

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FCoV Ag Test Kit

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

Introduction

Feline coronavirus (FCoV), a single-stranded positive-sense RNA virus (family Coronaviridae, genus *Alphacoronavirus*, species *Alphacoronavirus 1*), is a contagious pathogen responsible for acute gastroenteritis in cats and is found worldwide¹.

FCoV includes all strains (numerous), serotypes (types I and II) and biotypes or pathotypes (enteric or infectious peritonitis viruses) of the genus². According to the pathogenicity, FCoVs are divided into feline enteric coronavirus (FECV), which causes subclinical or mild enteritis in adult cats, and feline infectious peritonitis virus (FIPV), which causes a lethal enteric and systemic feline infectious peritonitis (FIP)^{3,4}. FIP can affect cats of any age but is most prevalent among cats less than 3 years of age and especially from 4 to 16 months of age³.

FCoV is mainly transmitted by the fecal-oral route⁴. Infected cats shed the virus for up to 24 months². Rarely, virus can be transmitted through saliva, by mutual grooming, by sharing the same food bowl, or through close contact. Sneezed droplet transmission is also possible⁴.

Principle

The RIDX™ FCoV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FCoV antigens in feline feces.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If FCoV antigens exist in the sample, that bind to the gold-conjugated FCoV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the FCoV 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 FCoV are used as capture and detector in the kit. The RIDX™ FCoV Ag Test Kit can detect FCoV antigens in feline feces with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™	+	13	1	14
FCoV Ag	-	1	52	53
Test	Total	14	53	67

Sensitivity: 92.86% (13/14, *95% CI: 68.53% ~ 98.73%)

Specificity: 98.11% (52/53, 95% CI: 90.06% ~ 99.67%)

Diagnostic Agreement: 97.01% (65/67, 95% CI: 89.75% ~ 99.18%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1.97×10^4 TCID₅₀/mL

3. Cross-Reactivity

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

Pathogen	Titer	Result
Feline calicivirus	1.00×10^5 TCID ₅₀ /mL	Negative
Feline parvovirus	$1.00 \times 10^{6.5}$ TCID ₅₀ /mL	Negative
<i>Escherichia coli</i>	3.56×10^8 CFU/mL	Negative
<i>Giardia</i> spp.	1.42×10^5 Cysts/ μ L	Negative
<i>Salmonella</i> spp.	1.00×10^6 CFU/mL	Negative

Kit Components

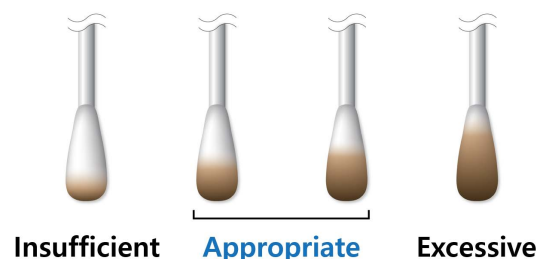
Component	Quantity/kit by CAT No.	
	CGM-FCG-11	CGM-FCG-12
1 FCoV Ag test device	10	2
2 Sample dilution buffer	10	2
3 Disposable swab	10	2
4 Disposable dropper	10	2
5 Instructions for use	1	1

Storage & Stability

1. Store the test kit at 2~30°C (35.6~86.0°F). **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.

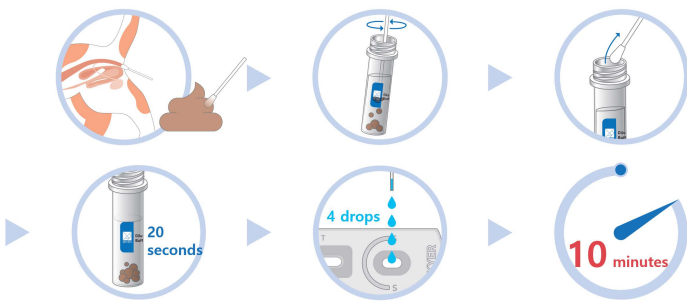
Sample Preparation

1. **Feline 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°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.
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°C / 59~86°F) 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 results at 10 minutes. **Do not read results that appear after 10 minutes.**

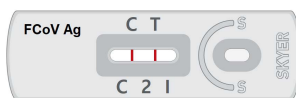


[Summary of Test Procedure]

Interpretation of Results

1. Positive result

Test (T) line and control (C) line within the result window indicate the presence of FCoV 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 cats. 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 test 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. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy*. 2019 Release. Ratification March 2020 (MSL #35).
2. Pedersen NC, Allen CE, Lyons LA. Pathogenesis of feline enteric coronavirus infection. *J Feline Med Surg*. 2008; 10(6) :529-541.
3. Pedersen NC. A review of feline infectious peritonitis virus infection: 1963-2008. *J Feline Med Surg*. 2009; 11(4): 225-258.
4. Hartmann K. Feline Infectious Peritonitis. *Vet Clin Small Anim*. 2005; 35: 39-79.

Symbol Descriptions

	License number
	Catalogue number
	Batch code, Lot number
	Consult instructions for use
	Contains sufficient for <n> tests
	Do not reuse
	<i>In vitro</i> 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