WANTAI RAPID TEST

Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)

Rapid Test for Detection of HIV-1 & HIV-2 Antibodies

FOR SERUM / PLASMA / WHOLE BLOOD SPECIMEN

INSTRUCTIONS FOR USE

Catalog No.:
WJ-1810, WJ-1850, WJ-1810E, WJ-1850E

INTENDED USE

Wantai Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is a single use, rapid device for qualitative detection of antibodies against Human Immunodeficiency Viruses (HIV) 1+2 in human serum, plasma or whole blood specimens. The device is intended for use in medical institutions by trained staff as an aid for the diagnosis of clinical conditions related to infection with HIV-1 and / or HIV-2 - the etiological agents of the acquired immunodeficiency syndrome (AIDS).

SUMMARY

The Human Immunodeficiency Viruses type 1 and type 2 are etiological agents of the acquired immunodeficiency syndrome (AIDS). HIV has been isolated from patients with AIDS, AIDS related complex (ARC) and from healthy individuals at high risk for AIDS[1]. Infection with HIV is followed by an acute flu-like illness. This phase may remain unnoticed and the relationship to HIV infection may not be clear in many cases[2]. The acute phase is typically followed by an asymptomatic carrier state, which progresses to clinical AIDS in about 50% of infected individuals within 10 years after seroconversion. Serological evidence of HIV infection may be obtained by testing for HIV antigens or antibodies. Antigen can generally be detected during the acute phase and during the symptomatic phase of AIDS only. Antibodies to HIV can be detected throughout virtually the total infection period, starting at or shortly after the acute phase and lasting until the end stage of AIDS. Therefore, the use of highly sensitive antibody assays is the primary approach in

in serodiagnosis of HIV infection[3].

Over the past two decades, a number of important advances have been made in the area of HIV testing[4]. Serologic methods which use recombinant[5,6,7] antigens have been developed to offer advantages in all testing settings. Among such advances, are the rapid tests[8] that can be performed on fingertip blood specimen and require only minimal procedural steps.

PRINCIPLE OF THE ASSAY

Wantai Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens corresponding to HIV-1 (gp120, gp41) and HIV-2 (gp-36) are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1+2 antigens are bound at the Test Zone (T) and antibodies are bound at the Control Zone (C). When the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in specimen, HIV 1/2 antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by the HIV 1+2 antigens generating a visible red line. If there is no HIV-1 or -2 antibody in specimen, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the antibodies aggregating in a red line, which indicates the validity of the test.

COMPONENTS

Components	WJ-1810	WJ-1850	WJ-1810E	WJ-1850E
Test Cassette	x10	x50	x10	x50
Diluent Buffer	x1 vial	x3 vials	x1 vial	x3 vials
Safety Lancet			x10	x50
Disposable Pipette			x10	x50
Alcohol Pad			x10	x50

Test Cassette:
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) in white plastic cassette packed in foil pouch. Single use only.

Diluent Buffer (Code "0", DIL | SPE):
3ml per vial. The Diluent Buffer can be stored at room temperature.
Stable for 18 months after opening.

Others:
- Instructions for use
- Safety lancets
- Alcohol pads containing 70% isopropyl alcohol
- Disposable pipettes for delivering of volume of 40µl - 50µl per drop. **Do not use the lancet if the cap is already pulled off.**

Materials required but not provided:
Clock or timer, specimen collection container, centrifuge, biohazard waste container.

SPECIMEN COLLECTION

Whole Blood specimen: Ask the person to clean hands. Choose a puncture site on his or her fingertip. Clean the fingertip with Alcohol Pad. Place the Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against the fingertip. **Wipe away the first drop of blood with sterile gauze or cotton.** Using the disposable specimen transfer device provided within the test kit to collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. **Do not test whole blood specimens if older than 3 days.**

Serum / Plasma specimen: Fresh serum or plasma specimen can be used. No special patient preparation required.

- **Plasma:** Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture. Separate the plasma by centrifugation.
- **Serum:** Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

Any visible particulate matters in the specimen should be removed by centrifugation or filtration.

Avoid the use of hemolytic, turbid, microorganism contaminated specimens or specimens stored for over 30 days at 2-8°C.

Store specimen at 2-8°C. Specimens not required for assay within 3 days should be stored frozen (-20°C or lower).

Avoid specimen deterioration by multiple freeze-thaw cycles.

STORAGE AND STABILITY

The Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) can be stored at room temperature (2-30°C, do not freeze!) for 18 months from the date of manufacture.

PRECAUTIONS AND SAFETY

Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is for *In Vitro Use Only* IVD

FOR PROFESSIONAL USE ONLY

1. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
2. **Once you have taken the cassette out of the pouch, carry out your testing as early as possible (no more than 20 minutes) to avoid cassette becoming moist.** The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
3. Make sure that the test is not expired (EXP Date indicated on the kit box).
4. If an automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. **Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.**
5. Do not modify the test procedure.
6. Do not reuse the test cassettes, lancets and pipettes. Autoclave before disposal.
7. A test giving an invalid result should be repeated.
8. Always add accurate volume of specimen.
9. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
10. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
11. Always interpret the results under good light conditions to avoid misreading of the test results.
12. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
13. Use automatic pipette, or the supplied disposable pipettes for the transfer of specimens onto the test cassette. If disposable pipettes are not provided, use pipettes from alternative suppliers which are capable of delivering of volume of 40µl-50µl per drop.

