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## INSTRUCTIONS FOR USE



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## 1. INFORMATION ON THE TEST-KIT

### TEST-KIT COMPONENTS

1 test-kit **FASTest® CRYPTO** Strip contains:

- 2 or 10 dipsticks, coated with monoclonal antibodies
- 2 or 10 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 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, **SA** – surface antigens

### 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%

Specificity 99.9%

(Comparison Method: Carbol Fuchsin Micro)

## 2. INTRODUCTION

Diarrhoea can lead to severe courses of disease up to death for all species. Among the diverse diarrhoea pathogens in pocket pets, pets and farm animals, especially *Cryptosporidium parvum* (*C. parvum*) is a great challenge for the veterinarian due to its common appearance and zoonotic potential. In reptiles, *C. parvum* often is diagnosed as non-pathogenic intestinal by-passer (infected food animals). *C. parvum* shedding reptiles therefore are a potential infection source for other animals as well as the owners (zoonosis).

Cryptosporidia form two types of infectious oocysts: 20% are thin-walled and stay in the host, where they cause reinfection through autoinfection. The remaining 80% are thick-walled and are excreted intermittently, i.e. not with every defecation, as dormancy stages. These are very resistant and can remain infectious for months. They can infect other animals as well as humans via drinking water (infectious dose Ø 10–100 oocysts).

Prevalences are very variable, in calves 25–100%, depending on the stock. Lambs, piglets and foals are affected, too. In german hedgehogs, prevalences of 21.6% (spring) and 36.6% (autumn) are discovered. Dogs (Germany, Austria ca. 0.5–1%) and cats (Germany, Austria ca. 1–3%) show considerably lower prevalences.

Clinical symptoms can vary depending on age and immune status of the animal. Neonates and young animals are predominantly affected. Caused by the high infectiveness, often a population problem arises. Double infections are not uncommon. Special attention should be paid in the fact that Cryptosporidia play an important role independent of the diarrhoea problem (asymptomatic shedders).

Therefore, **FASTest® CRYPTO** Strip enables the veterinarian to prove *C. spp.* early, specifically and on-site in pocket pets, pets and farm animals and therefore to introduce specific therapy, hygiene and prevention measures immediately.

## 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 point 4b/Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spoon.

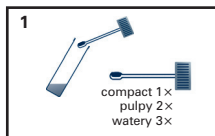
Non-cooled (15–25°C), the sample should be tested within 4 hours! At 2–8°C, the sample can be stored up to 4 days, permanently at minimum –20°C.

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.

**Endogenous and exogenous 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

- Open the sample tube with the buffer diluent.
- Mix the feces sample homogeneously (applicator, vortexer). Then mix the required sample volume (**compact: 1**

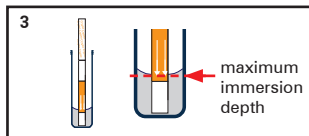


level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of feces) steadily into the buffer diluent (fig.1).

- Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).
- For sedimentation of gross feces particles place the sample tube on a flat and horizontal surface for 1–5 minutes.

## 5. TEST PROCEDURE

- Remove the dipstick from its foil pouch shortly before use.
- 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).
- 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\*).
- 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.

### 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 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 **FASTest® CRYPTO** Strip is based on latest rapid immunochromatographic technique. Positive feces samples contain *C. spp.* surface antigens as well as all of the vegetative cycle forms of *C. spp.*. These antigens 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-*Cryptosporidium* antibodies (mAbs) producing a red TEST line (**TL**). These mAbs guarantee a high level of specificity for the aetiological detection of *C. spp.* antigens.

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

The intensity or width of the TL depends on the concentration of *C. spp.* antigens in the introduced amount of sample. **FASTest® CRYPTO** Strip does not rely on the presence of intact *C. spp.* oocysts and/or vegetative cycle forms.

## 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.
- 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.
- Be aware, every animal tested positive is considered potentially infectious (ZOOONOSIS!) for humans, especially for kids!

### Interpretation of a **negative FASTest® CRYPTO** Strip

- No infection with *C. spp.*
- Infection, but feces sample does not contain *C. spp.* SA due to intermittent antigen shedding
- Infection, but concentration < 50–100 oocysts / 100 µg feces.

With ongoing diarrhoea and a **single** negative test

→ Calf: new test within max. 24h using a new feces sample (due to limited onset of therapy)

→ Other species: new test within 7 days using a new feces sample (optimal: serial feces sample\*\*); Ø prepatency time 7 days, depending on infection dose)

### Interpretation of a **positive FASTest® CRYPTO** Strip

**Attention: The stronger the intensity and the earlier the appearance of the TL, the higher the concentration of *C. spp.* SA.**

- „Intensity of diarrhoea“ can vary individually (age, immune status) or could not appear despite of a positive **FASTest® CRYPTO** Strip (asymptomatic eliminators!)
- Due to medical therapy, *C. spp.* SA could be shed short-term and in a higher rate because of the additional shedding of vegetative *C. spp.* cycle forms.
- Despite treatment, reinfections with “consisting pathogen reservoirs” in the animals’ environment and therefore a short prepatency time (Ø 7 days) can lead to a positive test result.

\*\* Serial feces sample: Individual testing of at least three consecutive feces samples. Only a multiple negative feces test rules out a *Cryptosporidium* infection!