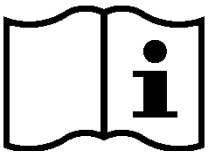
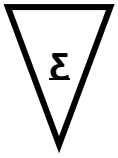


Useŕs Manual

Leishmania Antibody One-Step

For the detection of Leishmania antibody in serum or plasma samples of dogs

REF D1008-AB01



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January 2022

Please use only the valid version of the package insert provided with the kit.

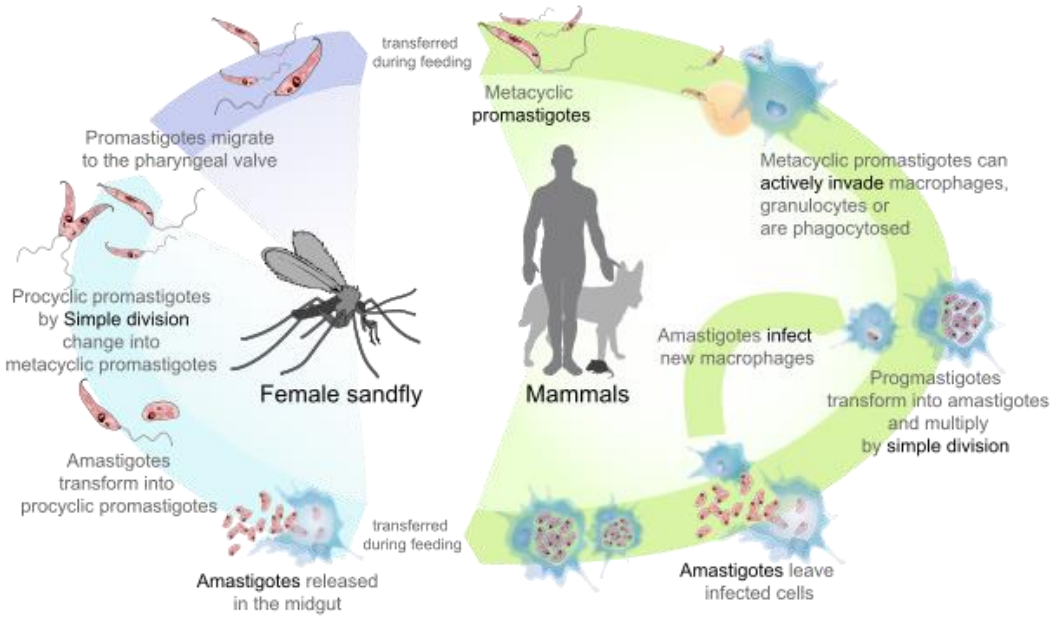
1. Table of Contents

2. Introduction

Leishmania is a parasite which causes Leishmaniasis in hyraxes, canids, rodents and humans. Leishmaniasis is transmitted by the bite of certain species of sandfly and causes skin sores which erupt weeks to months after the person affected is bitten by sandflies. Other consequences, which can manifest anywhere from a few months to years after infection, include fever, damage to the spleen and liver, and anaemia.

There are four main forms of Leishmaniasis:

- **Visceral Leishmaniasis** – the most serious form and potentially fatal if untreated. Caused exclusively by species of the L. donovani complex (L. donovani, L. infantum and L. chagasi) which are found in tropical and subtropical areas of all continents except Australia. **Visceral infections** are most common in Bangladesh, Brazil, India, Nepal and Sudan. They are also found in parts of China, such as Sichuan province, Gansu province and Xinjiang Uygur Autonomous Region.
- **Cutaneous Leishmaniasis** – the most common form which causes a sore (known as oriental sore) at the bite site, which heal in a few months to a year, leaving an unpleasant looking scar. This form can progress to any of the other three forms. It is caused by *Old World* Species L. major, L. tropica and L. aethiopica. In the *New World*, the most common culprits is L. mexicana. **Cutaneous infections** are most common in Afghanistan, Brazil, Iran, Peru, Saudi Arabia and Syria.
- **Diffuse cutaneous Leishmaniasis** – this form produces widespread skin lesions which resemble leprosy and is particulary difficult to threat. It is caused by L. aethiopia in Ethiopie and Kenya and by various subspecies of L. mexicana in Central and South America.
- **Mucocutaneous Leishmaniasis** – commences with skin ulcers which spread causing tissue damage to (particularly) nose and mouth. **Mucocutaneous infections** are most common in Bolivia, Brazil and Peru. They are also found in Karamay, China Xinjang, Uygur (Autonomous region). It is caused by the L. braziliensis.



Leishmaniasis is also known as a vector-borne disease which means the pathogenic microorganism is transmitted from an infected individual to another individual by an arthropod or other agent, sometimes with other animals serving as intermediary hosts.
The transmission of vector-borne diseases depends upon the attributes and requirements of at least three different living organisms: the pathologic agent, either a virus, protozoa, bacteria, or helminth (worm); the vector, which are commonly arthropods such as ticks or mosquitoes; and the human host. In addition, intermediary hosts such as domesticated and/or wild animals often serve as a reservoir for the pathogen until susceptible human populations are exposed. Other vector-borne diseases are for example babesiosis, cytauxzoonosis, bartonellosis, leishmaniasis, hepatozoonosis, heartworm and feline ehrlichiosis.

3. Intended use of the test kit

This One-Step test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect Leishmania antibody by use of a rapid immunochromatic assay.

