InTec PRODUCTS, INC.

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REF ITP02221-TC40

AQ+
HIV Ag/Ab Combo Rapid Test

For in vitro diagnostic use only. IVD
Please read the instructions for use carefully prior to use and strictly follow the instructions.

INTENDED USE

AQ+ HIV Ag/Ab Combo Rapid Test is an in vitro, qualitative immunoassay for the detection of Human Immunodeficiency Virus type 1 (HIV-1) antibody, type 2 (HIV-2) antibody and free HIV-1 p24 antigen in human whole blood (venous and fingertip), serum, plasma. It is intended for use as a point-of-care test to aid in the diagnosis of HIV infection.

SUMMARY

Acquired Immunodeficiency Syndrome (AIDS), is an infectious disease caused by human immunodeficiency virus (HIV). HIV does not directly cause any disease, but when the immune system is destroyed by HIV, the human body loses resistance and causes other diseases leading to death. AIDS is transmitted mainly through three routes: blood transmission, sexual transmission, and mother-to-child transmission. Common HIV detection methods include enzyme-linked immunosorbent assay, immunochromatography, immunoblotting and so on.

TEST PRINCIPLE

The test band region 1 (T1) on the nitrocellulose membrane is pre-coated with HIV antigens, the test band region 2 (T2) on the nitrocellulose membrane is pre-coated with HIV-1 p24 antibodies, and the control band region (C) on the nitrocellulose membrane is pre-coated with goat anti-chicken IgY antibodies. The fiberglass is pre-coated with microsphere-labeled HIV antigens, microsphere-labeled HIV-1 p24 antibodies and microsphere-labeled chicken IgY.
For HIV antibody positive specimens, HIV antibodies bind to the microsphere-labeled HIV antigens, then are captured by the HIV antigens in the test band region 1 (T1), forming a test band.
For free HIV-1 p24 antigen positive specimens, free HIV-1 p24 antigens bind to the microsphere-labeled HIV-1 p24 antibodies, then are captured by the HIV-1 p24 antibodies in the test band region 2 (T2), forming a test band.
For negative specimens, the microsphere-labeled HIV antigens and microsphere-labeled HIV-1 p24 antibodies flow past the test band region (T1 and T2), then no test band is formed at the test band region.
To ensure assay validity, a control band in the control band region (C) is incorporated in the assay device. The assay is only valid when the control band appears.

STORAGE CONDITIONS AND STABILITY

1. Storage condition: Sealed and dry stored at 2-30°C, shelf life: 24 months.
2. Manufacturing date and expiry date: Please refer to the label.

[Warnings] ⚠

1. The test environment should be kept at a certain humidity, protected from wind. Operate in strict accordance with the instructions to avoid testing at too high or too low temperature.
2. This kit can be stored at room temperature, beware of moisture. Reagents stored at low temperatures should be equilibrated to room temperature before use.
3. Appropriate biosafety assurance procedures should be in place for substances containing and suspected to contain an infectious agent, as follows:
   (1) Wear gloves to handle samples and reagents;
   (2) DO NOT pipette the specimen by mouth;
   (3) DO NOT smoke, eat, drink, cosmetic, and handle contact lenses while handling the samples and reagents;
   (4) Disinfect the spilled samples or reagents with disinfectants;
   (5) Decontaminate and dispose of all specimens, reagents and other potential contaminated materials in accordance with local regulations;
   (6) All components of the kit remain stable until the expiration date under proper handling and preservation.
   (7) DO NOT use expired test.
4. There is no inevitable relationship between the color intensity of the test line and the titer of the analyte in the sample.
5. This product is only for single use. DO NOT reuse the product. ②

REAGENTS AND MATERIALS SUPPLIED

Component	Test card	Plastic dropper	Sample diluent	Instructions for Use
40 Test (ITP02221-TC40)	40 pieces	40 pieces	2 mL x 2 vials	1 piece

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood sampling tools (lancet, capillary, venous puncture device, etc.)
- Biohazard waste container
- Disposable gloves.
- Disposable alcohol swab

PRECAUTIONS

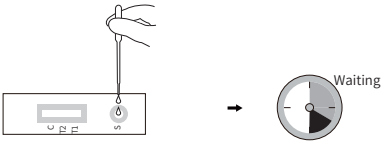
1. For human serum, plasma, venous whole blood or fingertip whole blood samples only, testing of other body fluids and samples may not obtain accurate results, and hemolysis, hyperlipidemia and hyperbilirubinemia samples should be avoided.
2. It is recommended that samples are collected and used immediately. Serum or plasma samples for short-term storage (tested within 7 days)may be stored at 2-8 °C. If long-term storage is required, samples should be stored at -20°C or below, and freeze-thaw should not exceed 3 cycles. If the whole blood samples cannot be timely detected, they should be stored at 2-8°C and detected within 7 days. Whole blood samples should not be frozen.
3. Samples must return to room temperature and be mixed well before testing.
4. Commonly used anticoagulants (EDTA, heparin, sodium citrate) in clinical practice do not affect the experimental results.
5. DO NOT open or remove the protective foil cover from the test unit until just prior to use.

TEST PROCEDURES

The Instructions for Use must be read completely before testing and the kit and samples to be tested must be removed from storage and equilibrated to room temperature (10°C-30°C) before use. Take the test card out of the aluminum foil bag, place it horizontally on a clean and flat table, and mark identification.

