Rapid FeLV Antigen & FIV Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FeLV Ag/FIV Ab Combo Test Kit

[CAT No. CGM-FLD-21]

Introduction

Feline leukemia virus (FeLV) and feline immunodeficiency virus (FIV) are among the most common causes of infectious disease of cats and are found worldwide. The prevalences of FeLV and FIV were reported as 4 to 14% and 5 to 14% respectively on the basis of massive, approximately 2.9 million cats, 9-years (2008~2016) observational study using point-of-care tests[1].

Belonging to the family Retroviridae, FeLV is classified in the genus *Gammaretrovirus*, FIV in the genus *Lentivirus*[2]. Although FeLV and FIV are both retroviruses, they differ in their potential to cause disease[3]. In most naturally infected cats, FIV does not cause a severe clinical syndrome. Most clinical signs in FIV-infected cats reflect secondary diseases, such as infections and neoplasia, to which FIV-infected cats are more susceptible[3]. FeLV is more pathogenic than FIV. Historically, the oncogenic FeLV was considered to account for most disease-related deaths and to be responsible for more clinical syndromes than any other single agent in cats[4]. In recent years prevalence and consequently the importance of FeLV as a pathogen in cats have been decreasing. Still, if present in closed households with endemic feline coronavirus, FeLV, FIV, or all of these infections, FeLV infection has the greatest impact on mortality[4].

Although the typical transmission modes of two viruses are different, close contact among cats living or fighting increases the risk of infection. The most important measure for the control of FeLV and FIV is the identification and segregation of infected cats[2].

Principles

The RIDX™ FeLV Ag/FIV Ab Combo Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FeLV antigen and FIV antibodies in feline blood.

This kit shows two letters which are the test (T) line and the control (C) line for each test on the surface of the device.

[FeLV Ag Test]

If FeLV antigen exists in the sample, that bind 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 highly selective and sensitive monoclonal antibody to FeLV is used as a capture and detector in the kit.

[FIV Ab Test]

If FIV antibodies exist in the sample, that bind to the gold-conjugated protein A. The complex moves through the membrane by capillary force and responds to the FIV antigen on the test line, resulting in a red line. The high-quality recombinant FIV antigen (p24) is used as capture in the kit.

The control line indicates that the test is performed correctly and should appear when the test is complete.

The RIDX™ FeLV Ag/FIV Ab Combo Test Kit can detect FeLV antigen and FIV antibodies in feline blood with high accuracy.

Performance

[FeLV Ag Test]

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%)

* CI: Confidence Interval

2. Cross-Reactivity

Below potential cross-reactivity substances did not affect the performance of the RIDX™ FeLV Ag Test.

Pathogen	Titer	Result
Feline calicivirus	1 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1.97 x 10^4 $TCID_{50}$/mL	Negative
Feline parvovirus	1 x $10^{5.5}$ $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^7 *G.* cyst/100µL	Negative

[FIV Ab Test]

1. Sensitivity & Specificity

		ELISA		
		+	-	Total
RIDX™ FIV Ab Test	+	30	3	33
	-	1	253	254
	Total	31	256	287

Sensitivity: 96.77% (30/31, 95% CI: 83.81% ~ 99.43%)
Specificity: 98.83% (253/256, 95% CI: 96.61% ~ 99.60%)
Diagnostic Agreement: 98.61% (283/287, 95% CI: 96.47% ~ 99.46%)

2. Cross-Reactivity

Below potential cross-reactivity substances did not affect the performance of the RIDX™ FIV Ab Test.

Pathogen	Titer	Result
Feline calicivirus	1 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1.97 x 10^4 $TCID_{50}$/mL	Negative
Feline herpesvirus	≥1/32, VN	Negative
Feline panleukopenia virus	≥1/160, HI	Negative
Toxoplasma gondii	≥1/50, IFA	Negative

Kit Components

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

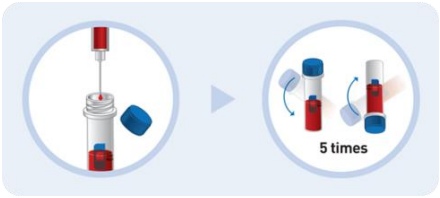
Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86℉). 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.

Sample Preparation

[Whole blood]

1. Collect 1mL (0.5~1.5mL) 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 EDTA.



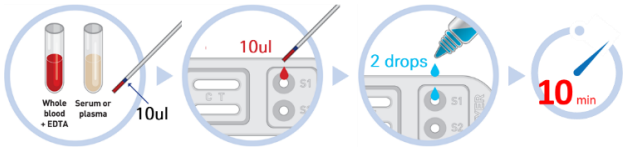
3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them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

[Serum or plasma]

1. Prepare serum and plasma using a standard procedure of clinical laboratory.
2. Serum or plasma, either fresh or stored at 2~8°C (35.6~46.4°F) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4°F).

Test Procedure

1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take 10μL blood sample (the anticoagulated whole blood, serum, or plasma) using capillary tube.
3. Add 10μL of sample into the sample hole (S).
4. Add 2 drops of the sample dilution buffer into the sample hole on the device.
5. Read test result at 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 or FIV antibodies.

[FeLV positive]

[FIV positive]

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* diagnosis only especially feline. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, capillary tube, anti-coagulant tube).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. 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.
2. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy*: 2019 Release. Ratification March 2020 (MSL #35).
3. Hartmann K. Clinical Aspects of Feline Retroviruses: A Review. *Viruses*. 2012; 4: 2684–2710.
4. Hartmann K. Clinical aspects of feline immunodeficiency and feline leukemia virus infection. *Vet Immunol Immunopathol*. 2011; 143(3–4): 190–201.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	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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