

Feline Coronavirus /Panleukopenia Virus/ Giardia Antigen Combo Rapid Test Kit

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST



Principles

The **BISAF[®]** FCoV/FPV/Giardia Ag Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FPV (Feline parvovirus, synonym of feline panleukopenia virus), FCoV (Feline coronavirus) and *Giardia* 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 the pathogenic antigens (FPV, FCoV or *Giardia*) exist in the sample, that bind to the gold-conjugated pathogens (FPV, FCoV or *Giardia*) specific antibodies. The antigen-antibody complex moves through the membrane by capillary force and responds to the pathogen (FPV, FCoV or *Giardia*) specific antibodies 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 antibodies to FPV (FCoV or *Giardia*) is used as capture and detector in the kit. The **BISAF[®]** FCoV/FPV/Giardia Ag Kit can detect FPV antigens, FCoV antigens and *Giardia* antigens in feline feces with high accuracy.

Performances

[FPV Ag Test]

1. Sensitivity & Specificity

		PCR		Total
		+	-	
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: $1 \times 10^{5.5}$ TCID₅₀/mL

3. Cross- Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the **BISAF[®]** FPV Ag Test.

Pathogen	Titer	Result
Feline calicivirus	1.00×10^5 TCID ₅₀ /mL	Negative
Feline coronavirus	1.00×10^6 TCID ₅₀ /mL	Negative
<i>Escherichia coli</i>	3.56×10^8 CFU/mL	Negative
<i>Giardia</i> spp.	1.42×10^5 Cysts/μL	Negative
<i>Salmonella</i> spp.	1.00×10^6 CFU/mL	Negative

[FCoV Ag Test]

1. Sensitivity & Specificity

		RT-PCR		Total
		+	-	
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%)

* CI: 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 **BISAF[®]** FCoV Ag Test.

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>Salmonella</i> spp.	1.00×10^6 CFU/mL	Negative
<i>Giardia</i> spp.	1.42×10^5 Cysts/μL	Negative

[Giardia Ag Test]

1. Clinical Sensitivity & Clinical Specificity

		Disease Status		Total
		+	-	
Giardia Ag Test	+	34	4	38
	-	1	109	110
	Total	35	113	148

Clinical Sensitivity: 97.14% (34/35, 95% CI*: 95.47% ~ 99.49%)

Clinical Specificity: 96.46% (109/113, 95% CI: 91.25% ~ 98.61%)

Diagnostic Accuracy: 96.62% (143/148, 95% CI: 92.34% ~ 98.55%)

* CI: Confidence Interval

2. Limit of Detection: 1.25 Cysts/μL

3. Cross- Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the **BISAF[®]** Giardia Ag Test.

Pathogen	Titer	Result
Canine coronavirus	1.00×10^6 TCID ₅₀ /mL	Negative
Canine distemper virus	1.00×10^5 TCID ₅₀ /mL	Negative
Canine influenza virus	1.00×10^6 EID ₅₀ /mL	Negative
Feline calicivirus	1.00×10^5 TCID ₅₀ /mL	Negative
Feline coronavirus	1.97×10^4 TCID ₅₀ /mL	Negative
Feline parvovirus	$1.00 \times 10^{5.5}$ TCID ₅₀ /mL	Negative

Kit Components

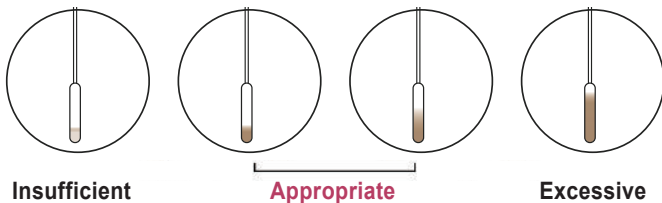
Component	Quantity/kit
1 FCoV/FPV/Giardia Ag device	1
2 Dilution buffer	1
3 Disposable swab	1
4 Instructions for use	1
5 Collection bag	1

Storage & Stability

- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

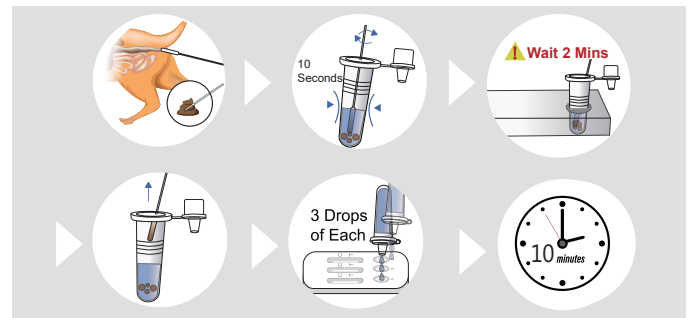
Sample Preparation

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. 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 fecal sample 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. Wait for 2 minutes to settle down the large particles.
5. Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Apply 3 drops of the mixed sample solution into the sample holes for each, drop by drop vertically.
8. Read test results at 10 minutes.



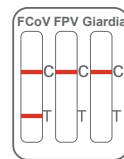
[Summary of Test Procedure]

Interpretation of Results

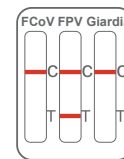
1. Positive Results

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

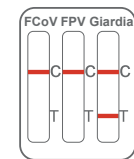
[FCoV positive]



[FPV positive]

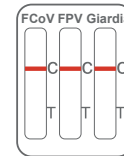


[Giardia positive]



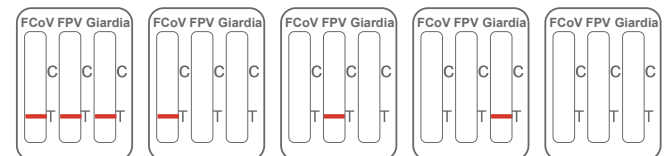
2. Negative Result

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* diagnostic use only for cats. 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, and 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.

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