

ONE STEP *Brucella melitensis*,
Brucella abortus and *Brucella suis* Antibody TEST

For veterinary diagnostic use only

Anigen Rapid GS.Brucella Ab Test Kit

Principles

The **Anigen Rapid GS.Brucella Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of *Brucella melitensis*, *Brucella abortus* and *Brucella suis* antibodies in serum, plasma, whole blood or milk of goat and sheep.

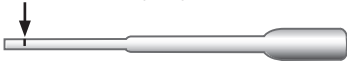
The **Anigen Rapid GS.Brucella Ab Test Kit** has two letters which are test ("T") line and control ("C") line on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the antibodies against *Brucella melitensis*, *Brucella abortus* and *Brucella suis* are present in sample, a purple test line would appear in the result window.

The specially selected *Brucella melitensis*, *Brucella abortus* and *Brucella suis* antigens are used in the test band as both capture and detector materials. These enable the Anigen Rapid GS.Brucella Ab Test Kit to identify *Brucella melitensis*, *Brucella abortus*, and *Brucella suis* antibody in goat and sheep sample with a high degree of accuracy.

Materials provided

Reagent	10 Test/Kit	5x10 Multi Test/Kit
Anigen Rapid GS.Brucella Ab Test Device	10	50
Assay diluent bottle	1	1
Anticoagulant tube	10	50
Disposable capillary tube	10	50
Instructions for use	1	1

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



Materials required, but not provided

Timer

Precautions

- 1) The test kit is for goat and sheep 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.
- 3) Do not reuse the test components.
- 4) Apply the assay diluent vertically.
- 5) Do not touch the membrane in the result window of test device.
- 6) Do not use the test kit beyond the stated expiration date marked on the 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, used kits and potentially contaminated materials safely in accordance with national and local regulations.
- 11) Strictly follow the test procedures to minimize false or invalid test results due to improper administration of the product usage or doses.
- 12) Although the Anigen Rapid GS.Brucella Ab Test Kit offers simple and quick measurement of *Brucella melitensis*, *Brucella abortus* and *Brucella suis* antibody in serum, plasma whole blood or milk of goat and sheep, there may be a difference in the detection performance with other clinical or laboratory methods with more sophisticated principles.

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.

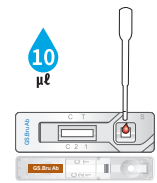
Collection and Preparation of Sample

- 1) Whole blood, plasma, serum or milk should be used with this test.
 - [Whole blood]** Collect the whole blood into the anticoagulant tube (Max. vol. 1.5 ml) 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 anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge to get plasma sample.
 - [Milk]** Collect the milk into the collection tube.
- 2) If serum, plasma or milk 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, lipaemic, icteric or bacterially contaminated samples should be avoided. Erroneous result may occur.

Procedure of the Test

- 1) All reagents samples must be at room temperature (15–30 °C) before use.
- 2) Remove the test kit from the foil pouch, and place it on a flat and dry surface.

- 3) Using a disposable capillary tube, dispense **10 µl of sample** into sample hole (S) on the test device.



- 4) Add **4 drops (approximately 120 µl) of the assay diluent** into the sample hole, drop by drop vertically.



- 5) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of assay diluent to the sample hole.



- 6) Interpret test results **at 20 minutes**. Do not interpret after 30 minutes.

Interpretation of the Result

1) Negative

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



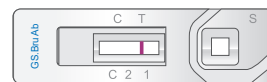
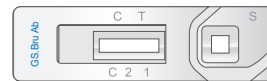
2) Positive

Test ("T") line and control ("C") line appear within the result window to indicate the presence of the antibodies against *Brucella melitensis*, *Brucella abortus* and *Brucella suis*.



3) Invalid

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



Limitations of the Test

- 1) Although the Anigen Rapid GS.Brucella Ab Test kit is very accurate for detecting *Brucella melitensis*, *Brucella abortus* and *Brucella suis*, a low incidence of false results can be occurred. Other clinical and laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed 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) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

Performance Characteristics

- 1) Comparison Test: Rose Bengal

Sample	Result			Diagnostic sensitivity and specificity (95 % Confidence Limit)	Kappa statistic
	+	-	Total		
Goat serum	+	59	1	Sn: 98.3 % (95 %CL=91.1 %~99.7 %) Sp: 100.0 % (95 %CL=92.9 %~100.0 %)	0.98
	-	0	50		
Sheep serum	+	52	1	Sn: 98.1 % (95 %CL=90.1 %~99.7 %) Sp: 96.5 % (95 %CL=90.2 %~98.8 %)	0.94
	-	3	83		

* Sn: Sensitivity, Sp: Specificity

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