clonatest®

GIARDIA CASSETTE CE

Giardia antigen

A rapid test for the qualitative detection of *Giardia* antigens in human faeces.

ONE STEP

COD CT45501
20 Test
For professional *in vitro* diagnostic use only

SUMMARY

The *Giardia* Cassette is a qualitative 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 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.

PACKAGING CONTENTS

REF CT 45501 20 Giardia cassettes
20 Stool collection tubes with buffer

STORAGE AND STABILITY

Store at 2-30ºC.
The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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 (2-4ºC/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.

MATERIALS REQUIRED

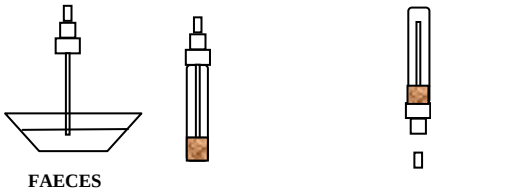
- Specimen collection container
- Disposable gloves
- Timer.

PROCEDURE

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample with 1 mL of the buffer. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up a little of sample (150 mg) . Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 150 uL into the specimen collection vial with buffer.

Illustration 1

Pick up the sample Mix the sample with the buffer Break the tip

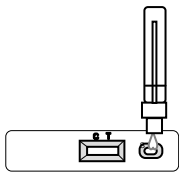


FAECES

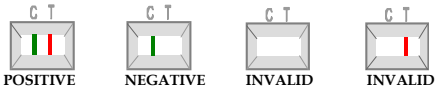
Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the *Giardia* Cassette from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the tip of the vial.
3. Use a separate Cassette 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 2

4 drops of the mixture sample + buffer



INTERPRETATION OF RESULTS



POSITIVE NEGATIVE INVALID INVALID

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

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

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 you local distributor.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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QUALITY CONTROL

Internal procedural controls are included in the test. A GREEN line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

It is recommended that a positive control and a negative control be evaluated to verify proper test performance when a new shipment of test devices are received.

CLINICAL SIGNIFICANCE

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.
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.

ANALYTICAL PERFORMANCE

SENSITIVITY AND SPECIFICITY

It was studied some stool samples (determined by microscopy techniques) from patients in a local Hospital in Spain. The result showed using *Giardia* Cassette:

- >99% of sensitivity and
- >99% of specificity

The samples were confirmed with microscopy technique.

CROSS-REACTIVITY

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

- *Entamoeba hystolitica*
- *Cryptosporidium parvum*

NOTES

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.

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.

LIMITATIONS

1. *Giardia* Cassette 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.
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 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 giardiasis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

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

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