

**One step test device for the qualitative detection of Buprenorphine in human urine.
For professional in vitro diagnostic use only.**

INTENDED USE

The **DrugControl BUPRENORPHINE TEST** is a lateral flow chromatographic immunoassay for the detection of Buprenorphine in human urine at the cut-off concentration shown below:

| TEST DEVICE | SUBSTANCE | CAS - No | Cut Off Limit Value [ng / mL] |
|----------------------|----------------------------------|--------------|-------------------------------|
| Buprenorphine | Buprenorphine | [52485-79-7] | 10 |
| | Buprenorphine 3-D-glucuronide | [-] | 15 |
| | Norbuprenorphine | [-] | 20 |
| | Norbuprenorphine 3-D-glucuronide | [-] | 200 |

This assay provides only a preliminary analytical test result. An 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 confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.



REAGENTS

The **DrugControl BUPRENORPHINE TEST** contains anti-Buprenorphine antibody-coupled particles and Buprenorphine-protein conjugate. The control line system contains a goat anti-mouse antibody.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the closed round vial until use.
- Do not moisten nitrocellulose membrane with urine samples.
- Dip test strip for at least 10-15 seconds in the urine specimen.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test device should be discarded according to federal state and local regulations.

STORAGE AND STABILITY

The **DrugControl BUPRENORPHINE TEST** can be stored at room temperature or refrigerated (2-30°C). The test is stable through the printed expiration date. The test must remain in the closed round vial until use.

- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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 precipitates should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing. 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.

MATERIALS

MATERIALS PROVIDED

- 25 test strips in a round vial with desiccant cap
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

BUPRENORPHINE 008A103-25

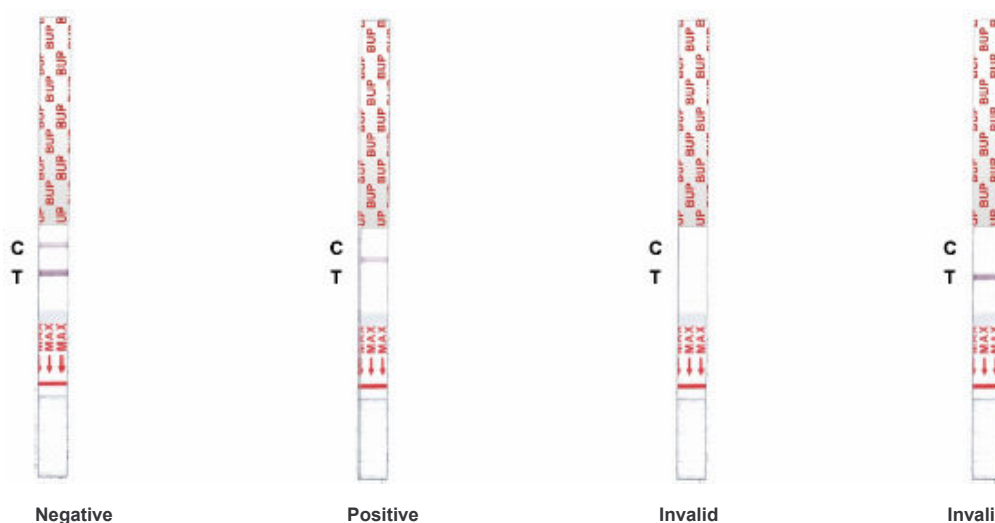


Dip the
DrugControl BUPRENORPHINE strip
into urine specimen for at least 10-15 seconds

DIRECTIONS FOR USE

- 1 Allow the test, urine specimen, and / or controls to reach room temperature (15 – 30 °C) prior to testing.
- 2 Bring the round vial to room temperature before opening it.
- 3 Remove the test device from the closed round vial and use it as soon as possible.
- 4 After removing a test strip immediately close the round vial tightly.
- 5 Immerse the test vertically in the urine specimen for at least 10-15 seconds.
- 6 Do not pass the maximum line (dipping line) on the test when immersing the strip.
- 7 Place the test on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear.
- 8 The result should be read at 5-8 minutes. Do not interpret after more than 10 minutes.

INTERPRETATION OF RESULTS



- 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 concentrations of the substances detectable with this test are below the cut-off concentration (substances & cut-off concentrations see table on page 1) or that they are not present.
- Positive:** One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the concentration of at least one of the substances detectable with this test exceeds the cut-off concentration (substances & cut-off concentrations see table on page 1).
- 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 distributor / manufacturer.

* **Note:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.