % 95%   | 92%   | 95%  | 96%   |
| 5% 97.5                             | 969   | % 99%   | 6 96%   | 95%  | 96%   |
| 8% 93.8                             | 969   | % 97%   | 6 94%   | 95%  | 96%   |
|                                     | 984<br>986<br>987<br>988<br>988<br>989<br>ET PP<br>556<br>909<br>97.5 | 300         200           7%         98%         99°           9%         98%         99°           3%         98%         99°           ET         PPX         EDE           5%         90%         95°           5%         97.5%         96° | MMA         300         2000         PCF           7%         98%         99%         91%           9%         98%         99%         99%           3%         98%         99%         95%           ET         PPX         EDDP         TRA           5%         90%         95%         95%           5%         97.5%         96%         99% | MMA         300         2000         PCP         TCA           7%         98%         99%         91%         95%           9%         98%         99%         99%         99%           3%         98%         99%         95%         97%           ET         PPX         EDDP         TRA         K2           5%         90%         95%         95%         92%           5%         97.5%         96%         99%         96% | MMA         300         2000         PCP         TCA         BUP           7%         98%         99%         91%         95%         90%           9%         98%         99%         99%         97.5%         97.5%           3%         98%         99%         95%         97%         93.8%           ET         PPX         EDDP         TRA         K2         COT           5%         90%         95%         95%         95%           97.5%         96%         99%         96%         95% |

## **Analytical Sensitivity**

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

| _  | A۱                   | ΛP                                    | BA   | ١R   | ΒZ   | ZO   | CC   | C  | TH  | Ю   | М   | ΓD  | MI   | EΤ  |
|----|----------------------|---------------------------------------|--|--|--|--|--|--|---|---|---|---|--|---|
| П  | -                    | +                                     | -  | +  | -  | +  | _  | +  | -   | +   | -   | +   | -  | +   |
| 30 | 30                   | 0                                     | 30   | 0  | 30   | 0  | 30   | 0  | 30  | 0   | 30  | 0   | 30   | 0   |
| 30 | 30                   | 0                                     | 30   | 0  | 30   | 0  | 30   | 0  | 30  | 0   | 30  | 0   | 30   | 0   |
| 30 | 25                   | 5                                     | 26   | 4  | 26   | 4  | 25   | 5  | 23  | 7   | 25  | 5   | 25   | 5   |
| 30 | 12                   | 18                                    | 10   | 20   | 14   | 16   | 15   | 15   | 14  | 16  | 12  | 18  | 13   | 17  |
| 30 | 5                    | 25                                    | 8  | 22   | 5  | 25   | 6  | 24   | 3   | 27  | 6   | 24  | 5  | 25  |
| 30 | 0                    | 30                                    | 0  | 30   | 0  | 30   | 0  | 30   | 0   | 30  | 0   | 30  | 0  | 30  |
|    | 30<br>30<br>30<br>30 | n<br>30 30<br>30 30<br>30 25<br>30 12 | 30 30 0<br>30 30 0<br>30 25 5<br>30 12 18<br>30 5 25 | n     -     +     -       30     30     0     30       30     30     0     30       30     25     5     26       30     12     18     10       30     5     25     8 | n     -     +     -     +       30     30     0     30     0       30     30     0     30     0       30     25     5     26     4       30     12     18     10     20       30     5     25     8     22 | n     -     +     -     +     -       30     30     0     30     0     30       30     30     0     30     0     30       30     25     5     26     4     26       30     12     18     10     20     14       30     5     25     8     22     5 | n     -     +     -     +     -     +       30     30     0     30     0     30     0       30     30     0     30     0     30     0       30     25     5     26     4     26     4       30     12     18     10     20     14     16       30     5     25     8     22     5     25 | n     -     +     -     +     -     +     -     +     -       30     30     0     30     0     30     0     30       30     30     0     30     0     30     0     30       30     25     5     26     4     26     4     25       30     12     18     10     20     14     16     15       30     5     25     8     22     5     25     6 | n         -         +         - | n         -         +         -         -         +         -         -         +         - | n         -         +         - | n         -         +         -         -         +         -         -         -         3         0         30         30         30         30         30         30 </td <td>n         -         +         -         -         -         3         0         30         0         30         0         30         0         30<td>n         -         +         -         -         -         3         0         30         0         30         0         30         0         30</td></td> | n         -         +         -         -         -         3         0         30         0         30         0         30         0         30 <td>n         -         +         -         -         -         3         0         30         0         30         0         30         0         30</td> | n         -         +         -         -         -         3         0         30         0         30         0         30         0         30 |

