**Call for partners: Sample sharing for FIND-WHO Initiative to conduct standardized 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 a FIND-WHO initiative to conduct a standardized evaluation of currently available molecular and immunologic diagnostic tests for Zika virus (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, 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 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. However, despite the surge of research and development of ZIKV diagnostics, there is limited data on the optimal approach to ZIKV diagnostic testing.

This call for partners is issued by FIND to support the development of evaluation panels for the evaluation of available, commercial ZIKV diagnostics and sample sharing to further future ZIKV and arbovirus research. The development of reference panels with well-characterized samples supports analytical and clinical validation of diagnostic results. Similarly, access to samples can support future panel development, which will be readily available to researchers worldwide.

**OBJECTIVES AND PARTNER REQUIREMENTS**

*Objective of the call:* To collect information on ZIKV (and other arbovirus) samples for inclusion into evaluation panels and development of a framework for sample sharing.

*Sample requirements*

* Well characterized samples from persons previously infected with ZIKV, either through an existing biorepository or partnership with hospitals or health centers
* Adequate sample volume (at least 1.0 ml)
* Sample types: serum, whole blood, and/or plasma
* Information about confirmatory assay(s) used

*Partner requirements*

* Ability to enter into agreement with FIND (legal entity or operating under a legal entity)
* Ability to export samples to our partner, Vitalant Research Institute (VRI), in the U.S.
* Willingness to sharing samples for diagnostic evaluation and inclusion in a future “virtual biobank” to support ZIKV and arbovirus research

We are especially interested in samples from sub-Saharan Africa, South America, and Southeast Asia. We are also interested in samples with known arbovirus exposure (e.g. dengue virus, yellow fever virus, Japanese encephalitis virus) and/or prior vaccination to yellow fever vaccine. Please see Appendix 1 for more information about particular samples of interest and Appendix 2 for the proposed reference panels.

**RESPONSIBILITIES**

* FIND will establish material transfer agreements (MTAs) between the partner and VRI
* FIND and VRI will support sample shipment to VRI
* FIND, VRI and partners will jointly review the composition of the evaluation panels
* FIND will work with partners to develop a framework for sample sharing to allow for expanded access and future research
* FIND and VRI will provide access to samples panels to partners for diagnostic development, evaluation, and other research uses

**BENEFITS**

Benefits for participating in this FIND initiative include:

* Early access to samples panels developed through this project
* Ability to shape sample sharing frameworks of an overarching virtual biobank
* Early access to results from the analytical and clinical validation of ZIKV diagnostics
* Authorship from manuscripts presenting results from the analytical and clinical validation studies, as well manuscripts describing the development of a virtual biobank and sample sharing framework

**TIMELINES**

The currently funded phase of this project will run until March 2020. Priority activities include:

* Responses to the call by 9th Aug 2019
* MTAs signed with partners by 15th Sep 2019
* Initial panels available by 1st November 2019
* Initial draft of the sample sharing framework available for feedback by 1st February 2020

**SEND SUBMISSIONS BEFORE 9th Aug 2019 TO:**

Devy Emperador devy.emperador@finddx.org

**FOR QUESTIONS, CONTACT:**

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**RESPONSE TEMPLATE**

**Call for partners: Sample sharing for FIND-WHO Initiative to conduct standardized evaluation of Zika Diagnostics**

NOTE: Up to three (5) pages max

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| --- | --- |
| **Name of responder(s)** | *List here the name of the main responders. Specify affiliations, roles and the names of the institutes.*  |
| **Contact details** | *Provide contact details of corresponding investigators for further communication with FIND.* |
| **ZIKV sample availability** *Describe the availability of ZIKV samples that your laboratory/team have access to. Include type and number of samples currently stored and volumes, if clinical information is available, and source of the sample. Also specify assay(s) used to confirm ZIKV status. Add a new line for multiple collections.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of collection, study, or panel** | **Sample type(s)** | **No. (vol) of aliquots** | **Location of collection / name of sample provider** | **Which of the following clinical variables are available? Select all that apply.** | **Which of the following sample data is available? Select all that apply.** | **ZIKV confirmatory test(s) used** |
| *Collection 1* | \_\_ Whole blood\_\_ Plasma\_\_ Serum\_\_ Urine\_\_ Other:  |  |  | \_\_ Age\_\_ Sex\_\_ Symptoms\_\_ Date of onset\_\_ Pregnancy status\_\_ Consent\_\_ Vaccination status | \_\_ Date of sample collection\_\_ Date of testing\_\_ Storage conditions (e.g. #  freeze/thaws)\_\_ Results from ZIKV testing \_\_ Results from other arbovirus tests\_\_ Data confirming acute/convalescent  status  |  |
| *Collection 2, etc.*  | *\_\_ Whole blood**\_\_ Plasma**\_\_ Serum**\_\_ Urine**\_\_ Other:*  |  |  | *\_\_ Age**\_\_ Sex**\_\_ Symptoms**\_\_ Date of onset**\_\_ Pregnancy status**\_\_ Consent**\_\_ Vaccination status* | *\_\_ Date of sample collection**\_\_ Date of testing**\_\_ Storage conditions (e.g. #*  *freeze/thaws)**\_\_ Results from ZIKV testing* *\_\_ Results from other arbovirus tests**\_\_ Data confirming acute/convalescent* *status* |  |

