BAR Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

A rapid test for the qualitative detection of Barbiturates in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The BAR Rapid Test Cassette(whole blood/serum/plasma) is a lateral flow chromatographic immunoassay for the detection of Barbiturates in whole blood or serum or plasma at a cut-off concentration of 100ng/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 CNS 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 400mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death[1].

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the whole blood or serum or plasma.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days2

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of barbiturates in whole blood or serum or plasma exceeds 100ng/ml.

【PRINCIPLE】

The BAR Rapid Test Cassette (whole blood/serum/plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Barbiturates, if present in the whole blood/serum/plasma 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 whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch 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】

- The BAR Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 µl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood/serum/plasma collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood/serum/plasma specimens. Whole blood/serum/plasma collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test cassettes • Droppers • Buffer • Package insert

Materials Required But Not Provided

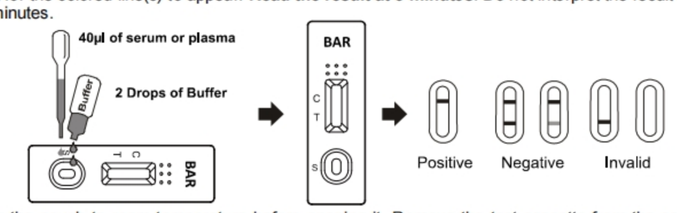
• Specimen collection containers • Centrifuge
•lancets (for fingerstick whole blood only) • Timer
•Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

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

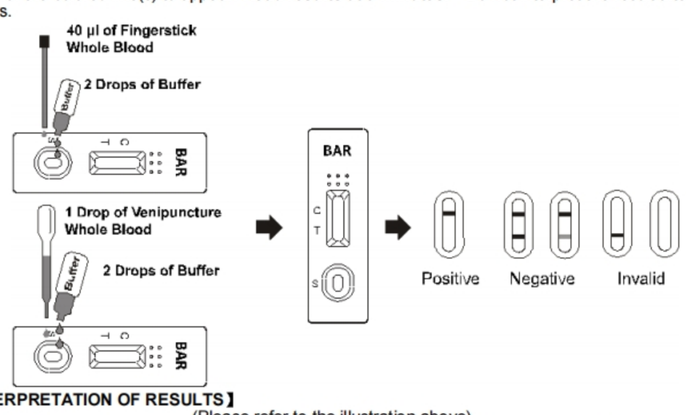
For serum or plasma specimen:

1. Bring the pouch to room temperature (15-30℃) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40ul), then add **2 drops of buffer** (approximately 80 µl) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result at 5 minutes**. Do not interpret the result after 10 minutes.



1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **1 drop of whole blood (**approximately 40µl) to the specimen well, then **add 2 drops of buffer** (approximately 80 µl), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 40µl of fingerstick whole blood specimen** to the specimen area of test cassette, then add **2 drops of buffer**(approximately 80 µl) and start the timer. See 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 Barbiturates 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 Barbiturates 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 region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The BAR Rapid Test Cassette (whole blood/serum/plasma) 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]
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood/serum/plasma specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood/serum/plasma.
4. A negative result may not necessarily indicate drug-free whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. 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 100ng/ml. Positive result means the concentration of Barbiturates is above the level of 100ng/ml. The BAR Rapid Test Cassette has a sensitivity of 100ng/ml

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using The BAR Rapid Test Cassette and GC/MS at the cut-off of 100ng/ml. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
	Results	Positive	Negative	
BAR Rapid Test Cassette	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
	Results	Positive	Negative	
BAR Rapid Test Cassette	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Barbiturates at the following concentrations of ±50%cutoff and 3x cutoff, The data are summarized below:

For whole blood:

BAR Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
100	Cut-off	30	16	14
150	+50%	30	0	30
300	3X	30	0	30

For serum or plasma:

BAR Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
100	Cut-off	30	16	14
150	+50%	30	0	30
300	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by The BAR Rapid Test Cassette (whole blood/serum/plasma) at 5 minutes.

Compound	Concentration (ng/ml)
Amobarbital	1,500
5,5-Diphenylhydantoin	2,500
Allobarbital	200
Barbital	2,500
Talbutal	80
Cyclopentobarbital	10,000
Pentobarbital	2,500
Alphenol	200
Aprobarbital	150
Butabarbital	80
Butalbital	2,500
Butethal	150
Secobarbital	100

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 Barbiturates, and 50% Barbiturates above and below the 100ng/ml cut-off was provided to each site. The following results were tabulated:

BAR Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	8	2	9	1	9	1
150	10	1	9	1	9	2	8

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or Barbiturates positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with The BAR Rapid Test Cassette (whole blood/serum/plasma) 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	β-Estradiol	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,
Cannabidiol	Hydrochlorothiazide	D-Norpropoxyphene	3-Acetate
Cannabinol	Hydrocodone	Noscapine	Tetrahydrocortisone
Chloralhydrate	Hydrocortisone	D,l-Octopamine	3-(β-D-glucuronide)
Chloramphenicol	O-Hydroxyhippuric acid	Oxalic acid	Tetrahydrozoline
Chlorothiazide	p-Hydroxyamphetamine	Oxazepam	Thiamine
(±) - Chlorpheniramine	p-Hydroxy-	Oxolinic acid	Thioridazine
Chlorpromazine	methamphetamine	Oxycodone	D,l-Tyrosine
Chlorquine	3-Hydroxytyramine	Oxymetazoline	Tolbutamide
Cholesterol	Ibuprofen	Papaverine	Triamterene
Clomipramine	Imipramine	Penicillin-G	Trifluoperazine
Clonidine	Iproniazid	Pentazocine hydrochloride	Trimethoprim
Cocaethylene	(±) - Isoproterenol	Perphenazine	Trimipramine
Cocaine hydrochloride	Isoxsuprine	Phencyclidine	Tryptamine
Codeine	Ketamine	Phenelzine	D,l-Tryptophan
Cortisone	Ketoprofen	Phentermine	Tyramine
(-) Cotinine	labetalol	Trans-2-phenylcyclo-	Uric acid
Creatinine	levorphanol	propylamine hydrochloride	Verapamil

Interfering Substances

The BAR Rapid Test Cassette (whole blood/serum/plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dl hemoglobin;up to 100 mg/dl bilirubin; and up to 200 mg/dl human serum albumin.

【BIBIIOGRAPHY】

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

CE

Number:
Revision date: 2026-01-14