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*FAST*est® CRYPTO-ROTA D2T

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of *Cryptosporidium parvum* and Rotavirus antigens in feces of pocket pets, pets and farm animals

INSTRUCTIONS FOR USE

Supplied Excusively To The UK Veterinary Market By
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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® CRYPTO-ROTA** D2T contains:
- 10 revolver test tubes **R** with 2 dipsticks each, coated with monoclonal antibodies against *C. parvum* and Rotavirus
- 10 sample tubes **P** 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
R - Revolver test tube, **P** – sample tube

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.

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*) and Rotavirus (RV) are a great challenge for the veterinarian due to their common appearance and their zoonotic potential.

Especially in cattle population, Rotavirus is widely spread (seroprevalence up to 100 %). Recent studies in Germany with small animals have shown prevalences in dogs and cats of 7 % and 8 %, respectively.

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.

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 as well as Rotavirus play important roles independent of the diarrhoea problem (asymptomatic shedders).

Therefore, ***FAST*est® CRYPTO-ROTA** D2T enables the veterinarian to prove both pathogens 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 issue 4.b/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 **P** with the buffer diluent.

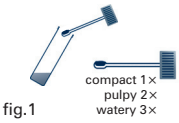

fig.1


fig.2


fig.3

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

c. Close **P** tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2). No sedimentation required. Immediately start with the test procedure 5.1.

5. TEST PROCEDURE

1. Remove the revolver test tube **R** from the test-kit shortly before use.
2. Open **R**, remove the red desiccant disk (fig.3) and introduce **P** containing the sample-buffer mixture (SBM) vertically into **R** (fig.4).
3. Turn the cap of **R** until hearing a clicking noise twice (fig.5). The SBM of **P** will run into **R**. To ensure a proper LF, the liquid level must not exceed the white sucking pad of the dipstick (fig.6, see also 7. Precautions for users*).
4. Place **R** on a flat and horizontal surface for incubation.

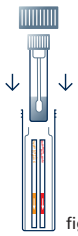
fig.4

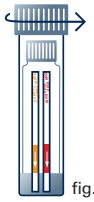
fig.5

fig.6

6. READING OF THE TEST RESULT

Read the test result after **5 (max. 10) minutes** by turning **R** slowly around its own axis (fig.5). Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

POSITIVE TEST RESULT (fig.7)
A red TEST line **of any intensity** (varying from very weak to strongly intensive) **and** a blue CONTROL line appear.

NEGATIVE TEST RESULT (fig.8)
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 **P** and **R** *.

fig.7
POSITIVE TEST RESULT

fig.8
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, associated sample tube **P** and revolver test tube **R** to ensure a precise assignment.
- Use a new sample tube **P** and revolver test tube **R** 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.

* If the LF does not appear one minute after closing the cap of **R** completely, swing **R** carefully 1–2× in a circle.

If the LF still does not appear, maybe a too large amount of feces was used. The test must be completely repeated/rescheduled. Carefully observe the advice for sample preparation (also see 4.b/ Specimen collection and preparation and fig.1).

8. TEST PRINCIPLE

The ***FAST*est® CRYPTO-ROTA** D2T is based on latest rapid immunochromatographic technique. For each of both pathogens of ND complex, there is an appropriate dipstick placed in the revolver test tube **R**. The dipsticks are characterised in colour as well as in writing: **Crypto = orange, Rota = red.**

The antigens in the feces sample will react at the conjugate pad with mobile monoclonal pathogen-specific antibodies (mAbs) bound to red latex particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed mAbs producing a red TEST line (**TL**). These mAbs guarantee a high level of specificity for the aetiologic detection of the particular pathogen.

The intensity or width of the TL depends on the concentration of each antigen in the introduced amount of sample.

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

In contrast to microscopic test methods depending on intact oocysts, the dipstick for *C. parvum* of ***FAST*est® CRYPTO-ROTA** D2T also detects surface antigens of vegetative Cryptosporidium forms or fragments of all Cryptosporidium forms, respectively.

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.
- The stronger the intensity and the earlier the appearance of the respective TL, the higher the concentration of *C. parvum* and/or Rotavirus antigens.
- 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.
- Because of intermittent antigen shedding, with ongoing diarrhoea a single negative *C. parvum* and/or Rotavirus test result should be confirmed by testing a serial feces sample (individual testing of at least three consecutive feces samples).
- „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. parvum* surface antigens could be shed short-term and in a higher rate because of the additional shedding of vegetative *C. parvum* cyclus forms and cause positive test result despite of therapy for a short time.