

## ONE STEP Avian Influenza Virus Antigen Test

For veterinary diagnostic use only

# Anigen Rapid AIV Ag Test Kit

### ■ Principles

**Anigen Rapid AIV Ag Test Kit** is a chromatographic immunoassay for the qualitative detection of avian influenza type A virus antigen in chicken or duck(excluding wild animal) cloaca, oropharynx or feces sample.

**Anigen Rapid AIV Ag Test Kit** has two letters which are test line (T) and control line (C) 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. A purple test line would appear in the result window if the avian influenza virus antigens are present with the detectable concentration in the sample.

The highly selective antibodies to avian influenza type A virus are used as a capture and detector in the assay. These antibodies are capable of detecting avian influenza virus antigen in chicken or duck(excluding wild animal) sample with a high accuracy.

### ■ Materials provided

Reagent	30 Tests/Kit
Anigen Rapid 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 chicken or duck(excluding wild animal) 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 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 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.

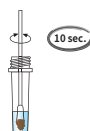
### ■ Collection and Preparation of Sample

- 1) Chicken or duck(excluding wild animal) cloaca, oropharynx or feces sample should be used with this test.
- 2) If the sample is not immediately tested, they should be stored at 2~8°C for 24 hours. For longer storage, freeze the sample at -20°C or below. Frozen samples should be brought to room temperature (15~30°C) prior to use.

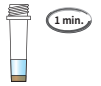
### ■ Procedure of the Test

- 1) Cloacal(or rectum) swab or oropharyngeal swab is recommended for the best sensitivity. Take a swab sample from a cloaca, oropharynx or feces with the disposable swab. Scattered wet feces are also available.

- 2) Insert the swab sample into the assay diluent tube and mix the swab sample for 10 seconds.



- 3) Wait for 1 minutes to settle down the samples.



- 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 the supernatant sample in the tube.



- 6) **Apply four(4) ~ five(5) drops of sample** into the sample hole, drop by drop.



- 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 **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

Test("T") line and control("C") line appear in the result window to indicate the presence of AIV antigen.



#### 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) This kit can detect all avian influenza virus type A antigen (H1-H16) regardless of high or low pathogenic avian influenza virus. Although Anigen Rapid AIV Ag Test Kit is very accurate in detecting avian influenza 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 is  $10^{4.8} \text{EID}_{50}/\text{ml}$ .
- 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.

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## Anigen Rapid AIV Ag Test Kit

### 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剂盒是一种用于定性检测鸡、鸭（不包括野生动物）泄殖腔、口咽或粪便样品中禽流感A型病毒抗原的层析免疫分析方法。试剂板表面有两条线，一条为“T”线，代表检测线；另一个是“C”，代表对照线。在加入样品之前，两条线应该是看不见的。对照线是作为操作过程质量控制的，又称之“质控线”。如果进行试验操作正确，并且对照线中的试剂还有效，对照线应该出现。如果样品中含有足够量的A型禽流感病毒，检测结果为出现两条紫色的条带。

本试剂盒采用A型禽流感的核蛋白作为捕获检测材料，这可确保试剂板高度精确地删掉检测到样品中的各种A型禽流感病毒。

#### ■ 提供的材料

提供的材料	30 份试纸
安捷禽流感抗原检测试纸	30
样本稀释液	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) 本产品只适用于鸡鸭(家禽)，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。
- 4) 请垂直使用吸管。
- 5) 请不要触摸试纸窗口。
- 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

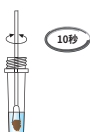
- 1) 试纸可以保存于室温(2~30°C)或者冷藏保存。**不要冷冻。**
- 2) 不要将试纸放置于太阳直射处。
- 3) 在有效期内的试纸是稳定的。

#### ■ 样品采集和准备

- 1) 本试验应使用鸡或鸭（不包括野生动物）泄殖腔、口咽或粪便样本。
- 2) 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。

#### ■ 测试步骤

- 1) 建议使用泄殖腔（或直肠）拭子或口咽拭子以获得最佳敏感性。用一次性拭子从泄殖腔、口咽或粪便中取拭子样本。散落的湿粪也可以使用。



- 2) 将棉签插入试管并搅拌10秒。



- 3) 静置试管 1 分钟。

- 4) 取出检测试纸并置于平坦干燥的平面。
- 5) 用一次性滴管，从试管吸取液上层吸取样品。



- 6) 加4~5滴样品到样品孔。



- 7) 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。



- 8) 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

窗口中只出现控制线(“C”线)。



##### 2) 阳性结果

在结果视窗中出现两条色线(“T”线和“C”线)，无论哪条线先出现，都表明为阳性。



##### 3) 无效试验

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。



#### ■ 检测的局限性

- 1) 本检测试剂盒可检测所有A型禽流感病毒抗原H1-H16，虽然本试剂盒具备很高的敏感度和特异度，但是也可能存在少许误差。当对检测结果产生怀疑时，请进行实验室其它方法检测。最终的诊断结果不应基于单一的检测结果，而应结合临床症状和其他检测结果由兽医作出综合诊断。检测限度为 $10^{4.8} \text{EID}_{50}/\text{ml}$ 。
- 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) 请严格按照说明书进行操作和结果判断，因操作不当或误判，BIONOTE公司和代理商将不对此负责。