BISAF VET

For Veterinary Use Only

Feline Herpesvirus 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 FHV Ag Test Kit is an immunochromatographic rapid diagnostic device for *in vitro* use, designed to qualitatively detect feline herpesvirus type 1 (FHV-1) antigens in feline ocular secretions, nasal discharge, or saliva specimens. This assay is intended solely for veterinary professional use and aids in the diagnosis of FHV-1 infection—a primary etiological agent of feline upper respiratory disease complex (URD). Results must be interpreted by qualified veterinary personnel in conjunction with clinical presentation, vaccination history, and supplementary diagnostic data.

Summary

Feline herpesvirus type 1 (FHV-1), an enveloped double-stranded DNA virus, induces severe ocular and respiratory disease in felids globally. The FHV Ag Test Kit provides a rapid, accurate, and user-friendly method for point-of-care detection of FHV-1 antigens. Demonstrating a clinical sensitivity of 96% and specificity of 98.8%, this immunochromatographic assay generates reliable results within 10 minutes, facilitating timely therapeutic intervention. The complete kit contains all requisite components for convenient deployment in clinical settings.

Test Principle

The assay employs a sandwich immunochromatographic methodology utilizing highly specific monoclonal antibodies against FHV-1 antigens. Colloidal gold-conjugated anti-FHV antibodies are impregnated onto the conjugate pad, while a second anti-FHV antibody is immobilized at the test line (T) region. Upon sample application, FHV-1 antigens (if present) bind to the gold-conjugated antibodies. The resulting complex migrates chromatographically along the membrane via capillary action. This complex is subsequently captured by immobilized antibodies at the test line (T), generating a visible red line. A control line (C), containing species-specific immunoglobulin, verifies procedural validity and reagent functionality.

Storage & Stability

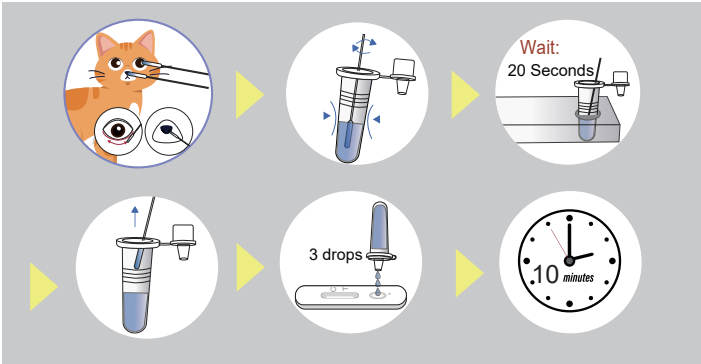
- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

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.



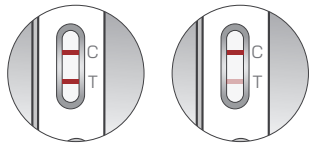
[Summary of Test Procedure]

Interpretation of Results

Positive(+)

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

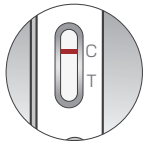
Two lines, one nextto C and one next to T, even faint lines, shows the test is positive.



Negative (-)

No presence of color band (“T”)

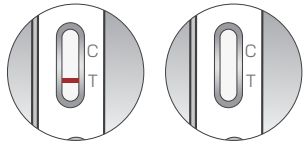
One red-coloredline only next to “C” indicates a negative result.



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 provides presumptive results for screening purposes. Positive results should be confirmed by polymerase chain reaction (PCR) or viral culture when clinically warranted.
2. Negative results do not preclude FHV-1 infection, particularly during early incubation phases or latent infection characterized by intermittent viral shedding.
3. Recent administration of modified-live FHV vaccines may induce transient viral shedding, potentially causing false-positive results for 7–14 days post-vaccination.
4. Specimens from cats undergoing monoclonal antibody therapy may yield false-positive results due to assay interference.
5. Performance depends on appropriate sample collection technique; suboptimal sampling may produce false-negative results.
6. Validation is restricted to the specified sample types; performance with blood, serum, tissue, or non-feline specimens remains unestablished.
7. Results require interpretation by a qualified veterinarian within the context of clinical signs and relevant epidemiological factors.

Clinical Evaluation:

The Feline Herpesvirus Antigen Test Kit demonstrates high diagnostic accuracy for simultaneous detection of Feline herpesvirus antigens 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 Herpesvirus Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
Positive	72	3	75
Negative	3	247	250
Total	75	250	325
Sensitivity	72/75,96%(95%C1: 88.89% to 98.63%)		
Specificity	247/250, 98.80%(95%C1:96.53% to 99.15%)		
Total coincidence rate	319/325, 98.15%(95%C1:96.03% to 99.15%)		

Limit of Detection (Analytical Sensitivity)

The analytical sensitivity of the FHV Ag Test Kit, determined using purified FHV-1 reference strain (ATCC VR-735), is 2.5 × 10^3 $TCID_{50}$/mL. This detection limit ensures reliable identification of clinically relevant FHV-1 infection in feline ocular and respiratory secretions.

Cross Reactivity

The following potentially cross-reactive pathogens were evaluated at high concentrations and showed no cross-reactivity with the FHV Ag Test Kit:

Pathogen	Concentration Tested	Result
Feline calicivirus (FCV)	1.0x10^5 $TCID_{50}$/mL	Negative
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 FHV Ag Test Kit:

Substance Category	Specific Substance	Concentration tested	Effect on Assay
Endogenous Substances	Hemoglobin (Whole Blood)	5%(v/v)	No Interference
	Salivary mucins	10%(v/v)	No Interference
	Brain tissue lipids	10%(w/v)	No Interference
	Cellular debris	15%(v/v)	No Interference
Preservatives	Sodium azide	0.1%(w/v)	No Interference
	Trimeroal	0.01%(w/v)	No Interference
	Formalin	0.1%(v/v)	No Interference
Medications	Antiviral drugs	1mg/mL	No Interference
	Antibiotics	1mg/mL	No Interference
	Sedatives	0.1mg/mL	No Interference
Environmental Contaminants	Dirt/soil particles	5%(w/v)	No Interference
	Plant material	5%(w/v)	No Interference
	Water contaminants	1%(v/v)	No Interference

Index of Symbols

	Consult Instruction for use	Σ	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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