First Romanian rapid tests manufacturer !

rev1

e-mail : sales@campmedica.ro
http:// www.campmedica.ro

"See Now" Barbiturate Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.2

INTRODUCTION

The *"See Now"* Barbiturate (BAR) Test is a rapid and convenient immunochromatographic in vitro assay. It is intended for the qualitative detection of the presence of BAR and its metabolites in urine at or above the cutoff level of 300 ng/ml. The device is designed for professional use. This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed.

SUMMARY OF THE TEST

Barbiturates are a class of central nervous system depressants. Phenobarbital is a long acting barbiturate derivative that has been used as a daytime sedative and very extensively as an anticonvulsant. Pentobarbital and Secobarbital are two examples of short acting barbiturate sedatives. Abuse of barbiturates can lead to respiratory collapse, coma and even death. Barbiturates are taken orally, rectally, or by intravenous and intramuscular injection. Short acting barbiturates will generally be excreted in urine as metabolites, while the long-acting barbiturates will primarily appear unchanged.

The *"See Now"* BAR Test device contains mouse monoclonal anti-amphetamine antibody colloidal gold conjugate pre-dried on a pad. Barbiturate-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane. The principle of the *"See Now"* BAR Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in urine, for limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the test window where the test reaction occurs. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone. A positive specimen produces only one color band in the control zone.

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. This control line should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

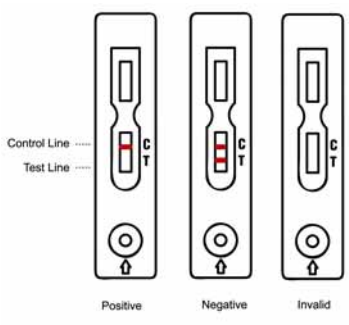
SPECIMEN COLLECTIONAND STORAGE

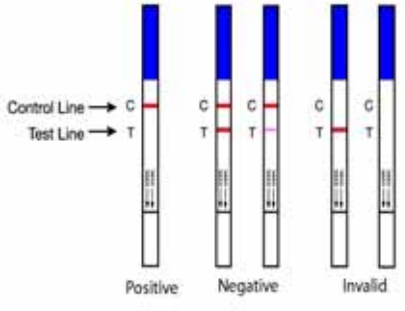
- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at –20ºC for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is maked with an arrow on the testing device
- For strip test, immerse the strip into the urine cup and take out the strip after 10 sec. Lay the strip on a flat, clean, dry, non-absorbent surface
- Read the results at 10 minutes. Ensure that the background of the test area is white before interpreting the result

INTERPRETATION OF RESULTS





Positive
Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

Negative
Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

Invalid
No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

Note: A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.

STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- *FOR IN VITRO DIAGNOSTIC USE ONLY.*
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

- Sensitivity

The *"See Now"* barbituate Urinary Test detects amphetamine and its metabolites in urine at concentrations equal to or greater than 300 ng/ml.

- Specificity

A study was conducted with the *"See Now"* Barbituate Urinary Rapid Test to determine the cross-reactivity of barbiturate-related compounds with the test device (Table I).

Table-I Concentration of barbituate-related compounds showing a positive response approximately equivalent to the barbituate cut off set for the test.

Structurally related compounds	ng/ml
Allobarbital	1.000
Alphenal	300
Amobarbital	1.000
Aprobarbital	300
Barbital	300
Butabarbital	300
Butalbital	2.000
Butethal	300
Pentobarbital	300
Phenobarbital	300

A separate study was conducted to determine the cross-reactivity of non-Barbituate related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table II.

Table- II Compounds tested and found not to cross-react with the test at a 1000 μg/ml concentration in urine

Acetaminophen Acetone, Albumin, Amitriptyline, D-Amphetamine, L-Amphetamine, Ampicillin, Aspartame, Aspirin, Atropine, Benzocaine, Benzoylecgonine, Bilirubin, Brom-pheniramine, Caffeine, Chloroquine, Chlorpheniramine, Chlorpromazine, Cocaine, Codeine, Creatine, Deoxy-ephedrine, Dextromethorphan, 4-Di-methyl- aminoantipyrine, Dopamine, Doxylamine, Ecgonine, Ecgonine Methyl Esther,	Ephedrine, Epinephrine, Erytromycin, Ethanol, Furosemide, Glucose, Guajacol Glyceryl Ether, Hemoglobin, Hydrocodone, Hydro-morphone, Imipramine, Isoproterenol, Lidocaine, Meperidine, Methadone, Methamphetamine, Metha-qualone, Methyl-Ephedrine, (+/-)3,4-Methylene- dioxymethamphet- amine, Methylphenidate, Morphine, Naloxone,	Naltrexone, Naproxen, Norephedrine, Nortrityline, Oxalic Acid, Oxazepam, Oxycodone, Penicillin-G, Pentermine, Phencyclidine, Pheniramine, Phenothiazine, L-Phenylephrine β-Phenyl-ethylamine, Procaine, D-Propoxyphene Quinidine, Ranitidine Sodium Chloride, Sulindac Thioridazine, Trifluorperazine Trimethobenzamide Tyramine, VitaminC

- Interference Testing

The following conditions were found not to interfere with the test.

Ethanol	1%
Methanol	1%
EDTA	80 mg/dl
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	1,000 μg/dl
Hemoglobin	1,000 μg/dl
Urinary Test pH:	pH 3 –pH
Specific Gravity:	1.003 – 1.040

- Accuracy

Accuracy of the *"See Now"* Barbiturate Urinary Test Device has been evaluated. A total of 80 clinic samples was tested (40 negative and 40 positive).

.

Conc. of Sample	No. of	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 500		35 / 0	35 / 0	35/ 0	105 /0
500 - 999		1 / 4	1 / 4	1 / 4	3/ 12
1000-1500		2 /3	2 / 3	2 / 3	6 / 9
> 1500		0 /35	0 /35	0 / 35	0 /105
% of Negative				97.5%	
% of Positive				95 %	
% of overall				96.3 %	

- Reproducibility

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.