Rapid Infectious Bronchitis Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ IBV Ag Test Kit

[Catalogue Number: LGM-YBG-11]

Introduction

Infectious Bronchitis Virus (IBV), a non-segmented, enveloped, positive-sense single-stranded RNA virus, belongs to the genus *Coronavirus* in the family Coronaviridae[1] and is the causative agent of Infectious Bronchitis (IB), an acute and highly contagious viral disease of chickens[2].

IBV exhibits extensive antigenic and genetic diversity. Phylogenetic analysis of the spike S1 gene divides IBV into six genotypes (GI-GVI) encompassing over 30 lineages[3, 4].

Chickens are the primary natural host of IBV. Other Galliformes (pheasants, quail, turkeys) and waterfowl (ducks, geese) may host related coronaviruses, but disease is chiefly a chicken concern[5]. Wild birds may serve as reservoirs, facilitating virus dissemination[3].

Clinical symptoms are pleomorphic and depend on the viral tropism, manifesting as respiratory distress (gasping, sneezing), renal disease (nephritis), or reproductive tract disorders (sudden drop in egg production, misshapen shells, watery albumen)[6, 7].

The morbidity rate in naive flocks approaches 100% due to its high transmissibility, while the mortality rate is variable, being highest in young chicks or in cases involving nephropathogenic strains[4]. The primary infection route is via inhalation of aerosolized viral particles. Transmission occurs rapidly through both direct contact and indirect contact with contaminated fomites[5].

IBV exhibits a pervasive global prevalence in commercial poultry operations[8]. Its economic importance is profound, ranking it as one of the most damaging pathogens in the poultry industry due to significant losses from reduced growth, decreased egg production, poor egg quality, and costs associated with vaccination and biosecurity[9].

Principle

The RIDX™ IBV Ag Test Kit is a lateral flow chromatographic immuno-assay for the qualitative detection of IBV 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 IBV antigen exists in the sample, it binds to the gold-conjugated anti-IBV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-IBV 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 spike (S) glycoprotein[3] of IBV and two different monoclonal antibodies to the QX strain[5] of IBV are used as captures and detectors in the kit. The RIDX™ IBV Ag Test Kit can detect IBV in poultry feces, cloaca, kidney, or trachea or these tissue homogenates with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ IBV Ag Test	+	14	0	14
	-	2	16	18
	Total	16	16	32

Sensitivity: 87.50% (14/16, *95% CI: 63.98% ~ 96.50%)
Specificity: 100% (16/16, 95% CI: 80.64% ~ 100%)
Diagnostic Agreement: 93.75% (30/32, 95% CI: 79.85% ~ 98.27%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 5 x $10^{4.8}$ EID_{50}/mL

3. Cross-Reactivity
Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ IBV 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
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

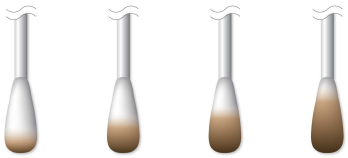
	Component	Quantity/kit
1	IBV Ag test device	10
2	Sample dilution buffer	10
3	Disposable swab	10
4	Dropper cap with filter	10
5	Paper rack for standing buffer tubes	1
6	Instructions for use	1

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

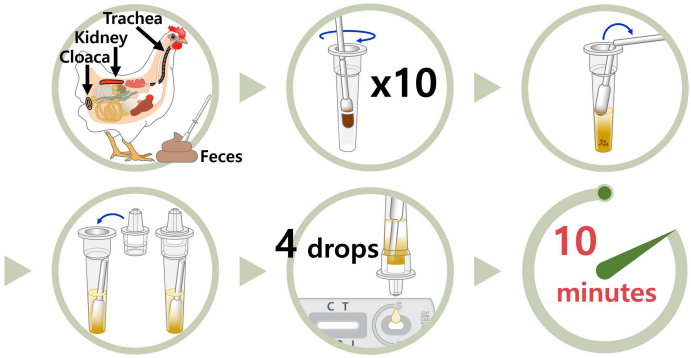
1. **Swabs form poultry feces, cloaca, kidney, or trachea or these tissue homogenates** should be used as specimens.
2. Sampling from feces: The amount of fecal sample may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive sample may induce a false positive result and slow migration.



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. 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.
5. 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.
6. **Place the sampled swab immediately into the sample dilution buffer of this kit just after collection.**

Test Procedure

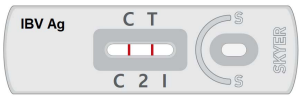
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Using a swab to collect specimen.
3. Put the swab into the sample dilution buffer tube and stir the solution 10 times with the swab to disperse the specimen into the buffer.
4. Break the head of the cotton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



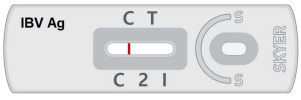
[Summary of Test Procedure]

Interpretation of Results

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

1. International Committee on Taxonomy of Viruses. *Virus Taxonomy: 2024 Release*. Email Ratification February 2025 (MSL #40).
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4. Lin SY, Chen HW. Infectious Bronchitis Virus Variants: Molecular Analysis and Pathogenicity Investigation. *International Journal of Molecular Sciences* 2017; 18: 2030.
5. Jackwood MW, de Wit S. Infectious Bronchitis. *Diseases of Poultry*, Fourteenth Edition. Editor-in-chief David E. Swayne. John Wiley & Sons, Inc. 2020; 167–188.
6. Hoerr FJ. The Pathology of Infectious Bronchitis. *Avian Diseases* 2021; 65: 598–609.
7. Zhao J, Zhao Y, Zhang G. Key Aspects of Coronavirus Avian Infectious Bronchitis Virus. *Pathogens* 2023; 12: 698.
8. Jackwood MW. Review of Infectious Bronchitis Virus Around the World. *Avian Diseases* 2012; 56: 634–641.
9. de Wit JJ. Cook JKA. Van der Heijden MJF. Infectious bronchitis virus variants: a review of the history, current situation and control measures. *Avian Pathology* 2011; 40(3); 223–235.

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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