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

FIND is leading a call for expressions of interest (EOI) to accelerate the availability and manufacturing scale-up of rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

This EOI is has been prepared in the context of the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar.¹ Launched by FIND and Unitaid, it supports the work plans of two working groups within the pillar: “R&D of tests & digital tools” (led by the Bill & Melinda Gates Foundation and the Praesens Foundation) and “Market readiness” (led by Unitaid and FIND).

Innovators, RDT developers, IVD manufacturers and LMIC-based diagnostic stakeholders are invited to apply.

A range of funding mechanisms could be applied according to the needs of each business case.

BACKGROUND

Since the beginning of the COVID-19 pandemic, molecular testing has played a critical role in the management of suspected cases as well as contact tracing worldwide. Testing capacity, however, remains highly centralized, and often insufficient to meet the current demand. While countries in all regions have experienced these challenges, the needs are more acute in low- and middle-income countries (LMICs), where fragile health systems and exclusive reliance on global supply chains have often left LMICs unable to access much-needed tests. This situation is further compounded by the lack of reliable, affordable and easy-to-use rapid tests for clinical diagnosis of COVID-19. While such tests would be beneficial to high-income countries (HICs), they are critical for establishing testing programmes in LMICs.

An estimated 500 million COVID-19 diagnostic tests will be needed in LMICs over the next 12 months, 75% of which in decentralized settings (i.e. primary healthcare, community-level care, hospital triage). There is emerging consensus about the important role that SARS-CoV-2 antigen-detecting rapid diagnostic tests (Ag RDTs) will play in filling this gap, as the primary diagnostic for active infection detection in decentralized settings where timely molecular testing is not available. A target product profile (TPP) for the use of Ag RDTs in this context will be published by WHO soon (this EOI will be updated to include a link to the publication as

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¹ The Access to COVID-19 Tools (ACT) Accelerator is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. It was set up in response to a call from G20 leaders in March and launched by the WHO, EC, France and the Bill & Melinda Gates Foundation in April 2020. The ACT-Accelerator is not a decision-making body or a new organization but works to speed up collaborative efforts among existing organizations to end the pandemic. It is a framework for collaboration that has been designed to bring key players around the table with the goal of ending the pandemic as quickly as possible by reducing COVID-19 mortality and severe disease through the accelerated development, equitable allocation, and scaled up delivery of tests, treatments and vaccines, thereby protecting health systems and restoring societies and economies in the near term. It draws on the experience of leading global health organizations which are tackling the world’s toughest health challenges, and who, by working together, are able to unlock new and more ambitious results against COVID-19. Its members share a commitment to ensure all people have access to all the tools needed to defeat COVID-19 and to work with unprecedented levels of partnership to achieve it.

The ACT-Accelerator has four pillars of work: diagnostics, therapeutics, vaccines and the health system connector. Crosscutting all of these is the workstream on access & allocation.
soon as it is available). More information is also available on the different diagnostic tests available for COVID-19, as well as the different use cases for RDTs.

While the situation is dynamic, several market challenges stand in the way of supplying LMICs with fit-for-purpose Ag RDTs (Figure 1).

**Figure 1. Market challenges to the equitable access of fit-for-purpose SARS-CoV-2 Ag RDTs in LMICs, and how this EOI aims to tackle these challenges.**

This EOI builds on existing investments and initiatives, both from within the diagnostics industry and from large innovative funding initiatives, such as RADx and X-Prize’s Fight for COVID-19, to provide catalytic support and ensure that the benefits of newly developed tools reach not only the richest economies, but also LMICs.

**SCOPE**

This EOI aims to fill current diagnostic gaps in the detection of active SARS-CoV-2 infection for case management and contact tracing purposes in decentralized settings. In this context, a test that detects the virus in a user-friendly, field-appropriate format is desirable. While both point-of-care nucleic acid testing platforms and Ag RDTs would be appropriate in these settings, this call is specifically for Ag RDTs.

The focus is on accelerating supply and availability of quality-assured and regulatory-approved fit-for-purpose Ag RDTs that at least meet the minimal WHO TPP requirements, with preference given to those that meet some or all the optimal requirements. Until the TPP is published, interim high-level guidance on performance and usability targets is provided in Appendix 1.

The ACT-Accelerator Diagnostics Pillar (ACT-A Dx) will engage end-to-end, from the development and deployment process to driving access to these fit-for-purpose Ag RDTs. This will include accelerating development, facilitating regulatory approvals, and increasing production capacity, addressing supply chain challenges, establishing mechanisms (such as volume guarantees) to de-risk the market, and strengthening local capacity for development and deployment of new tests within national testing strategies. This EOI is just one of several mechanisms being developed by ACT-A Dx and is focused on the downstream activities of
product development and manufacturing scale-up. Any support provided through this EOI will require a commitment to supplying Ag RDTs to LMICs under global access terms.

Proposals and business partnerships are sought in two areas:

1. **Accelerating development and market entry of improved, quality-assured SARS-CoV-2 Ag RDTs for expanded use in LMICs.** While products meeting performance, usability and affordability requirements could be scaled immediately, innovation focused on rapidly introducing improved products to the market is encouraged. Investments that may quickly yield Ag RDTs with improved performance and ease of use for LMICs, while remaining affordable, are valuable. We are calling for proposals that will catalyse the incorporation of innovations into existing and/or pipeline Ag RDTs in order to accelerate their entry to the market, within the timeframe of the COVID-19 response. These advances may be in the form of improved reagents, particles, sampling, sample processing, readers etc, which are suitable for LMIC adoption. Any advances must be translated into improved Ag RDTs in the near term (3–6 months), resulting in fit-for-purpose products that can be rapidly manufactured at scale.

2. **Rapidly creating the supply conditions (manufacturing capacity, diversity of supplier base, affordability) to meet the needs of LMICs.** Scale up of manufacturing capacity for fit-for-purpose Ag RDTs is urgently needed to guarantee supply to LMICs, as demand for Ag RDTs is likely to exceed any single diagnostic company’s existing RDT manufacturing capacity. In this context, we are calling for proposals from IVD companies that have developed qualifying Ag RDTs and are seeking to expand production capacity to support LMIC deployment. Given the current concentration of RDT manufacturing capacity in a handful of countries, and the ensuing risk to supply security that this poses, geographic diversification of manufacturing and partnerships with LMIC entities for production of quality RDTs in one or more LMIC regions is highly encouraged. In addition, we are calling for proposals from developers of fit-for-purpose Ag RDTs interested in licensing/partnering with companies with available high-quality manufacturing capacity. Proposals from IVD companies interested in offering their own excess production capacity to other developers are also welcome. Candidates may apply independently or in partnership and FIND/ACT-A Dx may facilitate the matchmaking on request.

**BENEFITS**

An initial budget envelope of US$30 million of grant funding, supplemented by loan funding from development banks, could be made available to support at least 2–4 proposals that offer best value for money. As additional funding becomes available, further proposals will be considered. Funding negotiations will be conducted independently for each proposal and will be tailored to the applicant’s needs and the specifics of each business case. Funding could take many forms, such as R&D grant funding, loans for infrastructure scale up, licensure agreements, and/or longer-term volume commitments.

Alongside financial support, the direct benefits of this programme include partnership opportunities and advisory/technical support. ACT-A Dx may provide, as needed:

- Support for technology transfer, manufacturing, supply chain sourcing and management.
- QMS expertise and support.
- Product development expertise, independent evaluations, access to specimen banks and reagents, and networks of clinical study partners.
- Business advisory services, including business model review and support for operational planning.
- Regulatory planning and market entry advice.
• Country partnerships and facilitation

Further, as part of the overall ACT-A initiative, this programme also facilitates connections and networking opportunities with a broad ecosystem of partners, to work towards offering other support mechanisms, such as market interventions.

INTERESTED PARTIES

Proposals are sought from innovators, RDT developers, IVD manufacturers, and LMIC-based diagnostic stakeholders interested in:

• Expanding their own production capacity, with commitment to LMIC supply
• Supporting geographic diversification of manufacturing in one or more LMIC regions with local partnerships, including (but not limited to) contract manufacturing for open-label products
• Partnering with readily available high-quality manufacturing capacity globally, or offering their own excess production capacity to other developers
• Licensing and/or technology transfer

Illustrative examples of proposals and business partnerships that could be suitable for this EOI are provided in Appendix 2, however other innovative models are also welcome.

SELECTION CRITERIA & PROPOSAL FORMAT

Primary selection criteria: ability to serve markets quickly and with significant volumes

Proposals must demonstrate the ability to deliver >50 million fit-for-purpose, quality-assured SARS-CoV-2 Ag RDTs to LMICs within a year of this EOI (preferably sooner), with the potential for further scale-up beyond the first year.

In addition:

• Proposals must include a clear and meaningful value proposition for improving the supply to LMICs of fit-for-purpose SARS-CoV-2 Ag RDTs. This may be accomplished by several means, but there must be commitment to supply a percentage of Ag RDTs to LMICs.
• Products must meet the WHO TPP (prior to TPP publication, interim high-level guidance is provided in Appendix 1). If funding for innovation/late stage product development is requested, the proposal shall include evidence supporting improvement over state-of-the-art RDTs in at least one (but preferably more) of the following: performance, affordability, and usability.
• Consideration will be given to the strengths of the commitments made to maximize equitable access, including the share of volumes committed to LMICs, proposed pricing arrangements, and willingness to share data/IP/know-how (for more information please refer to the FIND global access policy).
• Proposals must demonstrate experience and capacity to deliver on stated objectives.
• Proposals that address supply security by decentralizing manufacturing to LMICs, and that build sustainable capacity in LMICs, will be prioritized.

Full details on governance, eligibility and partner expectations are listed in Appendix 1.
Proposals should be submitted in PowerPoint, with no more than 20 slides that include the following information:

- Value proposition and expected impact
- Vision for proposed business model supporting the supply of tests in LMICs
- 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 interests

HOW TO APPLY

Proposals should be submitted via the FIND technology scouting submission web form. Please select ‘ACT-A Dx’ as the ‘Disease Area’ and ‘COVID-19 Ag RDTs’ as the ‘Disease Area Subtype’ on the form.

SELECTION PROCESS AND TIMELINES

This EOI opened on 4 July 2020, and the first deadline for receipt of submissions closed on 24 July 2020. Applications are now invited before a second deadline of 24 August 2020, 23:59 CET. Subject to additional funding commitments, a rolling process for further submissions will then be established to enable inclusion of manufacturers who are not at a stage where they can submit a proposal to meet the original deadlines.

The selection process is described in Figure 2. Following submission, a long list of candidates will be invited to present their pitch to the review panel in a live videoconference.

A short-list of candidates will then be invited to submit full proposals. These proposals may involve more than one applicant or stakeholder. While applicants are encouraged to identify partners early in the EOI process, FIND and other ACT-A Dx partners may assist in the matchmaking process at the candidate’s request. At this stage, candidates will be asked to submit a (joint) business plan, which will undergo a further round of review prior to selection.

FIND is leading this EOI on behalf of ACT-A Dx; management, evaluation and selection of proposals will be conducted according to FIND governance, policies and procedures (see Appendix 1). Proposals and partnerships selected for funding negotiations will then engage with the corresponding donors, who will follow their own procedures for contracting and monitoring.

A commitment to a compressed timescale is required, and it is anticipated that funding will be awarded, and contracts executed in 2–3 months.

Figure 2. Selection process. Note the review may include ACT-A Dx working group members, joint analysis of EOI responses and identification and design of high priority interventions.
QUESTIONS & FURTHER INFORMATION

Please contact: rfp_acta@finddx.org

Questions will be accepted and responded expediently while the EOI remains open.
APPENDIX 1: Governance, eligibility and partner expectations

This EOI will be executed according to FIND governance, policies and procedures. These are summarized below; full details can be found on the FIND website. Proposals and partnerships selected for funding negotiations will then engage with the corresponding donors, who will follow their own procedures for contracting and monitoring.

