

## One Step Buprenorphine Urine Test

Catalog No. See Pouch Label

*One Step Buprenorphine Urine Test is a rapid one step test for the qualitative detection of Buprenorphine and its principal metabolites in human urine at specified cut-off level.*

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

### INTENDED USE

One Step Buprenorphine Urine Test is a lateral flow chromatographic immunoassay for the detection of Buprenorphine in human urine at the cut-off concentration of 10 ng/mL. This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order 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 any drug of abuse test result, particularly when preliminary positive results are used.

### SUMMARY

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex, Buprenex, Temgesic and Suboxone, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/mL after therapeutic administration, but can range up to 20 ng/mL in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days. Wondfo One Step Buprenorphine Urine Test is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Buprenorphine in urine. The One Step Buprenorphine Urine Test yields a positive result when the Buprenorphine in urine exceed 10 ng/mL

### PRINCIPLE

One Step Buprenorphine Urine Test is a competitive immunoassay that is used to screen for the presence of Buprenorphine in urine. It is chromatographic absorbent device in which Buprenorphine and its metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding

sites.

When add four drops of the urine specimen to the sample well, 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 cut off (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.

### PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes

### CONTENT OF THE KIT

1. 25 tests per kit, one test in one pouch.
2. One pouch containing a test, a dropper and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use.

### STORAGE AND STABILITY

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

### SPECIMEN COLLECTION AND PREPARATION

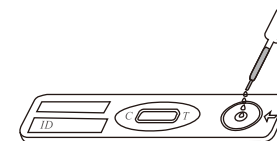
Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2°C~8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).

Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

### TEST PROCEDURE

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

1. Remove a testing device from the foil pouch by tearing at the notch and place it on a level surface.
2. Holding a sample dropper vertically, add exactly four drops of the urine specimen to the sample well.
3. Read results in 5 minutes. **Do not read after 5 minutes.**



### INTERPRETATION OF RESULTS

#### Positive (+)

A rose-pink band is visible in the control region. No color band appears in the test region. This positive result indicates that the Buprenorphine concentration is equal to or higher than the detection limit(10 ng/ml).

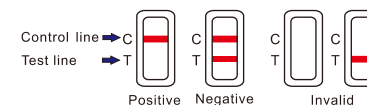
#### Negative (-)

A rose-pink band is visible in the control region and the test region. This negative result indicates that the Buprenorphine concentration is zero or below the detection limit(10 ng/ml).

#### Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, 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.



### QUALITY CONTROL

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. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. 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

### A. Sensitivity

One Step Buprenorphine Urine Test has set the screen cut-off for positive specimens at 10 ng/mL for Buprenorphine as a calibrator. The test device has been proved to detect above 10 ng/mL of Buprenorphine in urine at 5 minutes.

### B. Specificity and cross reactivity

To test the specificity of the test, the test device was used to test Buprenorphine, its metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
Buprenorphine	10
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-Glucuronide	200

### C. Interfering substances

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, for example Acetoacetic Aci, Acetone, Albumin etc., 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 Buprenorphine Urine Test at a concentration of 100 µg/ml.

4-Acetamidophenol	Maprotiline
Acetophenetidin	Meperidine
N-Acetylprocainamide	Meprobamate
Acetylsalicylic acid	Methadone
Aminopyrine	Morphine-3-β-Dglucuronide
Amityriptyline	Nalidixic acid
Amobarbital	Naloxone
Amoxicillin	Naltrexone
BUPicillin	Naproxen
Ascorbic acid	Niacinamide
Apomorphine	Nifedipine
Aspartame	Norcodein
Atropine	Norethindrone
Benzilic acid	D-Norpropoxyphene
Benzoic acid	Noscapine
Benzoyllecgonine	D, L-Octopamine
Benzphetamine	Oxalic acid
Bilirubin	Oxazepam
Brompheniramine	Oxolinic acid
Caffeine	Oxycodone
Cannabidiol	Oxymetazoline
Cannabinal	Papaverine
Chloralhydrate	Penicillin-G
ChlorBUPhenicol	Pentazocaine

Chlordiazepoxide  
Chlorothiazide  
(±) Chlorpheniramine  
Chlorpromazine  
Chlorquine  
Cholesterol  
Clomipramine  
Clonidine  
Cocaine hydrochloride  
Codeine  
Cortisone  
(-) Cotinine  
Creatinine  
Deoxycorticosterone  
Dextromethorphan  
Diazepam  
Diclofenac  
Diflunisal  
Digoxin  
Diphenhydramine  
Doxylamine  
Ecgonine hydrochloride  
Ecgonine methylester  
(IR,2S)-(-)-Ephedrine  
L-Ephedrine  
(-) Y Ephedrine  
Erythromycin  
β-Estradiol  
Estrone-3-sulfate  
Ethyl-p-aminobenzoate  
Fenfluramine  
Fenoprofen  
Furosemide  
Gentisic acid  
Hemoglobin  
Hydralazine  
Hydrochlorothiazide  
Hydrocodone  
Hydrocortisone  
O-Hydroxyhippuric acid  
3-Hydroxytyramine  
Ibuprofen  
Imipramine  
(-) Isoproterenol  
Isosuprine  
Ketamine  
Ketoprofen  
Labetalol  
Levorphanol  
Loperamide

Pentobarbital  
Perphenazine  
Phencyclidine  
Phenelzine  
Phendimetrazine  
Phenobarbital  
Phetoin  
L-Phenylephrine  
β-Phenylethylamine  
Phenylpropanolamine  
Prednisolone  
Prednisone  
Procaine  
Promazine  
Promethazine  
D, L-Propanolol  
Propiomazine  
D-Propoxyphene  
Quinidine  
Quinine  
Ranitidine  
Salicylic acid  
Secobarbital  
Serotonin  
Sulfamethazine  
Sulindac  
Temazepam  
Tetracycline  
Tetrahydrocortisone  
Tetrahydrozoline  
Δ 9-THC-COOH  
Thebaine  
Thiamine  
Thioridazine  
D, L-Thyroxine  
Tolbutamine  
Triamterene  
Trifluoperazine  
Trimethoprim  
Trimipramine  
Tryptamine  
D, L-Tyrosine  
Uric acid  
Verapamil  
Zomepirac

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## MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between 4°C and 30°C



Keep dry



Do not re-use

## BIBLIOGRAPHY OF SUGGESTED READING

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical