Giardia-Strip

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***In vitro* rapid diagnostic test for the detection of *Giardia lamblia* in human stool samples**

FOR IN VITRO USE ***EN***
FOR PROFESSIONAL USE ONLY
Reference: C-1013, 25 tests per kit

I. INTRODUCTION

Parasitary 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 diarrhoea in humans, particularly in immunodepressed people. 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 principally the 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 a malabsorption. The disappearance of villosities 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. More and more ELISA methods are also now available for the specific detection of cysts and/or trophozoïtes. Detection of this parasite in surface or distribution water can be undertaken by PCR type techniques.

Coris BioConcept has developed a rapid membrane test that can detect *Giardia lamblia* in non-concentrated faecal samples within 15 minutes. The test is based on the detection of a 65-kDA coproantigen, a glycoprotein that is present in the cysts and trophozoites of *G. lamblia*.

II. PRINCIPLE OF THE TEST

This is a ready-to-use test that is based on the use of a membrane technology with colloidal gold. A nitrocellulose membrane is sensitized with antibody directed against intestinal protozoan parasite *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 faecal sample must be diluted into the dilution buffer that is supplied with the test. When the liquid phase of the faecal suspension come into contact with the strip, the solubilised conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-*Giardia* antibody adsorbed onto the nitrocellulose. 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 (an anti-IgY polyclonal antibody) 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 15 minutes.

III. REAGENTS AND MATERIALS

1. Giardia-Strip (25)
The strips come in a bottle with a desiccant.

2. Instruction for use (1)

3. HC dilution buffer (15mL)
Saline solution buffered to pH 7.5 containing Tris, EDTA, NaN_3 (<0.1%), a detergent and blocking proteins.

4. Required materials :
- 3 or 5 mL test tubes;
- Sampling loops for taking the faecal samples.

Materials to be ordered separately:
- Giardia control test (Ref.: C-1093)
- Negative control (Ref.: CTR-1000)

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- If strips are stored in a container, the container must be resealed as soon as the necessary number of strips for the operation has been removed as the strips are sensitive to humidity. Make sure that the desiccant bag is present.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in this Information For Use package insert.

To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line indicated under the arrows printed on the sticker.

V. WASTE DISPOSAL

- Dispose of gloves, swabs, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened kit may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging.
- The strips remain stable for 15 weeks (in the closed container) after bottle opening if they are kept at between 4 and 30°C and in a dry environment.
- Avoid freezing strips and buffer.

VII. SPECIMEN HANDLING AND COLLECTION

The stool specimens must be tested as soon as possible after collection. If necessary, they may be stored at 2-8°C for 1 week or -20°C for longer periods of time.

Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

VIII. PROCEDURE

PREPARATIONS OF THE TEST:
Allow kit components, in unopened packaging, and specimens to reach room temperature (15-30°C) before performing a test.

Once opened, run the test immediately. Indicate the patient's name or specimen number on the tube. Place the marked test tubes in a rack.

SPECIMEN PREPARATION PROCEDURE:
1. Add **14** drops of the dilution buffer solution into a tube.
2. Dip a loop containing the stool sample into the tube. **The dilution ratio must be about 4% w/v**. For liquid samples, take 2 loops of 10 µL; for solid samples, take 1 loop.
3. Discard the sampling loop.
4. Vortex the preparation to homogenize. The entire stool sample must be suspended into the solution.
5. Dip the sensitized strip in the direction indicated by the red arrow.

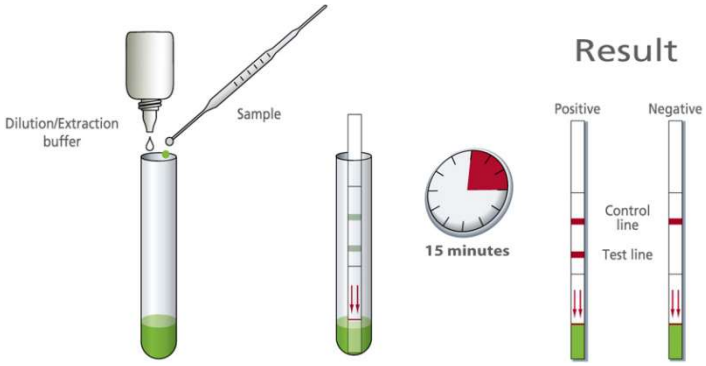
Leave to react for 15 minutes. Positive results may be reported sooner the moment the test and control lines become visible.

Do not take the appearance of new lines into account after the reaction time is passed.

The results must be read on still wet strips.

IX. INTERPRETING RESULTS

The results are to be interpreted as follows:



Negative test result: a reddish-purple line appears at the Control line (C) position (upper line). No other band is present.

Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens found in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new strip.

Note: during the drying process, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.

X. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend checking the test's performance regularly according to the laboratory's requirements. For the test, dip the strip in 500 µL of prepared control (see CTR-1000 or C-1093 instructions for use).

