ONE STEP Camel Brucella Antibody TEST

For veterinary diagnostic use only

* Anigen Rapid Camel Brucella Ab Test Kit

(Strip type)

Principles

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

The Anigen Rapid Camel Brucella Ab Test Kit has test(T) line and control(C) line on the surface of strip. 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, abortus,* or *suis* are present in camel sample, a purple test line would appear in the result window.

■ Materials provided (25 Tests/Kit)

- 1) 25 Camel Brucella Ab test strips
- 2) 25 Disposable capillary tubes (10 μl)
- 3) 25 Test tubes
- 4) 25 Anticoagulant tubes
- 5) 1 Paper rack for test tubes
- 6) 1 Assay diluents bottle
- 7) 1 Instructions for use
- \clubsuit <u>Black line</u> on the capillary tube is the indicator line for $10\mu l$



Materials required, but not provided

Timer

Precautions

- 1) The test kit is for camel serum, plasma or whole blood use only. Do not use for other animals
- 2) The test strip is sensitive to humidity as well as heat. Perform the test immediately after removing the test strip from the bottle.
- 3) Do not reuse the test components.
- 4) Apply the sample and assay diluents vertically.
- 5) Do not touch the membrane in the result window of test strip.
- 6) Do not use the test kit beyond the stated expiration date marked on the package label.
- 7) Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
- 8) Apply the assay diluents bottle vertically.
- 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.

■ Storage and Stability

- 1) Store the test kit at 2^40° 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

■ Collection and Preparation of Sample

1) Camel whole blood, serum, plasma or milk should be used with this test.

[Whole blood] Collect the whole blood into the anticoagulant tube (Max. vol. 1.5ml) provided. If anticoagulated whole blood is not used immediately or tested within 24 hours, it should be refrigerated at 2~8°C.

[Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30minutes 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) by and then centrifuge to get plasma.

[Milk] Collect the milk into the collection tube.

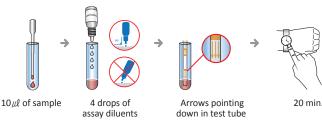
- 2) If serum, plasma or milk samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, freezing is recommended. Frozen samples should be brought to room temperature (15~30°C) prior to use.
- Samples containing precipitate may yield inconsistent test results. Such 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 must be at room temperature(15~30°C) before use.
- 2) Using a capillary tube, add 10 μ 0 of sample into the bottom of test tube and add the 4 drops(approximately 120 μ 0) of assay diluents vertically. Swirl the test tube to mix sample and assay diluents.

- 3) Remove the test strip from the bottle.
- 4) Place the test strip into the test tube with the arrows on the test strip pointing down vertically. Do not handle or move the test strip until the test is complete and ready for reading.
- 5) Start the timer. The sample will flow across the result window.
- 6) Interpret the test results at 20 minutes. Do not read after 30 minutes.

[Figure of Test Procedure]



■ Interpretation of the Result

1) Negative

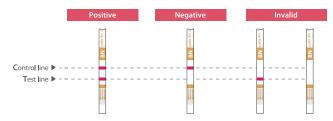
Only control("C") line appears in the result window.

Positive

Test("T") line and control("C") line appear within the result window to indicate the presence of the antibodies against *Brucella melitensis*, *abortus* or *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) The Anigen Rapid Camel Brucella Ab Test Kit will only indicate the presence of antibodies against Brucella melitensis, abortus, or suis in the camel serum, plasma, whole blood or milk. Other clinical and/or 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 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

- Sensitivity and specificity of Anigen Rapid Camel Brucella Ab Test Kit (Comparison with Rose Bengal Test)
 - ; A total of 106 camel samples were using Anigen Rapid Camel Brucella Ab Test Kit. The comparison results of Anigen Rapid Camel Brucella Ab Test Kit with Rose Bengal Test(RBT) showed Anigen Rapid Camel Brucella Ab Test Kit had good correlation with RBT.

			Reference assay: RBT		
			Positive	Negative	Total
	Anigen Rapid Camel Brucella Ab Test Kit	Positive	16	4	20
		Negative	0	86	86
		Total	16	90	106

*Sensitivity = 16/16 x 100 = 100%, *Specificity = 86/90 x 100 = 95.6%

 Reproducibility of Anigen Rapid Camel Brucella Ab Test Kit has been demonstrated by studies (within-run, between-run and batch-to-batch) with inhouse reference panels. All values were identical to reference panel acceptance criteria.

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