BUP
One Step Buprenorphine Test Device (Urine) Package Insert

Cat: BUP-102
Version: Z
Specimens: Urine
Effective Date: 2020-9

For professional *in vitro* diagnostic use only.

INTENDED USE

The BUP One Step Buprenorphine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Buprenorphine in human urine at a 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) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

INTRODUCTION

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. [1] 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.

The BUP One Step Buprenorphine Test Device (Urine) 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 BUP One Step Buprenorphine Test Device (Urine) yields a positive result when the Buprenorphine in urine exceed 10 ng/mL.

PRINCIPLE

The BUP One Step Buprenorphine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Buprenorphine, if present in the urine specimen below 10 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Buprenorphine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Buprenorphine level exceeds 10 ng/mL because it will saturate all the binding sites of anti-Buprenorphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains drug-bovine protein antigen conjugate on the membrane and the conjugate pad of each test contains monoclonal anti-drug antibody.

KIT COMPONENTS

Individually packed Test Devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Disposable pipettes	For adding specimens use.
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

Bring tests, specimens and/or controls to room temperature (15-30°C) before use.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

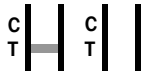
POSITIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The BUP One Step Buprenorphine Test Device (Urine) provides only a

qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory methods. [2,3]

2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

123 clinical urine specimens were analyzed by GC-MS and by the BUP One Step Buprenorphine Test Device (Urine).Each test was performed by three operators. Samples were divided by concentration into five categories: negative, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Method		GC/MS					
The BUP One Step Buprenorphine Test Device		Neg.	Neg. (< –50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (> +50 % cutoff)	% agreement with GC/MS
BUP 10	Positive	0	0	2	14	35	98.0%
	Negative	52	8	11	1	0	97.3%

B. Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The BUP One Step Buprenorphine Test Device (Urine) was tested in duplicate using fifteen drug free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

C. Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH adjusted urine was tested with the BUP One Step Buprenorphine Test Device (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

D. Cross-Reactivity

The following tables list the concentrations of compounds (ng/mL) above which the BUP One Step Buprenorphine Test Device (Urine) identified positive results at 5 minutes.

Buprenorphine related Compound	**Concentration (ng/mL)**
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine 3-D-Glucuronide	200

The following compounds yielded negative results up to a concentration of 100 µg/mL:

4-Acetamidophenol	Gatifloxacin	Penfluridol
Acetaminophen	Gemfibrozil	Penicillin G potassium salt
Acetylsalicylic Acid	Gentisic Acid	Penicillin G sodium salt
Albumin	Gliclazide	Perphenazine
Amoxicillin	Glipizide	Phenacetin
Ampicillin	Glyburide	Phenelzine Sulfate
Ampicillin trihydrate	Guaiacol	Phenothiazine
Aspartame	Guaifenesin	2-Phenylethylamine
Atropine	Hemoglobin	Pioglitazone
Baclofen	Hydralazine HCl	Piracetam
Benzoic Acid	Hydrochlorothiazide	Pravastatin sodium
Berberine Chloride Hydrate	Hydrocortisone	Prednisone
Bilirubin	Ibuprofen	Procaine
Caffeine	Isoprenaline	Promethazine hydrochlorine
Cephalexin	Ketoconazole	6-Propyl-2-thiouracil
Cephradine	Ketoprofen	Pyridoxine
Chloral hydrate	Lamotrigine	Pyrilamine Maleate
Chloramphenicol	L-Ascorbic acid	Pyrogallic
Chlorpheniramine Maleate	Levofloxacin	Quetiapine Fumarate
Chlorpromazine	Lidocaine	Quinine
Cholesterol	Lidocaine Monohydrate	Quinolinic acid
Ciprofloxacin hydrate	Lisinopril Dihydrate	R,R(-)-Pseudoephedrine
Clarithromycin	Lithium carbonate	Ranitidine base
Clonidine solution	Loperamide	Ranitidine
Creatinine	Loratadine	Riboflavin
D(-)-Norgestrel	L-Thyroxine sodium	Rifampicin
d,l-Propranolol	Maprotiline	Risperidone
Deoxycorticosterone	Meprobamate	Salicylic acid
Dextromethorphan solution	Minocycline	Sertraline HCl
Diciofenac	Mosapride Citrate	Simvastatin
Diflunisal	Nalidixic acid	Sodium 2-Propylvalerate
Digoxin	Naloxone HCl	Sulfamethazine
4-Dimethyl-aminoantipyrine	Naltrexone HCl	Sulindac
Diphenhydramine	Naproxen	Tetracycline
5,5-Diphenylhydantoin	Nicotinamide	Tetrahydrozoline
D-Lactose monohydrate	Nicotinic acid	Theophylline
D-Leucyl-L-tyrosine Hydrate	Nifedipine	Thiamine
Dopamine	Nimodipine	Thioridazine solution
Droperidol	Norethisterone Acetate	Tolbutamide
Enalapril Maleate	Norfloxacin Nicotinic	Topiramate
Erythromycin	Noscapine	2,4,7-Triamino-6-Phenylpteridine
Estradiol	(±)-Octopamine	Trimethoprim
Estrone	Ofloxacin	Tryptamine
Ethyl 4-aminobenzoate	Olanzapine	Tyramine
Fluoxetine	Oxalic acid, anhydrous	Uric acid
Fotemustine	Oxolinic acid	(±)-Verapamil
Furosemide	Paliperidone	Vitamin B1
Gabapentin	Pantoprazole sodium	Zomepirac

LITERATURE REFERENCES

1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002.
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit		Do not use if package is damaged
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	Caution		Date of manufacture	EC REP	Authorized Representative

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CE