The Opiates (OPI) Rapid Test Kit (Colloidal Gold)

Product Name

The Opiates (OPI) Rapid Test Kit(Colloidal Gold)

Intended Use

The Opiates (OPI) Rapid Test Kit is a rapid visual immunoassay for the qualitative detection of Opiates in human urine specimens at the cut-off concentrations of 2000ng/mL. The test kit is suitable for screening of Opiates abuse.

Test Principle

The OPI Rapid Test Device (Urine) detects OPI through visual interpretation of color development on the device. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Main Components

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

Specimen 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℃ for 2 days. For long-term preservation please store at -20 ℃. Avoid freeze and thaw repeatedly.

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.

Test Procedure

Place the reagent at room temperature for 30 minutes before use, and return to room temperature （20℃-30℃. Instructions must be read entirely before taking the test. Do not open the inner packaging until ready, it must be used within one hour if opend（Humidity:20%~90%,Temp:10℃-50℃）.

Strip:

1. Remove remove one strip from the canister. Canisters should be closed tightly after removing strips. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
2. Hold the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
3. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear.
4. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

Cassette:

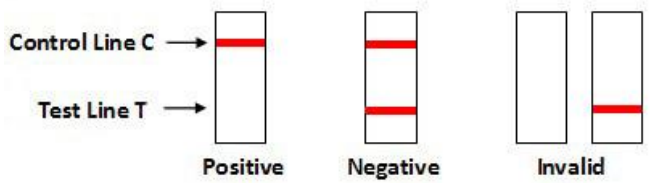
1. Take off the outer packing, put the cassette onto the desk with the sample window up. Drop 3 drops of specimen (120μl) vertically into the circular groove of cassette. Start the timer and wait for the colored band(s) to appear.
2. Observe the test results immediately within 5 minutes, the result is invalid over 8 minutes.

Interpretation of Result

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 bands 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.



Limitations

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

Attentions

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.