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| **Other arbovirus sample availability** *Describe the availability of other arbovirus samples your laboratory/team have access to. These include: DENV, YFV, JEV, and WNV. Include type and number of samples currently stored and volumes, if clinical information is available, and source of the sample. Also specify assay(s) used to confirm diagnosis. Add a new line for multiple collections.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of collection, study, or panel** | **Sample type(s)** | **No. (vol) of aliquots** | **Location of collection / name of sample provider** | **Which of the following clinical variables are available? Select all that apply.** | **Which of the following sample data is available? Select all that apply.** | **Confirmatory test(s) used** |
| *Collection 1* | \_\_ Whole blood\_\_ Plasma\_\_ Serum\_\_ Urine\_\_ Other:  |  |  | \_\_ Age\_\_ Sex\_\_ Symptoms\_\_ Date of onset\_\_ Pregnancy status\_\_ Consent\_\_ Vaccination status | \_\_ Date of sample collection\_\_ Date of testing\_\_ Storage conditions (e.g. #  freeze/thaws) \_\_ Results from other arbovirus tests\_\_ Data confirming acute/convalescent  status  |  |
| *Collection 2, etc.*  | *\_\_ Whole blood**\_\_ Plasma**\_\_ Serum**\_\_ Urine**\_\_ Other:*  |  |  | *\_\_ Age**\_\_ Sex**\_\_ Symptoms**\_\_ Date of onset**\_\_ Pregnancy status**\_\_ Consent**\_\_ Vaccination status* | *\_\_ Date of sample collection**\_\_ Date of testing**\_\_ Storage conditions (e.g. #*  *freeze/thaws)* *\_\_ Results from other arbovirus tests**\_\_ Data confirming acute/convalescent* *status* |  |

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**Appendix 1: Samples of interest for inclusion into evaluation panels**

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| **Category**  | **Description** |
| ZIKV convalescent | Samples from previously confirmed ZIKV infected individuals, collected >3 months after initial diagnosis  |
| ZIKV exposed | Samples from individuals with ZIKV IgM or IgG titers and NAT negative |
| ZIKV acute, convalescent, and exposed from pregnant women  | Acute: samples from confirmed ZIKV infected women who were pregnant, collected <2 weeks after symptom onset Convalescent: samples from previously confirmed ZIKV infected women who were pregnant collected >4 weeks after initial sample collection. Exposed: samples from probable ZIKV infected individuals with no paired acute/convalescent sample, with known yellow fever vaccination status |
| ZIKV and DENV co-infection | Samples from individuals with confirmed ZIKV and DENV co-infection, collected <2 weeks after symptom onset  |
| ZIKV acute, convalescent, and exposed from YFV or JEV vaccinated individuals | Acute: samples from confirmed ZIKV infected individuals, collected <2 weeks after symptom onset, with known YFV and/or JEV vaccination statusConvalescent: samples from previously confirmed ZIKV infected individuals, collected >4 weeks after initial sample collection, with known YFV or JEV vaccination status Exposed: samples from individuals with ZIKV IgM or IgG titers and NAT negative, with known YFV or JEV vaccination status |

JEV: Japanese encephalitis virus. NAT: nucleic acid. YFV: yellow fever virus.

**Appendix 2: Proposed evaluation panels\***

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| --- | --- |
| **Panels** | **Composition** |
| **MDx Qualification**  | **55 test samples** |
|  5 x 9 serial half-log dilutions (1.58x103-1.58x10-1 IU/ml) of intl. ZIKV RNA standards |
|  6 negative controls  |
|  1 DENV control  |
|  *1 CHIKV control*  |
| **MDx Analytical**  | **250 test samples** |
|  5 x 11 serial half-log dilutions (1.58x103-1.58x10-1 IU/ml) of intl. ZIKV RNA standards |
|  25 negative controls  |
|  1 DENV control  |
|  *1 CHIKV control*  |
| **MDx Clinical - plasma** | **30-50 ZIKV NAT(+)**  |
|  5 serial dilutions of high ZIKV VL  |
| **IgM qualification**  | **50 test samples** |
|  5 ZIKV NAT(+)/IgM(-)/IgG(-); 2 DENV IgG(-) |
|  20 ZIKV IgM(+), IgG(-); 5 DENV IgG(-) |
|  20 ZIKV IgM(+), IgG(+); 5 DENV IgG(-) |
|  5 arbovirus negative from non-endemic areas |
| **IgG qualification**  | **50 test samples** |
|  5 ZIKV NAT(+)/IgM(-)/IgG(-); 2 DENV IgG(-) |
|  40 ZIKV IgM(+), IgG(+); 5 DENV IgG(-) |
|  5 arbovirus negative from non-endemic areas |
| **Serology Evaluation**  | **100 test samples** |
|  10 sets longitudinal samples from acute ZIKV(+) infection through seroconversion |
|  5 sets DENV IgG(+) |
|  5 sets DENV naïve |
|  5 sets from ZIKV(+) post ZIKV IgM seroconversion |
|  2 sets longitudinal from DENV IgG(+) donors |
|  3 sets longitudinal from DENV naïve, exposed donors |
|  10 sets acute and remote DENV infection |
|  5 sets WNV exposed donors |
|  10 arbovirus negative controls, non-endemic areas |
|  10 arbovirus negative controls, arbovirus endemic areas |

\* Note: composition based on currently available samples at Vitalant Research Institute and are subject to change.