

Anigen Rapid C.Brucella Ab Test Kit

■ Principles

The **Anigen 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 **Anigen 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)

- 1) Ten (10) Anigen Rapid C.Brucella Ab Test Devices
- 2) One (1) Assay diluents bottle
- 3) Ten (10) Anticoagulant tubes
- 4) Ten (10) Disposable capillary tubes
- 5) One (1) Instructions for use

♣ **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.
- 3) Do not re-use the test components.
- 4) Apply the sample and assay diluents 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, reaction 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) 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 anticoagulants 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 use.
- 2) Remove the test device 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 of the test device.
- 4) Add 2 drops of assay diluents 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 diluents to the sample well.
- 6) Interpret test results at 10~20 minutes. Do not interpret after 30 minutes.

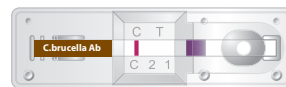
[Figure for test procedures]



■ Interpretation of the Result

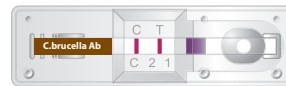
1) Negative result

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



2) Positive result

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



3) 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 Anigen 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) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

■ Expected Values

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

Anigen Rapid C.Brucella Ab Test Kit

布鲁氏杆菌抗体快速诊断试纸

■ 解释

Anigen布鲁氏杆菌抗体快速诊断试纸能以免疫色谱分析法定性地检测犬类全血、血浆或者血清中的犬布鲁氏杆菌抗体。

Anigen布鲁氏杆菌抗体快速诊断试纸表面有字母“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犬布鲁氏杆菌抗体，一条紫色的测试线会在结果窗中显示。

■ 提供的材料 (10份试纸)

- 1) 10份Anigen犬布鲁氏杆菌抗体快速检测试纸
- 2) 1份装有反应缓冲液的样品收集管
- 3) 10根一次性采样毛细管
- 4) 10根抗凝管
- 5) 一份使用说明

♣ 黑色线的刻度就是10 μ l的量。



■ 需要但未提供的

- 1) 计时器

■ 注意事项

- 1) 仅用于犬，不用于其他动物。
- 2) 测试板对湿度和温度敏感，请随用随拆。
- 3) 不要重复使用试纸。
- 4) 请垂直滴加样品或稀释液。
- 5) 不要触碰测试窗口的膜。
- 6) 不要使用过期产品。
- 7) 如果包装损坏请不要使用。
- 8) 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) 样品要作为有传染性来处理。请戴手套，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℃)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、血浆或全血。

[全血] 请使用含有抗凝剂的最大容量为1.5ml全血的采集管收集血液比如肝素、枸橼酸钠或EDTA,如果血液不是马上使用,请放于冰箱2-8度可冷藏24小时。

[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。

- 2) 全血要立刻使用,可以在2-8度放置24小时。
- 3) 样品包含的沉淀物必须静止沉淀后使用。
- 4) 溶血、脂血、黄疸或菌血要避免使用,会产生错误结果。

■ 测试步骤

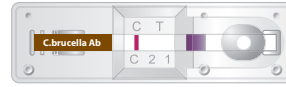
- 1) 所有反应物要到达室温。
- 2) 取出试纸,将它平放于宽敞和干燥的表面。
- 3) 用一次性滴管,滴加一滴(大约10 μ l)血清、血浆或者全血在样品孔
- 4) 然后滴加2滴缓冲稀释液。
- 5) 开始时,你可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动,再往样品孔中滴加一滴缓冲稀释液。
- 6) 10~20分钟判读结果,不要超过30分钟。



■ 判读结果

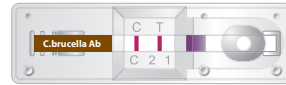
1) 阴性结果

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。



■ 测试限制

- 1) 即使Anigen布鲁氏杆菌抗体快速诊断试纸可以准确地检测犬布鲁氏杆菌抗体,一些极小的错误结果还是会发生。其他临床检查也是必须的。所有的诊断结果,不可以基于一项检测的结果,需要兽医通过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试纸的勿使用或误判断负责。

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