One step avian influenza virus type A and subtype H5 Antigen Test

For veterinary diagnostic use only

Anigen Rapid H5 AIV Ag Test Kit

Principles

Anigen Rapid H5 Avian Influenza Virus Antigen Test is a chromatographic immunoassay for the qualitative detection of avian influenza type A virus antigen and subtype H5 antigen in avian cloaca, trachea, kidney or feces.
Anigen Rapid H5 Avian Influenza Virus Antigen Test shows three letters which are test("1" and "2") lines 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 appear every time when the test has performed. If the avian influenza type A virus antigens and/or subtype H5 antigens are present in sample, purple test lines would appear in the result window.
The highly selective monoclonal anti-avian influenza virus common nucleotide protein (type A) antibody and monoclonal anti-avian influenza virus subtype H5 antibody are used as raw materials of the assay. These antibodies are capable of detecting avian influenza type A virus antigen and subtype H5 antigen in samples with a high accuracy.

Materials provided

Reagent	30 Multi Tests/Kit
Anigen Rapid H5 AIV Ag Test Device	30
Assay diluent tube	30
Disposable swab	30
Disposable dropper	30
Instructions for use	1

Materials required, but not provided

1) Timer

Precautions

1) The test kit is for avian 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 the test components.
4) Apply the sample using 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, 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.

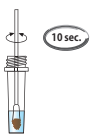
Collection and Preparation of Sample

1) Cloaca, trachea, kidney or 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.
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 left side. Excessive fecal amount may induce a false positive result and slow migration.

Not enough Good Good Too Much

Procedure of the Test

1) All reagents and samples must be at room temperature (15~30°C) before running assay.
2) Take a swab sample from cloaca, trachea or kidney using the disposable swab. Or take scattered wet feces using the swab(refer to figure of detailed Sample Collection &Test Procedures).
3) Insert the swab sample into the assay diluent tube and mix the swab sample for 10 seconds.



4) Wait for 1 minutes to settle down the samples.

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

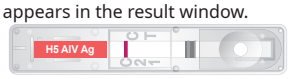
7) **Apply four(4) drops of sample** into the sample hole, drop by drop.

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 **20 minutes.**
Do not read the result after 30 minutes.

Interpretation of the Result

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



2) Positive result
AIV type A and AIV subtype H5 Ag Positive
The presence of Control line "C", Test line "1" and "2" within the result window indicates an avian influenza virus subtype H5 infection.

AIV type A Ag Positive & AIV subtype H5 Ag non-determined
The presence of Control line "C" and Test line "2" within the result window indicates an avian influenza virus infection. However, it is not determined if subtype H5 infected or not. It is recommended that the sample should be tested using other more sensitive diagnostic test(e.g. Real-time PCR) for confirmation.

3) Invalid Result
If the Control line "C" does not appear, the result might be considered invalid. The sample should be retested.

Limitations of the Test

1) Although the Anigen Rapid H5 AIV Ag Test Kit is very accurate in detecting avian influenza type A virus antigen and subtype H5 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.
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.

Cross-reactivity

AIV subtype H5 Ag test (Test line "1") showed no cross-reactivity with other H subtype (H1 ~ H4, H6 ~ H15) antigens of avian influenza virus type A, Newcastle Disease virus, Infectious Bronchitis virus and other microorganisms.

Doc. No. : I1505-12EC
Issued date : May. 20, 2019

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H5禽流感病毒抗原

兽医诊断使用

Anigen Rapid H5 AIV Ag Test Kit

H5 禽流感病毒抗原快速检测试剂盒

■ 解释

禽流感病毒抗原快速检测试验盒采用免疫层析(chromatographic immunoassay)检测技术对禽粪便中的禽流感抗原进行定性检测。
试剂板表面的“T”代表检测线；“C”代表对照线。在加入样品之前，两条线是不显示的。对照线用于监测操作过程。如果试验操作正确，并且对照线的检测试剂有效，对照线应该出现。如果样品中含有足够量禽流感病毒，检测结果为出现两条紫色的检测线。
该试剂盒特别选用H5亚型禽流感病毒单克隆抗体用作捕获材料和检测材料，这可确保试剂板高度精确地检测到粪便样品中的高致病性H5亚型禽流感病毒。

■ 提供的材料

提供的材料	30 份试纸
H5禽流感病毒抗原测试板	30
样品采集管，含稀释液	30
采样拭子	30
一次性滴管	30
使用说明书	1

■ 所需但未提供材料

1) 计时器

■ 注意事项

1) 本产品只用于禽类，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) 不要重复使用测试组件。
4) 请垂直使用吸管。
5) 请不要触摸试纸的窗口。
6) 请勿使用超出标签上标明的有效期的试剂。
7) 如果袋子损坏或密封破损，请勿使用。
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) 所有标本应按具有潜在传染风险物处理。处理样品时戴上防护手套。之后彻底洗手。
10) 请按照当地法律来处理一次性的医疗废弃物。

■ 储存和稳定性

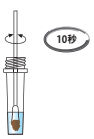
1) 试纸可以保存于室温(2~30°C)或者冷藏保存。**不要冷冻。**
2) 不要将试纸放置于太阳直射处。
3) 在有效期内的试纸是稳定的。

■ 样品采集和准备

1) 使用拭子从泄殖腔、气管、肾脏或者粪便采集样本。
2) 样品应在收集后立即进行测试。
3) 若不能即刻使用样品检测时，可置于2~8°C进行短期冷藏保管。若长期保存可在-20°C冷冻。冷冻的样品在使用前应恢复至室温(15~30°C)。
4) 采集的样品量非常重要。请根据示意图来集。过多的样本会显示假阳性和跑带缓慢。

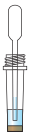
■ 测试步骤

1) 反应要在室温进行(15~30°C)。
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) 取出检测试纸并置于平坦干燥的平面。
6) 用一次性滴管，从试管吸取液上层吸取样品。



7) 加**4滴**样品到样品孔。

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) 20分钟后判断结果。不要超过 30分钟。

■ 结果的解释

1) 阴性结果

一个控制线“C”出现在结果窗口中。

2) 阳性结果

AIV型A和AIV亚型H5 Ag阳性

结果窗口中控制线“C”，测试线“1”和“2”的存在表示a 禽流感病毒亚型H5感染。

AIV型A Ag阳性和AIV亚型H5 Ag未确定

结果窗口中存在控制线“C”和测试线“2”表示A禽流感病毒感染。但是，尚未确定H5亚型是否被感染。建议使用其他更灵敏的诊断方法测试样品（例如实时PCR）进行确认。

3) 无效试验

如果未出现控制线“C”，则结果可能被视为无效。应该重新测试。

■ 检测的局限性

1) 尽管Anigen Rapid H5 AIV Ag测试试剂盒在检测A型禽流感病毒抗原和H5亚型抗原方面非常准确，但是也可能出现低概率的误差。如果获得可疑结果，可能需要进行其他临床或实验室检查。作为其他诊断测试，一个明确的临床诊断不应该基于单次测试的结果，而应该在评估所有临床和实验室检查结果后由兽医诊断。
2) 阅读窗口可呈现浅粉色背景色;这不会影响结果的准确性。
3) BioNote和代理商不会对试纸的勿使用或误判断负责。

■ 检测的交叉反应

H5亚型禽流感病毒抗原试验（检测线“1”）显示与其他A型禽流感病毒H亚型(H1~H4, H6~H15）抗原，新城疫病毒，传染性支气管炎病毒，及其他微生物无交叉反应。

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