Rapid Avian Influenza Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ AIV Ag Test Kit

[Catalogue Number: LGM-YAG-01, LGM-YAG-02]

Introduction

Avian influenza viruses (AIVs) are segmented, negative-sense, single-stranded RNA viruses of the family Orthomyxoviridae[1]. The natural reservoir for AIVs is wild aquatic birds, but they commonly infect other species, including humans. Type A influenza viruses are associated with outbreaks in commercial chickens and turkeys and are classified by the serological subtypes of the primary viral surface proteins, the hemagglutinin (HA) and neuraminidase (NA)[2]. To date, 16 HA (H1~H16) and 9 NA subtypes (N1~N9) have been found in AIVs isolated from aquatic birds[3].

Depending on the molecular criteria of the HA and the pathogenesis, AIVs have been classified highly pathogenic (HP) and low pathogenic (LP). Biologically, the difference between HPAI and LPAI is that HPAI is a systemic infection, and LPAI remains localized to the respiratory and intestinal tracts[4]. The generation of HPAIV appears to be a phenomenon associated with adaptation of LPAIV to chickens or turkeys[5].

In chickens, LPAIV infection primarily presents mild to moderate respiratory disease in the field. Lethargy, often seen as a decrease in feed and water consumption, and a reduction in egg production are also frequently observed. LPAIV can cause mortality, but it is rare and low. Turkeys seem to be both more susceptible to infection and disease from LPAIV than chickens[6].

The most striking feature of HPAIV in poultry is that it causes a rapid and high mortality rate that can reach 100% within 36 to 48 hours after infection[7]. It is common for chickens and turkeys to die soon after infection, with no gross lesions and clinical signs only be observed for 6 to 12 hours before death. Clinical signs include severe depression and/or neurological signs, and swollen heads are common. In chickens, hemorrhages may be seen in shanks, wattles, and combs, which may also be swollen and necrotic. These lesions are not seen in turkeys[7, 8].

Principle

The RIDX™ AIV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of avian influenza virus type A antigens.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the AIV antigen exists in the sample, it binds to the cellulose nanobeads-conjugated AIV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the AIV 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 monoclonal antibodies to the conservative AIV nucleocapsid protein (NP) are used as capture and detector in the kit. The RIDX™ AIV Ag Test Kit can detect various subtypes of AIV NPs in poultry fecal, cloacal, oropharyngeal swabs with high accuracy at the farm field.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ AIV Ag Test	+	97	1	98
	-	0	206	206
	Total	97	207	304

Sensitivity: 100% (97/97, *95% CI: 96.19% ~ 100%)
Specificity: 99.52% (206/207, 95% CI: 97.31% ~ 99.91%)
Diagnostic Agreement: 99.67% (303/304, 95% CI: 98.16% ~ 99.94%)

* 95% CI: 95% Confidence Interval

※ Virus concentration ≥ 1 x 10^4 EID_{50}/mL

2. Limit of Detection (LOD)

Influenza type A Virus Subtype	LOD
H3N2	5.0 x $10^{3.0}$ $TCID_{50}$/mL
H5N1	5.0 x $10^{3.0}$ $TCID_{50}$/mL
H5N2	1.0 x $10^{4.3}$ EID_{50}/mL
H5N6	1.0 x $10^{4.0}$ EID_{50}/mL
H5N8	0.5 x $10^{3.0}$ EID_{50}/mL
H9N2	1.0 x $10^{5.5}$ EID_{50}/mL

3. Cross-Reactivity

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

Pathogen	Titer
Infectious bursal disease virus (IBDV)	2.5 x $10^{7.0}$ EID_{50}/mL
Infectious bronchitis virus (IBV)	1.0 x $10^{6.5}$ EID_{50}/mL
Infectious laryngotracheitis virus (ILTV)	1.0 x $10^{5.5}$ EID_{50}/mL
Mycoplasma gallisepticum (MG)	2.0 x 10^{10} CFU/mL
Newcastle disease virus (NDV)	1.0 x $10^{6.3}$ EID_{50}/mL

