Diagnostic Kit for Antibody to Human Immunodeficiency Virus (1+2) (Colloidal Gold) 3-Lines

【For the qualitative detection of HIV-1/2 antibodies in serum/plasma】

INTENDED USE

Diagnostic Kit for Antibody to Human Immunodeficiency Virus (1+2) (Colloidal Gold) is a qualitative test for the detection of antibodies to Human Immunodeficiency Virus type 1 and 2 (HIV-1/2) in human serum/plasma. It is considered as an initial screening test for HIV-1/2 antibodies. All positive specimens must be confirmed with Western Blot or other qualified EIA.

PRECAUTION

1. For in vitro diagnostic uses only.
2. All patient samples should be treated as if capable of transmitting diseases.
3. Do not use test kit beyond expiration date.
4. Lcteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

SUMMARY AND EXPLANATION OF THE TEST

It has been shown that the acquired immunodeficiency syndrome (AIDS) is caused by viruses transmitted by sexual contact, transfusion, use of contaminated blood products and sharing contaminated needles. HIV-1 and HIV-2 viruses have been isolated from patients with AIDS and AIDS-related complex (ARC), high-risk persons for AIDS. HIV-1 and HIV-2 viruses delete T helper cells, a sub population of T cells for body defense, thus causing AIDS patients susceptible to opportunistic infections and developing malignant tumors. The incidence of specific antibodies to HIV-1/2 is high in AIDS, ARC and persons with high risk for AIDS. The HIV-1/2 Rapid Screen Test is designed to detect antibodies to HIV-1/2 in AIDS patients, ARC or high risk persons and identify any potential donors carrying these antibodies in serum specimens.

PRINCIPLE

Diagnostic Kit for Antibody to Human Immunodeficiency Virus (1+2) (Colloidal Gold) is a chromatographic immunoassay (CIA) for the detection of antibodies to HIV-1/2 in human serum/plasma. HIV-1/2 specific antigens are precoated onto membrane as a capture reagent on the test region. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with HIV-1/2 specific antigens. Antibodies to HIV-1/2, if present, a red colored band will develop on the membrane in proportion to the amount of HIV-1/2 antibodies present in the specimen. Absence of this red colored band in the test region suggests a negative result. To serve as a procedural control, red colored band in the control region will always appear regardless the presence of antibodies to HIV-1/2.

MATERIALS SUPPLIED

1. One pouched cassette with desiccant.
2. One piece of operating instruction.

MATERIALS NOT PROVIDED BUT REQUIRED

1. Specimen collection container, either plastic or class.
2. Timer.
3. Disposable gloves.

SPECIMENS COLLECTION AND STORAGE

Plasma

1. Have a certified phlebotomist collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by vein puncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing, or label and store it at
4. 2-8°C for up to one week. Plasma may be frozen at -20°C for at least three months.

Serum

1. Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by vein puncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
5. Carefully withdraw the serum for testing or label and store it at 2-8°C for up to one week. Serum may be frozen at -20°C for at least three months.

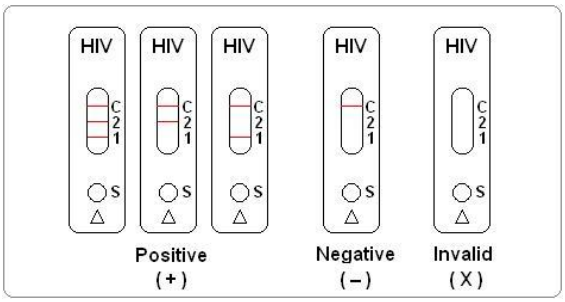
ASSAY PROCEDURE

Add 2 drops (70 µl) of sample (serum/plasma) into the sample well. Observe the result in 20 minutes.

QUALITY CONTROL

An internal procedural control is included in the test. Red line will appear in the control region (C).

INTERPRETATION OF RESULTS



Negative: No apparent band in the test region (1 and 2), only one red band appears in the control region (C). This indicates that no HIV1/2 antibodies have been detected.

Positive: In addition to the band in the control region (C), other one or two red bands will appear in the test region (1 and 2). This indicates that the specimen contains HIV1/2 antibodies.

Invalid: If no band appears in the control region(C), regardless of the presence or absence of line in the test region (1 and 2). It indicates a possible error in performing the test. The test should be repeated using a new device.

STORAGE AND STABILITY

Store HIV-1/2 Rapid Screen Test at temperature ranges 4-30 °C in the sealed pouch. Refer to the expiration date for stability. Do not freeze. Shelf-life of the sealed pouch is 24 months.

LIMITATION

1. The test is to be used for the qualitative detection of antibodies to HIV.
2. A negative result does not rule out infection by HIV because the antibodies to HIV may be absent or may not be present in sufficient quality to be detected at early stage of infection.
3. A positive result, even a weak positive, must be verified with a confirmation test.
4. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.

PRODUCT DISCLAIMER

This product has been manufactured under strict GMP regulation so to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals which may affect the result to a certain degree.

NOTE

The manufacture, the Distributor or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

REFERENCE

1. Centers for Disease control: Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome. Morbidity and Mortality Weekly Rep 34: 5-7, 1985.
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3. Popovic, M., et al: Detection isolation and continuous production of Cytopathic Retroviruses (HTLV.Ⅲ) from patients with AIDS and pre-AIDS. Science 1984; 224:497
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5. Centers for Disease contro,Update on Acquired Immune Deficiency Syndrome(AIDS)MMWR 1982; 31:507
6. Gallo, RC, et al: Frequent detection and isolation of Cytopathic Retroviruses (HTLV.Ⅲ) from patients with AIDS and a risk for AIDS.Science.1984; 224:500

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