

A rapid test for the qualitative detection of *Giardia Lamblia* in human stool samples. For professional in vitro diagnostic use only.

INTENDED USE

The *Giardia Lamblia* Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Giardia Lamblia* antigen in human feces specimen.

SUMMARY

Parasitic infections remain a very serious health problem worldwide. *Giardia Lamblia* is the most common protozoa known to be responsible for one of the main causes of severe diarrhea in humans, particularly in immunocompromised people. *Giardia Lamblia*, also known as *Giardia intestinalis*, is a flagellated parasite that colonizes and reproduces in the small intestine, causing giardiasis. The parasite attaches to the epithelium by a ventral adhesive disc, and reproduces via binary fission.^[1] Epidemiological studies, in 1991, showed that infections with *Giardia* increased in the United States with a prevalence of around 6% on 178,000 samples. Generally, the disease passes through a short acute phase followed by a chronic phase. Infection by *G. lamblia*, in the acute phase, is the cause of watery diarrhoea with elimination of trophozoites. The stools become normal again, during the chronic phase, with transient emissions of cysts.

The presence of the parasite on the wall of the duodenal epithelium is responsible for malabsorption. The disappearance of villusities and their atrophy lead to problems with the digestive process at the level of the duodenum and the jejunum, followed by weight loss and dehydration. The majority of infections remain asymptomatic, however.

The diagnosis of *G. lamblia* is carried out under microscopy after flotation on zinc sulphate or by direct or indirect immunofluorescence, on non-concentrated samples displayed on a slide.

The rapid test can detect *Giardia Lamblia* in fecal specimens within 10 minutes. It is based on the detection of a 65-kDa coproantigen, a glycoprotein that is present in the cysts and trophozoites of *G. lamblia*.

PRINCIPLE

Giardia Lamblia Rapid Test Cassette (Feces) is based on the use of a membrane technology with colloidal gold. A nitrocellulose membrane is sensitized with antibody directed against *Giardia Lamblia*. The test's specificity is ensured by an antibody specific to a *Giardia Lamblia* antigen that is conjugated to the colloidal gold. This conjugate is dried on a membrane.

The fecal sample must be diluted into the extraction buffer that is supplied with the test. When extracted specimen come into contact with the strip, the conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-*Giardia* antibody in the T line. If the sample contains the *G. lamblia* antigen, the conjugate-antigen complex will remain bound to the anti-*Giardia* reagent and a red line will develop. Solution continues to migrate to encounter a second reagent that binds the migration control conjugate, thereby producing a red control line that confirms that the test is working properly. The result is visible within 10 minutes.

REAGENTS

The test contains anti-*Giardia Lamblia* antibody particles and anti-*Giardia Lamblia* antibody coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). 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

The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media. Bring the necessary reagents to room temperature before use. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

- | | | |
|--|--|------------------|
| • Test Cassettes | Materials Provided | • Package Insert |
| • Specimen Collection Tubes with extraction buffer | | • Droppers |
| | Materials Required But Not Provided | |
| • Specimen Collection Containers | | • Timer |

DIRECTIONS FOR USE
SPECIMEN PREPARATION PROCEDURE:

- To collect fecal specimens:
Collect sufficient quantity of feces (1-2mL or 1-2g) in a clean, dry specimen collection container to obtain enough pathogens. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
To process fecal specimens:
 - For **Solid Specimens**:
Unscrew the cap of the specimen collection tube, then randomly **stab the specimen collection applicator into the fecal specimen at least 3 different sites** to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
 - For **Liquid Specimens**:
Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops of the liquid specimen (approximately 80 µL)** into the specimen collection tube containing the extraction buffer.
Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.
- Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Hold the specimen collection tube upright and **unscrew the tip** of the specimen collection tube. Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen (approximately 80 µL)** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Read the results at 10 minutes** after dispensing the specimen. Do not read results after 20 minutes. **Note:** If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 4 onwards in the above instructions for use.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: **Two colored lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *Giardia Lamblia* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C).** No line appears in the test line region (T).

INVALID: **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques 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 immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
- A positive or negative test result does not rule out the possibility that other pathogens may be present.
- This test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the test's sensitivity threshold. If a sample test negative, despite the observed symptoms, further testing with alternative methods are recommended.

PERFORMANCE CHARACTERISTICS
Sensitivity-Specificity

The *Giardia Lamblia* Rapid Test Cassette (Feces) was evaluated on 278 patients. The status of the samples was checked after concentration of parasites (Ritchie method) and microscopic slide reading.

Method	Microscopic		Total Results
	Positive	Negative	
<i>Giardia Lamblia</i> Rapid Test Cassette (Feces)	Positive	58	63
	Negative	3	215
Total Results	61	217	278

Relative sensitivity: 95.1% (95%CI*: 86.3%-99.0%);

Relative specificity: 97.7% (95%CI*: 94.7%-99.2%);

Accuracy: 97.1% (95%CI*: 94.4%-98.7%).