Low- and middle-income country access and quality

Applicants are expected to commit to:

- Abide by the FIND global access policy.
- Supplying a minimum volume/share of RDTs produced\(^2\) to the public sector in LMICs\(^3\) at affordable prices. Details to be negotiated.
- Submitting product to WHO prequalification programme and/or stringent regulatory authority, as relevant.
- Establishing and sustaining the highest IVD quality standards, during production scale-up.
- Undertaking activities in LMICs to support market introduction and access (e.g. local registration, sales and distribution activities), if partnership is undertaking commercialization.

Product

- The product can consist of an Ag RDT, a component of Ag RDTs (e.g. antibodies, particles, sample collection and preparation, know-how, readers), or innovations related to optimization of RDTs, manufacturing processes, etc.
- The proposed final Ag RDT needs to meet the minimum targets that will be set out in the forthcoming WHO TPP, with preference given to those that meet optimal requirements. In the interim, and only until the TPP is published, the following guidance on target requirements should be considered:
  - Use-case: early detection of SARS-CoV-2 active infection in suspect cases, in settings where molecular testing is not available in a timely manner.
  - Target settings: decentralized, outside of laboratories (e.g. primary healthcare, community level, hospital triage). Designed to be used by trained healthcare workers or, preferably, lay users after a short training course. No cold-chain storage required.
  - Usability: test should be simple to use with few sample handling and test operating steps. Ideally, the test can be read and interpreted visually, with the naked eye; but the use of a reader is acceptable if required to achieve the necessary clinical sensitivity. Standard upper respiratory specimens (nasopharyngeal and oropharyngeal swabs) are acceptable, but easier-to-collect specimens such as nasal swabs and oral fluids are preferred.
  - Performance: specificity should be excellent (\(\geq 97\%\)) to minimize risk of false positives, as the intent is to consider positive tests as true positives without further confirmation. Assay must not cross-react with other human coronaviruses, except for cross-reaction with SARS-CoV-1, which is acceptable. While maintaining a very high specificity, sensitivity should be maximized to minimize false negatives (\(\geq 80\%)\).

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\(^2\) Fulfilled by reserving in-house production capacity for LMICs, or through innovative schemes that foster regional production of RDTs in LMICs.

\(^3\) Note that definition of public sector buyer includes non-governmental organizations, global health procurers etc.
• The proposal should include evidence to support product performance claims, with a large evidence base being an advantage. Products in late stages of development are preferred.
• Products should be developed in accordance with ISO 13485:2016, within a QMS framework and internally validated.

Organizational

• Institutional commitment and ability to act quickly, as well as evidence of senior management, board-level, and key stakeholder support should be provided.
• Organization or key personnel track-record suggesting ability to effectively implement proposed activities should be provided.
• There is a preference for proposals that involve supporting geographic diversification and sustainable LMIC businesses.
• Proposal should demonstrate a long-term intention to sustain business beyond the COVID-19 programme, including viable business plan.
• Applicants are expected to be open to ongoing monitoring of the programme, including access targets, business sustainability, and quality.
APPENDIX 2: Example proposals and business partnerships that could be suitable for this EOI

Proposals from independent parties as well as pre-formed partnerships are welcome. While applicants are encouraged to identify partners (if needed) early in the EOI process, FIND and other ACT-A Dx partners may assist in the matchmaking process at the candidate’s request.

Example 1: An innovator or product developer of a fit-for-purpose Ag RDT partners with an established IVD company with existing production capacity to manufacture and commercialize product

Goal: Partnership accelerates development and access to products and/or innovations that can support quality-assured, fit-for-purpose Ag RDTs, by rapidly connecting promising innovations with established IVD companies that can take the innovation forward at scale (e.g. further product development, commercialization and manufacturing; incorporation of innovation into existing tests or manufacturing processes).

Opportunity: Developer can rapidly commercialize innovation in an equitable way, through accelerated introduction to and engagement with IVD company partners capable of scale. Innovations may include antibodies, particles, sample collection and preparation, know-how, readers, entire product, or other. Established IVD company can access a pool of potential innovations supporting improved Ag RDT performance, ease of use, manufacturing or quality, allowing the company to rapidly bring the highest performing Ag RDTs to market.

Deal: FIND and ACT-A Dx partners connect established IVD companies with developers with innovations and provide funding and technical support for transfer; applicants agree to access terms for LMICs. For example, assuming the innovation is successfully commercialized/implemented, a percentage of Ag RDTs are supplied to the public sector in LMICs at an affordable price (details to be negotiated with selected candidates).

Example 2: An LMIC entity with capacity to manufacture RDTs partners with an innovator or product developer that has developed a fit-for-purpose Ag RDT

Goal: To rapidly establish high-quality RDT production facilities in LMICs to serve regional LMIC demand. For example, an existing LMIC-based RDT manufacturer could expand/upgrade production capacity and/or its quality management system (QMS). Manufacturing scope may range from assembly and kitting only, to reagent production through to final packaging. Likewise, business models may vary, from manufacturing only, or may include additional aspects of product development and commercialization (e.g. local registrations, distributions, sales activities). This LMIC capacity may also be open-source, i.e. available to multiple RDT developers/IVD companies looking to better access and serve LMIC markets.

Opportunity: LMIC manufacturer can expand or upgrade RDT manufacturing business and increase visibility/market access in the region, providing a solid footing for a sustained, high-quality RDT business serving LMICs beyond the COVID-19 pandemic.

Deal: LMIC manufacturer receives transfer of RDT technology, as well as financial support and technical assistance to rapidly expand or upgrade high-quality production in LMICs; innovator / product developer gets Ag RDTs manufactured at scale. In exchange for support, partners commit to supplying Ag RDTs at affordable prices to the public sector in LMICs.
Example 3: An IVD company with established large manufacturing capacity offers its available production capacity to an IVD company that has developed a fit-for-purpose Ag RDT

**Goal:** Rapidly expand manufacturing capacity for Ag RDTs to ensure availability to LMICs by leveraging under-utilized rapid test production capacity, most likely through (but not restricted to) an OEM or contract manufacturing arrangement.

**Opportunity:** IVD companies that have not developed Ag RDTs but with available RDT manufacturing capacity may partner with a developer of Ag RDTs to manufacture product at scale through OEM, contract manufacturing, or other suitable arrangements.

**Deal:** FIND and ACT-A Dx partners connect companies with available manufacturing capacity with IVD companies with Ag RDTs and provide funding and technical support for transfer; applicants agree to access terms for LMICs. For example, a percentage of RDTs produced as a result of the partnership is supplied to the public sector in LMICs at an affordable price (details to be negotiated with selected candidates).

Example 4: An established IVD company that has developed a fit-for-purpose Ag RDT wants to expand manufacturing capacity to meet LMIC demand

**Goal:** Rapidly expand manufacturing capacity for Ag RDTs to ensure availability to LMICs. A range of models and structures are possible. For example, an established IVD manufacturer may scale up manufacturing by building or expanding their own facility. This facility may be based in a HIC or, preferably, in one or more LMICs for regional manufacturing and distribution. They may also license their Ag RDTs to independent rapid test companies that are manufacturing, commercializing and distributing to LMIC markets, or contract with such facilities for manufacturing only.

**Opportunity:** IVD companies that have developed Ag RDTs have an opportunity to rapidly and flexibly expand their production capacity to serve LMIC markets at minimal opportunity cost, while retaining rights to high-income country markets.

**Deal:** In exchange for funding to support necessary production expansion, partners commit to global access terms. For example, a percentage of RDTs produced as a result of the expansion is supplied to the public sector in LMICs at an affordable price (details to be negotiated with selected candidates).