Kit Components

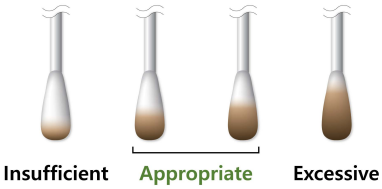
	Component	Quantity/kit by CAT No.	
		LGM-YAG-01	LGM-YAG-02
1	AIV Ag test device	30	10
2	Sample dilution buffer	30	10
3	Disposable swab	30	10
4	Dropper cap with sample filter	30	10
5	Instructions for use	1	1

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.

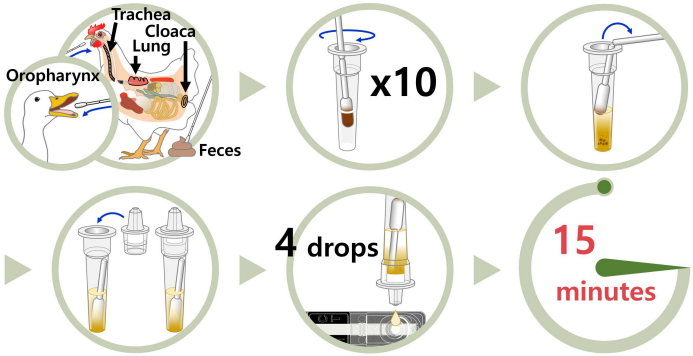
Sample Preparation

1. **Avian fecal, cloacal, or oropharyngeal swabs, or tissue (trachea or lung) homogenates swabs** should be used.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46.4℉) for up to 24 hours. For longer storage, freeze at −20°C (−4℉) or below. But, results from samples frozen for over one month may differ from those obtained before freezing. Frozen samples should be brought to room temperature (15~30°C/59~86℉) before use.
4. 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.



Test Procedure

1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Using a swab to collect specimen.
3. Put the swab into the sample dilution buffer 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 with a filter to the top of the buffer tube.
6. Apply 4 drops of the processed solution in the sample hole on the device.
7. Read test result at 15 minutes. **Do not read results after 15 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 AIV 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 birds. 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 sample hole of the test device.
5. The device should not be used if the foil pouch is damaged.
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.
8. If the test line shows a black or blue line instead of a red line, the reaction is unspecific, so carry out another detailed test.
9. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
10. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
11. 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 (ICTV). *Virus Taxonomy*: 2019 Release. Ratification March 2020 (MSL #35).
2. Rott R. The pathogenic determinant of influenza virus. *Vet Microbiol*. 1992; 33(1–4): 303–310.
3. Stallknecht DE. Ecology and epidemiology of avian influenza viruses in wild bird populations: waterfowl, shorebirds, pelicans, cormorants, etc. *Avian Diseases*. 2003; 47: 61–69.
4. Alexander DJ, Brown IH. History of highly pathogenic avian influenza. *Rev sci tech Off int Epiz*. 2009; 28(1): 19–38.
5. Suarez DL, Senne DA, Banks J, Brown IH, Essen SC, Lee C, Manvell RJ, *et. al*. Recombination resulting in virulence shift in avian influenza outbreak, Chile. *Emerg Infect Dis*. 2004; 10(4): 693–699.
6. Pantin-Jackwood MJ, Swayne DE. Pathogenesis and pathobiology of avian influenza virus infection in birds. *Rev Sci Tech Off Int Epiz*. 2009; 28(1): 113–136.
7. Swayne DE, Suarez DL. Highly pathogenic avian influenza. *Rev Sci Tech Off Int Epiz*. 2000; 19(2): 463–482.
8. França MS, Brown JD. Influenza pathobiology and pathogenesis in avian species. *Curr Top Microbiol Immunol*. 2014; 385: 221–242.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
	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