Serum and urine-based kits for diagnosis of human and canine visceral leishmaniasis (VL) and post kala-azar dermal leishmaniasis (PKDL) in field settings

USP Of Technology	To bring affordable, easy to handle and field adaptable point-of-care diagnosis (PoCD) to visceral leishmaniasis endemic regions of the world
Market Size/ Potential	Leishmaniasis diagnosis market covers analysis by disease type (VL. PKDL); pathological tests (ELISA, LFT); host type (human and canine), and geography (South America, Europe, Africa, and Asia)
Extent Of Indigenisation	India's public laboratories and research institutions have the expertise, resources, and collaborative networks to deliver working Lateral Flow Test (LFT) or Rapid Diagnostic Kit (RDT) prototypes and process chemical ingredients.
Import Substitution	Two major components of PoCD – Reagents and Instruments. Reagents include membranes and chemicals and instrument include dispenser, dryer and cutter, all are locally available. Thus low capital investment and labour cost.
Details Of Raw Material Supply Chain	Raw material like membranes (nitrocellulose, sample pad, adsorption pad, and conjugate pad) and chemicals are taken to research institutions, or various manufacturers that assembles them as LFT kit and evaluate with biological samples and finally distribute them to Gov. hospitals, pathological labs, private clinicians and NGOs
Scope For Overseas Market Penetration	Market penetration can be done with agreements and collaboration with countries covered in the global VL such as Nepal, Bangladesh, Sri Lanka, Brazil, Sudan, Ethiopia and Spain
Market size and opportunity (India and International)	The global leishmaniasis treatment market was valued at $97.9 million in 2022 and is projected to reach $135.8 million by 2029
Competitive products and advantages over competition	The **rK39 RDT**, satisfactory in **India (97% Sen. & 90% Spe)** but less sensitive in **Africa (Sen. 68%), Latin America (Sen. 85%)**. rK39-RDTs with urine samples low **specificity 66.2–77.08%.** Our RDT can detect VL, and PKDL serum and urine samples with high sensitivity and specificity, and in contract to rk39 our antigen has low reactivity with follow-up samples from cured individuals.
Number of samples tested/validated	More than 300 samples tested for our RDT kit validation (Patent applied). Samples include Indian VL, PKDL and controls serum and urine samples, as well as Brazilian human and canine VL and controls serum samples.
Cost of Sampling/testing	Cost for each RDT kit is approx. 1 USD.
Current stage of Development (Technology Readiness Level (TRL):	Medical Devices and Diagnosis category TLR 5/ 6
Other Information	Patent Applied: **PCT/IN2024/050371** Dated: **April 20, 2023** **Indian Priority Patent Application no : 202311028946**