Rapid Canine Coronavirus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ CCV Ag Test Kit

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

Introduction

Canine coronavirus (CCV), a single-stranded positive-sense RNA virus (family Coronaviridae, genus *Alphacoronavirus*), was first isolated in 1971 from military dogs in Germany suffering from acute gastroenteritis[1].

CCV infection is characterized by high morbidity and low mortality, as well as by a typical fecal-oral route of transmission[2]. CCV is shed at high titers with the feces of the infected dogs and the infection is restricted to the alimentary tract, leading to typical clinical signs of gastroenteric involvement including loss of appetite, vomiting, fluid diarrhea, dehydration, and sometimes death especially in puppies[2, 3].

Fatal disease commonly occurs as a consequence of mixed infections with CCV together with canine parvovirus, canine adenovirus or canine distemper virus[4].

Principle

The RIDX™ CCV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CCV antigens in canine feces. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the CCV antigen exists in the sample, it binds to the gold-conjugated CCV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the CCV 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 monoclonal antibody to CCV is used as a capture and detector in the kit. The RIDX™ CCV Ag Test Kit can detect CCV antigens in canine feces with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ CCV Ag Test	+	56	3	59
	-	3	118	121
	Total	59	121	180

Sensitivity: 94.92% (56/59, *95% CI: 86.06% ~ 98.26%)
Specificity: 97.52% (118/121, 95% CI: 92.92% ~ 99.15%)
Diagnostic Agreement: 96.67% (174/180, 95% CI: 92.92% ~ 98.46%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1 x 10^5 $TCID_{50}$/mL

3. Cross-Reactivity

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

Pathogen	Titer	Result
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/mL	Negative
Canine parvovirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/μL	Negative
Salmonella spp.	1.00 x 10^6 CFU/mL	Negative

Kit Components

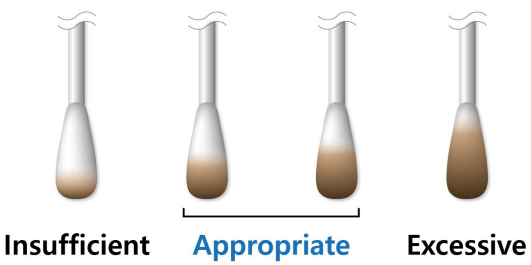
Component	Quantity/kit by CAT No.	
	CGM-CCG-11	CGM-CCG-12
1 CCV Ag test device	10	2
2 Sample dilution buffer	10	2
3 Disposable swab	10	2
4 Disposable dropper	10	2
5 Instructions for use	1	1

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 package label.

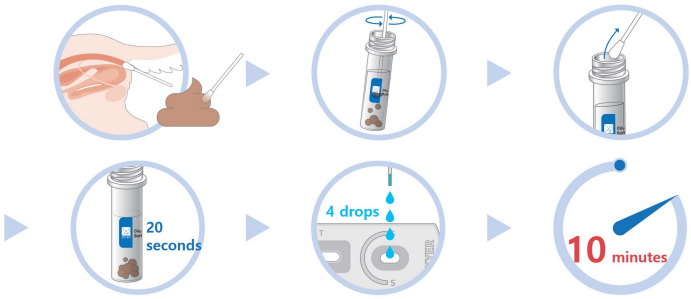
Sample Preparation

1. **Canine fecal swab** should be used for this test.
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 with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive fecal amount may induce a false positive result and slow migration.



Test Procedure

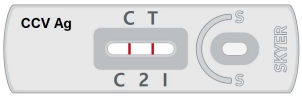
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect feces samples using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the 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. Apply 4 drops of the mixed sample into the sample hole (S), drop by drop vertically.
9. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**



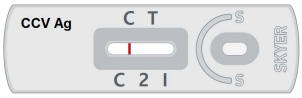
[Summary of Test Procedure]

Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of CCV 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. 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 of the test device.
5. The device should not be used if the foil pouch is damaged or has been stored with the seal open.
6. Do not use an expired test kit. The expiration date is marked on the package label.
7. Do not reuse the components (device, buffer, dropper, and swab).
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 in the accordance with 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. Binn LN, Lazar EC, Keenan KP, Huxsoll DL, Marchwicki RH, Strano AJ. Recovery and characterization of a coronavirus from military dogs with diarrhea. *Proc Annu Meet U S Anim Health Assoc*. 1974; 78: 359–366.
2. Tennant BJ, Gaskell RM, Kelly DF, Carter SD, Gaskell CJ. Canine coronavirus infection in the dog following oronasal inoculation. *Res Vet Sci*. 1991; 51(1): 11–18.
3. Evermann JF, Abbott JR, Han S. Canine coronavirus–associated puppy mortality without evidence of concurrent canine parvovirus infection. *J Vet Diagn Invest*. 2005; 17(6): 610–614.
4. Decaro N, Buonavoglia C. An update on canine coronaviruses: viral evolution and pathobiology. *Vet Microbiol*. 2008; 132: 221–234.

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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