Proflow™ Giardia

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3021 **20 Tests**

INTENDED USE

The Proflow™ Giardia test is a single use rapid membrane immunoassay for the qualitative detection of Giardia antigen in human faecal samples to aid in the diagnosis of giardiasis. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

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. The incidence of Giardia is generally higher in countries 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.

PRINCIPLE OF THE TEST

The Proflow™ Giardia test is a single use rapid membrane immunoassay for the qualitative detection of Giardia antigen in human faecal samples.

Monoclonal antibodies to Giardia antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate.

A green line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay. The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present.

A positive result will show a pink/red test line and a green control line, indicating that Giardia antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that Giardia antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3121 Proflow™ Giardia Test Device: 20 devices
- PL.3221 Proflow™ Giardia Sample Prep Device: 20 devices
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

- Collect sufficient quantity of faeces (1-2g or 1-2mL for liquid samples).
- Faecal samples should be collected in clean and dry containers (no preservatives or transport media).
- Samples may be stored at 2-8°C for 1-2 days or at -20°C for longer periods before testing.
- Allow all samples to equilibrate to room temperature before testing.
- Freezing and thawing cycles are not recommended.

TEST PROCEDURE

Use a separate sample collection vial and test for each sample or control. Allow the tests, faecal samples and buffer to reach room temperature prior to testing.

1. Introduce the swab or stick four times into the faeces up to the thread of the stick to pick up approx. 50 mg, and put back into the sample preparation device with buffer. For liquid stool samples, aspirate with a dropper and add 50 µL into the sample preparation device.
2. Shake the sample preparation device to ensure good sample dispersion.
3. Remove the Proflow™ Giardia test from its sealed pouch.
4. Break off the top of the vial on the sample preparation device.
5. Dispense 3 drops (100 uL) into the sample well on the test (S).
6. Read the result at 10 minutes.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.

The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a green line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

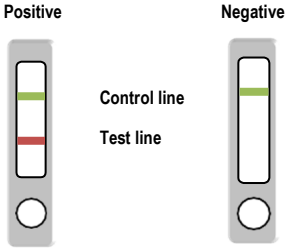
INTERPRETATION OF RESULTS

Positive

One pink/red line of any intensity will appear at the test line position; a green line will appear at the control line position. This indicates a reactive result that is interpreted as positive for Giardia antigen.

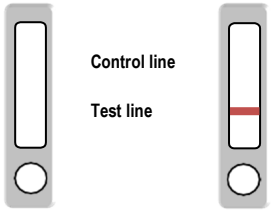
Negative

A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for Giardia antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a coloured line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



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LIMITATIONS OF THE PROCEDURE

- The Proflow™ Giardia test will only indicate the presence of Giardia (CWP1 and/or α1-giardin) in the sample (qualitative detection) and should be used for the detection of Giardia antigens in faecal samples only. Neither the quantitative value nor the rate of increase in Giardia 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.
- Some faeces samples can decrease the intensity of the control line.
- Do not use samples treated with solutions containing formaldehyde or its derivatives.
- The test must be carried out within 2 hours of opening the sealed bag.
- Mucous and/or bloody faecal samples can cause non-specific reactions. A positive result with a mucous or bloody sample should be confirmed with other techniques.
- 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 faeces decreases, making the sample less reactive. Faecal 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 clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

The infection caused by Giardia can be transmitted to a new host through contaminated water or food, or by person-to-person / animal-to-person contact. In one study, it was found that between 60 and 80% of Giardia infected children in day-care nurseries had an asymptomatic household contact. Asymptomatic individuals are an important reservoir in the spread of the infection.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Giardia test to 2 other commercial lateral flow tests. Results were confirmed by a qPCR technique (VIASURE Cryptosporidium, Giardia and *E. histolytica* Real Time Detection Kit, Certest Biotec), and are as follows:

		Competitor Kits		
		Positive	**Negative**	**Total**
IC test: Proflow™ Giardia	**Positive**	44	2	46
	Negative	1	79	80
	Total	45	81	126

		Giardia Device vs. competitor kits
		95% CI (Confidence Interval)
Sensitivity	97.8%	88.2-99.9%
Specificity	97.5%	91.4-99.7%
PPV	95.7%	85.2-99.5%
NPV	98.8%	93.2-100.0%

CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Giardia test. There was no cross-reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in faeces:

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

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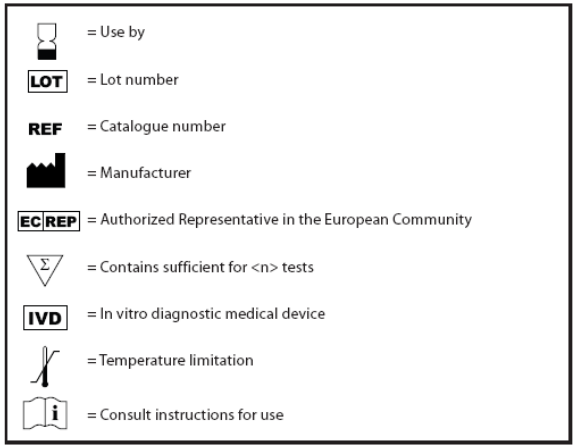

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