Rapid *Giardia* Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Giardia Ag Test Kit

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

Introduction

Giardia is a gastrointestinal parasite of mammals with a worldwide distribution[1]. This protozoan parasite has a wide range of host species and is a common cause of diarrheal disease in humans and animals (i.e., dogs, cats, cattle, deer, and beavers). *Giardia duodenalis* (synonym of *G. lamblia* and *G. intestinalis*[2]) causes giardiasis in dogs and cats[3]. Pooled giardiasis prevalence rates were 15.2% for dogs and 12% for cats[4].

Infected animals show a spectrum of clinical signs ranging from asymptomatic to severely affected, with disease manifesting in acute, intermittent, or chronic timeframes[1, 5]. Symptoms are more visible in younger animals than in the older. In some cases, dogs will exhibit diarrhea, due to maldigestion, malabsorption and increased motility, which is soft, frothy, greasy, and with a strong odor or excessive mucus[1, 3].

Once a person or animal has been infected with *Giardia*, the parasite lives in the intestines and is passed in feces. Hosts contract giardiasis through fecal-oral transmission of cysts, directly from infected individuals or contaminated fomites, or through ingestion of cysts in contaminated water or food[1]. As the cyst form, *Giardia* can sometimes survive for weeks or months outside the body and be found within every region[5].

Principle

The RIDX™ Giardia Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of *Giardia* cyst antigens in canine feces or feline feces. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the *Giardia* antigen exists in the sample, it binds to the gold-conjugated *Giardia* antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the *Giardia* 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 *G. duodenalis* is used as a capture and detector in the kit. The RIDX™ Giardia Ag Test Kit can detect *Giardia* antigens in canine feces or feline feces with high accuracy.

Performance

1. Clinical Sensitivity & Clinical Specificity

		Disease Status		
		+	−	Total
RIDX™ Giardia Ag Test	+	34	4	38
	−	1	109	110
	Total	35	113	148

Clinical Sensitivity: 97.14% (34/35, *95% CI: 95.47% ~ 99.49%)
Clinical Specificity: 96.46% (109/113, 95% CI: 91.25% ~ 98.61%)
Diagnostic Accuracy: 96.62% (143/148, 95% CI: 92.34% ~ 98.55%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1.25 *Giardia* Cysts/μL

3. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ Giardia 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
Feline calicivirus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Feline coronavirus	1.97 x 10^4 $TCID_{50}$/mL	Negative
Feline parvovirus	1.00 x $10^{5.5}$ $TCID_{50}$/mL	Negative

Kit Components

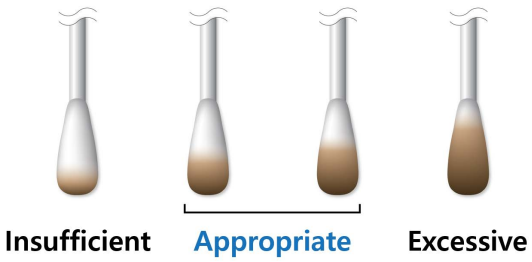
Component	Quantity/kit by CAT No.	
	CGM-VGG-11	CGM-VGG-12
1 Giardia Ag test device	10	2
2 Sample dilution buffer	10	2
3 Disposable swab	10	2
4 Disposable dropper	10	2
5 Instructions for use	1	1

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 package label.

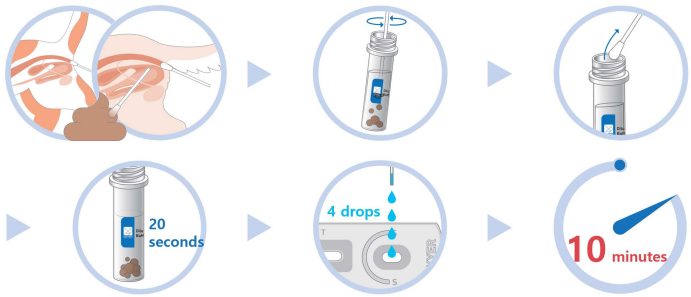
Sample Preparation

1. **Canine or feline fecal swabs** should be used for this test.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46.4℉) for up to 24 hours. 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. Frozen samples should be brought to room temperature (15~30°C/59~86℉) before use.
4. The amount of fecal sample with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive fecal amount may induce a false positive result and slow migration.



Test Procedure

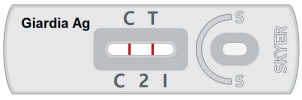
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect fecal sample using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the sample dilution buffer.
5. Wait for 20 seconds to settle down the large particles.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Take the supernatant sample in the tube by using a disposable dropper.
8. Apply 4 drops of the mixed sample into the sample hole (S), drop by drop vertically.
9. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**



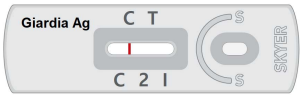
[Summary of Test Procedure]

Interpretation of Results

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



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 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 components (device, buffer, dropper, and swab).
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. Ballweber LR, Xiao L, Bowman DD, Kahn G, Cama VA. Giardiasis in dogs and cats: update on epidemiology and public health significance. *Trends Parasitol*. 2010; 26(4): 180–189.
2. Simner PJ. Medical parasitology taxonomy update: January 2012 to December 2015. *J Clin Microbiol*. 2017; 55: 43–47.
3. Bowman DD, Lucio-Foster A. Cryptosporidiosis and giardiasis in dogs and cats: Veterinary and public health importance. *Exp Parasitol*. 2009; 124(1): 121–127.
4. Bouzid M, Halai K, Jeffreys D, Hunter PR. The prevalence of Giardia infection in dogs and cats, a systematic review and meta-analysis of prevalence studies from stool samples. *Vet Parasitol*. 2015; 207(3-4): 181–202.
5. Feng Y, Xiao L. Zoonotic Potential and Molecular Epidemiology of Giardia Species and Giardiasis. *Clin Microbiol Rev*. 2011; 24(1): 110–140.

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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