Call for Expressions of Interest (EOI):

Evaluation of rapid diagnostic tests (RDTs) for diagnosis of visceral leishmaniasis disease in humans in eastern Africa

Deadline for submission: 23 January 2026 (16:00 CET)

Background

Access to safe, appropriate, and affordable diagnostics of good quality is critical in achieving targets set out by the 2021–2030 Neglected Tropical Diseases (NTD) road map. This is particularly important for neglected tropical diseases that require diagnosis for case management such as visceral leishmaniasis (VL). Few diagnostic tests are available for VL diagnosis and the performance of the test varies between geographical regions. Furthermore, there is currently only limited data on the performance of rapid diagnostics tests for VL in eastern Africa.

To fill that gap and support VL elimination efforts in Africa, the Special Programme for Research and Training in Tropical Diseases (TDR), hosted at the World Health Organization (WHO), and WHO's Department of Neglected Tropical Diseases, will conduct a research study aimed at evaluating the performance of rapid diagnostic tests for human VL in eastern Africa, starting with a laboratory-based study followed by a field study. This call for expressions of interest refers to the first laboratory-based research study.

Objective of the call

The present invitation focuses on: **Visceral leishmaniasis rapid diagnostic tests for diagnosis in humans.**

We are seeking expressions from manufacturers interested in participating in the research study which would evaluate their rapid diagnostic tests for diagnosis of human visceral leishmaniasis in eastern Africa. The invitation specifically pertains to a **visceral leishmaniasis rapid diagnostic in-vitro device.**

Evaluation scheme

Overview of the study:

The study will evaluate rapid diagnostic tests for the detection of anti-leishmaniasis antibodies or antigens. This will be a **laboratory-based evaluation** coordinated by TDR in several sites in eastern Africa. These evaluations will use a standardized protocol and validated archived samples. The tests will be evaluated against reference standards (parasitology, molecular assays, and/or validated serological tests) for **sensitivity** and **specificity** and for **reproducibility**, assay **simplicity and suitability for use** in developing countries. Each test will be evaluated at two or three laboratory sites each using a standardized panel of about 200 samples, of which about half are VL cases.

WHO will coordinate the work at the sites and the preparation of the study report.

All test manufacturers will be given the opportunity to review and comment on the evaluation results for their tests. Whilst such comments will be duly considered by WHO, please note that in order to safeguard the objectivity and independence of this study, WHO must at all times maintain full control over the evaluation of the test results and the content of any resulting publication.

The final results of the study will be published and made available to interested stakeholders active in the procurement of rapid diagnostic tests for VL.

Tests that demonstrate, through this research, good performance on the stored samples may be considered for inclusion in future field studies.

Manufacturers' contribution

Manufacturers confirmed to take part in the laboratory-based study will be requested to provide free of charge a total of 675 rapid tests (225 tests / laboratory sites) and supporting documentation, and enter into an agreement with WHO for the purposes of the study.

RDT profile of interest

This call for expressions of interest targets products meeting the following specifications:

1. The submitted product shall be an in-vitro rapid diagnostic test for the diagnosis of visceral leishmaniasis in humans.
2. The submitted product shall be available commercially for VL diagnosis in humans, or if the RDT itself is not yet commercially available, the product should be at an advanced stage of development and the manufacturer should have plans for commercial production.

3. The submitted product shall use rapid test format and/or technologies that can be used at, or near to, point-of-care.

4. The preferred criteria also include:

    - Sample types should include whole blood, serum or plasma.
    - The intended population should be or include the population at risk in eastern Africa.
    - Performance claims should ideally meet or exceed the sensitivity and specificity requirements of the Global Visceral Leishmaniasis Programme (sensitivity ≥95%, specificity ≥96.5%).
    - Test alignment with the minimum test characteristics set in the WHO target product profile (TPP) for a diagnostic test to confirm visceral leishmaniasis.

    The TPP is available as a reference at:
    https://iris.who.int/bitstream/handle/10665/378703/9789240098718-eng.pdf

Preliminary evidence on the diagnostic performance generated in the eastern Africa population will be an advantage.

Confidentiality

Any information provided to WHO in connection with the application or the study that is confidential should be clearly marked as such. WHO shall implement appropriate measures to safeguard the confidentiality of such information.

Without prejudice to any proprietary information, WHO shall publish the results of the study. WHO may, in accordance with its rules, regulations and policies publish the identity of the RDTs selected for evaluation and the corresponding evaluation results.

How to apply

Manufacturers whose in-vitro diagnostics are intended for **visceral leishmaniasis rapid diagnosis in humans** are encouraged to express their interest by completing a submission form (questionnaire), and uploading it together with the necessary supporting documentation through the following link: **Submit EOI here**.

Supporting documentation should include: (i) the product insert, (ii) any independent test performance data on human samples, and (iii) one of the following documents substantiated by the most recent inspection reports:

- An ISO 13485 certificate covering the product manufacturing activities; or
- A certificate ensuring that the IVD (device, reagents, and associated equipment) is manufactured at a site that is compliant with ISO 13485 requirements; or
- An equivalent quality management system recognized by a stringent regulatory authority of the Founding Members of the Global Harmonization Task Force (GHTF); or
- A letter from WHO ensuring that the manufacturing site has undergone inspection by the WHO Prequalification of In-Vitro Diagnostics Programme and has been found compliant with WHO prequalification requirements.

Review and selection

Submissions will be reviewed by an independent technical panel (see criteria and profile of interest in section "RDT profile of interest" above). Manufacturers selected to participate in the research study will be contacted with details on evaluation protocols, timelines, and contractual requirements. However, no explanation for the selection or rejection of any expression of interest will be provided, and the selection process will not be subject to any claims or appeal. WHO will not in any circumstances reimburse any costs or expenses associated with the submission of an expression of interest (including possible complementary information and documentation), nor any costs associated with possible further discussions. The submission and selection process set forth in this document will not be subject to claims for financial compensation of any kind whatsoever.

WHO reserves the right to freely decide on the selection of those entities who will be invited to participate in the research study and/or for further discussions and without having to provide any justification to entities who will not be so invited. WHO further reserves the right not to follow up on any expression of interest at all.

WHO shall have sole and absolute discretion to conduct the study in such a manner as it deems appropriate.

Contact:

For any questions related to the technical content and scope of this call, please contact:
Dr Christine Halleux (halleuxc@who.int), cc. Dr Lieselotte Cnops (lieselotte.cnops@who.int)

In case of technical issues with the online submission, please contact:
Michelle Villasol (villasolm@who.int), cc. Dr Lieselotte Cnops (lieselotte.cnops@who.int)

Note: there will be reduced support available between 20 December 2025 and 04 January 2026 – expect delays in responses during that period.

We would like to emphasize that it is not the mandate of TDR and WHO to issue any approvals or licenses for rapid diagnostic tests. This responsibility lies with national regulatory authorities. WHO does not, furthermore, as a matter of policy, endorse any specific commercial products over others.

In this regard the results of study, any manufacturer's or product's participation in the study, or WHO's name, acronym, or emblem may not be used for commercial and/or promotional purposes. Any use of the study results or of WHO's name, acronym, or emblem requires WHO's prior written authorization.