Human Immunodeficiency Virus Antibody HIV 1/2 Rapid Test Kit

(Immunochromatography)

Product Name

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

Intended Use

The test is based on the principle of sandwich immunoassay for a qualitative detection of antibody to human immunodeficiency virus HIV-1/HIV-2 in human serum or plasma.

Test Principle

Used gene recombination HIV1 and HIV2 mixed antigen P24, gp120, gp41, gp36 and Rab MAb HIV antibody coated on nitrocellulose as test line and control line. And meanwhile gold colloid recombination HIV mixed antigen P24, gp120, gp41, gp36, used double antigen sandwich GIA to detect antibody to HIV-1/HIV-2 in human serum or plasma.

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

1. Samples collected by venous conventional methods, test samples must be collected with a clean container, can be used anticoagulant heparin, EDTA, sodium citrate, sodium oxalate.

2. After collection, separate the serum and plasma as soon as possible, in order to avoid hemolysis.

3. Use fresh samples. Samples stored at 2-8 ℃ in refrigerator preferably not more than 3 days, if not tested immediately should be stored at -20 ℃.

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℃-30℃) 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℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ the sample window of the cassette up.

2. Drop 2 drops (50μl) serum or plasma vertically into the sample adding area of the strip/sample hole of cassette.

3. Add 1 drop (50μl) of sample buffer into the sample adding area of the strip/sample hole of cassette.

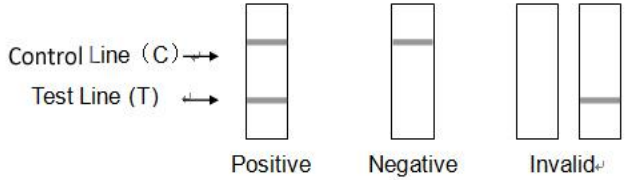
4. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

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 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.



1. The test kit is for the qualitative screening, cannot determine the exact content in the samples.

2. Whether the patient is infected with HIV, physicians should combine with clinical features and symptoms, and make comprehensive judgments.

3. Because the antibody does not exist or with low concentration, samples infected in a short time or in the window period, will show negative result.

Precaution

1. Operate according to the infectious disease laboratory procedures.

2. If the aluminum foil bag is broken, the kit is affected with damp, cannot be used.

3. Please use the kit in its expiration. Over the test time, the results are invalid.

4. Hyperlipidemia and jaundice samples have no effect to the detection results.

5.Slight hemolysis samples have no effect to the detection results, but serious hemolysis samples can produce background, impact the observation of test line (T), suggest using other test method.

6. 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.