



ACCESS TO TESTING WILL CHANGE THE COURSE OF THE COVID-19 PANDEMIC

GOAL

To ensure that effective, quality-assured and affordable tests for all needs linked to the COVID-19 pandemic are developed and equitably available for low- and middle-income countries (LMICs). In doing so, bring an end to this pandemic and be prepared for the next.

SITUATION

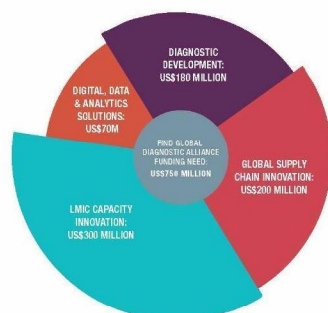
Testing is an essential tool to defeat the COVID-19 pandemic, enabling rapid disease diagnosis for patient management, and providing critical data to inform and monitor public health measures.

Developing a range of effective tests, improving production capacity, and mitigating supply chain interruptions are critical to minimize transmission, while maintaining functioning societies.

Diagnostics are not only at the centre of the health response to the COVID-19 pandemic, they are central to mitigating the major global economic disaster.

LMICs have the lowest testing rates as reported to the World Health Organization (WHO). Not only are existing diagnostics often inappropriate for use in LMICs, these countries cannot access enough tests due to high prices, and inadequate supply chains and procurement systems.

The consequences are significant both for mounting an effective public health response to reduce transmission and for providing care to patients when infections do occur. In a pandemic, no one is safe until everyone is safe: these obstacles are everyone's challenge.



TARGET: US\$750 MILLION

- To ensure effective diagnostics are not only developed but also mass-produced and made widely available through effective supply chains
- So that all countries have the capacity to buy, distribute and perform testing when and where needed
- To allow data from the testing to be recorded, analysed, and used to inform decision-making.

Diagnostic 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



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

Even before the COVID-19 pandemic, the uptake of diagnostics in LMICs was severely hampered by a number of constraints and market failures. The global pandemic is shining a floodlight on the impact of lack of testing capacity, in high-, middle-, and low-income countries alike, and it is critical for FIND to continue and expand its work as global convener of diagnostics. The recently formalized strategic collaboration between FIND and WHO to drive universal access to essential tests is central to the global COVID-19 response.

FIND has taken the first steps in bringing countries and partners together into a Global Diagnostics Alliance. The new Alliance will strengthen procurement systems, expertise and demand; accelerate development of LMIC-appropriate tests; increase availability and reduce prices through market-shaping interventions and pooled procurement; and ensure that robust data feed the entire process. Alongside WHO, Alliance partners will include The Global Fund and a number of private sector and public entities, with a focus on LMICs.

Given the unprecedented challenges of COVID-19 and the urgency of the pandemic, FIND is significantly accelerating the establishment of the Alliance.

These actions constitute an essential initial and urgent part of an overall, multi-year plan to strengthen testing capacity in LMICs within the larger COVID-19 response.

ACTIVITIES 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:

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

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

Rapidly ramp up country testing capacity and infrastructure for COVID-19

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.

ANNEX: ACTION PLAN FOR US\$750 MILLION INVESTMENT

IMMEDIATE NEED

NEAR-TERM 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**

DIAGNOSTIC DEVELOPMENT:
US\$180 MILLION

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

- 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

- 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)

GLOBAL SUPPLY CHAIN INNOVATION:
US\$200 MILLION

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

- 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

- 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, for example 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

LMIC CAPACITY INNOVATION:
US\$300 MILLION

Rapidly ramp up country testing capacity and infrastructure for COVID-19

- 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
 - Develop **innovative delivery strategies and trainings** leveraging community engagement
 - Support **creation or revision of national policies for inclusion of diagnostics**
 - Support **creation of national EDLs** (Essential Diagnostics Lists)

- 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 diagnostic 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