Rapid FPV Antigen & FCoV Antigen Test Kit

Document Number: SKR-IFU-FPG20197
Revised Date: 14 February 2023

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FPV/FCoV Ag Combo Test Kit

[CAT No. CGM-FPG-21]

Introduction

Feline panleukopenia virus (FPV, also known as feline parvovirus), a single-stranded DNA virus (family Parvoviridae, genus *Carnivore protoparvovirus 1*)[1], and feline coronavirus (FCoV), a single-stranded positive-sense RNA virus (family Coronaviridae, genus *Alphacoronavirus*, species *Alphacoronavirus 1*)[1], are contagious pathogens responsible for acute gastroenteritis in cats. FPV causes serious feline panleukopenia (FP). The clinical severity of FP varies with age, immune status, and co-infection, and symptoms of FP range from asymptomatic infection to acute syndrome with sudden death[2]. According to the pathogenicity, FCoVs are divided into two types: feline enteric coronavirus, which causes subclinical or mild disease in adult cats, and feline infectious peritonitis virus, which causes severe enteric and systemic feline infectious peritonitis[3].

Despite structural, genetic, molecular biological, and pathological differences, initial clinical signs of two viruses, including diarrhea, vomiting, fever, lethargy, and anorexia, are very similar when infected with cats. As infected cats shed viruses in feces, the common route of FPV and FCoV transmission is the fecal-oral route[3, 4].

Principles

The RIDX™ FPV/FCoV Ag Combo Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FPV antigens and FCoV antigens in feline feces. This kit shows two letters which are the test (T) line and the control (C) line for each test on the surface of the device. If viral antigens exist in the sample, that bind to the gold-conjugated virus (FPV or FCoV) specific antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the virus (FPV or FCoV) specific 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 FPV or FCoV for each are used as capture and detector in the kit. The RIDX™ FPV/FCoV Ag Combo Test Kit can detect FPV antigens and FCoV antigens in feline feces with high accuracy.

Performances

[FPV Ag Test]

1. Sensitivity & Specificity

		PCR		
		+	-	Total
RIDX™ FPV Ag Test	+	76	2	78
	-	2	123	125
	Total	78	125	203

Sensitivity: 97.44% (76/78, 95% CI*: 91.12% ~ 99.29%)
Specificity: 98.40% (123/125, 95% CI: 94.35% ~ 99.56%)
Diagnostic Agreement: 98.03% (199/203, 95% CI: 95.04% ~ 99.23%)

* CI: Confidence Interval

2. Limit of Detection: 1 x $10^{5.5}$ $TCID_{50}$/mL

3. Cross-Reactivity

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

Pathogen	Titer	Result
Feline calicivirus	1 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1 x 10^6 $TCID_{50}$/mL	Negative
Feline leukemia virus	Vaccine solution (≥1.0 RP)	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^7 *G.* cyst/100μL	Negative
Salmonella spp.	1 x 10^6 CFU/mL	Negative

[FCoV Ag Test]

1. Sensitivity & Specificity

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

2. Limit of Detection: 1.97 x 10^4 $TCID_{50}$/mL

3. Cross-Reactivity

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

Pathogen	Titer	Result
Feline calicivirus	1 x 10^5 $TCID_{50}$/mL	Negative
Feline leukemia virus	Vaccine solution (≥1.0 RP)	Negative
Feline parvovirus	1 x $10^{6.5}$ $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Salmonella spp.	1 x 10^6 CFU/mL	Negative
Giardia spp.	1.42 x 10^7 *G.* cyst/100μL	Negative

Kit Components

	Component	Number/Kit
1	FPV/FCoV Ag Combo Test device	10
2	Sample dilution buffer (1mL)	10
3	Disposable swab	10
4	Disposable dropper	10
5	Instructions for use	1

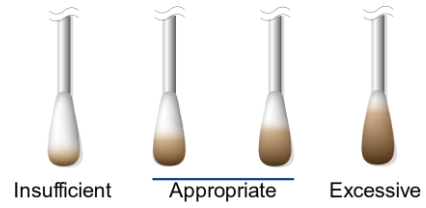
Storage & Stability

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

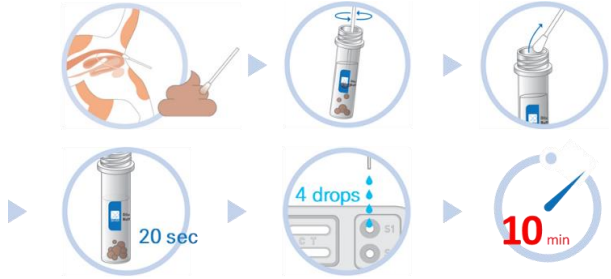
1. Feline feces swab should be used for this test.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46°F) for up to 24 hours. For longer storage, freeze at −20°C (−4°F) or below. Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.

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. Add 4 drops of the mixed sample into each sample holes (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 FPV antigens or FCoV antigens.

[FPV positive]

[FCoV positive]

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 feline. 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

1. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy*: 2019 Release. Ratification March 2020 (MSL #35).
2. Parrish CR. Pathogenesis of feline panleukopenia virus and canine parvovirus. *Baillieres Clin Haematol*. 1995; 8(1): 57–71.
3. Pedersen NC, Allen CE, Lyons LA. Pathogenesis of feline enteric coronavirus infection. *J Feline Med Surg*. 2008; 10(6): 529–541.
4. Truyen U, Addie D, Belák Corine Boucraut-Baralon C, Egberink H, Frymus T, Gruffydd-Jones T, Hartmann K, Hosie MJ, Lloret A, Lutz H, Marsilio F, Pennisi MG, Radford AD, Thiry E, Horzinek MC. Feline panleukopenia. ABCD guidelines on prevention and management. *J Feline Med Surg*. 2009; 11(7): 538–546.

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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