Version 08/2023

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*FAST*est®
CRYPTO-GIARDIA Strip

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of *Cryptosporidium* spp. and / or *Giardia duodenalis* antigens in feces 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® CRYPTO-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 96.7 % (*C.* spp) / 96.4 (*G. duodenalis*)
Specificity 99.9 % (*C.* spp.) / 98.6 % (*G. duodenalis*)
(Comparison Method: Carbol Fuchsin / ELISA)

2. INTRODUCTION

Cryptosporidia (*Cryptosporidium parvum*) and Giardia (*Giardia duodenalis*) are world-wide spread protozoan zoonotic pathogens colonising the intestinal tract of small pets, pets and farm animals as well as of humans. Neonates and young animals are predominantly affected. The prevalences vary depending on age, husbandry and immune status of the animals.

The transmission (direct contact, via contaminated food, water, objects, grooming as well as via flies etc.) occurs fecal-orally by uptake of the highly infectious and environmentally resistant oocysts or cysts, respectively, excreted by other animals. The infectious dose is 5 to 10 *G. duodenalis* cysts or 50 to 100 *C. parvum* oocysts. The life cycles of both protozoons are complex and show different states. *C. parvum* builds 2 permanent states: thin-walled autoinfective oocysts (20 %) and thick-walled oocysts (80 %) which are excreted by defecation. *G. duodenalis* forms a vegetative trophozoite state and a permanent cyst state, which is excreted by defecation. Excretion of both permanent states occurs in high concentrations and often intermittently. The permanent states are very resistant and can remain infectious for months. Asymptomatic animals can serve as chronic carriers. The prepatent period averages from Ø 5 to 16 days for *G. duodenalis* and Ø 2 to 4 days for *C. parvum*.

Both agents cause diarrhoea of different severity codes. Diarrhoea could occur from symptomatic (acute, chronic, self-limiting, periodic-intermittent or continuous) to asymptomatic. Independent on the progression, oocysts, cysts and / or trophozoites can be egested (primarily with strong diarrhoea). Immunosuppression, lack of appetite, pyrexia and dehydration may occur, as well as death. Co-infection with Rota and Corona viruses as well as *Tritrichomonas foetus* (cat) and enterotoxic *E.coli* often occurs.

For epidemiological reasons, all animals, clinical symptomatic and clinical asymptomatic, should be tested with ***FAST*est® CRYPTO-GIARDIA** Strip. This enables the veterinarian on-site to state an aetiological diagnosis and 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 feces, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling.

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

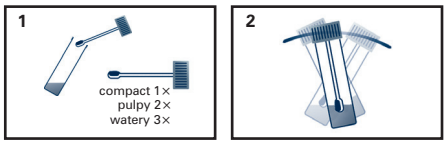
Non-cooled (**15–25 °C**), the sample should be tested within 4 hours! At **2–8 °C**, the sample can be stored up to 4 days, permanently **at minimum −20 °C**.

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.



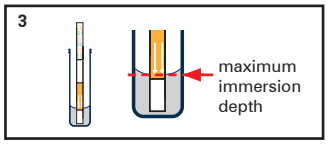
b. Mix the feces sample homogeneously (applicator, vortexer). Then mix the required sample volume (**compact: 1 level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of feces**) steadily into the buffer diluent (fig.1).

c. Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).

d. For sedimentation of gross feces 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 soonest the sample-buffer mixture (SBM) has reached the CL. If so, the green CL will appear slowly but surely (fig.4 / 5). If the CL will 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.

DOUBLE NEGATIVE TEST RESULT (fig.4)

Only the green CONTROL line appears. None of the two TEST lines (red / blue) appear.

NEGATIVE-POSITIVE, POSITIVE-NEGATIVE OR DOUBLE POSITIVE TEST RESULT (fig.5)

A red (*G. duodenalis*) and / or blue (*C.* spp.) TEST line **of any intensity** (varying from very weak to strongly intensive) and a green CONTROL line appear.

G. duodenalis (red) positive, *C.* spp. negative

G. duodenalis negative, *C.* spp. (blue) positive

G. duodenalis (red) positive and *C.* spp. (blue) positive

INVALID TEST RESULT

No green CONTROL line visible. The test should be repeated using a new dipstick*.

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 and a new dipstick 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® CRYPTO-GIARDIA** Strip is based on latest rapid immunochromatographic technique using two unique monoclonal antibodies for the detection of *C.* spp. and *G. duodenalis* antigens.

These antigens will react in the conjugate pad area with two different mobile monoclonal antibodies (mAbs), which are bound to coloured latex particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed mAbs in the area of the TEST lines producing one and / or two TEST lines (**TL**, red for *G. duodenalis* and blue for *C.* spp.).

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

In contrast to microscopic detection methods depending on intact oocysts / trophozoites and / or cysts, the ***FAST*est® CRYPTO-GIARDIA** Strip detects surface antigens (cell wall antigens) of all intact *Cryptosporidium* or *Giardia* forms as well as their cell wall fragments.

The mAbs guarantee a high degree of specificity for the aetiological detection of *C.* spp. and *G. duodenalis* antigens.

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- 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.
- The intensity of the colour of both TLs can vary, depending on the concentration of antigens in the feces sample.
- Due to intermittent antigen shedding a negative *C.* spp. and / or *G. duodenalis* test based on an ongoing diarrhoea should be confirmed with a new feces sample or with a serial fecel sample (individual testing of at least three consecutive feces samples) within 2–3 days.
- „Intensity of diarrhoea" can vary individually (age, immune status) or could not appear despite of a positive test result (asymptomatic eliminators!)
- Due to medical therapy, *C.* spp. surface antigens could be shed short-term and in a higher rate because of the additional shedding of vegetative *C.* spp. cyclus forms and cause positive test result despite of therapy for a short time.