Cost of rapid COVID-19 tests halved as global investment ensures availability of high volumes for low- and middle-income countries

- **Technology transfer, scale up and automation of manufacturing capacity will enable over 250 million high-quality tests to be made available for low- and middle-income countries (LMICs) at a price of less than US$2.50 per test**
- **A set of new agreements, the first of which with Premier Medical Corporation (PMC) of India, follow an open call for Expressions of Interest (EOI), launched last year by FIND and Unitaid on behalf of the Access to COVID-19 Tools (ACT) Accelerator, to drive equitable access to fit-for-purpose Ag RDTs for COVID-19**

GENEVA, SWITZERLAND – 22 JANUARY 2020. The Foundation for Innovative New Diagnostics (FIND) and Unitaid, on behalf of the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar, announced today that the first contracts have been finalized, following an open call for Expressions of Interest (EOI) that was launched on 4 July 2020 to drive equitable access to fit-for-purpose antigen-detecting rapid diagnostic tests (Ag RDTs) for COVID-19.

The agreement announced today, with Premier Medical Corporation (PMC), headquartered in Sarigam Gujarat, India, is the first in a set of investments in R&D, including technology transfer and manufacturing scale up, that will be announced in the coming weeks.

With support from FIND and Unitaid, the company is expanding and automating manufacturing capacity so that Ag RDTs can be made available to low- and middle-income countries (LMICs) for less than US$2.50 per test (excluding transportation and potential duties). Achieving World Health Organization (WHO) Emergency Use Listing (EUL) is a key contractual condition. The investment will enable current production of 3 million COVID-19 tests per month to be scaled up to 10 million per month by Q3 2021. The expanded manufacturing capacity can also be used in future to make affordable tests for other infectious diseases, including another potential pandemic.

This and subsequent investments stemming from the EOI will support technology transfer and scale up of regional manufacturing capacity, ultimately to enable over 250 million low-cost, high-quality tests to be made available for LMICs. Further development that will enable nasal sampling (less invasive than current nasopharyngeal swabbing) and enhanced test performance is also being supported as part of this project.

Testing continues to play a critical role in the COVID-19 pandemic, enabling patient care as well as providing decision makers with vital data to inform test-trace-isolate strategies and

lockdowns. Despite the introduction of two Ag RDTs in September 2020, testing capacity remains highly centralized in many countries, and often 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. While high-income countries are now conducting 252 tests per 100,000 people each day, in LMICs the rate is 10 times lower, at just 24 tests per 100,000 people.[1] 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.

The ACT-Accelerator estimates that 500 million COVID-19 diagnostic tests are needed in LMICs during 2021, 75% of which must be deployed in decentralized settings (i.e. primary healthcare, community-level care, hospital triage). Ag RDTs are the primary diagnostic test for detection of active SARS-CoV-2 infection in decentralized settings where timely molecular testing is not available.

Dr Catharina Boehme, CEO of FIND, said: "Ensuring LMICs have access to low-cost, high-quality Ag RDTs is of vital importance in our work to make sure that everyone who needs a test for COVID-19 can get one. This open, transparent EOI process has spurred new partnerships that mean new tests can be scaled up fast and in the volumes needed to drive down costs."

Dr Philippe Duneton, Executive Director of Unitaid, said: "Expanding access to rapid, high-quality diagnostics in LMICs, as part of a test and treat approach, is of crucial importance if we are to defeat this pandemic. The agreements we are announcing today are a vital part of that work, alongside our efforts in country preparedness, ensuring optimal conditions for these tests to be used on the ground."

Dr Tedros Adhanom Ghebreyesus, Director General of WHO, said: "Testing has been our compass in the fight against the pandemic and will continue to play a key role in gauging the effectiveness of vaccinations in communities. Today's announcement brings new hope for the many countries that have flown blind in the face of the pandemic because they could not access or afford diagnostic tools. I urge the global community to keep supporting the ACT-Accelerator and bridge the funding gap of more than US$5.3 billion still needed for diagnostics."

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Background notes

The EOI was launched on 4 July 2020 by FIND and Unitaid, on behalf of the R&D and Market Readiness Working Groups of the ACT-Accelerator Diagnostics Pillar. It aims to accelerate supply and availability of quality-assured and regulatory-approved fit-for-purpose SARS-CoV-2 Ag RDTs that meet WHO criteria of quality, cost and accessibility. Interventions include facilitating regulatory approvals, increasing production capacity, addressing supply chain challenges, and strengthening local capacity for development and deployment of new tests within national testing strategies. Driving down prices to enable faster LMIC uptake is critical. Over 100 applications were received, with 34 selected for review by a panel of external experts.

About FIND

[1] Median values of 7-day rolling averages in each income group. Data correct as at 7 January 2021, www.finddx.org/covid-19/test-tracker

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

About Unitaid
Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose and treat diseases more quickly, cheaply and effectively, in low- and middle-income countries. Its work includes funding initiatives to address major diseases such as HIV/AIDS, malaria and tuberculosis, as well as HIV co-infections and co-morbidities such as cervical cancer and hepatitis C, and cross-cutting areas, such as fever management. Unitaid is now applying its expertise to address challenges in advancing new therapies and diagnostics for the COVID-19 pandemic, serving as a key member of the Access to COVID Tools Accelerator. Unitaid is hosted by the World Health Organization. www.unitaid.org

About the 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 2020 and launched by WHO, the 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.

The Diagnostics Pillar of the ACT-Accelerator is focused on ensuring that everyone who needs a test can get one. Workstreams span research and development, market readiness, procurement, and country preparedness. Achievements to date include laboratory trainings in partnership with Africa CDC in early February, and a suite of online courses deployed within weeks. Nearly 20 million tests have been procured with the Diagnostics Consortium, ensuring diagnostic access for LMICs and readiness for test-and-treat implementation in these countries. Independent evaluations of antibody tests are also being conducted, as high-quality antibody tests are essential to understand population immunity for future vaccine roll out.

Media contacts

FIND
Sarah-Jane Loveday
Head of Communications
M: +41 (0) 79 431 62 44
media@finddx.org

Unitaid
Hervé Verhoosel
Communications Lead
M: +41 79 249 35 29
verhooselh@unitaid.who.int

Charlotte Baker
Communications Officer
M: +44 7904 460 181
bakerc@unitaid.who.int

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