BISAF VET

For Veterinary Use Only

Feline Coronavirus Antigen Test

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

Contents

	1 test/kit	5 tests/kit	25 tests/kit
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INTENDED USE

The FCoV Ag Test Kit is an immunochromatographic lateral flow assay intended for the qualitative detection of feline coronavirus (FCoV) antigens in feline fecal samples. This test is designed to aid in the clinical diagnosis of feline coronavirus infection, including feline infectious peritonitis (FIP), in conjunction with clinical signs and other diagnostic methods. This kit is for veterinary use only and is not intended for human use.

Summary

Feline coronavirus is a highly contagious pathogen that causes acute gastro-enteritis in cats and can lead to the fatal disease feline infectious peritonitis (FIP). The FCoV Ag Test Kit provides a rapid, accurate, and convenient method for detecting FCoV antigens in fecal samples. With high sensitivity (92.54%) and specificity (98.17%), this test delivers reliable results within 10 minutes, enabling veterinarians to make timely clinical decisions. The kit contains all necessary components for testing and requires minimal sample preparation.

Test Principle

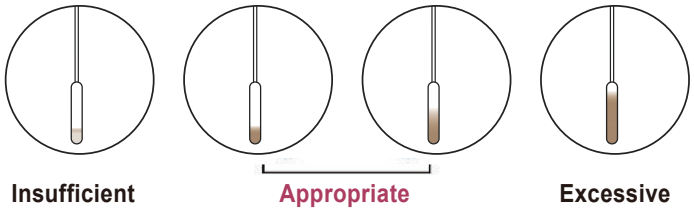
The FCoV Ag Test Kit is based on a lateral flow chromatographic immunoassay principle. The test utilizes highly specific monoclonal antibodies against FCoV for both capture and detection. When a fecal sample is applied to the device, any FCoV antigens present will bind to the gold-conjugated anti-FCoV antibodies. This complex migrates chromatographically along the membrane through capillary action. If FCoV antigens are present, they will be captured by the immobilized anti-FCoV antibodies at the test line (T), producing a visible red line. A control line (C) contains species-specific antibodies that capture the gold conjugate, serving as an internal procedural control to validate the test result.

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

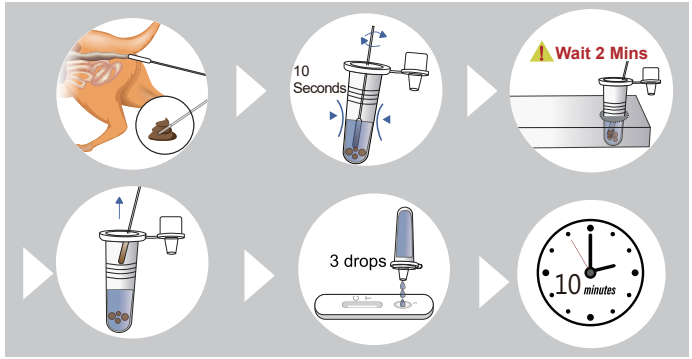
1. Canine fecal swab should be used for this test.
2. The samples should be tested immediately after collection.
3.If samples cannot be tested immediately, they should be stored at 2~8°C(35.6~46.4°F) for up to 24 hours. For longer storage, freeze at -20°C (-4°F) or below.Frozen samples should be brought 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 drysur-face.
7.Apply 3 drops of the mixed sample solution into the sample holes foreach , drop by drop vertically.
8.Read test results at 10 minutes.



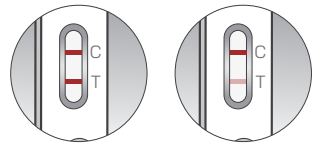
[Summary of Test Procedure]

Interpretation of Results

Positive(+)

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

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



Negative (-)

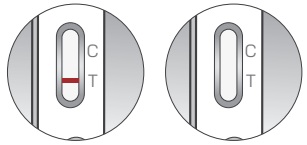
No presence of color band ("T")

One red-coloredline 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 regula tions.

Test Limitations

1.A negative result does not completely rule out FCoV infection, as antigen levels may be below the detection limit of the test during early or late stages of infection.
2. The test is designed specifically for fecal samples and has not been validated for other sample types (e.g., blood, serum, or effusion fluids).
3. False-negative results may occur due to improper sample collection, storage, or handling.
4. False-positive results may occur if the fecal sample contains excessive amounts of mucus or blood, or if the sample is contaminated with other substances.
5. Test results should be interpreted in conjunction with clinical signs, history, and other diagnostic findings by a qualified veterinarian.
6. The test performance may be affected if the recommended storage conditions or expiration date are not strictly followed.
7.This test is not quantitative and cannot determine the viral load or pathogenicity (FECV vs. FIPV) of the detected coronavirus.

Clinical Evaluation:

The Feline Coronavirus Antigen Test demonstrates high diagnostic accuracy for simultaneous detection of Feline Coronavirus antigens in feces samples . 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 Coronavirus Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
Positive	62	4	66
Negative	5	215	220
Total	67	219	286
Sensitivity	62/67, 92.54%(95%C1: 83.69% to 96.77%)		
Specificity	215/219, 98.17%(95%C1: 95.4% to 99.29%)		
Total coincidence rate	277/286,96.85%(95%C1:94.13% to 98.34%)		

Limit of Detection (Analytical Sensitivity)

The limit of detection for the Coronavirus Antigen Test Kit was determined to be 1.2 × 10^3 $TCID_{50}$/mL using reference FCV strain F9. This sensitivity level ensures reliable detection of FCoV antigens in clinical samples from infected cats.

Cross Reactivity

The following potentially cross-reactive pathogens were tested and showed no cross-reactivity with the FCoV Ag Test Kit at the concentrations indicated:

Pathogen	Concentration Tested	Result
Feline calicivirus (FCV)	1.0x10^5 $TCID_{50}$/mL	Negative
Feline parvovirus(FPV)	1.0x$10^{6.5}$ $TCID_{50}$/mL	Negative
Escherichia coli	3.56x10^8 CFU/mL	Negative
Giardia spp	1.42x10^5 cysts/μL	Negative
Salmonella spp	1.0x10^6 CFU/mL	Negative
Toxoplasma gondii	1.0x10^5 oocysts/mL	Negative
Clostridium perfringens	1.0x10^6 CFU/mL	Negative
Feline herpesvirus (FHV-1)	1.0x10^5 $TCID_{50}$/mL	Negative

Interfering Substances

The following substances have been evaluated for potential interference with the FCoV Ag Test Kit at the indicated concentrations. No significant interference was observed under the tested conditions.

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 Fat/Lipids	5 mg/mL	No Interference
Common Cat Litter	Bentonite Clay	2 mg/mL	No Interference
	Silica Gel	2 mg/mL	No Interference
	Paper-based	2 mg/mL	No Interference
	Walnut Shell	2 mg/mL	No Interference
Medications	Albendazole	1 mg/mL	No Interference
	Metronidazole	1 mg/mL	No Interference
	Pyrantel Parnate	1 mg/mL	No Interference
	Antibiotics (e.g.,Doxycycline)	1 mg/mL	No Interference
Disinfectants & Cleaners	Chlorhexidine	0.10%	No Interference
	Quaternary Ammonium	0.10%	No Interference
	Bleach (Sodium Hypochlorite)	0.05%	No Interference
	Iodophors	0.10%	No Interference

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Do not desterilize		

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