Atlas Medical CE

Buprenorphine Test Strip (Urine)

A rapid, one step test for the qualitative detection of Buprenorphine in human urine.

IVD *For in vitro diagnostic use only.*

Store at 2-30 °C

INTENDED USE

The Buprenorphine Strip test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10ng/mL.This test is calibrated to Buprenorphine (calibrator).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

INTRODUCTION

The BUP One Step Buprenorphine Test Strip (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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test strips .
- Package insert.

Materials Required But Not Provided

- Positive and negative urine controls
- Timer

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

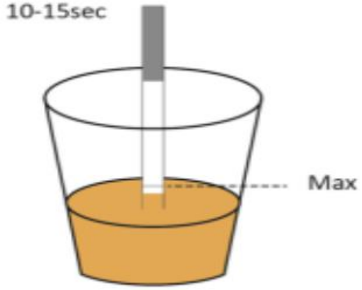
Urine Assay

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 precipitates should be centrifuged, filtered, or allowed settle to obtain a clear specimen for testing.

PROCEDURE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. **Immerse the test strip vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

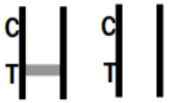


INTERPRETATION OF RESULTS

(Please refer to the illustration)

NEGATIVE: Two distinct colored lines appear. One band appears in the control region (C) and another band appears in the test region (T).

POSITIVE: One colored line appears in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control line (C) fails to appear. Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. 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: The intensity of color in the test region (T) may vary however any shade of color in the test region should be considered negative. Note that this is a qualitative test only and cannot determine the concentration of drugs in the specimen.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The BUP One Step Buprenorphine Test Strip (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.
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 of 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 cut-off level of the test.

6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

Accuracy of Buprenorphine Strip testwas established by analyzing 80 clinical urine specimens in parallel with GC-MS. The sensitivity of Buprenorphine Strip tests was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, and +50% cutoff. The results are summarized below:

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator C	Positive	0	0	2	15	25
	Negative	10	20	8	0	0

% agreement among positives is 98.3%

% agreement among negatives is 95.8%

B. Cutoff Characterization and Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for buprenorphine. The cut-off values 10ng/mL for the devices are verified.

C. Specificity and Cross-reactivity

The following table lists compounds that are positively detected in urine by Buprenorphine Strip:

Drug	Concentration(ng/ml)	%CrossReactivity
Buprenorphine	10	100%
Buprenorphine-3-D-Glucuronide	10	100%
Norbuprenorphine	50	20%
Norbuprenorphine-3-D-Glucuronide	100	10%
Morphine	Negative at 100,000	<0.01%
Oxymorphone	Negative at 100,000	<0.01%
Hydromorphone	Negative at 100,000	<0.01%

D. Precision

This study is performed 2 runs/day and lasts 25 days for each format with three lots.Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Buprenorphine concentration (ng/mL)	N	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
2.5	50	50	0	50	0	50	0
5	50	50	0	50	0	50	0
7.5	50	50	0	50	0	50	0
10	50	4	46	1	49	3	47
12.5	50	0	50	0	50	0	50
15.0	50	0	50	0	50	0	50
17.5	50	0	50	0	50	0	50
20	50	0	50	0	50	0	50

E. Effect of Urine Density and pH

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.009 to 1.030 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The Buprenorphine Strip was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravitydo not affect the test results.

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with the Buprenorphine Strip. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

F. Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or buprenorphine, positive urine. The following compounds show no cross-reactivity when tested with the Buprenorphine Stripat a concentration of 100 µg/mL.

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phentermine
Amitriptyline	Hemoglobin	Phenylephrine-L
Amoxicillin	Hydralazine	Phenylethylamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Phenylpropanolamine
D-Amphetamine	Hydrochlorothiazide	Prednisolone Acetate
L-Amphetamine	Hydrocodone	Prednisone
Amphetamine Sulfate	Hydrocortisone	Procaine(Novocaine)
Ampicinine (Ampicillin)	a-Hydroxyhippuric acid	Promazine
Apomorphine	p-Hydroxymethamphetamine	Promethazine
L-Ascorbic Acid	Ibuprofen	Propoxyphene,d-
Aspartame	Imipramine	Propranolol
Atropine	Isoxsuprine	Pseudoephedrine HCL
Benzilic acid	Isoproterenol-(+/-)	Quinidine
Benzphetamine	Ketamine	Quinine
Bezoic Acid	Labetalol	Ranitidine(Zantac)
Bilirubin	Levorphanol	Salicylic Acid
Caffeine	Loperamide	Secobarbital
Chloramphenicol	Maprotiline	Serotonin
Chlordiazepoxide HCL	Meprobamate	Sulfamethazine
Chloroquine	Methadone	Sulindac
Chlorothiazide	Methoxyphenamine	Temazepam
Chlorpheniramine	(+/-)-Methylenedioxy Amphetamine	11-Nor-Δ 9Tetrahydrocannabin
Chlorpromazine	Methylphenidate	Tetracycline
Cholesterol	Nalbuphine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone	hydrochloride L-Thyroxine
Cortisone	Naltrexone - hydrochloride	Thioridazine-Hydrochloride
Cotinine(-)	Naproxen	Triamterene
Creatinine	Niacinamide	Triflupromazine-Hydrochloride
Deoxyepinephrine	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	Norpropoxyphene	Tryptamine
Diflunisal	Noscapine	DL-Tryptophan
Digoxin	Oxazepam	Tyramine
Doxylamine	Oxymetazoline	D/L-Tyrosine
Ecgoninemethylester	Papaverine	Uric Acid
R(-)-Epinephrine	Penicillin	Verapamil
Erythromycin	Pentobarbital	Zomepirac
Estrone-3-sulfate	Perphenazine	

G.Lay User Study

A lay user study was performed at three intended user sites with 147 lay persons. For the device study,participants were 62 females and 85 males tested the buprenorphine sample. They had diverse educational and professional backgrounds and ranged in age from 18 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the

package insert, 1 blind labeled samples and a device. The results are summarized below.

%of Cutoff	Number of samples	Buprenorphine Concentration by GC/MS (ng/mL)	Lay person results		The Percentage of correct results(%)
			No. of Positive	No. of Negative	
-100%	21	**0**	**0**	**21**	**100**
-75% Cutoff	21	**2.2**	**0**	**21**	**100**
-50% Cutoff	21	**5.5**	**0**	**21**	**100**
-25% Cutoff	21	**7.6**	**1**	**20**	**95**
+25% Cutoff	21	**12.6**	**21**	**0**	**100**
+50% Cutoff	21	**16.2**	**21**	**0**	**100**
+75% Cutoff	21	**17.8**	**21**	**0**	**100**

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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry