

Access to COVID-19 Tools (ACT) Accelerator Diagnostics Partnership

INVESTING IN DIAGNOSTICS TO MANAGE THE COURSE OF THE COVID-19 PANDEMIC

May 2020

We have an opportunity to contain the humanitarian and economic fallout of the COVID-19 pandemic. Without mass testing – which relies on availability of high-performing, rapid tests – the disease will continue to spread. Innovation and scale up of these tests must be accelerated for deployment in all countries. For low- and middle-income countries, this investment would contribute to saving 9 million lives, and strengthen health systems to overcome the COVID-19 pandemic.

An investment of US\$6 billion is required to harness innovation and secure access to vital diagnostic tests over the next 12 months for low- and middle-income countries.

US\$2 billion of this is required immediately to expedite development, manufacturing and scale up of the rapid tests that will enable mass testing to be introduced globally – as well as procurement of tests to fill critical short-term gaps in low-income countries.

Through equal and adequate access to diagnostic tools and an investment in the capacity of all countries to conduct, analyse and process the data of extensive, systematic testing, the world can also mitigate the collective impact of the COVID-19 pandemic, enabling all countries to more rapidly restart economies and avoid the crippling effects of prolonged, repeated, and severe lockdowns. This could ease recessions, and therefore limit mass unemployment, widespread poverty and hunger in low- and middle-income countries.

The COVID-19 pandemic is a global health crisis. But it has also become much more than a health crisis: the world economy is threatened by the fallout of the pandemic. The combination of

the humanitarian catastrophe and economic crisis caused by an unchecked pandemic will also make it dramatically harder to achieve the Sustainable Development Goals. Much of the progress achieved in global health over the past two decades may be reversed.

The fight to protect health systems and restore the world economy – and billions of people's livelihoods and prosperity – is dependent on the decisions that will be made concerning public health interventions over the coming weeks and months. With global travel, trade and commerce being dependent on the virus not re-emerging from abroad, nobody is safe until everybody is safe. Only global investments in global solutions will succeed in defeating the virus.

THE URGENCY OF SCALING UP TESTING

Until a vaccine has been developed and produced for global use, diagnostics are the most important medical technology available today to limit the spread of COVID-19. Early evidence shows that testing is an essential component of an effective response strategy to the pandemic. Extensive and systematic testing (combined with tracing and quarantining of confirmed cases) is the only way countries, if they act early, can, avoid extensive and economically crippling, repeated lockdowns.

Given that a vaccine may be 12–24 months away from being a realistic global tool for control of the pandemic, millions of lives and the economic fall-out for all countries will depend on the speed with which we are able to produce and deploy sufficient tests to reach everyone who needs them, regardless of where they live. Testing will also be crucial to the roll out therapeutics and vaccines once they are available.

Time is not on our side: as infection numbers initially grow exponentially, the earlier extensive and systematic testing is introduced, the more effective it is in flattening the curve of the epidemic in each country.

Even a two-week advance in the lightening of suppression measures could translate into an increase of national income by 1 percent according to the World Bank.¹

Action over the coming weeks will therefore have a dramatically greater effect in slowing the spread than action several months from now. Rapid action will save large numbers of lives and costs to society.

Adequate access to diagnostics is therefore every government's essential tool to keep their nation's economy functioning throughout the pandemic.

1. *Incentives for Scaling Up Production and Delivery of Affordable Diagnostics: A Proposal for a COVID-19 Diagnostics Partnership*, World Bank Group, 30 April 2020.

THE NEED FOR INVESTMENT IN DIAGNOSTICS AND TESTING CAPACITY

Only the fast adoption of public health measures, of which rapid and effective testing is an essential component,² will allow healthcare demand to be kept within manageable levels and enable transmission to be suppressed. Experience in high-income countries (such as Germany and South Korea) has suggested that such an approach can significantly reduce the rate of epidemic spread.

While laboratory-based tests already exist, their use is limited. Mass testing strategies depend on simple, high-performing rapid tests, preferably that can be administered right at the point of care or even at home. We also need to effectively detect antibodies to determine prior infection. Production of all these tests must be dramatically increased to meet global demand.

Models of the progression of the pandemic in low- and middle-income countries³ have shown that testing, if deployed in a timely way as part of a broad package of interventions, could contribute to saving at least 9 million lives and avert at least 1.5 billion COVID-19 infections.

Current estimates indicate that 500 million tests are needed over the next 12 months in low- and middle-income countries (excluding China⁴) to enable such a life-saving scenario.

The global challenge is therefore two-fold: to develop new rapid diagnostic tests and to scale up the production of such reliable, affordable tests to a volume sufficient for all countries to access them; and strengthen low- and middle-income countries' ability to procure,

import, distribute tests and conduct testing, as well as analyse their results and manage the data in a way that assists governments in taking necessary action to limit the pandemic.

The challenge is also daunting: countries need to build greater technical capacity to deal with the pandemic, while already suffering weak and overloaded health systems, as well as ensuring an adequate supply of tests in an environment of limited supply, high competition, broken supply chains and complex ordering systems.

Overcoming these obstacles is possible.

THE ECONOMIC IMPACT OF IMMEDIATE INVESTMENTS

The impact of such an effort will be dramatic. If adequate access to testing is combined with a capacity to analyse data, trace contacts, and ensure humane quarantine arrangements for those who test positive, countries will be able to ease lockdowns, restart some international travel, and keep essential industries and services running.

A calculation by McKinsey & Co estimates a considerable difference in economic fallout in Africa between a best- and worst-case scenario.⁵ While an optimistic scenario of a contained outbreak in Africa will cut the continent's GDP growth from 3.9% to 0.4% in 2020, its worst-case scenario of a widespread and protracted outbreak sees an 8% percentage point drop in GDP to a (negative) growth of -3.9%. The Asian Development Bank estimates the difference in fallout in developing Asian nations (excluding China) between optimistic and pessimistic scenarios would be 0.17% GDP loss and 0.46% loss in GDP, respectively.⁶

THE INVESTMENTS EXPLAINED

The need of at least US\$6 billion over 12 months is a preliminary estimate, based on a number of assumptions. It is important to note that the number has been extrapolated from a severely limited amount of available data. These numbers may be revised as more information becomes available.

A key assumption is that cost-effective rapid diagnostic tests (RDTs), both antigen RDTs for screening and patient management as well as antibody RDTs for surveillance and serology studies, will be quickly introduced and scaled up, so that over the 12-month period, 75% of tests will be

RDTs, which are expected to cost only one-fifth of the currently available molecular tests.

If we see a significantly higher infection rate developing, or if we fail to rapidly introduce RDTs, the overall cost estimate for procurement/deployment would increase, while the target of 500 million tests will be harder to achieve, given the complexity of the molecular testing production and scale-up in countries.

As the cost of inaction is exponential in a spreading pandemic, US\$2 billion of the US\$6 billion must be raised immediately.

This funding will be invested in four areas:

1

R&D of tests & digital tools

Accelerate development of high performing, affordable rapid diagnostic tools, and create robust digital, data and analytics solutions

- Drive promising research and development of affordable, rapid, point-of-care and at-home tests, multiplex assays to detect multiple pathogens, and pan-viral sequencing tools for surveillance, against prioritized needs
- Develop digital and AI-based diagnostic tools for early detection, surveillance, and decision making
- Set up local innovation and manufacturing, which will include prioritization and capacity building of local manufacturers
- Enable technology transfer for local and regional manufacturing that will alleviate pressure on the global supply chain

**US\$300
MILLION
NEEDED NOW**

2

Market readiness

Prepare markets to accelerate implementation through regulatory support, market shaping and manufacturing scale-up

- Create a coordinated marketplace that enables pooled, large-volume procurement and fair allocation of available tests
- Set up advanced market commitments or similar mechanisms to guarantee affordable and sustainable supply
- Ensure manufacturing scale up for quality tests, including through innovative business models and know-how sharing
- Develop adaptive and flexible trial site network and establish sample banks for COVID-19
- Conduct robust performance evaluation studies of new tests; speed up regulatory approval of new tests

