



## Expression of Interest

### Test developers to participate in FIND-WHO Initiative to evaluate SARS-CoV-2 molecular 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. FIND is collaborating with WHO to conduct a standardized evaluation of currently available molecular diagnostic tests for SARS-CoV-2 in order 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.

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). Infection with SARS-CoV-2 causes respiratory symptoms, fever, fatigue and in severe cases, pneumonia, severe acute respiratory syndrome, organ failure and even death. 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 are developing their own molecular testing protocols; as well, companies are developing commercial assays.

This Expression of Interest (EOI) is issued by FIND for test developers interested in having their assays evaluated using a standardized, independent protocol. The results from this EOI will inform selection of assays to be included in analytical and clinical evaluation studies, which will take place at an independent, third-party reference laboratory. Results from these studies will be shared with the global health community to inform SARS-CoV-2 diagnostic testing approaches.

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](mailto:RFP_ET@finddx.org).

#### OBJECTIVES AND PARTNER ELIGIBILITY

*The objectives of the call are:*

- To gauge interest among test developers to participate in a FIND-WHO-coordinated, standardized evaluation of SARS-CoV-2 diagnostics
- 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, stated compatibility with most widely-available thermocycler platforms in low- and middle-income countries, and stated manufacturing capacity, distribution and quality management systems.



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

## 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 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.

## BENEFITS

Benefits for participating in this FIND initiative include:

- Independent, external assessment of product performance
- Ability to use data to supplement regulatory submissions
- Increased visibility by being a part of FIND's Dx 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 20 Feb 2020
- EOI call original deadline 26 Feb 2020 – **extended to 09 March 2020**

*Please note: even if your product will not be commercialized at the time of submission, all interested suppliers are encouraged to apply, as there will likely be multiple rounds of evaluation.*

## HOW TO APPLY BY 26 FEB 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 NAT 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.

## FOR QUESTIONS, CONTACT:

[rfp\\_et@finddx.org](mailto:rfp_et@finddx.org)