Rapid Feline Immunodeficiency Virus Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FIV Ab Test Kit

[Catalogue Number: CGM-FIB-11]

Introduction

Feline immunodeficiency virus (FIV; family Retroviridae; subfamily Orthoretrovirinae; genus *Lentivirus*) is an enveloped, RNA virus that infects domestic and wild cats worldwide, as well as hyenas[1]. Based on the sequence diversity of the gene, there are six different subtypes of FIV, A through F[2].

Most of the transmission is occurred by biting and major clinical signs are lethargy, fever, pallor, diarrhea, weight loss, muscle atrophy, stomatitis, neurologic signs of underlying neoplastic or immune-mediated disorders, or opportunistic infections[3].

The progression and severity of the disease are related to virus strain and host immunity. Infection of geriatric and neonatal cats is associated with more rapid progression and severity of disease than infection of young adult cats[4].

Although FIV is known not to infect humans, cats need regular testing on an annual basis.

Principle

The RIDX™ FIV Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of FIV antibodies 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 FIV antibody exists in the sample, it binds to the gold-conjugated protein A. The antibody-protein A complex moves through the membrane by capillary force and responds to the FIV antigen 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 high-quality recombinant FIV antigen (p24) is used as capture in the kit. The RIDX™ FIV Ab Test Kit can detect FIV antibodies in feline blood with high accuracy.

Performance

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%)

* 95% CI: 95% Confidence Interval

2. Cross-Reactivity

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

Antibody to Pathogen	Titer	Result
Feline herpesvirus	100, positive≥1:32, VN	Negative
Feline leukemia virus	80, positive≥1.0, RP	Negative
Feline panleukopenia virus	300, positive≥1:160, HI	Negative
Toxoplasma gondii	512, positive≥1:100, IFA	Negative

Kit Components

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

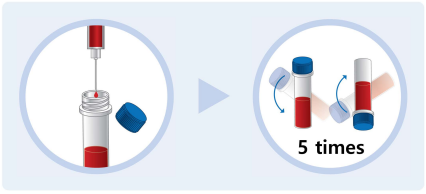
Storage & Stability

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).



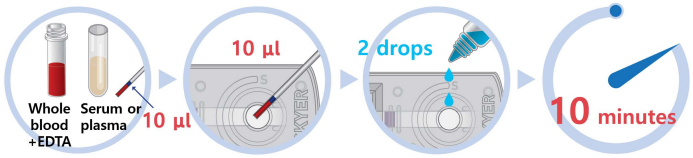
3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them 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°F) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4°F) 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. Add 10 μL 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. **Do not read results that appear after 10 minutes.**

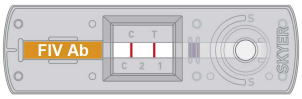


[Summary of Test Procedure]

Interpretation of Results

1. Positive result

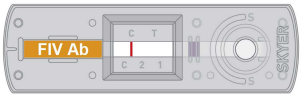
Test (T) line and control (C) line within the result window indicate the presence of FIV antibodies.



※ 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.

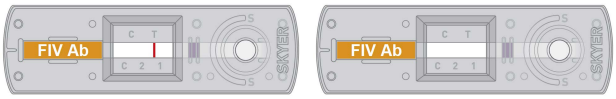
2. Negative result

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. Troyer JL, Pecon-Slattery J, Roelke ME, *et al*. Seroprevalence and genomic divergence of circulating strains of feline immunodeficiency virus among Felidae and Hyaenidae species. *J Virol*. 2005; 79(13): 8282-8294.
2. Bachmann MH, Mathiason-Dubard C, Learn GH, *et al*. Genetic diversity of feline immunodeficiency virus: dual infection, recombination, and distinct evolutionary rates among envelope sequence clades. *J Virol*. 1997; 71(6): 4241-4253.
3. Hartmann K. Clinical aspects of feline immunodeficiency and feline leukemia virus infection. *Vet Immunol Immunopathol*. 2011; 143(3-4): 190-201.
4. George JW, Pedersen NC, Higgins J. The effect of age on the course of experimental feline immunodeficiency virus infection in cats. *AIDS Res Hum Retroviruses*. 1993; 9(9): 897-905.

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

SKYER, INC.
#532, 416, Hwagok-ro, Gangseo-gu, Seoul, 07548,
Republic of Korea
TEL: +82-2-706-6801, FAX: +82-50-4096-6988
Technical support: marketing@skyer.co.kr
www.skyerdiagnostics.com
Korean Veterinary Diagnostics Manufacturer License No. 300