For veterinary diagnostic use only

Anigen Rapid NDV Ag Test Kit

■ Principles

The Rapid NDV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Newcastle Disease virus(NDV) antigen in oropharynx, spleen, or kidney from chicken.

The Rapid NDV Ag 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 NDV antigens exist in sample, a purple test line would appear in the result window.

The highly selective antibodies to NDV are used as a capture and detector in the assay. These antibodies are capable of detecting NDV antigen in chicken oropharynx, spleen or kidney.

Materials provided

<u> </u>	
Reagent	10 Tests/Kit
Anigen Rapid NDV Ag Test Device	10
Assay diluent tube	10
Disposable swab	10
Disposable dropper	10
Instructions for use	1

Materials required, but not provided

1) Timer

Precautions

- 1) The Rapid Test Kit is for chicken 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 the test components.
- 4) Apply the assay diluent 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 $\ensuremath{\mathsf{S}}$ protective gloves while handling samples. Wash hands thoroughly
- 10) 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) Chicken oropharynx, spleen, or kidney should be used for this test.
- 2) Poke the organ(oropharynx, spleen, or kidney) using a swab. Or Make the 20~50% homogenates of spleen or kidney using PBS. Ex) 50% homogenate: Mix 2g of spleen with 2ml of PBS, 20% homogenate: Mix 1g of spleen with 4ml of PBS.
- 3) If sample is not tested immediately, it should be refrigerated at $2\sim8^{\circ}\text{C}$ for up to 24 hours. For longer storage, freeze at or below -20°C in vials with airtight seals.

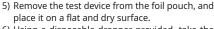
■ Procedure of the Test

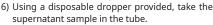
- 1) Allow all kit components and samples to room temperature before use.
- 2) Collect the samples using a swab.
- 3) Insert the swab into the assay diluent tube and mix a swab for 10 seconds.



1 min.









7) Apply four(4) drops of sample into the sample hole, drop by drop.



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 prepared sample to the sample hole.



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

■ Interpretation of the Result

One Control line "C" appears in the result window.



2) Positive result

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



3) Invalid Result

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 Rapid NDV Ag Test kit is very accurate in detecting Newcastle Disease virus 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 approximately 0.25 HAU.
- 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

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兽医诊断使用

* Anigen Rapid NDV Ag Test Kit

新城疫病毒抗原快速检测试验盒

■ 解释

新城疫病毒抗原快速检测试剂盒采用免疫层析(chromatographic immunoassay)技术对禽咽喉拭子、脾脏或肾脏中的新城疫病毒抗原进行定性检测。试剂板表面的"T"线代表检测线;"C"代表质控线。在加入样品之前,两条线是不显示的。质控线用监测操作过程。如果试验操作正确,且对照线检测试还有效,对照线应该出现。如果样品中含有足够量的新城疫病毒,检测视窗会出现紫色的检测线。

该试剂盒特别选用新城疫病毒抗体作为捕获和检测材料,这可确保试剂板高 度精确地检测到样品中的新城疫病毒。

■ 提供的材料

提供的材料	10份试纸
安捷新城疫病毒抗原检测试纸	10
稀释液	10
采样拭子	10
一次性滴管	10
使用说明书	1

■ 所需但未提供材料

1) 计时器

■ 注意事项

- 1) 本仅用于兽医诊断。
- 2) 为获得最佳效果,请严格遵守操作说明。
- 3) 所有标本应按照潜在传染风险物处理。
- 4) 在使用前不要打开或从其单独密封的小袋中取出检测卡。
- 5) 如果袋子损坏或密封破损,请勿使用。
- 6) 不要重复使用检测卡。
- 7) 所有的试剂,使用前必须回温。
- 8) 请勿使用超出标签上标明的有效期的试剂。
- 9) 请不要混合不同批号的试剂。
- 10) 请在农场中测试5个以上的样本。

■ 储存和稳定性

- 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。

■ 样品采集和准备

- 1) 使采取鸡口咽拭子、脾脏或肾脏样本。
- 2) 用PBS配置20%-50%的脾脏或肾脏组织匀浆。
- 3) 若不能即刻使用样品检测时,可置于2~8°C冷藏保管(24h内)。若长期保存可在-20°C冷冻保管使用前恢复至室温。

10秒

1分钟

■ 测试步骤

- 1) 反应要在室温进行。
- 2) 采集样本 (泄殖腔、气管、肾脏拭子或湿润粪便)
- 3) 将棉签插入试管并搅拌 10 秒。
- 4) 静置试管 1 分钟。
- 5) 充分混合样本,释放病毒。
- 6) 使用一次性滴管提取稀释样本的上清液。

7) 缓慢地滴加4滴混合液到样品孔中。



- 8) 开始后可以看到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。
- 9) 10分钟后判断结果。不要超过 20分钟。



■ 结果的解释

1) 阴性结果

只出现色带(C),说明是阴性结果。



2) 阳性结果

出现2条色带(T、C),无论哪个先出现,说明新城疫阳性。



3) 无效试验

如果结果窗不出现任何色带,或对照色带不出现,都说明试验无效,应该 重新检测。





■ 检测的局限性

- 1) 尽管安捷 NDV Ag检测试纸能够准确检测新城疫病毒,但是偶尔也会出现 极低的错误结果。如果对结果存在质疑时,请进行其他检测或者实验室检 测。最终的诊断结果不应以单项检测为准,需要综合多项检测及兽医的经 验做出最终判断。本检测试纸的检测限度约为0.25HAU。
- 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。

