

## ONE STEP IgG to Canine Parvovirus TEST

### Anigen Rapid CPV Ab Test Kit 2.0

#### Principles

Anigen Rapid CPV Ab Test Kit 2.0 is a chromatographic immunoassay for the semi-quantitative detection of IgG to parvovirus in canine serum, plasma or whole blood.

Anigen Rapid CPV Ab Test Kit 2.0 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 target antibodies are present in sample, a purple test line would appear in the result window.

The highly selective antigens are used as each capture and detector in the assay. These antigens are capable of detecting IgG antibody to canine parvovirus in sample with high accuracy.

#### Materials provided (10Tests/Kit)

- 1) Ten (10) Anigen Rapid CPV Ab Test 2.0 Devices
- 2) Ten (10) Assay diluents tubes
- 3) Ten (10) Disposable capillary tubes (5µl)
- 4) Ten (10) Anticoagulant tubes
- 5) Ten (10) Disposable droppers
- 6) One (1) Color scale (1~6) measurement
- 7) One (1) Instructions for use
- ♣ A black line on the capillary tube is the indicator line for 5µl.



#### 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 test components.
- 4) Apply the sample using disposable dropper 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 kits in the direct sunlight.
- 3) The test kit is stable within the expiration date 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 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.

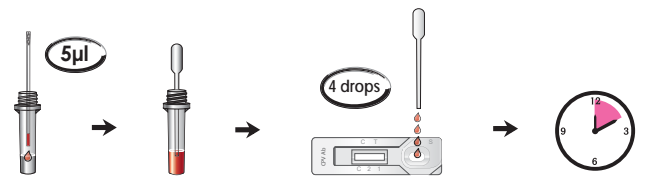
**[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum supernatant.

**[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 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

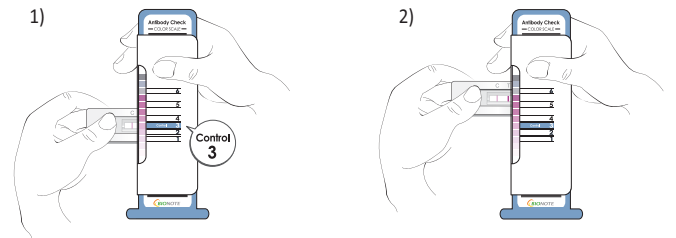
- 1) Allow all kit components and sample to reach room temperature prior to testing.
- 2) Collect 5µl of sample using capillary tube (black line), and then add the specimen into the assay diluents tube.
- 3) Remove the test kit from the foil pouch prior to use.
- 4) Using the disposable dropper provided, take the samples in the tube.
- 5) Add four (4) drops into the sample hole, drop by drop vertically.
- 6) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of prepared sample to the sample hole.
- 7) Interpret the test results at 10 minutes. Do not interpret after 20 minutes.

[Figure of Test procedure]



#### Use of color scale

- 1) Compare the color development on the control line with color scale and fix it to the scale 3.
- 2) Interpret the color intensity of the test line.



#### Interpretation of the Result

##### 1) Negative result

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



##### 2) Positive result

###### • Low titer (Below 1:40 as HI titer)

The color development of Test ("T") line is weaker than that of control ("C") line. (Color scale 1~2)



\*\*Antibody titer is low against CPV.

###### • Medium Titer (1:80 as HI titer)

The Test ("T") line has equal color development with control ("C") lines. (Color scale 3)



\*\*Antibody titer is medium against CPV. This is indicative of a good immune status.

###### • High Titer (Above 1:160 as HI titer)

The color development of Test ("T") line is higher than that of control ("C") line. (Color scale 4~6)



\*\*Antibody titer is high against CPV. This is indicative of a good immune status.

##### 3) Invalid result

If the control ("C") line is does not appear, the result might be considered invalid. The sample should be re-tested.



#### Limitation of the Test

- 1) Although the Anigen Rapid CPV Ab Test kit 2.0 is very accurate for detecting IgG to Canine parvovirus, 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: I2151-4E  
Revised Date: Jul. 21 2015

## Anigen Rapid CPV Ab Test Kit 2.0 安捷犬细小病毒IgG抗体抗原快速检测试纸

### 解释

犬细小病毒IgG抗体抗原快速检测试纸采用固相免疫色谱分析法快速的半定量地检测犬类血清、血浆或全血中的犬细小病毒抗体。犬细小病毒IgG抗体抗原快速检测试纸表面存在两根线。测试线和控制线在加样前都不可见。控制线表示该测试操作正常。当测试进行后控制线每次都会出现。如果样品中存在IgG，会出现测试线。

### 提供材料

- 1) 10份试纸
  - 2) 10份稀释缓冲液
  - 3) 10份一次性毛细管 (5 $\mu$ l)
  - 4) 10份抗凝管
  - 5) 10份一次性吸管
  - 6) 1份比色卡
  - 7) 1份使用说明
- ♣ 毛细管上的黑线代表 5 $\mu$ l.



