

## Anigen Rapid Toxoplasma Ab Test Kit

### Principles

**Anigen Rapid Toxoplasma Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of antibody against *Toxoplasma gondii* in serum, plasma or whole blood.

**Anigen Rapid Toxoplasma 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 *T.gondii* are present in sample, a purple test line would appear in the result window.

The highly selective recombinant *T.gondii* antigens are used as a capture and detector in the assay. These are capable of detecting antibodies against *T.gondii* in sample with high accuracy.

### Materials provided (10 Tests/Kit)

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

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



### Materials required, but not provided

Timer

### Precautions

- 1) The test kit is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
- 2) Do not reuse the test components.
- 3) Apply the sample using capillary tube and assay diluents dropping bottle vertically.
- 4) Do not touch the membrane in the result window of test device.
- 5) Do not use the test kit beyond the stated expiration date marked on the package label.
- 6) Do not use the test kit if the pouch is damaged or the seal is broken.
- 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) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
- 9) 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) Whole blood, serum or plasma should be used for 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.

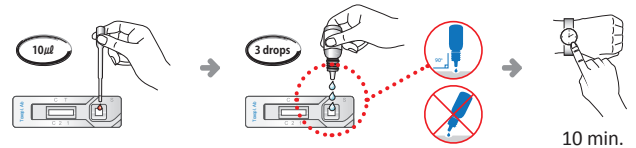
**[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum supernatant.

**[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 stored at 2~8°C. For longer storage, freeze at -20°C. Frozen samples should be brought to 15~30°C prior to use.
- 3) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 4) The use of hemolytic or bacterially contaminated specimens 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 the disposable capillary tube, **add 10  $\mu$ l of sample** into the sample hole.
- 4) Add **3 drops of the assay diluents** 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 diluents to the sample hole.
- 6) Interpret test results **at 10 minutes**. Do not interpret after 20 minutes.

[Figure of Test Procedure]



### Interpretation of the Result

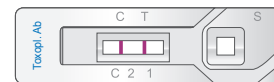
#### 1) Negative

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



#### 2) Positive

Test("T") line and control("C") line in the result window indicate the presence of antibody against *T.gondii*.



#### 3) Invalid

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



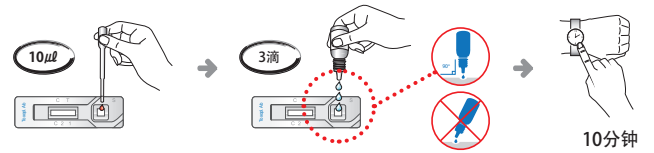
### Limitations of the Test

- 1) Although the Anigen Rapid Toxoplasma Ab Test kit is very accurate for detecting antibodies to *Toxoplasma gondii* in animal samples, but a low incidence of false results can occur. Other clinically 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.

# Anigen Rapid Toxoplasma Ab Test Kit

## 弓形虫抗体快速诊断试纸

## [测试步骤图解]



### 解释

Anigen弓形虫抗体快速诊断试纸采用免疫色谱分析法可以定性地检测血清、血浆或全血中的刚地弓形虫抗体。

Anigen弓形虫抗体快速诊断试纸条表面有字母“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刚地弓形虫抗体，一条紫色地测试线会在结果窗中显示。

高度选择性的单克隆抗体被用来准确捕捉样品中的刚地弓形虫抗体。

### 提供的材料 (10 份试纸)

- 1) 10块弓形虫抗体快速诊断试纸
- 2) 1瓶稀释液
- 3) 10根一次性滴管
- 4) 10根抗凝管
- 5) 1份使用说明

♣ 黑色线刻度为 10  $\mu$ l



### 需要但未提供的

计时器

### 注意事项

- 1) 该试纸对湿度和温度敏感，请临用前再打开包装。
- 2) 不要重复使用。
- 3) 请垂直使用吸管。
- 4) 请不要触摸试纸的窗口。
- 5) 请在有效期内使用。
- 6) 请不要使用包装破损的试纸。
- 7) 试纸的每个成分均进行质控，请勿混用不同批号的产品。
- 8) 请按具有潜在传染性的物质进行处理样品。
- 9) 请按照当地的法律来处理一次性医疗废弃物。

### 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) 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、黄疸或菌血症要避免使用,会产生错误结果。

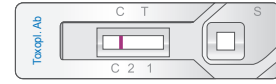
### 测试步骤

- 1) 需要在室温下使用 (15-30度)。
- 2) 取出试纸,将它平放于宽敞和干燥的表面。
- 3) 用一毛细管,滴加10  $\mu$ l血清、血浆或者全血在样品孔,然后滴加3滴缓冲稀释液。
- 4) 测试开始,你会发现在观察窗中出现一条紫色的条带.如果1分钟后条带仍然没有出现,多滴加一滴缓冲稀释液。
- 5) 10分钟判断结果。不要超过20分钟。

### 判读结果

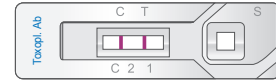
#### 1) 阴性结果

如果只有一条线(“C”)表示阴性结果。



#### 2) 阳性结果

控制线和测试线出现阳性。



#### 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) 即使Anigen弓形虫抗体快速诊断试纸可以准确地检测弓形虫,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。