# WHO Prequalification of Diagnostics Programme

# PUBLIC REPORT

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

# Number: PQDx 0005-005-00

**Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)**[1] with product codes WJ-1810, WJ-1810E, WJ-1850, WJ-1850E, WJ-1810EL, WJ-1850EL, WJ-18S10EL, WJ-18S50EL, WJ-18S10, WJ-18S50, WJ-18S10E, WJ-18S50E, WJ-18S10ELC and WJ-18S50ELC manufactured by **Beijing Wantai Biological Pharmacy Enterprise Co., Ltd**, **Rest-of-World regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 15 February 2016.

## Summary of prequalification status for Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)

| | Date | Outcome |
|---|---|---|
| **Prequalification listing** | 15 February 2016 | listed |
| **Dossier assessment** | 28 August 2015 | MR |
| **Site inspection(s) of quality management system** | 24 April 2015 | MR |
| **Product performance evaluation** | 6 January 2014 | MR |

MR: Meets Requirements

[1] The product was originally submitted under the name *Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold)*. It was later renamed as *Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)*.

**Report amendments and/or product changes**

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

| Version | Summary of amendment | Date of report amendment |
|---|---|---|
| 3.0 | Changes made to materials supplied with the IVD (addition of alcohol swabs to test kit) and, therefore, changes to labelling (including the instructions for use and outer kit box) for WJ-1810E and WJ-1850E | 26 May 2016 |
| 4.0 | Adding a new type of safety lancet while also preserving the current lancet that has been prequalified. Keeping the two lancet types will offer more options to the end users. Product codes for the new lancet type: WJ-1810EL, WJ-1850EL.<br>The manufacturer submitted a change request for «Introducing a new version of the product wherein the IFU, change results reading-time description from: "read the results from 10 minutes after specimen and buffer loading to a maximum of 30 minutes. Do not read the results after 30 minutes",<br>to: "read the results at 15 minutes, but no later than 20 minutes". Two new product codes with this reading time were added, WJ-18S10EL and WJ-18S50EL. | 3 July 2020 |
| 5.0 | The amendment was due to the addition of two kit configurations containing additional Capillary Tubes with product codes WJ-18S10ELC and WJ-18S50ELC. | 19 July 2024 |

**Intended use:**[2]

According to the claim of Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, *"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*

[2] This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.

*the acquired immunodeficiency syndrome (AIDS). The product is not intended for blood donor screening.*"

**Assay description:**

According to the claim of Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, "*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 bond at the Test Zone (T) and antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, 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) zone where they are captured by the HIV 1+2 antigens generating a visible red line. If there are no HIV 1 or 2 antibodies in sample, 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.*

*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. Any reactive specimen should be confirmed by another methodology*"

**Test kit contents**

| Component | 10 Test/kit (T/k) ( WJ-1810E)* | 10 T/k ( WJ-1810)* | 50 T/k (WJ-1850E)* | 50 T/k (WJ-1850) * | 10 T/k (WJ-1810EL) # | 50 T/k (WJ-1850EL) # | 10 T/k (WJ-18S10EL) * | 50 T/k (WJ-18S50EL)* | 10 T/k (WJ-18S10ELC) * | 50 T/k (WJ-18S10ELC)* |
|---|---|---|---|---|---|---|---|---|---|---|
| **Test cassettes**, individually packed in foil pouch | 10 | 10 | 50 | 50 | 10 | 50 | 10 | 50 | 10 | 50 |
| **Instructions for use** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Diluent buffer** | 1x 3ml bottle | 1x 3ml bottle | 3x 3ml bottles | 3x 3ml bottles | 1 | 3x 3ml bottles | 1 | 3x 3ml bottles | 1 | 3x 3ml bottles |
| **Safety Lancet**, single-use disposable safety lancets | 10 (None retractable) | N/A | 50 (none retractable) | N/A | 10 (retractable) | 50 (retractable) | 10 (retractable) | 50 (retractable) | 10 (retractable) | 50 (retractable) |
| **Disposable Pipette**, plastic, intended to deliver 40 -50µl per drop | 10 | N/A | 50 | N/A | 10 | 50 | 10 | 50 | 10 | 50 |
| **Capillary Tube (Rubber Head)** | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | 10 | 50 |
| **Alcohol swab**, 70% isopropyl alcohol | 10 | N/A | 50 | N/A | 10 | 50 | 10 | 50 | 10 | 50 |

**# Reading time: do not read results after 30 minutes.** *** Reading time: read the results at 15 minutes but not later than 20 minutes.**

**Materials required but not provided:**

- Clock or timer
- specimen collection container
- centrifuge
- biohazard waste container.

**Storage:**

The test kit should be stored at 2°C to 30 °C.

**Shelf-life**:

18 months

**Warnings/limitations:**

Refer to the latest version of the manufacturer's instructions for use.

**Prioritization for prequalification**

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd submitted an application for prequalification of Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device). Based on the established eligibility criteria, Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) was given priority for prequalification assessment.

## Product dossier assessment

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd submitted a product dossier for Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal report on the screening and assessment of a product dossier (PQDx_009 v2).

**Commitment for prequalification:**

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd committed to perform in-house testing on performance panels (including HIV-O specimens). The commitment was closed.

Based on the product dossier screening and assessment findings, the product dossier for Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) meets WHO prequalification requirements.

## Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (No. 31 Life Science Park Road, Changping District, 102206, Beijing, China) of Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) in December 2014 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v1). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities to the quality management system found at the time of the inspection were accepted 24 April 2015.

## Product performance evaluation

Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold)[3] (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.) was evaluated by WHO in the third quarter of 2012 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) is an immunochromatographic assay for the detection of HIV-1/2 antibodies in human whole blood, serum and plasma specimens. A volume of 80 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 1079 clinically-derived specimens, we found an initial sensitivity (95% CI) of 99.76% (98.7% - 100%) and an initial specificity (95% CI) of 98.33% (97.0% - 99.2%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.1% - 100%) and the final specificity (95% CI) was 98.48% (97.2% - 99.3%) compared to

[3] The product was later renamed *Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)*

the reference assays. Lot to lot variation was acceptable with the exception of one dilution series for which there was a 2-fold difference between lots.

For eight seroconversion panels, Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) detected on average 0.5 specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics).

For the mixed titer panel, Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], Anti-human Immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) correctly classified all specimens.

In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.09%. The invalid rate was 0.09%.

# Labelling

1. **Labels**
2. **Instructions for use**

# 1. Labels

## 1.1 Shipping box label

Beijing Wantai Biological Pharmacy Enterprise

Product Cat.No/ Name:

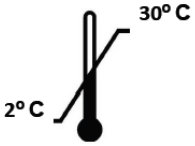
LOT:

EXP:

QUANTITY:

**SHIP TO:**

Carton No.