ASSAY PROCEDURE

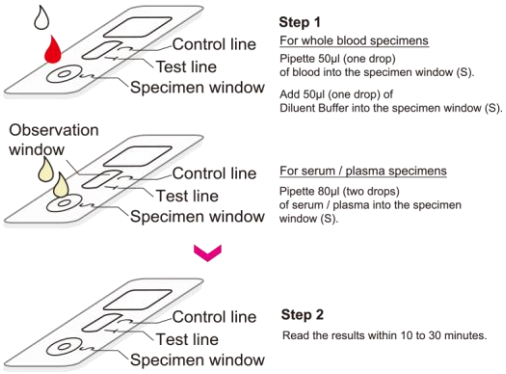
Place the cassette on flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately (within 20 minutes) after opening.

If specimen stored at 2-8°C or at -20°C are to be tested, such specimen should be completely thawed and equilibrated at room temperature first. All specimens and cassettes should be properly labeled

and identified to avoid mixing up of testing results.

1. **For whole blood specimens:** Open the pouch and add **50µl** (or **one drop** using the provided pipette) of whole blood into the specimen window (S). Immediately add **one drop** diluent buffer into the specimen window.
2. **For serum / plasma specimens:** Open the pouch and add **80µl** (or **two drops** using the provided pipette) of serum or plasma into the specimen window (S).
   Avoid dropping specimen or buffer in the observation window. Do not allow the specimen to overflow.
3. **Read the results from 10 minutes after specimen and buffer loading, to maximum of 30 minutes. Do not read the results after 30 minutes.**

PROCEDURE DIAGRAM

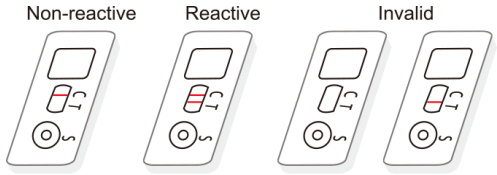


RESULTS

Quality Control: One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If no red line appears, the test is invalid - discard the test and repeat with new specimen and new cassette.

Reactive Results: One red line appears within 10 to 30 minutes next to the Test Zone (T) which indicates that antibodies to HIV 1+2 have been detected through using this test.

Non-reactive Results: No red line appears within 30 minutes next to the Test Zone (T) which indicates that no antibodies to HIV 1+2 have been detected with this test. However, this does not exclude the possibility from infection with HIV.



The reactive result obtained with Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) alone cannot be the final diagnosis of HIV. Any reactive results must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all reactive specimens with other tests is required to confirm any reactive result.

PERFORMANCE DATA

1. In a clinical evaluation of the performance of Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) conducted in China between 2002 and 2003, using 2657 confirmed negative and 670 positive specimens, sensitivity was 99.40% (666/670) and specificity was 100% (2657/2657).
2. Two international studies conducted in 2012 demonstrated sensitivity of 100% (200/200), and specificity of 99.20% (992/1000), and sensitivity of 100% (424/424) and specificity of 98.48% (648/658) respectively.
3. Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. holds data to demonstrate that the test reacts positive to HIV-1 subtypes A, B, C, D, F, G, H, J, K, HIV-1CRF01-AE, HIV-1 subtype-O*, and HIV-2. The test can detect all HIV-1 subtypes and HIV-2 contained in 1st International Reference Panel for anti-HIV [NIBSC code 02/210].
4. Results from HIV seroconversion panels: The mean seroconversion index on 8 different seroconversion panels which have been tested was 0.5 specimens compared to the benchmark assay Enzygnost Anti-HIV 1/2 Plus EIA. Thus the test detected HIV-1/2 antibodies on average, 0.5 specimens later than the benchmark assay. The seroconversion performance of Wantai's test was also compared against another, well-established on the market rapid test for detection of antibodies against HIV-1/2. Among the 8 tested panels, Wantai and the reference test showed equal detection on six panels, while the reference test showed better detection in two of the panels included in this study.

LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV, or late AIDS may not be detectable. For reactive results, line intensity cannot be used to evaluate the anti-HIV antibody levels. A test giving an invalid result should be repeated. Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) does not differentiate between recognition of HIV-1 antibodies and HIV-2 antibodies.
2. *The Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) has not been sufficiently validated for HIV-1 subtype O.
3. If after retesting of the initially reactive specimen, the test results are non-reactive, these specimen should be considered as non-repeatable (false reactive) and interpreted as non-reactive. As with many very sensitive rapid diagnostic tests, false reactive results can occur due to the several reasons, most of which are related but not limited to the quality of the specimen, operator error, and exposition of the test to humidity. For more information please contact Beijing Wantai technical support for further assistance.
4. Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is intended ONLY for testing of individual specimen. Do not use it for testing of cadaver specimen, saliva, urine or other body fluids, or pooled (mixed) blood.
5. Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is a qualitative assay and the results cannot be used to measure antibodies concentrations.

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