### 需要但未提供的材料

计时器

### 注意

- 1) 仅用于犬，不要用于其他动物。
- 2) 该试纸对湿度和温度敏感，请临用前再打开包装。
- 3) 不要重复使用试纸。
- 4) 请垂直使用吸管。
- 5) 请不要触摸试纸的窗口。
- 6) 不要使用超过有效期的试纸。
- 7) 请不要使用包装破损的试纸。
- 8) 同一批号的产品经过质量控制，不要混用不同批号的产品。
- 9) 所有样品需要按照具有潜在风险来操作。
- 10) 请按照当地法律来处理一次性的医疗废弃物。

### 保存和稳定性

- 1) 室温(2~30°C)保存或冷藏。在有效期前为稳定的。不要冰冻。
- 2) 不要置于阳光直射处。
- 3) 保质期前试纸是稳定的。

### 采样和准备

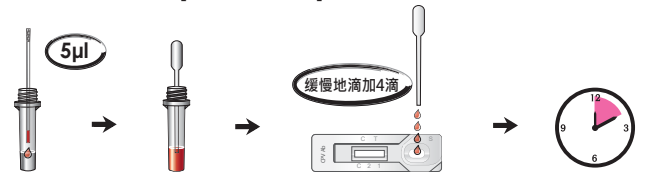
- 1) 测试需要血清、血浆或全血。  
[全血]请使用含有抗凝剂的最大容量为1.5ml全血的采集管收集血液比如肝素、枸橼酸钠或EDTA，如果血液不是马上使用，请放于冰箱2-8度可冷藏24小时。  
[血清]请使用不含有抗凝剂的采集管收集血液，静置30分钟后离心，采集上清液。  
[血浆]请使用含有抗凝剂的采集管收集血液，离心后采集上清液。
- 2) 全血要立刻使用，可以在2-8度放置24小时。
- 3) 样品包含的沉淀物必须静止沉淀后使用。
- 4) 溶血、脂血、黄疸或菌血要避免使用，会产生错误结果。

### 测试步骤

- 1) 所有反应物要到达室温。
- 2) 用毛细管采取5 $\mu$ l样品，加入稀释液中。
- 3) 临用前打开包装。
- 4) 用一次性吸管，吸取缓冲稀释液。
- 5) 缓慢地滴加4滴混合液到样品孔中。
- 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。

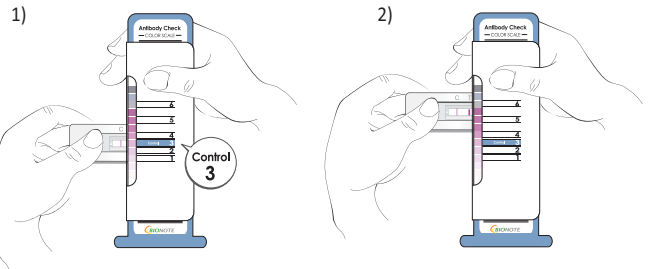
7) 10分钟判读结果，不要超过20分钟。

[测试步骤图解]



### 使用比色卡

- 1) 先用控制线的颜色深度在比色卡上进行比色。
- 2) 判读测试线的颜色深度。



### 判读结果

#### 1) 阴性结果

在结果视窗中仅出现一条紫色线(“C”线)，表明为阴性。



#### 2) 阳性结果

- 低滴度 (Below 1:40 as HI titer).  
T线深度比C线浅(比色卡1~2)。



- \*\* 犬细小病毒抗体滴度低。
- 中等滴度 (1:80 as HI titer).  
T线深度和C线类似(比色卡3)。



- \*\* 含有中度的犬细小病毒抗体，意味着良好的免疫状态。
- 高滴度 (Above 1:160 as HI titer).  
T线深度比C线深(比色卡4~6)。



- \*\* 犬细小病毒抗体滴度高。意味着良好的免疫状态。

#### 3) 重新测试

两条线都没有或只有一条测试线。



### 测试限制

- 1) 即使该试纸的准确性非常高，但是还是有可能出现小的错误的。和所有的诊断一样，必须结合临床其他的症状和检查来做出诊断。
- 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。

文件编号: I2151-4C  
修订日期: 2016-07-21