

GIARDIA ANTIGEN RAPID TEST (GIARDIA AG)



INTENDED USE

Giardia is a common intestinal parasite that affects not only cats and dogs but also humans. It can cause symptoms like diarrhea, vomiting, gas, and abdominal discomfort in pets. The Giardia Antigen Rapid Test is a lateral flow immunochromatographic assay for the qualitative detection of Giardia antigen (Giardia Ag) in pet’s feces or vomit specimen. Assay Time: 5-10 minutes

PRINCIPLE

The Giardia Antigen Rapid Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample hole on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated monoclonal antibodies. If there is Giardia antigen in the specimen, a visible T line will appears. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of Giardia antigen in the specimen.

REAGENTS AND MATERIALS

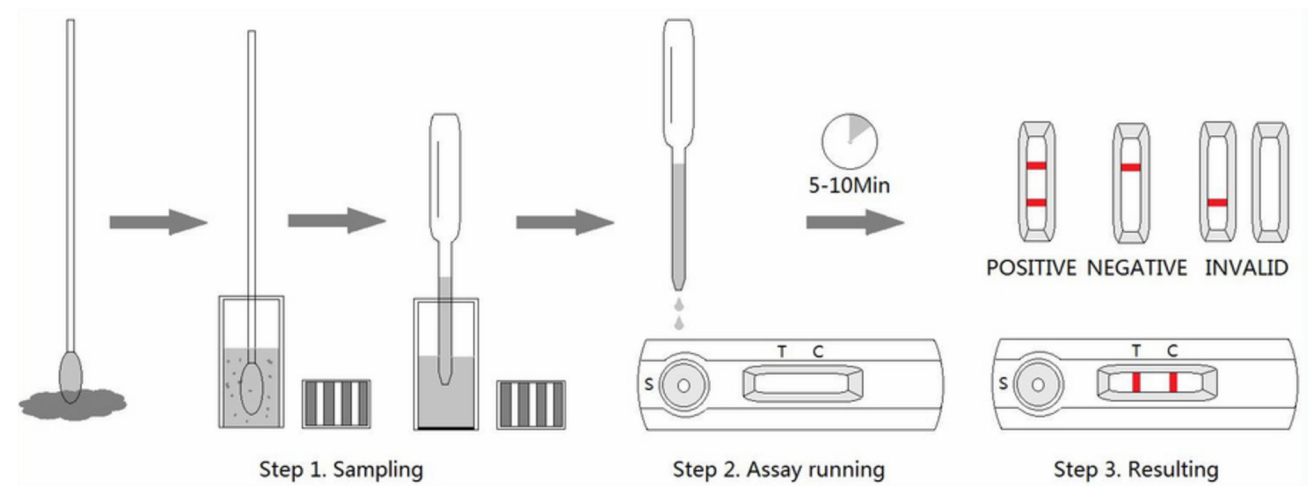
- Test devices, with disposable droppers
- Assay buffer
- Cotton swabs
- Products Manual

STORAGE AND STABILITY

The kit can be stored at room temperature (40-86°F/4-30°C). The test kit is stable through the expiration date marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

TEST PROCEDURE

- Collect dog’s fresh feces or vomit with the cotton swab from dog’s anus or from the ground.
- Insert the swab into the provided assay buffer tube. Agitate it to get efficient sample extraction.
- Take out the test device from the foil pouch and place it horizontally.
- Suck the treated sample extraction from the assay buffer tube and place 3 drops into the sample hole “S” of the test device.
- Interpret the result in 5-10 minutes. Result after 10 minutes is considered as invalid.



INTERPRETATION OF RESULTS

- **Positive (+):** The presence of both “C” line and zone “T” line, no matter T line is clear or vague.
- **Negative (-):** Only clear C line appear. No T line.
- **Invalid:** No colored line appears in C zone. No matter if T line appears.

PRECAUTIONS

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

LIMITATIONS

Giardia Antigen Rapid Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested that further confirmative method such as PCR with positive results to detect for additional parasites.

PERFORMANCE CHARACTERISTICS

		PCR		Total
		Positive	Negative	
Canine Giardia Antigen Rapid Test	Positive	49	1	50
	Negative	1	59	60
Total		50	60	110

Diagnostic Sensitivity = **98.00%** (95%CI: 88.53%~99.99%)
Diagnostic Specificity= **98.33%**. (95%CI: 90.30%-99.99%)
Total Agreement = **98.18%** (95%CI: 93.21%~99.91%)

LOT

Batch code

Contains sufficient for <n> tests

Temperature limitation

Use by

IVD

In vitro diagnostic medical device

Consult instructions for use

Do not reuse

Manufacturer

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