*Confidence Intervals

Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 3 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

To check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+07 organisms/ml. The following organisms were found negative when tested with the *Giardia Lamblia* Test Cassette (Feces):

Citrobacter freundii	Clostridium difficile	Coxsackie
Candida albicans	Chlamydia trachomatis	Echovirus
Enterococcus faecium	E.coli	Enterococcus faecalis
Gardnerella vaginalis	Neisseria gonorrhoea	Proteus mirabilis
Proteus vulgaris	Pseudomonas aeruginosa	Rotavirus
Salmonella infantis	Staphylococcus aureus	Adenovirus
Shigella dysenteriae	Shige flexneri	Corynebacterium diphtheria

BIBLIOGRAPHY

- Oxford textbook of Medicine. 1 (4th ed.). Oxford University Press. 2003. pp. 759-760. ISBN 0-19-262922-0.
- Johnston S.P. et al.; Evaluation of three commercial assays for detection of giardia and cryptosporidium organisms in fecal specimens; Journal Of Clinical Microbiology, p.623-626, Feb. 2003
- Garcia L. et al.; Detection of Giardia Lamblia and Cryptosporidium parvum antigens in human fecal specimens using the ColorPac combination rapid solid-phase qualitative immunochromatographic assay; Journal of Clinical Microbiology, p.1267-1268, Mar. 2000
- Dylan R. Pillai and Kevin C. Kain; Immunochromatographic Strip-based detection of Entamoebahystolytica-E. dispar and Giardia Lamblia coproantigen; Journal Of Clinical Microbiology, p.3017-3019, Sept. 1999
- McIver C.J. et al.; Diagnosis of enteric pathogens in children with gastroenteritis; Pathology 33(3): 353-8, Aug. 2001
- R.C. Andrew Thompson; Giardiasis as a re-emerging infectious disease and its zoonotic potential; International Journal for parasitology, 30 : 1259-1267, 2000
- MS Wolfe; Giardiasis; Clinical Microbiology Review, Vol5: 93-100, 1992
- D. Van Kerkhoven, M. Lontliac Microbiology Review, Vol5: 93-100, 199200 its zoono-strips: an in-vitro immunochromatographic test for the detection of Giardia Lamblia cyst in faecalspecime

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	In vitro diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

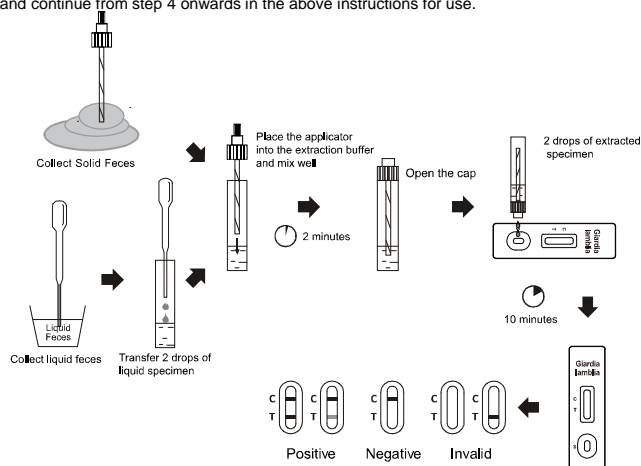
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Un test rapid pentru detectarea calitativă a Giardia Lamblia în probe de scaun uman.

UTILIZAREA PREVĂZUTĂ

Casetă de testare rapidă Giardia Lamblia (Fecale) este un imunotest cromatografic rapid pentru detectarea calitativă a Giardia Lamblia antigenul din speciunile de fecale umane.

REZUMAT

Infecțiile parazitare rămân o problemă de sănătate foarte gravă la nivel mondial. Giardia Lamblia este cea mai comună protozoară cunoscută a fi responsabilă pentru una dintre principalele cauze de diaree severă la oameni...

Studiile epidemiologice, în 1991, au arătat că infecțiile cu Giardia au crescut în Statele Unite, cu o prevalență de aproximativ 6% pe 178.000 de probe. În general, boala trece printr-o fază acută scurtă urmată de o fază cronică. Infecția cu Giardia Lamblia, în fază acută, este cauza diareei apoase cu eliminarea trofozoizilor.

Prezența parazitului pe peretele epitelului duodenal este responsabilă de malabsorbția. Dispariția vilozităților și atrofia lor duc la probleme cu procesul digestiv la nivelul duodenului și jejunului, urmate de slăbire și deshidratare.

PRINCIPIU

Casetă de testare rapidă Giardia Lamblia (Fecale) se bazează pe utilizarea unei tehnologii membranare cu aur coloidal. O membrană de nitroceluloză este sensibilizată cu anticorpi direcționați împotriva Giardia Lamblia.

REACTIVI

Testul conține particule de anticorpi anti-Giardia Lamblia și anti-Giardia Lamblia anticorpi acoperiți pe membrană.

PRECAUȚII

- Nu mai utilizați după data de expirare.
Testul trebuie să rămână în punga sigilată până la utilizare.
Nu mâncați, beți și nu fumați în zona în care sunt manipulate speciunile sau trusele.

