Atlas Medical

CE

Crypto-Giardia Device

One Step Cryptosporidium and Giardia Antigen Test Device

A rapid, one step test for the qualitative detection of *Cryptosporidium* and *Giardia* antigens in human faeces.

IVD For *in vitro* diagnostic and profesional use only

2 – 30°C Store At (2-30 º C)

INTENDED USE

The Crypto-Giardia Device is a rapid chromatographic immunoassay for the simultaneous qualitative detection of Cryptosporidium and Giardia (α-1 giardin and/or CWP1) antigens in human feces specimens to aid in the diagnosis of cryptosporidiosis and giardiasis.

INTRODUCTION

Cryptosporidiosis is a diarrhoeal disease caused by microscopic parasites of the genus *Cryptosporidium*. Once an animal or person is infected, the parasite lives in the intestine and passes in the stool. The parasite is protected by an outer shell that allows it to survive outside the body for long periods of time and makes it very resistant to chlorine-based disinfectants. Both the disease and the parasite are commonly known as "Crypto."

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 Crypto-Giardia Device is a qualitative lateral flow immunoassay for the detection of Crypto and Giardia (α-1 giardin and/or CWP1) antigens in human feces samples. The membrane is pre-coated with monoclonal antibodies against Cryptosporidium and Giardia (α-1 giardin and CWP1) antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Cryptosporidium and/or anti-Giardia (α-1 giardin and/or CWP1) antibodies, which were 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 conjugate and generate one or two coloured lines. A green coloured line 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.
- Buffer
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Disposable gloves and timer.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch 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.
- The presence of yellow lines in the results window (control and test line zone) that are visible before using the test are completely normal. That not means failure on test functionality.

STORAGE AND STABILITY

- 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.

SPECIMEN COLLECTION AND PREPARATION

- 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/36-46.4ºF) for 1-3 days prior to testing.
- For longer storage, maximum 1 month 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.

PROCEURES

To process the collected stool samples (see illustration 1):

1. Use a separate specimen collection vial for each sample with 1 mL of the buffer.
2. Unscrew the cap of the vial and introduce the stick two times into the fecal specimen to pick up a little of sample. Do not exceed the stick`s screw to avoid wrong results.
3. Close the vial with the buffer and stool sample.
4. Shake the vial in order to assure good sample dispersion.
5. For liquid stool samples, aspirate the faecal specimen with a dropper and add 125 uL into the specimen collection vial with buffer.

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 *Crypto-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 4 drops or 100 uL into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

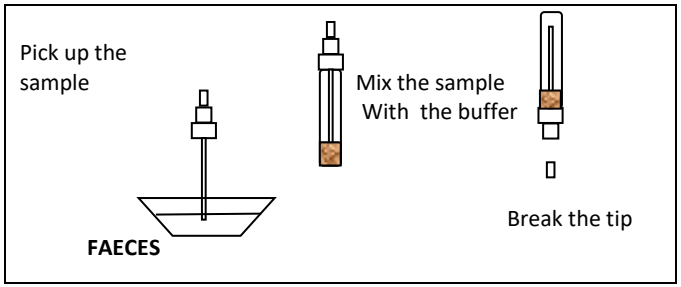
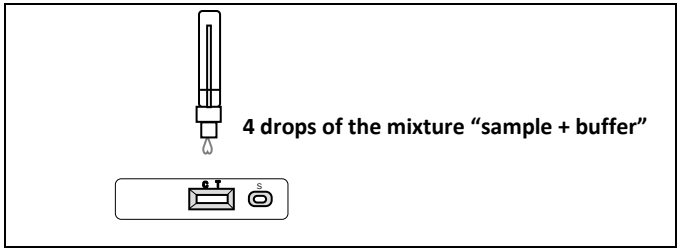


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3

Crypto positive: Two lines appear across the central window, a red test line marked with the letter T1 and a green control line marked with the letter C.

Giardia (α-1 giardin and/or CWP1) positive: Two lines appear across the central window, a red test line marked with the letter T2 and a green control line marked with the letter C.

Crypto-Giardia positive: Three lines appear across the central window, the two red test lines (T1 and T2) and the green control line marked with

the letter C.
NEGATIVE: Only one green line appears in the region marked with the letter C (control line).
INVALID: Total absence of the green control coloured line regardless the appearance or not of the red test lines. 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 your local distributor. See illustration 3.
Notes on the interpretation of results: The intensity of the red coloured test lines in the result line regions (T1 and T2) 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

Cryptosporidium has caused several large waterborne disease outbreaks of gastrointestinal illness, with symptoms that include diarrhea, nausea, and/or stomach cramps. People with severely weakened immune systems (that is, severely immunocompromised) are likely to have more severe and more persistent symptoms than healthy individuals.
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

1. Crypto-Giardia Device will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Cryptosporidium and Giardia (α-1 giardin and/or CWP1) antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Do not use specimens treated with solutions containing formaldehyde or its derivatives.
4. 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 cryptosporidiosis or giardiasis.
5. 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.
6. This test provides a presumptive diagnosis of cryptosporidiosis and/or giardiasis. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.
7. Mucous and/or bloody stool samples could cause non-specific reactions in the test. Mucous and/or bloody stool samples whose result is positive should be followed up with other techniques to confirm the result.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity
It was performed an evaluation using Crypto-Giardia Device vs the Evaluation Criteria. Evaluation criteria: two rapid tests were evaluated (Crypto-Giardia Device and other rapid tests from the competitor). The discrepant results were confirmed by qPCR technique (Viasure Cryptosporidium, Giardia & E. histolytica Real Time Detection Kits, CerTest). The results were as follows:

	Evaluation Criteria (Crypto line)			
IC test: *Crypto-Giardia* Device (Crypto line)		**+**	**-**	**Total**
	+	33	0	33
	-	2	91	93
	Total	35	91	126

	Evaluation Criteria (Giardia line)			
IC test: *Crypto-Giardia* Device (Giardia line)		**+**	**-**	**Total**
	+	43	2	45
	-	2	79	81
	Total	45	81	126

	***Crypto-Giardia* Device (Crypto line) vs Evaluation Criteria**		***Crypto-Giardia* Device (Giardia line) vs Evaluation Criteria**	
		95% CI (Confidence interval)		**95% CI (Confidence interval)**
Sensitivity	94.3%	80.8 – 99.3%	95.6%	84.9 – 99.5%
Specificity	100.0%	96.0 – 100.0%	97.5%	91.4 – 99.7%
PPV	100.0%	89.4 – 100.0%	95.6%	84.9 - 99.5%
NPV	97.8%	92.3 –99.7%	97.5%	91.4 - 99.7%

Cross-reactivity
It was performed an evaluation to determine the cross reactivity of Crypto-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* (Giardia line)	*Lactoferrin (human)*	*Shigella boydii/dysenteriae/ flexneri/ sonnei*
Astrovirus	*Entamoeba histolytica*	*Legionella*	*Streptococcus pyogenes*
Calprotectin	*Escherichia coli O:111/ O:026/ O157*	*Listeria monocytogenes*	*Streptococcus pneumococcal*
Campylobacter jejuni	*Giardia α-1 giardin / Giardia* CWP1 (Crypto line)	*Norovirus GI / Norovirus GII*	*Human (transferrin)*
Clostridium difficile Ag GDH / Tox A / Tox B	*Helicobacter pylori*	*Rotavirus*	*Yersinia enterocolitica O:3/O:9*
Clostridium perfringens	*Haemoglobin (human/ pig/ bovine)*	*Salmonella Enteritidis / paratyphi / typhi / typhimurium*	

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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 isdamaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry