Rapid *Toxoplasma* Antibody Test Kit

Document Number: SKR-IFU-VTB10071
Revised Date: 15 October 2025

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Toxoplasma Ab Test Kit

[Catalogue Number: CGM-VTB-11]

Introduction

Toxoplasma gondii is the protozoan parasitic agent of toxoplasmosis, a zoonotic disease of significant medical and veterinary importance worldwide[1]. *T. gondii*, a member of the family Sarcocystidae in the phylum Apicomplexa, developed the ability to infect almost any cell type of mammals and birds[2].

Domesticated and wild cats are the only known definitive hosts of *T. gondii* and are the main reservoirs of infection[1,2]. The clinical signs of toxoplasmosis in cats are generally fever, anorexia, or dyspnea, and are specifically neural, respiratory, cutaneous, or ocular involvement[3].

Fecal *T. gondii* oocysts are shed in large numbers by acutely infected cats once for approximately two weeks, except in cases of feline immune-suppression, such as co-infection with feline immunodeficiency virus or feline leukemia virus, which can result in secondary shedding[4]. The disease transmissible oocysts can survive in the environment for several months to more than 1 year, are remarkably resistant to disinfectants, freezing, and drying but are killed by heating to 70°C for 10 minutes[5].

Toxoplasmosis can cause severe ocular and neurological disease in humans. People become infected through the accidental consumption of feline fecal material, through food or water with fecal contamination, through the consumption of undercooked meat containing infective *T. gondii* cysts, through transplantation, or vertically from mother to fetus[2,6].

Principle

The RIDX™ Toxoplasma Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of *Toxoplasma* 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 *Toxoplasma* antibody exists in the sample, it binds to the gold-conjugated recombinant *Toxoplasma* antigen. The antibody-antigen complex moves through the membrane by capillary force and responds to the *Toxoplasma* 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 *T. gondii* antigen [surface antigen 1 (SAG1: p30) + dense granule protein (GRA1: p24)] is used as capture and detector in the kit. The RIDX™ Toxoplasma Ab Test Kit can detect *Toxoplasma* antibodies in feline blood with high accuracy.

Performance

1. Sensitivity & Specificity

		Immunofluorescence assay (IFA)		
		+	−	Total
RIDX™ Toxoplasma Ab Test	+	21	7	28
	−	1	139	140
	Total	22	146	168

Sensitivity: 95.45% (21/22, *95% CI: 78.20% ~ 99.19%)
Specificity: 95.21% (139/146, 95% CI: 90.43% ~ 97.66%)
Diagnostic Agreement: 95.24% (160/168, 95% CI: 90.89% ~ 97.57%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1/16 dilution of standard (IFA titer 512; positive≥1:100)

3. Cross-Reactivity

Below potential cross-reactivity substances did not affect the performance of the RIDX™ Toxoplasma 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

Kit Components

	Component	Number/Kit
1	Toxoplasma Ab Test device	10
2	Dilution buffer (4 mL)	1
3	Anticoagulant tube	10
4	Disposable capillary tube	10
5	Instructions for use	1

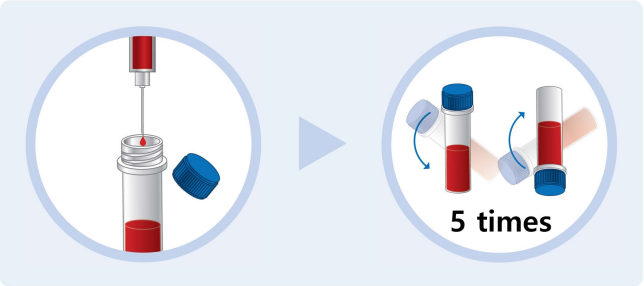
Storage & Stability

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).



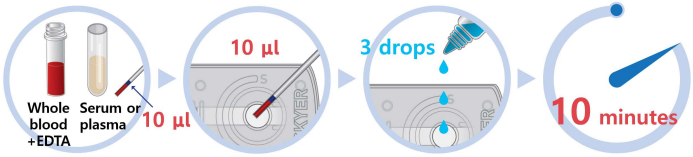
3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze anti-coagulated whole blood samples. If you cannot use the samples within 24 hours, store them 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) or below. But, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

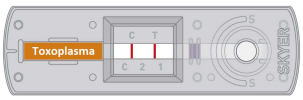
1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take 10 µL blood sample (the anticoagulated whole blood, serum, or plasma) using capillary tube.
3. Apply 10 µL (1 drop) of sample into the sample hole (S).
4. Apply 3 drops of the dilution buffer into the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

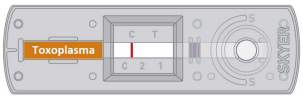
Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of *Toxoplasma* antibodies.

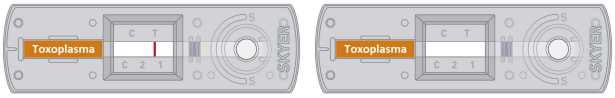


※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

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 (device, capillary tube, and anti-coagulant 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. Dubey JP, Lindsay DS, Lappin MR. Toxoplasmosis and other intestinal coccidial infections in cats and dogs. *Vet Clin North Am Small Anim Pract*. 2009; 39: 1009–1034.
2. Robert-Gangneux F, Dardé ML. Epidemiology of and diagnostic strategies for toxoplasmosis. *Clin Microbiol Rev*. 2012; 25: 264–296.
3. Calero-Bernal R and Gennari SM. Clinical Toxoplasmosis in Dogs and Cats: An Update. *Front Vet Sci*. 2019; 6(54): 1–9.
4. Malmasi A, Mosallanejad B, Mohebali M, Sharifian Fard M, Taheri M. Prevention of shedding and re-shedding of *Toxoplasma gondii* oocysts in experimentally infected cats treated with oral clindamycin: a preliminary study. *Zoon Pub Health*. 2009; 56: 102–104.
5. Hughes JM, Colley DG, Lopez A, Dietz VJ, Wilson M, Navin TR, Jones JL. Preventing congenital toxoplasmosis. *MMWR Recomm Rep*. 2000; 49(RR-2): 57–68, 70–75.
6. Jones JL, Dargelas V, Roberts J, Press C, Remington JS, Montoya JG. Risk factors for *Toxoplasma gondii* infection in the United States. *Clin Infect Dis*. 2009; 49: 878–884.

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