One Step Barbiturates Test Strip

INTENDED USE
The BAR One Step Barbiturates Test Strip 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 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.

PRECAUTIONS
- For healthcare professionals including professionals at point of care sites.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test strip should remain in the sealed pouch until use.
- The used test strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strips must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SUMMARY
Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticovulsants. 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 Strip is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody 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 strip. The antibody coated particles will then be captured by immobilized Barbiturates 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.

A procedural control is included in the test. A 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 below the detectable cut-off level.

NOTE: The shade of red in the test line region (T) will 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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

DIRECTIONS FOR USE
Allow the test strip, 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 strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and 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
(See illustration below)

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 below the detectable cut-off level.

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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. This may be considered as the internal negative control. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1. The BAR One Step Barbiturates Test Strip 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) are the preferred confirmatory methods.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.

A Positive Result indicates presence of the drug or its metabolites but does not...

• Test strips
• Package insert
• Specimen collection container
• Timer
• External Controls

MATERIALS PROVIDED
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

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### PERFORMANCE CHARACTERISTICS

**Accuracy**

A side-by-side comparison was conducted using the BAR One Step Barbiturates Test Strip 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:

<table>
<thead>
<tr>
<th>Method</th>
<th>BAR One Step Test Strip</th>
<th>GC/MS</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Secobarbital</td>
<td>50% secobarbital</td>
<td>50% secobarbital</td>
<td>50% secobarbital</td>
</tr>
<tr>
<td>Concentration (ng/mL)</td>
<td>0</td>
<td>150</td>
<td>225</td>
</tr>
<tr>
<td>Visual Result</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
</tr>
</tbody>
</table>

When compared to GC/MS at the cut-off concentration of 300 ng/mL, the following results were tabulated:

<table>
<thead>
<tr>
<th>Method</th>
<th>BAR One Step Test Strip</th>
<th>GC/MS</th>
<th>Total Results</th>
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</tr>
<tr>
<td>Visual Result</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**Precision**

A study was conducted at 3 physician’s 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:

<table>
<thead>
<tr>
<th>Secobarbital conc. (ng/mL)</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>126</td>
<td>165</td>
<td>360</td>
<td>292</td>
</tr>
<tr>
<td>Positive</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total Results</td>
<td>126</td>
<td>165</td>
<td>360</td>
<td>292</td>
</tr>
</tbody>
</table>

**Effect of Urinary Specific Gravity**

Fifteen (15) urine samples with specific gravity ranges from 1.000 to 1.037 were spiked with 150 ng/mL and 450 ng/mL of Secobarbital respectively. The BAR One Step Barbiturates Test Strip was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

**Effect of the Urinary pH**

Eighty (80) of these samples were also run using the BAR One Step Barbiturates Test Strip by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

**Effect of the Urinary pH**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Barbiturates positive urine. The following compounds show no cross-reactivity with the BAR One Step Barbiturates Test Strip at a concentration of 100 ng/mL.

### BIBLIOGRAPHY

2. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man* 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

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