



For information Use only- Not to be used for performing the assay. Refer to the insert



EN

Giardia-Strip, Giardia Uni-Strip, Giardia-CIT (C-1013, C-1513, C-1213)

In vitro Rapid Diagnostic Test for the detection of *Giardia lamblia* antigen in faecal specimens.

FOR IN VITRO USE

FOR PROFESSIONAL USE ONLY

Reference: C-1013, 25 tests per kit.

C-1513, 10 tests individually packed, sampling devices

C-1213, 20 tests individually packed

I. INTRODUCTION

Giardia lamblia is known to be responsible for one of the main causes of persistent diarrhoea in the developed world. This parasite is known to be highly pathogenic and its infectious stage is transmitted by faecal-oral contact.

Giardia lives in the intestine of infected humans and animals. It can be found in soil, food or water and surfaces that have been contaminated with feces from infected animal or human. In most people, the disease is self-limiting. Trophozoites are mainly excreted during the short-lived acute phase while cysts are voided in stools during the chronic phase that follows. Typical symptoms include diarrhoea, flatulence, upper intestinal cramps, abdominal distension, nausea and weight loss.

Microscopic examination is still the method of choice to detect a giardiasis. More and more ELISA methods are now available since microscopy is time consuming and need some skill.

Coris BioConcept has developed an rapid membrane test test that can detect cysts of *Giardia lamblia* in unconcentrated faecal samples within 15 minutes.

II. PRINCIPLE OF THE TEST

This is a ready-to-use test that is based on the use of a homogeneous membrane system technology with colloidal gold. The faecal sample must be diluted in the dilution buffer that is supplied with the test. A nitrocellulose membrane is sensitized with antibody to *Giardia lamblia* cysts.

The test's specificity is ensured by antibody specific to the *Giardia lamblia* cyst's membrane antigens that is conjugated to the colloidal gold. This conjugate is insolubilized on a polyester membrane.

When the strip is dipped into the faecal suspension, the solubilized 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 *G. lamblia* cysts the conjugate-cyst complex remains bound to the anti-Giardia reagent. The result – in the form of a red line that forms on the strip – is visible within fifteen minutes. The solution continues to migrate to encounter a second reagent (an anti-chicken IgY) that binds the surplus conjugate, thereby producing a second dark red line.

III. REAGENTS AND MATERIALS

Each kit contains Giardia- Strips, buffer, instruction for use and optimal components (for C-1513)

1. Individual Giardia-Strips

Each strip is sensitized with a anti-Giardia antibody that is specific to the *Giardia lamblia* cyst membrane antigens and a goat anti-chicken IgY antibody. These reagents are purified and adsorbed to nitrocellulose. The anti-Giardia conjugate is produced using antibody directed against the cyst membrane antigens and coupled to colloidal gold particles after purification.

2. Dilution Buffer (15 mL)

Saline solution buffered to pH 7.5 with TRIS and containing EDTA, Na₃ (<0.1%), a detergent, and charged proteins.

3. Instruction for use (1)

Required materials (supplied with C-1513 catalog number) :

- 3 or 5 mL test tubes
- Device for samples handling.
- cardboard rack

Materials available as options:

- Giardia control Test (Ref.: C-1093)

IV. SPECIAL PRECAUTIONS

-All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.

-The Giardia-Strips are for *in vitro* diagnosis only.

-Avoid touching the nitrocellulose with your fingers.

-Wear gloves when handling the samples.

-Dispose of gloves, swabs, test tubes, and sensitized strips in accordance with GLP.

-Never use reagents from another kit.

- If strips are stored in contenair, the contenair must be resealed as soon as the necessary number of strips for the operation has been removed, for the strips are sensitive to humidity. Make sure the dessicant packet is present.

- If strips are stored in individual pouches, pouch must be opened with care to avoid damaging the strip.

-Two green lines indicate the immunoreagents adsorption sites. The upper line is the migration control line and the lower line is the *Giardia lamblia* test line. The green color disappears during the test course.

-Discard the dilution buffer if it is contaminated with bacteria or mould.

-The reagents' quality cannot be guaranteed beyond their shelf-life dates or if the reagents are stored under inappropriate conditions.

-To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line placed under the arrows.

V. STORAGE

An unopened Giardia-Strip's kit may be kept at between 4 and 30°C and used until the shelf-life date on the packaging.

