ROJAN® BAR

One Step
Barbiturates Test Strip (Urine)
Package Insert

REF:R-1112	English

A rapid, one step test for the qualitative detection of Barbiturates (BAR) in urine.

For professional in vitro diagnostic use only.

INTENDED USE

The BAR One Step Barbiturates Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of Barbiturates in urine at a cut-off concentration of 300 ng/mL of Secobarbital. 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 produces 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 One Step Barbiturates Test Strip (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 One Step Barbiturates Test Strip (Urine) yields a positive result when the Barbiturates in urine exceeds the cut-off level.

PRINCIPLE

The BAR One Step Barbiturates Test Strip (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 Barbiturates-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 Barbiturates level exceeds the cut-off level, because it will saturate all the binding sites of anti-Barbiturates 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 long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

- Test strips
- Package insert

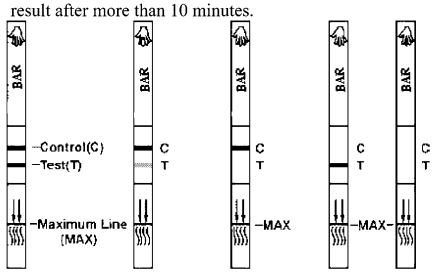
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 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 red line(s) to appear. The result should be read at 5 minutes. Do not interpret the test result after more than 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut-off level.

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen. It only indicates the level of tested drug in the specimen is less than 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 strip. 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 One Step Barbiturates 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) 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the BAR One Step Barbiturates Test Strip (Urine) and a commercially available BAR rapid test. Testing was performed on 292 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Secobarbital. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other BAR Rapid Test		Total Result
BAR One step test strip	Result	Positive	Negative	
	Positive	126	1	127
	Negative	0	165	165
Total result		126	166	292
%Agreement		≥%99	%99	%99

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method		GC/MS		Total Result
BAR One step test strip	Result	Positive	Negative	
	Positive	122	4	126
	Negative	10	156	166
Total result		132	160	292
%Agreement		%92	%98	%95

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 and 450 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Secobarbital Conc. (ng/ml)	Percent of cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	20	10
300	Cut-off	30	13	17
375	25%	30	8	22
450	50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the BAR One Step Barbiturates Test Strip (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100

Precision

A study was conducted at three physicians' offices 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 Conc. (ng/ml)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	2	13	8	7	6	9
375	15	2	13	1	14	2	13
450	15	0	15	0	15	0	15

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Secobarbital positive urine. The following compounds show no cross-reactivity when tested with the BAR One Step Barbiturates Test Strip (Urine) at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	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-amphetamine	D,L-Propranolol
Ampicillin	Ecgonine methylester	(±) - 3,4-Methylenedioxy	D-Propoxyphene
L-Ascorbic acid	(-) -ψ-Ephedrine	D,L-Amphetamine sulfate	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	®–Εστραδιολ	Nalidixic acid	Ranitidine
Benzilic acid	Estrone-3-sulfate	Naloxone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naltrexone	Serotonin
Benzoylecgonine	Fenoprofen	Naproxen	Sulfamethazine
Benzphetamine	Furosemide	Niacinamide	Sulindac
Bilirubin	Gentisic acid	Nifedipine	Temazepam
(±) - Brompheniramine	Hemoglobin	Norcodein	Tetracycline
Caffeine	Hydralazine	Norethindrone	Tetrahydrocortisone, 3-Acetate
Cannabidiol	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone
Cannabinol	Hydrocodone	Noscapine	3-(β-D-glucuronide)
Chloralhydrate	Hydrocortisone	D,L-Octopamine	Tetrahydrozoline
Chloramphenicol	O-Hydroxyhippuric acid	Oxalic acid	Thiamine
Chlorothiazide	p-Hydroxyamphetamine	Oxazepam	Thioridazine
(±) - Chlorpheniramine	p-Hydroxy-methamphetamine	Oxolinic acid	D,L-Tyrosine
Chlorpromazine	3-Hydroxytyramine	Oxycodone	Tolbutamide
Chlorquine	Ibuprofen	Oxymetazoline	Triamterene
Cholesterol	Imipramine	Papaverine	Trifluoperazine
Clomipramine	Iproniazid	Penicillin-G	Trimethoprim
Clonidine	(±) - Isoproterenol	Pentazocine hydrochloride	Trimipramine
Cocaethylene	Isoxsuprine	Perphenazine	Tryptamine
Cocaine hydrochloride	Ketamine	Phencyclidine	D,L-Tryptophan
Codeine	Ketoprofen	Phenelzine	Tyramine
Cortisone	Labetalol	Phentermine	Uric acid
(-) Cotinine	Levorphanol	Trans-2-phenylcyclo-propylamine hydrochloride	Verapamil
Creatinine	Loperamide	L-Phenylephrine	Zomepirac
Deoxycorticosterone	Maprotiline	®–Πενναλεπηγλαμινε	
Dextromethorphan			

BIBLIOGRAPHY

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. 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		Manufacturer	
IVD For *in vitro* diagnostic use only		Use by		Do not reuse	
2-30°C Store between 2-30℃		LOT Lot Number			

ISO, CE, GMP

Rojan Azma
Rojan Azma mfg. Co.
No. 41, Golestan 4, Baharestan Industrial Estate, 5th km Karaj-Qazvin Highway, Tehran-Iran
Tel: +98-261-47 60 610
www.rojanazma.com