BAR Barbiturates cassette CE

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REF	4415240	Barbiturates	40 tests
For professional *in vitro* diagnostic use only			

Barbiturates

A rapid test for the qualitative detection of Barbiturates in human urine.
ONE STEP

PRINCIPLE

La prueba de un solo paso LINEAR BAR Barbiturates cassette (orina) es un inmunoensayo cromatográfico rápido basado en el principio de uniones competitivas. La droga puede estar presente en la muestra de orina, compite frente al conjugado de la misma en los puntos de unión al anticuerpo. Durante la prueba, la muestra de orina migra hacia arriba por acción capilar. Si los Barbitúricos están presentes en la orina en concentraciones inferiores a 300 ng/ml, no saturarán los puntos de unión de los anticuerpos en la tira de la prueba. Las partículas recubiertas de anticuerpos serán capturadas por el conjugado inmovilizado de proteína-Barbitúrico y una línea visible de color aparecerá en la zona de la prueba. Esta línea de color no se formará en la zona de la prueba si el nivel de Barbitúrico está por encima de la del cut-off porque saturará todos los puntos de unión de los anticuerpos de anti-Barbitúricos. Una muestra de orina positiva no generará una línea coloreada en la zona prueba debido a la competencia de la droga, mientras que una muestra de orina negativa o una muestra con una concentración inferior a la del cut-off generará una línea en la zona de la prueba. Para servir como procedimiento de control, una línea coloreada aparecerá siempre en la zona de control si la prueba ha sido realizada correctamente y con un volumen adecuado de muestra.

REAGENT COMPOSITION

BAR Barbiturates test devices, contains mouse monoclonal anti-Barbiturates antibody-coupled particles and Barbiturates-protein conjugate. A goat antibody is employed in the control line system.

PACKAGING CONTENTS

REF 4415240 40 BAR Barbiturates test devices.
Disposable specimen droppers.

STORAGE AND STABILITY

Store at 2-30ºC.
The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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 clear specimen for testing.
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.

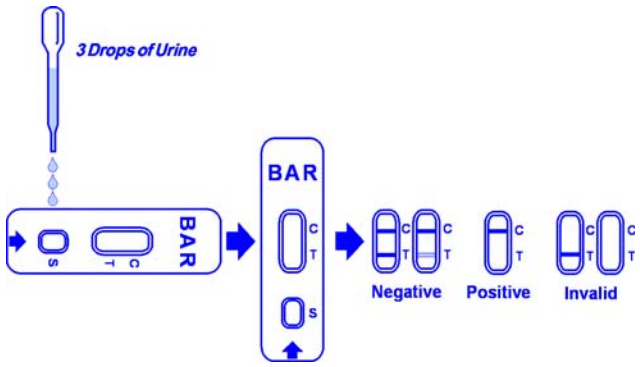
MATERIAL REQUIRED

- Timer.
- Specimen collection container .

PROCEDURE

Allow the test cassette, urine or serum 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 cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette 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 cassette, 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 15 minutes.



NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line should be in the test region (T). This negative result indicates that the Barbiturate concentration is below the detectable cut-off level.
*** NOTE:** The shade of red 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 using a new test strip. If the problem persists, discontinue using the lot 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.

CLINICAL SIGNIFICANCE

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 LINEAR BAR Barbiturates cassette 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 LINEAR BAR Barbiturates cassette yields a positive result when the Barbiturates in urine exceed the cut-off level 300 ng/mL.
Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

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ANALYTICAL PERFORMANCE

A. Accuracy

The accuracy of the LINEAR BAR Barbiturates cassette was compared and checked against a commercially available test with a threshold value of 300 ng/mL. 120 urine samples taken from volunteer test persons who claim to be non-consumers was examined under both tests. The results were 100% in agreement.

B. Reproducibility

The reproducibility of the LINEAR BAR Barbiturates cassette was verified by blind tests performed at a four different locations. All 60 utilized samples with a BAR-concentration of 150 ng/mL yielded a negative result. All 60 samples with a BAR-concentration of 600 ng/ml yielded a positive result. No significant differences were observed between test results of the different evaluation sites.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with a BAR-concentration of 150 ng/mL yield a negative result. Controls with a BAR-concentration of 600 ng/mL provide a positive result.

D. Specificity

The specificity of the LINEAR BAR Barbiturates cassette was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances were added to normal drug free urine.

The following compounds with a similar chemical structure yielded a positive result at the specified concentration:

COMPOUND	CONCENTRATION (ng/mL)
Secobarbital	300
Phenobarbital	300
Butalbital	3,000
Allobarbital	5,000
Alphenal	625
Amobarbital	600
Aprobarbital	600
Hexobarbital	>100,000
Butabarbital	75
Pentobarbital	300

All following listed compounds reacted negative up to a concentration of 100 µg/mL.

Acetamidophene
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
(+/-)-Chlorpheniramine
Chlorpheniramine
Creatine
Dexbrompheniramine
Dextromethorphan
4-Dimethylaminoantipyrine
Dopamine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Imipramine
(+/-)-Isoproterenol
Lidocaine
(+)-Naproxen
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
Phenylethylamine
Procaine
Quinidine
Ranitidine
Riboflavine
Sodium Chloride
Sulindac
Thioridazine
Trifluoperazine
Trimethobenzamide
Tyramine
Vitamin C

NOTES

1. The LINEAR BAR Barbiturates cassette 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.[1,2]
2. Adulterans, 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.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
4. 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.
5. Test does not distinguish between drugs of abuse and certain medications.

REFERENCES

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