One Step Buprenorphine (BUP) Test

Package Insert for Buprenorphine Single Test Strip, Cassette, and Dipcard.

INTENDED USE

The One Step Buprenorphine Test is an easy-to-use, lateral flow chromatographic immunoassay for the qualitative detection of Buprenorphine in urine at the following cut-off concentration or greater:

<table>
<thead>
<tr>
<th>Test</th>
<th>Calibrator</th>
<th>Cut-off</th>
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<tbody>
<tr>
<td>Buprenorphine</td>
<td>10 ng/mL</td>
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</table>

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The One Step Buprenorphine Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of drug and drug metabolites in human urine.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, is a combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule II drug just before FDA approval of Suboxone and Subutex.

The One Step Buprenorphine Test yields a positive result when the Buprenorphine in urine exceeds 10 ng/mL.

PRINCIPLE

The One Step Buprenorphine Test includes a chromatographic absorbent device in which the drug in the sample competes with a drug conjugate immobilized on a porous membrane for limited antibody sites.

Labeled-antibody-dye conjugates mixes with sample specimens and binds to the free drug present forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the test zone preventing the formation of a pink/orange color band when the drug concentration in the specimen is above 10 ng/mL. Unbound dye conjugates bind to the reagent in the negative control zone and produce a pink/orange color band, demonstrating that the reagents and device are functioning correctly. A negative specimen produces two distinct color bands in both the test region and the control region. A positive specimen produces only one color band in the control region.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Buprenorphine.

PRECAUTIONS

- For Professional Use Only
- For In vitro Diagnostic Use Only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until used.
- While urine is not classified by OSHA as the CDC as a biological hazard unless visibly contaminated with blood", the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test card and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test 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 HANDLING

Use fresh urine specimens. Urine specimens do not require any special handling or pretreatment. It is best to test urine specimens immediately after collection. However, if necessary, urine specimens may be refrigerated at 2 – 8°C (36 – 46°F) for two days or freeze at -20°C (-4°F) or colder for longer periods. The sample should be free from gross debris. Refrigerated samples should be allowed to warm to room temperature before testing.

MATERIALS

<table>
<thead>
<tr>
<th>Materials Provided</th>
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<tbody>
<tr>
<td>Test device</td>
</tr>
<tr>
<td>Desiccant</td>
</tr>
<tr>
<td>Disposable specimen dropper (for test cassette only)</td>
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<tr>
<td>Specimen collection container</td>
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<tr>
<td>Disposable gloves</td>
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<tr>
<td>Timer</td>
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</tbody>
</table>

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable specimen dropper (for test cassette only)
- Desiccant
- Disposable specimen dropper

DIRECTIONS FOR USE

Allow the test card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing. DO NOT INTERPRET RESULT AFTER 10 MINUTES.

For Strip

1) Remove the test strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non-absorbent clean surface.
3) Read results at 5 minutes.

For Cassette

1) Remove the test device from its foil wrapper by tearing along the slice (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the device with patient or control identifications.
2) Using the specimen dropper, withdraw the urine sample from the specimen cup and slowly dispense 3 drops (approximately 120uL) into the circular sample well, being careful not to overfill the absorbent pad.
3) Read results at 5 minutes.

For Dipcard

1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorbent clean surface.

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another apparent red or purple line adjacent should be in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable 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 device. If the problem persists, discontinue using the lot immediately and contact your supplier.

[Cassette]

[Strip]

[Dipcard]
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.

LIMITATIONS
1. The One Step Buprenorphine Test 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.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adults, such as bleach and/or alums, 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 and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
The following table lists the concentration of compounds (mg/mL) that were detected positive in urine by One Step Drug of Abuse Test at a read of 5 minutes.

Analytical Specificity
The table below lists the concentration of compounds (mg/mL) that were detected positive in urine by One Step Drug of Abuse Test at a read of 5 minutes.

Non Cross-Reacting Compounds

BIBLIOGRAPHY