Rapid Canine Influenza Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ CIV Ag Test Kit

[CAT No. CGM-CIG-11]

Introduction

Canine influenza viruses (CIV), belong to the species *Influenza A virus*, 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 most common symptom of 80% of exposed dogs 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. Some dogs become severely ill, with high fever, pneumonia, and secondary bacterial infection. The mortality rate is lower than 10%[5, 6].

In mammals, influenza viruses are usually transmitted in droplets and aerosols created by coughing and sneezing, and by contact with nasal discharges, either directly or indirectly. CIV are found in respiratory secretions, like the typical mammalian influenza viruses[5, 6].

Influenza is one of the most important zoonoses. There are no reports of human infections with CIV to date, although such infections are theoretically possible[7].

Principle

The RIDX™ CIV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CIV antigens in canine 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 CIV antigen exists in the sample, it binds to the cellulose nanobeads (CNB)-conjugated CIV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the CIV 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 CIV are used as capture and detector in the kit. The RIDX™ CIV Ag Test Kit can detect CIV antigens in canine nasal or pharyngeal secretions with high accuracy.

Performance

1. Clinical Sensitivity & Clinical Specificity

		Disease status		
		+	-	Total
RIDX™ CIV Ag Test	+	11	1	12
	-	1	125	126
	Total	12	126	138

Clinical Sensitivity: 91.67% (11/12, 95% CI: 64.61% ~ 98.51%)

Clinical Specificity: 99.21% (125/126, 95% CI: 95.64% ~ 99.86%)

Diagnostic Accuracy: 98.55% (136/138, 95% CI: 94.87% ~ 99.60%)

* CI: Confidence Interval

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

3. Cross-Reactivity

Below potential cross-reactivity substances did not affect the performance of the RIDX™ CIV Ag Test Kit.

Pathogen	Titer	Result
Canine coronavirus	1 x 10^6 $TCID_{50}$/mL	Negative
Canine distemper virus	1 x 10^5 $TCID_{50}$/mL	Negative
Canine parvovirus	1 x 10^6 $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^6 CFU/mL	Negative
Giardia spp.	1.42 x 10^7 *G.* cyst/100µL	Negative
Salmonella spp.	1 x 10^6 CFU/mL	Negative

Kit Components

	Component	Number/Kit
1	CIV Ag Test device	10
2	Sample dilution buffer	10
3	Disposable swab	10
4	Disposable dropper	10
5	Instructions for use	1

Storage & Stability

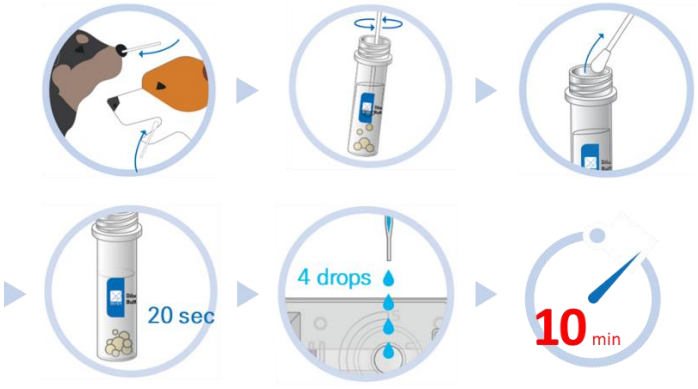
1. Store the test kit at 2~30℃ (35.6~86℉). Do NOT freeze.
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

1. 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°F) for up to 24 hours. For longer storage, freeze at −20°C (−4°F) or below. Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.

Test Procedure

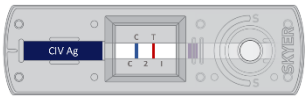
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect nasal and pharyngeal samples using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the sample dilution buffer.
5. Wait for 20 seconds to settle down the large particles.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Take the supernatant sample in the tube by using a disposable dropper.
8. Add 4 drops of the mixed sample into the sample hole (S), drop by drop vertically.
9. Read test results at 10 minutes.



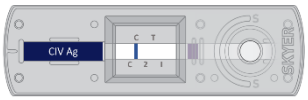
[Summary of Test Procedure]

Interpretation of Results

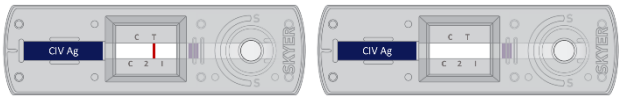
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of CIV antigens.



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* diagnosis only especially canine. 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 membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
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, swab).
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

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2. Song D, Kang B, Lee C, Jung K, Ha G, Kang D, Park S, Park B, Oh J. Transmission of avian influenza virus (H3N2) to dogs. *Emerg Infect Dis*. 2008; 14: 741-746.
3. Songserm T, Amonsin A, Jam-on R, et al. Fatal avian influenza A H5N1 in a dog. *Emerg Infect Dis*. 2006; 12: 1744-1747.
4. Dundon WG, Benedictis P, Viale E, Capua I. Serologic Evidence of Pandemic (H1N1) 2009 Infection in Dogs, Italy. *Emerg Infect Dis*. 2010; 16: 2019-2021.
5. Dubovi EJ. Canine Influenza. *Vet Clin Small Anim*. 2010; 40: 1063-1071.
6. Spickler, Anna Rovid. 2016. *Canine Influenza*. Retrieved from http://www.cfsph.iastate.edu/DiseaseInfo/factsheets.php.
7. Sun H, Blackmon S, Yang G, Waters K, Li T, Tangwangvivat R, Xu Y, Shyu D, Wen F, Cooley J, Senter L, Lin X, Jarman R, Hanson L, Webby R, Wan X-F. 2017. 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
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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