Rapid Severe Fever with Thrombocytopenia Syndrome Virus Ag Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Canine Feline SFTSV Ag Test Kit

[Catalogue Number: CGM-VSG-11]

Introduction

Severe Fever with Thrombocytopenia Syndrome Virus (SFTSV), an enveloped, a segmented, negative-sense RNA virus, is a tick-borne virus belonging to the genus *Bandavirus* in the family Phenuiviridae[1]. It was first identified in China in 2009 and is now recognized as an emerging public health threat in East Asian countries, including Japan, South Korea, and Vietnam[2, 3]. SFTSV is primarily affecting humans[4, 5], but it also plays a significant role in domestic animals like dogs and cats[6, 7].
Ticks of the species Haemaphysalis longicornis serve as the primary vector, but SFTSV RNA has also been detected in *Amblyomma testudinarium*, *Ixodes nipponensis*, *Rhipicephalus microplus*, *Hyalomma asiaticum*, and *Dermacentor nuttalli*[2, 3].
Infected pets often present with alarming clinical signs, including high fever, severe lethargy, and loss of appetite. Both species can suffer from vomiting and diarrhea[6, 7]. However, cats are more prone to developing severe illnesses, including thrombocytopenia, leukocytopenia and multi-organ dysfunction in severe cases[7, 8]. A hallmark of SFTSV infection is a significant drop in blood platelets and white cells, leading to complications that require immediate veterinary intervention.
While the primary route of transmission is tick bites, the virus's zoonotic potential is particularly concerning[2, 9]. Infected dogs and cats can directly transmit SFTSV to humans through contact with their bodily fluids. This direct transfer raises the risk for pet owners and veterinary workers, highlighting the need for caution and protective measures when handling potentially infected animals[3].

Principle

The RIDX™ Canine Feline SFTSV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of SFTSV in canine or feline whole blood or plasma.
This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the SFTSV antigen exists in the sample, it binds to the gold-conjugated anti-SFTSV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-SFTSV 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.
Two different monoclonal antibodies to SFTSV are used as a capture and detector in the kit. The RIDX™ Canine Feline SFTSV Ag Test Kit can detect SFTSV in whole blood or plasma samples from dogs or cats with high accuracy.

Performances

1. Sensitivity & Specificity with canine specimen

		PCR		
		+	-	Total
RIDX™ Canine Feline SFTSV Ag Test	+	43	0	43
	-	7	100	107
	Total	50	100	150

Sensitivity: 86.00% (43/50, *95% CI: 73.81% ~ 93.05%)
Specificity: 100% (100/100, 95% CI: 96.30% ~ 100%)
Diagnostic Agreement: 95.33% (143/150, 95% CI: 90.68% ~ 97.72%)

*95% CI: 95% Confidence Interval

2. Sensitivity & Specificity with feline specimen

		PCR		
		+	-	Total
RIDX™ Canine Feline SFTSV Ag Test	+	45	0	45
	-	5	100	105
	Total	50	100	150

Sensitivity: 90.00% (45/50, 95% CI: 78.64% ~ 95.65%)
Specificity: 100% (100/100, 95% CI: 96.30% ~ 100%)
Diagnostic Agreement: 96.67% (145/150, 95% CI: 92.43% ~ 98.57%)

3. Limit of Detection: 1 x $10^{2.8}$ $TCID_{50}$/mL

4. Cross-Reactivity

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

Pathogen	Titer
Canine coronavirus	1 x 10^6 $TCID_{50}$/mL
Canine distemper virus	1 x 10^5 $TCID_{50}$/mL
Canine parainfluenza virus	1 x 10^6 $TCID_{50}$/mL
Canine parvovirus	1 x 10^6 $TCID_{50}$/mL
Feline calicivirus	1 x 10^5 $TCID_{50}$/mL
Feline infectious peritonitis virus	1 x 10^8 $TCID_{50}$/mL
Feline panleukopenia	1 x 10^6 $TCID_{50}$/mL
Feline leukemia virus	5 x 10^8 copies/mL

Kit Components

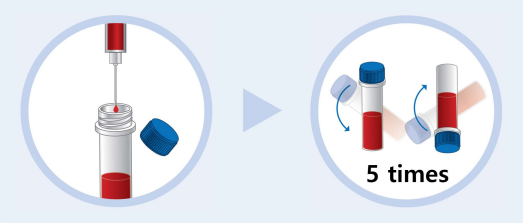
	Component	Quantity/kit
1	Canine Feline SFTSV Ag test device	10
2	Sample dilution buffer	1
3	Capillary tube	10
4	EDTA (Anticoagulant) tube	10
5	Instructions for use	1

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 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 EDTA (Ethylene diamine tetra acetic acid).

