

Request for Proposals

Accelerating the availability of affordable SARS-CoV-2 self-tests

Frequently Asked Questions

Submission procedure

Q1. How do I submit a proposal?

The application link can be found in the Request for Proposals (RFP) 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 25 slides in length. There is no template for the slides, however, submissions must include the following information:

Self-test value proposition

- Value proposition and expected impact:
 - a. An overview of the self-testing solution, including product characteristics and specifications, with a clear side-by-side reference to its alignment with the product requirements described in Appendix 1. The proposal must include the table summarizing the alignment to critical attributes (highlighted in grey in Appendix 1). Please provide explicit information about the cost per test indicating the shipping terms applied (e.g. ex works, landed costs, retail price) and currency.
 - b. If relevant, please include as an annex an overview of the existing digital solution and how it meets the use cases specified in the Supporting Tools section of Appendix 1. Please note if the digital solution is required to read and/or report the results or intended to improve the tests performance.
- Summary of evidence supporting any claims (e.g. product performance, manufacturing, and distribution capacity)
- Timelines, including detailed stage of development, proposed activities, and deliverables
- Estimated funding need and other support requirements
- Vision for introduction and distribution of self-tests in LMICs

Company experience and track record

- High-level company background (e.g. key products and markets, distribution footprint, vision for self-testing and LMIC markets after pandemic).
- Production overview including manufacturing capacity and utilization, available capacity for self-test, expansion plans, and key inputs supply security (e.g. antibodies, swabs, etc.)
- Company / key staff detail on experience relevant to this RFP (e.g. experience with LMIC markets, self-testing and over the counter markets, and WHO PQ / EUL or other stringent regulatory authorities).
- Partnerships (if relevant) and role of each entity
- Freedom to operate and existing licensing agreements, and declaration of any relevant interests

The slides should not be a copied and pasted version of a text document, but rather convey key aspects and messages to reviewers, in a reader-friendly format (e.g. minimum 12pt preferred). Tables and figures would be very helpful.

If you wish to provide more detailed information related to any of the points listed above, please include it in the Appendices in relevant file format (eg Word document, image etc). Please note that the review will be primarily focused on the main proposal, and all the required elements as described in the RFP should be included here. Appendices will be considered as supplementary material, at the reviewers discretion.

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 self-test products with readers acceptable?

Yes, test readout using a small, portable or hand-held, battery-operated device, ≤5 kg, with data export and connectivity capabilities is acceptable. Please note that the final product must meet the requirements listed in the Appendix 1 including the cost per test less than 3 US \$.

Q2. Can proposals for serology tests be submitted?

No. The target analyte specified in "[Appendix 1: Key product requirements](#)" is SARS-CoV-2 biomarker of acute infection (e.g., antigen, RNA). Therefore, a serology test would not qualify. Other types of diagnostic assays may be included in future RFPs under the Access to COVID-19 Tools Accelerator Diagnostics Pillar.

Q3. Do the initial proposals have to demonstrate full compliance with the key product requirements?

No. However, the final products must meet the product requirements provided in "[Appendix 1: Key product requirements](#)", developed based on the [WHO target product profiles \(TPP\)](#) for point of care tests for suspected COVID-19 cases and their close contacts.

We understand that at the time of submission, the product may still be in development phase and data supporting compliance with certain key product requirements may not be available. Please make sure to include in the proposal the table summarizing the current alignment to critical attributes (highlighted in grey in "[Appendix 1: Key product requirements](#)").

Q4. Does self-test product have to receive regulatory approval (eg FDA EUA) at the time of proposal submission?

No, it is not required. Self-testing solutions in late development stage will also be considered.

Q5. Are there any specific requirements regarding the evidence supporting the test's performance? Will support for validation of supplier specifications prior to establishing partnerships be provided?

The proposal shall include data on performance of professional use test, ideally, using one of the specimen types indicated in the key product requirements. Evidence on correlation of test performance in the hands of healthcare professionals vs untrained user is preferred but is not mandatory at this stage. Data from independent evaluations are preferred but datasets generated by the IVD developer/manufacturer are also acceptable.

No support for validation of performance prior to establishing partnerships will be provided. For selected proposals, multi-site clinical evaluation to support regulatory claims can be included in the project activities and conducted/supported by FIND.

Q6. 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 self-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.

Q7. Will the Request for Proposals support early stage proposals?

The product must be ready to enter clinical evaluation no later than Q3 2021. However, in exceptional cases where applicant can provide strong evidence to show significant value added with regards to both, usability AND cost, early stage would be considered if enough funding is available.

Q8. 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 RFP can be met and provided that the ultimate goal is to produce a commercialized COVID-19 self-test. A clear pathway to achieving this should be demonstrated as part of the proposal.

Budget, licensing and procurement considerations

Q1. The RFP states that there is funding for 2 to 3 proposals. Does this mean that only 2 to 3 entities will receive funding?

The total budget envelope for this RFP is 15 M US \$ that will be used to support 2 to 3 proposals. However, if the budget permits and at the discretion of the review committee, more than 3 proposals may be selected.

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

Yes. Target cost of goods sold (COGS), ex-works (not including shipping and distribution margins) for individually packaged product containing all materials required for testing and digital support tools will be <3 USD as a minimal requirement and <1 USD to meet the optimal requirement.

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 RFP include funding for purchasing tests?

This RFP does not include funding for procurement. However, partners within the Access to COVID-19 Tools Accelerator are addressing the need for market incentives to support the establishment of a stable market for the tests in low- and middle-income countries. It is also expected that domestic funding from low- and middle-income countries may cover a proportion of the procurement funds needs.

Q7. What is the expected duration of the project supported through this RFP?

The maximal duration of the project is 12 months. The project is expected to start early Q3 2021 and all project activities must be completed by the end of Q2 2022.

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

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