**Expression of Interest (EOI): Test developers to participate in FIND-WHO Initiative on standard evaluation of Zika diagnostics**

**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 is leading on a FIND-WHO initiative to conduct a standardized evaluation of currently available molecular and immunologic diagnostic tests for ZIKV in order to assess test performance and thereby better inform public health policy, surveillance programs, and clinical management of patients with suspected ZIKV infection.

Zika virus (ZIKV), once considered a cause of rare and mild infection, emerged in 2015-2016 as the cause of a global epidemic, with demonstrated capacity for rapid global spread and a cause of birth defects, other adverse pregnancy outcomes, and Guillain-Barré syndrome. In response, WHO declared Zika virus and its associated complications a Public Health Emergency of International Concern (PHEIC), and subsequently committed to a long-term program for ZIKV preparedness, prevention, and control. Despite the surge of research and development of ZIKV diagnostics, there is limited data on the optimal approach to ZIKV diagnostic testing.

This expression of interest is issued by FIND for test developers interested in evaluating their assays using ZIKV and arbovirus reference panels and samples. The results from this EOI will inform selection of assays for analytical and clinical evaluation studies, where we will provide blinded reference panels for testing on site, as well coordinate external evaluations of the assay to external laboratories with access to well-characterized samples. Results from these studies will be shared with the global health community to inform ZIKV diagnostic testing approaches.

**OBJECTIVES AND PARTNER ELIGIBILITY**

*The objective of the call are:*

* To gauge interest among test developers to participate in a FIND-led standardized evaluation of ZIKV diagnostics
* To include promising tests in the FIND-led evaluation using available reference panels and well-characterized samples

*Requirements for developers*

* Compliance with good laboratory practice (GLP)
* 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

**RESPONSIBILITIES**

* FIND will establish material transfer agreements (MTAs) between the developer, FIND, and potential external evaluation sites
* Vitalant Research Institute (VRI) will support reference panel shipment to the developer
* The developer will donate test kits to external evaluation sites
* FIND will provide developers with a generic study protocol and work with developers to harmonize the protocol to ensure comparability among different sites
* VRI will lead data review and analysis, and support data capture and security in collaboration with and among partners

**BENEFITS**

Benefits for participating in this FIND initiative include:

* Access to samples panels developed through this project
* Ability to use data for regulatory submissions

**TIMELINES**

The currently funded phase of this project will run until March 2020. Main project milestones include:

* Expressions of interest submitted to FIND by 4th October 2019
* Contracts signed by 5th November 2019
* Evaluation panels available by 15th November 2019
* Evaluation data available to FIND by 28th February 2020

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

**SEND SUBMISSIONS BY 4th October 2019 TO:**

Devy Emperador devy.emperador@finddx.org

**FOR QUESTIONS, CONTACT:**

Devy Emperador devy.emperador@finddx.org

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**[TEMPLATE] EOI: Test developers to participate in FIND-WHO Initiative on standard evaluation of Zika diagnostics**

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 [NAT reagents, ELISA kit, ELISA reagents, etc.]*
* *Sample analyte [ZIKV RNA, IgG, IgM, etc.]*
* *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 specimens tested and reference assay. If unavailable at the time of submission, include a timeline of when analytical performance data will be available.*  |
| **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.*  |
| **Regulatory Status** | *State whether the test has received regulatory approval or is for research use only.*  |
| **Quality management system** | *State any quality management system(s) and/or certification(s) in place for research & development and manufacturing (e.g. GxP, ISO, CLIA, etc.)* |
| **Other products available** | *List here the names of other products available, if applicable.*  |

**Appendix I: Protocol synopsis**

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| Title | Analytical and clinical validation of arbovirus diagnostics for ZIKV detection.  |
| Short title  | Validation of ZIKV diagnostics. |
| Background and rationale | Zika virus (ZIKV), once considered a cause of rare and mild infection, emerged in 2015-2016 as the cause of a global epidemic, with demonstrated capacity for rapid global spread and a cause of birth defects, other adverse pregnancy outcomes, and Guillain-Barré syndrome. In response, WHO declared Zika virus and its associated complications a Public Health Emergency of International Concern (PHEIC), and subsequently committed to a long-term program for ZIKV preparedness, prevention, and control. Despite the surge of research and development of ZIKV diagnostics, there is limited data on the optimal approach to ZIKV diagnostic testing.The goal of this study is to conduct a standardized, comparative assessment of available ZIKV diagnostics that will allow clinicians, public health organizations, laboratory managers, and emergency response plans to develop an optimal approach to ZIKV diagnostic testing.  |
| Primary objective | **Molecular assays*** 1. Determination of ZIKV RNA limit of detection (LOD) against a panel of ZIKV RNA concentrations derived from the ZIKV international standard
	2. Determination of diagnostic accuracy for ZIKV RNA detection against a panel of ZIKV and DENV positive samples

**Serology assays*** 1. Determination of diagnostic accuracy for ZIKV IgM detection against a panel of ZIKV and DENV positive samples
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| Study design | Laboratory-based study to assess assay LOD and test performance from blinded reference panels. This is a tiered evaluation of ZIKV molecular and serological diagnostics. Depending on currently published data, assays will be initiated in one of three evaluation phases: * Qualification: New assays or assays that have no external evaluation data will be evaluated using a reference panel consisting of a small subset of spiked or clinical samples.
* Analytical verification: Molecular assays that pass qualification criteria will be evaluated using a reference panel consisting of a large subset of spiked samples.
* Clinical evaluation: Molecular assays that meet qualification and analytical criteria, or serological assays that meet qualification criteria, will be evaluated using a reference panel consisting of a large subset of clinical samples from different geographic regions.
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| Study sites/setting | Manufacturing site laboratories, national reference laboratories, and academic laboratories  |
| Study population  | **Molecular assays:** Qualification and analytical validation panel consisting of ZIKV RNA international standard; clinical panel consisting of leftover anonymized blood donor samples **Serology assays:** Qualification panel and serology evaluation panels consisting of *leftover* blood donor samples and anti-ZIKV international standard |
| Study duration  | 4 months |
| Time schedule | Start Q4 2019 |