VECHEK™

Giardia Lamblia Rapid Test Cassette (Feces) Package Insert

REF VIGA-602	English

INTENDED USE

The *Giardia Lamblia* Rapid Test Cassette (Feces) is a lateral flow immunochromatographic assay for the qualitative detection of *Giardia Lamblia* antigen in animal's feces.

For veterinary use only.

PRINCIPLE

The *Giardia Lamblia* Rapid Test Cassette is a lateral flow immunochromatographic assay based on sandwich format. The test cassette has a testing window with an invisible T (test) zone and C (control) zone. During testing, sample is applied into the sample well on the test cassette. Giardia antigens, if present in the specimen, react with anti-Giardia antibodies coated colloidal gold particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-Giardia antibodies on the membrane in the test line region. If the specimen contains Giardia antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Giardia antigens, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lots and different products.

MATERIALS

Materials Provided

• Test cassettes •Droppers •Package insert
• Specimen collection tubes with extraction buffer

Materials Required but Not Provided

•Timer •Specimen collection containers

DIRECTIONS FOR USE

Allow the test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Collect sufficient quantity of feces (1-2mL or 1-2g) in a clean, dry specimen collection container to obtain enough pathogens. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

To process fecal specimens:

- For **Solid Specimens:**

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen at least 3 different sites to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

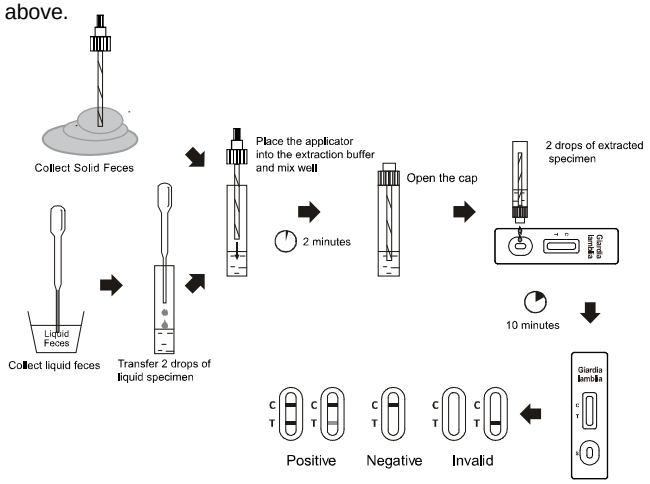
- For **Liquid Specimens:**

Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops** of the liquid specimen (approximately 80 µL) into the specimen collection tube containing the extraction buffer.

Tighten the cap onto the specimen collection tube, and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.

2. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
3. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube. Invert the specimen collection tube and transfer **2 full drops of the extracted specimen** (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
4. Read the results at **10 minutes** after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, regardless of T line being strong or faint.

Negative: Only clear C line appears.

Invalid: No colored line appears in C zone, regardless of T line's appearance.

ACCURACY

The *Giardia Lamblia* Rapid Test Cassette has been evaluated with specimens obtained from Veterinary hospital. Commercial Control Test is used as the reference method for the *Giardia Lamblia* Rapid Test. Specimens were considered positive if Commercial Control Test indicated a positive result.

Giardia Lamblia Rapid Test	Commercial Control Test		Total
	Positive	Negative	
Test Positive	39	5	44
Test Negative	2	116	118
Total	41	121	162

Relative Sensitivity: 95.12% (95%CI*: 83.47%-99.40%)
Relative Specificity: 95.87% (95%CI*: 90.62%-98.64%)
Accuracy: 95.68% (95%CI*: 91.30%-98.25%)
*Confidence Interval

CROSS-REACTIVITY

The *Giardia Lamblia* Rapid Test Cassette has been tested by Panleukopenia virus, Toxo, FIV and FeLV positive specimens. The results showed no cross-reactivity.

LIMITATION

The *Giardia Lamblia* Rapid Test Cassette is for veterinary use only. All results should be considered with other clinical information available from veterinarian. For confirming the results, confirmatory methods such as PCR and microscopy are recommended.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	30°C 2°C	Temperature limit
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use

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