ONE STEP Bovine TB Antibody RAPID TEST

For veterinary diagnostic use only

Anigen Rapid Bovine TB Ab Test Kit

■ Principles

The Anigen Rapid Bovine TB Test Kit is a chromatographic immunoassay for the qualitative detection of *Mycobacterium bovis* antibody in bovine whole blood, plasma or serum.
The Anigen Rapid Bovine TB Test Kit shows two letters which are test (T) line and control (C) line on the surface of device. The control line is a reference line which provides the test is performing properly. The control line has to be appeared at all times after the test has performed. If the antibodies against *Mycobacterium bovis* exist in sample, a purple test line would appear in the result window.
The highly selective recombinant *Mycobacterium bovis* antigens are used as a capture and detector in the assay. These antigens are capable of detecting *Mycobacterium bovis* antibodies in sample with high accuracy.

■ Materials provided

Materials	10 Tests/Kit
Anigen Rapid Bovine TB Ab Test Devices (See figure 1)	10
Disposable capillary tubes (See figure 2)	10
Developing buffer bottle	1
Whole blood diluent bottle	1
Test tubes	10
Anticoagulant tubes	10
Disposable droppers	10
Paper rack for test tubes	1
Instructions for use	1

Figure 1. Test Device

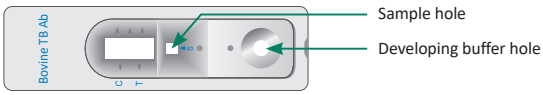
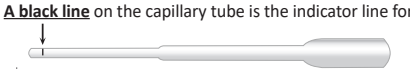


Figure 2. **A black line** on the capillary tube is the indicator line for 10µl.



■ Materials required, but not provided

1) Timer

■ Precautions

1) The test kit is for cattle 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 test components.
4) Apply the sample and developing buffer 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 qualitycontrol 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.
11) In case of using whole blood specimen, it may cause false negative result compared to serum and plasma specimens because whole blood specimen is diluted. Use of serum or plasma specimen is recommended for more accurate results excluding emergency situation.

■ 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.

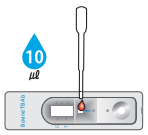
■ Collection and Preparation of Sample

1) Whole blood, serum or plasma should be used as a sample for this test.
   [Whole blood] Collect the whole blood into the anticoagulant 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

[Serum & Plasma sample]

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 the disposable capillary tube, add 10µl of serum or plasma to the sample hole(marked "S" on the test device) and wait for 1 minute.

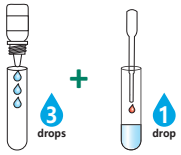


4) Add 3 drops of the developing buffer in dropping bottle into the developing buffer hole vertically.
5) Start the timer. The sample will flow across the result window. If it does not appear after 1minute, add one more drop of developing buffer to the developing buffer hole.

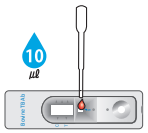
6) Interpret test results at 20 minutes.
   Do not interpret after 30 minutes.

[Whole blood sample]

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Add 3 drops of the whole blood diluent into the test tube.
3) Add 1 drop (30µl) of a whole blood sample using the disposable dropper and mix them for 1 minute.



4) Add 10µl of the mixed sample using a capillary tube to the sample hole (marked "S" on the test device) and wait for 1 minute.

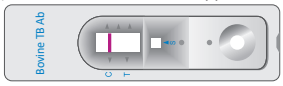


5) Add 3 drops of the developing buffer into the developing buffer hole.
6) Start the timer. The sample will flow across the result window. If it does not appear after 1minute, add one more drop of developing buffer to the developing buffer hole.

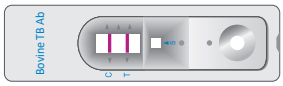
7) Interpret test results at 20 minutes.
   Do not interpret after 30 minutes.

■ Interpretation of the Test Results

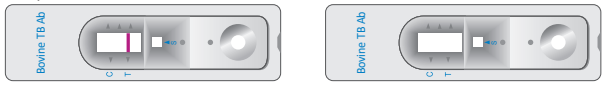
1) Negative result
The only control ("C") line in the result window appears.



2) Positive result
Test ("T") line and control ("C") line within the result window indicate the presence of antibody against Bovine TB.



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



■ Limitation of the Test

1) Although this test Kit is very accurate in detecting antibodies against Mycobacterum bovis in the specimen, a low incidence of false results can occur. 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.

■ Expected values

Anigen Rapid Bovine TB Test Kit has been compared with a PPD tests. The overall accuracy is greater or equal to 85.5%.

