

One Step Canine Corona Virus Antigen Test

For veterinary diagnostic use only

Anigen Rapid CCV Ag Test Kit

Principles

The Anigen Rapid CCV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Canine Corona virus (CCV) antigen in canine feces. The Anigen Rapid CCV Ag Test Kit has two lines 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 CCV antigens are present in sample, a purple test line would appear in the result window. The highly selective antibodies to CCV are used as a capture and detector in the assay. These antibodies are capable of detecting CCV antigens in canine feces with high accuracy.

Materials provided

Materials	5 Tests/Kit	10 Tests/Kit
Anigen Rapid CCV Ag Test Device	5	10
Assay diluents tube	5	10
Disposable swab	5	10
Disposable dropper	5	10
Instructions for use	1	1

Materials required, but not provided

- 1) Timer

Precautions

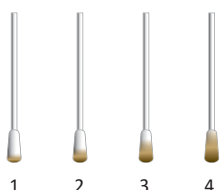
- 1) The test kit is for canine use only. Do not use for other animals.
- 2) The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
- 3) Do not reuse test components.
- 4) Apply the sample using disposable dropper vertically.
- 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 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

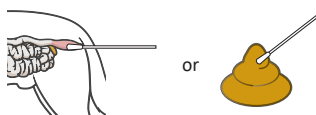
- 1) Canine feces swab should be used for this test.
- 2) The samples should be tested immediately after collection.
- 3) If samples are not tested immediately, they should be stored at 2~8°C for 24 hours. For longer storage, freeze at -20°C or below. Frozen samples should be brought to room temperature (15~30°C) prior to use.
- 4) The amount of fecal swab may affect the results. It is required to follow the swab amount of feces as shown in the picture on the below. Excessive fecal amount may induce a false positive result and slow migration.



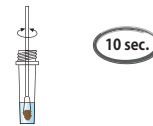
1. Not enough
2. Good
3. Good
4. Too Much

Procedure of the Test

- 1) All reagents must be at room temperature (15~30°C) before use.
- 2) Collect feces samples using a swab.



- 3) Insert the swab into the assay diluents tube and mix the swab until the sample has been dissolved into the assay diluents (Approximately 10sec).



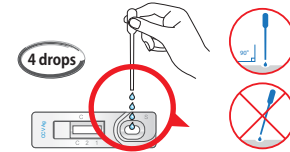
- 4) Wait for 1 minute to settle down the large particles.



- 5) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 6) Using the disposable dropper, take the supernatant sample in the tube.



- 7) Add four (4) drops of mixed sample into the sample hole (S), drop by drop vertically.



- 8) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of mixed sample to the sample hole.

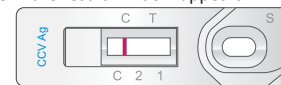
- 9) Interpret test results at **5~10 minutes**. Do not read the result after 20 minutes.



Interpretation of the Result

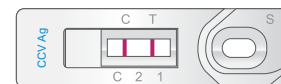
1) Negative result

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



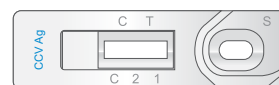
2) Positive result

Test ("T") line and control ("C") line within the result window indicate the presence of CCV antigen.



3) Invalid Result

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



Limitations of the Test

- 1) Although the Anigen Rapid CCV Ag Test kit is very accurate in detecting Canine Coronavirus antigen, a low incidence of false results can be occurred. Other clinically 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. The detection limit of this kit is about $1.97 \times 10^{4.0} \text{TCID}_{50}/\text{mL}$.
- 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.: I1104-6E
Revised date: May. 17, 2017

Anigen Rapid CCV Ag Test Kit

安捷冠状病毒抗原快速诊断试纸

■ 解释

安捷冠状病毒抗原快速诊断试纸能以免疫色谱分析法法定性地检测犬类粪便中的犬冠状病毒抗原。安捷冠状病毒抗原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犬冠状病毒抗原，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	5份试纸	10份试纸
安捷犬冠状病毒抗原快速检测试纸	5	10
装有反应缓冲液的样品收集管	5	10
样品收集棉签	5	10
一次性滴管	5	10
使用说明	1	1

■ 需要但未提供的

- 1) 计时器

■ 注意事项

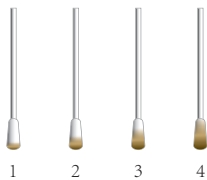
- 1) 仅用于犬，不要用于其他动物。
- 2) 该试纸对湿度和温度敏感，请临用前再打开包装。
- 3) 不要重复使用试纸。
- 4) 请垂直使用吸管。
- 5) 请不要触摸试纸的窗口。
- 6) 不要使用超过有效期的试纸。
- 7) 请不要使用包装破损的试纸。
- 8) 同一批号的产品经过质量控制，不要混用不同批号的产品。
- 9) 所有样品需要按照具有潜在风险来操作。
- 10) 请按照当地法律来处理一次性的医疗废弃物。

■ 保存和稳定性

- 1) 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。

■ 样品收集和准备

- 1) 该测试使用犬类的粪便。
- 2) 收集样品后必须立刻进行测试。
- 3) 如果样品不能马上检测，请置于2-8度可冷藏24小时，若放置于-20度可更久但使用时请恢复至室温。
- 4) 采集的样本量非常重要。请根据示意图来采集。过多的样本会显示假阳性和跑带缓慢。



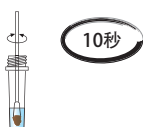
1. 不夠
2. 好
3. 好
4. 太多

■ 测试步骤

- 1) 需要在室温下使用(15-30度)。
- 2) 用棉签收集犬类的粪便。



- 3) 将棉签插入试管并搅拌 10 秒。



- 4) 静置试管 1 分钟。



- 5) 取出试纸，将它平放于宽敞和干燥的表面。
- 6) 用提供的吸管小心吸取上清液(不要将粪便颗粒吸取出来)。



- 7) 用滴管向样品孔中垂直并且精确地加入 4 滴混和液。



- 8) 当反应进行时，你会看到紫色的条带在试纸中间的结果窗中移动。如果一分钟以后仍然没有条带移动，请再往样品孔中加入一滴混和液。
- 9) 5~10分钟后判断结果。不要超过 20分钟。



■ 解释

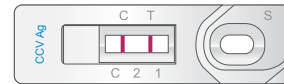
- 1) 阴性结果

如果只有一条线(“C”)表示阴性结果。



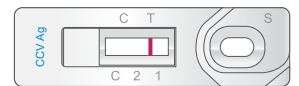
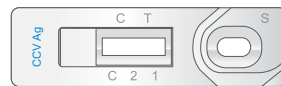
- 2) 阳性结果

如果在结果窗中出现两根条线(“C”和“T”)，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。



■ 测试限度

- 1) 即使安捷犬冠状病毒抗原快速检测试纸能极为精确地检测犬冠状病毒抗原，但是也会发生极低的错误结果。如果条件允许可以进行其他临床检查。一个准确的临床诊断结果不应该建立在一个单一测试结果上，而应该经过所有的临床和实验室诊断来评估。该测试最低检测限度是 1.97×10^4 TCID₅₀/ml 左右。
- 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。