## 1.2 Kit box label for WJ-1810, WJ-1810E

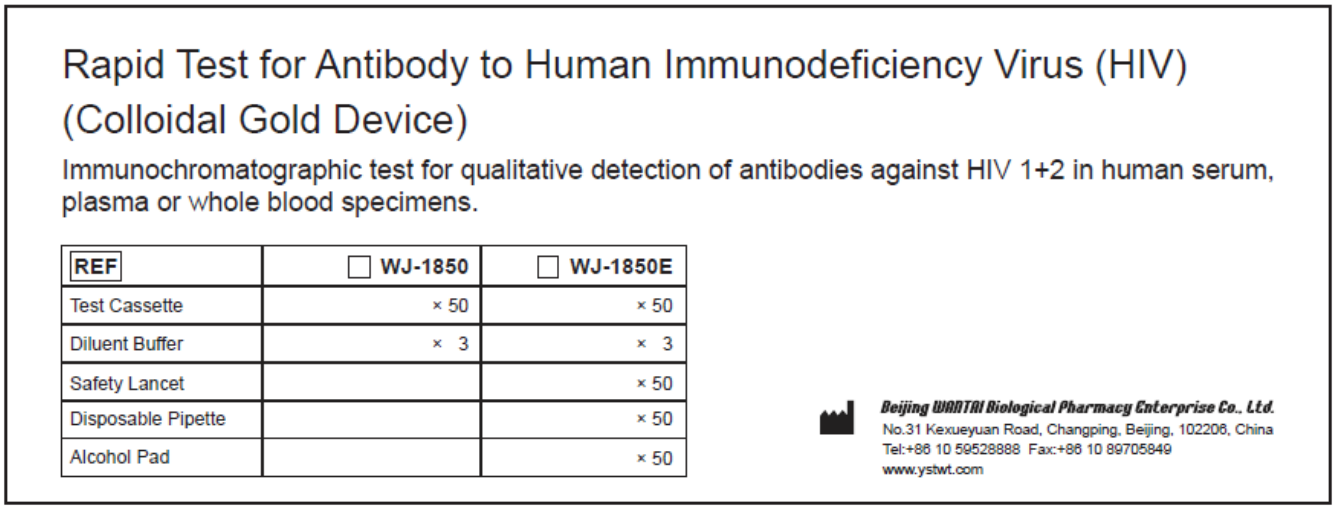
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV)
(Colloidal Gold Device)

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-1810 | ☐ WJ-1810E |
|---|---|---|
| Test Cassette | x 10 | x 10 |
| Diluent Buffer | x 1 | x 1 |
| Safety Lancet | | x 10 |
| Disposable Pipette | | x 10 |
| Alcohol Pad | | x 10 |

Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.
No.31 Kexueyuan Road, Changping, Beijing, 102206, China
Tel:+86 10 59528888 Fax:+86 10 80705849
www.ystwt.com

### 1.3 Kit box label for WJ-1850, WJ-1850E



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-1850 | ☐ WJ-1850E |
|---|---|---|
| Test Cassette | × 50 | × 50 |
| Diluent Buffer | × 3 | × 3 |
| Safety Lancet | | × 50 |
| Disposable Pipette | | × 50 |
| Alcohol Pad | | × 50 |

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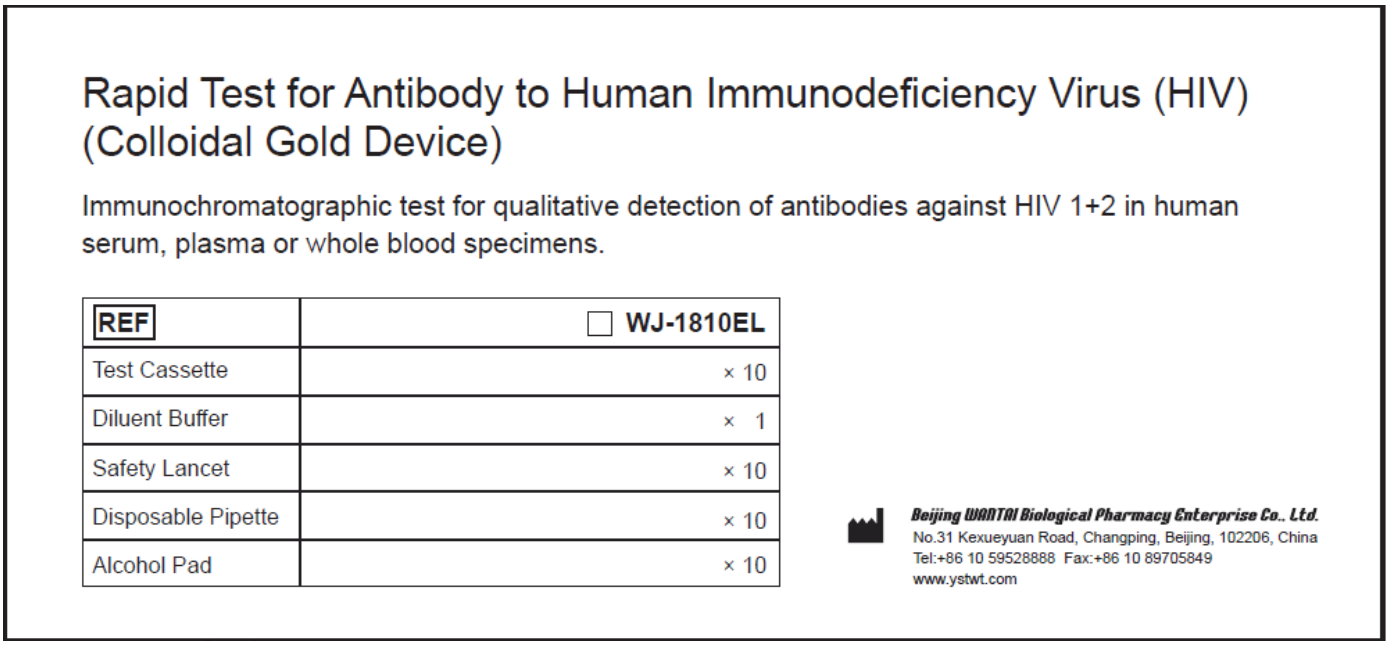
### 1.4 Kit box label for WJ-1810EL



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-1810EL |
|---|---|
| Test Cassette | × 10 |
| Diluent Buffer | × 1 |
| Safety Lancet | × 10 |
| Disposable Pipette | × 10 |
| Alcohol Pad | × 10 |

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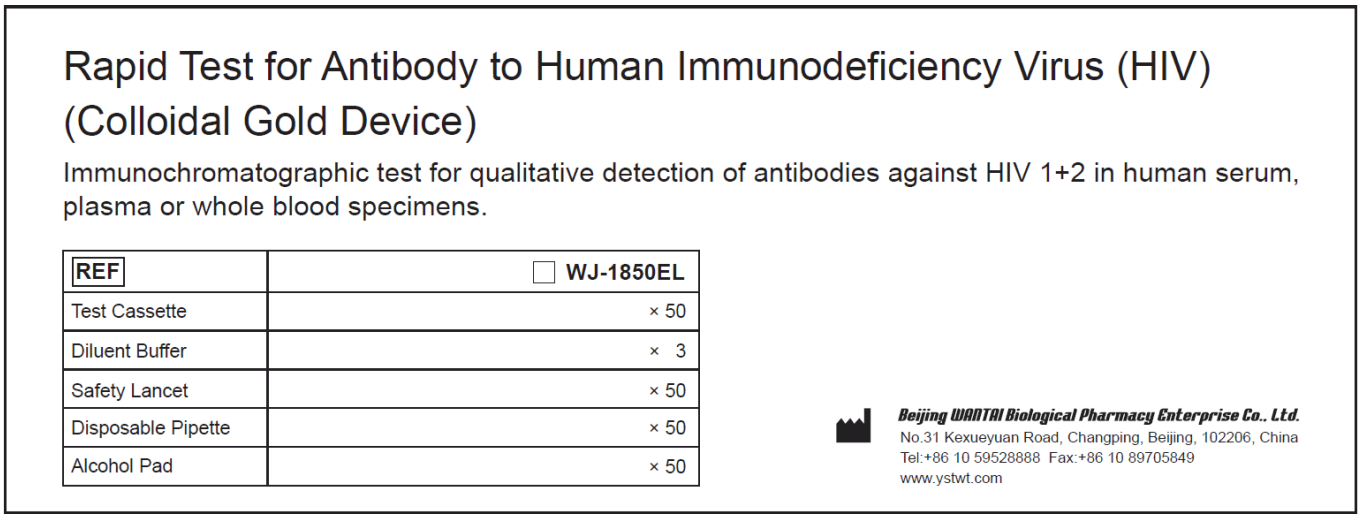
**1.6 Kit box label for WJ-1850EL**



