



Expression of Interest

Test developers to participate in FIND Initiative to evaluate SARS-CoV-2 Immunoassays/Serological Tests

BACKGROUND

The 2019 novel coronavirus (SARS-CoV-2), which is the causative agent for an ongoing outbreak (COVID-19) first reported on 31 Dec 2019 in China, is a new beta coronavirus (in the same family as SARS-CoV and MERS-CoV). WHO declared the COVID19 outbreak a Public Health Emergency of International Concern (PHEIC) on 30 January 2020. In recognition of the acute need to provide access to screening of suspect cases and diagnosis, many labs and companies are developing immunoassays that directly detect the virus or the subsequent host response, in the form of SARS-CoV-2 antibodies.

FIND, a global non-profit organization dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, is conducting a standardized evaluation of currently-available immunoassays for SARS-CoV-2. These evaluation studies will take place at multiple independent, third party laboratories and hospitals to assess test performance and thereby better inform public health policy, surveillance programs, and clinical management of patients with suspected SARS-CoV-2 infection, especially in resource-constrained settings.

This Expression of Interest (EOI) is for test developers interested in having their immunoassays (machine-based or lateral flow, rapid tests) evaluated using this standardized, independent protocol. The information submitted through the EOI will be used to inform selection of assays to be included the evaluation studies. Results from these studies will be shared with the global health community so that countries have objective and independent evidence on the performance of available SARS-CoV-2 immunoassays.

The **deadline to respond to the EOI is 11:59pm CET, 20 March 2020.**

Please note: if you have previously submitted an EOI to FIND for an immunoassay you DO NOT need to resubmit, unless you have updated information on performance or regulatory status.

FIND intends to use the information on tests submitted in response to this EOI to update the community's understanding of the SARS-CoV-2 diagnostic pipeline (<https://www.finddx.org/covid-19/>). All tests submitted to this EOI will automatically be included in the SARS-CoV-2 diagnostics pipeline tracker on FIND's website. If you do **not** want your product included please contact us directly: RFP_ET@finddx.org.

OBJECTIVES AND PARTNER ELIGIBILITY

The objectives of the EOI are:

- To gauge interest among test developers to participate in a standardized evaluation of SARS-CoV-2 immunoassays
- To select tests to be included in the evaluation studies

Requirements for developers:

- Compliance with good laboratory practice (GLP)
- RUO certification of kit, with finalized instructions for use
- Kit available for immediate procurement

Conditions to be considered for the evaluation:



Selection for inclusion in the evaluation studies will be done based on the stated performance of the test, ease of use, and stated compatibility with most widely-available immunoanalysis platforms in low- and middle-income countries (if applicable).

The basic performance characteristics of the submitted immunoassays should have already been tested and documented (in line with TRL 5 or above).

BENEFITS

Benefits for participating in this FIND initiative include:

- Independent, external assessment of product performance
- Ability to use performance data to supplement regulatory submissions, if applicable
- Increased visibility by being a part of FIND's pipeline tracker (see <https://www.finddx.org/covid-19/>)

TIMELINES

In recognition of the emergency nature of this outbreak, timelines are as follows:

- EOI call open 13 March 2020
- EOI call deadline 20 March 2020 (11:59pm CET)
-

Please note: even if your product will not be commercialized at the time of submission, all interested suppliers are encouraged to apply, as there may be multiple rounds of evaluation. Please include your projected readiness timeline in your submission.

HOW TO APPLY BY 20 MARCH 2020

Expression of interest (EOI) is to be submitted via FIND's Technology Scouting Submission Webform (<https://www.finddx.org/technologyreview/webform/>). Please select **'Outbreak'** as the 'Disease Area' and **'Expression of interest (EOI): SARS-CoV-2 Immunoassay evaluation'** as the 'Disease Area Subtype' on the form. Please upload a copy of your instructions for use in addition to your completed submission template.

RESPONSIBILITIES

- FIND will procure kits from suppliers who are selected to participate in the evaluation.
- FIND will arrange logistics to ensure kits are transported from company to site(s) of evaluation.
- FIND will provide selected suppliers with a generic study protocol summary once finalized.
- FIND will provide selected suppliers with an individual performance report and a comparative analysis of all included tests.
- Study collaborators will publish individual test performance results and comparative analysis results in a peer-reviewed, journal publication, in line with WHO recommendations to make all novel findings that contribute to the COVID-19 response rapidly and widely available.

FOR QUESTIONS, CONTACT: rfp_et@finddx.org