Giardia Lamblia Rapid Test Cassette (Feces)

Package Insert

REF IGL-602	English

A rapid test for the qualitative detection of Giardia Lamblia in human stool samples.
For professional in vitro diagnostic use only.

【INTENDED USE】

The *Giardia Lamblia* Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Giardia Lamblia* antigen in human feces specimen.

【SUMMARY】

Parasitic infections remain a very serious health problem worldwide. *Giardia Lamblia* is the most common protozoa known to be responsible for one of the main causes of severe diarrhea in humans, particularly in immunocompromized people. *Giardia Lamblia*, also known as *Giardia intestinalis*, is a flagellated parasite that colonizes and reproduces in the small intestine, causing giardiasis. The parasite attaches to the epithelium by a ventral adhesive disc, and reproduces via binary fission.[1]

Epidemiological studies, in 1991, showed that infections with *Giardia* increased in the United States with a prevalence of around 6% on 178,000 samples. Generally, the disease passes through a short acute phase followed by a chronic phase. Infection by *G. lamblia*, in the acute phase, is the cause of watery diarrhoea with elimination of trophozoites. The stools become normal again, during the chronic phase, with transient emissions of cysts.

The presence of the parasite on the wall of the duodenal epithelium is responsible for malabsorption. The disappearance of villosities and their atrophy lead to problems with the digestive process at the level of the duodenum and the jejunum, followed by weight loss and dehydration. The majority of infections remain asymptomatic, however.

The diagnosis of *G. lamblia* is carried out under microscopy after flotation on zinc sulphate or by direct or indirect immunofluorescence, on non-concentrated samples displayed on a slide.

The rapid test can detect *Giardia Lamblia* in fecal specimens within 10 minutes. It is based on the detection of a 65-kDA coproantigen, a glycoprotein that is present in the cysts and trophozoites of G. lamblia.

【PRINCIPLE】

Giardia Lamblia Rapid Test Cassette (Feces) is based on the use of a membrane technology with colloidal gold. A nitrocellulose membrane is sensitized with antibody directed against *Giardia Lamblia*. The test's specificity is ensured by an antibody specific to a *Giardia Lamblia* antigen that is conjugated to the colloidal gold. This conjugate is dried on a membrane.

The fecal sample must be diluted into the extraction buffer that is supplied with the test. When extracted specimen come into contact with the strip, the conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-Giardia antibody in the T line. If the sample contains the *G. lamblia* antigen, the conjugate-antigen complex will remain bound to the anti-Giardia reagent and a red line will develop. Solution continues to migrate to encounter a second reagent that binds the migration control conjugate, thereby producing a red control line that confirms that the test is working properly. The result is visible within 10 minutes.

【REAGENTS】

The test contains anti-*Giardia Lamblia* antibody particles and anti-*Giardia Lamblia* antibody coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette 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.

【SPECIMEN COLLECTION AND PREPARATION】

The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.

Bring the necessary reagents to room temperature before use.

If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package Insert
- Specimen Collection Tubes with extraction buffer
- Droppers

Materials Required But Not Provided

- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

SPECIMEN PREPARATION PROCEDURE:

1. To collect fecal specimens:

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.

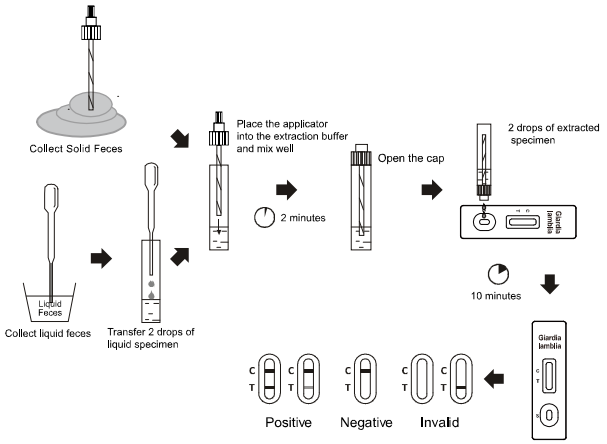
To process fecal specimens:

- 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, 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). Start the timer and continue from step 4 onwards in the above instructions for use.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* **Two lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *Giardia Lamblia* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
2. A positive or negative test result does not rule out the possibility that other pathogens may be present.
3. This test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the test's sensitivity threshold. If a sample test negative, despite the observed symptoms, further testing with alternative methods are recommended.

【EXPECTED VALUES】

In healthy non-infected individuals, The *Giardia Lamblia* Rapid Test should give a negative Test result. The *Giardia Lamblia* Rapid Test Cassette (Feces) has been compared with traditional thick or thin microscopic analysis. The correlation between the two systems is 97.1%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity - Specificity

The *Giardia Lamblia* Rapid Test Cassette (Feces) was evaluated on 278 patients. The status of the samples was checked after concentration of parasites (Ritchie method) and microscopic slide reading.

Method		Microscopic		Total Results
Giardia Lamblia Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	58	5	63
	Negative	3	212	215
Total Results		61	217	278

Relative sensitivity: 95.1% (95%CI*: 86.3%~99.0%); *Confidence Intervals
Relative specificity: 97.7% (95%CI*:94.7%~99.2%);
Accuracy: 97.1% (95%CI*: 94.4%~98.7%).

Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 3 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

To check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+07 organisms/ml. The following organisms were found negative when tested with the *Giardia Lamblia* Test Cassette (Feces):

Citrobacter freundii	Clostridium difficile	Coxsackie
Candida albicans	Chlamydia trachomatis	Echovirus
Enterococcus faecium	E.coli	Enterococcus faecalis
Gardnerella vaginalis	Neisseria gonorrhea	Proteus mirabilis
Proteus vulgaris	Pseudomonas aeruginosa	Rotavirus
Salmonella Infantis	Staphylococcus aureus	Adenovirus
Shigella dysenteriae	Shige flexneri	Corynebacterium diphtheria

【BIBLIOGRAPHY】

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Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	②	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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