FRENOVO

Brucella Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

Brucella Antigen Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

Brucella Antigen Rapid Test Kit is an in vitro qualitative immunochromatographic assay for the rapid detection of Brucella antigens in human serum, plasma or whole blood samples.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Brucella is a Gram-negative, non-motile bacterium without a capsule (though the smooth type has a microcapsule). It is positive for catalase and oxidase, an absolute aerobe, capable of reducing nitrate, and an intracellular parasite that can survive in many types of domestic animals. Brucella causes brucellosis, also known as undulant fever, a chronic zoonotic infectious disease with significant harm. In China, the main sources of infection for this disease are cattle, sheep, and pigs. Among them, the sheep type of Brucella has the strongest transmissibility to humans, the highest pathogenicity, and the most severe harm. Brucellosis mainly affects the reproductive systems and joints of humans and animals, causing considerable harm to the development of animal husbandry and human health.

Brucella Antigen Rapid Test Kit is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) line region and a C (control) line region before running the assay. When the sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated Brucella antibody. If there are Brucella antigens in the specimen, a visible T line will appear in the T region. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of Brucella antigens in the specimen.

KIT COMPONENTS

Each kit contains:

1. Test devices: 25 pieces test devices individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
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 Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use 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 sample collection tubes, 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 tube 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 sample collection tubes/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 collected specimen. 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 extraction 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.

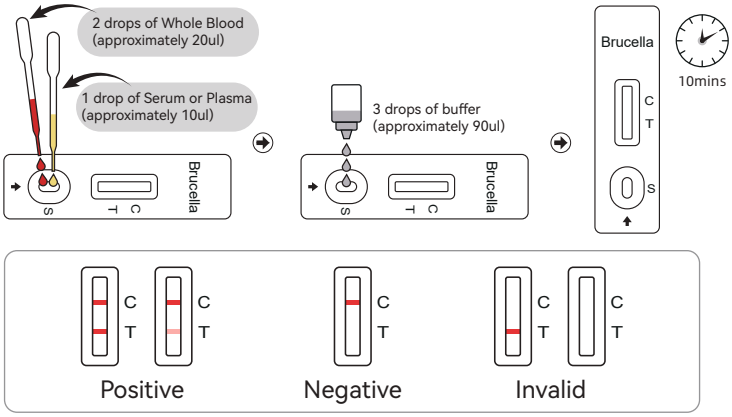
SAMPLE COLLECTION AND PREPARATION

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.

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. 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

POSITIVE: Test line and quality control line develop color. It is suggested that the Brucella antigen is positive.

NEGATIVE: Only the quality control line is colored in the test window. It is suggested that the concentration of Brucella antigen does not reach the detection level.

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. This kit is only used for qualitative detection and can not be used for the determination of antigen content.
2. The test results of this product are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered comprehensively with the information of symptoms / signs, medical history, other laboratory examinations, treatment response and epidemiology.
3. The results of sample testing are related to factors such as sample collection, testing, transportation and storage. Any error will affect the accuracy of the results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The performance of the Brucella Antigen Rapid Test Kit has been evaluated with 210 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with PCR method. The results show as summarized below:

Method		PCR		Total Results
Brucella Antigen Rapid Test Kit	Results	Positive	Negative	
	Positive	35	2	37
	Negative	1	172	173
Total Results		36	174	210

Clinical sensitivity=97.22% (85.47% ~ 99.93%)
Clinical specificity=98.85% (95.91% ~ 99.86%)
Accuracy=98.57% (95.88% ~ 99.70%)

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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