The rapid test for the detection of antibodies to Ehrlichia canis

Canine monocytic ehrlichiosis (CME) is a tickborne disease of dogs caused by Ehrlichia canis, an obligate intracytoplasmic rickettsia localizing in the reticuloendothelial cells of the liver, spleen, and lymph nodes and replicating primarily in mononuclear macrophages. The disease is diagnosed by clinical signs, hematologic abnormalities, demonstration of morulae in peripheral monocytes, and detection of serum antibodies to E. canis.

After an incubation period of 8 to 20 days, the course of the disease is divided into three phases: the first, acute phase the clinical symptoms are not pathognomonic and rather mild with nonspecific symptoms such as disturbed general health, fatigue, fever, swollen lymph nodes, anorexia, and dyspnea. The pathogen infects lymphocytes and monocytes. The second, subclinical phase may last several months up to years and is characterized by pathogen persistence, with an increased antibody production. These dogs appear clinically healthy. The third phase of is a chronic CME characterized by complex symptoms resulting from different organ manifestations of the pathogen and persistent antibody production. Nonspecific symptoms such as fever, anorexia, apathy also continue to dominate further. A serological test for antibodies against Ehrlichia canis should always be interpreted in conjunction with the present clinical symptoms. The detection of antibodies is possible after the seventh day of an infection, and indicates a past contact with the pathogen. However, the seroconversion can sometimes take up to four weeks. But even dogs with a stopped infection at an early stage may still have low antibody titers for several months and are serologically negative. Here is a regular examination is advised. The Fassisi EhrCanis requires a minimum of time and equipment and is very easy and quick to perform.

Literature

Swango LJ, Bankemper KW, Kong LI: 1989, Bacterial, rickettsial, protozoal, and miscellaneous infections. In: Textbook of veterinary internal medicine, ed. Ettinger SJ, Feldman EC, pp. 277-279. WB Saunders, Philadelphia.

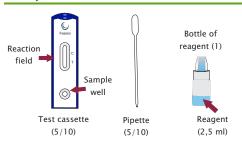
Selbitz HJ Truyen U (2011): 16.3.4. Gattung Ehrlichia in: Mayr A., M. Rolle (Hrsg.): Medizinische Mikrobiologie, Infektions- und Seuchenlehre. Enke Verlag, Stuttgart, 9, Auflage,

Bauer C, Brahm R, Daugschies A, Kietzmann M, Kohn B, Moritz A, Schnieder T, Wendland B (2011): Empfehlung zur Bekämpfung von durch Vektoren übertragenen Krankheiten bei Hunden und Katzen. Kleintierpraxis 56 (7): 373-385

Sensitivity and Specificity

Comparison test: IFA1 Study 2019			
N=100	Sensitivity	Specificity	TTP TTP: Total test performance
E. canis	92,50 %	96,67 %	95,00 %

Components of the test kit



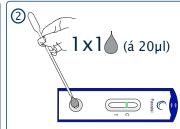
Symbols



Storage temperature

Instruction Manual







Test procedure

Open the pouch, remove the test cassette, place the test cassette on a flat surface and unscrew the bottle of reagent and place it aside.

- Take up the serum or plasma sample with the pipette.
- (2) Carefully put one (1) drop (20µl) of sample material into the sample well of the test cassette.
 - Allow the material to be drawn into the sample well. This may take a few seconds. Only after the sample has been completely drawn in may the reagent from step 3 be
- (3) Add two (2) drops of the reagent from the bottle of reagent into the sample well. Ensure that no air bubbles are formed.

If the fluid does not run up the test strips after 60 seconds, add an additional drop of the reagent into the sample well

Test result

The results of the test can be read after 10 minutes.

Positive test result:

If the test result is positive, two red lines will appear on the test strip in the reaction field of the test cassette. The upper line (control line) confirms the correct working of the test; the bottom line (test line) indicates a positive test result.

A weak test line should also be considered a positive antibody detection.

Note: A positive antibody detection alone is not conclusive, but is indicative in combination with a corresponding preliminary report.

Serology: Serological results must always be interpreted in combination with clinical findings. Negative serum results do not rule out an infection, because seronegative results may be obtained at any stage of infection. Positive serum results in endemic areas may be due to a previous infection.

Alternative procedure

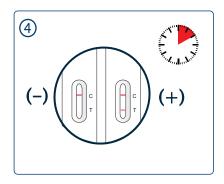


Hold the pipette at the drawing on the left. Mark the pipette with a black line at the marked position. This represents the 20 µl mark.

Take up as much sample material with the marked pipette that it can reach the mark (20 ul).

Now add this material to the sample well. Allow the material to be drawn into the sample well.

With this alternative test procedure you can ensure that you do not add too much sample material to the sample well and risk that the run slows down.



Negative test result:

Only a red line in the upper area of the reaction field (control line) becomes visible, no test line becomes visible. No antibodies were detected.

Invalid test result:

If no control line appears after the test is conducted, the test

Note: The C-line is not a reference line and may have a different line intensity than the T-Line.

For questions, comments or techincal questions, please contac our service department:



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- Use a new test cassette for every individual test.
- Only for one-time usage.
- For veterinary use only.
- Use only the original test components provided in the Fassisi kit.
- Use the test cassette within 60 minutes after opening the pouch.
- The test cassette must be in a horizontal position on a smooth surface under while the test is performed.
- Note the amount of sample material needed. An incorrect number of drops or too small drops may lead to false results.
- Consider the test results as invalid after the read out time.
- Do not use the test after the expiration date on the pouch.
- Dispose of all contaminated materials properly. Disinfect the work area after the test execution.

Storage of the test kits

The Fassisi test kit should be stored between 2-30°C.

Choice of sample material



Serum and plasma

Recommended sample material is a freshly collected serum or plasma to achieve the highest detection sensitivity.

Separate the serum or plasma from whole blood as quickly as possible, the specimen should be clear and non-hemolyzed.

GI-01-010-02-07

Manufacture

Whole blood

A whole blood sample should used as quickly as possible. Heparin blood and EDTA blood may also be used. Hemolyzed samples should not be used for testing.

Note: Whole blood samples have a lower detection sensitivity. In case of a negative test result with whole blood, the test should be repeated with a serum or plasma sample.