The strips remain stable for 15 weeks (**in the closed container**) after the tube is opened if they are kept between 4 and 30°C and in a dry environment.

The Giardia-Strip's kit must not be frozen.

Real-time long-term stability is under evaluation. Intermediate results are available at Coris- BioConcept.

VI. SAMPLES

The stool specimens must be tested as soon after they are collected. If necessary, they may be stored at 2-8°C for 24 hours or -20°C for longer periods of time.

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

VII. PROCEDURE

PREPARATIONS :

If the Giardia-Strip was kept at 4°C, let all the reagents warm up at room temperature before proceeding with the test.

Write the patient's name or specimen number on the test tube (foresee one test tube per sample).

Place the marked test tubes in a rack.

SPECIMEN PREPARATION PROCEDURE:

1. Add 0.5mL or 15 drops of the dilution buffer solution to each tube.
2. Plunge the inoculating loop containing the stool sample into the tube. The dilution ratio must be at most 4% w/v. For liquid samples, take 2 loops of 10 µL, for solid samples, take 1 loop.
3. Stir to homogenize the solution and let stand for 1-2 minutes.

- Discard the inoculating loop and immerse the sensitized strip in the direction indicated by the arrow.
- Let react for 15 minutes. Results must be read on wet strips after 15 minutes incubation.

VIII. INTERPRETING THE RESULTS

Results are to be interpreted as follows:

- 1 line (upper) = negative**
- 2 lines = positive**
- 0 line = invalid***

*The absence of the control line, which is the upper line, makes the result invalid. In this case, the sample must be retested.

The intensity of the test line may vary according to the quantity of antigens found in the sample. Any signal, even weak, on the test line must be regarded as a positive result. Nevertheless, the test is qualitative and cannot predict the quantity of antigens present in the sample. The clinical presentation and other test results must be taken into consideration to establish diagnosis.

During the drying process, a very faint shadow may appear at the test line. It should not be regarded as a positive result.

To store the results, let the strip dry after removing the absorbent material at its base.

IX. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend to check the test's performance regularly according to the laboratory's requirements. Giardia Control Test (C-1093) may be used for that purpose. Please refer to the Control Test package insert.

X. PERFORMANCE.

A. Detectability :

The detection limit has been evaluated by diluting a pure cysts solution (625000 cysts/mL) and results show that the number of cysts detected is of 3125 k/mL.

B. Sensitivity- Specificity (Correlation) :

An evaluation has been conducted on 100 human stool samples. Results were compared with those of an immuno-enzymatic rapid test.

Immuno-enzymatic rapid test Giardia Strip	Positive	Negative	Total
Positive	43	0	43
Negative	5	52	57
Total	48	52	100








Sensitivity: 89.6% (43/48)
Specificity: 100% (52/52)
Accuracy: 95% (95/100)

Positive Predictive value: 100%(43/43)
Negative predictive value: 91.2% (52/57)

C. Reproducibility

To check the intra-lot accuracy, same positive samples and a dilution buffer solution have been processed 15 times on sticks of the same production lot in the same experimental conditions. All observed results were correct as expected.

To check the inter-lot accuracy, same samples (positive and dilution buffer) were processed on three different production lots. All results were correct as expected.

REF	Catalogue number		Manufactured by
IVD	In vitro diagnostic medical device		Temperature limitation
	Contains sufficient for <n> tests	DIL SPE	Diluent specimen
	Consult instructions for use		Do not reuse
	Keep for the dry		Use by
DIL AS	Diluent assay	CONT NaN3	Contains Sodium azide

D. Interference

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: *Salmonella typhimurium*, Coronavirus, *Entamoeba histolytica*, *Entamoeba dispar*, several *E. coli* strains (including *E. coli O157:H7* and *E. coli c600-933W*), *Rotavirus*, *Adenovirus*, *Cryptosporidium parvum*, *E.coli F5*, *Salmonella enteritidis*. Tests for cross-reactivity has been tested on *Staphylococcus aureus* and found positive at high bacteria concentrations.

XI. LIMITS OF THE KIT

Giardia-Strip kit results must be compared with all other available clinical and laboratory information.

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

The Giardia-Strip is a chronic and acute-phase screening test. Stool specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold. If a sample is found negative despite off the symptoms observed, a second analysis must confirm the result.

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