

Expression of interest
**Driving equitable access to fit-for-purpose antigen-detecting
rapid diagnostic tests for COVID-19**

Frequently Asked Questions

Submission procedure

Q1. How do I submit a proposal?

The application link can be found in the Expression of Interest (EOI) document, which can be downloaded from the [FIND website](#). Please do not send submissions by email.

Q2. Is there a template for the submission and are there limits on the size and length?

Proposals should be submitted in PowerPoint format and should be no more than 20 slides in length. There is no template for the slides, however, submissions must include the following information:

- Value proposition and expected impact
- Vision for proposed business model supporting the supply of tests in low- and middle-income countries
- Summary of evidence supporting any claims (e.g. product performance, manufacturing capacity)
- Proposed activities, deliverables and timeline
- Freedom to operate and existing licensing agreements
- Estimated funding need and other support requirements (such as a request for matchmaking)
- Partnerships (if relevant) and role of each entity
- Team / key staff
- Declaration of any relevant interest

Please include all information in the PowerPoint submission. No additional written proposal is required at this stage.

Q3. How will I know that my submission has been received?

An acknowledgement of receipt will be sent once your submission has been received.

Q4. How will I know if my submission is being considered?

You will be contacted directly if your proposal is selected for further consideration.

Project type and eligibility

Q1. Are nucleotide-based technologies eligible if they are point-of-care and low cost?

No. This expression of interest focuses solely on antigen-detecting rapid diagnostic tests, and as such molecular tests are out of scope. Other types of diagnostic assays may be included in future Expressions of Interest under the Access to COVID-19 Tools Accelerator Diagnostics Pillar.

Q2. Are digital readers acceptable?

Yes, proposals for digital readers are acceptable providing they meet the requirements of the Expression of Interest.

Q3. Can proposals for serology tests be submitted?

No. This Expression of Interest focuses solely on antigen-detecting rapid diagnostic tests, and as such serology tests are out of scope. Other types of diagnostic assays may be included in future Expressions of Interest under the Access to COVID-19 Tools Accelerator Diagnostics Pillar.

Q4. Do the initial proposals have to demonstrate full compliance with the target product profile?

No, as the target product profile document is not yet publicly available, demonstrating compliance is not a requirement at this stage.

Q5. How does the sensitivity requirement of 80% relate to samples with very low viral load?

A sensitivity of 80% is required at the peak of infection when viral load is high. It is understood that sensitivity is likely to be reduced with lower viral loads, however, no cut-off values have been established for this Expression of Interest. Proposals that can demonstrate the ability to detect the most infectious cases across the active infectious period will be preferred.

Q6. Will support for validation of supplier specifications prior to establishing partnerships be provided?

This is not included as part of the Expression of Interest. However, FIND is conducting independent validation evaluations of diagnostic assays for COVID-19, and if there is interest, may consider supporting validation studies for accepted proposals.

Q7. Does the need for 'decentralized manufacturing' require establishment of manufacturing capacity in low- and middle-income countries?

No. Entities without decentralized manufacturing capacity can be matched through the Expression of Interest process with partners offering manufacturing capacity, if desired and appropriate. Alternatively,

applicants may propose to build this capacity internally if they are able to do so within the time frame required for this Expression of Interest.

Q8. Does each proposal need to list only one product? If so, will you accept more than one proposal from a single entity?

A single entity may submit more than one proposal. If an entity is currently developing or commercializing several COVID-19 antigen rapid diagnostic tests, they should be submitted as separate proposals. However, if the different products are complementary components of a single final product, it is preferable to submit one single proposal combining these components.

Q9. Will the Expression of Interest support early stage proposals?

The funding period for the Access to COVID-19 Tools Accelerator is 24 months, so relatively late-stage products are preferred. However, proposals for earlier stage products may be considered if sufficient evidence is provided to show that the timelines detailed in the Expression of Interest can be met. Early stage solutions that have the potential to transform performance, usability or affordability and that can feasibly be manufactured within 12 months would still be within the scope of the Expression of Interest.

Q10. Will there be support to connect innovators with other entities?

Yes, partnerships between innovators and other entities can be facilitated at the candidate's request, on the condition that the timelines of the Expression of Interest can be met and provided that the ultimate goal is to produce a commercialized COVID-19 antigen rapid diagnostic test. A clear pathway to achieving this should be demonstrated as part of the proposal.

Budget, licensing and procurement considerations

Q1. The Expression of Interest states that there is funding for 2 to 4 proposals. Does this mean that only 2 to 4 entities will receive funding?

The Expression of Interest includes budget for 2 to 4 final end-to-end proposals, including all components from development to manufacturing. These final proposals may be made up of a number of smaller proposals covering individual components.

Q2. Does the Expression of Interest include any expectations regarding the cost of the product?

There are no specific price-related expectations at this stage. However, cost will be a key selection criterion. Proposals that can commit to optimizing affordability in low- and middle-income countries and provide transparency on cost of goods, while retaining a reasonable profit margin to allow some return on investment, will be preferred. The target product profile will include more specific guidance on cost.

Q3. Are there any budget restrictions regarding indirect costs?

No, there are no specific budget restrictions for indirect costs. Indirect costs will be discussed as part of further negotiations for proposals that are selected for consideration.

Q4. Do proposals need to include a full Freedom to Operate assessment?

If a full Freedom to Operate assessment is available, please include it in your proposal. However, if a full assessment is not available at this stage, it is acceptable to include preliminary information on expected licensing requirements.

Q5. When partnerships are required, who will own the intellectual property of the final products?

This will be discussed as part of further negotiations for proposals selected for consideration, and will be decided on a case-by-case basis depending on the specifics of each partnership.

Q6. Will the manufacturers be responsible for managing procurement of the devices or does the Expression of Interest include funding for purchasing tests?

This Expression of Interest does not include funding for procurement. However, there is separate funding within the Access to COVID-19 Tools Accelerator that could be used for procurement of diagnostic tests. It is also expected that domestic funding from low- and middle-income countries will cover a proportion of funding needs. Additionally, the Access to COVID-19 Tools Accelerator may be used to assess market incentives to support the establishment of a stable market for the tests in low- and middle-income countries.

For additional information, please contact: rfp_acta@finddx.org

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