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-1850EL |
|---|---|
| Test Cassette | × 50 |
| Diluent Buffer | × 3 |
| Safety Lancet | × 50 |
| Disposable Pipette | × 50 |
| Alcohol Pad | × 50 |

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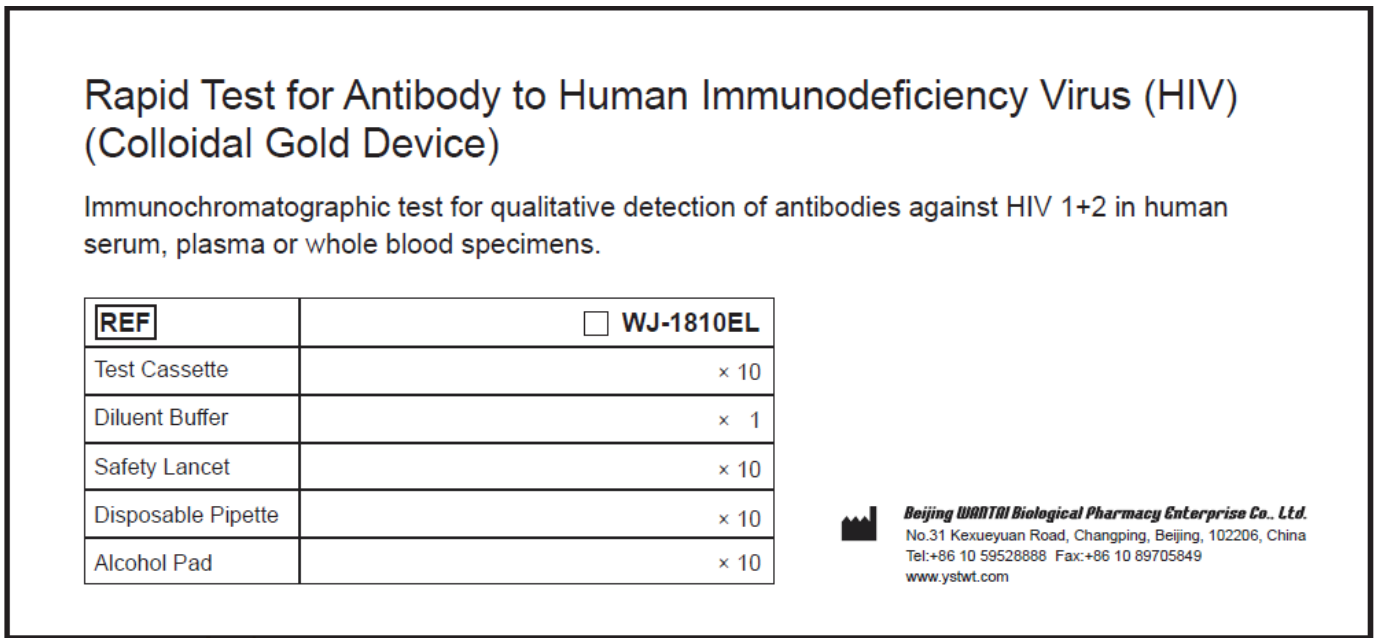
**1.7 Kit box label for WJ-18S10EL**



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-1810EL |
|---|---|
| Test Cassette | × 10 |
| Diluent Buffer | × 1 |
| Safety Lancet | × 10 |
| Disposable Pipette | × 10 |
| Alcohol Pad | × 10 |

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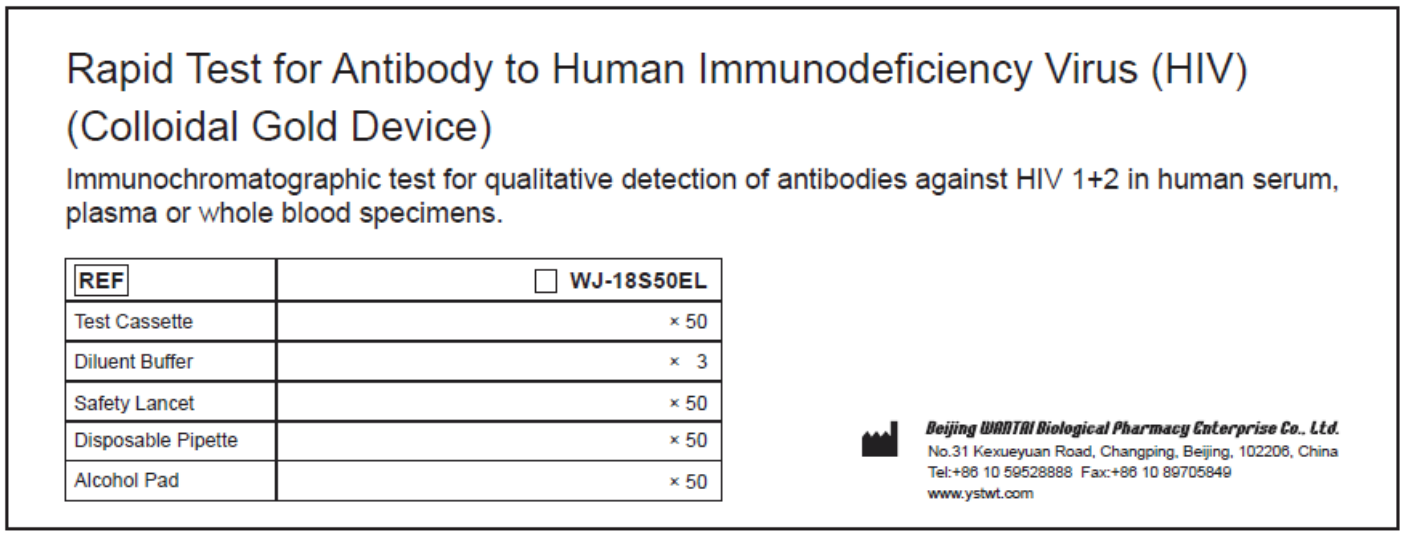
**1.8 Kit box label for WJ-18S50EL**



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | ☐ WJ-18S50EL |
|---|---|
| Test Cassette | × 50 |
| Diluent Buffer | × 3 |
| Safety Lancet | × 50 |
| Disposable Pipette | × 50 |
| Alcohol Pad | × 50 |

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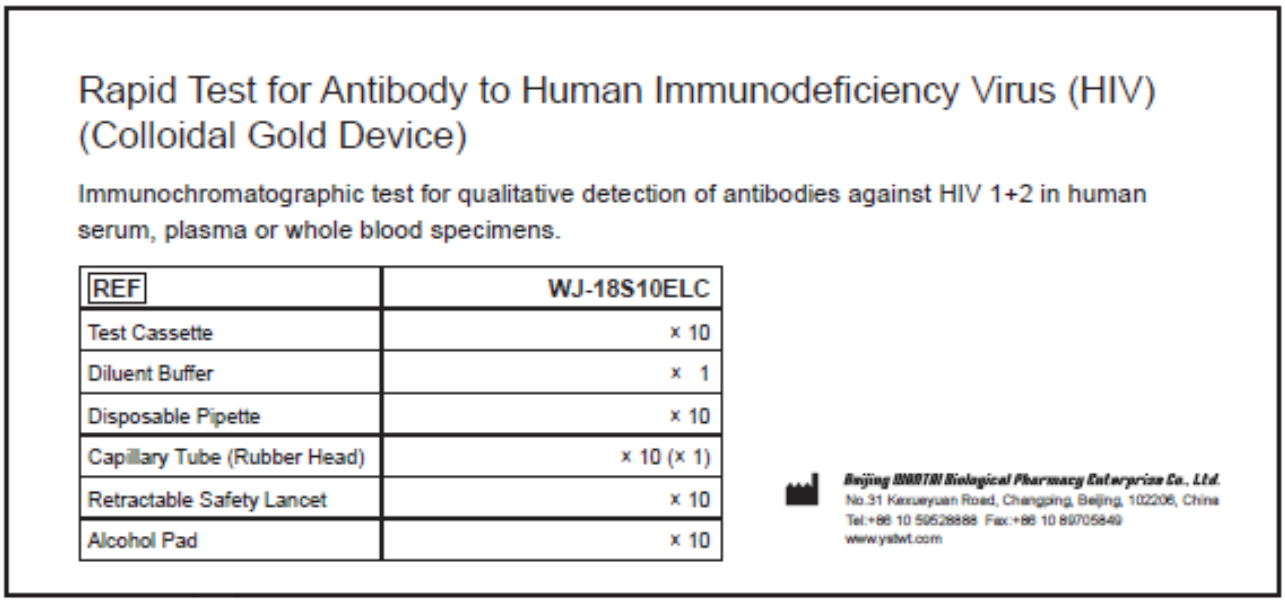
**1.9 Kit box label for WJ-18S10ELC**



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

Immunochromatographic test for qualitative detection of antibodies against HIV 1+2 in human serum, plasma or whole blood specimens.

| REF | WJ-18S10ELC |
|---|---|
| Test Cassette | × 10 |
| Diluent Buffer | × 1 |
| Disposable Pipette | × 10 |
| Capillary Tube (Rubber Head) | × 10 (× 1) |
| Retractable Safety Lancet | × 10 |
| Alcohol Pad | × 10 |

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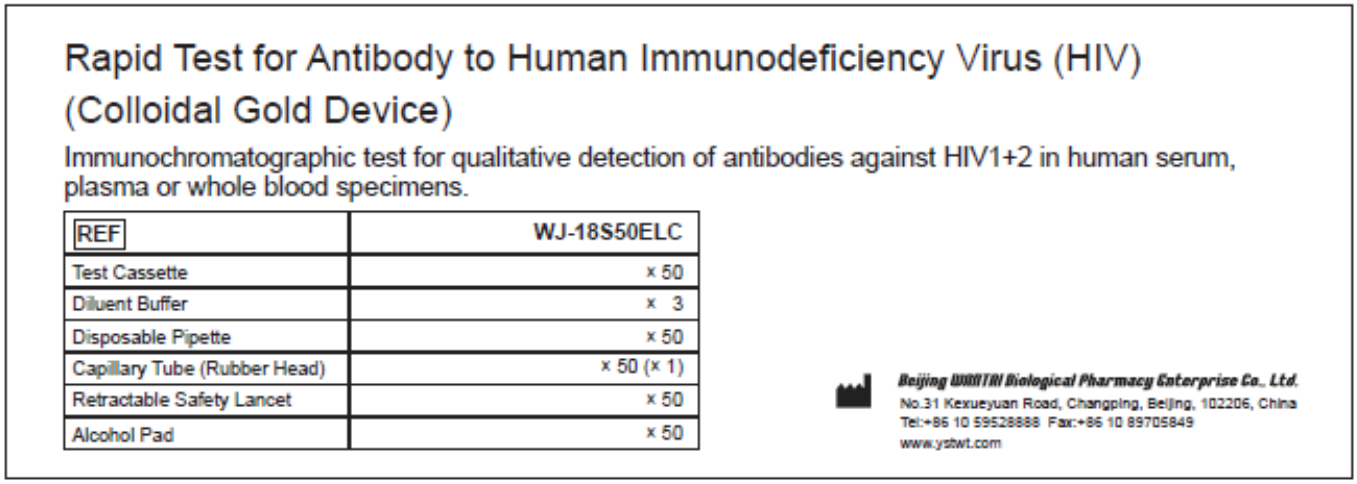
**1.10 Kit box label for WJ-18S50ELC**



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

Immunochromatographic test for qualitative detection of antibodies against HIV1+2 in human serum, plasma or whole blood specimens.

| REF | WJ-18S50ELC |
|---|---|
| Test Cassette | x 50 |
| Diluent Buffer | x 3 |
| Disposable Pipette | x 50 |
| Capillary Tube (Rubber Head) | x 50 (x 1) |
| Retractable Safety Lancet | x 50 |
| Alcohol Pad | x 50 |

