8. INTERPRETATION OF TEST RESULTS:

TESTINTERPRETATION:

The test result has to be read after an incubation time of 5 minutes by rotating the "Revolver-Test tube" (**R**) around its own axis - read one by one (fig. 5). Due to concentration of antigen material positive results may be observed earlier. Any colour variations which occur after 10 minutes should not be interpreted. The test result must be interpreted in the context of all available case history, clinical information, therapy and prophylaxis possibilities.

POSITIVE TEST RESULT (fig.6)

There is a clearly signed weak to strong intensive pink/purple TESTline in the TESTzone **and** a clearly signed weak to strong intensive pink/purple CONTROLline in the CONTROLzone. The sample include in respective positive case antigens of C.parvum (light green) and/or F5 (light blue) and/or BCV (yellow) and/or RV (red-orange).

NEGATIVE TEST RESULT (fig.6)

There is no pink/purple TESTline in the TESTzone **and** a clearly signed intensive pink/purple CONTROLline in the CONTROLzone. The sample include in respective negative case no antigens of C.parvum (light green) and/or F5 (light blue) and/or BCV (yellow) and/or RV (red-orange).

INCONCLUSIVE TEST RESULT

There is no or just one weak to strong intensive pink/purple TESTline in the TESTzone and no visible CONTROLline in the CONTROLzone.

⇨ Repetition by using a new "Revolver-Test tube" (**R**)!

Fig. 5

TEST RESULT
negative positive

Fig. 6

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.

*FAST*est® D4T bovine ad us.vet.

IN VITRO DIAGNOSTICUM

Testkit for the detection of Cryptosporidium parvum, bovine Coronavirus (BCV), E. coli-K99 (F5) and Rotavirus in feces of bovines

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INSTRUCTIONS FOR USE

1. INTRODUCTION:

Diarrhea caused by bovine Coronavirus (BCV), Cryptosporidium parvum (C. parvum), enterotoxic Escherichia coli K99 (F5) and Rotavirus (RV), is a major cause of severe illness and death in calf rearing. Especially C. parvum, but even Rotavirus are responsible for infectious diarrhea in domestic animals and humans (cryptosporidiose = zoonosis). Subject to age and immune state clinical signs could vary. Especially calves within the first two weeks of life (neonatal diarrhea, ND, scours) diarrhea occurs often with high mortality! Due to the high infection pressure a general diarrhea problem could occur in the farm. In this case aetologic diagnosis of all bovines regardless of which age (asymptomatic shedders) and a check-up of feeding and keeping management. Cryptospiridiose is a special disease of the ND complex because of its specific therapy. Therefore early diagnostic is an assumption for a successful therapy because medication has to begin within 24hours after onset of diarrhea! For this an early detection is necessary for a successful treatment as well as a fast beginning of prophylactical measures.

2. TESTPRINCIPLE:

***FAST*est® D4T bovine** is based on the newest immunochromatographic lateral-flow technique. There is to find an own membrane for each of the 4 diarrhea disease pathogens in the "Revolver-Test tube" **(R)**, which are coloured and labeled as follows: ND-Crypto = light green; ND-E.coli K99 (F5) = light blue; ND-Coronavirus = yellow; ND-Rota = orange-red. If the feces contains surface antigens of C. parvum oocysts (Anti-C.p.-mAb, or all vegetative forms), E. coli (F5) bacterium, bovine Coronavirus or Rotavirus, the antigens react in the conjugate pad area with mobile monoclonal Anti-agent-specific antibodies (mAB) which are bond to gold particles. This antigen-antibody complex migrates along the membrane (lateral flow) and will be bond in the TESTzone to respective agent specific and membrane fixed mAB which produce a more or less pink-purple TESTline. The used anti-agent-specific mAB ensure a high specificity and sensitivity for the exclusive detection of the respective antigens. The correct test procedure is proved by the occurrence of a second, intense pink-purple CONTROLline in the CONTROLzone. The intensity/width of the TESTline depends on the concentration of each of the 4 antigens in the tested sample volume. ***FAST*est® D4T bovine** detects in contrast to microscopic test methods which are depending on intact oocysts also surface antigens of vegetative Cryptospora forms repectively parts of all Cryptosporida forms.

