Rapid *Ehrlichia canis* Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ E. canis Ab Test Kit

[Catalogue Number: CGM-VEB-11]

Introduction

Ehrlichia canis, the intracellular Gram-negative bacteria in the family Anaplasmataceae of the order Rickettsiales[1], is the primary etiologic agent of canine monocytic ehrlichiosis (CME), also known as tropical canine pancytopenia, a tick-borne zoonotic disease[2]. The main, and probably the only, vector for *E. canis* is the tick *Rhipicephalus sanguineus*[3]. *R. sanguineus*, the brown dog tick, kennel tick, or pan-tropical dog tick, is considered the most widespread ixodid tick, colonising both human and canine dwellings[4].

Dogs with CME are often presented with epistaxis, which is the most dramatic sign of the disease. However, a large number of affected dogs develop severe pancytopenia and die without manifesting clinical signs of hemorrhage[2]. CME can be divided into acute, subclinical, and chronic phases. The acute phase of CME begins approximately 10 days, with a range of 8-20 days, after infection with *E. canis*, and can involve anemia, anorexia, ataxia, conjunctivitis, depression, fever, leukopenia, ocular discharge, thrombocytopenia, and vomiting that end with dogs undergoing partial recovery, with clinical signs subsiding, approximately 20 to 30 days after infection. Acute CME is usually followed by a subclinical phase that can last from months to years. The chronic phase of CME can be mild or severe, with recurrent clinical and hematologic signs that include pancytopenia, hemorrhage, monocytosis, lymphocytosis and weight loss[5].

Principle

The RIDX™ E. canis Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of *E. canis* antibodies in canine 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 *E. canis* antibody exists in the sample, it binds to the gold-conjugated anti-canine IgG. The complex moves through the membrane by capillary force and responds to the recombinant *E. canis* 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 highly selective and sensitive anti-canine monoclonal antibody and the high-quality recombinant *E. canis* outer membrane antigen (p30) are used as detector and capture respectively in the kit. The RIDX™ E. canis Ab Test Kit can detect *E. canis* antibodies with high accuracy.

Performance

1. Sensitivity & Specificity

		Immunofluorescence assay (IFA)		
		+	-	Total
RIDX™ E. canis Ab Test Kit	+	121	0	121
	-	2	305	307
	Total	123	305	428

Sensitivity: 98.37% (121/123, *95% CI: 94.26% ~ 99.55%)
Specificity: 100% (305/305, 95% CI: 98.76% ~ 100%)
Diagnostic Agreement: 99.53% (426/428, 95% CI: 98.31% ~ 99.87%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1/128 dilution of standard (IFA titer 300, positive ≥1:50)

3. Cross-Reactivity

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

Antibody to Pathogen	IFA Titer	Result
Babesia spp.	320, positive≥1:160	Negative
Canine distemper virus	100, positive≥1:25	Negative
Canine herpesvirus	80, positive≥1:20	Negative
Leishmania spp.	320, positive≥1:40	Negative
Toxoplasma spp.	128, positive≥1:16	Negative

Kit Components

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

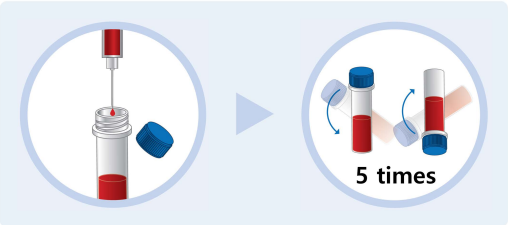
Storage & Stability

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 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).



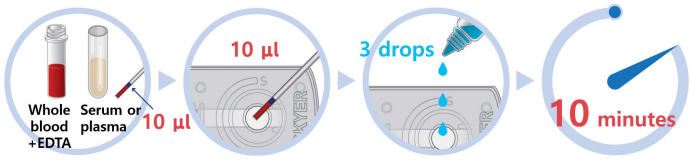
3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them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

[Serum or plasma]

1. Prepare serum and plasma using a standard procedure of clinical laboratory.
2. Serum, 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

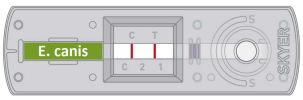
1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take 10 µL sample (the anticoagulated whole blood, serum, or plasma) using capillary tube.
3. Apply 10 µL (1 drop) of sample into the sample hole (S).
4. Apply 3 drops of the dilution buffer into the sample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



[Summary of Test Procedure]

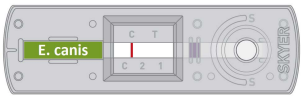
Interpretation of Results

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

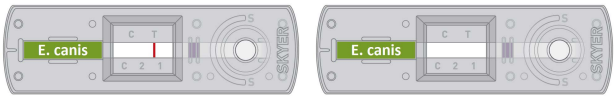


※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

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 dogs. 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. Dumler JS, Barbet AF, Bekker CP, Dasch GA, Palmer GH, Ray SC, Rikihisa Y, Rurangirwa FR. Reorganization of genera in the families *Rickettsiaceae* and *Anaplasmataceae* in the order *Rickettsiales*: unification of some species of *Ehrlichia* with *Anaplasma*, *Cowdria* with *Ehrlichia* and *Ehrlichia* with *Neorickettsia*, descriptions of six new species combinations and designation of *Ehrlichia equi* and 'HGE agent' as subjective synonyms of *Ehrlichia phagocytophila*. *Int J Syst Evol Microbiol.* 2001; 51(6): 2145-2165.
2. Huxsoll DL, Hildebrandt PK, Nims RM, Amyx HL, Ferguson JA. Epizootiology of tropical canine pancytopenia. *J Wildl Dis*. 1970; 6(4): 220-225.
3. Sainz A, Roura X, Miro G, Estrada-Pena A, Kohn B, Harrus S, Solano-Gallego L. Guideline for veterinary practitioners on canine ehrlichiosis and anaplasmosis in Europe. *Parasit Vectors*. 2015; 8: 75.
4. Gray J, Dantas-Torres F, Estrada-Pena A, Levin M. Systematics and ecology of the brown dog tick, *Rhipicephalus sanguineus*. *Ticks Tick-borne Dis*. 2013; 4(3): 171-180.
5. Stich RW, Schaefer JJ, Bremer WG, Needham GR, Jittapalapong S. Host surveys, ixodid tick biology and transmission scenarios as related to the tick-borne pathogen, *Ehrlichia canis*. *Vet Parasitol*. 2008; 158(4): 256-273.

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

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