Rapid Canine and Feline Influenza Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Canine Feline Influenza V Ag Test Kit

[Catalogue Number: CGM-VIG-11, CGM-VIG-12]

Introduction

Influenza viruses are segmented, negative-sense, single-stranded RNA viruses of the family Orthomyxoviridae[1]. Canine influenza viruses and feline influenza viruses, belong to the species *Influenza A virus* (IAV), genus *Alphainfluenzavirus* and family Orthomyxoviridae, and cause a highly contagious respiratory disease.

Two major influenza viruses have been acquired in dogs since 1999, the subtype H3N8 came from horses[1] and the subtype H3N2 came from birds[2]. The subtype H5N1 and H1N1 have also been isolated from dog flu[3, 4]. The cross-species transmissions of IAVs are common and canine IAV can occasionally be transmitted to cats[5, 6].

The most common symptom of 80% of exposed animals is a mild upper respiratory disease with 1 to 3 weeks persistent cough. Other possible clinical signs include ocular and nasal discharge, sneezing, fever, lethargy, and anorexia.

The mortality rate is lower than 10% in dogs[7]. However, some dogs and cats become severely ill with high fever and pneumonia by secondary bacterial infection. Furthermore in 2010, natural feline outbreaks with fever, tachypnoea, sneezing, coughing, dyspnoea and lethargy were noted in two animal shelters in South Korea. In one of these shelters, the morbidity rate was 100% and the mortality rate was 40% in dogs and cats[8].

Influenza is one of the most important zoonoses. IAVs are usually transmitted in droplets and aerosols created by coughing and sneezing, and by contact with nasal discharges, either directly or indirectly[7, 8].

To date, there have been no officially overlooked reports of human IAV infection from dogs and cats, although such infections are theoretically possible[9].

Principle

The RIDX™ Canine Feline Influenza V Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of canine and feline influenza viral antigens in canine and feline pharyngeal or nasal secretions.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device.

If the IAV antigens exist in the sample, it binds to the cellulose nanobeads (CNB)-conjugated IAV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the IAV 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.

The highly selective and sensitive two monoclonal antibodies to IAV are used as capture and detector in the kit. The RIDX™ Canine Feline Influenza V Ag Test Kit can detect IAV H3 and H5 subtype antigens in canine and feline nasal or pharyngeal secretions with high accuracy.

Performances

[For Canine Influenza A Virus]

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ CF IAV Ag Test	+	11	1	12
	-	1	125	126
	Total	12	126	138

Sensitivity: 91.67% (11/12, *95% CI: 64.61% ~ 98.51%)
Specificity: 99.21% (125/126, 95% CI: 95.64% ~ 99.86%)
Diagnostic Agreement: 98.55% (136/138, 95% CI: 94.87% ~ 99.60%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 5 x 10^3 $TCID_{50}$/mL for canine IAV H3N2

[For Feline Influenza A Virus]

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ CF IAV Ag Test	+	10	1	11
	-	1	113	114
	Total	11	114	125

Sensitivity: 90.91% (10/11, *95% CI: 62.26% ~ 98.38%)
Specificity: 99.12% (113/114, 95% CI: 95.20% ~ 99.84%)
Diagnostic Agreement: 98.40% (123/125, 95% CI: 94.35% ~ 99.56%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 5 x 10^3 $TCID_{50}$/mL for feline IAV H5N1

[Cross-Reactivity]

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

Pathogen	Titer	Result
Canine coronavirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Canine parvovirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Feline calicivirus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1.97 x 10^4 $TCID_{50}$/mL	Negative
Feline parvovirus	1.00 x $10^{5.5}$ $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^6 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/μL	Negative

Kit Components

	Component	Quantity/kit by CAT No.	
		CGM-VIG-11	CGM-VIG-12
1	CF IAV Ag Test device	10	2
2	Sample dilution buffer	10	2
3	Disposable swab	10	2
4	Dropper cap with filter	10	2
5	Instructions for use	1	1

Storage & Stability

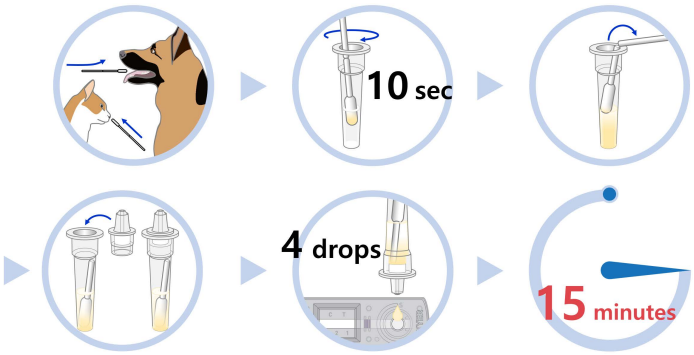
1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the label.

Sample Preparation

1. **Specimen (nasal or pharyngeal secretions) should be collected by using a swab.**
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°F) for up to 24 hours. For longer storage, freeze at −20°C (−4°F) 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°F) before use.

Test Procedure

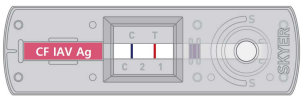
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect nasal or pharyngeal samples using a swab.
3. Put the swab into the sample dilution buffer and stir the solution to disperse the sample into the buffer (approximately 10 seconds).
4. Break the head of the cotton swab and discard the rod.
5. Attach a dropper cap with a filter to the top of the buffer.
6. Apply 4 drops of the sample solution in the sample hole on the device.
7. Read test results at 15 minutes. **Do not read results after 15 minutes.**



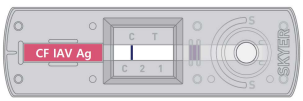
[Summary of Test Procedure]

Interpretation of Results

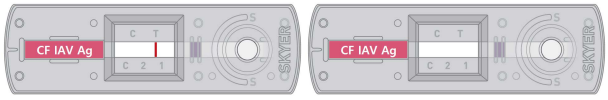
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of Influenza A virus antigens.



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 dogs and cats. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the sample pad of the test device.
4. The device should not be used if the foil pouch is damaged or opened.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, buffer, dropper cap).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. Crawford PC *et al.*, Transmission of equine influenza virus to dogs. *Science*. 2005; 310: 482–485.
2. Song D *et al.*, Transmission of avian influenza virus (H3N2) to dogs. *Emerg Infect Dis*. 2008; 14: 741–746.
3. Songserm T *et al.*, Fatal avian influenza A H5N1 in a dog. *Emerg Infect Dis*. 2006; 12: 1744–1747.
4. Dundon WG *et al.*, Serologic Evidence of Pandemic (H1N1) 2009 Infection in Dogs, Italy. *Emerg Infect Dis*. 2010; 16: 2019–2021.
5. Krammer F *et al.*, Influenza. *Nature Rev. Dis. Prim.* 2018; 4:3.
6. Frymus T *et al.*, Influenza Virus Infections in Cats. *Viruses*. 2021; 13: 1435.
7. Dubovi EJ, Canine Influenza. *Vet Clin Small Anim*. 2010; 40: 1063–1071.
8. Song DS *et al.*, Interspecies transmission of the canine influenza H3N2 virus to domestic cats in South Korea, 2010. J Gen Virol. 2011; 92: 2350–2355.
9. Sun H *et al.*, Zoonotic risk, pathogenesis, and transmission of avian-origin H3N2 canine influenza virus. *J Virol*. 2017; (91) 21: e00637–17.

Symbol Descriptions

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