

## ONE STEP Bovine *Brucella abortus* Antibody TEST

For veterinary diagnostic use only

### Anigen Rapid B.Brucella Ab Test Kit

#### ■ Principles

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

The Anigen Rapid B.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 abortus* are present in sample, a purple test line would appear in the result window.

#### ■ Materials provided

Reagent	10 Tests/Kit
Anigen Rapid B.Brucella Ab Test Device	10
Assay diluent bottle	1
Disposable capillary tube	10
Instructions for use	1

Figure1. A black line on the capillary tube is the indicator line for 10 $\mu$ l.



#### ■ Materials required, but not provided

- 1) Timer

#### ■ Precautions

- 1) The test kit is for bovine 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 sample and 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.

#### ■ 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.

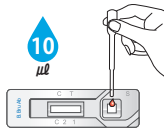


#### ■ Collection and Preparation of Sample

- 1) Bovine whole blood, serum, plasma or milk should be for this test.  
**[Whole blood]** Collect the whole blood into the anticoagulant tube. 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 blood to get supernatant.  
**[Plasma]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge blood 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.

- 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 and 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, dry surface.
- 3) Using a capillary tube, add 10 $\mu$ l of sample into the sample hole (S) on the test device.  

- 4) Add 4 drops (approximately 120 $\mu$ l) of assay diluent into the sample hole(S) 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.
- 6) Interpret the test results at 20 minutes. Do not interpret after 30 minutes.  


#### ■ Interpretation of the Result

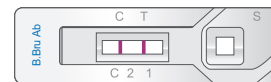
##### 1) Negative

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



##### 2) Positive

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



##### 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 B.Brucella Ab Test Kit is very accurate for detecting antibodies against *Brucella abortus*, a low incidence of false results can be occurred. 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 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.

Doc. No. : I2301-6EC  
Issued date : Jul. 01, 2019

## Anigen Rapid B.Brucella Ab Test Kit

### 牛布鲁氏杆菌病抗体快速检测试剂盒

#### ■ 解释

Anigen牛布鲁氏杆菌病抗体快速检测试剂盒能以免疫层析法定性地检测牛全血、血清、血浆及牛奶中的牛布鲁氏杆菌抗体。

Anigen牛布鲁氏杆菌病抗体快速检测试剂盒表面有字母“T”和“C”作为测试线和控制线。在提供任何样品前，测试线和控制线在结果窗中都不显示。控制线被用作程序控制。如果测试正常地完成，控制线试剂会工作，而且控制线会始终显示。如果在样品中含有足够的牛布鲁氏杆菌抗体，一条紫色的测试线会在结果窗中显示。

#### ■ 提供的材料

提供的材料	25 份试纸
Anigen牛布鲁氏杆菌病抗体快速检测试剂盒	25
瓶缓冲液	1
一次性采样毛细管	25
使用说明书	1

图1. 黑色线刻度为 10μl



#### ■ 需要但未提供的

- 1) 计时器

#### ■ 注意事项

- 1) 仅用于牛，不用于其他动物。
- 2) 检测卡对湿度和温度敏感，请随用随拆。
- 3) 请不要重复使用检测卡。
- 4) 请垂直滴加样品和稀释液。
- 5) 请不要触碰测试窗口的膜。
- 6) 请不要使用过期产品。
- 7) 如果包装损坏请不要使用。
- 8) 请不要混用不同批次的产品因为每批产品都经过自身的质控标准。
- 9) 样品要作为传染源来处理。请戴手套操作，操作后请洗手。
- 10) 请适当处理废弃物，不要污染环境。

#### ■ 保存和稳定性

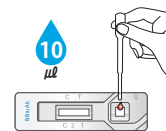
- 1) 试纸可以保存于室温(2~30°C)或者冷藏保存。**不要冷冻。**
- 2) 在有效期内的试纸是稳定的。
- 3) 不要将试纸放置于太阳直射处。

#### ■ 采样和准备

- 1) 测试需要血清、血浆、全血或牛奶。
  - [全血] 用EDTA或者肝素抗凝管采集血样。采样后的抗凝血液需要在24小时内测试。如果不能在有效时间内测试需要冰块或者冰箱保存(2~8°C)，但是不能冰冻保存。
  - [血清] 请使用不含有抗凝剂的采集管收集血液，静置30分钟后离心，采集上清液。
  - [血浆] 请使用含有抗凝剂的采集管收集血液，离心后采集上清液。
  - [牛奶] 采集原乳。
- 2) 血清、血浆、全血或牛奶要立刻使用，可以在2-8度放置。如需更长时间保管时，请置于低于-20°C或以下进行冷冻。冷冻的样品在使用前应恢复至室温(15~30°C)。
- 3) 样品包含的沉淀物必须静止沉淀后使用。
- 4) 溶血、脂血、黄疸或菌血症要避免使用，否则会产生错误结果。

#### ■ 测试步骤

- 1) 所有待检样品温度应为室温。
- 2) 取出检测卡，将它平放于宽敞和干燥的表面。
- 3) 用一次性滴管，滴加一滴(大约 10μl)血清、血浆、全血或牛奶在样品孔中。



- 4) 然后滴加4滴缓冲稀释液。
- 5) 开始时，可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动，再往样品孔中滴加一滴缓冲稀释液。



- 6) 20分钟判读结果，不要超过30分钟。

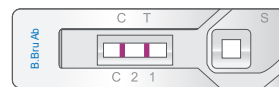


#### ■ 结果的解释

- 1) 阴性结果  
如果只有一条线(“C”)表示阴性结果。



- 2) 阳性结果  
如果在结果窗中出现两根条带(“T”和“C”)，无论那条先出现都表明阳性结果。



- 3) 无效的结果  
如果在反应开始后紫色条带看不见，结果可被认为是无效的。可能使用方法不当或者试纸已经变质。推荐重新测试样品。



#### ■ 检测的局限性

- 1) 虽然Anigen牛布鲁氏杆菌病抗体快速检测试剂盒可以准确地检测出牛布鲁氏杆菌抗体，但不可避免有极小的可能产生结果误差。不可以局限于一种检测结果，必须结合其他临床检查，需要兽医综合所有的临床和实验室数据后得出结论。
- 2) 阅读窗口可能会显示粉红色的背景，这不会影响结果的准确性。
- 3) 安捷公司和代理商不会对检测卡的使用不当或错误判定负责。