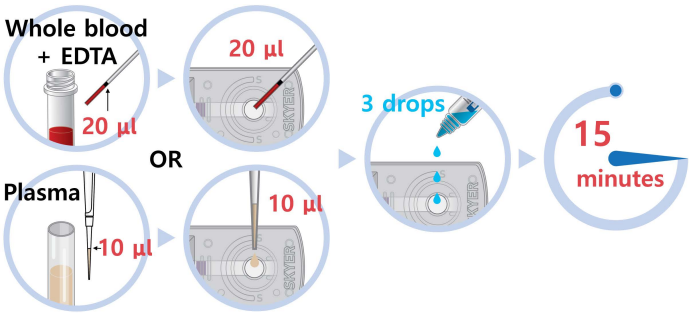


3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them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

[Plasma]
1. Prepare plasma using a standard procedure of clinical laboratory.
2. 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

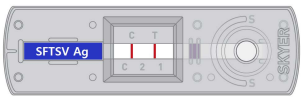
1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take 20 µL of the anticoagulated whole blood using capillary tube. Or Take 10 µL of the plasma using micropipette. (Micropipette and tips are not included in this kit.)
3. Apply the taken sample into the sample hole (S).
4. Apply 3 drops (approximately 100 µL) of the sample dilution buffer into the sample hole on the device.
5. Read test results at 15 minutes. **Do not read results that appear after 15 minutes.**



[Summary of Test Procedure]

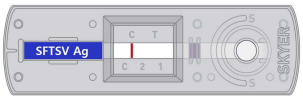
Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of the SFTSV antigens.

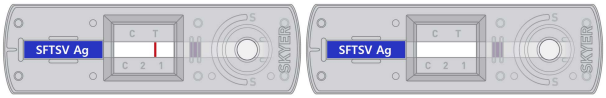


※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

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 dogs and 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 sample pad of the test device.
5. Do not use the test device 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 components (device, capillary tube, and EDTA tube).
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. *Virus Taxonomy: 2024 Release*. Email Ratification February 2025 (MSL #40).
2. Casel MA *et al.*, Severe fever with thrombocytopenia syndrome virus: emerging novel phlebovirus and their control strategy. *Experimental & Molecular Medicine* 2021; 53: 713–722.
3. Robles NJC *et al.*, Epidemiology of severe fever and thrombocytopenia syndrome virus infection and the need for therapeutics for the prevention. *Clinical and Experimental Vaccine Research* 2018; 7: 43–50.
4. Yu XJ *et al.*, Fever with Thrombocytopenia Associated with a Novel Bunyavirus in China. *New England Journal of Medicine* 2011; 364: 1523–1532.
5. Cui N *et al.*, Severe fever with thrombocytopenia syndrome bunyavirus-related human encephalitis. *Journal of Infection* 2015; 70: 52–59.
6. Han SW *et al.*, Severe fever with thrombocytopenia syndrome in canines from the Republic of Korea. *Ticks and Tick-borne Diseases* 2020; DOI: 10.1016/j.ttbdis.2020.101454.
7. Park ES *et al.*, Severe Fever with Thrombocytopenia Syndrome Phlebovirus causes lethal viral hemorrhagic fever in cats. *Scientific Reports* 2019; 9: 11990.
8. Matsuu A *et al.*, Natural severe fever with thrombocytopenia syndrome virus infection in domestic cats in Japan. *Veterinary Microbiology* 2019; 236: 108346.
9. Sansilapin C *et al.*, Severe fever with thrombocytopenia syndrome (SFTS) in Thailand: using a one health approach to respond to novel zoonosis and its implications in clinical practice. *One Health Outlook* 2024; 6: 18.

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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