

## Anigen Rapid B. Brucella Ab/B. TB 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/B. TB Ab Test Kit is a chromatographic immunoassay for the qualitative detection of *Brucella abortus* antibody in whole blood, plasma, serum, and milk and *Mycobacterium bovis* antibody in bovine plasma and serum. Bovine Tuberculosis is a serious bacterial disease caused by *Mycobacterium bovis* that usually affects the respiratory system, and is capable of infecting most mammals. B. TB is a chronic disease that has affected animal health throughout recorded history.

The Anigen Rapid B. Brucella Ab/B. TB Ab Test 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* antibody and/or *Mycobacterium bovis* antibodies in the specimen.

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

### 2. Materials Provided

This Test Kit contains following items to perform the assay.

- 1) Ten (10) Rapid B. Brucella Ab/B. TB Ab Test Devices
- 2) Assay diluent for B. Brucella Ab Test, 1 bottle (3ml)  
(The B.TB Ab Test is not required of the assay diluent)
- 3) Instructions for use
- 4) Ten (10) Specimen droppers for B.TB Ab testing
- 5) Ten(10) Capillary tubes (20  $\mu$ l/drop) for B.Brucella Ab testing
- ♣ A dark color score line on the capillary tube is the indicator line for 20  $\mu$ l.

Capillary tube

### 3. Precautions

Anigen Rapid B. Brucella Ab/B. TB Ab Test Kit should be stored at room temperature. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch. If the test kit was stored in the refrigerator, the test kit should be taken out from the refrigerator before 10 minutes of beginning the test. Do not use it beyond the expiry date.

### 4. Specimen Collections and Storage

- 1) B. Brucella Ab Test : Whole blood, Serum, plasma or raw milk can be used for the test
- 2) Plasma is the straw-colored blood in which the blood cells are suspended.  
**[Plasma collection method]**  
Collect the whole blood in the test tube. Before clotting of the whole blood, centrifuge the whole blood for 10 minutes at 10,000 rpm. Take the upper portion(straw colored blood) on the test tube.
- 3) Serum is straw-colored blood plasma without fibrinogen and other clotting factors. Serum samples with trace hemolysis (light red color) and moderate lipemia (milky appearance) may have little or no effect on test results. Avoid using samples that are heavily hemolyzed (dark red color) or grossly lipemic.

#### [Serum collection method]

Collect whole blood in the test tube and then leave it at least for 4 hours until the whole blood is clotted. When serum is clotted,

**Method 1:** Take the upper portion serum (straw colored blood). When serum is on the clot, be careful not to aspirate any of the clotted material or blood cells.

**Method 2:** To obtain the serum sample for the best result, Centrifuge the clotted whole blood for 10 minutes at 10,000 rpm. Take the upper portion serum (straw colored blood) on the test tube

Take the plasma or serum samples from the area indicated



- 4) [Milk] Collect the raw milk
- 5) If specimens are not immediately tested they should be refrigerated at 2 ~ 8 °C. For storage periods greater than three days, freeze the specimen at – 20 °C or below. Bring specimens to room temperature prior to testing.
- 6) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to testing.

### 5. Warnings

- 1) For veterinary 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, in a biohazard container.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.

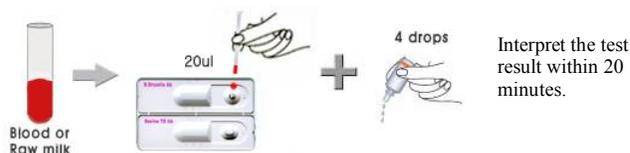
### 6. Test Procedures

- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) **[B. Brucella Ab]** Slowly add one drop (20  $\mu$ l) by the capillary tube (with a dark color score line for indicating a volume of 20  $\mu$ l) 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.
- 2) **[B.TB Ab]** Slowly **add four (4) drops of serum or plasma** to the sample hole(s) with the specimen dropper. If the migration has not appeared after 1 minute, add one more drop of the specimen to the sample hole.
- 3) A test result will be seen as a purple band in the result window of the kit.
- 4) **Interpret test result within 20 minutes.** Do not interpret after 20 minutes.
- 5) Even if the intensity of the purple band color is faint, it should be interpreted as positive if it appears within 20 minutes.

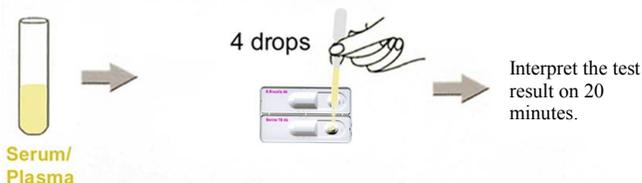
**Caution:** The above interpreting time is based on reading the test results at room temperature of 15 ~ 30 °C. If your room temperature is not significantly more than 15 °C, then the interpreting time should be properly increased.

#### [Test Procedures]

#### [B. Brucella Ab]



#### [B.TB Ab]



## 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).

### 1) Negative result

The presence of only one band within the result window on **both of the B. Brucella Ab/B. TB Ab** test areas indicates a negative result.



### 2) Simultaneous B. Brucella Ab and B.TB Ab Positive result

The presence of two color bands (“T” and “C”) within the result window on **both of the B. Brucella Ab/B. TB Ab** test areas respectively, no matter which band appears first, indicates a positive result of B. Brucella antibody and B.TB antibody simultaneously.



### 3) B. Brucella Ab Positive result

The presence of two color bands (“T” and “C”) within the result window on the B. Brucella Ab test area, and the presence of only one band (“C”) within the result window on the B.TB Ab test area, no matter which band appears first, indicates a positive result of B. Brucella antibody.



### 4) B.TB Ab Positive result

The presence of two color bands (“T” and “C”) within the result window on the B.TB Ab test area, and the presence of only one band (“C”) within the result window on the B. Brucella Ab test area, no matter which band appears first, indicates a positive result of B.TB antibody.



### 5) Invalid Result

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) Anigen Rapid B. Brucella Ab/B. TB Ab Test Kit will only indicate the presence of antibodies against *Brucella abortus* and *Mycobacterium bovis* 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.

## 9. Expected Values

The Anigen Rapid B. Brucella Ab Kit has been compared with the Rose Bengal and Milk Ring Tests. The overall accuracy is greater or equal to 97.0%. and Anigen B. TB Ab Test Kit has been compared with the PPD test. The overall accuracy is greater or equal to 85.5%

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