ONE STEP Canine Influenza Virus Antigen Test

For veterinary diagnostic use only

Anigen Rapid CIV Ag Test Kit

■ Principles

Anigen Rapid CIV Ag Test Kit is a solid phase immunochromatographic assay for the rapid, qualitative detection of canine influenza virus strain antigen in a canine pharyngeal swab or nasal swab.

Anigen Rapid CIV Ag Test Kit has the letters "T" and "C" as the Test line and Control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any samples. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple test line will be visible in the result window if there is enough Canine Influenza virus antigen in the specimen.

The specially selected Canine Influenza virus antibodies are used in the test band as both capture and detector materials. These enable the Anigen Rapid CIV Ag Test Kit to identify Canine Influenza virus antigen in canine specimen with a high degree of accuracy.

■ Materials provided (10 Tests/Kit)

Materials	10 Tests/Kit
Anigen Rapid CIV Ag Test device	10
Assay diluents tube	10
Disposable swab	10
Disposable dropper	10
Instructions for use	1

■ Materials required, but not provided

1) Timer

■ Precautions

1) The test Kit is for canine use only. Do not apply to 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 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 sample 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.

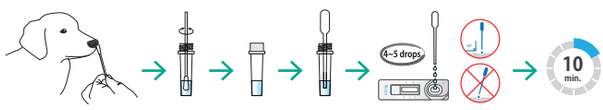
■ Collection and Preparation of Sample

1) The test for CIV antigen should be performed the canine pharyngeal swab or nasal swab.
2) After collecting the specimen using swab, the specimen should be immediately extracted and tested.
3) If specimens are not immediately tested, they should be refrigerated at 2~8°C. For storage not less than 48 hours, freeze the specimen at -20°C or below.

■ Procedure of the Test

1) Collect the pharyngeal or nasal swab with the disposable swab.
2) Insert the swab into the assay dilunets tube and mix the swab until the sample is dissolved into the assay diluents.
3) Leave the tube until the large particles is settled down to the bottom of the tube. (Approximately 1 minute)
4) Remove the test device from the foil pouch, and place it on a flat and dry surface.
5) Using a disposable dropper provided, take an aliquot from the extracted and mixed sample in the tube.
6) Add 4~5 drops into the each sample hole with the disposable dropper.
7) 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.
8) Interpret test results at **5~10 minutes.** Do not read the result after 20 minutes.

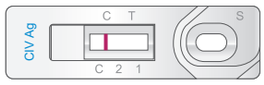
[Test procedure]



■ Interpretation of the Result

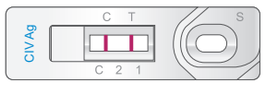
1) Negative result

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



2) Positive result

Test ("T") line and control ("C") line within the result window indicate the presence of CIV 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 CIV Ag Test kit is very accurate in detecting Canine Influenza virus antigen, 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 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.: I1107-4E
Revised date: Aug. 10, 2017

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

犬流感抗原

兽医诊断使用

Anigen Rapid CIV Ag Test Kit
安捷犬流感抗原快速检测试纸

■ 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	10份试纸
安捷犬流感病毒抗原快速检测试纸	10
装有1.0ml缓冲稀释液的样品收集管	10
样品收集棉签	10
一次性滴管	10
一份使用说明	1

■ 需要但未提供的

1) 计时器

■ 注意事项

1) 仅适用于犬，不适用于其他动物。
2) 试纸板对温度和湿度及其敏感，再从铝箔袋中拿出试纸板后立即进行试验。
3) 不要重复使用测试组件。
4) 垂直使用一次性滴管。
5) 切勿触摸结果窗口内的薄膜。
6) 切勿使用超过有效期的试剂盒。
7) 切勿使用真空包装袋破损的试剂盒。
8) 切勿混用不同批次的测试组件。
9) 应及时处理具备潜在感染性的样品。处理时请佩戴防护手套，事后彻底清洁双手。
10) 请根据国家或地方法规，对所有样品、测试组件、污染材料进行净化处理。

■ 保存和稳定性

1) 试剂盒保存温度为2~30℃。**切勿冷冻。**
2) 请避免阳光直射。
3) 试剂盒在有效期内是稳定的。

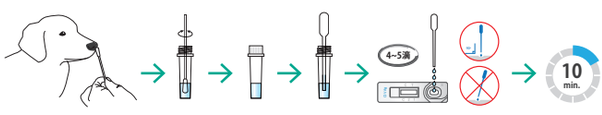
■ 样品的收集和制备

1) 对CIV 抗原的检测应采用犬咽拭子或鼻腔拭子。
2) 试样采集后应立即进行检测。
3) 不能即刻使用的样品，可在2~8℃下冷藏保存48小时。若需长期，可在-20℃下冷冻保管。

■ 测试步骤

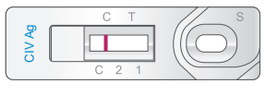
1) 使用一次性棉签收集鼻腔或咽部拭子。
2) 将棉签放入含有稀释液的试管中，并充分混匀直到样品溶解在稀释液中。
3) 静置试管，至大颗粒沉淀。（大约1分钟）。
4) 取出试纸，将其平放于宽敞和干燥的平面。
5) 使用一次性滴管，采集混合液。
6) 滴4 ~ 5滴混合液到试纸的样品孔中。
7) 启动计时器。可观察到紫色反应物流经结果窗口。若一分钟后没有出现流经现象，需在样品孔再滴加一滴混合液样品。
8) 请在5~10分钟内分析结果。切勿在20分钟后分析结果。

[测试过程图解]

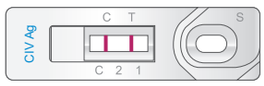


■ 判读试纸

1) 阴性结果
只有控制(“C”)线出现在结果窗口中。



2) 阳性结果
控制（“C”）线和测试（“T”）线均出现在结果窗口。说明样品中存在CIV 抗原。



3) 无效结果
若控制(“C”)线没有出现，则测试结果无效。应重新进行检测。

■ 测试的局限性

1) 尽管安捷犬腺病毒抗原快速检测试纸能极为精确地检测犬腺病毒抗原，但是也会发生极低的错误结果。该试纸是作为筛选而使用。如果允许的话需要结合其他临床检查共同得出结果。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。
2) 阅读窗口可能会出现浅粉色背景，这不会影响结果的准确性。
3) Bionote和其经销商不会为误用或误读而导致的结果承担责任。

文件编号: I1107-6C
修订日期: 2017-08-10

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