scil v-Leishmania

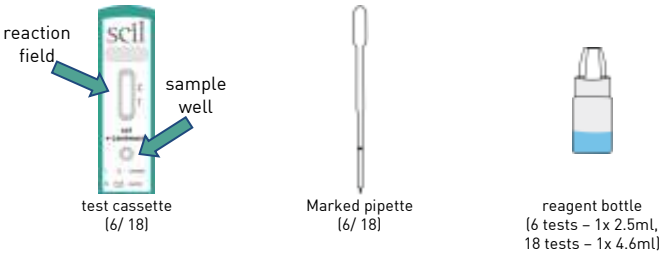
Immunological Rapid Test

FOR VETERINARY USE ONLY!

TEST INFORMATION

The protozoal organism Leishmania infantum is endemic in the Mediterranean region and transmitted by female sandflies. Development of disease depends on the host's immune status, leading to incubation periods of month to years in certain patients. Leishmaniasis is a chronic disease with lymphadenopathy, involvement of the gastrointestinal tract (i.e. diarrhea, vomitus), lymphadenopathy, and cutaneous lesions. Renal failure may develop in later stages of the disease and often leads to complications. As eradication of parasites is not possible, early detection of disease and lifelong treatment of the patient are required. scil v-Leishmania detects antibodies against Leishmania organism and facilitates rapid identification of infected patients.

TEST COMPONENTS



PLEASE NOTE PRIOR TO USE

Please use a new test cartridge for every individual test as cartridges are for single use only.
scil Rapid Test kits are for veterinary use only.
Use only test components provided by scil animal care company.
Use the test cassette within 60 minutes after opening the pouch and place the test cassette in a horizontal position on a smooth surface 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 test results.
After opening the pouch, use the test cassette within one hour. Consider the test results as invalid after the read-out time.
Do not use the test after the expiration date on the pouch.
Dispose all contaminated materials properly and disinfect the work area after the test execution.

STORAGE

scil Rapid Test kit should be stored between 2-30°C.

REFERENCE

Laia Solano-Gallego, et al.: Serological diagnosis of canine leishmaniosis: comparison of three commercial ELISA tests a rapid test and an in-house IFAT. Parasites & Vectors 7:111, 2014.

Maia C, et al.: Leishmania infection and host-blood feeding preferences of phlebotomine sandflies and canine leishmaniasis in an endemic European area, the Algarve Region in Portugal. Mem Inst Oswaldo Cruz 108: 481–487, 2013.

World Organisation for Animal Health (OIE): Leishmaniosis. In Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. 7th edition; 2012:240–250.

MANUFACTURER

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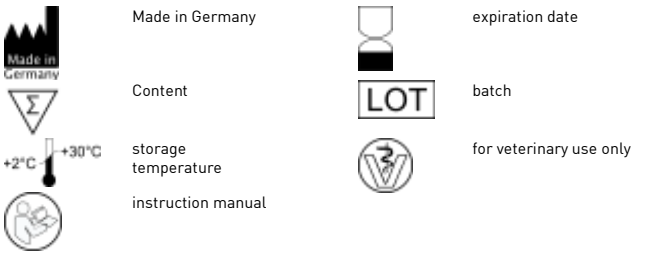
SYMBOLOGY



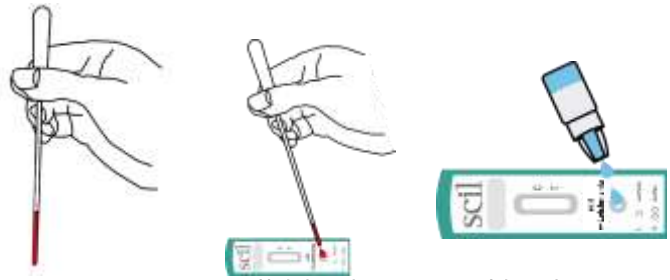
SAMPLE MATERIAL

Best sample material is a **freshly collected serum, plasma, supernatant of whole blood or whole blood.**
Separate the **serum or plasma** from whole blood as quickly as possible. Clear, non-hemolyzed specimens can prevent a slight background staining. **Supernatant of whole blood:** Let the whole blood sample stand for some time, so that the blood sediments. The supernatant of the sedimented blood can be carefully taken up with the pipette and be used for test procedure.
A **whole blood sample** should be used as quickly as possible. **Heparin or EDTA** blood may also be used.
The sample must be at room temperature (15-25°C) and should be mixed well before used for testing.

TEST PROCEDURE

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

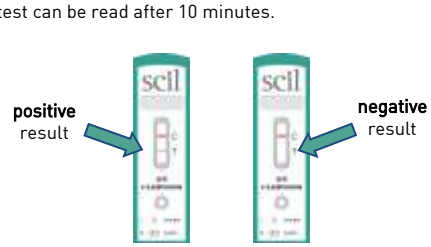
1. Aspirate sample material with the pipette up to the mark (20 µl).
2. Apply the sample material completely on the sample well.
3. Add two (2) drops of the reagent from the bottle of reagent into the sample well.



Ensure that no air bubbles are formed. If air bubbles occur, pop them with the pipette. The liquid starts running up the test strip after a short time (< 60 seconds). If whole blood is used, the fluid first needs to permeate into the test. This may take a little bit longer time than for serum. If the fluid does not run up the test strips after 90 seconds, add an additional drop of the **reagent** into the sample well, or press with the tip of the pipette into the sample well to reactivate the run of the test.

TEST EVALUATION

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



For a **positive result, two red lines** appear in the reaction field of the test cassette. A red line in the **T-region (T)** of the reaction field indicates a positive test result. Also a faint test line is considered as a positive test result.
The second red line in the **C-region (C)** indicates the control line, which indicates the correct performance of the test. The C-line is not a reference line and may have a different line intensity than the T-Line.
The **use of whole blood samples may lead to a lower detection sensitivity.** In case of a negative test result with whole blood, despite an existing suspicion of an infection, the test should be repeated with a serum or plasma sample from the whole blood, to obtain the maximum detection sensitivity.

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.

TEST PERFORMANCE

	Sensitivity	Specificity	Reference	n
Leishmania	90.91%	96.00%	ELISA*	47

*Enzyme-linked Immunosorbent Assay

Vers.:ENG20230102