Rapid *Leishmania* Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Leishmania Ab Test Kit

[CAT No. CGM-VLB-11]

Introduction

Leishmaniasis is a vector-borne zoonotic disease caused by protozoan parasites of the genus *Leishmania* of the family *Kinetoplastidae* and transmitted primarily by the hematophagous activities of female phlebotomine sand flies, belonging to the genera *Lutzomyia* (New World) and *Phlebotomus* (Old World), between animals and to humans[1, 2].
Canine leishmaniasis (CanL) caused by *Leishmania infantum* is among the most important parasitic diseases of dogs, occurring on all continents, except Oceania[1]. CanL is a systemic disease potentially involving any organ, tissue, or body fluid and manifests as non-specific clinical signs[3, 4]. Skin lesions are the most frequent manifestation among them (e.g., non-pruritic exfoliative dermatitis, erosive-ulcerative dermatitis, nodular-, popular-, and pustular dermatitis, onychogryphosis) and may be seen along with other clinical signs (e.g., generalized lymphadenomegaly, mucous membranes pallor, splenomegaly, polyuria and polydypsia, blepharitis, nodular conjunctivitis, keratoconjunctivitis, anterio uveitis, ulcerative lesions) or abnormalities (e.g., loss of body weight, lethargy, appetite change, fever, vomiting, diarrhea). Chronic renal failure is a serious consequence of disease progression and is the leading cause of death from CanL[5].

Principle

The RIDX™ Leishmania Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of *Leishmania* 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 *Leishmania* antibodies exist in the sample, that bind to the gold-conjugated anti-canine IgG monoclonal antibody. The complexes move through the membrane by capillary force and respond to the recombinant *Leishmania* 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 IgG monoclonal antibody and high-quality recombinant *Leishmania* antigen (rK39) are used as detector and capture respectively in the kit. The RIDX™ Leishmania Ab Test Kit can detect *Leishmania* antibodies in canine blood with high accuracy.

Performance

1. Sensitivity & Specificity

		IFA		
		+	-	Total
RIDX™ Leishmania Ab Test	+	120	0	120
	-	3	305	308
	Total	123	305	428

Sensitivity: 97.56% (120/123, 95% CI*: 93.07% ~ 99.17%)
Specificity: 100% (305/305, 95% CI: 98.76% ~ 100%)
Diagnostic Agreement: 99.30% (425/428, 95% CI: 97.96% ~ 99.76%)

* CI: Confidence Interval

2. Cross-Reactivity
Below potential cross-reactivity substances did not affect the performance of the RIDX™ Leishmania Ab Test Kit.

Pathogen	Titer (IFA)	Result
Barbesia spp.	320, positive≥1:160	Negative
Canine distemper virus	100, positive≥1:25	Negative
Canine herpesvirus	80, positive≥1:20	Negative
Ehrlichia canis	300, positive≥1:50	Negative
Toxoplasma spp.	512, positive≥1:100	Negative

Kit Components

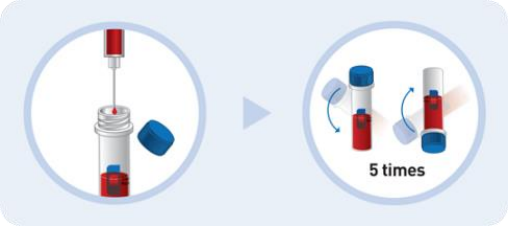
	Component	Number/Kit
1	Leishmania Ab Test device	10
2	Dilution buffer	1
3	Anticoagulant tube	10
4	Disposable capillary tube	10
5	Instructions for use	1

Storage & Stability

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

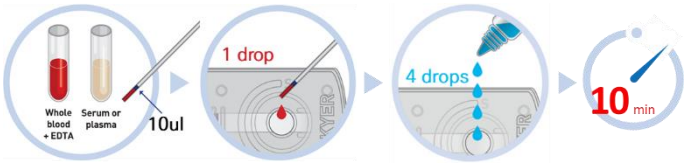


3. The anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46℉) or keep them on ice. Do not freeze anti-coagulated whole blood samples. If you cannot use the samples within 24 hours, store them in 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°F) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4°F).

Test Procedure

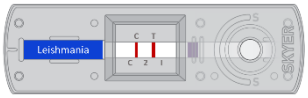
1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take 10µL blood sample (the anticoagulated whole blood, serum, or plasma) using capillary tube.
3. Add 10µL (1 drop) of sample into the sample hole (S).
4. Add 4 drops of the sample dilution buffer into the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



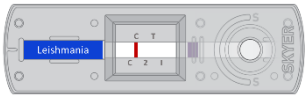
[Summary of Test Procedure]

Interpretation of Results

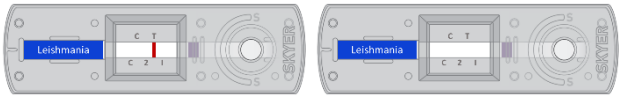
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of *Leishmania* antibodies.



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 canine. 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. Dantas-Torres F, Solano-Gallego L, Baneth G, Ribeiro VM, Cavalcanti MP, Otranto D. Canine leishmaniosis in the Old and New Worlds: unveiled similarities and differences. *Trends Parasitol*. 2012; 28(12): 531–538.
2. Ribeiro RR, Michalick MSM, Silva ME, Dos Santos CCP, Frézard FJG, Silva SM. Canine Leishmaniasis: An Overview of the Current Status and Strategies for Control. *Biomed Res Int*. 2018; 2018: 1–12. Article ID 3296893.
3. Ciaramella P, Oliva G, Luna RD, Gradoni L, Ambrosio R, Cortese L, Scalone A, Persechino A: A retrospective clinical study of canine leishmaniasis in 150 dogs naturally infected by *Leishmania infantum*. *Vet Rec*. 1997; 141(21): 539–543.
4. Koutinas AF, Polizopoulou ZS, Saridomichelakis MN, Argyriadis D, Fytianou A, Plevraki KG: Clinical considerations on canine visceral leishmaniasis in Greece: a retrospective study of 158 cases (1989–1996). *J Am Anim Hosp Assoc*. 1999; 35(5): 376–383.
5. Pena MT, Naranjo C, Klauss G, Fondevila D, Leiva M, Roura X, Davidson MG, Dubielzig RR. Histopathological features of ocular leishmaniosis in the dog. *J Comp Pathol*. 2008; 138(1): 32–39.

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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