

VITASSAY

Giardia

Rapid test for the qualitative detection of giardia in human stool samples.

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For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Giardia is a rapid one step immunochromatographic assay for the qualitative detection of giardia in human stool samples.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of giardia infection (giardiasis).

INTRODUCTION

Giardia is a common cause of acute gastroenteritis in humans and many animal species across the globe.

Giardia nowadays is recognized as the most common parasitological cause of diarrhea, with 280 million infections per year.

The main symptoms is watery, foul smelling diarrhea, often accompanied by nausea, abdominal cramps or gurgling, bloating and weight loss. Symptoms of variable severity may persist for weeks.

Additionally, international travelers returning from endemic areas and asymptomatic carries may play an important role in the spreading of these infections.

Furthermore, chronic giardiasis can lead to malabsorption and failure to thrive in children increasing the disease burden due to this infection. Although Giardia does cause disease, it can also be asymptomatic in humans and animals.

Since it has a fecal-oral transmission cycle and is contracted by ingestion of contaminated water or food or by person-to-person contact, the highest disease burden is found in areas where sanitary conditions are poor.

PRINCIPLE

Vitassay Giardia is a qualitative immunochromatographic assay for the detection of giardia in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against giardia.

During the process, the sample reacts with the antibodies against giardia, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a **red** line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the **green** control line always appears.

The presence of this **green** line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Giardia**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/35.6-86°F) on the sealed pouch.

The test is stable until the expiration date printed.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
<ul style="list-style-type: none">• 25 tests/kit Vitassay Giardia.• Instructions for use.• 25 vials with diluent for the sample dilution.	<ul style="list-style-type: none">• Specimen collection container.• Disposable gloves.• Timer.

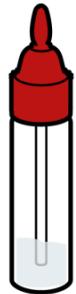
SPECIMEN COLLECTION

Collet sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

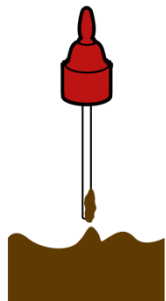
Samples can be stored in the refrigerator (2-8°C/36-46.4°F) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20°C (-4°F). Samples must be brought to room temperature before testing.

SPECIMEN PREPARATION

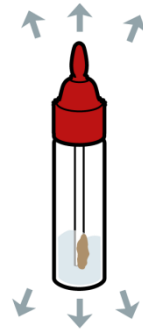
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2), and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.
3. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).



Vial for sample dilution.



Insert the stick in 4 different areas of the stool.



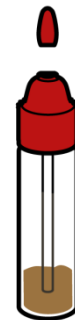
Put the sample into the vial, close the cap and shake.

PROCEDURE

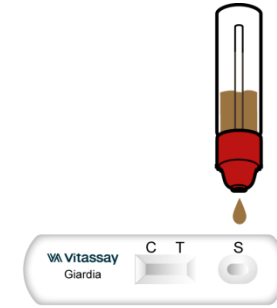
Allow the test, stool sample, controls and diluent to reach room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample to obtain a good sample dilution.
2. Remove the **Vitassay Giardia** from its sealed bag just before using it.
3. Take the vial containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.



Cut the end of the cap.



Dispense 4 drops in the circular window marked with the letter S.

INTERPRETATION OF THE RESULTS

CT	NEGATIVE	There is no Giardia presence. No infection caused by Giardia.
	Only one green line in the control zone (C).	
CT	POSITIVE	There is presence of Giardia. Infection caused by Giardia.
	In addition to the green line (control line C), a red line appears (test line T).	
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. Note: Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay Giardia**. **Green** line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Giardia** must be carried out within 2 hours of opening the sealed bag.
- Only fresh or fresh-frozen unpreserved and unfixed stool samples can be tested.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.

- The intensity of test line may vary depending on the concentration of antigens.
- 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.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay Giardia** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of Giardia in fecal samples; nevertheless, a positive result should be followed up with additional laboratory techniques (biochemical method or by microscopy) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens in the sample is lower than the detection limit. If symptoms or situation still persist, a Giardia determination should be carried out with another technique (for example: microscopy).

EXPECTED VALUES

The highest rates of infection are therefore encountered in developing countries (10-30% in young children), while in developed countries, infections occur mostly in persons living in closed communities, homosexual men, immigrants and, of increasing importance, travellers returning from highly endemic countries (2-5% of symptomatic patients).

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation, with fecal samples, was performed using **Vitassay Giardia** and these results were confirmed using a microscopy technique and PCR (positive results).

Results were as follows:

		Microscopy technique/PCR		
		Positivo	Negativo	Total
Vitassay Giardia	Positivo	61	0	61
	Negativo	2	191	193
	Total	63	191	254

Vitassay Giardia vs microscopy technique/PCR			
Sensitivity	Specificity	PPV	NPV
97%	>99%	>99%	99%

The results showed that **Vitassay Giardia** has a high sensitivity and specificity to detect Giardia.

Cross reactivity







No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

<i>Campylobacter jejuni</i>	<i>Helicobacter pylori</i>	<i>Shigella boydii</i>
<i>Campylobacter coli</i>	<i>Listeria monocytogenes</i>	<i>Shigella dysenteriae</i>
<i>Clostridium difficile</i>	<i>Salmonella enteritidis</i>	<i>Shigella flexneri</i>
<i>Cryptosporidium parvum</i>	<i>Salmonella paratyphi</i>	<i>Shigella sonnei</i>
<i>Escherichia coli</i>	<i>Salmonella typhi</i>	<i>Staphylococcus aureus</i>
<i>Entamoeba histolytica</i>	<i>Salmonella typhimurium</i>	

REFERENCES

1. MAHA BOUZID; KAPIL HALAI; DANIELLE JEFFREYS; PAUL R. HUNTER. "The prevalence of Giardia infection in dogs and cats, a systematic review and meta-analysis of prevalence studies from stool samples". Veterinary pathology 207 (2015) 181-202.
2. HALA A. EL-NAHAS; DALIA A. SALEM; ABEER A. EL-HENAWY; HOSAM I. EL NIMR; HASAN A. ABDEL-GHAFFAR; ALI M. EL-MEADAWY. "Giardia diagnostic methods in human fecal samples: a comparative study". Cytometry Part B (Clinical Cytometry) 84B:44-49 (2013).
3. TOMAS JELINEK; STEFAN NEIFER. "Detection of Giardia lamblia stool samples: a comparison of two enzyme-linked immunoabsorbent assays [version 1; referees: 1 approved, 1 approved with reservations]". F1000Research 2013, 2:39.
4. MARTA MAEO, PhD; MARIA MATEO, PhD, ANA MONTOYA, PhD, BEGOÑA BAILO, AS; JOSÉ M. SAUGAR, PhD; MARIA AGUILERA, AS; ISABEL FUENTES, PhD; DAVID CARMENA, PhD. "Detection and molecular characterization of Giardia duodenalis in children attending day care centers in Majadahonda, Madrid, Central Spain. MD Journal, Volume 93, Number 15, October 2014.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	in vitro diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code		Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number



