Atlas Medical

Giardia Device
One Step Giardia Antigen Test Device

IVD For *in vitro* diagnostic and professional use only

2 - 30°C Store at 2-30°C CE

INTENDED USE

The Giardia Device test is a rapid chromatographic immunoassay for the qualitative detection of Giardia antigens in human feces specimens to aid in the diagnosis of giardiasis.

INTRODUCTION

Giardiasis is a diarrhoeal illness seen throughout the world. It is caused by a flagellate protozoan parasite, Giardia intestinalis, also known as G. lamblia and G. duodenalis.

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.

PRINCIPLE

The Giardia Device is a qualitative immunoassay for the detection of Giardia antigen in human feces 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 coloured lines. A green coloured 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.

MATERIALS

MATERIALS PROVIDED

- Devices.
- Package insert.
- Stool collection vial with buffer.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Disposable gloves.
- Timer.

PACKAGING CONTENT

REF **8.16.31.0.0020 (20 Test Cassette, 1mLx20 Buffer)**

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.

STORAGE AND STABILITY

- 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.

SPECIMEN COLLECTION, STORAGE AND STABILITY

- Collect sufficient quantity of the specimen (1-2 g or 1-2 ml for liquid sample).
- The specimen can be stored in the refrigerator (2-8°C) for 1-3 days prior to testing.
- For longer storage (maximum 1 month) the specimen must be kept frozen at (-20°C). 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.

Specimen preparation (see illustration):

Stool samples should be collected in clean containers containers (no preservatives or transport media). The assay should be done right after collection.

- Unscrew the cap and use the stick to pick up by introducing the stick four times (125 µL for liquid sample).
- Shake the tube in order to assure good sample dispersion.

PROCEDURE

Test Procedure (see illustration 2)

Allow the tests, stool samples and buffer to reach to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the Giardia Device 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 tip of the vial.
3. Use a separate device for each sample. Dispense exactly 3 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

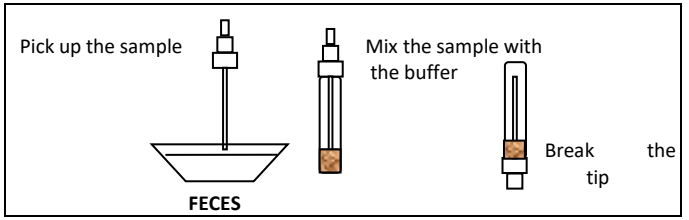
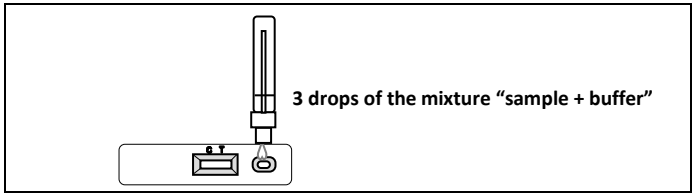
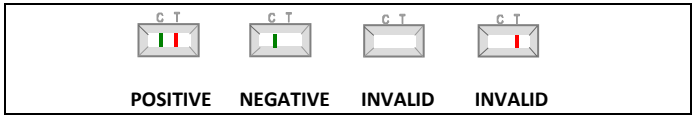


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3



POSITIVE: Two lines appears across the central window. In the result line region, a **red** test line marked in the illustration 3 with the letter T, and in the control line region, a **green** control line marked in the illustration 3 with the letter C.

NEGATIVE: Only one **green** band appears across the control line region marked with the letter C at the illustration 3 (control line).

INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. See illustration 3. 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 you local distributor.

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 antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

EXPECTED VALUES

Giardia is prevalent throughout the world, including temperate, high-income countries, such as the UK and the United States. Several studies have examined acquisition of giardiasis in international travellers.

QUALITY CONTROL

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- *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 feces 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 feces 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

Atlas Giardia Devices is compared with other two commercial kits and if results are discrepant for some of them. These samples are evaluated by commercial qPCR test.

	Evaluation Criteria			
***Giardia* Device**		+	-	Total
	+	44	2	46
	-	1	79	80
	Total	45	81	126

	***Giardia* Device vs Evaluation Criteria**	
		95% CI (Confidence interval)
Sensitivity	97.8%	88.2 – 99.9%
Specificity	97.5%	91.4 – 99.7%

Cross-reactivity

It was performed an evaluation to determine the cross reactivity of Giardia Device. There is not cross reactivity with common intestinal pathogens, other organisms, substances and/or fecal markers occasionally present in feces:

Adenovirus	*Cryptosporidium parvum*	*Legionella*	*Streptococcus pyogenes*
Astrovirus	*Entamoeba histolytica*	*Listeria monocytogenes*	*Transferrin (human)*
Calprotectin	*Escherichia coli O:111; O:026; O157:H7*	*Norovirus GI/Norovirus GII*	*Yersinia enterocolitica O:3/O:9*
Campylobacter jejuni	*Helicobacter pylori*	*Rotavirus*	*Lactoferrin (human)*
Clostridium difficile GDH/Toxin A/Toxin B	*Hemoglobin (human/bovine and pig)*	*Salmonella enteritidis/paratyphi A/typhi/typhimurium*	*Clostridium perfringens*
Shigella boydii/dysenteriae/ flexneri/ sonnei			

REFERENCES

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2. Practice. 2nd ed. Elsevier, Philadelphia. 2006:984-8.
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ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry