GIARDIA-DIPSTICK

in *Vitro* diagnostics use

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

1. INTRODUCTION AND INTENDED USE

Giardiasis is a diarrhoeal illness seen throughout the world. It is caused by a flagellate protozoan parasite, Giardia . lamblia .

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 (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 of America, 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 diarrhoea in high-income countries

Mascia Brunelli has developed Giardia-Dipstick, a rapid chromatographic immunoassay test for the qualitative detection of Giardia antigens in human faeces specimens to aid in the diagnosis of giardiasis.

2. TEST PRINCIPLE

The *Giardia-Dipstick* is a qualitative lateral flow immunoassay for the detection of *Giardia* antigen 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 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 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

3. REAGENTS AND MATERIALS

Each kit contains:

1. Giardia dipstick (25 devices)
2. Dilution buffer (1 x 17,5 ml)
3. Instruction for use (1)

4. Required materials (not supplied)

Specimen collection container
Disposable gloves
Timer, testing tube or vial, dropper.

5. 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.

6. STORAGE

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

7. SPECIMEN 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 (2-8ºC/36-44ºF) for 1- day 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.

8. PROCEDURES

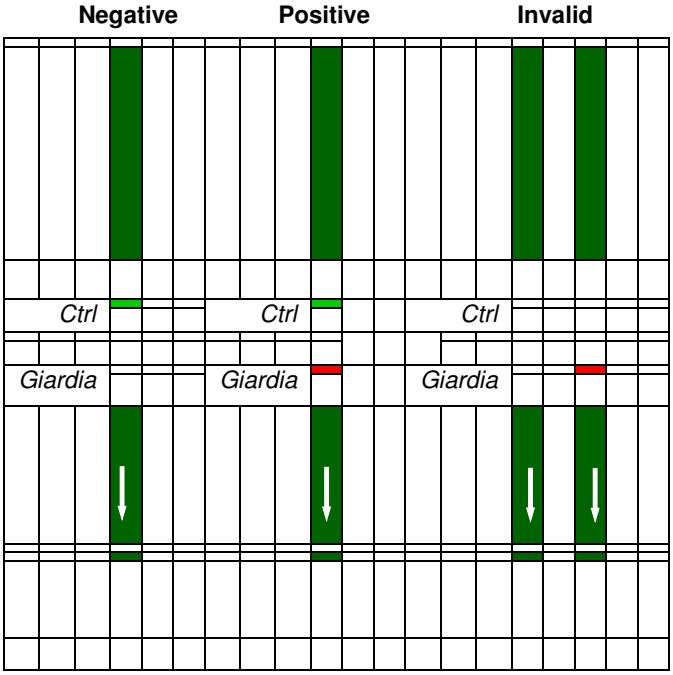
8.1 To process the collected stool samples :

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pack with dipstick until ready to perform the assay**.**

8.2 Test Procedure

1. Use a separate swab or stick, dropper and testing tube or vial for each sample. Dispense 0,5Ml or 10 drops of the buffer into a testing tube. Introduce the swab or stick two times into the faecal specimen to pick up a little sample (150mg) and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 150µL into the testing tube or vial with buffer.
2. Use a separate test strip for each sample. Leave the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer.
3. Read the result at **10 minutes** after dispensing the sample.

9. INTERPRETETIONS OF RESULTS



POSITIVE: Two lines appears across the central window. In the result line region, a **red** test line and in the control line region, a **green** control line.

The intensity of the red coloured band in the result line region 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.

NEGATIVE: Only one green band appears across the control line region.

INVALID: **A total absence** of the green control coloured band regardless the appearance or not of the red test line.

Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents 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 Mascia Brunelli.

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

10. CHARACTERISTICS

10.1 SENSITIVITY AND SPECIFICITY

It was studied some stool samples (determined by microscopy techniques) from patients in a local Hospital . The result showed using *Giardia* Strip 99% of sensitivity and >99% of specificity.
The samples were confirmed with microscopy technique.

10.2 CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *Giardia* Dipstick. There is not cross reactivity with common gastrointestinal parasites occasionally present in feces.
Acinetobacter lwoffi, 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

11. TEST LIMITATIONS

Giardia Dipstick 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.

12. REFWERENCES (see Italian version)

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

SIZE (25 tests) **COD. VC1013**

Dipstick	1 x 25 strips - pack with dipstick
Dilution Buffer:	1 x 17,5 ml.
Instruction for use	1 item

EDMA Code 15 70 01 90 00 CE IVD

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