

# Feline Panleucopenia Antigen Test

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST



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## INTENDED USE

The Feline Panleukopenia Virus Antigen Test is a rapid immunochromatographic assay designed for the qualitative detection of feline panleukopenia virus (FPV) antigens in feline fecal samples. This test is intended for veterinary in vitro diagnostic use as an aid in the diagnosis of FPV infection in cats. It provides rapid results within 10 minutes, facilitating timely clinical decision-making for the management of panleukopenia infections. Results should be interpreted by qualified veterinary professionals in conjunction with clinical symptoms and epidemiological findings.

## Summary

Feline panleukopenia, caused by FPV, is a highly contagious and often fatal disease primarily affecting the gastrointestinal tract and immune system of cats. The FPV Ag Test Kit offers a rapid, accurate, and convenient method for in-clinic detection of FPV antigens in fecal specimens. Demonstrating excellent clinical performance (sensitivity: 97.44%; specificity: 98.40%), this immunochromatographic assay enables veterinarians to rapidly identify infected animals, particularly kittens experiencing mortality rates exceeding 90%. The complete kit includes all necessary components for efficient testing, requiring minimal sample preparation.

## Test Principle

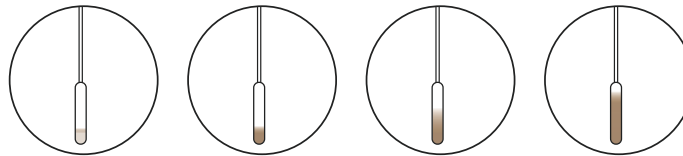
Based on the principles of sandwich immunochromatography, this assay employs high-affinity monoclonal antibodies specific to feline panleukopenia virus (FPV) antigens. Colloidal gold-conjugated anti-FPV monoclonal antibodies are impregnated onto the conjugate pad, while complementary capture antibodies are immobilized within the test line (T) region. Upon application of a fecal specimen, any FPV antigens present form complexes with the gold-conjugated antibodies. Capillary action mediates transport of these antigen-antibody complexes along the nitrocellulose membrane, where they are captured by immobilized antibodies at the test line (T), generating a visually discernible colored line. A control line (C), utilizing species-specific anti-immunoglobulin antibodies, verifies proper procedural execution, reagent functionality, and membrane integrity.

## 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. 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°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.



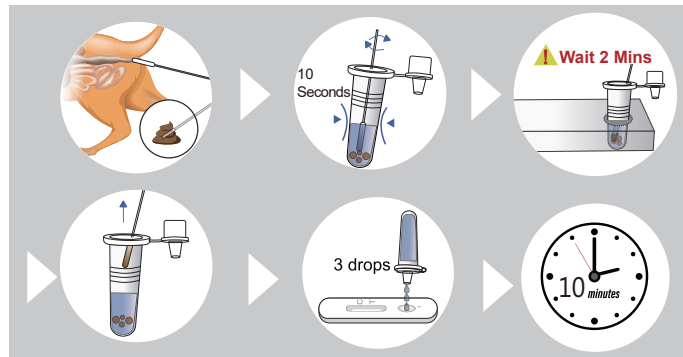
Insufficient

Appropriate

Excessive

## 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.



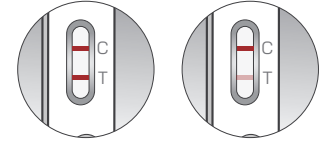
[Summary of Test Procedure]

## Interpretation of Results

### Positive(+)

Presence of two color bands "T" and "C"

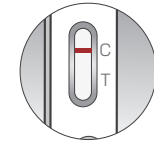
Two lines, one next to C and one next to T, even faint lines, shows the test is positive.



### Negative (-)

No presence of color band ("T")

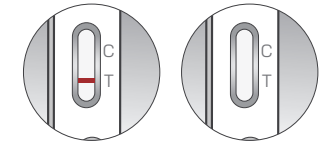
One red-colored line only next to "C" indicates a negative result.



### Invalid

No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



## Precautions & Warnings

### 1. Intended Use & Validity

- For veterinary in vitro diagnostic use only. Not for human or other animal use.
- Do not use beyond the expiration date printed on the package label.
- Do not use if the foil pouch is damaged or already open.

### 2. Handling & Storage

- Store at 2~30°C. Do not freeze or expose to direct sunlight.
- Once opened, use the test device within 10 minutes.
- Avoid touching the membrane area of the test device.

### 3. Operational Guidelines

- Use only components provided in the kit. Do not reuse any items.
- Do not mix components from different lot numbers.
- Ensure all reagents and samples are at room temperature (15~30°C) before use.

### 4. Safety & Disposal

- Treat all samples as potentially infectious.
- Wear protective gloves during handling and wash hands thoroughly afterward.
- Dispose of used kits and samples in accordance with local biohazard regulations.

## Test Limitations

1. This test detects FPV antigens but cannot differentiate between vaccine strains and wild-type virus
2. Recent vaccination with modified-live FPV vaccines may yield false-positive results for 7-14 days post-vaccination
3. Negative results do not exclude FPV infection, particularly during early stages of infection or in cases with low viral shedding
4. Sample quality significantly impacts test performance; improper collection or excessive fecal matter may affect results
5. The test is designed for feline fecal samples only and not validated for other sample types or species
6. Results should be interpreted by qualified veterinarians considering all clinical and epidemiological factors
7. Freeze-thaw cycles may affect antigen integrity and test performance

## Clinical Evaluation:

The FPV Antigen Test demonstrates high diagnostic accuracy for simultaneous detection of Feline Panleukopenia Virus antigens in fecal specimens. Validation studies comparing against RT-PCR show excellent sensitivity and specificity for the targets, providing reliable results for clinical use. The following data summarize the clinical performance characteristics:

Feline Panleukopenia Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
<b>Positive</b>	76	2	78
<b>Negative</b>	2	123	125
<b>Total</b>	78	125	203
<b>Sensitivity</b>	76/78, 97.44%(95% C1:91.12% to 99.29%)		
<b>Specificity</b>	123/125, 98.40%(95% C1:94.35% to 99.56%)		
<b>Total coincidence rate</b>	199/203, 98.03%(95% C1:95.04% to 99.23%)		

## Limit of Detection (Analytical Sensitivity)

The analytical sensitivity of the FPV Ag Test Kit was determined to be  $1 \times 10^5$  TCID<sub>50</sub>/mL using standardized FPV reference strains. This detection limit ensures reliable identification of clinically relevant FPV infections in feline fecal samples.

## Cross Reactivity

The following potentially cross-reactive pathogens were evaluated and showed no cross-reactivity with the FPV Ag Test Kit:

Pathogen	Concentration Tested	Result
Feline Calicivirus (FCV))	$1.0 \times 10^5$ TCID <sub>50</sub> /mL	Negative
Feline Coronavirus (FCoV)	$1.0 \times 10^6$ TCID <sub>50</sub> /mL	Negative
Feline Herpesvirus-1 (FHV-1)	$1.0 \times 10^5$ TCID <sub>50</sub> /mL	Negative

Feline Immunodeficiency Virus (FIV)	$1.0 \times 10^5$ TCID <sub>50</sub> /mL	Negative
Feline Leukemia Virus (FeLV)	$1.0 \times 10^5$ TCID <sub>50</sub> /mL	Negative
Escherichia coli	$3.56 \times 10^8$ CFU/mL	Negative
Salmonella spp	$1.0 \times 10^6$ CFU/mL	Negative
Chlamydia felis	$1.0 \times 10^6$ IFU/mL	Negative
Giardia spp	$1.42 \times 10^5$ cysts/ $\mu$ LL	Negative












## Interfering Substances

The following substances were evaluated for potential interference with the FPV Ag Test Kit:

Substance Category	Specific Substance	Concentration tested	Effect on Assay
Endogenous Substances	Hemoglobin (Whole Blood)	4%(v/v)	No Interference
	Mucin	5 mg/mL	No Interference
	Bilirubin	0.4 mg/mL	No Interference
	Intestinal Lipids	5 mg/mL	No Interference
Medications	Antibiotics	1 mg/mL	No Interference
	Antiparasotics	1 mg/mL	No Interference
	Anti-diarrheal agents	1 mg/mL	No Interference
Dietary Components	Plant fibers	5%(w/v)	No Interference
	Hair	5%(w/v)	No Interference
	Food particles	5%(w/v)	No Interference

**Note:** While these substances showed no interference at tested concentrations, grossly contaminated samples may affect test performance. For optimal results, use fresh fecal samples and follow recommended collection procedures.

## Index of Symbols

	Consult Instruction for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Do not desterilize		



Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd  
Address: Room.1304 & Room.1306 , No.48, Xinyu Road, Xiangshan Community Xinqiao Street, Baoan District, Shenzhen, Guangdong, China. 518 000



Riomavix S.L.  
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain  
Tel.: +34 658 396 230  
E-mail: leis@riomavix.com



Importer & Distributor: BISAF Sp. z o.o.  
Add: ul. Rdestowa 5, 54-530 Wrocław, Poland  
Website: www.bisaf.pl