Expression of interest (EOI)

Test developers to participate in a FIND initiative to evaluate rapid diagnostic tests for Ebola

EXECUTIVE SUMMARY

- FIND, the global alliance for diagnostics, is leading an Expression of Interest (EOI) to identify Ebola virus (EBOV) rapid test developers, to evaluate test performance, and to assess the availability of tests for use in low- and middle-income countries (LMICs).
- Test evaluation will be performed by US Centers for Disease Control and Prevention (CDC), Viral Special Pathogens Branch.
- Two phases of evaluation include: (1) a validation panel of spiked whole-blood samples, and (2) analytical and clinical performance using whole blood and oral fluid samples. Only tests meeting minimum performance specifications in Phase 1 will proceed to Phase 2.
- Suppliers are expected to meet procurement of minimum 500 rapid tests and 2 test readers (if applicable) for evaluation by October 2022 at the latest.
- FIND intends to select up to 10 EBOV AgRDTs for evaluation.
- A longer-term goal of FIND is to identify innovations for future EBOV test development.

OBJECTIVES AND SCOPE

FIND, the global alliance for diagnostics, is seeking to assess whether high quality EBOV AgRDTs will be available for use in LMIC healthcare settings, specifically Level 1 or Level 2 healthcare facilities. This EOI is a call for test developers who are interested in having their Ebola virus (EBOV) antigen rapid diagnostic test (AgRDT) evaluated using an independent, standardized protocol.

The information submitted in response to this EOI will be used to inform the selection of tests to be included in a round of independent evaluation studies. The results of these studies will be published and shared with the global health community, so that affected countries have objective and independent evidence about the performance of available EBOV AgRDTs. The main objectives of this EOI are:

- To gauge the interest among test developers to participate in a standardized evaluation of Ebola AgRDTs
- To select tests to be included in the independent evaluation studies
- To identify new developers and potential innovations in EBOV AgRDT development

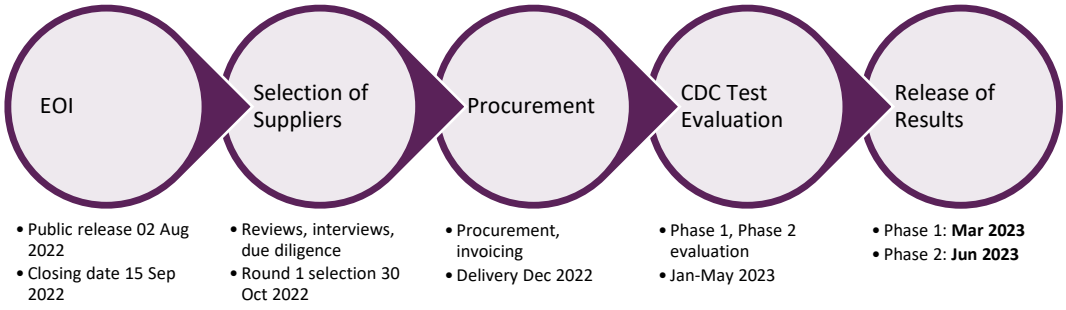
The submission of multiplex tests (e.g. tests that detect both malaria and EBOV using a single sample) will be considered, but FIND's focus will be on the evaluation of the EBOV test component.

TIMELINE

The deadline for applications for the first round of testing is 11:59 PM CEST, 15th September 2022. Depending on resources, FIND may launch a second round of testing for submissions received until 11:59 PM CEST, 30th October 2022.

The expected timeline for this initiative is as follows (may vary depending on applicant):

1. EOI open for submission (**02 Aug 2022**; 1st round closing **15 Sep 2022**)
2. FIND internal review process (~1 month)
3. Selection notification (1 month, **30 Oct 2022**)
4. Procurement of tests and readers (if applicable), and delivery in evaluation site (1-2 months, **30 Dec 2022**)
    - Phase 1: Minimum 25 AgRDT devices
    - Phase 2: Up to 500 EBOV AgRDT devices
    - 2 POC RDT reader instruments (if applicable)
5. Independent test evaluation with US CDC (3-6 months)
    - Phase 1: a validation panel. Five spiked whole-blood samples, repeated in triplicate, will be run on all included tests. Tests meeting the **minimum performance standard (90% sensitivity, 95% specificity)** compared with PCR will move forward to Phase 2.
    - Phase 2: analytical and clinical performance. Analytical performance evaluation will consist of accuracy, limit of detection, and exclusivity testing. The clinical performance evaluation will include 50 samples each of whole blood and oral fluid from known EBOV PCR-positive individuals and 50 samples each of whole blood and oral fluid from known EBOV PCR-negative individuals.
6. Release of evaluation results (3 months)
    - Phase 1 results (~3 months, tentatively Mar 2023)
    - Phase 2 results (~6 months, tentatively Jun 2023**)**



Test developers will have an opportunity to review the results and provide comments prior to their results being published.

Neither CDC nor FIND will endorse any particular assay or test developer over any other as a result of this performance evaluation study.

EOI REQUIREMENTS AND SELECTION PROCESS

While test evaluation is intended for commercialized and late-stage products, FIND encourages any EBOV AgRDT developer to apply through this EOI to alert FIND to early-stage developments and innovations which may be addressed in later EOI/RFPs.

Submitted EBOV AgRDTs will be selected for evaluation based on a scoring system that takes into consideration:

- Stage of development
- Performance
    - Supplier-reported analytical performance data for EBOV Ag detection
    - Supplier-reported clinical performance data for EBOV Ag detection, if available; the quality and relevance of the clinical study will also be considered (size of the study population/number of EBOV-positive cases/number of samples with low viral loads)
- Ease-of-use and robustness of the test and reader (if applicable)
    - Sample types
    - Internal controls
    - Stability and shelf-life
- QMS: Controls, QA/QC, GMP, ISO certification
- Manufacturing potential
    - Product volume vs cost
    - Plans for manufacturing and/or technology transfer
- Distribution capacity
    - Market channels in low- and middle-income country (LMIC) countries is a plus
- Regulatory status
    - Stringent regulatory authority (SRA) approval > self-certified IVD > RUO

HOW TO APPLY

To respond to this EOI, please submit information about your company/organization and Ebola AgRDT via the FIND Technology Pipeline Submission Form. If you have multiple tests, please submit each test separately.

Submission instructions:

- If you have previously submitted a test or proposal via the FIND online portal, you will already be registered in our database. Please log in using your company's website and contact email. If you are submitting for the first time, please sign up with FIND by providing your organization's name, website and contact details.
- At the end of the page entitled 'General information', please specify the purpose of your submission by selecting '***EOI: EBOV Ag RDTs Evaluation***' and proceed with the submission.
- Please upload your instructions for use (IFU), performance report(s), and certification(s) at the end of the submission form. Any other relevant supporting material can also be attached.
- A comment section is available at the end of the submission form. Please include any further information you feel it is important to share with us.

For any questions about the submission process please contact RFP_ET@finddx.org

PLEASE SEND SUBMISSIONS, BY 15th SEPTEMBER 2022, TO:

FIND Technology Pipeline Submission Form

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT:

RFP_ET@finddx.org