

# Giardia Lamblia Rapid Test Cassette (Feces)

## Package Insert

### 【INTENDED USE】

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

### 【PRINCIPLE】

Giardia lamblia Rapid Test Cassette is a lateral flow immunochromatographic assay based on sandwich format. The test cassette has a testing window. During testing, sample is applied into the sample well on the cassette. Giardia antigen, 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 lot 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.

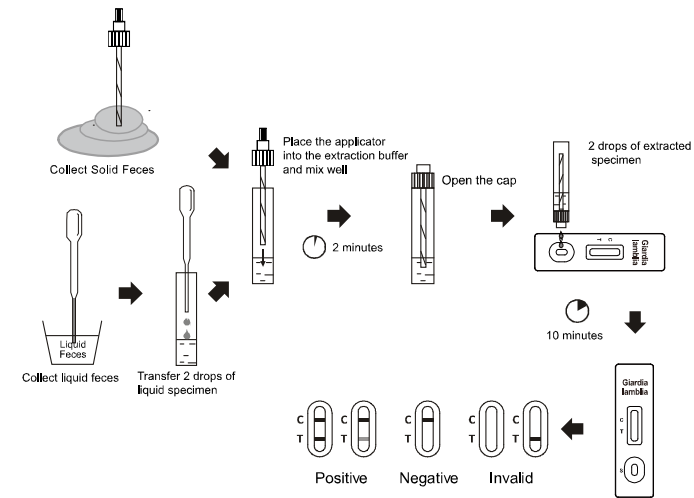
Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.

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.

### 【LIMITATION】

1. This test is an acute-phase screening test.
2. In the life history of giardia, there are two different stages of development: trophozoite and cysts. Generally speaking, cysts exists in formed faeces and trophozoite exists in watery feces with diarrhea. This kit is used for detecting of giardia at the trophozoite stage.
3. All results should be combined with clinical information obtained by veterinarians.

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Effective Date: