CE IVD

FRENOVO

Tuberculosis (TB) Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Tuberculosis (TB) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Tuberculosis (TB) Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti-Mycobacterium Tuberculosis (TB) in human serum, plasma and whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with M. TB.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Tuberculosis is a chronic, communicable disease caused principally by M. TB hominis (Koch' s bacillus), occasionally by M. TB bovis. The lungs are the primary target, but any organ may be infected. The risk of TB infection has exponentially declined in the 20th century. However, the recent emergence of drug-resistant strains, particularly among patients with AIDS, has rekindled interest in TB. The incidence of infection was reported around 8 million cases per year with a death rate of 3 million per year. The mortality exceeded 50% in some African countries with high HIV rates.

The initial clinical suspicion and radiographic findings, with subsequent laboratory confirmation by sputum examination and culture are the traditional method(s) in the diagnosis of active TB. Recently, serological detection of active TB has been the subject of a number of investigations, particularly for patients who are unable to produce adequate sputum, or smear-negative, or suspected to have extra pulmonary TB.

FRENOVO Tuberculosis (TB) Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing M.TB antigens conjugated with colloid gold (M.TB conjugates) and chicken IgY-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). and a control band (C band). The T band is pre-coated with non-conjugated M.TB antigens, and the C band is pre-coated with goat anti-chicken IgY. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to M. TB if present in the specimen will bind to the M.TB conjugates. The immunocomplex is then captured on the membrane by the pre-coated M.TB antigens, forming a burgundy colored T band, indicating a M.TB Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-chicken IgY/chicken IgY-gold conjugate regardless the presence of any antibodies to M.TB. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 2.0 ml in dropper bottle.
3. Droppers: 20 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)
- Micro-pipette

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 kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Tuberculosis (TB) Rapid Test Kit 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 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 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 cassettes 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 whole 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 as soon as possible . 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. 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.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. 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 cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1 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 or Plasma 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 25ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

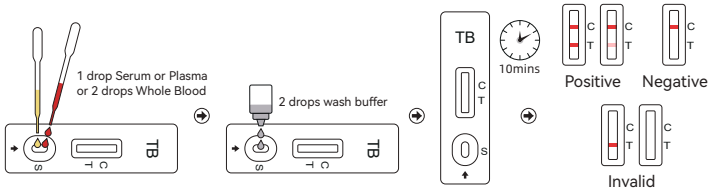
To use a micro-pipette: Pipette and dispense 25ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer.

For 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 (two drops/approximately 50ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

To use a micro-pipette: Pipette and dispense 50ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer.

3 Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that TB antibodies has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, TB antibodies has been detected and the result is positive. Approval

Invalid result: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the color in the test line region(s) will vary depending on the concentration of TB antibodies in the specimen.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of TB antibodies in serum, plasma or whole blood specimens only.
2. A positive result may not indicate previous Tuberculosis infection. Consider other Information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
3. A negative result can occur if the quantity of the antibodies to M.TB present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Method		PCR		
TB Antibody Rapid test	Results	Positive	Negative	Total Results
	Positive	95	10	105
	Negative	5	270	275
Total Results		100	280	380

Summary Results:
Clinical sensitivity =95.00% (95%CI*88.72%～98.36%)
Clinical specificity = 96.43% (95%CI*93.53%～98.27%)
Accuracy=96.05% (95%CI*93.57%～97.77%)

Interference Substances

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

Substance	Tested Concentration
Hemoglobin	6 mg/ml
Bilirubin	0.4 mg/ml
Triglycerides	15 mg/ml
Cholesterol	4 mg/ml
Human Anti-mouse Antibody (HAMA)	100 IU /ml
Rheumatoid Factor	1500 IU/ml
Antinuclear Antibody (ANA)	1:640
α-interferon	2 ng/ml
Lopinavir	2 μg/ml
Tobramycin	10 mg/L
Ribavirin	40 mg/L
Hemoglobin	6 mg/ml
Bilirubin	0.4 mg/ml
Zanamivir	140 ng/ml
Ritonavir	50 μg/ml
Tramadol	12 μg/ml
Azithromycin	5 μg/ml
Meropenem	10 mg/ml
Oseltamivir	1000 ng/ml
Mupirocin	10 mg/ml
benzocaine	1.5 mg/ml
Peramivir	20 μg/ml
Epinephrine	500 pmol/L

Cross Reaction

Cross-reactivity of The kit was evaluated using serum samples containing antibodies to other pathogens, which has no effect on the negative and positive test results, and there is no cross-reaction.

IgM potential cross-reactant	IgG potential cross-reactant
Influenza A virus (H1N1, H3N2)	Influenza A virus (H1N1, H3N2)
Influenza B virus (Yamagata IgM,Victoria IgM)	Influenza B virus (Yamagata IgG, Victoria IgG)
Endemic human coronavirus (OC43, 229E)	Endemic human coronavirus (OC43, 229E)
CMV IgM	CMV IgG
Rubella IgM	Rubella IgG
Toxo IgM	Toxo IgG
HSV IgM	HSV IgG
Coxsackie virus group B IgM	Coxsackie virus group B IgG
Epstein-Barr virus IgM	Epstein-Barr virus IgG
Enterovirus 71 IgM	Enterovirus 71 IgG
Coxsackie virus type A16 IgM	Coxsackie virus type A16 IgG
Varicella zoster virus IgM	Varicella zoster virus IgG
Mumps Virus IgM	Mumps Virus IgG
Respiratory syncytial virus IgM	Respiratory syncytial virus IgG
Adenovirus IgM	Adenovirus IgG
Chlamydia pneumoniae IgM	Chlamydia pneumoniae IgG
Mycoplasma pneumoniae IgM	Mycoplasma pneumoniae IgG
Measles virus IgM	Measles virus IgG

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°C 30°C	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	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

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