# Avian Influenza Virus (AIV) Antigen Rapid Test

REF KINER5006

Ver 1.0

IVT For In-Vitro Test Only

1 x 40 tests



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**Introduction:**

Avian Influenza Virus (AIV) is a highly contagious viral pathogen belonging to the Influenza A genus of the Orthomyxoviridae family, primarily affecting domestic and wild birds. The virus is classified into multiple subtypes based on hemagglutinin (H) and neuraminidase (N) surface proteins and ranges from low pathogenic to highly pathogenic forms. AIV poses significant economic and public health concerns due to its rapid spread in poultry populations and its potential for zoonotic -2).

**Intended Use:**

The Avian Influenza Virus (AIV) Antigen Rapid Test is used for qualitative detection of AvianInfluenza Virus antigens in avian clinical specimens such as cloacal swabs, tracheal swabs, or other appropriate respiratory or fecal samples.

**Principle:**

This Rapid Test is an immuno-chromatographic test, using colloidal gold immunoassay method to detect the indicated antigen/antibody. After the addition of the sample, as per the instruction for use (IFU), the sample moves along with the colloidal gold labeling protein. If the relevant protein is present, it will develop a reddish color line near the space marked as “T”. This indicates the sample is Positive and if a line is not developed or seen, it indicates the sample is Negative for the tested antigen/antibody.

**Materials Provided:**

1. Cassette: with a pad in the device.
2. Sample Diluent - 3 ml

**Materials to be provided by the End-User:**

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000 ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

**Handling / Storage:**

1. All reagents should be stored at 2ºC to 8ºC for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25ºC). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

**Health Hazard Warnings:**

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

**Sample Preparation and Storage:**

Cloacal Swabs: Cloacal swabs should be collected aseptically using sterile swabs by gently inserting the swab into the cloaca and rotating it several times to collect fecal and mucosal material. The swab should be immediately placed into the sample extraction buffer or an appropriate viral transport medium and mixed thoroughly to release the specimen. Samples should be tested as soon as possible after collection; if testing is delayed, they may be stored at 2–8ºC for up to 24–48 hours or frozen at –20ºC or below for longer storage. Repeated freeze–thaw cycles should be avoided.

Tracheal Swabs: Tracheal swabs should be collected aseptically using sterile swabs by gently inserting the swab into the trachea and rotating it to absorb respiratory secretions. After collection, the swab should be placed into the sample extraction buffer or viral transport medium and mixed thoroughly, ensuring maximum release of the specimen. Testing should be performed immediately whenever possible; if delayed, samples may be stored at 2–8ºC for up to 24–48 hours or frozen at –20ºC or below for extended storage, avoiding repeated freeze–thaw cycles.

Oropharyngeal Swabs: Oropharyngeal swabs should be collected using sterile swabs by gently swabbing the oropharyngeal cavity while avoiding contamination with feed or external debris. The swab should be placed immediately into the sample extraction buffer or suitable viral transport medium and mixed well to release the collected material. Samples should be tested promptly after collection; if testing is delayed, specimens may be stored at 2–8ºC for up to 24–48 hours or frozen at –20ºC or below for longer periods, and repeated freeze–thaw cycles should be avoided.

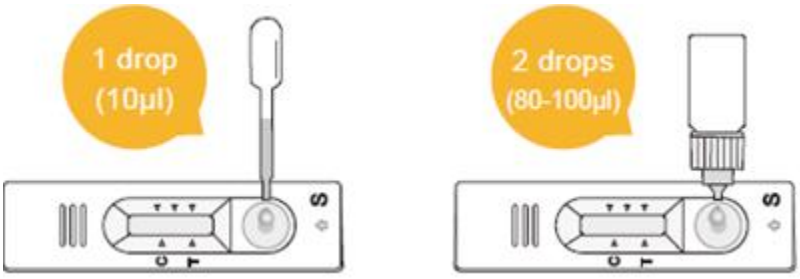
**Preparation Before Use:**

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20ºC - 30ºC) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20ºC - 30ºC). Please use immediately when the humidity＞60%.

**Assay Procedure:**

**For Cloacal/ Tracheal or Oropharyngeal**

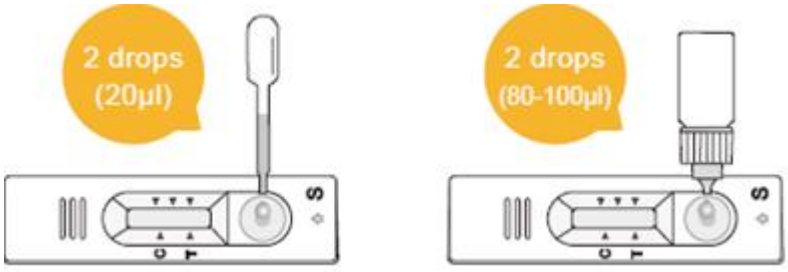
1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of prepared sample (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.




**For Whole Blood**

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with

the sample well up.
2. Add two (2) full drops of whole blood (20 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

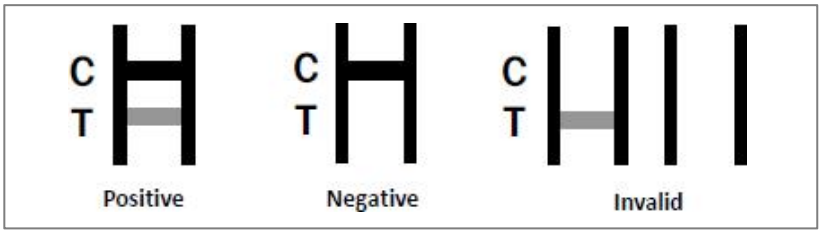



**Interpretation of Results:**

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.




**Quality Control:**

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

**Performance Characteristics of the Kit:**

Sensitivity:
Negative coincident rate with Molecular testing: ≥ 97%, Positive coincident rate with Molecular testing: ≥ 75%.

**Limitations of Method**

Any diagnosis should not be based on the results of in vitro methods alone. Veterinarians are suggested to consider all clinical and laboratory findings possible to state a diagnosis. This reagent is designed for the qualitative screening test.

**Safety Precautions:**

- Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Source materials maybe derived from human body fluids or organs used in the preparation of this kit were tested and found negative for HBsAg and HIV as well as for HCV antibodies. However, no known test guarantees the absence of such viral agents. Therefore, handle all components and all patient samples as if potentially hazardous.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
  - Do not smoke, eat or drink while handling kit material
  - Always use protective gloves
  - Never pipette material by mouth
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

**Symbols**


Use by

Lot/Batch

Catalog number


Temperature limitation


Caution, consult accompanying documents


Manufacturer

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