FRENOVO

HIV Ab/Ag Rapid Test Kit (4th Generation)

Instructions For Use

PRODUCT NAME

HIV Ab/Ag Rapid Test Kit (4th Generation)

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO HIV Ab/Ag Rapid Test Kit (4th Generation) is a rapid chromatographic immunoassay for the qualitative detection of HIV-1 p24 antigen and antibodies (IgG, IgM, IgA) to anti-HIV-1(including O) and-2 virus in human serum, plasma, whole blood.The test is a screening test for p24 antigen (HIV-1) and HIV antibodies (anti-HIV-1 & anti-HIV-2) and is for in vitro diagnostic use only.

sUMMARY AND PRINCIPLES OF THE PROCEDURE

First confirmed case of AIDS was identified in 1983 and by 1984 the etiologic agent, the Human Immunodeficiency Virus (HIV), subsequently named HIV-1 was isolated. Shortly afterwards in 1985 another retrovirus subsequently named HIV-2 was isolated in Africa. These two viruses belong to the retrovirus group and are slow viruses. The structure, gene organization and serological behavior of HIV-1 & HIV-2 and their complete nucleotide sequence has been determined. During initial infection, the HIV-1 p24 antigen appears (after 2 weeks) in detectable levels, before anti-HIV (after 4 weeks) but becomes undetectable as the antibodies are formed and their level increases (seroconversion). 4th generation HIV immunoassays incorporate HIV p24 antigen along with HIV antibody detection which allows the identification of acute HIV infections by reducing the window period.
FRENOVO HIV Ab/Ag Rapid Test Kit (4th Generation) is a lateral flow immunochromatographic assay. When the specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. IgG, IgM, or IgA antibodies to HIV-1 or HIV-2, if present in the specimen, migrate through the conjugate pad where they bind to the HIV conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1+2 antigen, forming a burgundy colored band on the Ab region, indicating a positive test result. Absence of the Ab band in the test region suggests an HIV -1 and HIV-2 antibody negative result.
HIV-1 p24 antigen, if present in the specimen, migrates through the conjugate pad where they bind to the P24 conjugate. The immunocomplex is then captured on the membrane by the pre-coated HIV-p24 antibody, forming a burgundy colored band on the Ag region, indicating a positive test result. Absence of the band Ag in the test region suggests an HIV-p24 antigen negative result.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Wash Buffer Solution: 2.0 ml in dropper bottle.
3. Droppers: 25 pieces droppers of 25 ul
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kitis for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit rapid test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2,Heparin sodium,Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

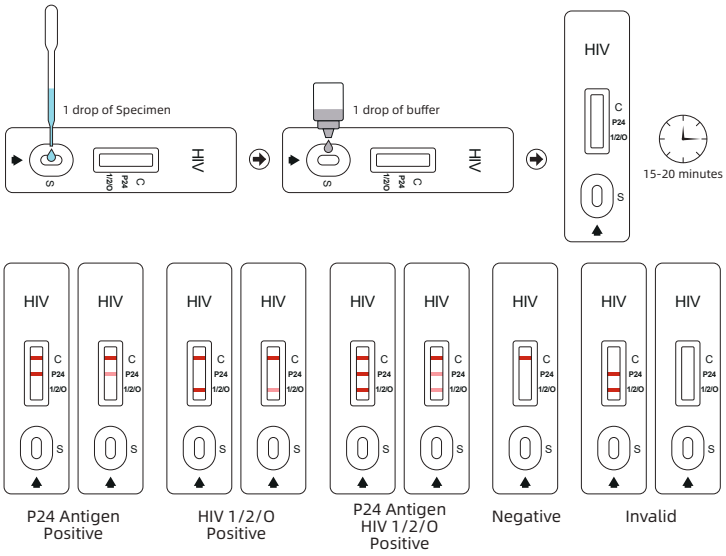
1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.

2. For Serum /Plasma /Whole blood Specimens.

   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop / approximately 30ul), then add one drop of buffer(approximately 30ul)to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   To use a micro-pipette: Pipette and dispense 30ul of specimen to the sample well of the test cassette, then add one drop of buffer (approximately 30ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

3. Wait for the colored line(s)to appear. The test result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

Negative result:
If only the C band is present, the absence of any burgundy color in both test bands (band P24 and band 1/2/O) indicates that neither HIV antibodies nor HIV p24 antigen is detected in the specimen. The result is negative.

Positive result:
1. In addition to the presence of the C band, if the 1/2/O band is developed, the test indicates the presence of antibodies to HIV-1 and/or HIV -2 in the specimen. The result is HIV-1+2 Ab positive.
2.In addition to the presence of the C band, if the P24 band is developed (including faint line), the test indicates the presence of HIV-p24 in the specimen. The result is HIV-p24 positive.
3. In addition to the presence of the C band, if both the P24 band and the 1/2/O band are developed, the result is both HIV-1+2 Ab and p24 antigen positive.

Invalid result:
if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be conducted again.

LIMITATIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closely. Failure to follow the procedure may give inaccurate results.
2. The intensity of the test band does not correlate with antibody titer or antigen level of the specimen.
3. A non-reactive result indicates absence of detectable HIV-1, HIV-2 antibodies and/or HIV p24 antigen. However, a nonreactive test result does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.
4. A non-reactive result can occur if the quantity of the HIV-1/HIV-2 antibodies and/or HIV p24 antigen present in the specimen is below the detection limits of the assay, or the antibodies /antigen that are detected are not present during the stage of disease in which a sample is collected.
5. If the symptom persists, while the result from is a non-reactive result, it is recommended to re-test the patient a few days later or test with alternative test methods.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The serum and plasma samples of patients with or without symptoms were detected with The kit and an SFDA licensed HIV 1+2 Ab reference kit. The results indicated that The kit(Whole Blood/ Serum/ Plasma)has a high sensitivity and specificity as summarized below：

HIV clinical study		Reference		
HIV Ab/Ag Rapid Test Kit (4th Generation)	Results	Positive	Negative	Total Results
	Positive	340	1	341
	Negative	0	993	993
Total Results		340	994	1334

Accuracy Results:
Clinical sensitivity:100%,
Clinical specificity: >99%,
Accuracy>99%.

Interference Substances
The following potential interfering substances have been tested using The kit and no interference was observed：

Substance	Tested Concentration
Bilirubin	20 mg/dL
Creatinine	442 μmol/L
Glucose	55 mmol/L
Albumin	60 g/L
Salicylic Acid	4.34 mmol/L
Heparin	3,000 U/L
EDTA	3.4 μmol/L
Hemoglobin	2g/L
Human IgG	150mg/dL
Sodium citrate	3.8%

Cross Reaction
Cross-reactivity was tested with specimens from other infectious disease; the results are shown in the following table:

Specimen	HIV Ab/Ag Rapid Test Kit (4th Generation)	
	Ab reactivity	Ag reactivity
HBsAg Positive Serum	Negative	Negative
HAV Positive Serum	Negative	Negative
HCV Positive Serum	Negative	Negative
Dengue Positive Serum	Negative	Negative
Syphilis Positive Serum	Negative	Negative
TB Positive Serum	Negative	Negative
H. pylori Positive Serum	Negative	Negative
ANA Positive Serum	Negative	Negative
HAMA Positive Serum	Negative	Negative
RF Positive Serum	Negative	Negative

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2℃ 30℃	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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