SCREEN®

SCREEN 1 BUPRENORFINA (Urine) Package Insert

REF: SC-0029-25	English

A rapid test for the qualitative detection of Buprenorphine in human urine.For medical and other professional in vitro diagnostic use only.

INTENDED USE

The BUP Rapid Test Panel (Urine) is a rapid 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.

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.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 Rapid Test Panel (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 Rapid Test Panel (Urine) yields a positive result when Buprenorphine in urine exceeds 10 ng/mL.

PRINCIPLE

The BUP Rapid Test Panel (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.

REAGENTS

The test contains mouse monoclonal anti-Buprenorphine antibody-coupled particles and Buprenorphine-protein conjugate. A goat antibody is employed in the control line system.

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 at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister 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.
Specimen Collection
Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

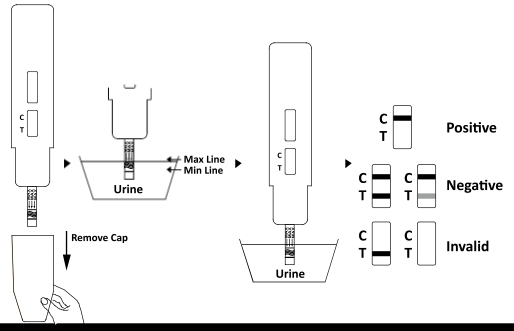
MATERIALS

Materials Provided
- Test Panels
- Package insert

Materials Required But Not Provided
- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. **The result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
NEGATIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Buprenorphine concentration is below the detectable level (10 ng/mL).
***NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.
POSITIVE: One colored line appears in the control region (C). No line appears in the test line region (T). This positive result indicates that the Buprenorphine concentration exceeds the detectable level (10 ng/mL).
INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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.

LIMITATIONS

1. The BUP Rapid Test Panel (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. [2,3]
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 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.

EXPECTED VALUES

This negative result indicates that the Buprenorphine concentration is below the detectable level of 10ng/ml. Positive result means the concentration of Buprenorphine is above the level of 10ng/ml. The BUP Rapid Test Panel has a sensitivity of 10ng/ml.

PERFORMANCES CHARACTERISTICS

Accuracy
A side-by-side comparison was conducted using BUP Rapid Test Panel and a commercially available BUP rapid test. Testing was performed on 94 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other BUP Rapid Test		Total Results
BUP Rapid Test Panel	Results	Positive	Negative	
	Positive	43	0	43
	Negative	0	51	51
Total Results		43	51	94
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The BUP Rapid Test Panel and GC/MS at the cut-off of 10ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
BUP Rapid Test Panel	Results	Positive	Negative	
	Positive	105	0	105
	Negative	1	144	145
Total Results		106	144	250
% Agreement		99.1%	>99.9%	99.6%

Analytical Sensitivity
A drug-free urine pool was spiked with Buprenorphine at the following concentrations: 0 ng/mL, 5 ng/mL, 7.5 ng/mL, 10 ng/mL, 12.5 ng/mL 15 ng/mL and 30 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Buprenorphine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
5	-50%	30	30	0
7.5	-25%	30	26	4
10	Cut-off	30	14	16
12.5	+25%	30	3	27

15	+50%	30	0	30
30	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by The BUP Rapid Test Panel (Urine) at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Buprenorphine	10	Buprenorphine 3-D-Glucuronide	50
Norbuprenorphine	50	Norbuprenorphine 3-D-Glucuronide	100

Precision

A study was conducted at 3 hospitals by laypersons using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Buprenorphine, 25% Buprenorphine above and below the cutoff and 50% Buprenorphine above and below the 10 ng/mL cutoff were provided to each site. The following results were tabulated:

Buprenorphine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	8	2
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities were spiked with Buprenorphine to the concentrations of 5 ng/mL, and 15 ng/mL. The BUP Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the 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 Buprenorphine to 5 ng/mL and 15 ng/mL. The spiked, pH-adjusted urine was tested with The BUP Rapid Test Panel (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

