FIND

INNOVATIVE DIAGNOSIS AND PARTNERSHIPS FOR ALL

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INTRODUCTION & BACKGROUND

FIND, THE GLOBAL ALLIANCE FOR DIAGNOSTICS

SEEKS TO ENSURE EQUITABLE ACCESS TO RELIABLE DIAGNOSIS AROUND THE WORLD

We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of **sustainable, resilient health systems**

- Established in 2003 as a product development & delivery partnership
- Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member
- ISO-certified quality management system for IVD clinical trial

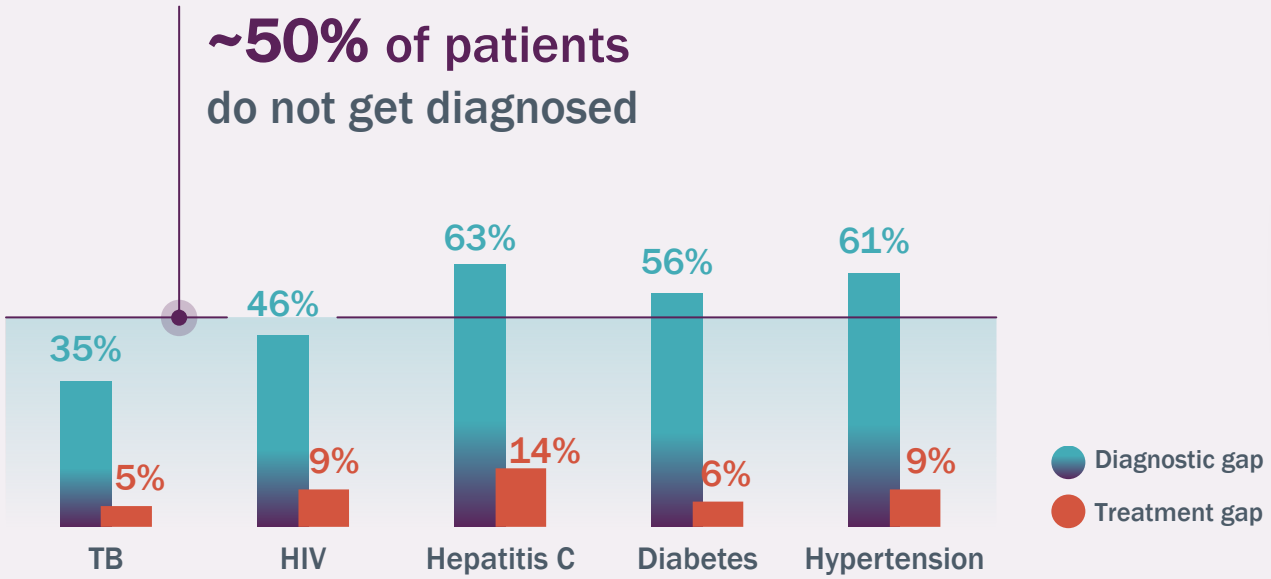
2021 STRATEGY: EXPECTED IMPACT

Save 1 million lives
through accessible, quality diagnosis

Save US$1 billion
in healthcare costs to patients and health systems

Empower 10+ countries
with diagnostic data to inform policy and care

UNADDRESSED DIAGNOSTIC GAPS
ARE MASSIVE



Basic diagnostic capacity is available in only **1%** of primary care clinics and **14%** of hospitals in some LMICs[1]

Appropriate tests do not exist for **60%** of infectious agents with outbreak potential[2] and **50%** of the top 20 diseases responsible for most lives lost[3]

[1] Leslie et al. *Bull World Health Organ* 2017;95:738–748, http://dx.doi.org/10.2471/BLT.17.191916.
[2] Kelly-Cirino et al. *BMJ Glob Health* 2019;4:e001179. doi:10.1136/bmjgh-2018-001179
[3] Pai et al. Analysis from Global Burden of Disease Report 2020

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CONTEXT: KEEPING THE PROMISE

