



## Call for study partners: comparative assessment to evaluate the performance of immunoassays for the detection of Lassa virus-specific antibodies

### BACKGROUND

FIND is a global non-profit organization dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases. Recently, FIND received funding to support diagnostic preparedness for Lassa fever virus (LASV), a virus that causes haemorrhagic fever affecting 100,000–300,000 individuals annually throughout West Africa, and which is a high-priority pathogen under the WHO R&D Blueprint Initiative. With local and international partners, FIND is supporting diagnostic preparedness for LASV through the development and evaluation of diagnostic tests that are fit-for-use in affected countries; laboratory capacity building to evaluate and implement new tests in the development pipeline; and establishing sample archives and standards to support future development.

Detection of LASV relies on viral culture, molecular diagnostics, and immunoassays to detect viral antigen and/or LASV-specific IgG and IgM. However, challenges in biosafety, a lack of reference standards, and limited access to geographically diverse samples make it difficult to conduct comparative evaluations of available tests. Data on the analytical and clinical performance of available tests, particularly for immunoassays detect LASV-specific IgG and IgM are needed to inform seroepidemiological studies to better understand the prevalence of LASV in West Africa, especially in the planning of vaccine trials.

This call for study partners is issued by FIND to solicit applications to participate in a FIND-led comparative assessment study to evaluate the performance of available Lassa fever immunoassays for the detection of LASV-specific antibodies.

### OBJECTIVES AND PARTNER ELIGIBILITY

*Objective of the study:* To assess the clinical performance of currently available immunoassays against a reference standard (to be determined, but may include IFA, ELISA, etc).

#### *Requirements for study partners*

- Access to well-characterized samples from people previously infected with LASV, either through an existing biorepository or partnership with hospitals or health centers with collections in areas with active LASV transmission (e.g. in Guinea, Liberia, Nigeria, Sierra Leone)
  - o Sample volumes should ideally be enough for use in multiple tests (i.e. >0.5 mL). However, if an existing repository is unavailable or sample volumes are insufficient, study partners should have the ability to collect samples from patients who are confirmed as LASV positive
- Ability to import and conduct research on high-containment samples
- Compliance with good laboratory practice (GLP) and experience in good clinical practice (GCP)
- Ability to enter into agreement with FIND (legal entity or operating under a legal entity)
- Operations (e.g. financial, logistics) in place to receive and report on use of external funding; and to receive and use test kits per GCP
- Compliance with data capture and security during study (e.g. ability to incorporate OpenClinica, FIND's clinical data capture system)



## RESPONSIBILITIES OF FIND

- FIND will provide tests and any associated reagents as part of the study
- Funding support for laboratories will be available, to a maximum of USD 200,000 (may be split between partners to ensure geographic breadth of samples)
- FIND will provide partners with a generic study protocol, and work with partners to harmonize the protocol to ensure comparability among different laboratories
- FIND's Data Services group will lead data review and analysis, and support data capture and security in collaboration with and among partners

## TIMELINES

- Expression of interest and a summary (3 pages MAX) for the envisioned study is to be submitted by **5 April 2019**. A template for this document is provided below.
- Submission review and due diligence will be performed by FIND staff. Final selection of study partners will be done by **19 April 2019**. Contract review and signatures are expected to be complete by **15 May 2019**.
- Alignment of the study protocol with selected study partners will be finalized by **15 June 2019**.
- Study expected start **1 August 2019**.

### *Conditions:*

- Given that the study will inform evidence-based policy, FIND reserves the right to assess, or have assessed, the partners and monitor protocol implementation and compliance. FIND will need to have access to all data for analysis by an independent statistician and evidence compilation for external stakeholders (e.g. WHO, CEPI) – this does not affect study publication by the investigators.

## SEND SUBMISSIONS BEFORE 5 APRIL 2019 TO:

Devy Emperador, Scientific Officer: [devy.emperador@finddx.org](mailto:devy.emperador@finddx.org)

## FOR QUESTIONS, CONTACT:

Devy Emperador, Scientific Officer: [devy.emperador@finddx.org](mailto:devy.emperador@finddx.org)

Cassandra Kelly-Cirino, Director of Emerging Threats [cassandra.kelly@finddx.org](mailto:cassandra.kelly@finddx.org)

**TEMPLATE Call for study partners: Comparative assessment studies to evaluate the performance of immunoassays for the detection of Lassa virus-specific antibodies**

NOTE: Up to three (3) pages max

<p><b>Name of Applicant(s)</b></p>	<p><i>List here the name of the main applicant and co-applicants.</i></p> <p><i>Specify affiliations, roles and the names of the institutes where the study will be conducted.</i></p>
<p><b>Justification</b></p>	<p><i>Describe your group’s capabilities to do the comparative assessment study. Include prior experience in diagnostic assay evaluations, clinical studies, laboratory capabilities, and involvement in any research consortia.</i></p>
<p><b>Sample availability</b></p>	<p><i>Describe the availability of samples (both retrospective and prospective) that your laboratory/team have access to. Include type and number of samples currently stored, volumes, if clinical information is available, and whether prospective sampling of convalescent patients is possible. Also include availability of LASV-negative samples.</i></p>
<p><b>Study setting</b></p>	<p><i>In which country/countries were/will samples be collected, and where/how will you enrol your study population if prospective sampling is to occur.</i></p>
<p><b>Budget / funding</b></p>	<p><i>Provide a high-level estimation of the total study budget required. Although the study protocol will be finalized and agreed upon after selection, assume 5 assays will be evaluated with 300 samples for developing the budget estimation.</i></p> <p><i>Please specify if co-funding is available to support the comparative assessment and specify for which items you request co-funding from FIND (plus an estimation of the total co-funding required).</i></p>
<p><b>Contact details</b></p>	<p><i>Provide contact details of corresponding investigators for further communication with FIND.</i></p>