**US\$100
MILLION
NEEDED NOW**

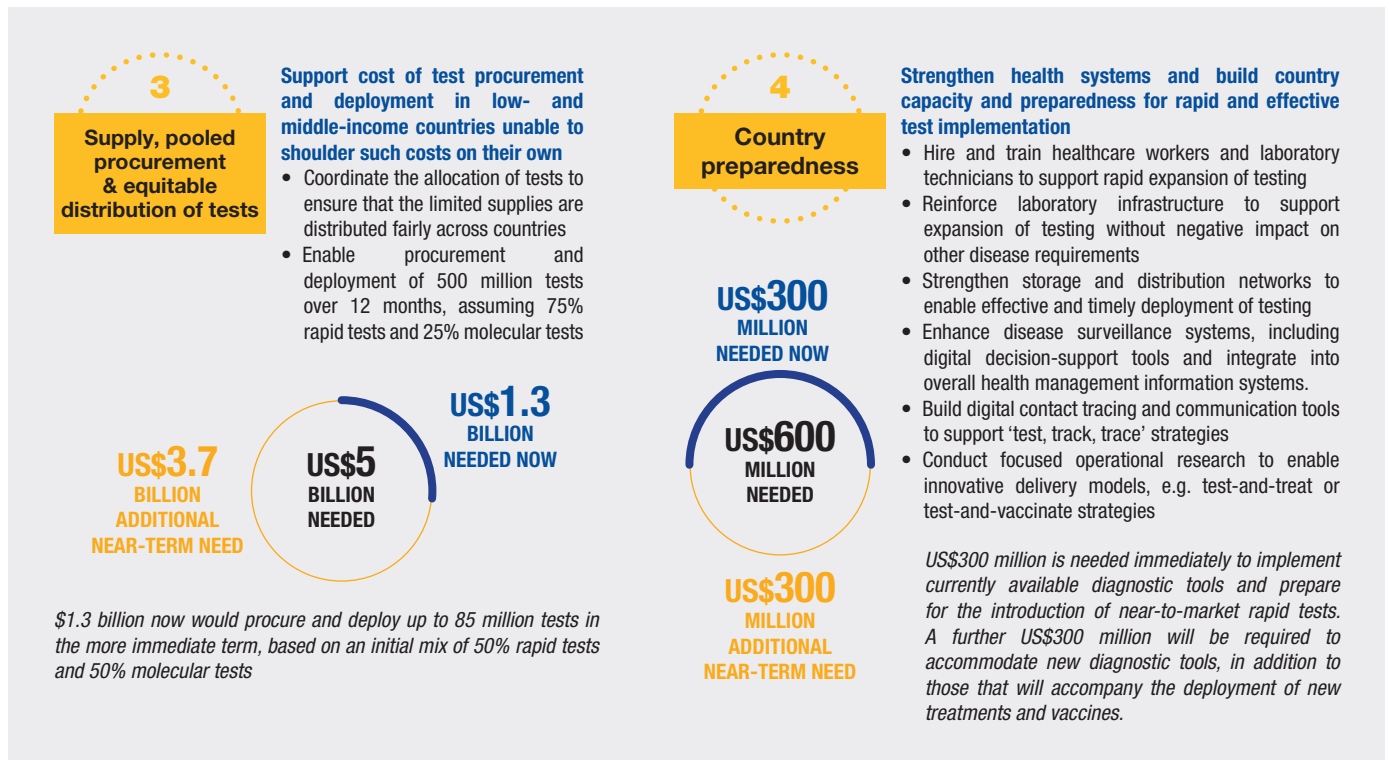
2. Other essential measures include isolation of cases and wider social distancing.

3. *The Global Impact of COVID-19 and Strategies for Mitigation and Suppression*, Imperial College COVID-19 Response Team, Neil M. Ferguson, Azra C. Ghani, et al.

4. China is excluded because it has developed its own diagnostic capabilities.

5. *Tackling COVID-19 in Africa*, McKinsey & Co, April 2020.

6. *ADB brief – The Economic Impact of the COVID-19 Outbreak on Developing Asia*, Asian Development Bank, April 2020.



FACING A NEW CHALLENGE BASED ON A SOLID TRACK RECORD

The challenges posed by the COVID-19 pandemic are unprecedented. Yet, the organizations engaged in collaboration under the Diagnostics Partnership of the ACT Accelerator have between them an impressive track record of success in implementation and in creating lasting impact.

The co-convenor of the Diagnostics Partnership, FIND, a global diagnostics alliance, has over 17 years of deep technical and practical experience in the definition of needs, development of fit-for-purpose products, generation of evidence for regulators and policymakers, analysis of market dynamics, the introduction of new products, and strengthening of laboratory systems. FIND has been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to LMICs in the last 5 years.

The other co-convenor, The Global Fund, is the largest multilateral financing instrument to fight the three pandemics of AIDS, tuberculosis and malaria and support health systems. Over the past 19 years, it has raised and invested US\$45 billion against the three pandemics, saving over 32 million lives and strengthening health systems in its programme countries. It has a proven record in strengthening procurement and delivery systems.

Key participating partners in the Diagnostics Partnership are the World Health Organization (WHO), which leads on the product allocation across all three partnerships of the ACT Accelerator in addition to coordinating the consolidated procurement platform for COVID-19 diagnostics; the World Bank; UNICEF; and Unitaid, which in addition

to being a partner in the Diagnostics Partnership is also a co-convenor for the Therapeutics Partnership. Other ACT Accelerator partners are also active, including the Bill & Melinda Gates Foundation, the Wellcome Trust, with additional partners coming on board.

The work of the ACT Accelerator aligns with the UN COVID-19 Supply Task Force set up by the United Nations to coordinate the procurement and distribution of personal protective equipment, diagnostic tests and oxygen to countries with overstretched healthcare systems. This initiative is run by the World Health Organization and the World Food Programme, along with the multiple partners of United Nations. Between them, these organizations have an unparalleled presence in countries and the world's largest procurement, logistics and distribution capacity for humanitarian assistance.

Led by WHO, the consolidated procurement platform for COVID-19 diagnostics is already organizing centralized procurement of millions of vital COVID-19 diagnostic tests for low- and middle-income countries. This Consortium applies a coordinated approach to allocating COVID-19 test to ensure that the limited supply of tests is distributed equitably across countries. In May, the Consortium is deploying 6 million tests across over 100 countries.

The ACT Accelerator Diagnostics Partnership is committed to working with civil society and community representatives in its work to ensure appropriate human-rights based approaches within the workstream. Community engagement will be vital to the deployment of effective diagnostics and testing programmes.



On behalf of the ACT Accelerator Diagnostics Partnership