FOR SERUM OR PLASMA SAMPLE:

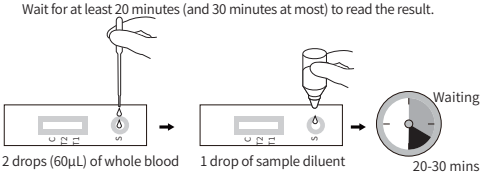
a. Serum or plasma sample: Pipette 60 µL (or 2 drops vertically from the dropper) of serum or plasma sample into the sample well (S). Wait for at least 20 minutes (and 30 minutes at most) to read the result.



2 drops (60µL) of serum or plasma — 20-30 mins

FOR VENOUS WHOLE BLOOD/FINGERTIP WHOLE BLOOD SAMPLE:

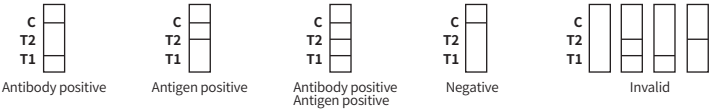
b. Venous whole blood/fingertip whole blood sample: Pipette 60 µL (or 2 drops vertically from the dropper) of venous whole blood or fingertip whole blood sample into the sample well (S), and then add 1 drop sample diluent vertically . Wait for at least 20 minutes (and 30 minutes at most) to read the result.



2 drops (60µL) of whole blood — 1 drop of sample diluent — 20-30 mins

INTERPRETATION OF TEST RESULTS

The results should be interpreted 20~30 minutes after sample addition and invalid after 30 minutes.



1. Antibody Positive: Colored bands at both the control line (C) and the antibody test line (T1).
2. Antigen positive: Colored bands at both the control line (C) and antigen test line (T2).
3. Antibody positive and antigen positive: Colored bands appear at the control line (C), antibody test line (T1), and antigen test line (T2).
4. Negative: Colored band at the control line (C), no colored band at the antibody detection line (T1) or at the antigen detection line (T2).
5. Invalid results: No colored bands appear at the control line (C), indicating that the test is invalid. Carefully read the product insert again and retest with new reagents. Contact your local supplier If the invalid result persists
6. Note: The color intensity of color band may be different. However, any color band appearing at the control line (C) regardless of the intensity of the color, even a very weak color band, within the specified reading time, should be interpreted as a positive result.

LIMITATIONS of THE TEST ⚠

1. This product is only used for in vitro qualitative detection of HIV-1 antibody, HIV-2 antibody and free HIV-1 p24 antigen in human serum, plasma, venous whole blood or fingertip whole blood samples. Specimen other than those specified may not supply accurate results.
2. This kit cannot determine the amount of antigen and antibody in the sample.
3. The test results of this kit are only for clinical reference and shall not be used as the sole basis for clinical diagnosis and treatment. Negative test results should not exclude the possibility of infection, which may be caused by low levels of antibody or antigen concentration in the sample which below the sensitivity of this kit. It is recommended to use other methods with higher sensitivity to confirm the suspected negative results. Samples with positive test results should be retested or confirmed using different methodologies. Confirmed diagnosis of HIV infection should be made in combination with the patient' s clinical history, symptoms and other diagnostic results.
4. This kit only detects free p24 antigen and cannot detect p24 antigen in complex with antibody. Antigen test lines may give negative results when only the p24 antigen and antibody complex is present in the sample.

PERFORMANCE CHARACTERISTICS

[Specificity]

A total of 100 confirmed negative samples were tested with this product and enzyme-linked immunosorbent assay reagents were used as control reagents. Specificity coincidence rate 100%; 95% CI: 96.3% ~ 100%.

[Sensitivity]

HIV Antibody: A total of 100 confirmed HIV antibody positive samples were tested with this product, and the immunochromatographic reagent was used as the control reagent. Sensitivity coincidence rate 100%; 95% CI: 96.3% ~ 100%.

HIV Antigen: A total of 50 confirmed HIV-1 p24 antigen positive samples were tested with this product using immunochromatographic reagents as control reagents. Sensitivity coincidence rate 100%; 95% CI: 92.9% ~ 100%.

KEY TO SYMBOL TO USE

⚠	CAUTION	☂	KEEP DRY		DO NOT REUSE		USE-BY DATE
☀	KEEP AWAY FROM SUNLIGHT		CONSULT INSTRUCTIONS FOR USE	Σ N	CONTAINS SUFFICIENT FOR (N) TESTS	STERILE EO	STERILIZED USING ETHYLENE OXIDE
	TEMPERATURE LIMITATION	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		DO NOT USE IF PACKAGE IS DAMAGED	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
LOT	BATCH CODE	REF	CATALOGUE NUMBER	CE	EUROPEAN CONFORMITY		MANUFACTURER

BIBLIOGRAPHY

1. Guidelines for Preparation of Instructions for Use of In Vitro Diagnostic Reagents ([2014] No. 17).
2. AIDS Hepatitis C Group of Chinese Society of Infectious Diseases, Chinese Center for Disease Control and Prevention, Li Taisheng. Chinese Guidelines for the Diagnosis and Treatment of AIDS (2021 Edition).
3. National Health Commission of the People's Republic of China, WS 293-2019 Diagnosis of AIDS and HIV Infection.
4. Centers for Disease Control. Recommendation for prevention of HIV transmission in health care setting. MMWR 36, Supplement No. 2S, 1987.

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