

Instruction Manual

Fassisi® ParCo is used for the detection of specific antigens of canine Parvovirus (CPV) and canine Coronavirus (CCV) in faeces.¹

CORONAVIRUS AND PARVOVIRUS

Canine Coronavirus (CCV) and canine Parvovirus type 2 (CPV-2) are the causative agents of gastroenteritis. Canine Coronavirus (CCV) is the second leading viral cause of diarrhoea in puppies with canine Parvovirus being the leader. Unlike Parvovirus, Coronavirus infections are not generally associated with high death rates. Canine Coronavirus is a single stranded RNA type of virus. Canine Coronavirus is widespread in the dog population worldwide. The virus was first recognized in 1971 in Germany. Most adult dogs have antibodies to this disease which indicates that they were, at one time, exposed to the virus. There is a broad range of symptoms shown by dogs that are infected with Parvovirus. The majority of cases are seen in dogs less than 6 months of age especially in puppies younger than 12 weeks of age.

It is estimated that almost half of all virus-type diarrhoea is infected with both Parvovirus and Coronavirus. It is estimated that more than 87 % of all dogs have had exposure to Coronavirus at one time or another. If the dog is infected immediate treatment is required; therefore, it is imperative that the cause of the illness is quickly and accurately identified.²

TESTING

The Fassisi® ParCo solution is an immunoassay sandwich and is creating for the professional use for the veterinarian. It functions by forming a sandwich between marked antibodies and trial antigens and immobilized antibodies. The Fassisi® ParCo is a highly sensitive immunoassay that comes in a handy test cassette.

EXPLANATION OF THE TESTING PROCESS

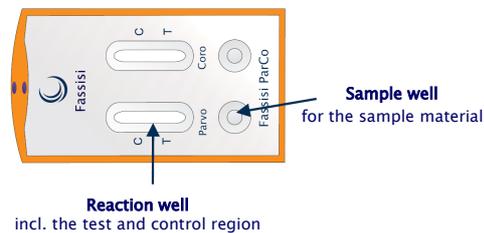
Two absorption pads are located on both of the test strips incl. a nitrocellulose membrane with specific antibodies and gold conjugate pad.

Three drops of the specimen are to be pipetted to every sample well. There is one test strip located behind the well which features absorption pads that soak up the fluids from the specimen. The gold-marked antibodies (Ab and mAb-Au) will mix-in with the specimen. The mixture will then begin to flow. After a few seconds the fluid level will rise and cross the test line, and shortly thereafter it will cross the control line as well. The gold-marked antibodies (Ab) will bind to the antigens (Anti Ab) found on the control line. Although the control line will be covered in liquid it will remain constantly visible. If the substance being tested for - with specific antigen (Ag) - is found in the specimen, the gold-marked antibodies (Anti-Ag mAb-Au), which are located on the test line, will bind with the respective antigen from the test sample. A sandwich consisting of antibody, antigen, and the gold-marked antibody will form on the test line. If none of the virus is detected in the specimen, there will in turn be no antigen; consequently, there would be no antigen to bind with the gold-marked antibodies on the test line to create the sandwich effect. If no additional test line appears, the result of the test is negative.

CONSTITUTION OF THE TEST CASSETTE

The test strip is located behind the plastic cover. The sample well is lying on the right side. The reaction well is located in the middle of the test cassette. The test and the control region are

located on the reaction well. The labelling field above the reaction well shows the test and control region.



STORAGE AND EXPIARATION

Fassisi® ParCo must be storage at room temperature (2°C and 30°C). The expiration is 18 months after manufacturing

CAUTION

- Only for professional use.
- Only for one use.
- Use the test cassette within 10 minutes after opening.
- Please use appropriate amount the sample.
- Give no sample solution in the reaction field.
- Avoidance of cross reactions use for each sample a new sample tube.
- Do not touch the reaction field.
- Use only the original Fassisi® buffer in the kit.
- Feces could be infectious. Be careful with the waste disposal.
- Use no cassettes after shelf-life.
- Do not use the test if the packing is damaged.
- Consider the test results as invalid after denoted time.

REAGENTS, MATERIALS, INSTRUMENTS

I. Contents:

- 5 double test cassettes incl. drying pad
- 5 sample tubes incl. cotton swab
- 5 test tubes incl. 1 ml dilution buffer
- 1 instruction manual

II. Additional Necessary Materials

- Timer

QUALITY CONTROL

In order to ensure the proper functioning of the kit, external controls are utilized as a matter of good laboratory practice. The controls should consist of a negative and positive control with minimal analyte content. It can be determined through the use of a weak positive control that a test was not negatively impacted and that the analyte can be detected with the given sensitivity of the test system.