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 BUP Rapid Test Panel (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	5,5-Diphenylhydantoin	Lithium carbonate	Trans-2- phenyl
Acetone	Disopyramide	Loperamide	cyclopropylamine
Acetophenetidin	Doxylamine	Maprotiline	L-Phenylephrine
Acetylsalicylic acid	Ecgonine hydrochloride	Meperidine	B-Phenylethylamine
N-Acetylprocainamide	Ecgonine methylester	Mephentermine	Phenylpropanolamine
Albumin	EDDP	Meprobamate	(D,L-norephedrine）
Aminopyrine	Efavirenz (Sustiva)	Methadone	(±) Phenylpropanolamine
Amitriptyline	EMDP	D-Methamphetamine	Prednisolone
Amobarbital	Ephedrine	L-Methamphetamine	Prednisone
Amoxapine	(1r,2s)-(-)Ephedrine	Methaqualone	5 beta-
Amoxicillin	(-)-ψ-Ephedrine	Methoxyphenamine	pregnane3alpha17alpha-
L-Amphetamine	(±)-Epinephrine	(-) 3,4-Methylenedioxy-	21triol 21
Ampicillin	Erythromycin	amphetamine (MDA)	Procaine
Apomorphine	β-Estradiol	(+) 3,4 Methylendioxy-	Promazine
Aspartame	Estrone-3-sulfate	methamphetamine	Promethazine
Atropine	Ethanol (Ethyl alcohol)	Methylphenidate	D,L-Propanolol
Benzilic acid	Ethyl-p-aminobenzoate	Methyprylon	D-Propoxyphene
Benzoic acid	Etodolac	Methaqualone	D-Pseudoephedrine
Benzoylecgonine	Famprofazone	Metoprolol	Quinacrine
Benzphetamine	Fenfluramine	Morphine sulfate	Quinidine
Bilirubin	Fenoprofen	Morphine-	Quinine
(±)-Brompheniramine	Fentanyl	3-β-D-glucuronide	Ranitidine
Buspirone	Fluoxetine	Nalidixic acid	Riboflavin
Caffeine	Furosemide	Nalorphine	Salicylic acid
Cannabidiol	Gentisic acid	Naloxone	Secobarbital
Cannabinol	D (+) Glucose	Naltrexone	Serotonin
Chloralhydrate	Guaiacol Glyceryl Ether	Methyprylon	(5-hydroxytyramine)
Chloramphenicol	Guaiacol Glyceryl Ether	Metoprolol	Sodium chloride
Chlordiazepoxide	carbamate	Nimesulide	Sulfamethazine
Chloroquine	Hemoglobin	Norcodeine	Sulindac
Chlorothiazide	Hydralazine	Morphine sulfate	Temazepam
(+)-Chlorpheniramine	Hydrochlorothiazide	Alpha-	Tetracycline
(±)-Chlorpheniramine	Hydrocodone	Naphthaleneacetic Acid	Tetrahydrocortisone,
Chlorpromazine	Hydrocortisone	Norethindrone	3-acetate
Chlorprothixene	Hydromorphone	Normorphine	Tetrahydrozoline
Cholesterol	p-Hydroxyamphetamine	D-Norpropoxyphene	Thebaine
Cimetidine	O-Hydroxyhippuric acid	Noscapine	Theophylline
Clomipramine	p-Hydroxymethamphetamine	D,L-Octopamine	Thiamine
Clonidine	p-Hydroxynorephedrine	Orphenadrine	Thioridazine
Cocaine HCl	Hydroxyzine	Oxalic acid	(chlorpromazine)
Codeine	3-Hydroxytyramine	Oxazepam	L-Thyroxine
Cortisone	Ibuprofen	Oxolinic acid	Tolbutamine
(-) Cotinine	Imipramine	Oxycodone	Cis-Tramadol
Creatinine	Iproniazid	Oxymetazoline	Trazodone
Cyclobarbital	(-)-Isoproterenol	Oxymorphone	Triamterene
Cyclobenzaprine	Isoxsuprine	Papaverine	Trifluoperazine
Deoxycorticosterone	Kanamycin	Pemoline	Trimethobenzamide
(-) Deoxyephedrine	Ketamine	Penicillin-G	Trimethoprim
R (-) Deprenyl HCl	Ketoprofen	Pentazocine	Trimipramine
Dextromethorphan	Labetalol	Pentobarbital	Tryptamine
Diazepam	L-Ascorbic acid	Perphenazine	D, L-Tryptophan
Diclofenac	L-Ephedrine	Phencyclidine	Tyramine
Dicyclomine	L-Epinephrine	Phenelzine	D, L-Tyrosine
Diflunisal	Levorphanol	Pheniramine	Uric acid
Digoxin	Lidocaine	Phenobarbital	Verapamil
4-Dimethylaminoantipyrine	Lindane	Phenothiazine	Zomepirac
Diphenhydramine	(hexachlorocyclohexane)	Phentermine	

BIBLIOGRAPHY

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 Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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