

**Title:** Serum and Urine-based Rapid Tests for Diagnosis of Human and Canine Visceral Leishmaniasis (VL) and Post Kala-azar Dermal Leishmaniasis (PKDL) in Field Settings.**INTRODUCTION:**

Early diagnosis is a key factor for effective control of neglected tropical diseases like VL (kala-azar). Development of a field adaptable rapid test which is equally effective in all endemic areas has been a thrust for decades. Moreover, if the test is non-invasive and can distinguish infected from cured patients it would be the advantage over current diagnostics.

CHALLENGE/APPLICATION DOMAIN:

CSIR-IICB has developed serum and urine-based lateral flow tests (LFT) for rapid diagnosis of human and canine visceral leishmaniasis (VL) and post kala-azar dermal leishmaniasis (PKDL) in field settings. We have invented and validated several leishmanial proteins as biomarkers, such as soluble, recombinant, and fusion proteins in rapid test formats.

Opportunity:

The commercially available tests that are in use for VL diagnosis are mostly invasive and are not used as a test of cure. Most of the serum-based rapid tests do not perform equally well in all endemic areas. Moreover, the diagnosis of PKDL through these rapid tests is not consistent. There is no effective urine-based test available in the market for VL diagnosis.

CSIR-IICB has validated our dipstick technology in six countries including, India, Sri Lanka, Nepal, Spain, Ethiopia and Brazil and found it better than commercially available test in serological diagnosis. We have developed a urine-based LFT for non-invasive diagnosis of VL and PKDL. The antibody titre decreases significantly in urine after treatment, so the urine-based test shows its affectivity as a test of cure. Additionally, LFT was evaluated with Brazilian and Italian canine serum samples and found very effective for diagnosis of canine VL.

STAGE OF TECHNOLOGY DEVELOPMENT:

The technology is ready to use as lateral flow strip test. Materials used for LFT such as antigens, are prepared in the laboratory indigenously. Test is simple in storage, handling and performance in rural settings.

REFERENCES/ PATENTS:

Indian Patent Application: 96/DEL/2015, dated: 13/01/2015

PCT: PCT/IN2015/000268, dated: 29/06/2015

Some other patents relevant to the title are under process of filing.

PROJECT INVESTIGATOR:

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