Rapid Response™

***Giardia lamblia* Test Cassette**

(Feces)

REF GLV-9C20 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ *Giardia lamblia* Test Cassette (Feces) is an in vitro immunoassay for the direct and qualitative detection of *G. lamblia* from human feces. It is intended to aid in the rapid diagnosis of Giardiasis. The test is for professional use only.

Introduction

Giardiasis, caused by *Giardia lamblia* (also known as *G. intestinalis*), is one of the most common parasitic human diseases globally[1]. In 2013, there were about 280 million people worldwide with symptomatic giardiasis[1]. Rates are as high as 7% in the developed world and 30% in the developing world[2]. The World Health Organization classified it as a neglected disease.

Giardia usually spreads when *G. lamblia* cysts within feces contaminate food or water which is then eaten or drunk[2]. It may also spread between people and from other animals. Cysts may survive for nearly three months in cold water.[2] Symptoms are caused by *Giardia* organisms infecting the cells of the duodenum and jejunum of the small intestine[3] and blocking nutrient absorption. Most people are asymptomatic; only about a third of those infected exhibit symptoms. If the infection is not treated, these symptoms may last for six weeks or more.

For diagnosis of Giardiasis, the traditional basis is identification of *G. lamblia* trophozoites or cysts via a stool ova and parasite examination. PCR can be used to identify the subtypes of *Giardia*. Stool culture is not routinely used because of the difficulty of reproducibly isolating *Giardia* from patient fecal samples. However, stool cultures are beneficial in ruling out other pathogens as the cause of a patient's symptoms. Stool antigen ELISA, IFA, or rapid test may be helpful, if the results from 3 O&P tests are negative and giardiasis is still suspected.

The Rapid Response™ *Giardia lamblia* Test (Feces) takes only 10 minutes and requires a small quantity of human feces to perform. It is an easy, rapid and sensitive diagnostic method for Giardiasis.

Principle

The Rapid Response™ *Giardia lamblia* Test Cassette (Feces) detects *G. lamblia* through visual interpretation of color development. Anti-*G. lamblia* antibodies are immobilized on the test region of the nitrocellulose membrane. A fecal sample is added to the sample diluent tube with buffer to release the parasitic antigens. During testing, the extracted antigens bind to anti-*G. lamblia* antibodies conjugated to colored particles on the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-*G. lamblia* antibodies at the detection zone. Excess colored particles are captured at the internal control zone.

The presence of a colored band in the test region indicates a positive result for the particular bacterial antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working.

Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Used testing materials should be discarded according to local regulations.

Materials

Materials provided

- Individually packaged test devices
- Product insert
- Sample dilution tube with buffer
- Disposable droppers

Materials required but not provided

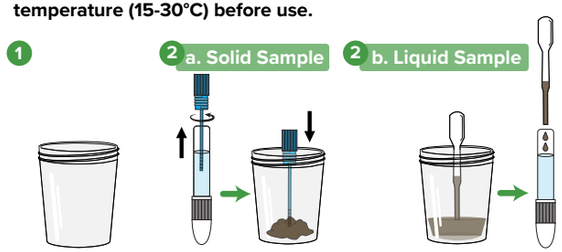
- Centrifuge
- Specimen collection container
- Clock, timer or stopwatch
- Disposable latex gloves

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Test Procedure

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.



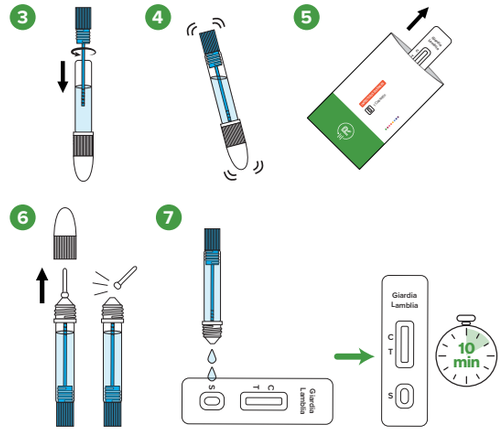
Specimen collection and pre-treatment:

1. Use clean, dry specimen containers for specimen collection. Best results will be obtained if the assay is performed within 2 hours after collection.
   NOTE: Specimens collected in the specimen container may be stored for 3 days at 2~8°C or for 6 months at -20°C.
2. **a. <u>For Solid Specimens</u>:**
   Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 120 mg of feces.
   b. <u>For Liquid Specimens</u>:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 120 uL) of the liquid specimen into the sample diluent tube.
3. Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
4. Shake the specimen collection tube to mix the specimen and the diluent buffer thoroughly.

