ONE STEP Canine Brucella Antibody RAPID TEST KIT

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 canins* 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 are working. A purple "Test Line" will be visible in the result window if there are enough *Brucella canis* antibody in the specimen.

The specially selected *Brucella canis* antigens are 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) Diluent bottles
3) Instructions for use
4) Ten (10) Capillary tubes for 20ul

A score line for volume of 20 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 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.

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 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.
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). They should be brought to room temperature prior to use.
5) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

6. Test Procedures

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Take 20 ul of serum, plasma, or whole blood to the dark score line of a capillary tube.
3) Slowly **add 20 ul** of serum, plasma, or whole blood to the sample well with capillary tube with a score line for volume of 20 ul and then add **4 drops** with bottle containing diluent buffer. If the migration is not appeared in 1 minute, add one more buffer to sample well.
3) As the test result, you can see the purple band in the result window of the kit.
4) Interpret test results within **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 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 at any time preclude the possibility of canine brucellosis.

9. Expected Values

The Anigen Rapid C. Brucella Ab Test Kit has been compared with a Rose Bengal Tests. The overall accuracy is greater or equal to 90.0%.

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