Giardi lamblia Rapid Test Cassette (Feces)

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. AllTest has developed a rapid test that can detect *Giardia lamblia* in fecal specimenswithin 15 minutes. The test 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. Solutioncontinues to migrate to encounter a second reagent that binds the migration controlconjugate, thereby producing a red control line that confirms that the test is workingproperly. The result is visible within 15 minutes.

【REAGENTS】

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

【PRECAUTIONS】

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for in vitro diagnostic use only.
- Pouch must be opened with care
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Quality cannot be guaranteed beyond the stated shelf-lifeor if Test kit is not stored under required conditions as indicated in the insert.

【STORAGE AND STABILITY】

- An unopened pouch may be kept at between 2 and 30°C and used until the shelf-life date indicated on the packaging. Once the pouch is opened, run the test immediately.
- Avoid freezing devices and buffer.

【SPECIMEN COLLECTION AND PREPARATION】

The stool specimens must be tested as soon as possible after collection. If necessaryoriginal fecal specimen could be stored at 2-8°C for 3 days or -20°C for longer periodsof time; extracted specimen in buffer could be stored at 2-8°C for 1 week or -20°C forlonger periods of time.

Make sure that the specimens are not treated with solutions containing formaldehydeor its derivatives.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package Insert
- Specimen collection tubes with extraction buffer
- Droppers

Materials Required But Not Provided

- Specimen collection container
- Timer

【DIRECTIONS FOR USE】

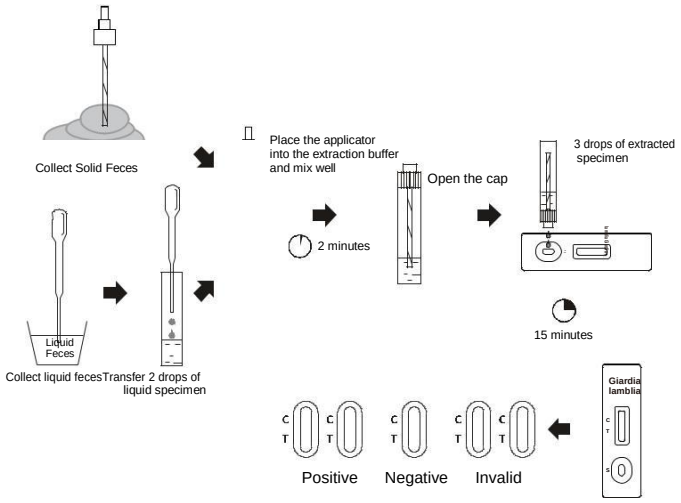
SPECIMEN PREPARATION PROCEDURE:

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.

2. 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.
3. 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.
4. Hold the specimen collection tube upright and **unscrew the tip** of the specimen collection tube. Invert the specimen collection tube and **transfer 3 full drops of the extracted specimen** (approximately 120 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.
5. Read the results at **15 minutes** after dispensing the specimen. Do not read results after 20 minutes.
6. **Note:** If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.



【INTERPRETATION OF RESULTS】

Negative test result: a reddish-purple line appears across the central reading window at the Control line (C) position. No other band is present.

Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens found in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new test device.

Note: during the drying process, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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】

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.

A positive or negative test result does not rule out the possibility that other pathogens may be present.

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 tetsnegative, despite the observed symptoms, further testing with alternative methods are recommeneded.

【EXPECTED VALUES】

In healthy non-infected individuals, The *Giardia lamblia* Rapid Test should give a negative Test results. The *Giardia Lamblia* Rapid Test Cassette (Feces) has been compared with traditional thick or thin microscopic analysis. The correlation between the two systems is 97.5%..

【PERFORMANCE CHARACTERISTICS】

A. Detection Limit

The detection limit was evaluated by diluting a pure cysts solution (625,000 cysts/mL) and the results show that the number of cysts detected is 3,125 cysts/mL.

B. Sensitivity - Specificity

1) The *Giardia Lamblia* Rapid Test Cassette was evaluated on 396 patients. The status of the samples was checked after concentrationof parasites (Ritchie method) and microscopic slide reading.

Method		Microscopic		Total Result
Giardia Lamblia Rapid Test Cassette(Feces)	Results	Positive	Negative	
	Positive	77	7	84
	Negative	3	309	312
Total Result		80	316	396

Relative sensitivity: 96.2% (95%CI*: 89.4%~99.2%);
Relative specificity: 97.8% (95%CI*:95.5%~99.1%);
Accuracy: 97.5% (95%CI*: 95.4%~98.8%). *Confidence Intervals

C. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 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.

D. Interference

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: *Salmonella typhimurium, Coronavirus, several E. coli strains (including E. coli O157:H7 and E. coli c600-933W), Rotavirus, Adenovirus, Cryptoposridiumparvum, E.coli F5, Salmonella enteritidis, Chylomastixmesnilii, Entamoeba coli, Endolimaxnanus, Blastocystishominis, Rhabditis larvae, Enterobiusvermicularis, Strongyloidesstercoralis, Hymenolepis nana, isospora belli, Entamoebahartmanii, Entamoebahisto/dispar, Enterobiusvermicularis, Isosporahominis.*

Tests for cross-reactivity has been tested on Staphylococcus aureus and found positive at high bacteria concentrations.

【BIBLIOGRAPHY】

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

MANUFACTURER
SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD.ŞTİ.
ORUÇ REİS MAH. GİYİMKENT SİT.17.SOK.NO:23A
ESENLER-ISTANBUL/TURKEY
PHONE:00902124381639

CE