Expression of Interest (EOI)

Test developers to participate in a FIND initiative to evaluate point-of-care tests for monkeypox

EXECUTIVE SUMMARY

- FIND, the global alliance for diagnostics, is leading an Expression of Interest (EOI) to identify monkeypox (MPX) point-of-care (POC) test developers, to evaluate test performance and assess the availability of tests for use in lower-level health facilities.
- Test evaluation will be performed at FIND partner sites in Europe and sub-Saharan Africa; the limit of detection and clinical sensitivity and specificity will be evaluated.
- Suppliers are expected to supply a minimum of 1000 tests and two test readers (if applicable) for evaluation by December 2022 at the latest.
- FIND intends to select up to three antigen rapid diagnostic tests (AgRDTs) and two POC/near-POC molecular tests for evaluation.

OBJECTIVES AND SCOPE

FIND seeks to assess the performance of MPX POC tests for their potential use in level 1 to 3 healthcare facilities. This EOI is a call for test developers who are interested in having their MPX AgRDT or POC molecular test 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 MPX POC tests. The main objectives of this EOI are:

- To gauge interest among test developers in participating in a standardized evaluation of MPX POC tests
- To select tests to be included in the independent evaluation studies

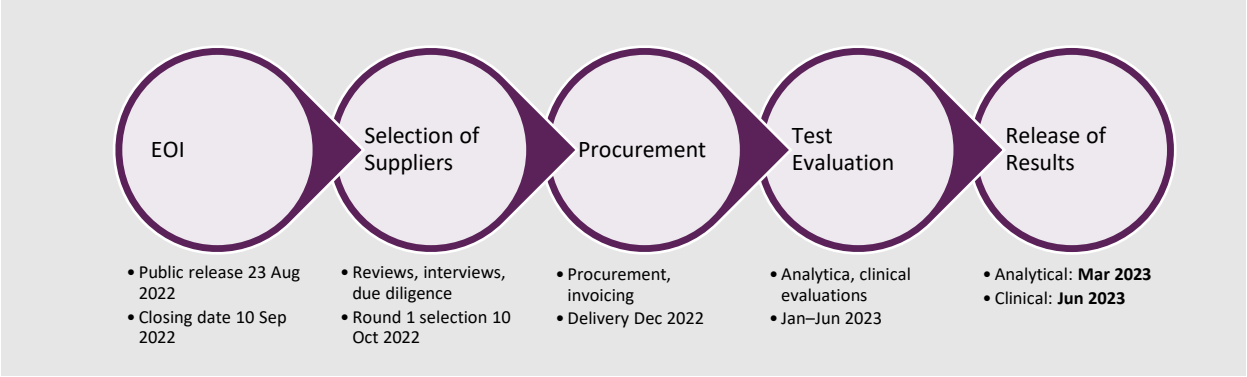
TIMELINE

The deadline for applications for the first round of testing is 11:59 PM CEST, 10 September 2022. Another round of submissions may be considered, depending on resources and initial responses.

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

1. EOI open for submission (**23 Aug 2022**; first round closing **10 Sep 2022**)
2. FIND internal review process (<1 month)
3. Notification of successful applicants (1 month, **10 Oct 2022**)

4. Procurement of tests and readers (if applicable) and delivery to the evaluation site (1–2 months, **1 Dec 2022**)
    - AgRDTs:
        - Up to 1,000 devices
        - Two POC AgRDT reader instruments (if applicable)
    - POC molecular test:
        - Up to 1,000 tests
        - One reader instrument (if applicable)
5. Independent test evaluation (2–6 months)
    - Analytical evaluation to assess the limit of detection and percent agreement at one study site
    - Clinical evaluation to assess sensitivity and specificity at two to three study sites
6. Release of evaluation results (approximately 1–2 months)
    - Analytical evaluation (approximately 1 month, tentatively March 2023)
    - Clinical evaluation (approximately 3 months, tentatively June 2023)



Test developers will have an opportunity to review the results and provide comments prior to their results being published. However, FIND and our evaluation partners will have final jurisdiction over publications.

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

EOI REQUIREMENTS AND SELECTION PROCESS

This evaluation is intended for commercialized products. Submitted tests will be selected for evaluation based on a scoring system that takes into consideration:

- Performance
    - Supplier-reported analytical performance data for MPX Ag or DNA detection
    - Supplier-reported clinical performance data for MPX Ag or DNA detection, if available; the quality and relevance of the clinical study will also be considered (e.g. the size of the study population and the number of MPX-positive cases)
- Ease-of-use and robustness of the test and reader (if applicable)
    - Sample type(s)
    - Internal controls
    - Stability and shelf-life

- Quality management system
    - Controls
    - Quality assurance/quality control
    - Good Manufacturing Practice
    - ISO certification
- Manufacturing potential
    - Product volume versus cost
- Distribution capacity: market channels in low- and middle-income countries is a plus
- Regulatory status: stringent regulatory authority approval > self-certified *in vitro* diagnostic device (IVD) > research use only (RUO)

HOW TO APPLY

To respond to this EOI, please submit information about your company/organization and MPX POC test 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: MPX POC Test 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.

PLEASE SEND SUBMISSIONS, BY 10 SEPTEMBER 2022, TO:

FIND Technology Pipeline Submission Form

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT:

RFP_ET@finddx.org