BISAF VET

For Veterinary Use Only

Feline Coronavirus Antigen Test

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

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INTENDED USE

The Feline Calicivirus Antigen Test constitutes a rapid immunochromatographic assay intended for the qualitative detection of feline calicivirus (FCV) antigens within ocular secretions, nasal discharge, or saliva specimens collected from feline subjects. This diagnostic procedure is designated for veterinary application as an adjunctive tool in the diagnosis of FCV infection, the principal etiological agent responsible for feline upper respiratory tract disease. Test results should be correlated with clinical manifestations, patient history, and supplementary diagnostic methodologies.

Summary

Feline calicivirus represents a highly prevalent and contagious pathogen responsible for upper respiratory infections and oral disease in feline populations. The FCV Ag Test Kit provides a rapid, precise, and readily operable solution for the detection of FCV antigens at the point of care. Demonstrating a sensitivity of 97.12% and specificity of 98.43%, this assay yields reliable results within 10 minutes, thereby expediting therapeutic interventions. The complete kit comprises all requisite materials for immediate analysis.

Test Principle

The assay operates on the principle of a sandwich immunochromatographic technique. Two highly specific monoclonal antibodies directed against distinct epitopes of FCV are employed: one conjugated to colloidal gold nanoparticles (detector antibody) and the other immobilized onto the nitrocellulose membrane (capture antibody). Upon sample application, FCV antigens present in the specimen bind to the colloidal gold-conjugated antibodies. The resultant complex migrates along the membrane via capillary action. If FCV antigens are present, they are captured by the immobilized antibodies at the test line (T), generating a visible chromogenic signal. A control line (C) verifies procedural integrity and reagent functionality.

Storage & Stability

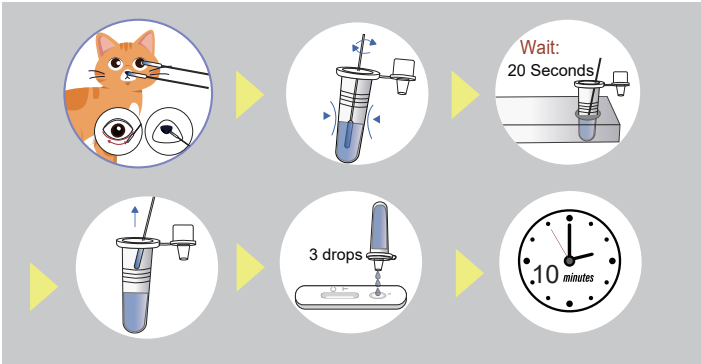
- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

Sample Preparation

1. Specimen (Ocular or nasal secretions) should be collected by using a swab.
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. Frozen samples should be brought to room temperature (15~30°C/59~86℉) before use.

Test Procedure

1. All reagents and samples must be at room temperature (15~30℃/59~86℉) before use.
2. Collect Ocular or nasal secretions 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 20 seconds 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 hole , drop by drop vertically
8.Read test results at 10 minutes.



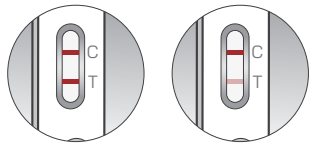
[Summary of Test Procedure]

Interpretation of Results

Positive(+)

Presence of two color bands “T”and “C”

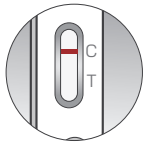
Two lines, one nextto C and one next to T, even faint lines, shows the test is positive.



Negative (-)

No presence of color band (“T”)

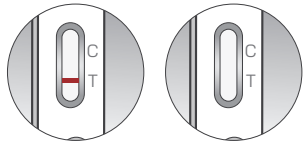
One red-coloredline only next to “C” indicates a negative result.



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 regulations.

Test Limitations

1. This test is intended for screening purposes and yields presumptive findings. Positive results necessitate confirmation by polymerase chain reaction (PCR) and/or other validated diagnostic techniques.
2. Negative results do not definitively exclude FCV infection, particularly in samples collected during the initial or terminal phases of infection when antigen concentrations may fall below the assay's detection threshold.
3. Recent vaccination with modified-live FCV vaccines may induce transient false-positive results for 3-10 days post-vaccination.
4. Cats undergoing monoclonal antibody therapy may produce secondary antibodies potentially causing false-positive results.
5. Assay performance is contingent upon appropriate sample collection, handling, and storage procedures. Suboptimal samples may yield erroneous outcomes.
6. The test is validated exclusively for feline specimens and has not been evaluated for use with samples from other species.
7. Test results should not constitute the sole basis for diagnostic or therapeutic decisions.

Clinical Evaluation:

The Feline Calicivirus Antigen Test demonstrates high diagnostic accuracy for simultaneous detection of Feline Calicivirusantigens in ocular secretions, nasal discharge, or saliva 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 Coronavirus Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
Positive	101	2	103
Negative	3	125	128
Total	104	127	231
Sensitivity	101/104, 97.12%(95%C1: 91.86% to 99.01%)		
Specificity	125/127, 98.43%(95%C1: 94.44% to 99.57%)		
Total coincidence rate	226/231,97.84%(95%C1:95.03% to 99.07%)		

Limit of Detection (Analytical Sensitivity)

The limit of detection for the FCV Ag 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 FCV antigens in clinical samples from infected cats.

Cross Reactivity

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

Pathogen	Concentration Tested	Result
Feline Panleukopenia Virus (FPV)	$1.0x10^6$ $TCID_{50}$/mL	Negative
Feline Coronavirus (FCoV)	$1.0x10^6$ $TCID_{50}$/mL	Negative
Feline Herpesvirus-1 (FHV-1)	$1.0x10^5$ $TCID_{50}$/mL	Negative
Feline Immunodeficiency Virus(FIV)	$1.0x10^5$ $TCID_{50}$/mL	Negative
Feline Leukemia Virus (FeLV)	$1.0x10^5$ $TCID_{50}$/mL	Negative
Chlamydiafelis	$1.0x10^6$ IFU/mL	Negative
Bordetellabronchiseptica	$1.0x10^8$ CFU/mL	Negative

Interfering Substances

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

Substance	Concentration tested	Effect on Assay
Mucin	5mg/mL	No Interference
Whole blood	4%(V/V)	No Interference
Ophthalmic ointment	5%(V/V)	No Interference
Nasal decongestants	1%(V/V)	No Interference
Antibiotics (enrofloxacin)	1mg/mL	No Interference
Disinfectants(chlorhexidine)	0.1%	No Interference
Saline eye drops	10%(V/V)	No Interference
Cat food particles	5mg/mL	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				

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