“TEST, TEST, TEST” FOR COVID-19
ACCESS TO QUALITY TESTS IN LOW- AND MIDDLE-INCOME COUNTRIES IS CRITICAL TO THE GLOBAL EXIT STRATEGY

THE COVID-19 RESPONSE DEPENDS ON SIMPLE, LOW-COST TESTS

Diagnostic testing is not only at the centre of the health response to the COVID-19 pandemic, it is central to mitigating the major global economic disaster.

The COVID-19 exit route is front of mind for governments and businesses alike, and effective tests and testing strategies are the linchpin for getting people back to work across the globe.

Fast results from comprehensive, rapid testing allow healthcare professionals and policy makers to make informed decisions. Testing enables disease diagnosis for patient management, and provides critical data to inform and monitor public health measures.

Countries like Germany and South Korea have shown that a focus on testing can have a major impact on containing the spread of the pandemic. But these are countries with strong, well-resourced laboratory systems, and their strategies depend on complex diagnostics.

In a pandemic, no one is safe until everyone is safe. Slowing transmission in LMICs with already-fragile health systems is essential to global health security.

Alongside greater technical capacity, these countries need to be able to access simple, low-cost tests to be able to carry out mass testing. Today, high prices, broken supply chains, and complex ordering systems make this impossible.

TARGET: US$750 MILLION

US$750 million will ensure appropriate, effective diagnostics can be mass-produced and made widely available to LMICs through effective supply chains. This will enable all countries to buy the tests they need, both for patient management and policy decisions.

If you don’t test, you are not ahead of the curve. We are playing catch-up and that is a very, very tough thing to do.

Dr John Nkengasong, Director of the Africa Centres for Disease Control & Prevention

Test development: US$180 million
Development of tests for clinical management, surveillance and long-term outbreak preparedness
• Open point-of-care platforms
• Improved rapid tests, including home-based tools
• Digital technologies, such as rapid diagnostic test readers
• Pan-viral sequencing

Global supply chain innovation: US$200 million
Drive innovative supply chain models, including tech and know-how sharing
• Production scale up of critical raw materials and tests
• Increased dedicated pandemic preparedness manufacturing capacity
• Manufacturing partnerships with global access terms
• Digital marketplace to enable transparent and easy procurement and forecasting

LMIC capacity innovation: US$300 million
Build domestic capacity and infrastructure in LMICs
• Testing capacity
• Quality assurance
• Clinical trials and biobanking networks
• Innovative diagnostic delivery models and connectivity

Digital, data & analytics solutions: US$70 million
Robust data solutions
• Mapping, modeling and data utilization
• Online tools for real-time decision making
• Data standards

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A GLOBAL DIAGNOSTICS ALLIANCE WILL ENSURE THAT TESTS ARE AVAILABLE FOR THOSE WHO NEED THEM

Even before COVID-19 hit, the uptake of diagnostic tests in LMICs was severely hampered by numerous constraints and market failures. A recently formalized strategic collaboration between FIND and WHO to drive universal access to essential tests has become central to the global COVID-19 response.

Given the unprecedented challenges of COVID-19 and the urgency of the pandemic, FIND is significantly accelerating the establishment of a Global Diagnostics Alliance as part of an overall, multi-year plan to strengthen testing capacity in LMICs. Alongside WHO, Alliance partners will include The Global Fund to Fight AIDS, Tuberculosis and Malaria and a number of private sector and public entities, with a focus on LMICs.

The Alliance brings together countries and partners to strengthen procurement systems, accelerate development of LMIC-appropriate tests, increase test availability and reduce prices (through market-shaping interventions and pooled procurement), and generate robust data to feed the entire process.

Filling these gaps is critical to the global COVID-19 response, as well as ensuring preparedness for future pandemics and underpinning the achievement of universal health coverage (UHC) in support of the UN Sustainable Development Goals.

COVID-19 is painfully demonstrating that testing bottlenecks are a major threat to global health security - collectively we are only as strong as the weakest health system.

Professor Patricia Garcia, School of Public Health at Cayetano Heredia University and former Minister of Health for Peru

A CTIVITIES ALREADY UNDERWAY

FIND has been working closely with global health stakeholders, particularly WHO, since January 2020 as part of the global response to the COVID-19 pandemic:

• Building global pipeline tracker of critical diagnostic tests (over 500 now listed, including digital tools)
• Launching evaluations of prioritized tests – with initial results already published – to drive availability of accurate and quality-assured tests of all types, with a key focus on the needs of LMICs alongside global applicability
• Mapping diagnostic supply chains for COVID-19 to identify and tackle key bottlenecks
• Putting in place initial training and capacity-building at country and regional levels, including freely available online training
• Facilitating know-how transfer from developers to manufacturers in LMICs
• Partnering in global platforms to ensure equitable allocation and demand aggregation of prioritized tests

INVESTMENT IMPACT

US$750 million is needed for FIND and partners as a Global Diagnostics Alliance to allow urgent actions with critical impact in LMICs:

1. Accelerate development of high-quality, affordable (<US$5) rapid diagnostic tests
2. Secure equitable access to 1 billion tests over 12 months through innovative manufacturing partnerships and a marketplace for demand aggregation
3. Rapidly ramp up country testing capacity and infrastructure for COVID-19
4. Create robust digital, data and analytics solutions for early detection, surveillance and decision making

Diagnostics are our first line of defence against COVID-19. Every dollar invested in testing today is a dollar invested in our future global health security and an opportunity to protect the health advances of recent decades.

