Rapid Newcastle Disease Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ NDV Ag Test Kit

[Catalogue Number: LGM-YNG-11]

Introduction

Newcastle Disease Virus (NDV), a single-stranded, negative-sense RNA virus, belongs to the genus *Avulavirus* within the family Paramyxoviridae[1]. It is the causative agent of Newcastle Disease (ND), a highly contagious disease that primarily affects avian species, particularly domestic poultry[2].

Despite their antigenic homogeneity within a single serotype, NDV strains are categorized by their intracerebral pathogenicity index (ICPI), clinical signs, and mortality rates in chickens: lentogenic (ICPI: 0.0–0.7, Mortality: Negligible), mesogenic (ICPI: 0.7–1.3, Mortality: Up to 10%), and velogenic (ICPI: 1.3–2.0, Mortality: Up to 90%), with velogenic strains further distinguished as viscerotropic (vvNDV) or neurotropic (nvNDV)[3, 4]. Strains are further divided into genotypes (Class I and Class II, with over 20 genotypes identified) reflecting their genetic diversity and host adaptation[5].

Clinically, infected birds may experience a range of symptoms from severe respiratory distress (dyspnea, coughing), to nervous system disorders (torticollis, paresis, paralysis)[4]. Digestive issues like greenish watery diarrhea and general symptoms of depression and reduced appetite are also common[4]. Economic losses are exacerbated by sudden drops in egg production and the production of abnormal eggs[6].

The primary infection route is via inhalation of aerosolized viral particles or ingestion of contaminated material. Transmission occurs rapidly through both direct contact with infected birds (via feces and respiratory secretions) and indirect contact with contaminated fomites, such as equipment, vehicles, feed, water, and personnel[4, 7].

While NDV poses a low risk to human health, those in close contact with infected birds may experience mild symptoms, such as conjunctivitis[2, 7].

Principle

The RIDX™ NDV Ag Test Kit is a lateral flow chromatographic immuno-assay for the qualitative detection of NDV in poultry.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the NDV antigen exists in the sample, it binds to the gold-conjugated anti-NDV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-NDV antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.

Two different monoclonal antibodies to the haemagglutinin-neuraminidase (HN) glycoprotein of NDV[3] are used as a capture and detector in the kit. The RIDX™ NDV Ag Test Kit can detect NDV in poultry trachea, spleen, or kidney, or these tissue homogenates with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ NDV Ag Test	+	15	0	15
	-	2	16	18
	Total	17	16	33

Sensitivity: 88.24% (15/17, *95% CI: 65.66% ~ 96.71%)
Specificity: 100% (16/16, 95% CI: 80.64% ~ 100%)
Diagnostic Agreement: 93.94% (31/33, 95% CI: 80.39% ~ 98.32%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1 x $10^{4.3}$ EID_{50}/mL

3. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ NDV Ag Test Kit.

Pathogen	Titer
Avian influenza virus (AIV)	1 x 10^5 EID_{50}/mL
Infectious bursal disease virus (IBDV)	1 x 10^7 EID_{50}/mL
Infectious bronchitis virus (IBV)	1 x 10^7 EID_{50}/mL
Mycoplasma gallisepticum	1 x 10^8 CFU/mL
Mycoplasma synoviae	1 x 10^8 CFU/mL

Kit Components

	Component	Quantity/kit
1	NDV Ag test device	10
2	Sample dilution buffer	10
3	Disposable swab	10
4	Dropper cap with filter	10
5	Paper rack for standing buffer tubes	1
6	Instructions for use	1

Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

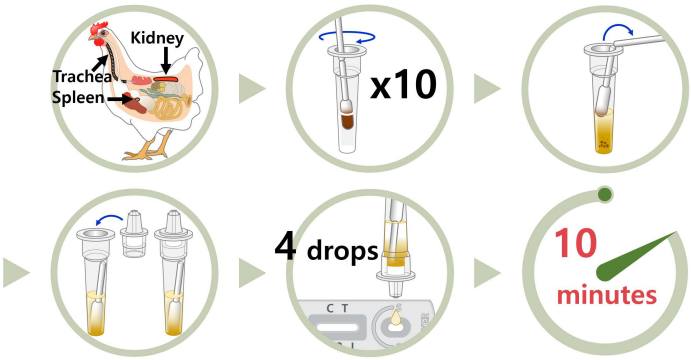
Sample Preparation

1. **Swabs form poultry trachea, spleen, or kidney, or these tissue homogenates** should be used as specimens.
2. Sampling from trachea: Position the carcass on its back, extend the neck, and open the beak to expose the trachea. Insert the swab into the trachea and rotate it to collect the specimen. The swab may appear clear, pale yellow, or mucoid due to mucus.
3. Sampling from spleen: Position the carcass on its back and open the abdominal cavity by incising the body wall. Find the spleen, which is located under the proventriculus adjacent to the liver. If necessary, make a small incision in the spleen surface with scissors, and insert the swab to collect tissue samples. The swab may appear red or dark brown due to the spleen tissue.
4. Sampling from kidney: Position the carcass on its back and open the abdominal cavity by incising the body wall. Find the kidneys, which are located along the dorsal body wall adjacent to the vertebral column. If necessary, make a small incision in the kidney surface with scissors, and insert the swab to collect tissue samples. The swab may appear red due to the vascular nature of the kidney tissue.
5. **Place the sampled swab immediately into the sample dilution buffer of this kit just after collection.**

Test Procedure

1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Using a swab to collect specimen.
3. Put the swab into the sample dilution buffer tube and stir the solution 10 times with the swab to disperse the specimen into the buffer.
4. Break the head of the cotton swab and discard the rod.

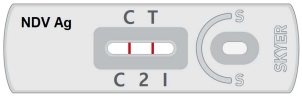
5. Attach a dropper cap to the top of the buffer tube.
6. Apply 4 drops (approximately 100 μL) of the processed solution in the sample hole on the device.
7. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**



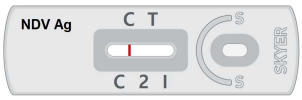
[Summary of Test Procedure]

Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of NDV antigens.



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



3. Invalid results
If the control (C) line does not appear, the result might be considered invalid. The sample should be retested.

Precautions

1. This test kit is for veterinary *in vitro* diagnostic use only for poultry. Do not use this test kit for other animals.
2. This rapid kit is only for preliminary screening. The final decision should be made by a qualified veterinarian based on the results of this kit, clinical symptoms and evaluation by a veterinarian, and, if necessary, the results of additional detailed diagnostic procedures.
3. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
4. Do not touch the membrane in the sample hole on the device.
5. The device should not be used if the foil pouch is damaged or opened.
6. Do not use an expired test kit. The expiration date is marked on the package label.
7. Do not reuse the components of the kit except the paper rack.
8. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
9. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
10. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

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3. Aldous EW, Alexander DJ. Detection and differentiation of Newcastle disease virus (avian paramyxovirus type 1). *Avian Pathology* 2001; 30: 117–128.
4. Cattoli G, Susta L, Terregino C, Brown C. Newcastle disease: a review of field recognition and current methods of laboratory detection. *Journal of Veterinary Diagnostic Investigation* 2011; 23(4): 637–656.
5. Miller PJ, Decanini EL, Afonso CL. Newcastle disease: Evolution of genotypes and the related diagnostic challenges. *Infection, Genetics and Evolution* 2010; 10: 26–35.
6. Bello MB, Yusoff K, Ideris A, Hair-Bejo M, Peeters BPH, Omar AR. Diagnostic and Vaccination Approaches for Newcastle Disease Virus in Poultry: The Current and Emerging Perspectives. *BioMed Research International* 2018; 7278459.
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Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

SKYER, INC.
#532, 416, Hwagok-ro, Gangseo-gu, Seoul, 07548, Republic of Korea
TEL: +82-2-706-6801, FAX: +82-50-4096-6988
Technical support: marketing@skyer.co.kr
www.skyerdiagnostics.com
Korean Veterinary Diagnostics Manufacturer License No. 300