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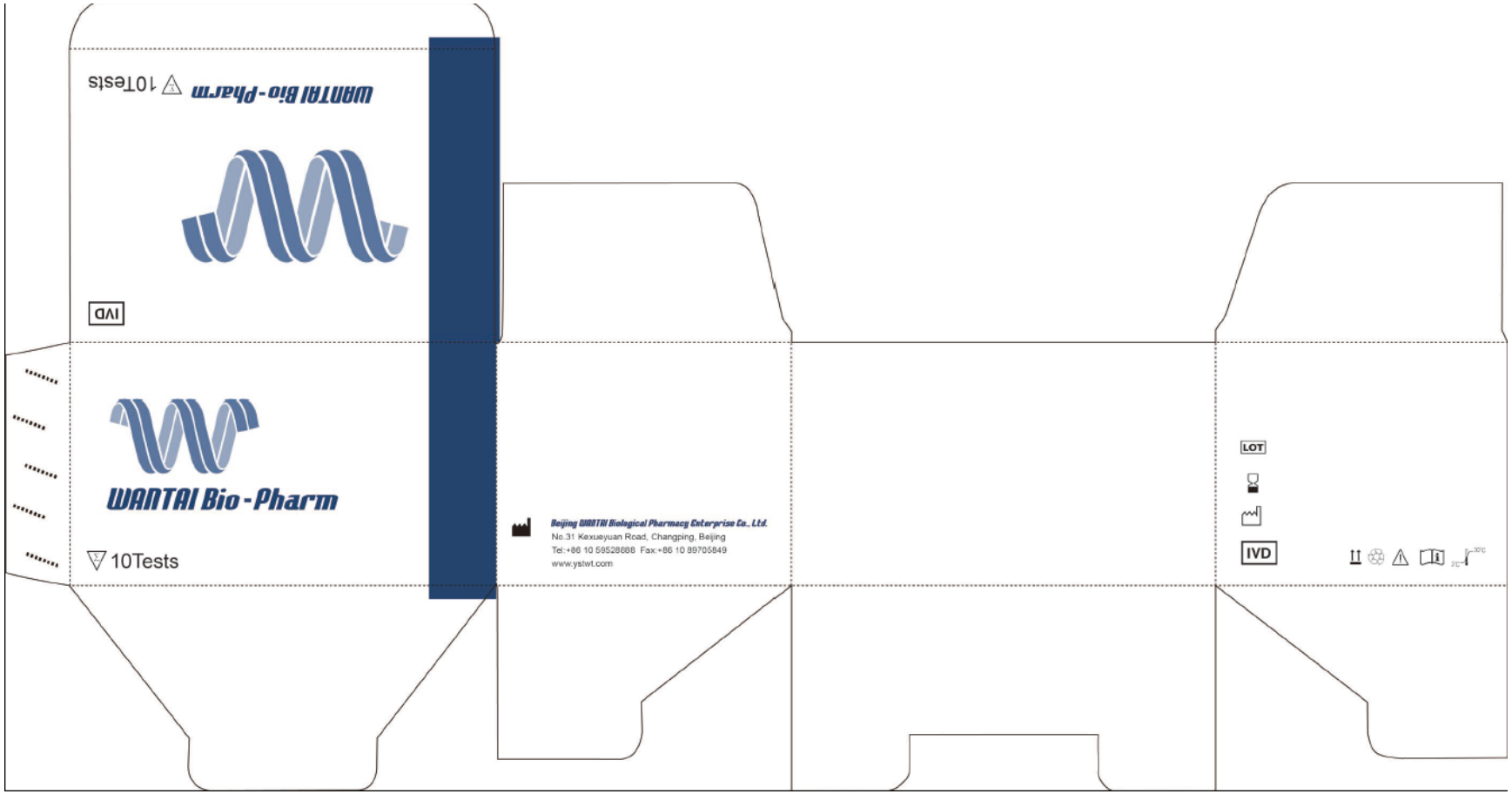
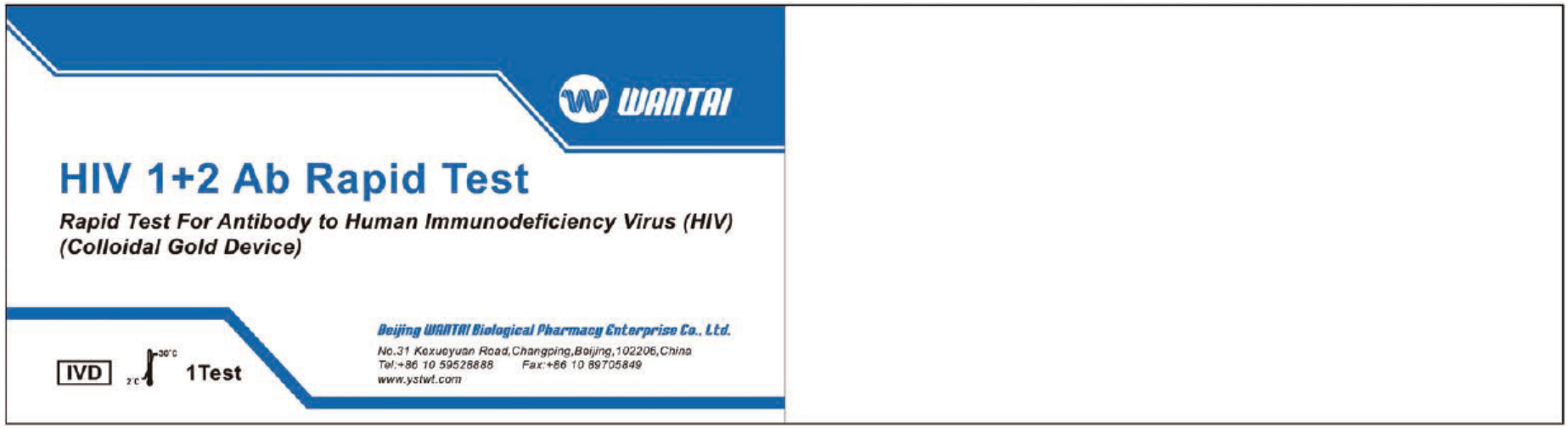
**1.11 Box label for WJ-1850, WJ-1850E, WJ-1850EL, WJ-18S50EL, and WJ-18S50ELC.**

**1.12 Box label for WJ-1810, WJ-1810E, WJ-1810EL, WJ-18S10EL, and WJ-18S10ELC**



**1.13 Pouch label for WJ-1810, WJ-1810E, WJ-1810EL, WJ-18S10EL, WJ-18S10ELC WJ-1850, WJ-1850E, WJ-1850EL, WJ-18S50EL, and WJ-18S50ELC**



## 2. Instructions for use[4]

[4] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

# 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-18S10, WJ-18S50, WJ-18S10E, WJ-18S50E

### 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). The product is not intended for blood donor screening.

### 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 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 capillary 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 anti-HIV 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-18S10 | WJ-18S50 | WJ-18S10E | WJ-18S50E |
|---|---|---|---|---|
| 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

**Capillary whole blood specimen:** Ask the person to clean hands. Allow the finger to dry before pricking. Choose the finger less callused for pricking. 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.** Use the disposable pipette provided within the test kit to collect blood from the puncture site.

**Venous whole blood specimen:** Draw blood following laboratory procedure to obtain venous whole 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 matter 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 (not 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.
5. **Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.**
6. Do not modify the test procedure.
7. Do not reuse the test cassettes, lancets and pipettes. Dispose waste as per national standard or regulatory guideline.
8. A test giving an invalid result should be repeated.
9. Always add sufficient volume of specimen.
10. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
11. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
12. Always interpret the results under good light conditions to avoid misreading of the test results.
13. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
14. 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

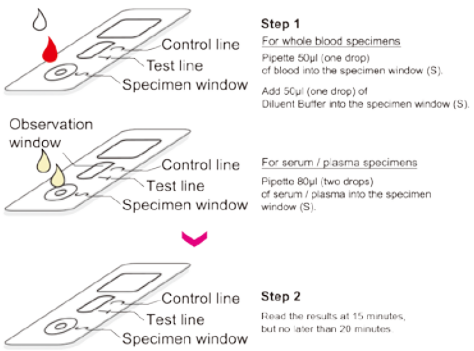
**Place the cassette on flat surface. Before opening,**

**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 capillary whole blood specimens:** Add **50µl** (or **one drop** using the provided disposable pipette) of capillary whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For venous whole blood specimens:** Invert gently the blood collection tube with the blood specimen at least 4 times to make a homogeneous mixture. Add **50µl** (or **one drop** using the provided disposable pipette) of venous whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For serum / plasma specimens:** Add **80µl** (or **two drops** using the provided disposable 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.**
2. **Read the results at 15 minutes, but no later than 20 minutes.**

## PROCEDURE DIAGRAM

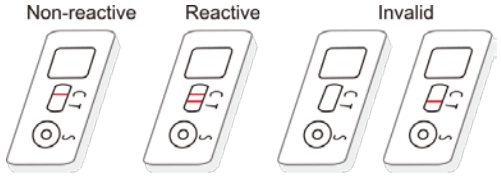



## RESULTS

**Quality Control:** One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If red line does not appear at the Control Zone, the test is invalid - discard the test and repeat with new specimen and new cassette.

