



Expression of Interest (EOI): Test developers to participate in FIND-WHO Initiative to evaluate SARS-CoV-2 point-of-care multiplex molecular diagnostics

This expression of interest (EOI) is issued by FIND for test developers interested in having their SARS-CoV-2 point-of-care (POC) multiplex (Mx) molecular assays evaluated using a standardized, independent protocol. The information submitted through the EOI will be used to inform selection of assays to be included in this round of independent 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 POC Mx molecular assays.

The deadline to respond to the EOI is 11:59 PM CET, 18th March 2022.

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 POC Mx tests
- To select tests to be included in the evaluation studies

Requirements for developers:

- Compliance with good laboratory practice (GLP)
- Regulatory approved assay or at least RUO certification of kit, with finalized instructions for use
- Kit available for immediate procurement

Conditions to be considered for the evaluation:

The POC Mx platform shall be marketed in LMICs or evidence of commercialization strategy in LMICs should be provided. The platform should ideally be suitable for use in low level healthcare settings, specifically Level 1 or Level 2 healthcare facilities. Submissions of multiplex tests (e.g. tests including Flu A and B, RSV testing additionally to SARS-CoV-2 detection) will be prioritized but the FIND independent evaluation will focus on the evaluation of SARS-CoV-2 test component with the possibility of evaluating other respiratory virus test components as well.

Test submissions will be selected through a scoring system taking into consideration:

- Performance
 - supplier-reported analytical performance for SARS-CoV-2 detection
 - supplier-reported clinical performance for SARS-CoV-2 detection. The quality and relevance of the clinical study will also be considered (size of the related study population/number of COVID-19 positive cases/samples with low viral loads)
- Ease of use of the test and instrument robustness
 - instrument characteristics
 - sample type
 - maintenance requirements
 - presence of internal controls
 - stability and shelf-life
- Manufacturing and distribution capacity (especially related to the ability of the company to access LMICs market)
- Regulatory status – products with approval from stringent regulatory bodies such as FDA EUA or WHO EUL are scored higher than CE-IVD self-reported tests which are in turn scored higher than RUO tests



HOW TO APPLY

To respond to this EOI, please submit information about your company and SARS-CoV-2 point-of-care multiplex molecular tests via the [FIND Technology Pipeline Submission Form](#). If you have multiple tests, please submit them separately.

Submission instructions:

- If you had previously submitted a test or proposal via our online portal, you are already registered in our database. Please Login using your company website and contact email. If you are connecting for the first time, please Sign Up providing your organization name, website and contact details.
- At the end of the page entitled 'General information', please specify the purpose of your submission by selecting '**EOI: POC MDx evaluation**' and proceed with the submission.
- Please upload your IFU and performance report(s), when available, at the end of the submission form. Any other relevant supporting material can also be attached.
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- Please also provide supporting evidence on variant performance, precising whether this originates from in-silico analysis, experimental data (lab-generated) or clinical data. Please upload all supporting documents to support your responses such as study data or reports.
- A comment section is also available at the end of the submission form. Please include any important information you would like to share

For any question on the submission process please contact testdirectory@FINDDX.org

NEXT STEPS AND ESTIMATED TIMELINE AFTER SUBMISSION

- Submit your technology through the technology pipeline submission form
- The review process of submissions is expected to take approx. one month
- Outcome of the selection process will be shared with all suppliers end of March/beginning of April
- If your product is selected, we will send you a purchase order for approx. 2000 tests and request to loan 2 to 3 instruments
- The analytical performance of your assay will be evaluated at one partner site and the clinical performance will be evaluated in a prospective study at two different study sites until we reach a minimum of 100 SARS-CoV-2 PCR positive samples

Please be aware this is a fairly long process and timelines are highly dependent on COVID-19 positivity rates. Once tests are purchased, we estimate to send back results from the first clinical site within 3 months and send back full results within 6 months.

SEND SUBMISSIONS BY 18 MARCH 2022

TO: RFP_ET@finddx.org

FOR QUESTIONS, PLEASE CONTACT:

RFP_ET@finddx.org