Version 01/2022

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*FAST*est® GIARDIA Strip

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In vitro diagnosticum

Test-kit for the qualitative detection of *Giardia duodenalis* antigens in the faeces of pocket pets, pets and farm animals

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® GIARDIA** Strip contains:
- 2, 10 or 25 dipsticks coated with monoclonal antibodies
- 2, 10 or 25 sample tubes with 2.0 ml buffer diluent each
- 1 instructions for use

STABILITY AND STORAGE

Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

LOT Lot number

In vitro diagnosticum

Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.

Follow instructions for use precisely

TL – TEST line, **CL** – CONTROL line, **LF** – Lateral flow

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from the use of this product.

ACCURACY

Sensitivity 97.2 %
Specificity 99.5 %
(Comparison Method: ELISA)

2. INTRODUCTION

Giardia is known to be one of the most common enteritic parasites in pocket pets, pets, farm and wild animals as well as in humans (zoonosis) world-wide. *G. duodenalis* occurs in varying genotypes (A to G), which differ in their infectivity and their host spectrum. Types A and B have zoonotic potential.

Newborns and young animals are mostly affected. Prevalences vary in cats and dogs, depending on age (>70 % under 1 year), husbandry (10 % in single husbandry up to 100 % in breedings and animal shelters) and immune status.

Transmission (direct contact, by contaminated food, water, objects, grooming and vectors like flies etc.) happens fecal-orally by ingestion of highly infectious and very resistant cysts being discharged by other animals or humans. Only five to ten cysts are enough to cause an infection.

G. duodenalis has an asexual life cycle. In the duodenum of the infected animals, two so-called trophozoites emerge from the incorporated cysts (excystment). These multiply by duplication and attach via suckers to the duodenal surface. Free trophozoites turn into their permanent forms, the cysts (encystment), especially in the ileum. These are excreted in large amounts (10^7/g faeces) and mostly intermittent, i.e. not with every defecation. The prepatent period averages 5 to 16 days.

The main symptom of giardiasis is diarrhoea, more or less intensive, that can run from symptomatic (acute, chronic, self-limiting, periodic-intermittent or continuous) to asymptomatic. Independent on the progression, cysts and/or trophozoites can be egested (primarily with strong diarrhoea).

Giardia cysts can be differentiated from cysts of different coccidia species only by microscopically experienced people. This is also true for Giardia and *Tritrichomonas foetus* trophozoites. For that reason, modern aetiological coprodiagnostics using ***FAST*est® GIARDIA** Strip should be preferred to microscopical proof.

For epidemiological reasons, all clinically symptomatic and clinically asymptomatic animals should be tested with ***FAST*est® GIARDIA** Strip. This enables the veterinarian in the clinic to introduce a specific treatment as well as a broad prophylaxis.

3. INFORMATION ON THE SPECIMEN MATERIAL

Due to the normally inhomogeneous or nest-like dissemination of antigens in the faeces, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling.

For the test, the required amount of faeces as described in point 4b/Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spoon.

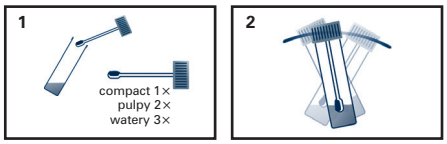
Non-cooled (**15–25 °C**), the sample should be tested within 4 hours! At **2–8 °C**, the sample can be stored up to 4 days, permanently **at minimum −20 °C**.

Keep in mind that the sample material, as well as all used test-kit components, should have reached room temperature at the time of application.

Endogeneous and exogeneous interfering substances of the sample (e.g. proteases, mucosa components, blood, but also viscosity, pH-value as well as grass and cat litter) **can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on the TL and CL.**

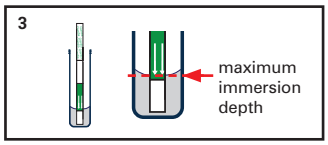
4. SPECIMEN COLLECTION AND PREPARATION

a. Open the sample tube with the buffer diluent.
b. Mix the faeces sample homogeneously (applicator, vortexer). Then mix the required sample volume (**compact: 1 level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of faeces**) steadily into the buffer diluent (fig.1).
c. Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).
d. For sedimentation of gross faeces particles place the sample tube on a flat and horizontal surface for 1–5 minutes.