4. Principle of the test kit

This Leishmania One-Step test is based on a chromatographic test strip and the detection of antibodies against Leishmania. A specific monoclonal anti-dog immunoglobulin is conjugated to colloidal gold particles and purified Leishmania proteins are immobilized on the strip in the test zone “T”. Leishmania antibodies in a sample that is applied to the strip at the sample zone “S” will bind to the gold particles which then migrate to zone “T”. A colour change in zone “T” indicates a positive test.
Labelled colloidal gold particles are also immobilized on the test strip in the control zone “C”, to indicate that the test is working properly.

5. Contents

- 24x Pouches, each containing 1 test strip and 1 pipette
- 24x Buffer vial
- 1x Protocol

6. Handling and storage of specimens

The One-Step should be stored at room temperature (±21°C). An opened package can be used until the expiry date. An opened package must be used immediately. If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test. Samples may be used fresh or may be kept frozen below -20°C before use.

7. Sample material

It is advised to test fresh serum or plasma samples. Do not use haemolytic or lipemic serum.

8. Precautions

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serials lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

9. Test protocol

1. Unpack the test strip and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **2 drops** of the sample to the buffer vial by using the pipette (Figure 1).
3. Mix well by using the pipette.
4. Add **4 drops** of the buffer vial containing the sample, with the included pipette ***slowly*** to the sample zone "S" zone (Figure 3).
5. Read the result after 20 – 30 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

Figure 1

Figure 2

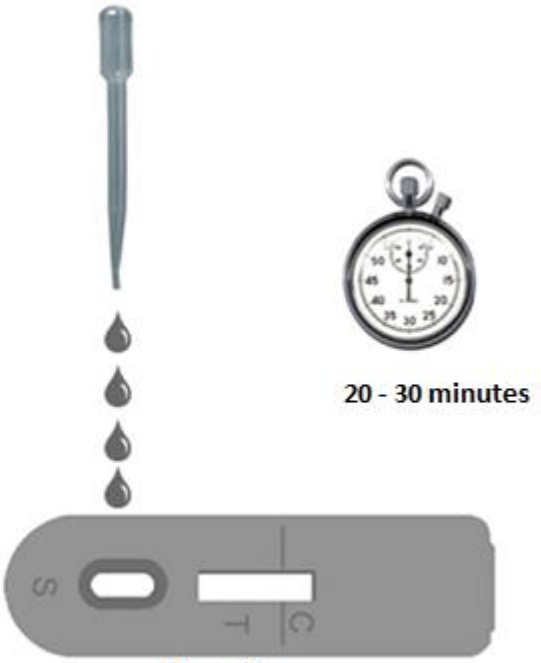


Figure 3

10. Validation of the test

To validate an EVL One-Step a control line should always be visible at control zone "C". If no control line is visible the test should be considered invalid.
Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

11. Interpretation of the test results

Positive:
Two lines are visible in zone “T” and in zone “C” (Figure A). The sample contains Leishmania antibodies.
Positive results may vary in optical density due to variations in viral concentrations in the sample.

Weak positive:
Two lines are visible, a weak line in zone “T” and a line in zone “C” (Figure B). The sample contains low concentrations Leishmania antibodies.

Negative:
Only one line is visible in zone “C” (Figure C). The sample does not contain Leishmania antibodies.

Not valid:
No line is visible in zone “C” (fig. D). Repeat the test procedure with a new test cassette.

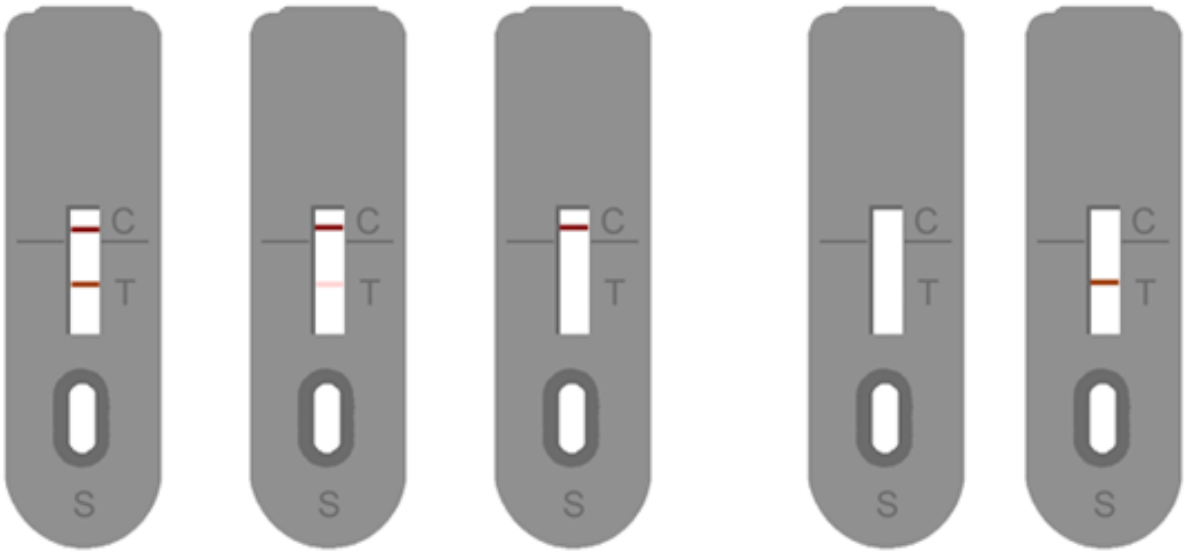


Figure A: Positive

Figure B: Weak positive

Figure C: Negative

Figure D: Not Valid

12. Symbols used with EVL ASSAYS

Symbol	English
	Consult instructions for use
	European Conformity
IVD	In vitro diagnostic device
RUO	For research use only
REF	Catalogue number
LOT	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.