Buprenorphine Test Dip card
Package Insert

Package insert for testing of following drug: Buprenorphine

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

For in vitro diagnostic use only.

INTENDED USE

The Clarity Buprenorphine Test is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of Buprenorphine in human urine at a Cut-Off concentration of 10 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when the prescription drug Buprenorphine is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level 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. GC/MS 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.

For in vitro diagnostic use only.

SUMMARY

The test is intended for use as the process to provide health care professionals and consumers with information concerning the presence or absence of the above stated drug in a urine sample.

During testing, a urine sample migrates upward on the test Dip card. A drug-positive urine sample will not generate a colored line in the test line region, while a drug-negative urine sample or a sample containing a drug concentration less than the cut-off will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of sample has been added.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The Test Dip card should remain in the sealed pouch until use.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated 35.6-86°F (2-30°C). The Test Dip Card is stable through the expiration date printed on the sealed pouch. The Test Dip Card must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SAMPLECOLLECTION AND PREPARATION

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used.

MATERIALS

Materials Provided

• Test Dip Card • 1 Package insert • Disposable Gloves

MATERIALS REQUIRED BUT NOT PROVIDED

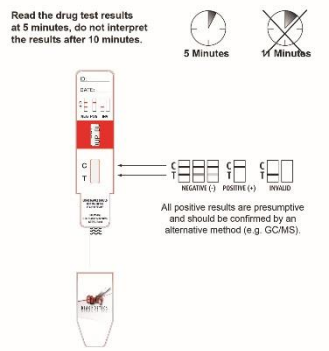
•Timer •Positive and Negative Controls •Urine Specimen Cups

DIRECTIONS FOR USE

If refrigerated, allow the test device to come to room temperature, 59-86°F (15-30°C) prior to testing.

1) Remove the Clarity Drug Urine Test Dip Card from the foil wrapper.
2) Fill a specimen cup (not provided) with fresh urine. Dip the Clarity Drug Urine Test Dip Card into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the Clarity Buprenorphine Urine Test Dip Card in the urine or you may take the Dip Card out after a minimum of 15 seconds in the urine and lay the Dip Card flat on a non-absorptive clean surface.
3) Read results at 5 minutes and do not throw away the urine. Urine used may be needed for confirmation testing.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.
POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.
INVALID: Control line fails to appear. Insufficient sample volume or not conducting the test as instructed are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact Clarity Diagnostics Technical Support at 1-877-485-7877

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present.

What Is A False Positive Test?

The definition of a false positive test would be an instance where the Clarity Buprenorphine Urine Test is positive even though the target drugs are not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by Clarity Buprenorphine Urine Test. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

1. The Clarity Buprenorphine Test Dip Card provides only a qualitative, preliminary analytical result. A secondary analytical method may be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause incorrect results.
3. Substances, such as bleach and/or alum, in urine samples may produce incorrect results regardless of the analytical method used.
4. A positive result 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 cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample 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. Please contact our Technical Support at 1-877-485-7877 for information on which controls work with the Clarity Drug Urine Test Dip Card.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine samples were analyzed by GC/MS and by the Clarity Buprenorphine Test Dip card. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Clarity Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93.3%

% agreement among negatives is 100%

Discordant Results of Buprenorphine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	BUP23	10.2	Negative
Viewer A	BUP67	10.6	Negative
Viewer A	BUP12	10.4	Negative
Viewer B	BUP23	10.2	Negative
Viewer B	BUP12	10.4	Negative
Viewer C	BUP23	10.2	Negative
Viewer C	BUP67	10.6	Negative
Viewer C	BUP12	10.4	Negative

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 value 10ng/mL for the device is verified

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the Clarity Buprenorphine Test Dip card Device.

Drug	Concentration (ng/ml)	% Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine -3-D-Glucuronide	20	50%
Morphine	Negative at 100000	Not detected
Oxymorphone	Negative at 100000	Not detected
Hydromorphone	Negative at 100000	Not detected

PRECISION

This study was performed 2 runs/day and lasted 25 days for each format with three lots. Three operators who didn't know the sample number system participated in the study. Each of the 3 operators tested 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	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
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	28	22	22	28	28	22
12.5	50	0	50	0	50	0	50
15	50	0	50	0	50	0	50
17.5	50	0	50	0	50	0	50
20	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The Clarity Buprenorphine Test Dip card was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

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 Clarity Buprenorphine Test Dip card. 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 Clarity Buprenorphine Test Dip card at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Deoxyepinephrine	Meprobamate	Promazine
N-Acetylprocainamide	Dextromethorphan	Methadone	Promethazine
Acetylsalicylic Acid (Aspirin)	Diazepam	Methoxyphenamine	Propoxyphene,d-
Aminopyrine	Diflunisal	(+/-)-Methylenedioxyamphetamine(MDA)	Propranolol
Amitriptyline	Digoxin	Methylphenidate	Pseudoephedrine HCL
Amoxicillin	Doxylamine	Nalbuphine	Quinidine
Amobarbital	Ecgonine methylester	Nalidixic acid	Quinine
D-Amphetamine	R(-)-Epinephrine	Naloxone hydrochloride	Ranitidine(Zantac)
L-Amphetamine	Erythromycin	Naltrexone hydrochloride	Salicylic Acid
Amphetamine Sulfate	Estrone-3-sulfate	Naproxen	Secobarbital
Ampicinine(Ampicillin)	Ethyl-p-aminobenzoate	Niacinamide	Serotonin
Apomorphine	Fenoprofen	Nifedipine	Sulfamethazine
L-Ascorbic Acid	Furosemide	Norethindrone	Sulindac
Aspartame	Gentisic acid	Norpropoxyphene	Temazepam
Atropine	Hemoglobin	Noscapine	11-Nor-Δ9-Tetrahydrocannabinol
Benzilic acid	Hydralazine	Oxazepam	Tetracycline
Benzphetamine	(+/-)-4-Hydroxyamphetamine HCL	Oxymetazoline	Tetrahydrozoline
Bezoic Acid	Hydrochlorothiazide	Papaverine	Thiamine
Bilirubin	Hydrocodone	Penicillin	L-Thyroxine
Caffeine	Hydrocortisone	Pentobarbital	ThioridazineHydrochloride
Chloramphenicol	a -Hydroxyhippuric acid	Perphenazine	Triamterene
Chlordiazepoxide HCL	p-Hydroxymethamphetamine	Phencyclidine	Trifluprom azine Hydrochloride
Chloroquine	Ibuprofen	Phenelzine	Trimethoprim
Chlorothiazide	Imipramine	Phenobarbital	Trimipramine
Chlorpheniramine	Isoxsuprine	Phentermine	Tryptamine
Chlorpromazine	Isoproterenol-(+/-)	Phenylephrine-L	DL-Tryptophan
Cholesterol	Ketamine	Phenylethylamine	Tyramine
Clomipramine	Labetalol	Phenylpropanolamine	D/L-Tyrosine
Clonidine hydrochloride	Levorphanol	Prednisolone Acetate	Uric Acid
Cortisone	Loperamide	Prednisone	Verapamil
Cotinine(-)	Maprotiline	Procaine(Novocaine)	Zomepirac
Creatinine			

Lay User Study

A lay user study was performed at three intended user sites with 140 lay persons. For a Dip card study, participants were 47 females and 93 males tested the Buprenorphine sample. They had diverse educational and professional backgrounds and ranged in age from 21 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 samples. 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 sample and a device. The typical results are summarized below.

% of Cutoff	Number of samples	BUP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	2.5	0	20	100%
-50% Cutoff	20	5	0	20	100%
-25% Cutoff	20	7.5	2	18	90%
+25% Cutoff	20	12.5	18	2	90%
+50% Cutoff	20	15	20	0	100%
+75% Cutoff	20	17.5	20	0	100%

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2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), ResearchMonograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to beUsed by the Consumer, 1997.

ADDITIONAL INFORMATION AND RESOURCES

National Clearinghouse for Alcohol and Drug Information, Phone: 1-800-729-6686

Center for Substance Abuse Treatment, Phone: 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org, 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org, 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 2°C and 30°C


Keep dry


Do not re-use


Manufacturer

Clarity Diagnostics LLC
1060 Holland Drive, Suite A
Boca Raton , Florida -33487
Tech Support: 1-877-485-7877

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