**Reactive Results:** One red line appears at 15 to 20 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 at 15 to 20 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 of 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 serum or plasma 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.
5. Serum to plasma and whole blood equivalence was demonstrated on 25 positive and 25 negative serum / EDTA-K2 plasma – whole blood / EDTA-K3 plasma – whole blood / sodium heparin plasma – whole blood / sodium citrate plasma – whole blood couples. Whole blood obtained by fingerprick and venipuncture was validated on 25 positive and 25 negative fingerprick whole blood / venous whole blood couples. No complement interference was observed on 25 same day fresh serum samples spiked with a small amount of an HIV positive sample.
6. 200 hospitalized patients and 200 samples of pregnant women (including 20 samples of multipara) were tested and were all negative on the Wantai test.
7. 99/100 samples containing potentially cross reactive substances were negative on the Wantai test. One out of the 5 Malaria positive samples was false reactive with Wantai test.

| | Non-reactive | Reactive |
|---|---|---|
| Anti-HBc positive | 15 | 0 |
| Anti-HBs positive | 15 | 0 |
| Anti-HCV positive | 10 | 0 |
| Anti-HTLV I/II positive | 10 | 0 |
| Anti-HEV positive | 10 | 0 |
| Anti-HAV positive | 5 | 0 |
| Rheumatoid factor positive | 10 | 0 |
| CMV IgM Ab positive | 5 | 0 |
| EBV IgM Ab positive | 5 | 0 |
| Malaria positive | 4 | 1 |
| Syphilis positive | 5 | 0 |
| Herpes positive | 5 | 0 |

## LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure 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 using Wantai test, 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 whole blood, serum or plasma. 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.

## BIBLIOGRAPHY


1. Gallo, R.C., Saluahuddin, S.Z., Popovic, M., et al. (1984) Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224: 500-503.
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8. Granade, T., 2005. Use of rapid HIV antibody testing for controlling the HIV pandemic. Expert Rev. Anti Infect. Ther. 3, 957-969.



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**IFU VER: 20/01 (Jun.30,2020)**

# 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). The product is not intended for blood donor screening.

### 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 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 capillary 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 anti-HIV 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

**Capillary whole blood specimen:** Ask the person to clean hands. Allow the finger to dry before pricking. Choose the finger less callused for pricking. 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.** Use the disposable pipette provided within the test kit to collect blood from the puncture site.

**Venous whole blood specimen:** Draw blood following laboratory procedure to obtain venous whole 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 matter 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 (not 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.
5. **Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.**
6. Do not modify the test procedure.
7. Do not reuse the test cassettes, lancets and pipettes. Dispose waste as per national standard or regulatory guideline.
8. A test giving an invalid result should be repeated.
9. Always add sufficient volume of specimen.
10. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
11. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
12. Always interpret the results under good light conditions to avoid misreading of the test results.
13. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
14. 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

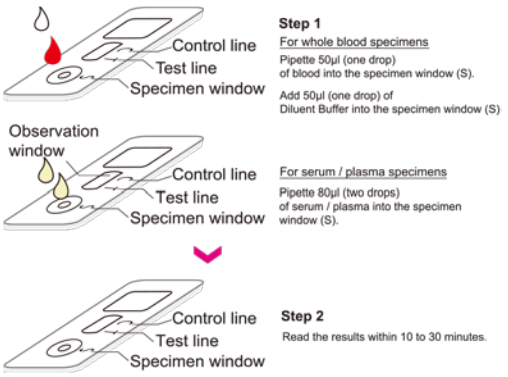
**Place the cassette on flat surface. Before opening,**

**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 capillary whole blood specimens:** Add **50µl** (or **one drop** using the provided disposable pipette) of capillary whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For venous whole blood specimens:** Invert gently the blood collection tube with the blood specimen at least 4 times to make a homogeneous mixture. Add **50µl** (or **one drop** using the provided disposable pipette) of venous whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For serum / plasma specimens:** Add **80µl** (or **two drops** using the provided disposable 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.**
2. **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

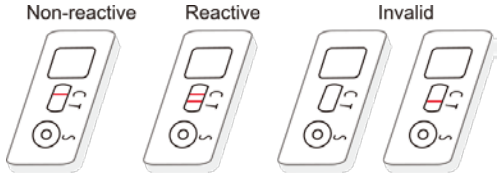



## RESULTS

**Quality Control:** One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If red line does not appear at the Control Zone, 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 of 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 serum or plasma 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.
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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.
5. Serum to plasma and whole blood equivalence was demonstrated on 25 positive and 25 negative serum / EDTA-K2 plasma – whole blood / EDTA-K3 plasma – whole blood / sodium heparin plasma – whole blood / sodium citrate plasma – whole blood couples. Whole blood obtained by fingerprick and venipuncture was validated on 25 positive and 25 negative fingerprick whole blood / venous whole blood couples. No complement interference was observed on 25 same day fresh serum samples spiked with a small amount of an HIV positive sample.
6. 200 hospitalized patients and 200 samples of pregnant women (including 20 samples of multipara) were tested and were all negative on the Wantai test.
7. 99/100 samples containing potentially cross reactive substances were negative on the Wantai test. One out of the 5 Malaria positive samples was false reactive with Wantai test.

| | Non-reactive | Reactive |
|---|---|---|
| Anti-HBc positive | 15 | 0 |
| Anti-HBs positive | 15 | 0 |
| Anti-HCV positive | 10 | 0 |
| Anti-HTLV I/II positive | 10 | 0 |
| Anti-HEV positive | 10 | 0 |
| Anti-HAV positive | 5 | 0 |
| Rheumatoid factor positive | 10 | 0 |
| CMV IgM Ab positive | 5 | 0 |
| EBV IgM Ab positive | 5 | 0 |
| Malaria positive | 4 | 1 |
| Syphilis positive | 5 | 0 |
| Herpes positive | 5 | 0 |

## LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure 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 using Wantai test, 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 whole blood, serum or plasma. 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.

## BIBLIOGRAPHY


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**IFU VER: 20/01 (Jun.30,2020)**

# 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-18S10EL, WJ-18S50EL

### 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). The product is not intended for blood donor screening.

### 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 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 capillary 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 anti-HIV 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-18S10EL | WJ-18S50EL |
|---|---|---|
| Test Cassette | x10 | x50 |
| Diluent Buffer | x1 vial | x3 vials |
| Retractable 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
- Retractable 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

**Capillary whole blood specimen:** Ask the person to clean hands. Allow the finger to dry before pricking. Choose the finger less callused for pricking. Choose a puncture site on his or her fingertip. Clean the fingertip with Alcohol Pad. Place the Retractable 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.** Use the disposable pipette provided within the test kit to collect blood from the puncture site.

