Newcastle Disease Virus (NDV) Antigen Rapid Test

REF KINER5079

Ver 1.0

IVT For In-Vitro Test Only

1 x 40 tests

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Introduction:

Newcastle Disease Virus (NDV) is a highly contagious avian paramyxovirus that affects a wide range of bird species, particularly poultry. The disease is characterized by respiratory distress, neurological signs, decreased egg production, and high mortality in severe outbreaks. NDV poses a major threat to the poultry industry worldwide due to its rapid spread and significant economic impact. Early detection and effective surveillance of NDV are essential for timely outbreak control, vaccination program assessment, and the implementation of biosecurity measures.

Intended Use:

The Newcastle Disease Virus (NDV) Antigen Rapid Test is used for qualitative detection of Newcastle Disease Virus antigen in avian clinical samples such as tracheal swabs, cloacal swabs, tissue homogenates or fecal specimens.

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 i f 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 1000ul
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:

Tracheal Swab Samples: Tracheal swabs should be collected aseptically from birds using sterile swabs and immediately placed into the provided sample extraction buffer or an appropriate viral transport medium. The swab should be mixed thoroughly to release viral antigen into the buffer before testing. Samples should be tested as soon as possible after collection. If testing is delayed, prepared samples may be stored at 2–8 °C for up to 24–48 hours. For longer storage, samples can be frozen at −20 °C or below, avoiding repeated freeze–thaw cycles.

Cloacal Swab Samples: Cloacal swabs should be collected using sterile swabs inserted gently into the cloaca and rotated to ensure adequate sample uptake. Swabs should be immediately transferred into sample extraction buffer and mixed thoroughly. Cloacal swab samples should be tested promptly. If storage is required, they may be kept at 2–8 °C for up to 24–48 hours or frozen at −20 °C or below for extended storage, avoiding repeated freeze–thaw cycles.

Tissue Homogenates: Tissue samples such as trachea, lung, spleen, or brain should be collected aseptically from freshly deceased birds. The tissues should be homogenized in an appropriate volume of sample extraction buffer or phosphate-buffered saline to obtain a uniform suspension. Clarified homogenates should be used for testing as soon as possible. If immediate testing is not feasible, homogenates can be stored at 2–8 °C for up to 48 hours or frozen at −20 °C or below for longer-term storage, avoiding repeated freeze–thaw cycles.

Fecal Samples: Fresh fecal samples should be collected aseptically from poultry houses or directly from birds. Approximately 1–2 g of fecal material should be mixed thoroughly with the provided sample extraction buffer to release viral antigen. Prepared samples should be tested immediately. If testing is delayed, fecal samples may be stored at 2–8 °C for up to 24 hours or frozen at −20 °C or below for longer storage, avoiding repeated freeze–thaw cycles.

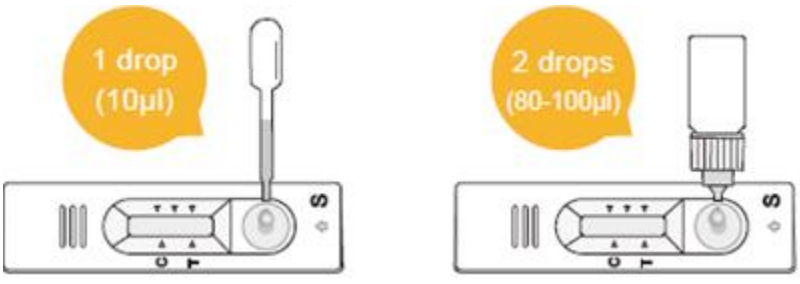
Preparation Before Use:

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 tracheal / cloacal / tissue homogenates / fecal specimens.

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 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.

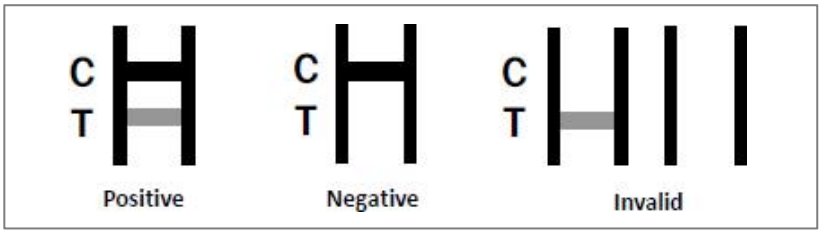


Interpretation of Results:

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.
- 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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