

I Introduction

Cryptosporidia (*C. parvum*) and Giardia (*G. duodenalis*) are world-wide spread protozoan parasitic 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 cysts excreted by other animals. The infectious dose is 5 to 10 *G. duodenalis* cysts or 50 to 100 *C. parvum* oocysts.

Both pathogens cause diarrhoea of different severity codes. These can run from symptomatic to asymptomatic. Independent of the progression, cysts and / or trophozoites can be egested (primarily with strong diarrhoea). In combination with immunosuppression, lack of appetite, pyrexia and dehydration may occur, as well as death.

Coinfections with Rota and Coronaviruses as well as *Trichomonas foetus*, mainly in cats, are often. For epidemiological reasons, all animals, clinical symptomatic and clinical asymptomatic, have to be tested with **FASTest® CRYPTO-GIARDIA** Strip. This enables the veterinarian in the clinic an etiological diagnostics and therefore to introduce a specific treatment as well as a broad prophylaxis.

II Test principle

The **FASTest® CRYPTO-GIARDIA** Strip bases on an immunochromatographic "sandwich principle" for the detection of *C. parvum* and *G. duodenalis* surface antigens (*C. parvum* oocysts and all vegetative forms of *C. parvum*; cysts and / or trophozoites of *G. duodenalis*) in feces samples. When antigens are present in the sample, these react in the conjugate area with two different mobile monoclonal groups of antibodies. These antigen-antibody complexes flow through the membrane ("lateral flow") and are caught in the area of the tests lines by membrane fixed catcher antibodies, forming one and/or two more or less coloured test lines. The antibodies used herein guarantee a high degree of specificity for the detection of *C. parvum* and *G. duodenalis* antigens in the feces sample. When no antigens are present, no test lines can be seen. The correct procedure of the test is shown by formation of a third line, the control line.

III Test-kit components

- 1 Test-kit FASTest® CRYPTO-GIARDIA** Strip contains:
- 2 or 10 dipsticks coated with monoclonal antibodies against *C. parvum* or *G. duodenalis*
 - 2 or 10 sample tubes with 2.0 ml buffer diluent
 - Instructions for use

IV Storage and stability

- Store at room temperature (15–25°C).
- Stored correctly, the test-kit kann be kept until end of expiry date.
- Avoid the test-kit being subjected to excess heat or freezing.

V. Information on the test sample material

FASTest® CRYPTO-GIARDIA Strip can be used for dog and cat. Due to the nest like dissemination of *C. parvum* and *G. duodenalis* antigens in the feces matrix, the sample has to be mixed up homogeneously (spatula, vortex mixer) before testing. Constituents like grass, mucosa membrane, extreme blood feces should not be placed into the sample tube to avoid unspecific reactions or migration interferences ("lateral flow"). Exceeding sample volume could lead to brownish staining of the test and / or control lines or to a flowback of C line material into the sample buffer fluid (no or weak appearance of the C line). Both could lead to a complicated or impossible test interpretation. The test has to be repeated using adequate (less) sample volume. The sample material could be stored for 2 days at 2-8 °C. For a longer storage, the original feces sample or the supernatant of the sample tube could be stored at -20 °C or more.

VI Special information

- FOR VETERINARY USE ONLY!
- Do not use the test once the expiry date has passed.
- Do not use reagents from different kits.
- The sample material must be seen as potentially infectious and should be disposed of professionally after use.
- Follow instructions for use precisely.

VII 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 use of this product.

FASTest® CRYPTO-GIARDIA Strip
ad us. vet.

Test-kit for the detection of
Cryptosporidium parvum and/or *Giardia duodenalis*
in the feces of the dog and cat

In vitro diagnostics

INSTRUCTION FOR USE

DIAGNOSTIK
MEGACOR

Lochauerstraße 2 • 6912-Hörbranz AUSTRIA
www.megacor.com • info@megacor.at

VIII Test preparation

1. Remove as many sample tubes as needed from the test-kit, label them with a patient name or ID number.

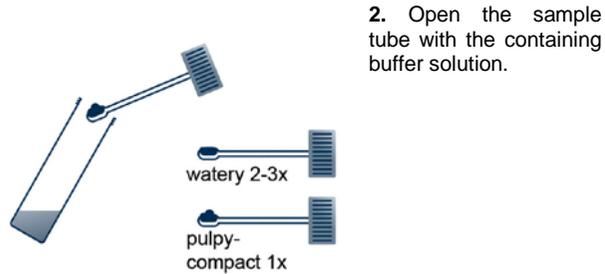


fig.1

3. Mix the feces sample homogeneously (applicator, vortexer). Open the sample tube and stir the required feces sample volume into the buffer diluent (fig. 1: pulpy-compact: 1 (one) resp. fluid-watery 2 (two) – max 3 (three) coated spoons of feces).



fig.2

4. Close the tube tightly and rotate it easily to get the feces-buffer fluid mixed homogeneously (fig. 2).

5. For optimal sedimentation of greater particles, put the sample tube for approx. 1 to 5 minutes on a flat and horizontal surface.

IX Test procedure

1. Remove the dipstick from the pouch shortly before use. Do not touch either test or control zones of the dipstick with your fingers.

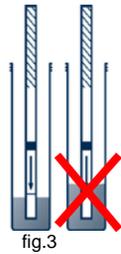


fig.3

2. Introduce the dipstick vertically with the arrows pointing downwards into the sample tube with the feces-buffer fluid for at least 1 minute (fig. 3). In doing so, the feces-buffer fluid surface should not exceed the lower limit of the yellow plastic cover labelled with white arrows (too much feces-sample volume!).

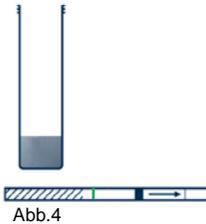


Abb.4

3. Remove the dipstick from sample tube (feces-buffer fluid) soonest the sample buffer diluents-fluid has reached the control line. If so, the green control line will appear slowly but surely (fig. 4).

4. Place the dipstick on a flat surface (fig. 4).

X Interpretation of the test results



Read the test results 5 minutes after the dipstick has been placed in the sample tube with feces-buffer fluid.

An interpretation of the test results after 10 minutes is not acceptable.

The formation of a green control line shows a correct test procedure, independent on a negative or positive test result.

The intensity of the colour of the two test lines can vary, depending on the concentration of antigens in the feces sample.

Double negative test result

C. parvum and *G. duodenalis* negative

Only the green control line appears.

None of the two test lines (red/blue) appear.



Due to intermittent antigen shedding a negative *C. parvum* and/or *G. duodenalis* test based on an ongoing diarrhoea should be confirmed with a new feces sample or with a fecal sample collection from 2-3 days.

Negative-positive, positive-negative or double positive test result

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



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



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



Inconclusive test result

The dipstick shows no green C line or only one or two T lines. In both cases, the test should be repeated using a new dipstick.



Any colour variation of the test lines are to be interpreted as unspecific reactions and do not have any diagnostic value.

Common information

The interpretation of the test results should be considered in combination with anamnesis, clinic, therapy and prophylaxis measures.