



User's Manual

Canine / Feline Giardia Antigen One-Step

*For the detection of Giardia spp. antigen in
faeces samples*

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Please use only the valid version of the package insert provided with the kit.

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2. Introduction

Giardiasis is a intestinal disease caused by the parasite Giardia. The widespread protozoal parasite is found in humans and animals.

Once infected with Giardia, the parasite lives in the intestine shedded into the stool. Outside the body Giardia can survive for weeks or even months.

The parasite occurs commonly in densely populated environments such as kennels, pet shops and animal shelters.

Giardia cysts present in faeces and the environment are immediately infectious to other animals. The parasite can be contracted by ingesting these cysts from contaminated ground, food or drinking water, only a few cysts are needed to cause infection

Giardia infection can cause a variety of intestinal symptoms:

- Watery, soft, sometimes intermittent, diarrhoea
- Gas
- Foul-smelling, greasy poop that can float
- Stomach cramps or pain
- Upset stomach or nausea
- Dehydration

Symptoms of giardiasis generally begin by having 2 to 5 loose stools (poop) per day and progressively increasing fatigue. Other, less common symptoms include fever, itchy skin, hives, and swelling of the eyes and joints. Over time, giardiasis can also cause weight loss. However, the majority of infected dogs and cats do not present clinical signs. Prognosis is good in most cases but young, debilitated, geriatric or immunocompromised animals are at increased risk of complications

Therapy is needed in animals testing positive for Giardia and suffering from clinical signs.

3. Intended use of the test kit

This One-Step test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect Giardia antigen by use of a rapid Immunochromatic assay.

4. Principle of the test kit

The Giardia antigen One-Step is based on a chromatographic principle in which a monoclonal antibody reacts with epitopes of the Giardia. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the test zone "T". Giardia in the faeces sample that is applied to the test strip at the sample zone "S", will bind to the colloidal gold particles which then migrate to zone "T". A colour change in zone "T" indicates a positive test. Labelled colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

5. Contents

- 24 x Pouches, each containing 1 test strip, 1 pipette and 1 cotton swab
- 24 x Buffer vial
- 1 x Protocol

6. Handling and storage of specimens

The One-Step should be stored at room temperature ($\pm 21^{\circ}\text{C}$). An unopened package can be used until the expiry date. An opened package must be used immediately. If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test. Samples may be used fresh or may be kept frozen below -20°C before use.

7. Sample material

It is advised to test fresh faeces or rectal swab samples. Test the samples as concentrated as possible.

8. Precautions

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serials lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

9. Test protocol

1. Unpack the test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Take an individual faecal sample using the included swab.
3. The swab should be washed in the buffer vial (Figure 1).
4. Squeeze the swab to the wall of the buffer vial to leave as much liquid as possible.
5. Let the particles, if present, sink to the bottom. If necessary centrifuge the sample.
6. Add **4 drops** of the supernatant (upper liquid) of the buffer vial containing the sample, with the included pipette **slowly** to the sample zone "S" (Figure 3).
7. Read the result after 15 – 30 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

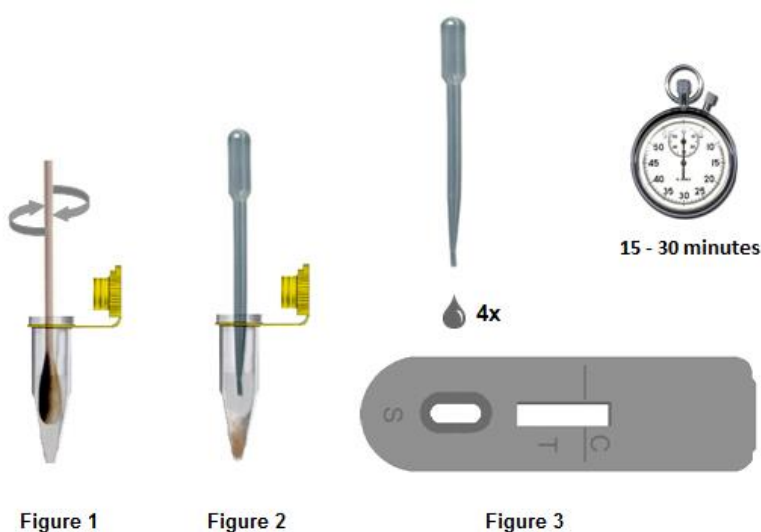


Figure 1

Figure 2

Figure 3

10. Validation of the test

To validate an EVL One-Step a control line should always be visible at control zone "C". If no control line is visible the test should be considered invalid.

Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

11. Interpretation of the test results

Positive:

Two lines are visible in zone “T” and in zone “C” (Figure A). The sample contains Giardia antigen.

Positive results may vary in optical density due to variations in parasite concentrations in the sample.

Weak positive:

Two lines are visible, a weak line in zone “T” and a line in zone “C” (Figure B). The sample contains low concentrations Giardia antigen.

Negative:

Only one line is visible in zone “C” (Figure C). The sample does not contain Giardia antigen.

Not valid:

No line is visible in zone “C” (Figure D). Repeat the test procedure with a new test cassette.

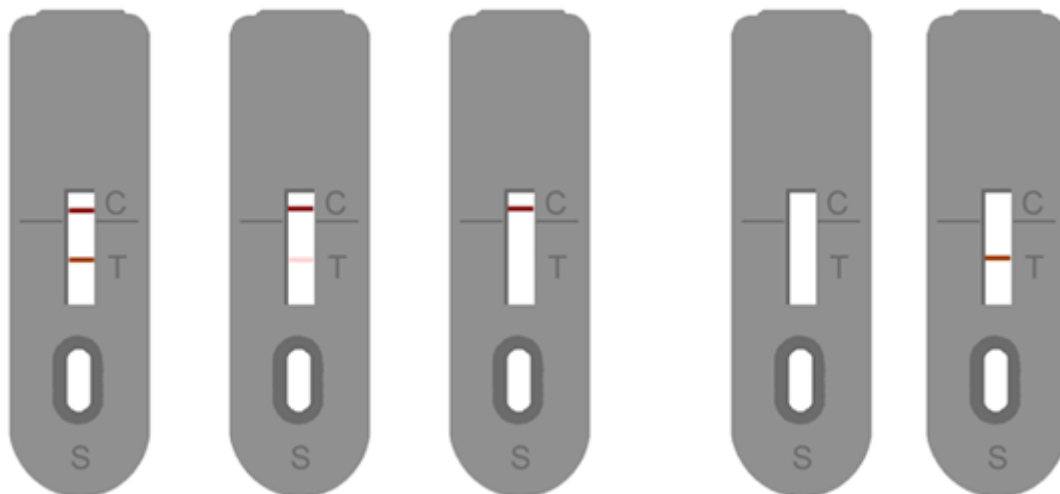


Figure A:
Positive

Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid



12. Symbols used with EVL ASSAYS

<u>Symbol</u>	<u>English</u>
	Consult instructions for use
	European Conformity
	In vitro diagnostic device
	For research use only
	Catalogue number
	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.