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*FAST*est® CDV-CPV Ab

ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against the Canine Distempervirus (CDV) and the Canine Parvovirus (CPV) in whole blood, plasma or serum of the dog

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® CDV-CPV** Ab contains:
- 2 or 10 double test cassettes coated with recombinant antigens
- 2 or 10 buffer diluent tubes **A** with 1.0 ml buffer diluent each
- 2 or 10 disposable plastic pipettes (5 µl with black mark)
- 2 or 10 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE

15–25°C 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

CDV Ab: Sensitivity 99.9 % – Specificity 99.8 %
CPV Ab: Sensitivity 99.9 % – Specificity 94.0 %
(Comparison Method: CDV Ab: SN titre / CPV Ab: HAI titre *)

2. INTRODUCTION

Antibodies (Ab) are basic modules of the humoral immune response. They are passed by passively via the colostrum as so-called maternal antibodies (mAb) onto the yet immunoincompetent newborns or induced actively by natural field infection or vaccination. The ab titre is varying individually in each animal, depending on multiple factors. The titre can persist over an extended period of time, partially lifelong, in efficient protection concentration (= reliable immunity by protective abs) or can fall below the efficient protection concentration (non-reliable immunity) in the course of time. Depending on presence or NON-presence of abs in the sample, the veterinarian can make a quick and reliable decision regarding the necessity of "vaccination or not?" in the following questions.

According to the opinion of the German Standing Vaccination Commission for Veterinary Medicine (StIKo Vet) on Ab testing*, after active immunization and/or field infection (active immune response with Ab formation), every titre is protective or no titre is an indication for immediate vaccination.

Testing of field-infected or completely vaccinated animals

➔ before planned routine vaccination ("titre check")

Testing of puppies

1. to estimate the appropriate point in time for the first immunization (1st primary immunization): Screening using ***FAST*est® CDV-CPV** Ab is possible. According to the StIKo Vet statement, semi-quantitative rapid test results should be confirmed using SN titre (CDV) or HAI (CPV) in order to determine the quantitative titre.

2. to determine the optimal vaccination time point of a litter, it is possible to determine the maternal ab status representatively for the other puppies (so-called "fraternal ab titre"). For this purpose, a ***FAST*est® CDV-CPV** Ab must be performed **on at least two randomly selected puppies per litter**.

3. to check the success of a basic immunization as early as possible from the 6th month of life.

Being fast, safe and reliable, for pet owner and breeder these important questions can be answered practically by ***FAST*est® CDV-CPV** Ab. This enables the veterinarian an appropriate and customized vaccination diagnostics and strategy, adapted to dog and pet owner.

3. INFORMATION ON THE SPECIMEN MATERIAL

Exactly **5 µl (of attached plastic pipette with mark) 15–25°C warm whole blood (WB**, native blood with anticoagulant**), plasma (P) or serum (S)** are needed. **Native blood without anticoagulant should not be used due to potential micro agglutination** (e.g. migration delay on the membrane, unspecific reaction)!

Mix the sample material well before use!

Non-cooled (**15–25°C**), WB, P and S should be tested within 4 hours! At **2–8°C**, WB, P and S can be stored up to 4 days. **Serum and/or plasma samples** can be permanently stored **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. albumin, fibrinogen, lipids, CRP, heterophilic antibodies, especially type IgA, as well as viscosity, pH-value and excess EDTA) **as well as native blood 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. Draw sample **up to the mark (≙ 5 µl sample volume)** using the disposable 5 µl plastic pipette. **The meniscus must be above the black line** (fig.1).

b. Open the cap of the buffer diluent tube **A** and mix the 5 µl of the sample by repeatedly press and release of the pipette into the buffer diluent (fig.2). Discard the pipette.

c. Close the buffer diluent tube **A** well. Mix the sample-buffer mixture (SBM) homogeneously by careful swinging.

5. TEST PROCEDURE

1. Remove the double test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Open the buffer diluent tube **A** containing the SBM. Place **4 drops (ca. 160–200 µl) of the SBM** slowly into the sample window S of the CDV test cassette using the disposable plastic pipette (without mark; hold pipette vertically, fig.3). **Repeat this step for the CPV test cassette.**
3. Add 1 additional drop of SBM into the sample window S if there is no beginning pink-purple LF visible within 1 minute after adding the SBM.

