FRENOVO

Brucella IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Brucella IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Brucella IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of antibodies (IgG and IgM) to Brucella in human serum, plasma or whole blood.It is intended to be used by healthcare professionals to aid in the diagnosis of active and/or past Brucella infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Brucella is one of the world' s major zoonotic pathogens and is responsible for enormous economic losses, as well as considerable human disease in endemic areas. Humans become infected by coming in contact with animals or animal products that are contaminated with these bacteria. The heterogeneous and non-specific clinical symptoms mean that a diagnosis of brucellosis always requires laboratory confirmation.

The presence of anti-Brucella IgM in blood samples suggests an acute or recent Brucella infection.

In most infected individuals, anti-Brucella IgM rapidly increases in titer over a period of 2-3 weeks post-infection, and then declines to non-detectable levels within 3 to 6 months. Anti-Brucella IgG can be detected at the onset of symptoms, and levels remain elevated throughout the life of an individual.

FRENOVO Brucella IgG/IgM Rapid Test a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a colored conjugate pad containing Brucella antigens conjugated with colloidal gold (Brucella conjugates) and a control antibody conjugated with colloidal gold; 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with mouse anti-human IgG for detection of anti-Brucella IgG. The M line is pre-coated with mouse anti-human IgM for detection of anti-Brucella IgM. The C line is pre-coated with a control antibody. When an adequate volume of test specimen and sample diluent are dispensed into the sample and buffer wells, respectively, the specimen migrates by capillary action across the test strip. If anti-Brucella IgG is present in the specimen, it will bind to the Brucella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a colored G line, indicating a Brucella IgG positive test result. If anti-Brucella IgM is present in the specimen it will bind to the Brucella conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a colored M line, indicating a Brucella IgM positive test result. Absence of any test lines (G or M) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies, regardless of color development on the test lines (G and M). If no control line (C line) develops, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 25 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 1 dropper bottle of 3.5 ml .
3. Droppers: 25 pieces droppers of 10 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 Brucella IgG/IgM 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 Brucellae 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 Brucellae 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 Brucellae 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 byvenipuncture 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.

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 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 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

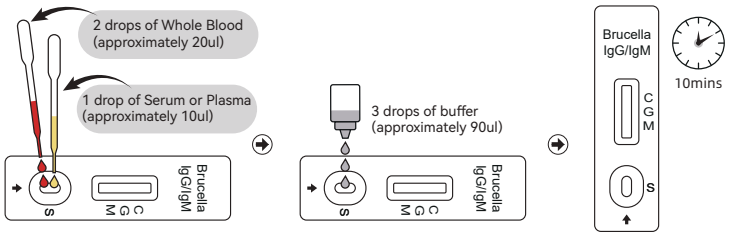
To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

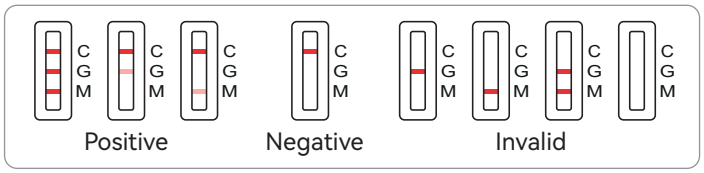
For Whole Blood Specimens

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 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) 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

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not Brucellae to match. the result is positive for IgG&IgM antibodies and is indicative of secondary Brucella infection.

IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for Brucella specific-IgG and is probably indicative of secondary Brucella infection.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for Brucella specific-IgM antibodies and is indicative of primary Brucella infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Brucella antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

INVALID: 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.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Brucella IgG/IgM antibodies in serum, plasma or whole blood specimens only.
2. A negative test result cannot exclude a recent infection. A positive result may not indicate previous Brucella 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. Infection may progress rapidly. If the symptom persists, while the result from FRENOVO Brucella IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to test with an alternative test method, such as bacterial culture method.Results from this test should not be used to diagnose or to exclude acute Brucella infection or to inform infection status.

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:

Brucella IgM Study		PCR		
Brucella IgG/IgM Rapid test	Results	IgM Positive	IgM Negative	Total Results
	IgM Positive	95	5	100
	IgM Negative	2	95	97
Total Results		97	100	197

Brucella IgM Study Summary Results:
Clinical sensitivity =97.94 % (95%CI* 92.75% ~ 99.75%)
Clinical specificity =95.00 % (95%CI* 88.72% ~ 98.36%)
Accuracy=96.47 % (95%CI* 92.82% ~ 98.56%)

Brucella IgG Study		PCR		
Brucella IgG/IgM Rapid test	Results	IgG Positive	IgG Negative	Total Results
	IgG Positive	58	7	65
	IgG Negative	4	93	97
Total Results		62	100	162

Brucella IgG Study Summary Results:
Clinical sensitivity=93.55 % (95%CI* 84.30% to 98.21%)
Clinical specificity=93.00 % (95%CI* 86.11% to 97.14%)
Accuracy=93.21% (95%CI*88.18% to 96.56%)

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
Toxo IgM	Toxo IgG
Salmonella IgM	Salmonella IgG
Staphylococcus aureus IgM	Staphylococcus aureus IgG
Leptospira IgM	Leptospira IgG
Mycobacterium bovis IgM	Mycobacterium bovis 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		

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