BUPRENORPHINE (BUP)
008A104

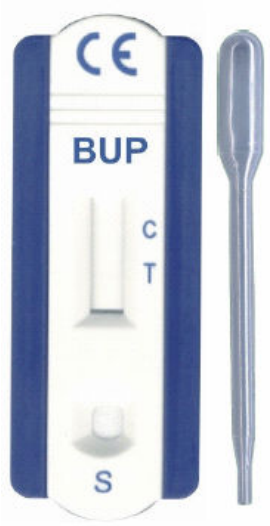
One step test device for the qualitative detection of Buprenorphine in human urine.
For professional in vitro diagnostic use only.

INTENDED USE

The *Drug*Control **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 *Drug*Control **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 sealed pouch until use.
- Do not moisten nitrocellulose membrane with urine samples.
- Add 3 drops of specimen (min. 180 µl per assay).
- 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 *Drug*Control **BUPRENORPHINE TEST** 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

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

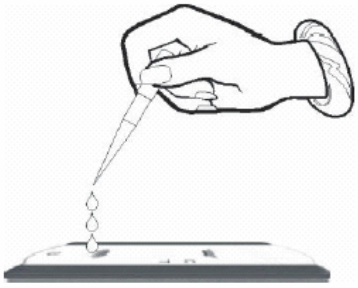
- Test device
- Dropper
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

DrugControl®

BUPRENORPHINE (BUP)
008A104

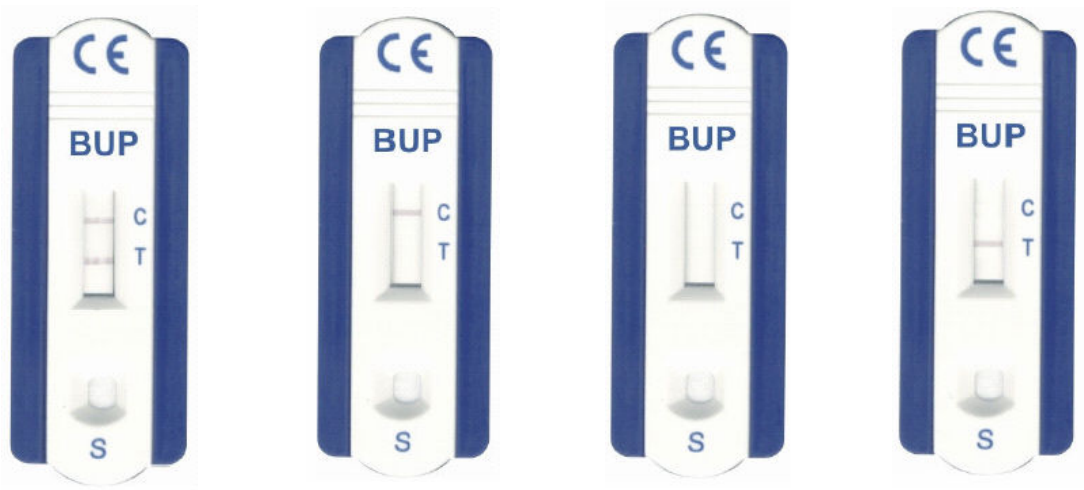


Pipette urine specimen into the sample well
of *Drug*Control **BUPRENORPHINE TEST**

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 pouch to room temperature before opening it.
3. Remove the test device from the sealed pouch and use it as soon as possible.
4. Place the test device on a clean and level surface.
5. Add 3 drops of urine (min. 180 µl) to the specimen well (S).
6. Avoid trapping air bubbles in the specimen well (S).
7. Place the test on a 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 read results after more than 10 minutes.

INTERPRETATION OF RESULTS



Negative **Positive** **Invalid** **Invalid**

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 device. 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.

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg • Germany
Telefon: +49-4102 – 80090
Fax: +49-4102 – 50082
e-mail: info@ultimed.de

ulti med Products (Belgium) BVBA
Honzebroekstraat 137 • 8800 Roeselare
Phone: +32 +51 200 425
Fax: +32 +51 200 449
e-mail: belgium@ultimed.org

CE

August 2005
/ F