Rapid Feline Leukemia Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FeLV Ag Test Kit

[Catalogue Number: CGM-FLG-11]

Introduction

Feline leukemia virus (FeLV; family Retroviridae; subfamily Orthoretrovirinae; genus *Gammaretrovirus*) is an enveloped, oncogenic RNA virus[1].

FeLV is spread vertically and horizontally from infected queens to their kittens and horizontally among cats that live together. There is an age-related increase in resistance to FeLV infection; kittens have the highest risk of becoming progressively infected[2]. The infected cats shed infectious virus in body fluids, including saliva, nasal secretions, milk, urine, and feces. Cats typically acquire FeLV via the oronasal route but can also become infected through bite wounds[2].

Clinical signs associated with FeLV infection are quite varied and can be classified as tumors, immune suppression, hematologic disorders, immune-mediated diseases, and other syndromes including neuropathy, reproductive disorders, fading kitten syndrome[3]. The death rate of progressively FeLV-infected cats in multi-cat households has been estimated at approximately 50% in two years and 80% in three years, but is much lower today, at least for cats that are well taken care of and that are kept strictly indoors in single-cat households[4].

Principle

The RIDX™ FeLV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FeLV antigens in feline blood.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the FeLV antigen exists in the sample, it binds to the gold-conjugated FeLV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the FeLV antibody 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 antibody to FeLV is used as a capture and detector in the kit. The RIDX™ FeLV Ag Test Kit can detect FeLV antigen in feline blood with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ FeLV Ag Test	+	44	0	44
	-	0	75	75
	Total	44	75	119

Sensitivity: 100% (44/44, *95% CI: 91.97% ~ 100%)

Specificity: 100% (75/75, 95% CI: 95.13% ~ 100%)

Diagnostic Agreement: 100% (119/119, 95% CI: 96.87% ~ 100%)

* 95% CI: 95% Confidence Interval

2. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ FeLV Ag Test Kit.

Pathogen	Titer	Result
Feline calicivirus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1.97x 10^4 $TCID_{50}$/mL	Negative
Feline parvovirus	1.00 x $10^{5.5}$ $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/μL	Negative

Kit Components

	Component	Number/Kit
1	FeLV Ag test device	10
2	Dilution buffer	1
3	Anticoagulant tube	10
4	Disposable capillary tube	10
5	Instructions for use	1

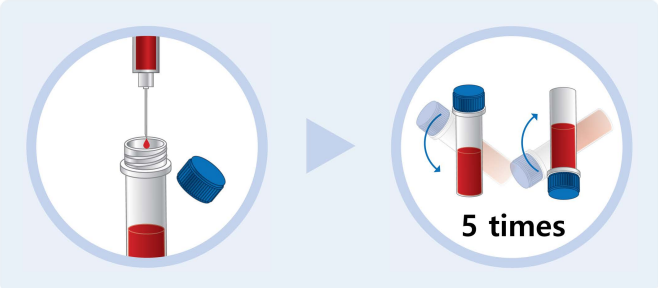
Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

[Whole blood]

1. Collect 1 mL (0.5~1.5 mL) of the whole blood sample and put it into an anticoagulant tube.
2. Close the cap on the anticoagulant tube and invert the tube 5 times to mix blood sample and ethylene diamine tetra acetic acid (EDTA).



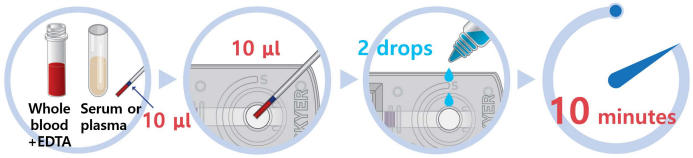
3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them in a form of serum or plasma.

[Serum or plasma]

1. Prepare serum and plasma using a standard procedure.
2. Serum or plasma, either fresh or stored at 2~8°C (35.6~46.4℉) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4℉) or below. But, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

1. All test components and samples must be at room temperature (15~30°C/59~86℉) before use.
2. Take 10 μL blood sample (the anticoagulated whole blood, serum, or plasma) using capillary tube.
3. Apply 10 μL of sample into the sample hole (S).
4. Apply 2 drops of the sample dilution buffer into the sample hole on the device.
5. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**

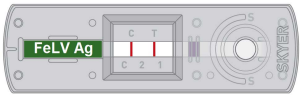


[Summary of Test Procedure]

Interpretation of Results

1. Positive result

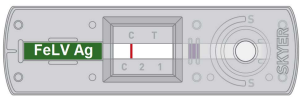
Test (T) line and control (C) line within the result window indicate the presence of FeLV antigen.



※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

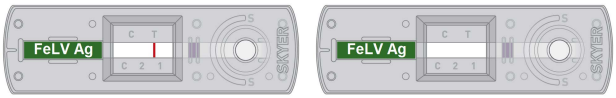
2. Negative result

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. This rapid kit is only for preliminary screening. The final decision should be made by a qualified veterinarian based on the results of this kit, clinical symptoms and evaluation by a veterinarian, and, if necessary, the results of additional detailed diagnostic procedures.
3. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
4. Do not touch the membrane of the test device.
5. The device should not be used if the foil pouch is damaged or has been stored with the seal open.
6. Do not use an expired test kit. The expiration date is marked on the package label.
7. Do not reuse the test components.
8. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
9. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
10. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy*: 2019 Release. Ratification March 2020 (Master Species List #35). https://talk.ictvonline.org/taxonomy
2. Little S, Levy J, Hartmann K, Hofmann-Lehmann R, Hosie M, Olah G, St Denis K. 2020 AAFP Feline Retrovirus Testing and Management Guidelines. *J Feline Med Surg*. 2020; 22(1): 5-30.
3. Hartmann K. Clinical aspects of feline immunodeficiency and feline leukemia virus infection. *Vet Immunol Immunopathol*. 2011; 143(3-4): 190-201.
4. Hartmann K. Clinical Aspects of Feline Retroviruses: A Review. *Viruses*. 2012; 4: 2684-2710.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σ_n	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

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