FIND and partners are developing and evaluating diagnostic tests for early and accurate diagnosis of leishmaniasis, detection of infection in asymptomatic patients and treatment monitoring. These include tests to detect Leishmania antigens and DNA as well as anti-Leishmania antibodies. FIND is also developing strategies to improve access to visceral leishmaniasis (VL) diagnosis in endemic regions in Kenya.

FIND has been scaling up the fight against leishmaniasis by addressing critical diagnostic gaps for the disease through:

- improved and innovative diagnostic solutions;
- improving detection of asymptomatic infections and post-kala-azar dermal leishmaniasis (PKDL)

Leishmaniasis is a neglected tropical disease caused by protozoan parasites belonging to the genus Leishmania that are transmitted through the bites of sandflies. It comprises a group of infections with important clinical and epidemiological diversity spread across 98 countries in Africa, Asia, Europe and the Americas. Approximately 200,000 to 400,000 cases of visceral leishmaniasis (VL) and 700,000 to 1.2 million cases of cutaneous leishmaniasis (CL) are reported each year. The most serious form is VL, which is 90% fatal if left untreated. Treated patients of VL sometimes develop a condition known as post-kala-azar dermal leishmaniasis (PKDL), which presents as dermal lesions that can harbour parasites for years and can act as a reservoir of VL.
**CURRENT STATUS**

FIND and Kalon Biological have developed an ELISA kit that detects parasite antigens in the urine of VL patients. Evaluations conducted in Bangladesh and Kenya in collaboration with DNDi, icddr,b and KEMRI have shown this tool can be used for VL diagnosis and treatment monitoring. The kit is undergoing further evaluation in Kenya; and in Bangladesh, in collaboration with the Liverpool School of Tropical Medicine (LSTM), its performance in PKDL diagnosis and detection of asymptomatic infection is also under evaluation.

**FUTURE PLANS**

The feasibility of developing rapid tests for VL and dermal leishmaniasis (CL, PKDL) is being explored. A collection of well-characterized monoclonal antibodies (mAb), provided by Dr Diane McMahon-Pratt and Dr Charles Jaffe, will be screened using an assembly of clinical samples and Leishmania strains representing the diversity of the main Leishmania-endemic regions. The most promising mAb pairs will be used to develop prototype RDTs that will be evaluated in clinical trials in endemic countries.

**MOLECULAR DETECTION TEST**

Detection of Leishmania DNA in peripheral blood of VL patients would be a significant improvement to parasitological examination based on invasive sampling (i.e. spleen, bone marrow and lymph node aspiration). FIND, in collaboration with Eiken Chemical Co. and other partners, has developed a kit for detecting Leishmania DNA using the loop-mediated isothermal amplification (LAMP) technology. The ready-to-use Loopamp™ Leishmania Detection Kit detects Leishmania DNA with very high sensitivity and specificity. Since it is based on dried immobilized reagents, it does not need cold chain for transport and can be stored at ambient temperature. The results are read visually using LED light, or real time fluorimetry or tubidimetry, meaning that the test can be performed with less laboratory equipment than other DNA detection tests and by technicians with limited training in molecular biology.

**CURRENT STATUS**

In a clinical trial carried out in Sudan, in collaboration with the IEND, and in Spain, with the Instituto de Salud Carlos III (ISCIII), the test showed excellent performance for human VL diagnosis using peripheral blood, which allows replacing the need for invasive lymph node and bone marrow aspirates when parasite confirmation is needed.

The Loopamp™ Leishmania Detection Kit has also shown an excellent performance in CL diagnosis. In a clinical trial conducted in Kabul, in collaboration with the NMLCP, HealthNetTPO, and AMC it showed results comparable to real-time PCR.

**FUTURE PLANS**

Further evaluation of the Loopamp™ Leishmania Detection Kit for VL diagnosis is being conducted in Kenya and Bangladesh by KEMRI and icddr,b, respectively. With LSTM and icddr,b we are also evaluating the potential of the kit to diagnose PKDL and detect asymptomatic infection in Bangladesh. And for CL, tests are being evaluated in Sudan by the IEND and in Suriname by the AMC, Anton de Kom University and the Ministry of Health.

In collaboration with ISCIII, we have demonstrated the efficacy of the Loopamp™ Leishmania Detection Kit for canine leishmaniasis diagnosis using bone marrow, a prospective evaluation is being carried out to assess its performance using peripheral blood from dogs.
IMPROVING ACCESS TO VL DIAGNOSIS AS A KEY FOR VL CONTROL IN EASTERN AFRICA

Five million people live at risk of contracting VL in Kenya, which has been listed by WHO among the top 14 high burden countries for VL. Highly endemic counties in Kenya are Baringo, Isiolo, Marsabit, Turkana, Wajir and West Pokot, where the disease occurs in well-defined foci, and the likelihood of elimination is high if the population living in these areas is fully covered by a surveillance programme.

With targets for VL elimination being reached in the Indian sub-continent, WHO has recently encouraged partners working in VL control to explore the possibility of eliminating the disease in specific foci in eastern Africa. We believe that improving access to diagnosis and treatment of VL is the cornerstone to successful VL elimination.

This can be achieved through:
- increasing the number of laboratories with VL diagnostic capacity;
- increasing the number of health workers trained in good clinical laboratory practices;
- improving local awareness of the availability of screening and treatment of VL through education and communication by targeting primary healthcare providers and communities.

In collaboration with the Kenya and Turkana County Ministries of Health, FIND has characterized and mapped 68 health facilities in three highly endemic subcounties in Turkana, identified gaps in VL diagnosis, conducted training of health workers, upgraded strategically located laboratories and delivered information materials. FIND is also working with WHO and DNDi to ensure access to VL treatment in the region.