3. TESTKIT COMPONENTS:

1 Testkit *FAST*est® D4T bovine contains:

- 10 Revolver-Test tubes (labeled with R), each with 4 Test membranes, coated with monoclonal Antibodies against BCV, E.coli(F5), C. parvum or Rota
- 10 Sample tubes with 2 ml Buffer diluents labeled with (**P**)
- Instructions for use

4. STORAGE AND SHELF LIFE:

• Store at room temperature (15-25°C)
• Stored correctly the product can be kept up to the expiry date.
• Avoid the Test kit being subjected to excess heat or freezing.

5. INFORMATION ON THE TEST SAMPLE MATERIAL:

***FAST*est® D4T bovine** is just for the detection of diarrhea at calves. Due to the nest like dissemination of the respective antigen in the matrix the feces sample has to be mixed up homogenous (spatula, vortex-mixer). Constituents like grass, mucosa membrane, extreme bloody feces should not be placed into the sample tube to avoid "unspecific reactions" resp. migration interferences. Immoderate sample volume could lead to brownish staining of the test and/or CONTROLlines resp. to a flowback of C-line materials into the sample buffer fluid (nor or weak appearance of the CONTROLline). The test has to be repeated using adequate sample volume.
The sample material could be stored for 2 days at 8°C. For a longer storage the original feces sample resp. the supernatant of the sample tube could be stored at -20°C or more.

6. SPECIAL INFORMATION:

• FOR VETERINARY USE ONLY!
• ***FAST*est® D4T bovine** can be used for **bovines only.**
• Do not remove any test components (room temperature!) from their individually sealed pouches until immediately before their use.
• Do not use reagents from different kits, lot- numbers or if the expiry date has passed.
• The Buffer diluent contains low concentrations of toxic sodium acid as a preservative; therefore avoid any skin contact and/or ingestion.
• The sample material must be seen as potentially infectious.
• Follow instructions for use precisely.

7. TESTPROCEDURE:

7.1 SPECIMEN COLLECTION AND DILUTION:

a. Label sample tube (**P**) and Revolver-Test tube (**R**) for ensuring affilation to the accordant feces sample.

b. Open Sample tube with buffer diluents (**P**). (fig.1)

c. Mix the feces sample homogenous (applicator, vortexer). Take

- **1 (one) coated spoon of pulpy-compact feces**
- **2 (two) coated spoons of fluid-watery feces**

with the spoon on the cap of the sample tube (**P**) and mix it into the buffer diluent of the sample tube (**P**). (fig.1)

d. Close the sample tube (**P**) tightly and mix the feces sample with the buffer diluent homogenously by rotating the sample tube (**P**) in a slight and circular way. (fig. 2)

7.2 Test procedure:

a. Remove the Revolver-Test tube (**R**) not until testing and label it with the patient name or ID number.
b. Open the Revolver-Test tube (**R**), **take the red desiccant disc off** and put the feces-buffer diluents (**P**) into the Revolver-Test tube (**R**) vertically. (fig.3)
c. Turn the cap until hearing a clicking noise for two times. The feces-buffer diluent will run into the Revolver-Test tube (**R**). Absorption pad area shouldn´t be exceeded by liquid level. (fig.4)
d. Put the Revolver-Test tube (**R**) on a flat surface. The feces-buffer diluent will be absorbed by the test membranes. The correct test procedure is proved by the occurrence of a second pink/purple CONTROLline. (fig.6)

7.3 Testinterpretation:

Test result must be read after 5 minutes! Testlines - of any colour - which occur beyond these 10 minutes have no diagnostic value!