Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IBA-402	English

A rapid test for the qualitative detection of Brucella abortus antigen in human whole blood, serum or plasma specimen.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Brucella abortus antigen in human whole blood, serum or plasma specimen.

【SUMMARY】

Brucella abortus is a gram-negative bacterium that is found in cattle populations[1]. This intracellular parasite is a blood borne pathogen that causes premature abortion of a cattle fetus. What makes this bacterium so dangerous is that it is zoonotic, meaning it can be transferred from an animal to a human host and still remain pathogenic[2]. In humans this disease cause both acute and chronic symptoms, but can be treated with antibiotics. Because of this economic effect on the cattle business and the disease potential in humans, the US has spent close to $3.5 billion trying to vaccinate the cattle herds in the US[3]. It is possible for B. abortus to be spread from wild populations of elk and bison into domestic cattle herds and this is why the US government continues to be vigilant in tracking potential cases within herds[4].

【PRINCIPLE】

The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Brucella abortus antigen in human whole blood, serum or plasma specimen. The membrane is pre-coated with mouse anti-Brucella abortus. During testing, the Brucella abortus antigen in whole blood, serum or plasma specimen reacts with the dye conjugate, which has been pre-coated anti-Brucella abortus on the conjugate pad. The mixture then migrates upward on the membrane by capillary action, reacts with mouse anti-Brucella abortus antibodies on the membrane on Test Line region. If the specimen contains Brucella abortus antigen, a colored line will appear in test line region. The absence of the colored lines in test line region indicates that the specimen does not contain Brucella abortus antigen. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains anti-Brucella abortus antibodies coated particles and anti-Brucella abortus antibodies coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not exchange or mix buffer and test cassettes from kits of different lot numbers.
8. Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.
9. Be sure to add sufficient buffer to the cassette's buffer well. Invalid result may occur if inadequate buffer is added.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- 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 for more than three times
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

- Test Cassettes
- Buffer
- Disposable Specimen Droppers
- Package Insert

Materials Required But Not Provided

- Micropipette and Disposable Tips (optional)
- Lancets (for fingerstick whole blood only)
- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

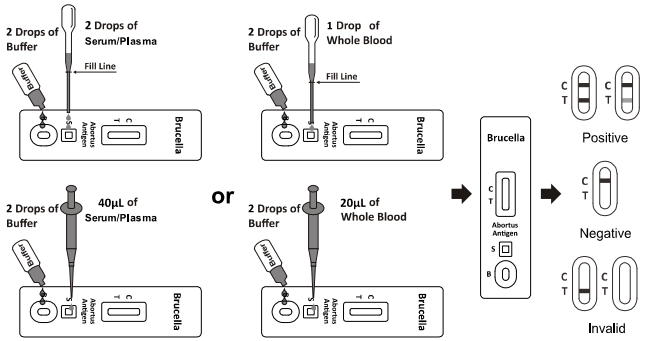
1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

   For serum or plasma specimen:

   - Use a disposal specimen dropper: Hold the dropper vertically, draw the specimen about 1cm above the Fill Line, and transfer **2 drops of serum or plasma** (approximately 40μL) to the specimen well (S), then add **2 drops of buffer** (approximately 120μL) into the buffer well (B). See illustration below and start the timer.
   - Use a micropipette: Transfer **40μL of serum or plasma specimen** to the specimen well (S), then add **2 drops of buffer** (approximately 120μL) into the buffer well (B). See illustration below and start the timer.

   For whole blood specimen:

   - Use a disposal specimen dropper: Hold the dropper vertically, draw the specimen about 1cm above the Fill Line, and transfer **1 drop of whole blood** (approximately 20μL) to the specimen well (S), then add **2 drops of buffer** (approximately 120μL) into the buffer well (B). See illustration below and start the timer.
   - Use a micropipette: Transfer **20μL of whole blood** to the specimen well (S), then add **2 drops of buffer** (approximately 120μL) into the buffer well (B). See illustration below and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Brucella abortus antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

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

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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.

【LIMITATIONS】

1. The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of Brucella abortus antigen in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in Brucella abortus antigen concentration can be determined by this qualitative test.
2. The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antigens of Brucella abortus in the specimen and should not be used as the sole criterion for the diagnosis of Brucella abortus antigen infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Brucella abortus infection.

【EXPECTED VALUES】

The Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with latex agglutination method, demonstrating an overall accuracy of 98.8%.

【PERFORMANCE CHARACTERISTICS】

Clinical Sensitivity, Specificity and Accuracy

The performance of the Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with 240 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with latex agglutination method. The results show that the relative sensitivity of the Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is 97.5% and the relative specificity is 99.0%.

Brucella Abortus Antigen Rapid Test Cassette vs. Latex Agglutination

Method		Latex Agglutination		Total Results
Brucella Abortus Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	39	2	41
	Negative	1	198	199
Total Results		40	200	240

Relative Sensitivity: 97.5% (95%CI*: 86.8%~99.9%);
Relative Specificity: 99.0% (95%CI*: 96.4%~99.9%);
Overall Accuracy: 98.8% (95%CI*: 96.4%~99.7%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

【BIBLIOGRAPHY】

1. Detilleux, Philippe G., Billy L. Deyoe, and Norman F. Cheville. 1990. "Penetration and intracellular growth of Brucella abortus in nonphagocytic cells in vitro." Infection and Immunity, vol. 58, no. 7. American Society for Microbiology. (2320-2328).
2. Christopher W. Olsen "Brucellosis in Humans" Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison. December 2004
3. D. T. Newby, T. L. Hadfield, and F. F. Roberto. "Real-Time PCR Detection of Brucella abortus: a Comparative Study of SYBR Green I, 5'-Exonuclease, and Hybridization Probe Assays" Applied and Environmental Microbiology. 2003 August; 69(8): 4753-4759
4. US Department of Agricultue. Food Safety Education. Last Modifited February 6, 2006.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

Hangzhou AllTest Biotech Co., Ltd.
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