Human Immunodeficiency Virus Antibody HIV1/2 Rapid Test Kit (Colloidal Gold)

Product Name

Human Immunodeficiency Virus Antibody HIV 1/2 Rapid Test Kit (Colloidal Gold)

Intended Use

The reagent is used to detect the HIV 1/2 antibody in serum / plasma / whole blood qualitatively.

Human immunodeficiency virus is the causative agent of AIDS(Acquired Immune Deficiency Syndrome). AIDS is the end stage of a long process in which the immune system of an infected person and its ability to control infections or malignant proliferative disorders are progressively destroyed, and is mainly transmitted through sexual contact in general, and mother to child transmission of blood-borne infection in three ways.

Test Principle

The test utilizes antibodies including a mixed HIV1 and HIV2 antigen (P24, gp120, gp41, gp36), and Rabbit anti-HIV antibody on the nitrocellulose membrane with colloidal gold marked HP antigen as an mark tracer. The reagent is used to detect the HIV 1/2 antibody in serum / plasma / whole blood according to the principle of double antibody sandwich method and gold immunochromatography assay.

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mixed HIV antigen(P24, gp120, gp41, gp36), nitrocellulose membrane coated with mixed HIV antigen(P24, gp120, gp41, gp36)，control line coated with goat rabbit anti-HIV antibody.

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. Do not open the inner packaging until ready, it must be used in one hour if opened.

Sample Requirements serum/plasma/whole blood

1. Serum: Use disposable syringe (vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, take the supernatant after centrifugation of blood for detection.

Plasma: Use vacuum blood collection tube with anticoagulation to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection.

Whole blood: Use the fresh whole blood specimens.

2. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

3. Serum and plasma specimens may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃ for 2 years. Repeat freeze and thaw for no more than 3 times. Whole blood specimens with anticoagulation may be stored at 2-8℃ for 24 hour, and should be used immediately without anticoagulatio n. Frozen whole blood samples should not be used. (If blood coagulation occurs, serum samples are suggested to use.)

Test Methods

Different kinds of reagent, and different batches of the same reagent can not be exchanged for use.

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

Strip： 1. Put the stripe onto the desk with the sample adding area up.

2. Drop 1 drop (25μl) of serum/plasma/whole blood vertically onto the sample pad of strip. Add about 2 drops of (100μl) specimen buffer onto the sample pad of the strip.

3. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Cassette： 1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 1 drop (25μl) of specimen vertically into the circular groove of cassette. Add about 2 drops of (100μl) specimen buffer into the circular groove of cassette.

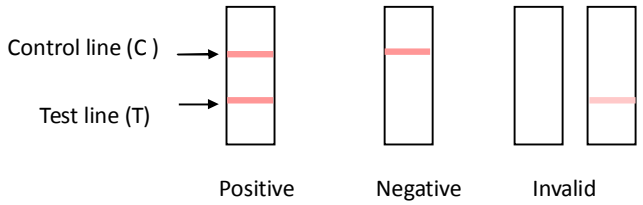
3. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Result Judgment

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

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

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.



Limitations

1. This reagent is designed for the qualitative screening test. Concentration of HIV 1/2 cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
4. Abnormal results may occur according to operator error or drug use. If AIDS is still suspected, a specimen should be collected later and tested again.
5. Negative result does not completely ruled out HIV 1/2 infection, it only indicate that the specific antibodies of the HIV does not exist or the concentration is below detection limit. Mutation, silent infection and sensitivity will also lead to the negative detection results.

Performance Characteristics

1. Negative specificity:

The coincidence rate should exceed 18/20 when detecting national negative quality control specimens with kits of HIV 1/2.

The coincidence rate should be 20/20 when detecting internal negative quality control specimens with kits of HIV 1/2.

2. Positive specificity:

The coincidence rate should be 20/20 when detecting national positive quality control specimens with kits of HIV 1/2.

The coincidence rate should be 20/20 when detecting internal positive quality control specimens with kits of HIV 1/2.

3. Limit of detection:

At least one of the three results should be positive when detecting HIV national limit quality control specimens with the kits of HIV 1/2. The coincidence rate should at least be 1/3, the plasma matrix (S1) should result in negative.

The plasma matrix (S1) should result in negative, while S2 and S3 result in positive when detecting internal limit quality control specimens.

4. Repeatability:

The results should be consistent and the coloration degree should be consistent when detecting the national/internal precision control specimens by 10 kits of the same batch.

5. Analytical sensitivity:

Bilirubin with a concentration below 146.7μmol/L, triglyceride with a concentration below 8.74mmol/L has no effect on the detection results. Hemolysis with a Hb concentration exceed 6.5g/L may affect the determine of the results. Other detection method is suggested.

The addition of positive HAV specimens, HBsAg, HBeAg and HBcAb positive specimens, HBsAg, HBeAb and HBcAb positive specimens, positive HCV specimens, positive HEV specimens and positive syphilis specimens showed no cross-reactivity. Rheumatoid factors will not affect the results.

6. Hook effect: the hook effect will not occur even the HIV 1/2 concentration is high.

Attentions

1. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Do not use after the expiration date.
2. Reagents should be used as soon as possible after opened.This reagent can not be reused for disposable.
3. The strength of the test line doesn't indicate antibody titer. The positive results cannot be used as the basis for the diagnosis, and should be further confirmed by the test.
4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstates an effective reagent.
5. Please contact the local epidemic prevention station if the specimen confirmed as positive samples.
6. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.