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*FAST*est® ROTA Strip

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Rotavirus group A antigens in 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® ROTA** 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 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 97.5 %
Specificity 99.9 %
(Comparison Method: E.M., ELISA)

2. INTRODUCTION

Rotavirus from the family of Reoviridae is found world-wide and acts as the causative agent of severe diarrhoea (gastro-enteritis) in almost every mammal species (especially cattle, pig, dog, cat and horse), birds and humans. Rotavirus is considered to be species specific, but can also be transmitted from species to species, then causing a rather asymptomatic course of disease.

The transmission from animal specific Rotavirus to humans is scientifically proven, so that the zoonotic potential cannot be denied.

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

Rotavirus is highly contagious and shed in large amounts via faeces. Due to the high tenacity, the low infection dose and the short incubation period of 1.5 hours to 2 days, Rotavirus can cause severe diarrhoea (dehydration, loss of weight, acidosis) within a short time, which can induce serious onsets in group husbandry (mortality in calves up to 10 %).

The awareness of the potential hazard of other live stocks/animal species as well as humans by dumping infectious agents in surface waters and agricultural used areas (fertilization) increases constantly.

This, as well as the increasing close human-animal contact with pets, is a great diagnostic challenge for the veterinarian. Using ***FAST*est® ROTA** Strip on-site allows the veterinarian a rapid and specific detection of Rotavirus. This enables the veterinarian to initiate specific therapy and prevention measures.

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 mandatory 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.

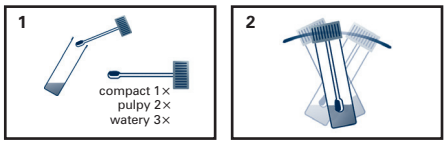
Non-cooled (**15–25 °C**), the sample should be tested within 4 hours! At **2–8 °C**, the sample can be stored up to 4 days, permanently **at minimum −20 °C**.

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.**

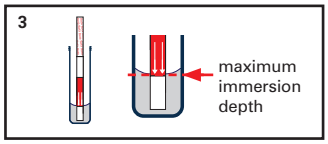
4. SPECIMEN COLLECTION AND PREPARATION

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 precautions for users *).
4. Place the dipstick on a flat and horizontal surface for incubation.



6. READING OF THE TEST RESULT

5 min

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 ***FAST*est® ROTA** Strip is based on latest rapid immunochromatographic technique using two unique monoclonal antibodies.

Positive faeces samples contain Rotavirus antigens. These antigens will react in the conjugate pad area with mobile monoclonal antibodies against Rotavirus group A (anti-Rv mAbs), which are bound to red latex particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-Rv mAbs producing a red TEST line (**TL**). These anti-Rv mAbs guarantee a high level of specificity for the aetiologic detection of Rotavirus.

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

The intensity or width of the test line depends on the concentration of Rotavirus antigens in the tested sample.

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 detection of Rotavirus using the ***FAST*est® ROTA** Strip is an important but only one diagnostic component to verify the diagnosis "Rotavirus infection".
- In view of the multifactorial origins of the neonatal diarrhoea complex, even with a positive test result it must be considered that other diarrhoea causing pathogens can be present in the sample, too.
- In case of a reasonable suspicion of an infection, a single negative test result should always be confirmed by testing of a second faeces sample.
- 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)**.