**Venous whole blood specimen:** Draw blood following laboratory procedure to obtain venous whole 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 matter 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 (not 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.
5. **Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.**
6. Do not modify the test procedure.
7. Do not reuse the test cassettes, lancets and pipettes. Dispose waste as per national standard or regulatory guideline.
8. A test giving an invalid result should be repeated.
9. Always add sufficient volume of specimen.
10. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
11. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
12. Always interpret the results under good light conditions to avoid misreading of the test results.
13. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
14. 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

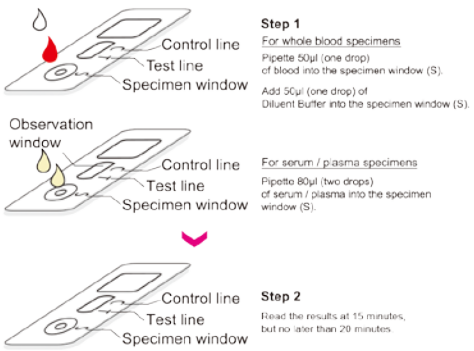
**Place the cassette on flat surface. Before opening,**

**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 capillary whole blood specimens:** Add **50µl** (or **one drop** using the provided disposable pipette) of capillary whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For venous whole blood specimens:** Invert gently the blood collection tube with the blood specimen at least 4 times to make a homogeneous mixture. Add **50µl** (or **one drop** using the provided disposable pipette) of venous whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
   **For serum / plasma specimens:** Add **80µl** (or **two drops** using the provided disposable 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.**
2. **Read the results at 15 minutes, but no later than 20 minutes.**

## PROCEDURE DIAGRAM

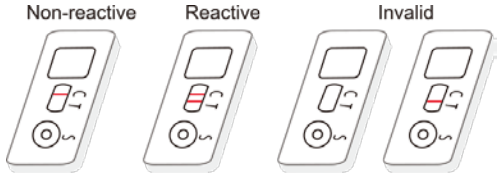



## RESULTS

**Quality Control:** One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If red line does not appear at the Control Zone, the test is invalid - discard the test and repeat with new specimen and new cassette.

**Reactive Results:** One red line appears at 15 to 20 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 at 15 to 20 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 of 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 serum or plasma 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.
5. Serum to plasma and whole blood equivalence was demonstrated on 25 positive and 25 negative serum / EDTA-K2 plasma – whole blood / EDTA-K3 plasma – whole blood / sodium heparin plasma – whole blood / sodium citrate plasma – whole blood couples. Whole blood obtained by fingerprick and venipuncture was validated on 25 positive and 25 negative fingerprick whole blood / venous whole blood couples. No complement interference was observed on 25 same day fresh serum samples spiked with a small amount of an HIV positive sample.
6. 200 hospitalized patients and 200 samples of pregnant women (including 20 samples of multipara) were tested and were all negative on the Wantai test.
7. 99/100 samples containing potentially cross reactive substances were negative on the Wantai test. One out of the 5 Malaria positive samples was false reactive with Wantai test.

| | Non-reactive | Reactive |
|---|---|---|
| Anti-HBc positive | 15 | 0 |
| Anti-HBs positive | 15 | 0 |
| Anti-HCV positive | 10 | 0 |
| Anti-HTLV I/II positive | 10 | 0 |
| Anti-HEV positive | 10 | 0 |
| Anti-HAV positive | 5 | 0 |
| Rheumatoid factor positive | 10 | 0 |
| CMV IgM Ab positive | 5 | 0 |
| EBV IgM Ab positive | 5 | 0 |
| Malaria positive | 4 | 1 |
| Syphilis positive | 5 | 0 |
| Herpes positive | 5 | 0 |

## LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure 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.
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4. Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is intended ONLY for testing of individual whole blood, serum or plasma. 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.

## BIBLIOGRAPHY


1. Gallo, R.C., Saluahuddin, S.Z., Popovic, M., et al. (1984) Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224: 500-503.
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8. Granade, T., 2005. Use of rapid HIV antibody testing for controlling the HIV pandemic. Expert Rev. Anti Infect. Ther. 3, 957-969.



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**IFU VER: 20/01 (Jun.30,2020)**

# 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-1810EL, WJ-1850EL

### 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). The product is not intended for blood donor screening.

### 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 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 capillary 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 anti-HIV 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-1810EL | WJ-1850EL |
|---|---|---|
| Test Cassette | x10 | x50 |
| Diluent Buffer | x1 vial | x3 vials |
| Retractable 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
- Retractable 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

**Capillary whole blood specimen:** Ask the person to clean hands. Allow the finger to dry before pricking. Choose the finger less callused for pricking. Choose a puncture site on his or her fingertip. Clean the fingertip with Alcohol Pad. Place the Retractable 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.** Use the disposable pipette provided within the test kit to collect blood from the puncture site.

**Venous whole blood specimen:** Draw blood following laboratory procedure to obtain venous whole 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 matter 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 (not 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.
5. **Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.**
6. Do not modify the test procedure.
7. Do not reuse the test cassettes, lancets and pipettes. Dispose waste as per national standard or regulatory guideline.
8. A test giving an invalid result should be repeated.
9. Always add sufficient volume of specimen.
10. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
11. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
12. Always interpret the results under good light conditions to avoid misreading of the test results.
13. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
14. 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 capillary whole blood specimens:** Add **50µl** (or **one drop** using the provided disposable pipette) of capillary whole blood into the specimen window (S). Immediately add **one drop** of diluent buffer into the specimen window.
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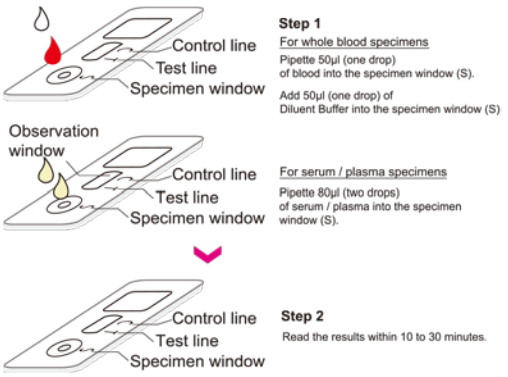
   **For serum / plasma specimens:** Add **80µl** (or **two drops** using the provided disposable pipette) of serum or plasma into the specimen window (S).
   **Avoid dropping specimen or buffer in the observation window. Do not allow the specimen to overflow.**
2. **Read the results from 10 minutes after specimen and buffer loading, to maximum of 30 minutes. Do not read the results after 30 minutes.**

## PROCEDURE DIAGRAM

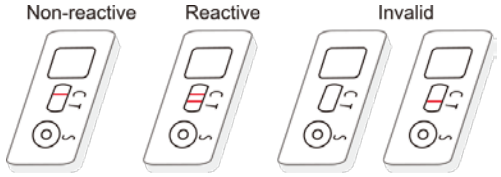



## RESULTS

**Quality Control:** One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If red line does not appear at the Control Zone, 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 of 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 serum or plasma specimens, sensitivity was 99.40% (666/670) and specificity was 100% (2657/2657).
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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.
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6. 200 hospitalized patients and 200 samples of pregnant women (including 20 samples of multipara) were tested and were all negative on the Wantai test.
7. 99/100 samples containing potentially cross reactive substances were negative on the Wantai test. One out of the 5 Malaria positive samples was false reactive with Wantai test.

