ACTaccelerator
ACCESS TO COVID-19 TOOLS

FIND
Because diagnosis matters

FIND LAUNCHES CALL FOR PROPOSALS TO ACCELERATE AVAILABILITY OF LOW-COST SELF-TESTING SOLUTIONS FOR COVID-19 IN LOW- AND MIDDLE-INCOME COUNTRIES

- **Call aims to expand access to testing services through self-administered tests appropriate for use in low- and middle-income countries (LMICs)**
- **As part of a comprehensive testing programme for COVID-19, self-testing options could transform the COVID-19 response by reducing community spread, when linked to appropriate responses for isolation, contact tracing and care**
- **Innovators, developers and manufacturers of *in vitro* diagnostics, and LMIC-based diagnostic stakeholders, are invited to submit proposals**
- **Launch of this request for proposals (RFP) is the latest milestone for the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar, co-convened by FIND and the Global Fund**

Geneva, Switzerland – 31 March 2021 – The Foundation for Innovative New Diagnostics (FIND) announced today the launch of a request for proposals (RFP) to accelerate the development, manufacturing, and market availability of accurate, affordable, quality-assured and easy-to-use SARS-CoV-2 self-tests for use in low- and middle-income countries (LMICs). As part of a comprehensive testing programme, self-administered tests could expand access to testing services, potentially transforming the COVID-19 response by reducing community spread, when linked to appropriate responses for isolation, contact tracing and care. This RFP has been prepared in the context of the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar, co-convened by FIND and the Global Fund.

Testing continues to play a critical role in the COVID-19 pandemic, enabling patient care as well as providing decision makers with vital data on real-world vaccine coverage and the emergence of variants, and informing test-trace-isolate strategies and lockdowns. While a third antigen rapid test gained World Health Organization (WHO) Emergency Use Listing on 17 March 2021,[1] testing capacity is still highly centralized in many countries, and insufficient to meet the current demand.

This is especially true in LMICs, where fragile health systems and exclusive reliance on global supply chains have often left healthcare providers unable to access urgently needed tests. For every test conducted in a low-income country, over 80 are being conducted in high-income countries.[2] These issues arise from a lack of access to the laboratories needed for processing more complex molecular tests, and populations who often live far from health centres and need rapid results to avoid multiple journeys.

[1] WHO Emergency Use Listing for in vitro diagnostics detecting SARS-CoV-2, 18 March 2021. https://extranet.who.int/pqweb/sites/default/files/documents/210318_eul_covid19_ivd_update.pdf
[2] FIND SARS-COV-2 test tracker, data as at 16 March 2021. www.finddx.otg/covid-19/test-tracker

Modelling suggests that frequent testing with a rapid turnaround time has a greater impact on transmission than one-time testing using more sensitive but slower laboratory-based diagnostics.[3] Such serial testing strategies may detect individuals with high viral loads, who are most infectious to others, and may facilitate early isolation of the infectious individual, ultimately reducing transmission.

Currently, there are no affordable SARS-CoV-2 self-tests for use in resource-limited settings. Although the US Food and Drug Administration (FDA) has approved five tests for at-home use, their high price prohibits widespread adoption in LMICs. However, low-cost technologies, initially developed for administration by healthcare professionals, could be adapted for affordable self-testing.

Given the higher risk of user error with self-tests, compared with professionally administered tests, a central focus of the RFP is to address the availability of self-test solutions that are exceptionally easy to use, which could be because of their product design (such as easy to obtain samples, intuitive test interpretation, or accessible instructions), and/or supporting tools (such as digital solutions).

Proposals are invited from innovators, *in vitro* diagnostics (IVD) manufacturers and LMIC-based diagnostic stakeholders. An initial budget envelope of US$15 million of grant funding will be available to support 2–3 proposals that offer best value for money. 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.

Emma Hannay, Chief Access Officer and ACT-Accelerator Lead for FIND, said: "Even with vaccines now becoming available, it is clear that we will be living with COVID-19 for a long time, and testing will continue to be critical to keep people safe. We have seen in other infectious diseases such as HIV what a powerful impact self-testing can have in combatting epidemics – it is a key element in our arsenal against COVID-19, enabling people to take control of their own health."

Peter Ngo'la Owiti, Community Representative on the ACT-A Facilitation Council, said: "Even as rapid test prices have dropped, only developed countries have scaled up their testing, while LMICs still have a big access gap. Most of the testing in LMICs goes on in the higher level of healthcare settings only, leaving a big population that lives in the rural areas untested. We urgently need new use cases for widespread community and self-testing."

Peter Sands, Executive Director of the Global Fund, said: "Testing is a critical tool to fight COVID-19. We need to ensure that testing is accessible to everyone, from central hospitals to the remotest communities, and self-administered tests will enable places without laboratory facilities to monitor and stop the spread of COVID-19. Only with equitable and expanded access to testing can we successfully fight this pandemic."

The RFP has been launched to support the work plans of two working groups within the ACT-Accelerator Diagnostics 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). As set out in the 2021 ACT-Accelerator Strategy and Budget, this year the Diagnostic Pillar aims to:

- Ensure equitable access to new and existing tests, including the procurement and distribution of at least 900 million molecular and antigen rapid tests (including self-tests)
- Stimulate rapid and effective uptake of appropriate and quality-assured diagnostics in countries

[3] Hoehl et al, 2021 (pre-print): https://www.medrxiv.org/content/10.1101/2020.12.04.20243410v1

- Drive development and at-scale availability of affordable, transformative, digitally integrated tests.

The specific activities supported as part of this initiative will vary according to the needs of each applicant. For full details on the RFP and information on how to apply, please visit: www.finddx.org/rfp-covid19-self-tests/. Two Q&A workshops for potential applicants will be held via Zoom on Monday 12 March 2021: please register for the 09:00 CET workshop here, or the 17:00 CET workshop here.

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About the Access to COVID-19 Tools (ACT) Accelerator

The Access to COVID-19 Tools ACT-Accelerator, is a new, 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, European Commission, 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 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 areas of work: diagnostics, therapeutics, vaccines and the health system connector. Cross-cutting all of these is the workstream on Access & Allocation.

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

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