**Call for Expressions of Interest (EOI) from test developers: 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 viral haemorrhagic fever affecting between 100,000 – 300,000 individuals throughout West Africa and 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 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 for vaccine and therapeutic efficacy trials.

The purpose of this expression of interest (EOI) is to solicit researchers and commercial companies with immunoassays for the detection of Lassa virus (LASV)-specific IgG and IgM to update the landscape of available immunoassays. The results of this EOI will inform selection of assays for comparative assessment studies that are intended to provide evaluation data from clinically relevant samples that developers can use to support further assay development or regulatory submission. Similarly, results from the comparative assessment study will be shared with the global health community to inform test use for LASV clinical diagnosis, epidemiology, and vaccine development activities.

**OBJECTIVES**

The objectives of this call are:

* To update the landscape of available immunoassays for the detection of LASV-specific IgG and IgM
* To gauge interest among test developers to participate in a FIND-led comparative assessment study
* To include promising tests in a FIND-led comparative assessment study using clinically relevant samples

*Requirements for test developers*

FIND is particularly interested in immunoassays with previously published methods, data supporting sensitivity and specificity of IgG and/or IgM detection, data supporting pan-LASV IgG and/or IgM detection, and tests that can be performed in settings with limited biosafety access.

**BENEFITS OF WORKING WITH FIND**

* FIND will support procurement of commercially available tests, where relevant. However, a maximum purchase price may be set depending on the volume of responses received.
* FIND will share test performance results with the provider as well as comparative results for other assays in a de-identified format

**TIMELINES**

* Expression of interest and completion of the company and technology questionnaire (including analytical performance data) is to be submitted by **5th April 2019**. The questionnaire is provided separately.
* Submission review and due diligence will be performed by FIND staff. FIND staff will contact applicants in case of any questions and confirm interest in test evaluation.
* FIND will procure tests from the selected test developer(s) after the protocol is finalized (tentatively **June-July 2019)**.
* FIND will provide results to test developer(s) by **30th November 2019.**

*Conditions:*

* Where developers consider there is information to remain confidential, FIND can provide its standard Mutual Non-disclosure Agreement for execution.

**SEND SUBMISSIONS BEFORE 5th April 2019 TO:**

Devy Emperador devy.emperador@finddx.org

**FOR QUESTIONS, CONTACT:**

Devy Emperador devy.emperador@finddx.org

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**TEMPLATE for**

**Call for test developers: Immunoassays for the detection of Lassa virus-specific antibodies**

NOTE: Up to three (3) pages max

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| **General details** |
| **Name of applicant:**  | *List here the name of the main applicant and co-applicants. Can include name of company and/or principal investigator for lab-developed tests.*  |
| **Contact details:**  | *Provide here contact details of corresponding investigators for further communication with FIND.* |

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| **Test details** |
| **Name of test** | *Provide here the name of test.* |
| **Test description** | *Briefly describe the assay. Should include information on:* * *Test type [ELISA kit, ELISA reagents and validated platforms, IFA etc.]*
* *Sample analyte [LASV IgG/ IgM to GP/NP/Z]*
* *Sample type, etc.*
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| **Analytical performance** | *Provide results from analytical performance studies and references to published papers. Should include data on limit of detection (LOD), cross reactivity, and accuracy (i.e. test sensitivity and specificity). Include reference assay. If unavailable at the time of submission, include a timeline of when analytical performance data will be available.* *Minimum requirements of assay:* * *LOD: not specified but must include information on lowest concentration of test, preferably in ng/ml*
* *Cross-reactivity: no cross-reactivity to antibodies against other arenaviruses*
* *Sensitivity: >90%*
* *Specificity: >95%*
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| **Clinical performance**  | *Provide results from clinical performance studies and references to published papers, if available. Include reference assay.* |
| **Cost** | *Provide cost per kit/reagent.*  |

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| **Organization details** |
| **Type of organization** | *Describe type of organization (e.g. academic research laboratory, government laboratory, registered company, etc.)*  |
| **Location** | *Provide the location where your organization/company is registered.*  |
| **Website** | *Provide the web link to your organization/company’s website, if available.*  |
| **Test supply** | *Answer the following question.* Is research group/organization/company the manufacturer of the test presented to FIND? [ ] Yes [ ] No*If YES: please detail the location of manufacturing site and production capacity.* *If NO: please describe how end-users can obtain tests.*  |
| **Other products available** | *List here the names of other products available, if applicable.*  |