One Step Buprenorphine Urine Test

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 specimen is applied to the sample pad, 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 ºC ~ 30 ºC in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.

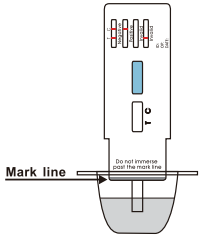
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2ºC~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

1. Test must be in room temperature (10ºC to 30ºC)
2.

a. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
b. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
c. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the “MAX” line printed on the front of the device.
d. Lay the device flat on a clean, dry, non-absorbent surface.
e. Read the result at 5 minutes. **Do not read after 5 minutes.**



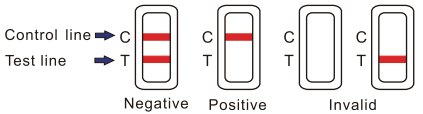
INTERPRETATION OF RESULTS

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 analites. 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 at10 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
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
BUPicillin
Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Maprotiline
Meperidine
Meprobamate
Methadone
Morphine-3-β-Dglucuronide
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Bilirubin
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
ChlorBUPhenicol
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
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocaine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phendimetrazine
Phenobarbital
Phetoin
L-Phenylephrine
β-Phenylethlamine
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
∆ 9-THC-COOH
Thebaine
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tyrosine
Uric acid
Verapamil
Zomepirac
Levorphanol
Loperamide

BIBLIOGRAPHY OF SUGGESTED READING

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3. Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
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   McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

MEANING OF SYMBOLS ON PACKAGE


Keep away from sunlight

Store between 4°C and 30°C


Keep dry


Do not re-use