Atlas Medical CE

One Step
Barbiturates Test Device (Urine)

A rapid, one step test for the qualitative detection of Barbiturates in human urine.

IVD *For in vitro* diagnostic *use only.*

2 30°C Store at (2-30º C)

INTENDED USE

The BAR One Step Barbiturates Test Device (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 Barbiturates, please refer to 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 (GCIMS) 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.

INTRODUCTION

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

PRINCIPLE

The BAR One Step Barbiturates Test Device (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.

MATERIALS

Materials Provided

- Test devices(Contain mouse monoclonal anti-Barbiturates antibody coupled particles and Barbiturates-protein conjugate. A goat antibody is employed in the control line system).
- Disposable droppers
- Package Insert

Materials Required But Not Provided

- Specimen collection container
- Timer

PRECAUTIONS

- *For in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette 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.

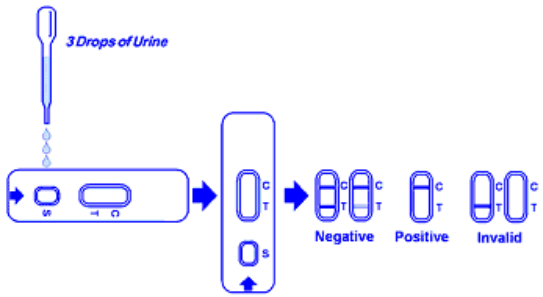
Specimen Storage

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

Allow the test device, 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 device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of** urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should **be read at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to illustration above)

NEGATIVE:` Two lines **appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Barbiturates concentration is the detectable cut-off level..
NOTE:
The shade of red in the test region (T) may 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 (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 device. 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 red line appearing in the control 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 Device (Urine)
2. provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrolStry (GC/MS) is the preferred confirmatory method.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. 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.
5. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
6. 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.
7. 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 Device (Urine) and a commercially available BAR rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		**Other BAR Rapid** Test		**Total** Results
BAR One Step Test Device	Results	Positive	Negative	
	Positive	126	1	127
	Negative	0	165	165
Total Results		126	166	292
% Agreement with this Rapid Test Kit		>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**
BAR One Step Test Device	Results	Positive	Negative	**Results**
	Positive	122	4	126
	Negative	10	156	166
Total Results		132	160	292
% Ag**reement with GC/MS Analysis**		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 Concentration (ng/mL)	**Percent of Cut-off**	n	**Visual Result**	
			Negative	Positive
0	0	30	30	0
150	-50°0	30	30	0
225	-25%	30	20	10
300	Cut-off	30	13	17
375	+25%	30	8	22
450	+50%	30	0	30
600	100%	30	0	30

Analytical Specificity

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

Compound	**Concentration (n /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 3 physicians' offices by untrained operators using 3 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

Effect of Urinary Specific Gravity

Fifteen (15) urine samples with specific gravity ranging from 1.001 to 1.032 were spiked with 150 ng/mL and 450 ng/mL of Secobarbital respectively. The BAR One Step Barbiturates Test Device (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 One Step Barbiturates Test Device (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 Secobarbital positive urine. The following compounds show no cross-reactivity when tested with the BAR One Step Barbiturates Test Device (Urine) at a concentration of 100 ng/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidin
N-
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amoxicillin
Ampidllin
L-Ascorbic acid
DL-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic **add**
Benzoic **add -**
Benzoylecgonine
Benzphetamine
Bilirubin
(±) -
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(±) -
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaethylene
Cocaine
Codeine
Cortisone
Estrone-3-sulfate
Ethyl-p-
Fenoprofen
Furosemide
Gnti sic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric
p-
p-Hydroxy-
methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - **Isoproterenol**
Isoxsupnne
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
MDE
Meperidine
Meprobamate
Methadone
(L)
Methoxyphenamine
(±)-3.4-
amphetamine hydrochloride
(±)-3,4-Metrylenedioxymetlr acetate
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Perphenazine
Phencyclidine
Phenelzine
Phentermine
Trans-2-pherrykydo-
propylamine
L-Phenylephrine
P-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
DL-Propranolol
D-Propoxyphene
D-Pseudoephednne
Quinacnne
Quinidine
Quinine
Ranitidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline

(-) Cotinine	amphetarrune hydrochloride	
Creatinine	Morphine3-0-0 glucuronide ((S-D-glucuronide)	
Deoxycorticosterone	Morphine Sulfate	**Tetrahydrozoline**
Dextromethorphan	Nalidwc acid	Thiamine
Diazepam	Naloxone	Thiondazine
Diciofenac	Naltrexone	DL-Tyrosine
Diflunisal	Naproxen	Tolbutamide
Digoxin	Niacinamide	Triamterene
Diphenhydramine	Nifedipine	Trifluoperazine
Doxylamine	Norcodein	Trimethoprim
Ecgonine	Norethindrone	Trimipramine
Ecgonine	**D-Norpropoxyphene**	Tryptamine
(-) -W-Ephedrine	Noscapine	DL-Tryptophan
[1R,2SI (-) Ephedrine	DL-Octopamine	Tyramine
(L) - Epinephrine	Oxalic acid	Uric add
Erythromycin	Oxazepam	Verapamil
p-Estradiol		Zomepirac

REFERENCES

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3. Hawks RL.CN Chiang. Urine testing for drugs of abuse. National institute for drugs of abuse (NIDA) Research Monograph 73, 1986

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry