

## VIASURE *Leishmania* Real Time PCR Detection Kit

- ▶▶ Leishmaniasis is a vector-borne disease caused by a protozoan parasite from the genus *Leishmania*. This parasite can infect both humans and other mammals after being bitten by a female phlebotomine sandfly. more than 20 species of *Leishmania* cause clinical manifestations (disease development), which are classified in three main forms: cutaneous leishmaniasis (CL), visceral leishmaniasis (VL), and mucocutaneous leishmaniasis (MCL). CL is the most common variety of leishmaniasis worldwide, consisting of ulcers ranging from small-localized lesions to large ulcers all over the body.

Leishmaniasis has been historically widespread in tropical climates across multiple territories. It is endemic in Asia, the Middle East, Northern Africa, the Mediterranean and South and Central America, being found in 89 countries. 1.5 to 2 new million new cases occur worldwide annually, and 70,000 deaths per year are attributed to this disease.

- ▶▶ The diagnosis of leishmaniasis has been carried out traditionally by combination of direct and indirect diagnostic methods. Several serological assays are available, including direct agglutination test, ELISA, immunofluorescence and western blot, but should be interpreted in the context of clinical history. Molecular methods based on amplification of nuclear or kinetoplast DNA are very sensitive and allow for the identification of the *Leishmania* species. Molecular tests are especially important where simpler techniques fail (eg., in mucosal lesions where parasites are sporadic, and in chronic lesions).
- ▶▶ The small 18S subunit is commonly selected for the PCR assays allowing to detect different *Leishmania* species distributed worldwide.



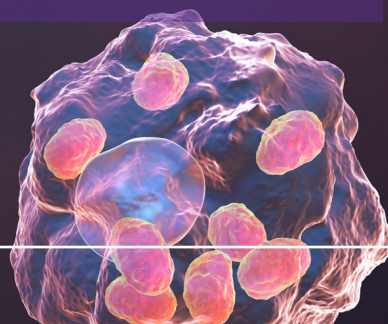
"Ready & Easy-to-use" kits.  
**Lyophilised product**



Transport and storage at **room temperature**.  
**Shelf-life: 24 months**



Validated according to **ISO 13485**  
and **CE marked**





## VIASURE *Leishmania* Real Time PCR Detection Kit

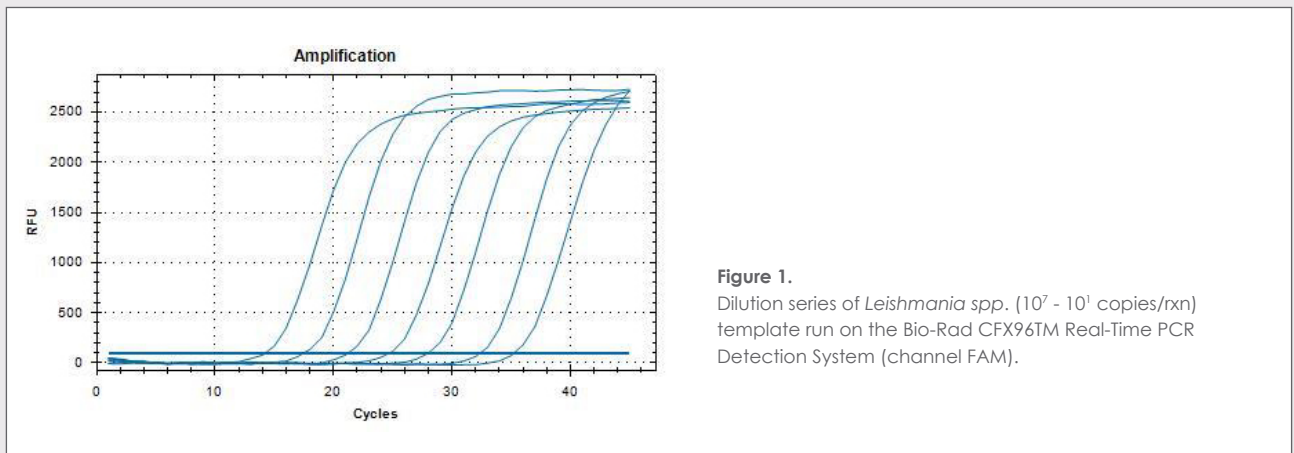
**VIASURE *Leishmania* Real Time PCR Detection Kit** is a real-time PCR test designed for the qualitative detection of DNA from species of *Leishmania* in skin biopsy, blood and bone-marrow aspirate samples from individuals suspected of *Leishmania* spp. infection (or leishmaniasis) by their healthcare professional (HCP).

**This test is intended for use as an aid in the diagnosis of visceral leishmaniasis (VL) and cutaneous leishmaniasis (CL) in combination with clinical and epidemiological risk factors.**

DNA is extracted from clinical specimens, amplified using qPCR and detected using fluorescent reporter dye probes specific for *Leishmania* species.

### Analytical sensitivity

▶▶ **VIASURE *Leishmania* Real Time PCR Detection Kit** has a detection limit of 10 genome copies per reaction for *Leishmania* spp. (18S rRNA gene) with a positive rate of ≥95% on blood samples.



**Figure 1.** Dilution series of *Leishmania* spp. ( $10^7$  -  $10^1$  copies/rxn) template run on the Bio-Rad CFX96TM Real-Time PCR Detection System (channel FAM).

### References - VIASURE *Leishmania* Real Time PCR Detection Kit -

6 x 8-well strips, low profile \_\_\_\_\_ VS-LEI106L  
 12 x 8-well strips, low profile \_\_\_\_\_ VS-LEI112L  
 96-well plate, low profile \_\_\_\_\_ VS-LEI113L  
 9 x 4-well strips, Rotor-Gene® \_\_\_\_\_ VS-LEI136  
 1 x 8-well strips, low profile \_\_\_\_\_ VS-LEI101L  
 2 x 4-well strips, Rotor-Gene® \_\_\_\_\_ VS-LEI101  
 TUBE FORMAT: 4 tubes x 24 reactions \_\_\_\_\_ VS-LEI196T

6 x 8-well strips, high profile \_\_\_\_\_ VS-LEI106H  
 12 x 8-well strips, high profile \_\_\_\_\_ VS-LEI112H  
 96-well plate, high profile \_\_\_\_\_ VS-LEI113H  
 18 x 4-well strips, Rotor-Gene® \_\_\_\_\_ VS-LEI172  
 1 x 8-well strips, high profile \_\_\_\_\_ VS-LEI101H

For more information and use procedure, read the instructions for use included in this product.



>5BHD<5FA 57 5@7C FDC F5HCB  
 %\*)' \$'J Ybhi fU '6j X"zG jN')%&  
 9bWjbcž7 5'-%(' \*  
 H\`.;,\$\$"+\*")\*)  
 >Ubr8L.Vt:a " j0z:4>Ubr8L"Vt:a



VIASURE/LEI-0621EN