| Drug Conc.<br>(Cut-off range) |    | MD | MA | M0<br>30 |    | O<br>20 |    | PO | CP | TO | CA | Вι | JP | 0) | ΧY |
|-------------------------------|----|----|----|----------|----|---------|----|----|----|----|----|----|----|----|----|
| (Cut-on range)                |    | -  | +  | -        | +  | -       | +  | -  | +  | -  | +  | -  | +  | -  | +  |
| 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  | 24       | 6  | 25      | 5  | 26 | 4  | 24 | 6  | 26 | 4  | 26 | 4  |
| Cut-off                       | 30 | 10 | 20 | 10       | 20 | 14      | 16 | 15 | 15 | 14 | 16 | 1  | 29 | 3  | 27 |
| +25% Cut-off                  | 30 | 4  | 26 | 3        | 27 | 5       | 25 | 7  | 23 | 6  | 24 | 0  | 30 | 0  | 30 |
| +50% Cut-off                  | 30 | 0  | 30 | 0        | 30 | 0       | 30 | 0  | 30 | 0  | 30 | 0  | 30 | 0  | 30 |

| Drug Conc.      | _  | KE | ĒΤ | PF | PΧ | ED | DP | TF | RA | K  | 2  | CC | TC | E٦ | ΓG |
|-----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| (Cut-off range) | n  | -  | +  | _  | +  | _  | +  | _  | +  | _  | +  | -  | +  | _  | +  |
| 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 | 27 | 3  | 26 | 4  | 23 | 7  | 26 | 4  | 25 | 5  | 25 | 5  | 24 | 6  |
| Cut-off         | 30 | 2  | 28 | 1  | 29 | 12 | 18 | 14 | 16 | 6  | 24 | 12 | 18 | 10 | 20 |
| +25% Cut-off    | 30 | 0  | 30 | 0  | 30 | 2  | 28 | 5  | 25 | 2  | 28 | 6  | 24 | 5  | 25 |
| +50% Cut-off    | 30 | 0  | 30 | 0  | 30 | 0  | 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)                            | na/ml                 |
|--|-----------------------|
| d-Amphetamine (AMF)                          | <b>ng/mL</b><br>1,000 |
| d.I-Amphetamine                              | 3,000                 |
| I-Amphetamine                                | 50,000                |
| (+/-) 3,4-methylenedioxyamphetamine          | 5,000                 |
| Phentermine                                  | 3,000                 |
| D 1% (DAD)                                   |                       |
| 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  Decolly Iffusionem              | 1,500                 |
| Desalkylflurazepam Diazepam                  | 400<br>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)                                |                       |
| Benzoylecgonine                              | 300                   |
| Cocaine HCI                                  | 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-methylenedioxumethamphetamine(MDMA) | 2,000                 |
| b-Phenylethylamine                           | 50,000                |
| Trimethobenzamide                            | 10,000                |

| Methylenedioxymethamphetamine(MDMA)               |                 |
|---|-----------------|
| 3,4-Methylenedioxymethamphetamine HCI(MDMA)       |                 |
| 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           |
| Morphinie-3-b-d-glucuronide                       | 1,000           |
| Thebaine  | 30,000          |
| Methadone(MTD)                                    |                 |
| Methadone<br>Doxylamine                           | 300<br>50,000   |
| Болучанние  | 30,000          |
| Opiate (OPI)                                      | 0.000           |
| Morphine  | 2,000           |
| Codeine   | 2,000           |
| Ethylmorphine<br>Hydrocodone                      | 5,000           |
| Hydrocodone<br>Hydromorphine                      | 12,500          |
| ⊣yaromorpnine<br>Levorphanol                      | 5,000<br>75,000 |
| s-Monoacetylmorphine                              | 5,000           |
| S-Worldacetymorphine Morphine 3-β-D-glucuronide   | 2,000           |
| Norcodeine  | 12,500          |
| Normorphine                                       | 50,000          |
| Oxycodone   | 25,000          |
| Oxymorphine                                       | 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 Norbuprenorphine 3-D-Glucuronide | 20              |
|   | 200             |
| Oxycodone(OXY)                                    | 100             |
| Oxycodone Dihydrocodeine                          | 20,000          |
| Dirrydrocodeirie<br>Codeine                       | 100,000         |
|   | 100,000         |
| Hydromorphone                                     |                 |
| Hydromorphone<br>Morphine                         | >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               | 1,000    |
| (indole-D5)  |          |
| 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  $\mu g/mL$ .

## **Non Crossing-Reacting Compounds**

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

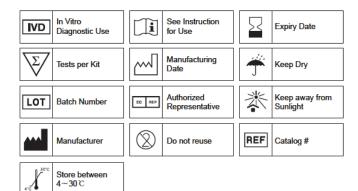
| Clarithromycin        | Levonorgestrel       | Tetracycline  |
|-----------------------|----------------------|---------------|
| Clopidogrel bisulfate | Levothyroxine sodium | Trazodone HCI |
| Clozapine             | Lidocaine HCI        | Triamterene   |
| Cortisone             | Lisinopril           | 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.

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#### Index of Symbols





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