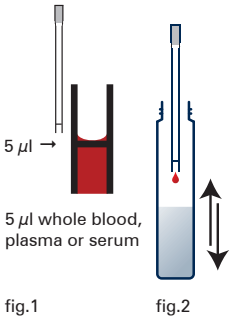

fig.1 fig.2

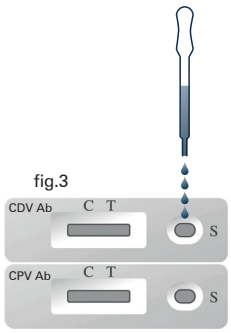

fig.3

6. READING OF THE TEST RESULT

10 min

Read the test result **10 minutes** after addition of the SBM into the respective CDV Ab and CPV Ab sample window S.

POSITIVE TEST RESULT
PROTECTIVE TITRE

Colour intensity **C ≤ T**
CDV ≈ SN* titre **≥ 1:16**
CPV ≈ HAI* titre **≥ 1:80** *

Colour intensity **C > T**
CDV ≈ SN titre **< 1:16**,
CPV ≈ HAI titre **< 1:80** *

NEGATIVE TEST RESULT
NON-PROTECTIVE TITRE

T not visible
Indication for immediate vaccination *

INVALID TEST RESULT

No CONTROL line visible. The test should be repeated using a new test cassette.

* See Introduction: Every titre is protective or no titre is an indication for immediate vaccination. Please also note the information under 9. Information for the interpretation.

* SN titre from serum neutralisation test
HAI titre from hemagglutination inhibition test

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 double test cassette to ensure a precise assignment.
- Use a new buffer diluent tube, new pipettes and a new double test cassette for each sample.
- The ***FAST*est® CDV-CPV** Ab is not suitable for the detection of Distempervirus or Parvovirus (Panleukopenia) IgG antibodies in cats.
- **ATTENTION:** Partially filled and/or insufficient mixed EDTA, Citrate or Heparin tubes could create invisible microclots resulting in lateral flow delay and/or unspecific reactions (e.g. greyish shadow like lines).
- 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® CDV-CPV** Ab is based on an immunochromatographic "sandwich principle".

The anti-CDV or anti-CPV antibodies of the sample first react with the recombinant CDV or CPV antigens of the sample pad, second with the mobile monoclonal gold labeled antibodies of the conjugate pad. During the following "lateral flow" (**LF**) along the nitrocellulose membrane, these antigen-antibody complexes are captured by fixed polyclonal antibodies forming a pink-purple TEST line **T**. The colour intensity of T can vary depending on the anti-CDV or anti-CPV antibody concentration of the sample.

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

Evaluation of ***FAST*est® CDV-CPV** Ab is done by comparison of the colour intensities of T with C.

The threshold titre (sustainable immunity or not) of ***FAST*est® CDV** Ab (1:16) is adjusted by Golden Standard Test (serum neutralisation test).

The threshold titre (sustainable immunity or not) of ***FAST*est® CPV** Ab (1:80) is adjusted by Golden Standard Test (hemagglutination inhibition test).

* Source: https://www.openagrar.de/servlets/MCRFileNodeServlet/openagrar_derivate_00005786/Stellungnahme_Antikoerpertestung_2017-10-19.pdf (German)

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 (e.g. greyish, shadow-like lines) has to be considered as unspecific reactions and therefore as negative test result.
- Due to anticoagulated whole blood and/or red hemoglobin background of the test membrane caused by hemolytic blood samples, the visibility of T, especially in case of weak positive samples, could be from worse to not visible.
- Any coloured lines appearing after 20 minutes do not have any diagnostic value.
- An insufficient sample volume (see point 4a, fig.1) can lead to the formation of a weak TEST line (T<C). In this case, a second test should be carried out with the prescribed sample volume (see fig.1).
- The ***FAST*est® CDV-CPV** Ab only detects the presence or absence of anti-CDV or anti-CPV IgG abs in the specimen and should not be used as the sole criterion for the diagnosis of the CDV or CPV IgG immune status in dogs.
- Estimation of the timing of the first/second/third immunization for puppies: immediate vaccination is recommended if the test result is negative (CDV Ab and/or CPV Ab). If the result is positive, it should be noted that, particularly in the case of live viral vaccines, the vaccine antigens are neutralized in the presence of high maternal Ab levels and therefore no active immunity is induced in the vaccinated individual.