| | Non-reactive | Reactive |
|---|---|---|
| Anti-HBc positive | 15 | 0 |
| Anti-HBs positive | 15 | 0 |
| Anti-HCV positive | 10 | 0 |
| Anti-HTLV I/II positive | 10 | 0 |
| Anti-HEV positive | 10 | 0 |
| Anti-HAV positive | 5 | 0 |
| Rheumatoid factor positive | 10 | 0 |
| CMV IgM Ab positive | 5 | 0 |
| EBV IgM Ab positive | 5 | 0 |
| Malaria positive | 4 | 1 |
| Syphilis positive | 5 | 0 |
| Herpes positive | 5 | 0 |

## LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure 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.
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**IFU VER: 20/01 (Jun.30,2020)**

# 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-18S10ELC, WJ-18S50ELC

### 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). The product is not intended for blood donor screening.

### 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 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 capillary 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 anti-HIV 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-18S10ELC | WJ-18S50ELC |
|---|---|---|
| Test Cassette | x10 | x50 |
| Diluent Buffer | x1 vial | x3 vials |
| Disposable Pipette | x10 | x50 |
| Capillary Tube (Rubber Head) | x10 (x1) | x50 (x1) |
| Retractable Safety Lancet | 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
- Retractable safety lancets
- Alcohol pads containing 70% isopropyl alcohol
- Disposable pipettes.
- Capillary tubes with rubber head.

**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

**Capillary whole blood specimen:** Ask the person to clean hands. Allow the finger to dry before pricking. Choose the finger less callused for pricking. Choose a puncture site on his or her fingertip. Clean the fingertip with Alcohol Pad. Place the Retractable Safety Lancet on a selected puncture site. Forcefully press the tip of the Retractable Safety Lancet against the fingertip. **Wipe away the first drop of blood with sterile gauze or cotton.** Use the capillary tube provided within the test kit to collect capillary whole blood from the puncture site for the test. Make sure that the volume of the whole blood collected between the blue line and the red thin line marked on the capillary tube (The end marked with the red bold line is the insertion end of the rubber head).

**Venous whole blood specimen:** Draw blood following laboratory procedure to obtain venous whole blood. **Do not test whole blood specimens if older than 3 days.** Use the disposable pipette provided within the test kit to collect venous whole blood from the collection tube for the test.

**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.

Use the disposable pipette provided within the test kit to collect serum or plasma from the collection tube for the test.

Any visible particulate matter 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 laboratory personnel using the product must be appropriately trained and use appropriate laboratory and personal protective equipment 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 (not 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.
5. **Use different disposal pipette tips or capillary tubes for each specimen in order to avoid cross-contaminations.**
6. Do not modify the test procedure.
7. Do not reuse the test cassettes, lancets, capillary tubes and pipettes. Dispose waste as per national standard or regulatory guideline.
8. A test giving an invalid result should be repeated.
9. Always add sufficient volume of specimen. When collecting capillary whole blood with capillary tube, it is recommended to make capillary tube horizontal or the insertion end of the rubber head slightly tilted downward in order that the blood easily move into the capillary tube. The collected capillary whole blood must be slowly and thoroughly pumped out with the rubber head.
10. **Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.**
11. If whole blood specimen is migrating too slowly on the test strip, add one additional drop of diluent buffer to the cassette.
12. Always interpret the results under good light conditions to avoid misreading of the test results.
13. Seek immediate medical attention in case of injuries due to improper handling of the kit components including the test cassette and the lancet.
14. Use automatic pipette, or the supplied capillary tube or disposable pipettes for the transfer of specimens onto the test cassette.
15. If the capillary tube is cracked, do not use it. Properly handle it to prevent puncture.

## 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.**

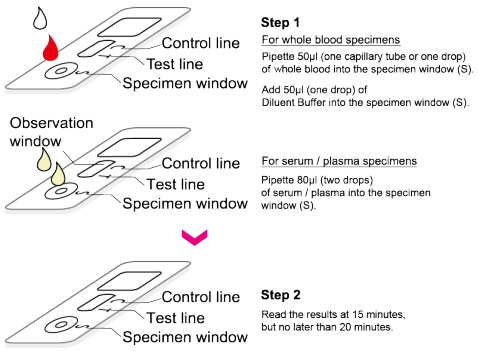
1. **For capillary whole blood specimens:** Use the provided capillary tube to slowly collect capillary whole blood (50µl) from the puncture site of the fingertip according to the specimen collection instructions, then insert the rubber head to the insertion end of capillary tube, gently squeeze the rubber head to add all whole blood collected into the specimen window (S). Immediately add one drop of diluent buffer into the specimen window.

   **For venous whole blood specimens:** Invert gently the blood collection tube with the blood specimen at least 4 times to make a homogeneous mixture. Use the provided disposable pipette to collect venous whole blood from the collection tube, then add one drop (50µl) of whole blood into the specimen window (S). Immediately add one drop of diluent buffer into the specimen window.

   **For serum / plasma specimens:** Use the provided disposable pipette to collect serum or plasma from the collection tube, then add two drops (80µl) 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.**
2. **Read the results at 15 minutes, but no later than 20 minutes.**

## PROCEDURE DIAGRAM

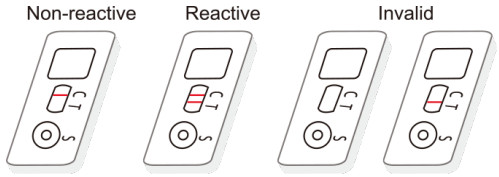



## RESULTS

**Quality Control:** One red line will always appear next to the Control Zone (C) indicating the validity of the test. **Invalid test run:** If red line does not appear at the Control Zone, the test is invalid - discard the test and repeat with new specimen and new cassette.

**Reactive Results:** One red line appears at 15 to 20 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 at 15 to 20 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 of 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 serum or plasma 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.
5. Serum to plasma and whole blood equivalence was demonstrated on 25 positive and 25 negative serum / EDTA-K2 plasma – whole blood / EDTA-K3 plasma – whole blood / sodium heparin plasma – whole blood / sodium citrate plasma – whole blood couples. Whole blood obtained by fingerprick and venipuncture was validated on 25 positive and 25 negative fingerprick whole blood / venous whole blood couples. No complement interference was observed on 25 same day fresh serum samples spiked with a small amount of an HIV positive sample.
6. 200 hospitalized patients and 200 samples of pregnant women (including 20 samples of multipara) were tested and were all negative on the Wantai test.
7. 99/100 samples containing potentially cross reactive substances were negative on the Wantai test. One out of the 5 Malaria positive samples was false reactive with Wantai test.

| | Non-reactive | Reactive |
|---|---|---|
| Anti-HBc positive | 15 | 0 |
| Anti-HBs positive | 15 | 0 |
| Anti-HCV positive | 10 | 0 |
| Anti-HTLV I/II positive | 10 | 0 |
| Anti-HEV positive | 10 | 0 |
| Anti-HAV positive | 5 | 0 |
| Rheumatoid factor positive | 10 | 0 |
| CMV IgM Ab positive | 5 | 0 |
| EBV IgM Ab positive | 5 | 0 |
| Malaria positive | 4 | 1 |
| Syphilis positive | 5 | 0 |
| Herpes positive | 5 | 0 |

## LIMITATIONS

1. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure 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 using Wantai test, 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 whole blood, serum or plasma. 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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