ONE STEP Bovine Brucella Antibody RAPID TEST

Anigen Rapid B. Brucella Ab Test Kit

1. Explanation of the Test

Bovine Brucellosis is an infectious disease caused by the bacteria of the genus *Brucella abortus*. Humans become infected by coming in contact with animals or animal products that are contaminated with these bacteria.

The Anigen Rapid B. Brucella Ab Kit is a chromatographic immunoassay for the qualitative detection of *Brucella abortus* antibody in whole blood, plasma, serum, and milk.

The Anigen Rapid B. Brucella Ab Kit has a letter T and C as "Test Line" and "Control Line" on the surface of the kit. Both the "Test Line" and "Control Line" in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. The Control line should always appear if this procedure is performed properly, and the test reagents of the control line are working. A purple "Test Line" will be visible in the result window if there are enough *Brucella abortus* antibodies in the specimen.

The specially selected *Brucella abortus* antigens are used in the test and as both capture and detector materials. These enable the Anigen Rapid B. Brucella Ab Kit to identify *Brucella abortus* antibodies in specimens, with a high degree of accuracy.

2. Materials Provided

Anigen Rapid B. Brucella Ab Kit contains the following items to perform the assay.

1) Ten(10) B. Brucella Ab Test Kits
2) Assay diluent, 1 bottle
3) Instructions for use
4) Capillary tube (20 ㎕/drop), 10ea

♣ A dark color score line on the capillary tube is the indicator line for 20 ㎕.

3. Precautions

The Anigen Rapid B. Brucella Ab Kit should be stored at room temperature. The test multi-device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiry date.

4. Specimen Collection and Storage

1) [whole blood] Collect the whole blood using a suitable anti-coagulant. Use the whole blood within 1 day after collection. Do not use hemolysed blood.
2) [serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
3) [milk] Collect the raw milk
4) If specimens are not immediately tested they should be refrigerated at 2 ~ 8℃. For storage periods greater than three days, freeze the specimen at – 20℃ or below(serum, plasma). Specimens should be brought to room temperature prior to testing.
5) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to testing.

5. Warnings

1) For *in-vitro* diagnostic use only.
2) Do not eat or smoke while handling specimens.
3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4) Avoid splashing or aerosol formation.
5) Clean up spills thoroughly using an appropriate disinfectant.
6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, using a biohazard container.
7) Do not use the test kit if the pouch is damaged or the seal is broken.

6. Procedure of the Test

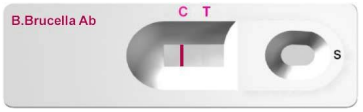
1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Slowly add one drop (20 ㎕) by a capillary tube (with a dark color score line for indicating a volume of 20 ul) of serum, plasma, whole blood, or raw milk to the sample well, and then add 4 drops with the bottle containing Assay diluent. If the migration has not appeared after 1 minute, add one more drop of Assay diluent to the sample well.
3) A test result will be seen as a purple band in the result window of the kit.
4) Interpret the test results at 20 minutes. Do not interpret after 20 minutes.

Caution: The above interpreting time is based on reading the test results at room temperature of 15 ~ 30℃. If your room temperature is significantly no more than 15℃, then the interpreting time should be properly increased.

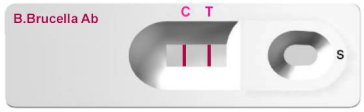
7. Interpretation of the Test

1) A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control line **(C)**.
2) The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test line **(T)**.

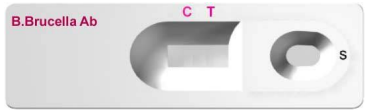
Negative : The presence of only one purple color band within the result window indicates a negative result.



Positive : The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.



Invalid : If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



8. Limitations of the Test

1) The Anigen Rapid B. Brucella Ab Kit will only indicate the presence of antibodies against *Brucella aboruts* in the specimen.
2) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the veterinarian.
3) 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 Brucellosis.

9. Expected Values

The Anigen Rapid B. Brucella Ab Kit has been compared with a Rose Bengal and Milk Ring Tests. The overall accuracy is greater or equal to 97.0%.

Date Issued : Feb,11. 2005
I 2301-0

Manufactured by **BioNote, Inc.**
2-9 Seogu-dong, Hwaseong-si, Gyeonggi-do, Korea 445-170
Tel.: +82 31 211 0516, Fax.: +82 31 8003 0618
http://www.bionote.co.kr