ONE STEP Canine Brucella Antibody Test

For veterinary diagnostic use only

Rapid C.Brucella Ab Test Kit

Principles

The Rapid C.Brucella Ab Test Kit is a chromatographic immunoassay for the qualitative detection of Brucella canis antibodies in canine whole blood, plasma or serum. The Rapid C.Brucella Ab Test Kit has two letters which are test (T) line and control (C) line on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the antibodies against Brucella canis in the sample, a purple test line would appear in the result window. The highly selective Brucella canis antigens are used as a capture and detector in the assay. These antigens are capable of detecting antibodies against Brucella canis directly, with a high accuracy.

Materials provided (10 Tests/Kit)

Reagent	10 T/Kit
Rapid C.Brucella Ab Test Device	10
Assay diluent bottle	1
Anticoagulant tube	10
Disposable capillary tube	10
Instructions for use	1

Black line on the capillary tube is the indicator line for 10 µl.

Materials required, but not provided

1. Timer

Precautions

1. The test kit is for canine use only. Do not use for other animals.
2. The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch. Do not re-use the test components.
3. Apply the sample and assay diluent vertically.
4. Do not touch the membrane in the result window of test device.
5. Do not use the test kit beyond the stated expiration date marked on the
6. package label.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
10. Decontaminate and dispose of all samples, reaction kits and potentially contaminatedmaterials safely in accordance with national and local regulations.

Storage and Stability

1. Store the test kit at 2~30°C. **DO NOT FREEZE.**
2. Do not store the test kit in the direct sunlight.
3. The test kit is stable within the expiration date that marked on the package label.

Collection and Preparation of Sample

1. Canine whole blood, serum, or plasma should be used with this test. **[Whole blood]** Collect the whole blood into the anti-coagulant tube(Max. vol.1.5ml) provided. If anticoagulated whole blood is not immediately tested, they should be refrigerated at 2~8°C and used within 24 hours. **[Serum]** Collect the whole blood into the collection tube(NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum supernatant. **[Plasma]** Collect the whole blood into the collection tube(containing anti-coagulants such as heparin, EDTA and sodium citrate) and then centrifuge to get plasma.
2. If serum or plasma samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, freezing is recommended. Frozen samples should be brought to room temperature (15~30°C) prior to use.
3. Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.
4. The use of hemolytic or bacterially contaminated samples should be avoided Erroneous result may occur.

Procedure of the Test

1) All reagents and samples must be at room temperature (15~30°C) before

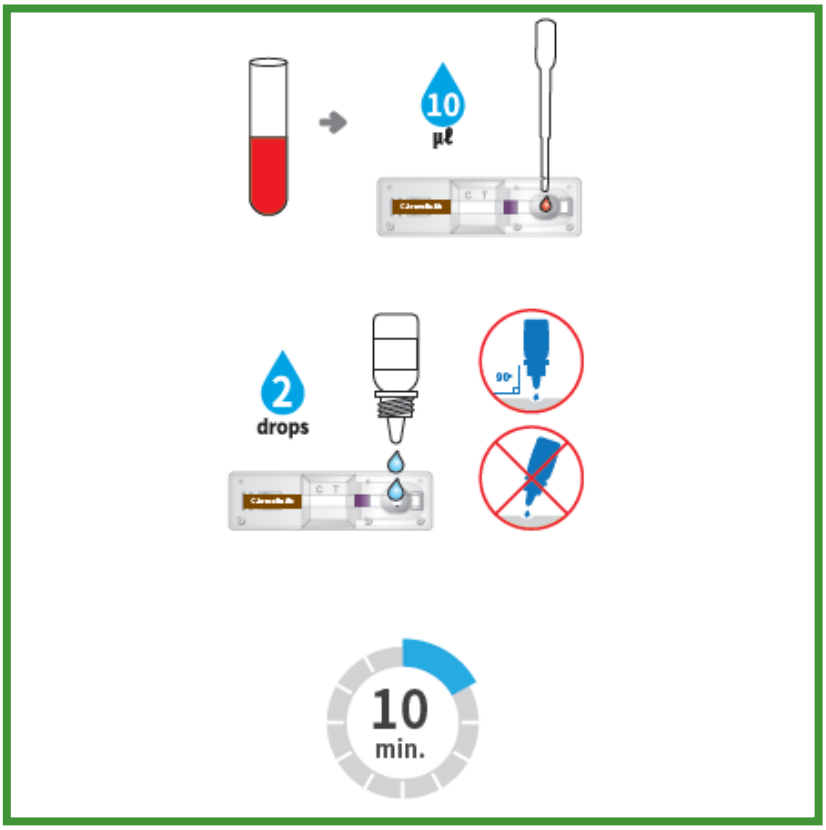
2) Remove the test device from the foil pouch, and place it on a flat and dry

3) Using a disposable capillary tube dispense 10 µl of sample into sampl hole of the test device.

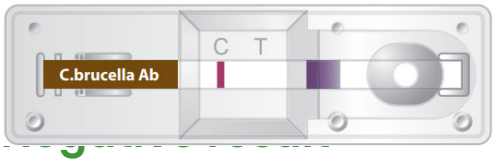
4) Add 2 drops of assay diluent into the sample hole vertically.

5) As the test begins to work, you will see purple color move across the result window in the center of the test device. If the migration has not appeared after 1 minute, add one more drop of the assay diluent to the sample well.

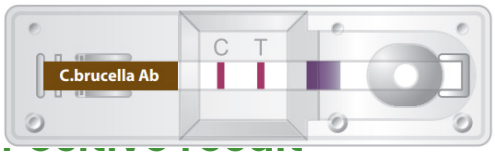
6) Interpret test results at 10~25 minutes. Do not interpret after 30 minutes.



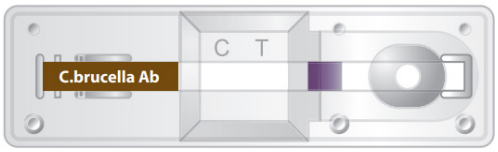
Interpretation of the Result

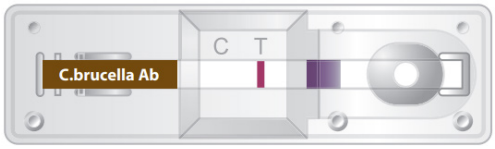


One control ("C") line appears in the result window.



The two color bands ("T" and "C") within the result window indicate the presence of antibody against Brucella canis.





Invalid Result

If the control("C") line does not appear, the result might be considered invalid. The samples should be re-tested.

Limitations of the Test

1. Although the Rapid C.Brucella Ab Test kit is very accurate for detecting antibodies to Brucella canis, but a low incidence of false results can occur. Other clinical tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the veterinarian after all clinical and laboratory findings have been evaluated.
2. The reading window may show a light pink background coloration; this will not affect the accuracy of the results
3. The manufacturer and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

Expected Values

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

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