

# Anigen Rapid C. Brucella Ab Test Kit

## 1. Explanation of the Test

Canine Brucellosis is an infectious disease caused by the bacteria of the genus *Brucella canis*. The Anigen Rapid C. Brucella Ab Test Kit is a chromatographic immunoassay for the qualitative detection of *Brucella canis* antibody in whole blood, plasma, or serum.

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

The specially selected *Brucella canis* antigen is used in test and as both capture and detector materials. These enable the Anigen Rapid C. Brucella Ab Test Kit to identify to *Brucella canis* antibodies in specimens, with a high degree of accuracy.

## 2. Materials Provided

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

- 1) Ten (10) Anigen Rapid C. Brucella Ab Test Kits
- 2) One (1) Assay Diluent bottles
- 3) Ten (10) Capillary tubes for 10ul
- 4) One (1) Instructions for use

A score line for volume of 10 ul



## 3. Precautions

- 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 all specimens, reaction kits and potentially contaminated materials, in a biohazard container.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.

## 4. Storage and Stability

The Anigen Rapid C. Brucella Ab Test Kit should be stored at room temperature. The test kit is sensitive to humidity, and as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

## 5. Specimen Collection and Storage

- 1) [Whole blood] Collect the whole blood by using the suitable anti-coagulant. Use the whole blood within 1 day after collection. Do not use the hemolysis blood.
- 2) [Serum or Plasma] Centrifuge whole blood to get plasma or serum specimen.
- 3) If specimens are not immediately tested they should be refrigerated at 2 ~ 8°C. For keeping specimens more than three days with fresh, them at - 20°C or below (serum, plasma). They should be brought to room temperature before use.
- 4) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified before assaying.

## 6. Test Procedures

- 1) Remove the test kit from the foil pouch, and place it on the flat, dry surface.
- 2) Take 10ul of serum, plasma, or whole blood to the dark score line of a capillary tube.
- 3) Slowly add 10 ul of serum, plasma, or whole blood to the sample well with capillary tube with a score line for volume of 10ul and then add 2 drops (approximately 60ul) with bottle containing diluent buffer. If the migration is not appeared within 1 minute, add one more buffer to sample well.

- 4) As the test result, you can see the purple band in the result window of the kit.
- 5) Interpret test results at 20 minutes.
- 6) Please do not read after 20 minutes.



※ Caution: Please ignore the test results after 20 minutes.

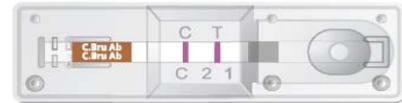
## 7. Interpretation of the Test

- 1) A color band which would be appeared in the left section of the result window shows that the test is works properly, and it called is the Control line (C).
- 2) The right section of the result window called test band indicates the test results. If another color band appears on the test band. (T).

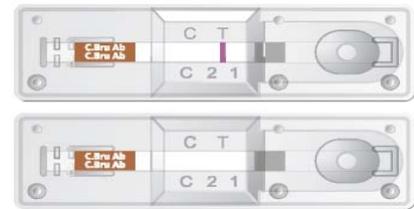
**Negative** : The presence of only one purple color band within the result window indicates a negative result.



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



**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 to take the test again with same specimen.



## 8. Limitations of the Test

- 1) The Anigen Rapid C. Brucella Ab Test Kit will only indicate the antibody presence against *Brucella canis* 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 symptom is persist, additional testing using other clinical methods is recommended. A negative result does not preclude the possibility of canine brucellosis.

## 9. Expected Values

The Anigen Rapid C. Brucella Ab Test Kit has been compared with 2-mercapto-ethanol Rapid Slide Agglutination Test. The overall accuracy is greater or equal to 90.0%.

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