GIARDIA CARD

in *Vitro* diagnostics use

Immunochromatographic test for the qualitative detection of Giardia antigens in human faeces

I. INTRODUCTION AND INTENDED USE

Giardia Card is a immunochromatographic rapid test for the qualitative detection of Giardia antigens in human faeces.
Giardiasis is a diarrheal illness caused by a very small parasite, *Giardia lamblia* (also known as *Giardia intestinalis or Giardia duodenalis*). Once an animal or person is infected with *Giardia*, the parasite lives in the intestine and is passed in the stool. The parasite is protected by an outer shell (cyst) and can survive outside the body and in the environment for a long time.
Giardia is a common cause of gastrointestinal disturbance in both high- and low-income countries. The incidence of *Giardia* is generally higher in low-income countries where access to clean water and basic sanitation is lacking. In high-income countries, *Giardia* infection is associated with ingestion of contaminated water, person-to-person spread, recent foreign travel, and recreational swimming.
Giardia infection has become one of the most common causes of waterborne disease in humans. The most common symptoms of giardiasis include: diarrhea, loose or watery stool, stomach cramps and upset stomach. These symptoms generally begin 1-2 weeks after infection, and may last 2-6 weeks in healthy individuals. Sometimes symptoms last longer, and may lead to weight loss and dehydration. Some people will have no symptoms. However, people with weakened immune systems (e.g., persons with HIV/AIDS, cancer patients, and transplant patients) or the elderly may have a more serious infection that can lead to severe illness or death.

II. PRINCIPLE OF THE TEST

The Giardia Card is a qualitative immunochromatographic assay for the determination of Giardia antigens in human faeces 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 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 one or two coloured lines. A green coloured band always appears in the control line (third line) and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents

III. REAGENTS AND MATERIALS

Each kit contains:
25 devices for the immunochromatographic reaction. The device is in a sealed pouch with an essicant.
25 vials with 1 mL of Buffer Diluent. Mixture of biological buffer containing salts, detergents, proteins and sodium azide like preservative. The Sodium Azide is present at concentration < 0,1%.
1 Instruction for use
Required materials and reagents (not supplied)
Testing tubes. specimen collection container, Disposable gloves and container, Plastic pipette and Timer**.**
Giardia Controls Ref. UD80007.

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

IV. SPECIAL PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

V. SPECIMENS COLLECTION

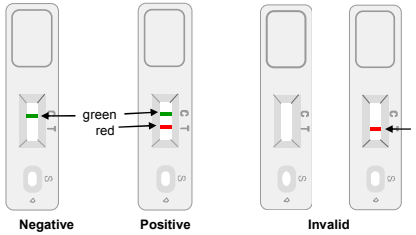
Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing. Make sure that specimens are not treated with solutions containing formaldehyde or its derivatives.

VI. PROCEDURE

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouch until ready to perform the assay.
1. Use a separate vial for each sample. Unscrew the tap and use the stick to pick up a little sample (approx. 150mg), if the stool sample was liquid take approx. 150 µL using a pipette, and add the sample into the stool collection tube.
2. Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.

3. Remove the *Giardia* Card device from its sealed bag just before using Cut the end of the top. Dispense exactly 4 drops into the circular window marked with an arrow, avoiding to add solid particles with the liquid.
4. Read the result at **10 minutes** (the coloured bands appear).

VII. INTERPRETING THE RESULTS



NEGATIVE: Only one **green** control band appears across the central window in the site marked with the letter C (control line).

POSITIVE: In addition to the **green** control band across the central window in the site marked with the letter C (control line), a **red** band (test line) also appears in the site marked with the letter T (result region).

INVALID: A total absence of the control coloured band. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test.

NOTES ON THE INTERPRETATION OF RESULTS:
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigen present in the specimen. However, neither the quantitative value, nor the rate of increase in antigen can be determined by this qualitative test.

VIII. PERFORMANCE

Sensitivity and Specificity
It was studied some stool samples, *Giardia* positive and negative evaluated by microscopy. The result showed:
>99% of sensitivity
>99% of specificity.
Cross-reactivity
It was performed an evaluation to determine the cross reactivity of Giardia Card. There is not cross reactivity with common intestinal parasites occasionally present in faeces: Acinetobacter Iwoffi, Campylobacter jejuni, Aeromonas hydrophila, E. coli 0157:H7, Salmonella typhimurium, Salmonella enteritidis, Enterobacter cloacae, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, Serratia marcescens, Shigella flexneri, Stenotrophomonas maltophilia, Helicobacter pylori, Yersinia enterolitica 01, Yersinia enterolitica 03, Yersinia enterolitica 09, Rotavirus, Adenovirus (A to F groups), Adenovirus 40/41, Campylobacter coli, E. coli 0117:H7, E. coli O55:H7, E. coli O157 VT neg (EH431), E. coli O157 VT neg (EH546), E. coli O157:H19, E. coli O7:H1, E. coli O116:H-, E. coli K99, Cryptosporidium parvum, Escherichia hermanii, Entamoeba hystolitica,Brucella melitensis, Brucella abortus.

IX. LIMITS OF THE KIT

- *Giardia* Card will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of *Giardia* antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Do not use specimens treated with solutions containing formaldehyde or its derivatives.
- 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.
- After one week of infection, the number of parasites in faeces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
- 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.

X. REFERENCES

1. MARSHALL, M.M., et al., "Waterborne Protozoan Pathogens", *Clinical Microbiology Review*, Jan. 1997, pp 67-85
2. DYLAN R. PILLAI and KEVIN C, KAIN, "Immunochromatographic Strip-Based Detection of *Entamoeba histolytica-E. dispar* and *Giardia lamblia* Coproantigen". *Journal of Clinical Microbiology*, Sept. 1999, Vol. 37, No 9, p. 3017-3019.
3. LYNNE S. GARCIA et al., "Commercial Assay for Detection of *Giardia lamblia* and *Cryptosporidium parvum* Antigens in Human Fecal Specimens by Rapid Solid-Phase Qualitative Immunochromatography", *Journal of Clinical Microbiology*, Jan. 2003, Vol. 41, No. 1, p. 209-212.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non sterile
	Consult Instructions for Use		Use By (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests)
GIARDIA CARD
Vial with 1 mL of Diluent Buffer
Instruction for use

Ref. VC1016
25 Device (Card)
25 vials
1 item

EDMA Code 15 70 01 90 00

CE IVD