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Visceral Leishmaniasis Rapid Diagnostic Test Performance

World Health Organization

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Abbreviations

BHU	Banaras Hindu University
CL	Cutaneous leishmaniasis
DAT	Direct Agglutination Test
EA	East Africa
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
HEC	Healthy endemic control
HIV	Human immunodeficiency virus
ICT	Immunochromatographic tests
ID	Identification number
ISC	Indian subcontinent
ITM	Institute Tropical Medicine
KIT	Royal Tropical Institute
LN	Lymph node
QA	Quality assurance
RDT	Rapid diagnostic test
rK 39	Recombinant antigen 39
rKE 26	Recombinant antigen 26
RFA	Request for applications
SA	South America
SOP	Standard Operating Procedure
TDR	Special Programme for Research and Training in Tropical Diseases
VL	Visceral Leishmaniasis
VL-LN	Visceral Leishmaniasis Laboratory Network
WHO	World Health Organization

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Executive Summary

Visceral Leishmaniasis (VL) is one of the world's most neglected diseases, affecting the poorest people in developing countries. Some 500,000 new cases occur annually with 90% of all VL cases in the Indian subcontinent (Bangladesh, India, Nepal), Sudan, Ethiopia and Brazil. Leishmaniasis is a poverty-related disease associated with malnutrition, weakness of the immune system, displacement, poor housing, illiteracy, gender discrimination, and lack of resources.

Up until the 1990s, accurate VL diagnosis necessitated parasitological confirmation by microscopy or culture of the blood, bone-marrow, lymph nodes or spleen. The invasiveness and potentially fatal complications associated with splenic aspiration motivated the development of non-invasive serological tests such as direct agglutination test (DAT) and immunochromatographic lateral-flow assays, commonly referred to as rapid diagnostic tests (RDT).

Enthusiasm and rapid uptake of RDTs for VL, particularly in the Asian region, has translated into the emergence of several commercialized tests targeting serum antibodies to rK39 and other antigens, e.g. rKE 16. However, there are few head-to-head evaluations of diagnostic accuracy for these tests. Therefore, in collaboration with clinicians and laboratory scientists in endemic regions, TDR coordinated a multicentre and multiregional comparative evaluation of commercially available antibody-detecting RDTs to inform country policy. This report describes the performance of four commercially available rK39 and rKE16 antibody detecting RDTs in three global regions of VL endemicity (Indian subcontinent (ISC), East Africa (EA), South America (SA)) using well characterized panels of human sera; a fifth RDT was evaluated in the ISC.

VL RDT Evaluation Programme

All companies manufacturing RDTs for VL under license ISO-13485 Quality System Standard or US FDA 21 CFR were invited to submit tests for evaluation; 4 responded to the call contributing 5 products in total. This report describes the performance of these five commercially available rK39 and rKE16 antibody detecting RDTs. Nine laboratories were chosen in three global endemic regions; namely ISC (n=4), South