5. TEST PROCEDURE

1. Remove the dipstick from its foil pouch shortly before use.
2. Introduce the dipstick vertically and with the arrows pointing downwards into the sample tube for at least 1 minute. The liquid level (meniscus!) must not exceed the white arrowheads (fig.3).
3. Remove the dipstick from sample tube as soon as the sample-buffer mixture (SBM) has reached the CL. If so, the blue CL will appear slowly but surely (fig.4/5). If the CL does not appear after 5–10 minutes, a new SBM must be prepared and sedimented for at least 5 minutes. The dipstick must be held only in the supernatant until the LF has reached the CL (see also 7. Precautions for users*).
4. Place the dipstick on a flat and horizontal surface for incubation.



6. READING OF THE TEST RESULT

Read the test result after **5 (max.10) minutes**. Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

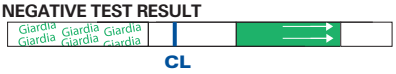
POSITIVE TEST RESULT (fig.4)
A red TEST line **of any intensity** (varying from very weak to strongly intensive) **and** a blue CONTROL line appear.

NEGATIVE TEST RESULT (fig.5)
Only a blue CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly. Please also note issue 9.4.

INVALID TEST RESULT
No CONTROL line visible. The test should be repeated using a new dipstick *.

fig.4
POSITIVE TEST RESULT

fig.5
NEGATIVE TEST RESULT



7. PRECAUTIONS FOR USERS

- The guidelines for working in medical laboratories must be observed. It is recommended to wear disposable gloves and other personal protective equipment (protective clothing, possibly a face mask). Wash and disinfect hands after completing the test.
- Label sample material and associated sample tube to ensure a precise assignment.
- Use a new sample tube for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin/eye contact and/or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

* To avoid an application error/external influence (e.g. too much sample material, too short sedimentation time, components in the faeces that clog the pores of the suction pad), the test can be repeated. Use a new dipstick and carefully observe the sample preparation. It is advisable to only hold the dipstick in the supernatant when repeating the test until the LF has reached the CL.

8. TEST PRINCIPLE

The ***FAST*est® GIARDIA** Strip is based on latest rapid immunochromatographic technique.

Surface antigens of intact or fractionated *Giardia duodenalis* cysts and/or trophozoites will react at the conjugate pad with mobile antibodies bound to red latex particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed monoclonal anti-Giardia antibodies (mAbs) producing a red TEST line (**TL**). The intensity or width of the TL depends on the concentration of *Giardia* antigens in the introduced amount of sample.

A correct test procedure will be indicated by a second, blue CONTROL line (**CL**).

The used mAbs guarantee a high level of specificity for the aetiologic detection of *G. duodenalis* antigens.

The ***FAST*est® GIARDIA** Strip does not rely on the presence of intact cysts and/or trophozoites.

9. INFORMATION FOR THE INTERPRETATION

1. The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
2. Any non-described colour or contour variation of TL and CL within the indicated incubation time or after more than 10 minutes (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
3. TL can vary both in intensity (from weak to intense red) and width. Therefore, any red line appearing within the required incubation time is to be interpreted as a positive test result.
4. Because of intermittent antigen shedding, with ongoing diarrhoea a single negative test result should be confirmed by testing a **serial faeces sample (individual testing of at least three consecutive faeces samples)**.
5. Drug therapy can lead initially to an increase of cyst and/or trophozoite shedding. Reinfections due to the prepatence could also appear. Both could result in positive test results. First of all, therapy control should be based on clinical symptoms (decrease of diarrhoea in quantity and quality), not only of a single test result.
6. Be aware, every dog or cat tested positive is considered potentially infectious for animals and humans (zoonosis!), especially for kids!