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*FAST*est® PARVO Card

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Parvovirus antigens in the feces of the dog, cat and mink

INSTRUCTIONS FOR USE

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

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® PARVO** Card contains:
- 5 or 15 test cassettes coated with monoclonal antibodies
- 5 or 15 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

T – TEST line, **C** – 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 96.0 %
Specificity 99.9 %
(Comparison Method: Electron microscopy, ELISA)

2. INTRODUCTION

The Canine Parvovirus (CPV) was first described in 1978 as cause of diarrhoea in dogs. At first the virus was detected in North America, but it spread quickly world-wide.

The Canine Parvovirus (CPV), the Feline Panleukopenia Virus (FPV) and the Mink Enteritis Virus (MEV) show structural similarities. Puppies are infected through an oronasal path at an early age. The virus is excreted by infected animals via feces and remains infectious in the environment up to one year. Thereby, kennels can be permanently contaminated. The clinical symptoms of Parvovirus enteritis are severe diarrhoea, vomiting, anorexia, dehydration and panleukopenia.

Fecal samples can be used for detection of the parvovirus specific antigens CPV-1, CPV-2, CPV-2a, CPV-2b und CPV-2c.

The use of ***FAST*est® PARVO** Card enables the veterinarian to quickly confirm an aetiological diagnosis of a CPV infection, to start the therapy immediately and to initiate the required quarantine procedures.

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 4b/Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spiral feces collection stick.

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 T and C.**

4. SPECIMEN COLLECTION AND PREPARATION

a. Open the sample tube with the buffer diluent.
b. Introduce the spiral feces collection stick (cs) several times at various points into the well homogenized feces. Pull it out and introduce the feces sticking on the cs (0.2 g) into the sample tube (fig.1)
NOTE: In case of **watery** feces, introduce the cs into the feces and then immediately into the sample tube. Mix well with the buffer. **Repeat this step three times in a row!**
c. Close the sample tube tightly and shake it gently until the sample has been dissolved homogeneously into the buffer diluent (fig.2).

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Shake the sample tube again to dissolve the specimen homogeneously. Then break the tip of the sample tube (opposite side of the blue screw cap) manually.
3. Hold the sample tube vertically (blue screw tap pointing upwards) and discard the first two drops. Then add **three drops** of the sample-buffer mixture into the **round sample window** of the test cassette (fig.3).

fig.1

fig.2

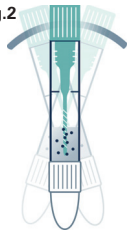
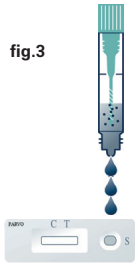


fig.3



6. READING OF THE TEST RESULT

Read the test result **5 minutes** after the three drops have been dropped into the round sample window.

POSITIVE TEST RESULT (fig.4)
A pink-purple TEST line of **any intensity** (varying from weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.5)
Only a pink-purple 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 test cassette.

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 test cassette 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.

8. TEST PRINCIPLE

The ***FAST*est® PARVO** Card is based on latest rapid immunochromatographic technique.

Positive feces samples contain Parvovirus antigens CPV-2a, 2b, 2c and its subtypes 2c(a) and 2c(b). These antigens will react in the conjugate pad area with mobile monoclonal anti-Parvovirus antibodies (anti-Pv mAbs), which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-Pv mAbs producing a pink-purple TEST line (**T**).

These anti-Pv mAbs guarantee a high level of specificity for the aetiologic detection of Parvovirus. The intensity or width of the test line depends on the concentration of Parvovirus antigens in the tested sample.

A correct test procedure will be indicated by a second, pink-purple CONTROL line (**C**).

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 T and C 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.
- T can vary both in intensity and width. Therefore, any pink-purple line appearing within the required incubation time is to be interpreted as a positive test result.
- Clinical healthy animals with or without dectectable contact to Parvovirus shedders or to deseased animals can shed Parvovirus and therefore react positive in the ***FAST*est® PARVO** Card. That's why, as a matter of principle, the Parvovirus antigen status of an animal before vaccination should be tested with ***FAST*est® PARVO** Card.
- Vaccination with modified-live high titre CPV-2 vaccine may result in shedding of Parvovirus for a period of 3 to 14 days post vaccination. The ***FAST*est® PARVO** Card can become positive due to the fact of a recent Parvovirus vaccination.
- Because of intermittent antigen shedding, during incubation time (4–6, max. 9 days) or early phase of Parvovirus infection or with ongoing diarrhoea, a single negative test result should be confirmed by testing a serial feces sample (individual testing of at least three consecutive feces samples).