Rapid Feline Panleukopenia Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FPV Ag Test Kit

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

Introduction

Feline panleukopenia virus (FPV, also known as feline parvovirus), a single-stranded DNA virus (family Parvoviridae, genus *Carnivore protoparvovirus 1*)[1], are contagious pathogens responsible for acute gastroenteritis in cats.

FPV causes serious feline panleukopenia (FP)[2]. 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. Cats of all ages can be infected with FPV, but it is especially fatal to kittens. Mortality rates of FPV-infected kittens are over 90%[3]. FPV infected cats have anorexia, lethargy, bloody diarrhea, vomiting, leukopenia, lymphopenia, neutropenia, or thrombocytopenia. Symptoms usually appear in 4 to 6 days after infection, sometimes in 2 to 14 days[3, 4].

As FPV are shed in feces, urine, saliva, and nasal secretions, routes of FPV transmission generally involve the fecal-oral route, direct contact or by inhalation of respiratory aerosols[5].

Principle

The RIDX™ FPV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FPV 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 the FPV antigen exists in the sample, it binds to the gold-conjugated FPV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the FPV 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 anti-FPV monoclonal antibodies to FPV are used as capture and detector in the kit. The RIDX™ FPV Ag Test Kit can detect FPV antigens in feline feces with high accuracy.

Performance

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%)

* 95% CI: 95% Confidence Interval

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

3. Cross-Reactivity

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

Pathogen	Titer	Result
Feline calicivirus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	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

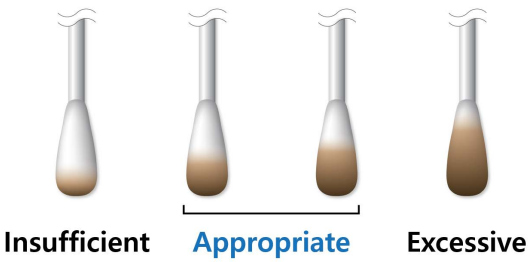
	Component	Quantity/kit by CAT No.	
		CGM-FPG-11	CGM-FPG-12
1	FPV Ag test device	10	2
2	Sample dilution buffer	10	2
3	Disposable swab	10	2
4	Disposable dropper	10	2
5	Instructions for use	1	1

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.

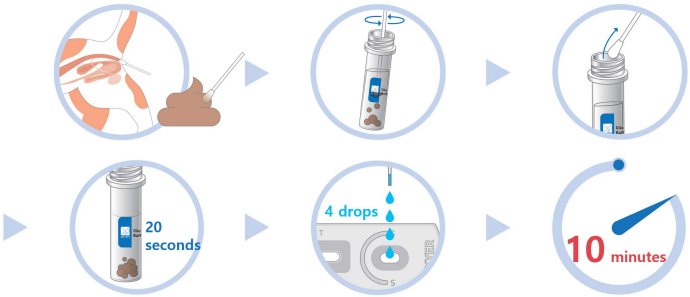
Sample Preparation

1. **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℉) 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°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

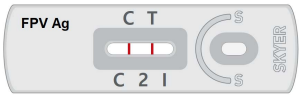
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect feces samples using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the 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. 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.**



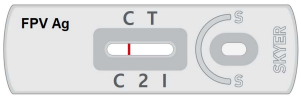
[Summary of Test Procedure]

Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of FPV 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 (Master Species List #35). https://talk.ictvonline.org/taxonomy
2. Parrish CR. Pathogenesis of feline panleukopenia virus and canine parvovirus. *Baillieres Clin Haematol*. 1995; 8(1): 57–71.
3. Kruse BD, Unterer S, Horlacher K, Sauter-Louis C, Hartmann K. Prognostic Factors in Cats with Feline Panleukopenia. *J Vet Intern Med*. 2010; 24(6): 1271–1276.
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.
5. Bloom ME, Kerr JR. Pathogenesis of parvovirus infections. *Parvoviruses*. Hodder Arnold, London. 2006; 2: 323–341.

Symbol Descriptions

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