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*FAST*est® PARVO Strip

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In vitro diagnosticum

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

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® PARVO** Strip contains:
- 2, 10 or 25 dipsticks coated with monoclonal antibodies
- 2, 10 or 25 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 96 %
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** Strip 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 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.**

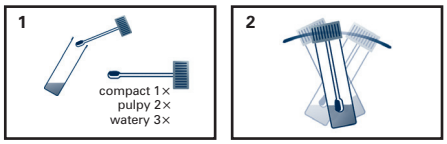
4. SPECIMEN COLLECTION AND PREPARATION

a. Open the sample tube with the buffer diluent.

b. Mix the 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).

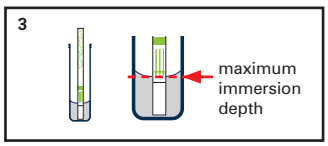
c. Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).

d. For sedimentation of gross feces 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 green arrowheads (fig.3).
3. Remove the dipstick from sample tube soonest 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 will 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*).
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 coloured TEST line of **any intensity** (varying from weak to strongly intensive) and a red CONTROL line appear.

NEGATIVE TEST RESULT (fig.5)
Only a red 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 (original size – position of CL and TL)

fig.5
NEGATIVE TEST RESULT (original size – position of CL)

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® PARVO** Strip is based on latest rapid immunochromatographic sandwich 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 colloidal gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-Pv mAbs producing a red TEST line (**TL**). These anti-Pv mAbs guarantee a high level of specificity for the aetiologic detection of Parvovirus.

The intensity or width of the TL depends on the concentration of Parvovirus antigens in the tested sample.

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

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.
- Clinical healthy animals with or without dectectable contact to Parvovirus shedders or to diseased animals can shed Parvovirus and therefore react positive in the ***FAST*est® PARVO** Strip. That is why, as a matter of principle, the Parvovirus antigen status of an animal should be tested with ***FAST*est® PARVO** Strip before vaccination.
- 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** Strip 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).