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ANNEX: ACTION PLAN FOR US$750 MILLION INVESTMENT

IMMEDIATE NEED

- Develop diagnostics R&D pipeline to identify novel tests emerging for prioritized diseases
- Develop adaptive and flexible trial site network for COVID-19
- Conduct rapid validation of new tests getting approval; leverage AI-based image analysis software
- Prioritize and evaluate rapid diagnostic tests and self-testing diagnostics
- Drive completion of development of new diagnostic assays to be used in existing labs or no labs
- Collect and bank samples for rapid validation of tests
- Research and develop diagnostics
  - Point-of-care rapid diagnostic tests (key characteristics: adapted to LMIC settings, easy to operate, affordable)
  - Home-based self-testing kits
  - Digital diagnostic tools that leverage diagnostic data (e.g. for patient management, contact tracing)
- Develop pan-viral sequencing tools
- Secure COVID-19 test volumes for LMICs; lock in required capacity with commitment to ramp-up
- Drive prices down supporting strategic investments (e.g. co-funding, volume guarantees, volume buy-downs)
- Address up and down stream supply bottlenecks (e.g. raw materials procurement, exporting of goods)
- Invest in manufacturing scale up, facilitate tech / know-how transfers to meet LMICs needs
- Support WHO in allocation of tests – create demand estimates
- Bundle supplies to ensure countries have all commodities needed to conduct testing (e.g. swabs, vials)
- Fund innovative pricing mechanisms to increase affordability of diagnostics (e.g. volume buy-downs, volume guarantees)
- Fund innovative upstream supply chain activities (e.g. production capacity expansion, funding to secure raw material supply, knowledge transfer sub-licensing contracts, local production / increased local footprint)
- Fund innovation downstream supply chain / distribution activities (e.g. regional / local storage facilities, last-mile delivery network)
- Drive and inform global diagnostics R&D agenda based on thorough gap analysis and country needs assessment
- Expand clinical trial network to support R&D for ongoing epidemics and future outbreaks
- Enable quality product development with open-access resources: e.g. creating quality assurance panels and proficiency panels, collecting and storing well-characterized specimen banks
- Support local innovation and manufacturing, which may potentially include prioritization and capacity building of local manufacturers
- Design and roll-out an online marketplace to match supply and demand for highest priority diagnostics by country to optimize access and procurement
- Populate online marketplace with quality-assured suppliers
- Negotiate long-term agreements based on demand forecasts; foster innovative delivery methods and supply chain and negotiate innovative pricing models, such as reagent rental based on total cost of ownership to sustain accessible pricing
- Invest in supply chain innovations for LMICs, leveraging tech & know-how sharing
- Conduct operational procurement and supply activities (e.g. freight, customs management) along with partners

TEST DEVELOPMENT: US$180 MILLION

Accelerate development of high-quality, affordable (<US$5) rapid diagnostic tests

GLOBAL SUPPLY CHAIN INNOVATION: US$200 MILLION

Secure equitable access to 1 billion tests through innovative manufacturing partnerships and a marketplace for demand aggregation

US$100 million will enable development of 3–5 new rapid tests for COVID-19

US$50 million will buy 500 new mobile testing stations
IMMEDIATE NEED

- Create supply and demand planning for tests, focusing on linking tests to expected patient demand
- Develop digital decision support tools to use alongside validated tests to aid rapid, accurate diagnosis
- Develop digital tools to link test results to national health programmes to inform national epidemic and diagnostics strategy real time
- Create online capacity-building resources for rapid dissemination of testing-related information (e.g., online training courses)
- Set up in-country surveillance of epidemic via existing open-source tools
- Develop testing use cases (e.g., understanding population infection levels, triaging/screening) and identify gaps based on existing diagnostics performance and supply chain
- Develop national testing strategies tailored to local context
- Expand laboratory network based on optimized laboratory network blueprint
- Hire and train new health workers to increase testing capacity
- Develop local innovation and local production
- Invest in innovative delivery models (e.g., leveraging communities)
- Implement network optimization for resource utilization and planning
- Creation of master protocols based on type of tests which can be easily implemented in wide trial networks and repurposed for future outbreaks

NEAR-TERM NEED

- Evaluate country capacity and readiness to support effective diagnosis of priority diseases; develop and roll-out tailored capacity building efforts
- Develop and implement innovative delivery strategies, such as lab network optimization and capacity building, through trainings and community engagement
- Support creation or revision of national policies for inclusion of diagnostics
- Support creation of national EDLs (Essential Diagnostic Lists)

ANNEX: ACTION PLAN FOR US$750 MILLION INVESTMENT

LMIC CAPACITY INNOVATION: US$300 MILLION
Rapidly ramp up country testing capacity and infrastructure for COVID-19

- Create online dashboards to prioritize R&D pipeline and inform decision makers (e.g., test pipeline, test performance tracker)
- Develop online tool to analyze real-time COVID-19 evolution against test usage and performance to measure impact of diagnostics strategy and identify gaps; develop in a way that it can be applied for future outbreaks
- Define standards for diagnostic data reporting for countries
- Develop model to simulate the impact of different testing strategies in different countries
- Acquire and set up servers to store, manage and retrieve large sets of diagnosis data
- Build connectivity network to enable efficient exchange of data among different public & private institutions
- Roll-out new interoperability standards for diagnostics data
- Conduct in-country data collection activities to support decision making

DIGITAL, DATA & ANALYTICS SOLUTIONS: US$70 MILLION
Create robust digital, data and analytics solutions for early detection, surveillance and decision making

- Create online tools to analyze real-time country epidemiological data from prioritized diseases against test usage and performance to measure impact of diagnostics strategies and identify gaps
- Develop common standards for diagnostic data to be captured; facilitate uptake of data collection procedures and protocols
- Develop tool to measure impact of diagnostic strategies and identify gaps using real-time epidemiological data for prioritized diseases; empower countries to make evidence-informed decisions
- Create dashboards for disease burden/surveillance data to inform decision making