



## BAR Rapid Test Dipstick (Urine) Package Insert

<b>REF DBA-101/111</b>	<b>English</b>
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A rapid test for the qualitative detection of Barbiturates in human urine.  
For medical and other professional in vitro diagnostic use only.

### INTENDED USE

The BAR Rapid Test Dipstick (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.

The BAR Rapid Test Dipstick (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 Dipstick (Urine) yields a positive result when the Barbiturates in urine exceeds the cut-off level.

### PRINCIPLE

The BAR Rapid Test Dipstick (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 Barbiturate-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. **NOTE:** Once the canister has been opened, the remaining test(s) are stable for 50 days only.

### 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.

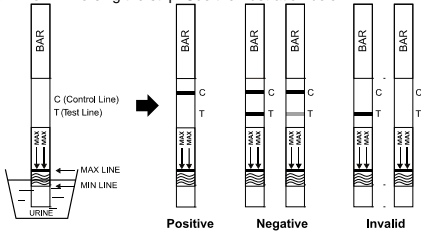
### MATERIALS

- Test Dipsticks
- Materials Provided
  - Package insert
- Materials Required But Not Provided
  - Timer

### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the Rapid Test Dipstick from the sealed pouch and use it within one hour.
- With arrows pointing toward the urine specimen, immerse the rapid test dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Rapid Test Dipstick when immersing the strip. See the illustration below.



- Place the rapid test dipstick 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 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

- The BAR Rapid Test Dipstick (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.<sup>2,3</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- 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 Dipstick has a sensitivity of 300ng/mL

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using The BAR Rapid Test Dipstick 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
	Results	Positive	
BAR Rapid Test Dipstick	Positive	37	37
	Negative	0	58
	Total Results	37	58
% Agreement	>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The BAR Rapid Test Dipstick 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
	Results	Positive	
BAR Rapid Test Dipstick	Positive	98	100
	Negative	4	150
	Total Results	102	250
% Agreement	96.1%	98.6%	97.6%

#### Analytical Specificity

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 900ng/mL. The result demonstrates >99% 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 Dipstick (Urine) at 5 minutes.

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

#### Precision

A study was conducted at three hospitals by laypersons 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	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	0	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 Dipstick (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 Dipstick (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 Dipstick (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
Amoxityline	Doxylamine	Methoxyphenamine	Promethazine
Amoxicillin	Egonine hydrochloride	(±) - 3,4-Methylenedioxyamphetamine	D,L-Propranolol
Antipyrine	Egonine methylester	(±) - 3,4-Methylenedioxy methamphetamine	D-Proprorphedrine
Ampicillin	L-Ascorbic acid	[1R,2S] (-) Ephedrine	D-Pseudoephedrine
D,L-Amphetamine sulfate	L - Epinephrine	Morphine-3-β-D glucuronide	Quinacrine
Apomorphine	Erythromycin	Morphine Sulfate	Quinidine
Aspartame	β-Estradiol	Nalidixic acid	Quinine
Atropine	Estrone-3-sulfate	Naloxone	Ranitidine
Benzic acid	Ethyl-p-aminobenzoate	Naltrexone	Salicylic acid
Benzoic acid	Fenoprofen	Naproxen	Serotonin
Benzofenone	Furosemide	Niacinamide	Sulfamethazine
Benzphetamine	Genistic acid	Nifedipine	Sulindac
Bilirubin	Hemoglobin	Norcodeine	Temazepam
(±) - Brompheniramine	Hydralazine	Norethindrone	Triacetyline
Caffeine	Cannabidiol	Hydrochlorothiazide	Tetrahydrocortisone,
Cannabidiol	Cannabinal	Hydrocodone	3-Acetate
Chloralhydrate	Chloramphenicol	Hydrocortisone	Tetrahydrocortisone
Chlorazepamide	Chlorothiazide	O-Hydroxyhippuric acid	3-(β-D-glucuronide)
(±) - Chlorpheniramine	Chlorpromazine	p-Hydroxyamphetamine	Tetrahydrozoline
Cholestero	Cholesterol	3-Hydroxytyramine	Thiamine
Clomipramine	Clonidine	Imipramine	Oxalic acid
Cocaeethylene	Cocaine hydrochloride	Codeine	Oxycodone
Cocaine hydrochloride	Cortisone	Ketoprofen	Oxymetazoline
Codeine	(-) Cotinine	Labelitol	Papaverine
Creatinine	Creatinine	Levorphanol	Penicillin-G
Dextromethorphan	Deoxytocosterone	Loperamide	Pentazocine hydrochloride
	Dextrorphan	Maprotiline	Phenazine
			Phenelzine
			Phentermine
			Phenylethylamine
			Propylamine
			Tripropamine
			Triamterene
			Trimethoprim
			Trimethoprim
			Tripropamine
			Trypanolone
			D,L-Tryptophan
			Tyramine
			Uric acid
			Verapamil
			Zomepirac

### BIBLIOGRAPHY

- Tietz NW. *Textbook of Clinical Chemistry*. W.B. Saunders Company. 1986; 1735
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*, 2nd Ed. Biomedical Publ., Davis. CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

### Index of Symbols

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

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Number: 145012704  
Effective date: 2015-07-20



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