**BUP**

**One Step Buprenorphine Test Strip**

**Package Insert**

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

**INTENDED USE**

The One Step Buprenorphine Test Strip is a lateral flow chromatographic immunoassay for the detection of Buprenorphine in human urine at a level relative to the Buprenorphine cut-off concentration of 10 ng/mL. This assay is intended for use by professionals to assist in the determination of drug compliance.

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) or chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

**REAGENTS**

The test strip contains mouse monoclonal anti-Buprenorphine antibody-coupled particles and Buprenorphine-protein conjugate. A goat antibody is employed in the control line system.

**SPECIMEN COLLECTION AND PREPARATION**

Urine specimens 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 obtain a clear specimen for testing.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**PRINCIPLE**

The One Step Buprenorphine Test Strip is an immunassay 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. Buprenorphine, if present in the urine specimen below 10 ng/mL, will not saturate the binding sites of antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized Buprenorphine conjugate and a visible colored line will show up in the test region. The colored line will not form in the test region if the Buprenorphine level exceeds 10 ng/mL because it will saturate all the binding sites of anti-Buprenorphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test region.

To serve as a procedural control, a colored line will always appear in the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**INTERPRETATION OF RESULTS**

(Please refer to illustration below)

**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). A negative result indicates that the Buprenorphine concentration is below the detectable level of 10 ng/mL.

**POSITIVE:** One colored line appears in the control region (C). No line appears in the test region (T). A positive result indicates that the Buprenorphine concentration exceeds the detectable level (10 ng/mL).

**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 the manufacturer.

**SUMMARY**

The One Step Buprenorphine Test Strip 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 (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) are the preferred methods.

It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

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 but does not indicate level or intoxication, administration route or concentration in urine.

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.

Test does not distinguish between drugs of abuse and certain medications.
A drug-free urine pool was spiked with Buprenorphine at the following concentrations: 0 ng/mL, 5 ng/mL, 10 ng/mL, 15 ng/mL, and 20 ng/mL. The assay cut-off level of 10 ng/mL was selected to correlate with the LC/MS analysis cut-off for Buprenorphine. The result demonstrates 99% accuracy at 50% above and below the cut-off concentration. The data are summarized below:

### Specificity

The following table lists compounds that are positively detected in urine by the One Step Buprenorphine Test Strip at 5 minutes.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
<th>Cross-Reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Norbuprenorphine</td>
<td>20</td>
<td>100</td>
</tr>
<tr>
<td>Buprenorphine 3-D-glucuronide</td>
<td>15</td>
<td>87</td>
</tr>
<tr>
<td>Norbuprenorphine 3-D-glucuronide</td>
<td>200</td>
<td>5</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 10 urine samples containing concentrations of 5 ng/mL, 10 ng/mL, 15 ng/mL, and 20 ng/mL. The results demonstrate 99% accuracy at 50% above and below the cut-off and 50% Buprenorphine above and below the 10 ng/mL cut-off were provided to each site. The following results were tabulated:

### BIBLIOGRAPHY


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