XI. PERFORMANCE

A. Sensitivity - Specificity

An evaluation has been performed on 94 stool samples in comparison with an ELISA kit. The following results were obtained:

ELISA / Coris BioConcept	Positive	Negative	Total
Positive	22	3	25
Negative	0	69	69
Total	22	72	94

		95 % Confidence Interval[1]
Sensitivity:	100 %	(81.5 to 100 %)
Specificity:	95.8 %	(87.5 to 98.9 %)
Positive Predictive value:	88 %	(67.7 to 96.9 %)
Negative Predictive value:	100 %	(93.4 to 100 %)
Agreement:	96.8 % (91/94)	

A second evaluation of test has been performed in comparison with microscopic examination on a panel of 56 typed stool samples. The results are listed in the following table.

Microscopic analysis / Coris BioConcept	Positive	Negative	Total
Positive	10	5*	15
Negative	0	41	41
Total	10	46	56

*: 3/5 samples are Giardia-positive by PCR method

		95 % Confidence Interval[1]
Sensitivity:	100 %	(71.7 to 100 %)
Specificity °:	95.3 %	(82.9 to 99.2 %)
Positive Predictive value:	86.7 %	(58.4 to 97.7 %)
Negative Predictive value:	100 %	(89.3 to 100 %)
Agreement:	96.4 % (54/56)	

°: the Specificity value takes into account the PCR results of discrepant samples

B. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 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.

C. Interference:

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative:

Campylobacter coli, Campylobacter jejuni, Clostridium difficile, Enterobacter cloacae, Enterococcus faecalis, Escherichia hermanni, Haemophilus influenza, *Klebsiella pneumoniae, Legionella bozemanii* (sg1), *Legionella longbeachae, Legionella pneumophila, Moraxella catarrhalis, Neisseria meningitides* (B,C), *Neisseria sicca, Proteus mirabilis, Pseudomonas aeruginosa*, *Salmonella enteritidis, Salmonella typhimurium, Serratia marcescens, Shigella flexneri, Shigella sonnei*, Staphylococcus aureus, *Streptococcus van* (B,C,F,G), *Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes, Vibrio cholera, Vibrio parahemolyticus, Escherichia coli, Mycoplasma hominis, Ureaplasma urealyticum, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium tuberculosis, Escherichia coli K99*, Coronavirus, *Helicobacter pylori*, Norovirus, Rotavirus, Adenovirus 40/41, Cryptosporidium parvum,*Yersinia enterocolitica* (1,3,9).

XII. LIMITS OF THE KIT

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 test does not rule out the possibility that other pathogens may be present.

Kit test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold. If a sample is given a negative result despite the observed symptoms, any other relevant test should be run to check the sample.

XIII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:

1. Record the kit batch number
2. If possible, keep the clinical sample in the freezer during the complaint management
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

[1] Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," *Statistics in Medicine,* **17**, 857-872 (1998).

XIV. BIBLIOGRAPHIC REFERENCES

A. **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

B. **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 Cinical Microbiology, p.1267-1268, Mar. 2000

C. **William E. Aldeen et al.**; *Comparison of nine commercially available enzyme-linked immunosorbent assays for detection of Giardia lamblia in fecal specimens*; Journal of Clinical Microbiology, p. 1338-1340, May 1998

D. **Dylan R. Pillai and Kevin C. Kain.**; *Immunochromatographic Stip-based detection of Entamoeba hystolytica-E. dispar and Giardia lamblia corproantigen*; Journal Of Clinical Microbiology, p.3017-3019, Sept. 1999

E. **Henry H. Stibbs et al.**; *Enzyme Immunoassay for detection of Giardia lamblia cyst antigens in formalin-fixed and unfixed human stool*; Journal Of Clinical Microbiology, p.1665-1669, sept.1988

F. **McIver C.J. et al.**; *Diagnosis of enteric pathogens in children with gastroenteritis*; Pathology 33(3): 353-8, Aug. 2001

G. **R.C. Andrew Thompson**; *Giardiasis as a re-emerging infectious disease and its zoonotic potential*; International Journal for parasitology, 30 : 1259-12678, 2000

H. **MS Wolfe**; *Giardiasis*; Clinical Microbiology Review, Vol5: 93-100, 1992

I. **D. Van Kerkhoven, M. Lontié, J. Verhaegen and V. Lagrou**; *Evaluation of the giardia-strips: an in-vitro immunochromatogtaphic test for the detection of Giardia lamblia cyst in faecal specimen*

J. **T. K. T. Nguyen et al**. : *Evaluation of an immunochromatographic assay: Giardia-Strip® (Coris BioConcept) for detection of Giardia intestinalis in human fecal specimens*; European Journal of Clinical Microbiology & Infectious Diseases, p. 623-625, April 2012

Last update: DECEMBER 2017

REF	Catalogue number		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Batch code
	Consult instructions for use		Do not reuse
	Keep dry		Use by
DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide
DIL AS	Diluent assay		