*FAST*est® CPV Ab.

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Test-kit for the semiquantitative Detection of IgG Antibodies to Canine Parvovirus in the Whole Blood, Plasma or Serum of the Dog

In-vitro diagnosticum

INFORMATION FOR USE

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1. Introduction

Canine parvovirus (CPV) is one of the most important cause of viral gastroenteritits in dogs worldwide. The disease is characterized by severe enteritis and lymphopenia with high mortality especially in non-immune dogs. Antibody titers to CPV are important to prediction of canine health and preparing of vaccination program.

Using the in clinic ***FAST*est® CPV** Ab. test qualifies the veterinarian due to the individual tested Parvo-IgG-Antibody-Status making a fast decision concerning the optimal date of first immunisation (especially in puppies because of the interference by maternal antibodies), the optimal date of revaccination, the success control after vaccination as well as for the trade off for individual health risks (Complications due to vaccination, Immune status of Parvovirus infected, immunosuppressive dogs, planned trips on exhibitions, dog school, boarding kennels and screening the immune status in breederies with "Parvovirosis-Case History") and to develop more reliable and efficient individual vaccination schedule.

2. Test Principle

The ***FAST*est®** Ab. Test-kit is based on a lateral-flow immunochromatographic assay. The nitrocellulose membrane shows three pre-coated lines ("C1-line" and "C2-line" containing immobile polyclonal "Control-Line Antibodies", "T-line" containing immobile polyclonal Capture-Line Antibodies), furthermore a Sample pad containing specific CPV-Antigens and a Conjugate pad containing two different monoclonal resp. polyclonal mobile Gold conjugated Antibodies.

Once the specimen and the Buffer diluent is added to the Sample pad, anti-CPV IgG`s in the specimen sample first react with purified specific CPV-Antigens and second with mobile monoclonal Gold conjugated Antibodies located in the Conjugate pad. Flowing laterally along the membrane this complex is intercepted in the "T-line" by immobile "Capture-Line antibodies" forming a pink/purple "T-line" showing different Colour intensity due to the anti-CPV-IgG`s concentration in the specimen. Parallel to it mobile Gold conjugated Antibodies of the Conjugate pad flow laterally along the membrane reacting with the immobile polyclonal "Control-Line Antibodies" located in the "C1-" resp. in the "C2-line" forming a pink/purple "C1-" resp. "C2"-line. Both Control lines "C1" and "C2" are also used for procedural control, therefore they should always appear if the test procedure is performed properly and the test reagents of the Control lines are working.

3. Testkit Components

1 *FAST*est® CPV Ab. Test-kit contains:

- 2 or 10 Test cassettes, coated with Canine Parvovirus Antigen.
- 2 or 10 Disposable Specimen loops (1 µl vol.).
- 2 or 10 Dropper bottles A (red cap) containing 0,25 ml Buffer diluent.
- Information for use.

4. Storage and Shelf Life

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

5. Information on the Test Sample Material

- Whole Blood, Plasma or Serum samples may be used with this test.
- Whole Blood (without anticoagulans) samples should be used.
- If serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 to 8°C for 2 to 3 days. After this period they should be frozen at -20°C or below.
- Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- The use of hemolytic, lipaemic, icteric or bacterially contaminated specimens should be avoided. Erroneous result may occur.

6. Special Information

- FOR VETERINARY USE ONLY!
- The ***FAST*est® CPV** Ab. can not be used for the detection of Panleukopenia-IgG-Antibodies in cat specimens.
- All specimens should be handled as being potentially infectious and disposed accordently.
- Do not remove any test components (room temperature!) from their individually sealed pouches until immediately before their use.
- Do not use test kit components from different kits, lot numbers or beyond the stated expiration date.
- The Buffer diluent contains low concentration of toxic sodium azide as a preservative, therefore avoid skin contact and/or ingestion.
- Follow information for use precisely.

IMPORTANT INFORMATION

- ***FAST*est® CPV** Ab. detects semiquantitative the presence or non-presence of IgG-Antibodies to CPV in the specimen and should not be used as the sole criterion for the diagnosis of CPV infection.
- As with all diagnostic tests, all results must be considered with other clinical information available to the veterinarian.

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 use of this product.

Comparison Study:

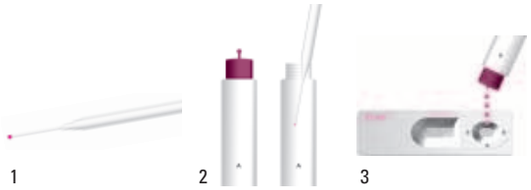
between ***FAST*est® CPV** Ab. Test and Hemagglutination-Inhibition (HI) Test showed good correlation.

Titer of HI Test	***FAST*est® CPV** Ab. T-line (Test line)	Titer of HI Test	***FAST*est® CPV** Ab. T-line (Test line)
< 1 : 10	-	< 1 : 160	++
1 : 10	+/-	1 : 320	++
1 : 20	+	1 : 640	+++
1 : 40	+	1 : 1280	+++
1 : 80	++		

+ : The strength of T-line is lower than that of C1-lines.
++: The strength of T-line is between CI- and C2-lines.
+++: The strength of T-line is higher than that of C2-line

A. SPECIMEN COLLECTION AND DILUTION

a. Add 1 µl of specimen using the disposable loop (Abb.1) by dipping the circular end of this loop into the specimen.
b. Open the red cap of the Dropper bottle A and add these equivalent amount of specimen (1 µl vol.) by placing carefully the circular end of the loop into Buffer diluent of the Dropper bottle A (Abb.2).
c. Gently stir the specimen filled loop into the Buffer diluent to ensure ade quate mixing of the specimen into the Buffer diluent (Abb.2). Then remove the loop and close again the Dropper bottle A.



B. TEST PROCEDURE

a. Remove the test cassette from the foil pouch and place it on a flat surface.
b. Cutt off the tip of the red bottle cap with a scissors and add the entire volume of the specimen-Buffer diluent (Dropper bottle A) into the SAMPLE window „S" (Abb. 3).

C. INTERPRETATION OF TEST RESULTS

Read and interpretate the test results exactly 20 minutes after adding the specimen-Buffer diluent-fluid into the SAMPLE window „S". Any coloured lines that should appear after 30 minutes have no diagnostic value!

INCONCLUSIVE TESTRESULT

No T-line and no C-Lines visible!
Test is not valid! Repeat the test using a new test kit!

POSITIVE TESTRESULT (Prolonged Vaccination Interval possible)

High Titer (≡ HI-Titer > 1:640)

Colour intensity T-line > C2-line
- High Antibody titer to CPV
- Indicative of a very good CPV-Immune status

Medium Titer
(≡ HI-Titer ≥ 1:80 – 1:320)

Colour intensity T-line between C1-line and C2-line
- Medium Antibody titer to CPV
- Indicative of a good CPV-Immune status

Protektive Parvovirus-Antibody-Titer ≥ 1:80

NEGATIVE TESTRESULT (Parvo Vaccination recommended)

Low Titer (≡ HI-Titer < 1:80)

Colour intensity T-line < C1-line
- low Antibody titer to CPV
- Indicative of a poor CPV-Immune status
- **!Vaccination within 1 month requested!**

No Titer

No T-line, but both C-lines visible
- No CPV antibodies detectable
- Indicative of a very poor CPV-Immune status
- **!Vaccination immediately requested!**