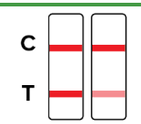
Testing:

5. Remove the test device from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within 2 hours.
6. Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 2 drops of solution into the specimen well (S) of the test device.
   Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
7. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not read results after 20 minutes.

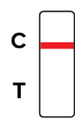
NOTE: If the specimen does not migrate (presence of particles), centrifuge the specimens contained in the sample diluent tube. Collect 100 µL of supernatant, dispense into the specimen well (S) of a new test device and start afresh following the instructions mentioned above.



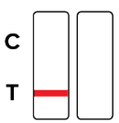
Results Interpretation



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and one band appears in the test region (T).



NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the prescribed reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response™ *Giardia lamblia* Test Cassette (Feces) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of Giardiasis, only.
2. Following certain anti-parasitic treatments, the concentration of *G. lamblia* may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during treatment.
3. Failure to follow the procedure and interpretation of results may adversely affect test performance and/or invalidate the test result.
4. A high dose “hook effect” may occur where the color intensity of test band decreases as the concentration of antigen increases. If a “hook effect” is suspected, dilution of specimens may increase color intensity of the test band.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics

Clinical Performance:

360 fecal samples were collected and tested on the Rapid Response™ *Giardia lamblia* Test Cassette (Feces) and compared with a commercial *Giardia lamblia* EIA. Comparison for all subjects is shown in the following table:

	Giardia lamblia EIA		
Rapid Response™ Giardia lamblia Test Cassette (Feces)	**Positive**	**Negative**	**Total**
Positive	119	1	120
Negative	2	238	240
Total	121	239	360

Relative Sensitivity: 98.3% (94.2%~99.5%)*
Relative Specificity: 99.6% (97.7%~99.9%)*
Overall Agreement: 99.2% (97.6%~99.7%)*
*95% Confidence Interval

Cross Reactivity:

The Rapid Response™ *Giardia lamblia* Test Cassette (Feces) has been evaluated for cross-reactivity with the microorganisms listed below. None of the strains present interference with the assay performance.

Salmonella typhi	*Salmonella paratyphi C*
Enterococcus faecalis	*Campylobacter coli*
Shigella flexneri	*Clostridium difficile*
Klebsiella pneumonia	*Rotavirus*
Astrovirus	*Coxsackievirus A16*
Entameoba coli	*Cryptosporidium spp.*
Salmonella paratyphi A	*Escherichia coli*
Enterococcus faecium	*Campylobacter jejuni*
Shigella sonnei	*Staphylococcus aureus*
Gardnerella vaginalis	*Adenovirus 2, 40, 41*
Enterovirus 68	*Coxackievirus B5*
Entamoeba dispar	*Cyclospora spp.*
Salmonella paratyphi B	*Escherichia coli O157:H7*
Helicobacter pylori	*Campylobacter fetus*
Shigella dysenteriae	*Satphylococcus epidemidis*
Candida albicans	*Norovirus*
Enterovirus 71	*Hepatitis A virus*
Entamoeba histolytica	*Trichomonas hominis*

Bibliography

1. Esch KJ, Petersen CA (January 2013). "Transmission and epidemiology of zoonotic protozoal diseases of companion animals". Clin Microbiol Rev. 26 (1): 58–85. doi:10.1128/CMR.00067-12. PMC 3553666 Freely accessible. PMID 23297259.
2. Minetti, C; Chalmers, RM; Beeching, NJ; Probert, C; Lamden, K (27 October 2016). "Giardiasis". BMJ (Clinical research ed.). 355: i5369. doi:10.1136/bmj.i5369. PMID 27789441.
3. Barry MA, Weatherhead JE, Hotez PJ, Woc-Colburn L (2013). "Childhood parasitic infections endemic to the United States". Pediatr Clin North Am. 60 (2): 471–85. doi:10.1016/j.pcl.2012.12.011. PMID 23481112.

Glossary of Symbols

Consult instructions for use
Test per Kit
EC REP Authorized Representative
35.6°F 2°C 86°F 30°C Store between 35.6°F to 86°F (2°C to 30°C)
Use by
Do Not Reuse
LOT Lot Number
IVD For *in vitro* diagnostic use only
REF Catalogue #

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