Tricyclic Antidepressant (TCA) Rapid Test Kit (Colloidal Gold)

Product Name

Tricyclic antidepressant (TCA) Rapid Test Kit (Colloidal Gold)

Intended Use

Adopting highly specific antibody-antigen reaction and immunochromatographic technique, the test kit is used for qualitative detection of tricyclic antidepressant in urine and is suitable for screening of tricyclic antidepressant abuse.

Test Principle

The test kit adopts highly specific antibody-antigen reaction and immunochromatographic technique, and the kit contains tricyclic antidepressant conjugate that is fixed on the membrane beforehand and colloidal gold marked anti-TCA monoclonal antibody.

When testing, the urine chromatography up under the capillary effect. If the concentration of TCA in urine is lower than 1000ng/ml, colloidal gold antibody can't combine with TCA completely, there will appear a purple strip in test area (T). If the concentration of TCA in urine is higher than 1000ng/ml, colloidal gold combine with TCA completely, there will appear no purple strip in test area (T). During the testing process, because of lacking antibody-antigen reaction competitive reaction, there will appear a purple strip in test area (T).

Main Components

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

Specimen requirement

1. Urine samples must be collect clean, dry and it does not contain any preservative glass containers. If a urine sample is visible turbidity form, must first centrifugal, filter or until the precipitation take clear liquid upper detection.

2. Samples should be used as soon as possible after being collected, it can't be placed at room temperature for a long time. If it can't be tested timely, it can be preserved for 3 days at 2-8 $^{\circ}$ C, it need to be frozen at -20 $^{\circ}$ C for long-term preservation.

Storage and Expiry

Store at room temperature 4-30 $^\circ C$, avoid hot and sunshine, dry place, not frozen, valid for 24 months.

Test Procedure

Read the instruction carefully before testing. Beforehand, make the test kit and sample recovered to room temperature $15-30^{\circ}$ C. The foil pouch can not be torn open until everything gets ready.

1. Open the foil pouch and take out the test strip/ cassette.

2. Test Procedure

2.1 Strip: Invade one end with an arrow of the strip into the container that filled with urine, take it out after 5s and put in on a clean and flat table. Note that the liquid level of urine can't excess the MAX line

of the test strip.

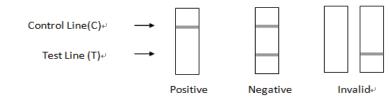
2.2 Cassette: Drop three drops (about 100uL) of urine sample in the sampling well with a pipette.

3. Read the test results within 5-10 minutes, it is invalid beyond 10 minutes.

Interpretation of Result

Positive: There only appear one purple strip in the control area (C), no purple strip appears in the test area (T).Positive result indicates: The concentration of TCA is higher than threshold value (1000ng/mL). **Negative:** There appear two purple strips, one is in test area (T) and the other is in control area(C).Negative result indicates: The concentration of TCA is lower than threshold value (1000ng/mL). **Note:** The color depth of purple strip in test area (T) may be different, within the prescribed observing period, regardless of the depth of the strip color, it should be judged as negative results in spite of a very weak purple strip.

Invalid: There is no purple strip in the control line(C), which indicates that incorrect operation or reagent failure, please re-test.



Limitations

1. This kit is only suitable for detection of reagent urine sample TCA.

2. The kit is for qualitative screening reagent, the content of TCA in urine can't be determined.

3. The kit is only used for screening, the negative result can't be used as basis for diagnosis.

Attentions

1. The kit is only for in vitro diagnosis, and is suitable for testing urine sample, it may cause abnormal results with other samples or solutions.

2. Please ensure that suitable amount of samples are used for testing, more or less sample amount may lead to deviation results.

3. Please use it within validity period; before using, check if the package is complete, it can't be used any more if it has damage. The results are invalid beyond testing time.