

H5 AIV Antigen

AffiVET® Rapid Test Kit

AFG-VR-73

10 Tests



Material Required

(10) Rapid H5 AIV Ag Test Devices

(10) Assay diluent tubes

(10) Disposable swabs

(10) Disposable droppers

(01) User Manual

(01) Timer – Not Provided

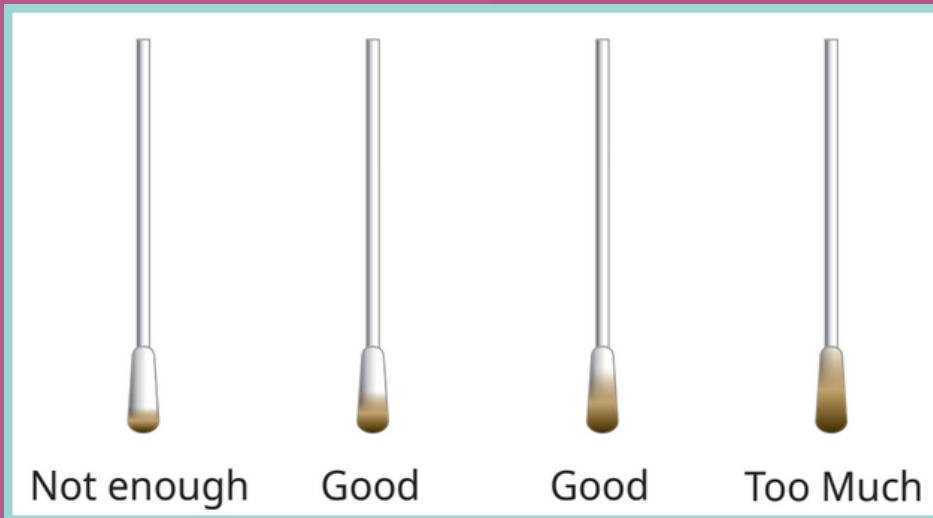
Storage & Stability

- 1) Store the test kit at 2 to 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 marked on the package label.

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.





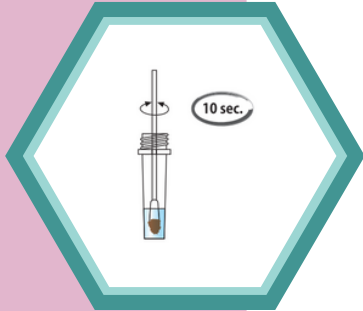
Sample Collection & Preparation

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

Test Procedure

1) All reagents and samples must be at room temperature (15~30°C) before running the assay.

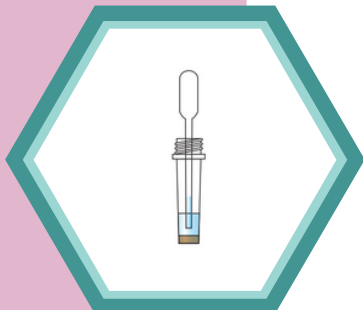
2) Take a swab sample from cloaca, trachea or kidney using the disposable swab. Or take scattered wet feces using the swab (refer to figure of detailed Sample Collection & Test Procedures).



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



4) Wait for 1 minute 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.



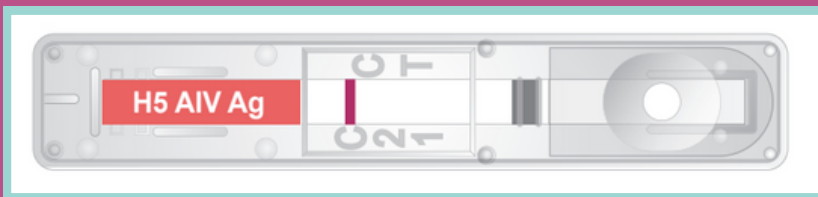
8) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of prepared sample to the sample hole.

9) Interpret test results at 20 minutes. Do not read the result after 30 minutes.

Result Interpretation

- Negative result

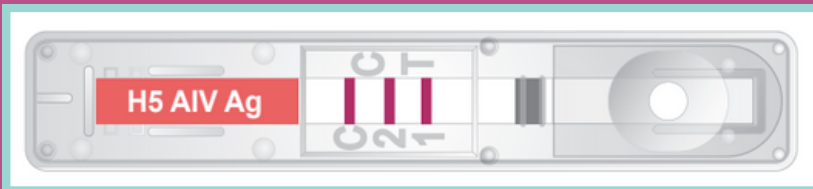
Only control ("C") line appears in the result window.



- Positive result

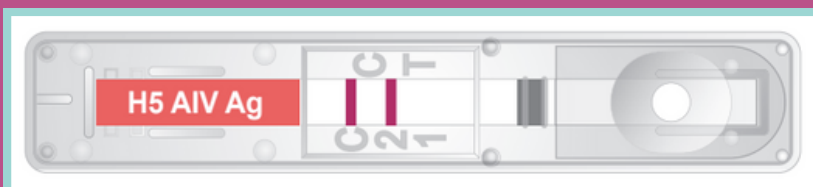
AIV type A and AIV subtype H5 Ag Positive

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



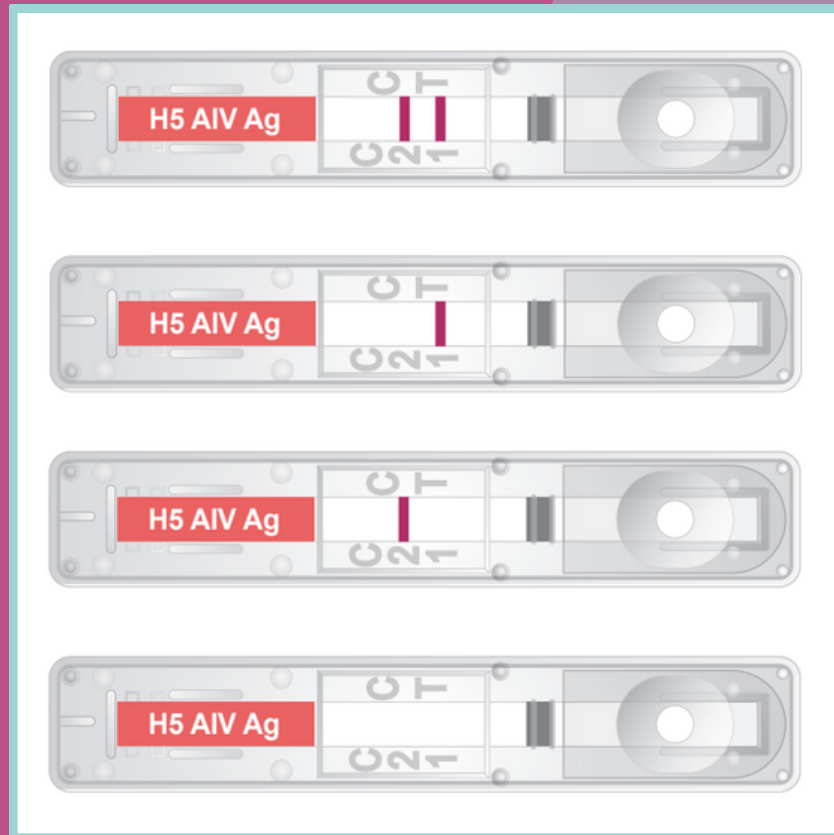
AIV type A Ag Positive & AIV subtype H5 Ag non-determined

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.



- **Invalid Result**

If the Control line “C” does not appear, the result might be considered invalid. The sample should be retested.



- **Test Limitations**

1) Although the AffiVET® 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) AffiGEN Inc. 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.

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