

Loop mediated isothermal amplification (LAMP) assay for a reliable and rapid diagnosis of *Leishmania* infection

ICMR is seeking potential agencies interested in validation of Loop mediated isothermal amplification (LAMP) assay at multiple centres for a reliable and rapid diagnosis of *Leishmania* infection.

Product/Process:

Method for detection of *Leishmania* parasites in clinical samples of kala-azar and post kala azar dermal leishmaniasis (PKDL).

Application/Uses:

The test provides a diagnosis of Kala-azar and PKDL with more than 97% sensitivity.

1. This molecular assay is applicable for sensitive and specific detection of *Leishmania* parasites in a rapid and cost effective manner.
2. The assay is applicable for detection of various *Leishmania* species including *L. donovani* and *L. tropica* that are relevant in Indian context.
3. The assay detect 1 fg DNA of *L. donovani* (equivalent to <1 parasite) and 1 pg DNA of *L. tropica* (equivalent to <10 parasite) making it suitable to detect the early and asymptomatic infection which remain undetected by serological assays.
4. This highly sensitive and specific assay is ideal for mass screening in endemic areas as the Government of India has set up the goal of elimination of kala-azar by the year 2020.
5. An Indian patent application has been filed.

Salient Technical Features:

1. The invention provides a method for detection of leishmanial parasites in clinical samples in a rapid, sensitive and specific manner.
2. The assay is highly sensitive, specific and rapid for detection of *Leishmania donovani* parasite DNA in peripheral blood of KA patients and skin lesions of PKDL patients.
3. Indian patent application has been filed.

Scale of Development:

This method has been developed up to laboratory scale and validated by third party in endemic area.