One Step
Barbiturates Test Device (Urine)
Package Insert

(Catalog Number: 1184-C)

BIOMERICA

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

For in vitro diagnostic *use only.*

INTENDED USE

The One Step Barbiturates Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Barbiturates (Secobarbital) in urine at a cut-off concentration of 300 ng/mL.

This assay provides only a 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.

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

PRINCIPLE

The 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 detectable 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 detectable cut-off level because it will saturate all the binding sites of anti-Barbiturates antibody.

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 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 device contains anti-Barbiturates antibody coupled particles and Barbiturates-protein conjugate. A goat antibody is employed in the control line system.

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 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 device is stable through the expiration date printed on the sealed pouch. The test device 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.

MATERIALS

Materials Provided

- Test devices
- Disposable droppers
- Package insert

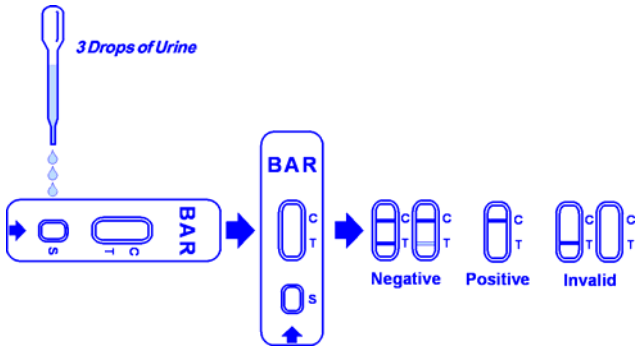
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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 positive 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 One Step Barbiturates Test Device (Urine) provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods. [1, 2, 3]
2. The One Step Barbiturates Test Device (Urine) is a qualitative screening assay and cannot determine either the drug concentration in the urine or the level of intoxication.
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 or 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.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the One Step Barbiturates Test Device (Urine) was evaluated by testing clinical urine specimens. These clinical urine specimens were previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		**GC/MS**		**Total Results**
Biomerica **One Step Test Device**	**Results**	Positive	Negative	
	Positive	42	3	45
	Negative	3	219	222
Total Results		45	222	267
% Agreement with GC/MS Analysis		93%	99%	98%

Specificity

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

Compound	**Concentration (ng/mL)**
Secobarbital	300
Amobarbital	300
Aprobarbital	200
Butalbital	2500
Butabarbital	75
Phenobarbital	100
Pentobarbital	300
Cyclopentobarbital	600
Alphenol	150
Butethal	100

Effect of Urinary Specific Gravity

Fifteen (15) urine specimens of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Secobarbital respectively. The 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 does not affect the test results.

Effect of the 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 One Step Barbiturates Test Device (Urine) in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does 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 urine not associated with Barbiturates. The following compounds show no cross-reactivity when tested with the One Step Barbiturates Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
Ascorbic acid
D,L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine
Bilirubin
Brompheniramine
Caffeine
Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine methylester
(-) Y Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meperidine
Meprobamate
Methoxyphenamine
(+) 3,4-Methylenedioxy-amphetamine
(+) 3,4-Methylenedioxy-methamphetamine
Morphine-3-β-D glucuronide
Morphine Sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentobarbital
Perphenazine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3 Acetate
Tetrahydrocortisone 3 (β-D glucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D, L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

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

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc., 1533 Monrovia Avenue
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EC REP

CE

according to IVDD 98/79/ EC
MDSS
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