Rapid Infectious Bursal Disease Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ IBDV Ag Test Kit

[Catalogue Number: LGM-YFG-11]

Introduction

Infectious Bursal Disease Virus (IBDV) is a non-enveloped, double-stranded RNA virus belonging to the genus *Avibirnavirus* of family Birnaviridae[1]. Infectious bursal disease (IBD), also known as Gumboro disease, caused by IBDV infection, is a highly contagious disease of young chickens characterized by immunosuppression and variable mortality. First identified in Gumboro, Delaware, in 1962, IBDV remains one of the most economically significant pathogens in the global poultry industry[2, 3].

Two serotypes have been identified: serotype 1 viruses, which include multiple classic, variant, and very virulent strains, manifest clinical signs in chickens, while serotype 2 viruses demonstrate no overt symptoms during replication[4, 5].

After ingestion, IBDV replicates in gut-associated macrophages before targeting B lymphocytes in the bursa of Fabricius[6]. Peak lymphoid depletion occurs 3–5 days post-infection, causing profound immunosuppression[6]. Clinically infected chicks (3–6 weeks old) show depression, ruffled feathers, anorexia, watery or hemorrhagic diarrhea, soiled vents, and trembling[7]. Mortality rates can vary significantly depending on the strain. For instance, classic strains can result in mortality rates of 10–50%, while highly virulent variants, vvIBDV, can lead to nearly 100% mortality[6, 8].

The virus spreads by the fecal-oral route through contaminated litter, feed, water, equipment, and farm personnel. IBDV is highly stable in poultry houses, surviving weeks without disinfection[3]. Intensive broiler and layer operations face the greatest risk of disease transmission, though backyard flocks can serve as reservoirs for reintroduction into commercial farms[9].

Principle

The RIDX™ IBDV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of IBDV 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 IBDV antigen exists in the sample, it binds to the gold-conjugated anti-IBDV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-IBDV 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.

Very specific monoclonal antibody to the VP2 protein, a major host protective immunogen of IBDV[8], are used as a capture and detector in the kit. The RIDX™ IBDV Ag Test Kit can detect IBDV in poultry bursa of Fabricius or cloaca, or these tissue homogenates with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ IBDV Ag Test	+	12	0	12
	-	1	15	16
	Total	13	15	28

Sensitivity: 92.31% (12/13, *95% CI: 66.69% ~ 98.63)
Specificity: 100% (15/15, 95% CI: 79.61% ~ 100%)
Diagnostic Agreement: 96.43% (27/28, 95% CI: 82.29% ~ 99.37%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1 x $10^{5.8}$ EID_{50}/mL

3. Cross-Reactivity

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

Pathogen	Titer
Avian influenza virus (AIV)	1 x 10^5 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
Newcastle disease virus (NDV)	1 x 10^5 EID_{50}/mL

Kit Components

	Component	Quantity/kit
1	IBDV 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

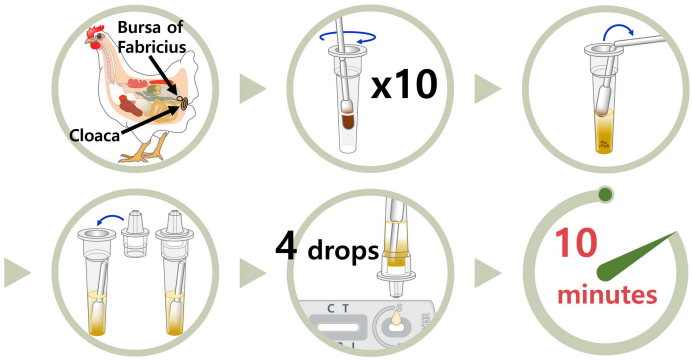
1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Collection and Preparation

1. **Swabs form poultry bursa of Fabricius or cloaca, or these tissue homogenates** should be used as specimens.
2. Sampling from bursa of Fabricius: During necropsy, expose the bursa of Fabricius by cutting the cloaca region and cut the bursa of Fabricius to open it. Use a swab to rub the inside and collect the specimen.
3. Sampling from cloaca: For a live bird, gently hold its wings and legs to keep it still. Make sure its tail is pointing downward to reveal its cloaca. For carcass, position the bird to expose the cloaca. Insert the swab into the cloaca and rotate it to collect the specimen. The swab may appear dark brown due to fecal material or gray and mucoid if mucus is present.
4. **Place the sampled swab immediately into the sample dilution buffer of this kit just after collection**.

Test Procedure

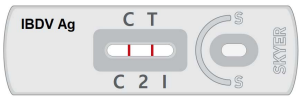
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Using a swab to collect specimen.
3. Put the swab into the sample dilution buffer tube and stir the solution 10 times with the swab to disperse the specimen into the buffer.
4. Break the head of the cotton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



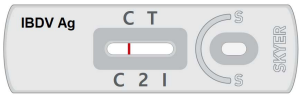
[Summary of Test Procedure]

Interpretation of Results

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

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