Rapid Canine Heartworm Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ CHW Ag Test Kit

[Catalogue Number: CGM-CHG-11, CGM-CHG-12]

Introduction

Canine Heartworm (CHW), *Dirofilaria immitis*, is a parasitic mosquito-borne nematode that causes canine dirofilariasis worldwide[1]. Adult *D. immitis* lives in the right side of the heart, the pulmonary artery, and associated blood vessels of infected dogs, causing pulmonary hypertension, congestive heart failure, and damage to other organs[2]. *D. immitis* harbors intracellular bacteria named *Wolbachia pipientis,* a Gram-negative bacteria. *Wolbachia* has the potential to play an important role in the pathogenesis and immune response to filarial infection[1, 3]. The immunopathology of filarial disease is extremely complex and the clinical manifestations of infection are strongly dependent on the type of immune response elicited by the parasite[1].
Dogs show a mild persistent cough, reluctance to exercise, fatigue after moderate activity, decreased appetite, and weight loss at the early stage of the infection[1, 2]. If CHW infected dogs are not treated, large numbers of heartworms can develop a sudden blockage of blood flow within the heart leading to a life-threatening form of cardiovascular collapse.
CHW is a zoonotic parasite and is transmitted by mosquitoes. *D. immitis* is responsible for human pulmonary dirofilariasis throughout the world[3, 4].

Principle

The RIDX™ CHW Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of canine heartworm antigens 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 CHW antigen exists in the sample, it binds to the gold-conjugated anti-canine CHW antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the CHW monoclonal 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.
The highly selective and sensitive monoclonal antibody to *D. immitis* is used as capture in the kit. The RIDX™ CHW Ag Test Kit can detect CHW antigens in canine blood with high accuracy.

Performance

1. Clinical Sensitivity & Clinical Specificity

		Disease Status		
		+	-	Total
RIDX™ CHW Ag Test	+	53	0	53
	-	2	30	32
	Total	55	30	85

Clinical Sensitivity: 96.36% (53/55, *95% CI: 97.68% ~ 99.00%)
Clinical Specificity: 100% (30/30, 95% CI: 88.65% ~ 100%)
Diagnostic Accuracy: 97.65% (83/85, 95% CI: 91.82% ~ 99.35%)

* 95% CI: 95% Confidence Interval

2. Male and female *D. immitis* can be diagnosed.

3. Cross-Reactivity
Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ CHW Ag Test Kit.

Pathogen	Titer	Result
Canine coronavirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/mL	Negative
Canine parvovirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/μL	Negative
Salmonella spp.	1.00 x 10^6 CFU/mL	Negative

Kit Components

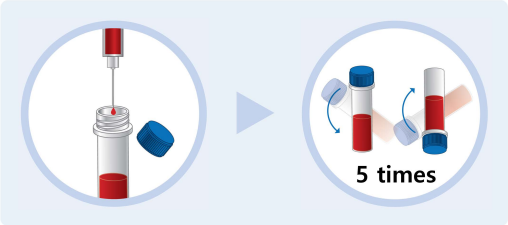
Component	Quantity/kit by CAT No.	
	CGM-CHG-11	CGM-CHG-12
1 CHW Ag test device	10	2
2 Anticoagulant tube	10	2
3 Disposable dropper	10	2
4 Instructions for use	1	1

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).

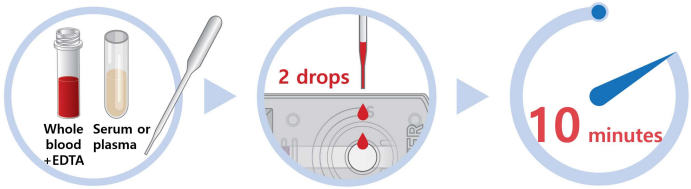


3. The Anticoagulated whole blood samples should be used immediately after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze anti-coagulated whole blood samples. If you cannot use the samples within 24 hours, store them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

[Serum or plasma]
1. Prepare serum or plasma using a standard procedure of clinical laboratory.
2. Serum or plasma, either fresh or stored at 2~8°C (35.6~46.4℉) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4℉) or below. But, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

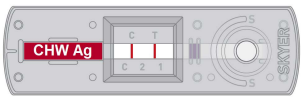
1. All test components and samples must be at room temperature (15~30°C/59~86°F) before use.
2. Take canine blood sample (the anticoagulated whole blood, serum or plasma) using a dropper.
3. Apply 2 drops of the sample solution into the sample hole (S).
4. Read test result at 10 minutes. **Do not read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



[Summary of Test Procedure]

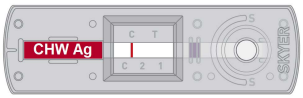
Interpretation of Results

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

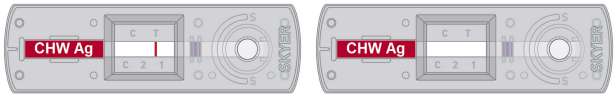


※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

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. 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, dropper, 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. McCall JW, Genchi C, Kramer LH, Guerrero J, Venco L. Heartworm Disease in Animals and Humans. *Adv Parasitol*. 2008; 66: 193–285.
2. Hoch H, Strickland K. Canine and feline dirofilariasis: prophylaxis, treatment, and complications of treatment. *Compend Contin Educ Pract Vet*. 2008; 30: 146–151.
3. Simón F, Siles-Lucas M, Morchón R, González-Miguel J, Mellado I, Carretón E, Montoya-Alonso JA. Human and animal dirofilariasis: the emergence of a zoonotic mosaic. *Clin Microbiol Rev*. 2012; 25: 507–544.
4. Dantas-Torres F, Otranto D. Dirofilariosis in the Americas: a more virulent Dirofilaria immitis? *Parasit Vectors*. 2013; 6(1): 288.

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