SAMPLE PREPARATION

The sample should be tested as quickly as possible after the collection. If this is not possible, the specimen can be stored at temperatures from between 2°C and 8°C for a period of up to 24 hours. If it is necessary for the specimen to be stored longer, it must be kept at a temperature of -20°C. Take measures to ensure

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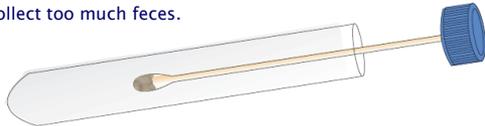
Violenstraat 10 · 7731 WN Ommen · The Netherlands
phone +31(0) 529 466675 · Website www.heberex.nl · Email: info@heberex.nl

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that the sample is not contaminated with formaldehyde solutions or derivatives. **ATTENTION:** Samples and other materials should be used like infectious materials.

SAMPLING

Use the cotton swab (inside the sample tube) to collect a touch feces. See carefully that only the upper head is covered. Don't collect too much feces.

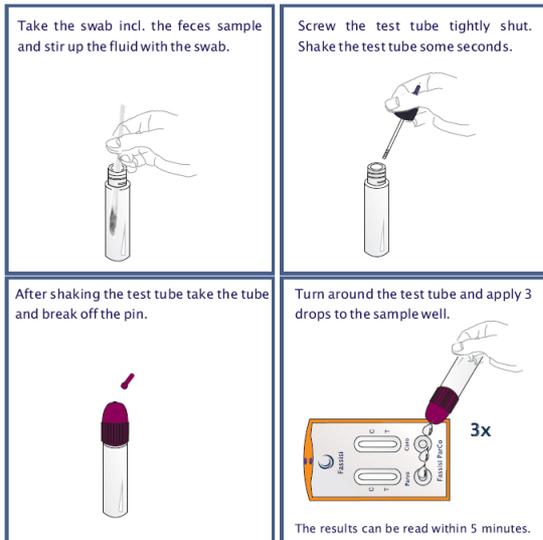


If you have no feces on side please give the sample tube to the animal owner. The owner is able to collect the feces by his own and bring the sample tube immediately back to the veterinarian practise. The test should be performed as soon as possible after sample collection.

Continue with the test procedure

TEST PROCEDURE

- 1) Bring all materials to be used during the test to room temperature.
- 2) Open the sample tube. Inside you find the cotton swab with the feces sample. Take the swab and place the swab into the test tube with the dilution buffer.
- 3) Stir up the fluid with the swab.
- 4) Screw the test tube tightly shut. The dilution buffer in the tube will treat and conserve the sample.
- 5) Shake the test tube some seconds.
- 6) Take a test cassette from the protective wrapper.
- 7) Take the test tube and break off the pin very strong.
- 8) Turn around the test tube and apply 3 drops to both sample wells.



Use for every sampling a new test tube and a new test cassette.

TEST EVALUATION

The results of the test can be read within 5 minutes.

Positive Result:

The test is positive when a control line (C) and test line (T) appears in the reaction well as shown in Figure 1: CPV was detected.



If a weakly defined line appears, the test result is nevertheless positive. The red colour in the test region will vary depending on the concentration of anti CPV antigen present.



Negative Result:

The test is negative when only the control line appears. No weakly defined test lines are visible as in Figure 2. The image selected here displays a clear negative test result, no CPV and CCV was detected

Invalid Result:

If no control line appears after the test is conducted the test is invalid. In this case, it is likely that the test was not properly conducted or that the expiration date had already lapsed. If this occurs, a new test must be conducted.



ATTENTION: Do not read the test results after 10 minutes. Results interpreted after 10 minutes can be misleading.

DISPOSAL

An accurate disposal can be recommended. Feces sample and test cassettes should be collect in a plastic bag. Subsequent the plastic bag should dispose in the normal domestic waste.

TEST PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity in feces

Fassisi® ParCo	Enzym-linked Immunosorbent Assay	
	Sensitivity	Specificity
Parvovirus	95,76 %	80,77 %
Coronavirus	91,30 %	76,92 %

Test study in 2009

LITERATUR

1) Masato Nakamura et al.: "Monoclonal Antibodies That Distinguish Antigenic Variants of Canine Parvovirus", Clinical and Diagnostic Laboratory Immunology, , p. 1085-1089, Vol. 10, No. 6, November 2003

2) Ishiwata K, Minagawa T, Kajimoto T: "Clinical effects of the recombinant feline interferon-omega on experimental parvovirus infection in beagle dogs." in: J Vet Med Sci. 1998 Aug;60(8):911-7.

SYMBOLS USED

	Read User instructions carefully		Only for one use
	Content	LOT	Lot number
	Storage temperature		Expiry date

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Violenstraat 10 · 7731 WN Ommen · The Netherlands
phone +31(0) 529 466675 · Website www.heberex.nl · Email: info@heberex.nl