

## The Buprenorphine (BUP) Rapid Test Kit (Immunochromatography)

### Product Name

The Buprenorphine (BUP) Rapid Test Kit (Immunochromatography)

### Intended Use

The Buprenorphine (BUP) Rapid Test Kit is a rapid visual immunoassay for the qualitative detection of Buprenorphine in human urine samples at the cut-off concentrations of 10ng/mL. The test kit is suitable for screening of Buprenorphine abuse.

### Test Principle

This kit uses specific antigen-antibody reaction, combining Gold Immunochromatography Assay experiment, highly specific and sensitive competition method to detect the Buprenorphine (BUP) in urine.

When testing, urine chromatography upward by capillary action. If the concentration of Buprenorphine (BUP) in urine is below the limitation, colloidal gold antibodies can not combine all of Buprenorphine (BUP), thus colloidal gold antibodies combines with the Buprenorphine (BUP) conjugates on the film, appear a red line in the test area (T). If the concentration of Buprenorphine (BUP) in urine is higher than the limitation, no red line appears due to the competition reaction in the test area. Whether Buprenorphine (BUP) exists in the urine, a red line will appear in the control area (C).

### Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

### Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

### Sample requirement

The urine sample has to be collected in the plastic urine cup or glass containers which are clean, dry, without preservatives. If the urine is turbid, take the supernatant after centrifugation for detection, or filter out the precipitation before detection.

The sample should be tested as soon as possible, and should not be stored at room temperature for a long time. Urine samples should be used immediately, and may be stored at 2-8°C for 2 days. For long-term preservation please store at -20 °C. Avoid freeze and thaw repeatedly.

### Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10°C-50°C)

### Strip:

1. Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the sample, the interface of urine should not exceed the MAX line, take it out after 5s and place the test stripe on a clean and level surface.
2. Observe the test results immediately within 5-10 minutes, the result is invalid over 10 minutes.

### Cassette:

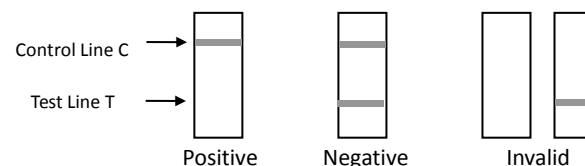
1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 3 drops of sample (120µl) vertically into the sample hole of cassette.
3. Observe the test results immediately within 5-10 minutes, the result is invalid over 10 minutes.

### Result Judgment

**POSITIVE:** One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

**NEGATIVE:** Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

**INVALID:** No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



### Limitation

1. The kit is only suitable for testing of BUP in urine.
2. The kit is for the qualitative detection reagents, can not determine the content of BUP in urine.
3. The kit is only used for screening, the negative result can't be used as basis for diagnosis.

### Precaution

1. For in vitro diagnostic only. For urine sample test only.
2. Please make sure that the right amount of sample is used for testing, too much or too little sample volume may lead to wrong results.
3. Please use within the validity period; please check if the packaging is intact before use. The test results are invalid beyond the test time.
4. During the interpretation time, as long as two lines can be observed clearly visible (no matter the color is deep or light), the result should be judged as negative.
5. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.