I. Intended Use

The Biomerica *Giardia* test is a rapid chromatographic immunoassay for the qualitative detection of *Giardia* antigens in human stool samples. The *In Vitro* test is intended **for professional use only.**

II. Summary and Explanation

Giardiasis is a diarrheal illness seen throughout the world. It is caused by a flagellate protozoan parasite, *Giardia intestinalis*, also known as *G. lamblia* and *G. duodenalis.* The incidence of *Giardia* is generally higher in low-income countries (e.g. many countries of Africa, Asia, and South and Central America) where access to clean water and basic sanitation is lacking. Nearly all children in this setting will acquire *Giardia* at some point in their childhood, and the prevalence of the parasite in young children can be as high as 10%-30%. In areas such as Western Europe and the United States, *Giardia* infection is associated with ingestion of contaminated water, person-to-person spread, recent foreign travel, and recreational swimming. *Giardia* may be a cause of 2%-5% of cases of diarrhea in high-income countries.

III. Principles of the Procedure

The Biomerica *Giardia* test is a qualitative immunoassay for the detection of *Giardia* antigen in human stool samples. The membrane is pre-coated with antibodies against *Giardia* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Giardia* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugates and generate colored lines. A green colored band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

IV. Materials Provided

1. Test device in foil pouch
2. Stool collection vial with buffer
3. Instructions for use

V. Materials Required but Not Provided

Timer and Gloves

VI. Warning and Precautions

Safety Precautions: Human stool should be handled as if capable of transmitting infectious agents. It is recommended that these specimens be handled using established good laboratory working practices. The test should be discarded in a proper biohazard container after testing.

For *in vitro* diagnostic use: Do not use the kit beyond the expiration date printed on the outside of the foil pouch. Discard all used test devices into a proper biohazard container. The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged. The test must be carried out within 2 hours of opening the sealed pouch.

VII. Kit Storage and Stability

The *Giardia* antigen tests can be stored refrigerated or at room temperature (2-30°C). The test is usable until the expiration date stamped on the foil pouch. Do not freeze.

VIII. Quality Control

Although the *Giardia* antigen test contains an internal quality control (green color band in the Control region) good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

IX. Specimen Collection And Preparation

Collect sufficient quantity of stool sample (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample should be totally thawed, and brought to room temperature before testing.

Make sure that specimens are not treated with solutions containing formaldehyde or its derivatives.

X. Test Procedure

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick twice into the stool sample to pick up a small amount of sample 150 mg total. Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate about 150 µL into the specimen collection vial with buffer and close it.

Test Procedure (see illustration 2). Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the *Giardia* test from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops or 100 µL into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

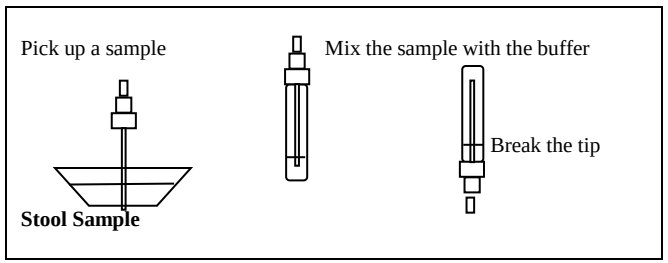
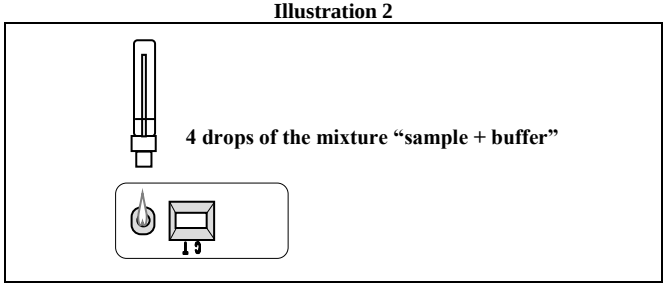
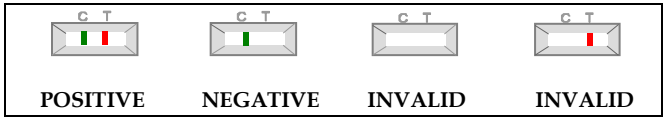


Illustration 2



XI. Interpretation of Results



POSITIVE: Two lines appear across the central window, in the Test region (a pink test line in the region marked with the letter T) and in the Control region (a green control line in the region marked with the letter C).

NEGATIVE: Only one band appears in the Control region (a green control line in the region marked with the letter C).

INVALID: A total absence of the control line regardless of the appearance of the test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the test materials 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 and contact your local supplier.

The intensity of the pink colored band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Internal procedural controls are included in the test:
- A green line appearing in the control region (C) confirms sufficient specimen volume and correct procedural technique.

XII. Limitations of the Test

1. *Giardia* device will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of *Giardia* antigens in fecal specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An insufficient amount of sample could cause an invalid result.
3. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
4. Do not use specimens treated with solutions containing formaldehyde or its derivatives.
5. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of giardiasis.
6. After one week of infection, the number of parasites in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
7. This test provides a presumptive diagnosis of giardiasis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

XIII. Performance Characteristics

Sensitivity and specificity
In-house study of the performance of the *Giardia* test was done using 41 samples confirmed negative and 36 confirmed positive for *Giardia* antigen. The samples were confirmed with microscopy technique.

The results of the study are given in Table 1.

TABLE 1

Giardia Test	Samples determined by microscopy		
	+	-	Total
+	36	0	36
-	0	41	41
Total	36	41	77

Sensitivity >99%
Specificity >99%

Cross-Reactivity
Results of the cross reactivity study revealed that there is no cross reactivity with these common intestinal pathogens, other organisms and substances occasionally present in feces.
-*Entamoeba hystolitica* -*Cryptosporidium parvum*

XIV. References

1. Hill DR, Nash TE. Intestinal Flagellate and Ciliate Infections. In: Guerrant RL, Walker DH, Weller PF, eds. Tropical Infectious Diseases. Principles, Pathogens & Practice. 2nd ed. Elsevier, Philadelphia. 2006:984-8.
2. Copue S, Delabre K, Pouillot R et al. Detection of Cryptosporidium, *Giardia* and *Enterocytozoon bieneusi* in surface water, including recreational areas: a one year prospective study: FEMS Immunol Med Microbiol. 2006; 47:351-9.
3. Stuart JM, Orr HJ, Warburton FG, et al. Risk Factors for Sporadic Giardiasis: A Case-Control Study in Southwestern England. Emerg. Infect Dis. 2003; 9, 2

XV. Ordering information

ORDERING: Send purchase order to:
Telephone: 949-645-2111
Fax: 949-553-1231
E-mail: bmra@biomerica.com
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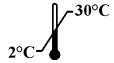

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INTERNATIONAL VERSION

EZ-GIARDIA

One-Step Giardia Test

October 2014

REF **1501, 1501-15**

Immunoassay kit for the detection of *Giardia* antigen in human stool specimen

FOR *IN VITRO* DIAGNOSTIC USE ONLY

FOR PROFESSIONAL USE ONLY

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