DEPOZITARE ȘI STABILITATE

Trusa poate fi păstrată la temperatura camerei sau la frigider (2-30°C). Casetă de testare este stabilă până la data de expirare imprimată pe punga sigilată.

RECOLECTAREA ȘI PREGĂTIREA PROBELOR

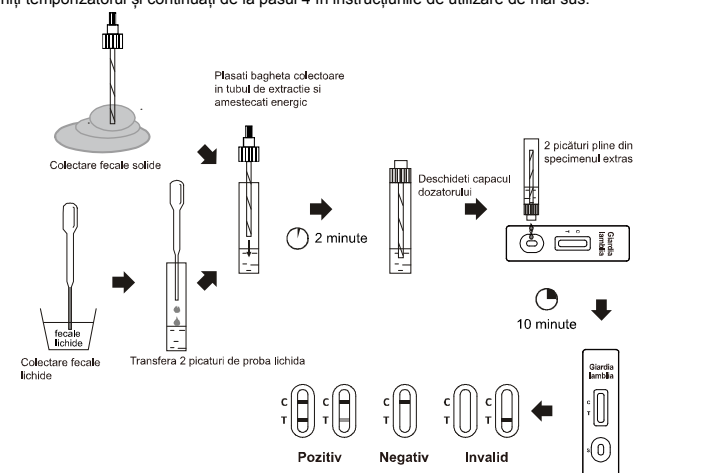
Eșantionul de fecale trebuie colectat într-un recipient curat, uscat, impermeabil, care nu conține detergenți, conservanți sau medii de transport.

MATERIALE

- Casetă de testare
Tuburi de colectare a probelor cu tampon de extracție
Picuratoare
Recipiente de colectare a probelor

INSTRUCȚIUNILE DE UTILIZARE

PROCEDURA DE PREGĂTIREA EȘTIEI:
1. Pentru a colecta speciunile fecale:
Colectați o cantitate suficientă de fecale (1-2 ml sau 1-2 g) într-un recipient de colectare a probelor curat și uscat...



INTERPRETAREA REZULTATELOR

POZITIV: Apar două linii colorate. O linie colorată ar trebui să fie în regiunea liniei de control (C) și o altă linie colorată aparent ar trebui să fie în regiunea liniei de testare (T).

NEGATIV: O linie colorată apare în regiunea liniei de control (C). Nu apare nicio linie în regiunea liniei de testare (T).

INVALID: Linia de control nu apare. Volumul insuficient al probei sau tehnicile procedurale incorecte sunt cele mai probabile motive pentru defectarea liniei de control.

CONTROL DE CALITATE

Controalele procedurale interne sunt incluse în test. O linie colorată care apare în regiunea de control (C) este un control procedural intern valid.

Standardurile de control nu sunt furnizate împreună cu acest kit; cu toate acestea, se recomandă ca controalele pozitive și negative să fie testate ca o bună practică de laborator pentru a confirma procedura de testare și pentru a verifica performanța corespunzătoare a testului.

LIMITARI

- Testul este calitativ și nu poate prezice cantitatea de antigene prezente în probă.
Un rezultat pozitiv sau negativ al testului nu exclude posibilitatea ca alți agenți patogeni să fie prezenți.

CARACTERISTICI DE PERFORMANȚĂ

Sensibilitate specificitate

Casetă de testare rapidă Giardia Lamblia (Fecale) a fost evaluată pe 278 de pacienți. Starea probelor a fost verificată după concentrarea parazitilor (metoda Ritchie) și citirea microscopică a lamel.

Table with 4 columns: Metodă, Rezultate, Microscopic (Pozitiv, Negativ), Rezultate totale. Shows data for Giardia Lamblia (Fecale) test results.

Sensibilitate relativă: 95,1% (IC 95%*: 86,3%–99,0%); Intervale de încredere

Specificitate relativă: 97,7% (95%CI*: 94,7%–99,2%);

Precizie: 97,1% (95%CI*: 94,4%–98,7%).

Repetabilitate și reproductibilitate

Pentru a verifica acuratețea intra-lot (repetabilitate), aceleași probe pozitive și o soluție tampon au fost procesate de 3 ori pe truse din același lot de producție în aceleași condiții experimentale.

Reactivitate încrucișată

Reactivitatea încrucișată cu următoarele organisme a fost studiată la 1,0E+07 organisme/mL. Următoarele organisme au fost găsite negative atunci când au fost testate cu Casetă de testare rapidă Giardia Lamblia (Fecale):

Table listing various microorganisms tested for cross-reactivity, including Citrobacter freundii, Clostridium difficile, Coxsackie, etc.

BIBLIOGRAFIE

- 1. manual de medicină în Oxford. 1 (al 4-lea.). Presa Universitatii Oxford. 2003. p. 759-760.
2. Johnston SP și colab.; Evaluarea a trei teste comerciale pentru detectarea organismelor giardia și cryptosporidium în speciunile fecale...

Lista de simboluri

Table defining symbols used in the instructions: IVD, LOT, REF, EC, REP, and warning symbols for temperature, expiration, and attention.

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