BAR Rapid Test Cassette (Urine)
Package Insert

REF DBA-102
English

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

INTENDED USE

The BAR Rapid Test Cassette (Urine) is a lateral flow chromatographic immunoassay for the detection of Barbiturates in urine at a cut-off concentration of 300 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.
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

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of Barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine. The detection period for the Barbiturates in the urine is 4-7 days.[1]
The BAR Rapid Test Cassette (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 Barbiturates in urine. The BAR Rapid Test Cassette (Urine) yields a positive result when the Barbiturates in urine exceeds the cut-off level.

PRINCIPLE

The BAR Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs that 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. Barbiturates, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Barbiturate-protein 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 Barbiturate level exceeds the cut-off level because it will saturate all the binding sites of anti-Barbiturate 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 less 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 mouse monoclonal anti-Barbiturates antibody coupled particles and Barbiturates-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 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 particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. 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 cassettes
- Droppers
- Package insert

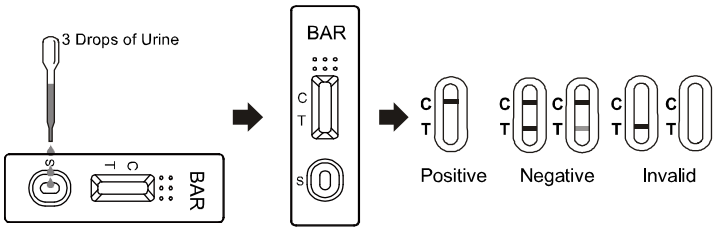
Materials Required But Not Provided

- 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 cassette from the sealed pouch and use it within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
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

(Please refer to the illustration above)

NEGATIVE:* Two 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 Barbiturate concentration is below the detectable cut-off level.
***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Barbiturate concentration exceeds the detectable cut-off level.

INVALID: Control line 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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

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 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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The BAR Rapid Test Cassette (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) is the preferred confirmatory method.[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 Barbiturates concentration is below the detectable level of 300ng/ml. Positive result means the concentration of Barbiturates is above the level of 300ng/ml. The BAR Rapid Test Cassette has a sensitivity of 300ng/ml.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The BAR Rapid Test Cassette and a commercially available BAR rapid test. Testing was performed on 95 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other BAR Rapid Test		Total Results
BAR Rapid Test Cassette	Results	Positive	Negative	
	Positive	37	0	37
	Negative	0	58	58
Total Results		37	58	95
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The BAR Rapid Test Cassette and GC/MS at the cut-off of 300ng/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
BAR Rapid Test Cassette	Results	Positive	Negative	
	Positive	98	2	100
	Negative	4	146	150
Total Results		102	148	250
% Agreement		96.1%	98.6%	97.6%

Analytical Sensitivity

A drug-free urine pool was spiked with Secobarbital at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL, 450 ng/mL and 900 ng/mL The result demonstrates 97% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Secobarbital Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	27	3
300	Cut-off	30	15	15
375	+25%	30	3	27
450	+50%	30	0	30
900	3X	30	0	30

Analytical Specificity

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

Compound	Concentration(ng/mL)	Compound	Concentration (ng/mL)
Amobarbital	5,000	Cyclopentobarbital	30,000
5,5-Diphenylhydantoin	8,000	Pentobarbital	8,000
Allobarbital	600	Alphenol	600
Barbital	8,000	Aprobarbital	500
Talbutal	200	Butabarbital	200
Butalbital	8,000	Butethal	500
Phenobarbital	300	Secobarbital	300

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no Secobarbital, 25% Secobarbital above and below the cut-off, and 50% Secobarbital above and below the 300 ng/mL cut-off was provided to each site. The following results were tabulated:

Secobarbital Concentration (ng/mL)	n per	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	2	8	1	9	2	8
450	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Secobarbital respectively. The BAR Rapid Test Cassette (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 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 Secobarbital to 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with The BAR Rapid Test Cassette (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 Barbiturates positive urine. The following compounds show no cross-reactivity when tested with The BAR Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophenol	Diazepam	MDE	Phenylpropanolamine
Acetophenetidin	Diclofenac	Meperidine	Prednisolone
N-Acetylprocainamide	Diflunisal	Meprobamate	Prednisone
Acetylsalicylic acid	Digoxin	Methadone	Procaine
Aminopyrine	Diphenhydramine	L-Methamphetamine	Promazine
Amitryptyline	Doxylamine	Methoxyphenamine	Promethazine
Amoxicillin	Ecgonine hydrochloride	(±) - 3,4-Methylenedioxy-	D,L-Propranolol
Ampicillin	Ecgoninemethylester	amphetamine	D-Propoxyphene
L-Ascorbic acid	(-) -ψ-Ephedrine	(±) - 3,4-Methylenedioxy	D-Pseudoephedrine
D,L-Amphetamine sulfate	[1R,2S] (-) Ephedrine	methmphetamine	Quinacrine
Apomorphine	L - Epinephrine	Morphine-3-β-D glucuronide	Quinidine
Aspartame	Erythromycin	Morphine Sulfate	Quinine

Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
(±) - Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(±) - Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaethylene
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxyamphetamine
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Perphenazine
Phencyclidine
Phenelzine
Phentermine
Trans-2-phenylcyclo-propylamine hydrochloride
L-Phenylephrine
β-Phenylethylamine
Ranitidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-Acetate
Tetrahydrocortisone 3-(β-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D,L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D,L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY

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3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse.* National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

	Attention, see instructions for use
	For in vitro diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Authorized Representative
	Catalog #
	Tests per kit
	Use by
	Lot Number
	Manufacturer
	Do not reuse
	Consult Instructions for Use


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