Doc. No. : I2302-10EC
Issued date : Aug. 23, 2019

Manufactured by BIONOTE
BioNote, Inc.
22 Samsung1ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea
TEL: 82-31-211-0516 I FAX : 82-31-8003-0618 I www.bionote.co.kr

牛结核病抗体快速检测试剂盒

兽医诊断使用

Anigen Rapid Bovine TB Ab Test Kit
安捷牛结核病抗体快速检测试剂盒

■ 原理

牛结核病(Bovine Tuberculosis)是一种严重的细菌性疾病，由牛结核分支杆菌感染呼吸系统引起。牛结核分支杆菌能够感染大多数哺乳动物。此疾病是一种慢性疾病。牛结核病抗体快速检测测试盒是一种免疫层析法(chromatographic immunoassay)检测技术,可以利用全血、血清或血浆中的牛结核分支杆菌抗体进行定性检测。

试验中使用特别选择的牛结核分支杆菌抗原用作捕获材料，这可确保试剂板高度精确地检测到样品中的牛结核分支杆菌抗体。

试剂板表面有两个字母，一个是“T”，代表检测线，另一个是“C”，代表对照线。在加入样品之前，两条线是看不见的。对照线用于操作的对照作用。如果进行试验操作准确，并且对照线中的试剂还有效，对照线应该出现。如果样品中含有足够量的牛结核分支杆菌抗体，检测结果应出现紫色的检测线。

■ 提供的材料

提供的材料	25份试纸
快速牛结核病抗体测试板	25
毛细管	25
缓冲液	1
全血样品提取液	1
试管	25
抗凝管	25
一次性滴管	25
纸质试管架	1
使用说明	1

图1. 测试板

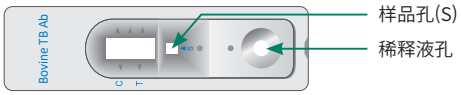


图2. 黑色线刻度为 10µl.

■ 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) 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。
11) 使用全血检测时，由于检测样本浓度相对较低，可能会引起部分假阴性的结果。为了获得准确的检测结果，建议您使用血清或血浆进行检测。

■ 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。

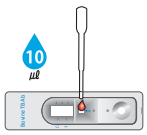
■ 采样和准备

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) 血清或血浆要立刻使用。若不马上使用时，请置于2-8°C冷藏保管24小时内使用。
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。

■ 检测步骤

[血清和血浆样本]

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) 用毛细管吸取1滴（10µl）血清或血浆样本，于样品孔（标有“S”）中滴 加1滴样本，等待1分钟。

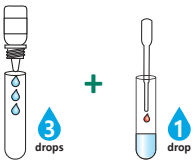


4) 然后在扩展孔中滴加3滴扩展液。
5) 开始时，你可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动，再往样品孔中滴加一滴缓冲稀释液。

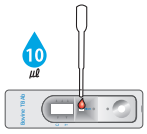
6) 20分钟判读结果，不要超过30分钟。

[全血样本]

1) 取出试纸，将它平放于宽敞和干燥的表面。
2) 加3滴稀释液到试管中以稀释全血。
3) 利用滴管取1滴（30µl）全血加入其中，混合1分钟。



4) 用毛细管吸取1滴（10µl）全血样本，于样品孔（标有“S”）中滴 加1滴样本，等待1分钟。

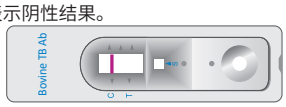


5) 然后在扩展孔中滴加3滴扩展液。
6) 开始时，你可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动，再往样品孔中滴加一滴缓冲稀释液。

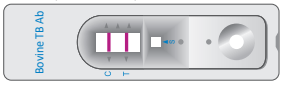
7) 20分钟判读结果，不要超过30分钟。

■ 结果的解释

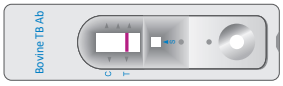
1) 阴性结果
如果只有一条线(“C”)表示阴性结果。



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
如果试验操作完成后，未出现对照紫色线(C)，说明结果无效。可能操作不当造成，建议重新检测。



■ 解释

1) 即使Anigen牛结核病抗体快速检测试剂盒可以准确地检测牛结核分支杆菌抗体，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。

■ 检测结果

本方法的检出率大于结核菌素皮内试验(PPD test),整体检出率大于等85.5%。

Manufactured by BIONOTE
BioNote, Inc. 百易奥生物公司
韩国京畿道华城市三星1路4街 22 18449
TEL: 82-31-211-0516 ‖ FAX: 82-31-8003-0618 ‖ www.bionote.co.kr