Keeping the Promise:

Product Development Partnerships' Role in the New Age of Health Research and Product Development

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DNDi
Drugs for Neglected Diseases *initiative*

IVCC
Building Partnerships
Creating Solutions
Saving Lives

EVI

International Partnership for Microbicides

iavi

International Vaccine Institute

TBVI
TuBerculosis Vaccine Initiative

MMV
Medicines for Malaria Venture

Medicines Development for Global Health

TB Alliance

PATH

1. PDPs are the global leaders in developing new health technologies where lack of traditional market incentives have stalled progress

- Since 2010, this coalition of PDPs have delivered 66 new health technologies—treatments, vaccines, diagnostics, vector controls, and devices.
- Products have reached more than 2.4 billion people, mostly in LMICs
- Highlights include:
  - First ever drug approved for treatment of highly drug-resistant forms of tuberculosis
  - Single dose treatment to prevent relapse of *P. vivax* malaria
  - First all-oral cure for all stages of sleeping sickness.
- Advances are concentrated in diseases of poverty where investment and innovation have long been stagnant; market forces don't drive innovation in these fields

PDPs DELIVER INNOVATION

Many PDPs were established around the turn of the century. This past decade has seen the fruits of previous investment.

Products developed and marketed by PDPs featured in the report

2. PDP pipelines are robust and poised to deliver a significant number of innovative technologies in the near-term

- PDPs featured in the report have more than 375 potential new technologies in their pipelines
  - Approximately 25% of those products in late-stage development.
- Portfolios are built through diverse partnerships – across sectors and geographies
- Products in development stand to impact some of world's oldest and deadliest diseases, including those that disproportionately impact women and children

PDPs FEATURED IN THE REPORT HAVE MORE THAN

375

POTENTIAL NEW TECHNOLOGIES IN THEIR PIPELINES

3. PDPs achieve impact by developing products appropriate for the people and contexts in which they will be used

- PDPs closely engage with local communities, care providers, researchers, and policy makers to ensure they are designing products for use in the settings where they are most needed
- Attributes to enable use in low-resource settings are prioritized
- This is the first step to driving widespread and equitable access to PDP-developed products

PRODUCTS DEVELOPED BY PDPs FEATURED IN THE REPORT HAVE REACHED 2.4+ BILLION PEOPLE AROUND THE WORLD

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PARTNERSHIP WITH GHIT & JAPANESE PARTNERS

ESTABLISHED TRACK RECORD WITH

JAPANESE PARTNERS

Recent/ongoing collaborations

FUJIFILM

KYOCERA

Otsuka

SUDx-Biotec

LSI Medience

FUJIREBIO

RIT/JATA The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association

TAUNS

Tests listed in FIND COVID-19 test directory

SHIMADZU

FUJIREBIO

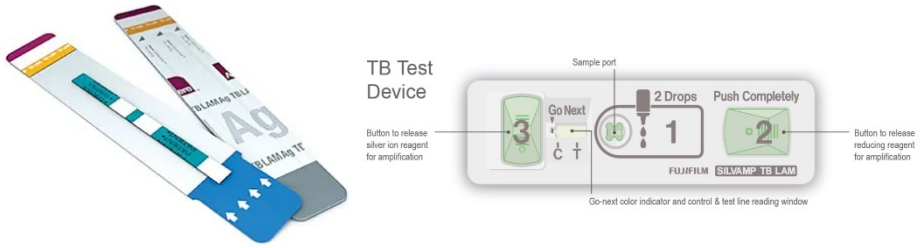
MBL MEDICAL & BIOLOGICAL LABORATORIES CO., LTD

EIKEN CHEMICAL CO.,LTD.

DENKA DENKI KAGAKU KOGYO KABUSHIKI KAISHA

Canon CANON MEDICAL SYSTEMS

FUJIFILM SILVAMP TB LAM PAVED THE WAY TO A NEW GENERATION OF POINT-OF-CARE TB TESTS

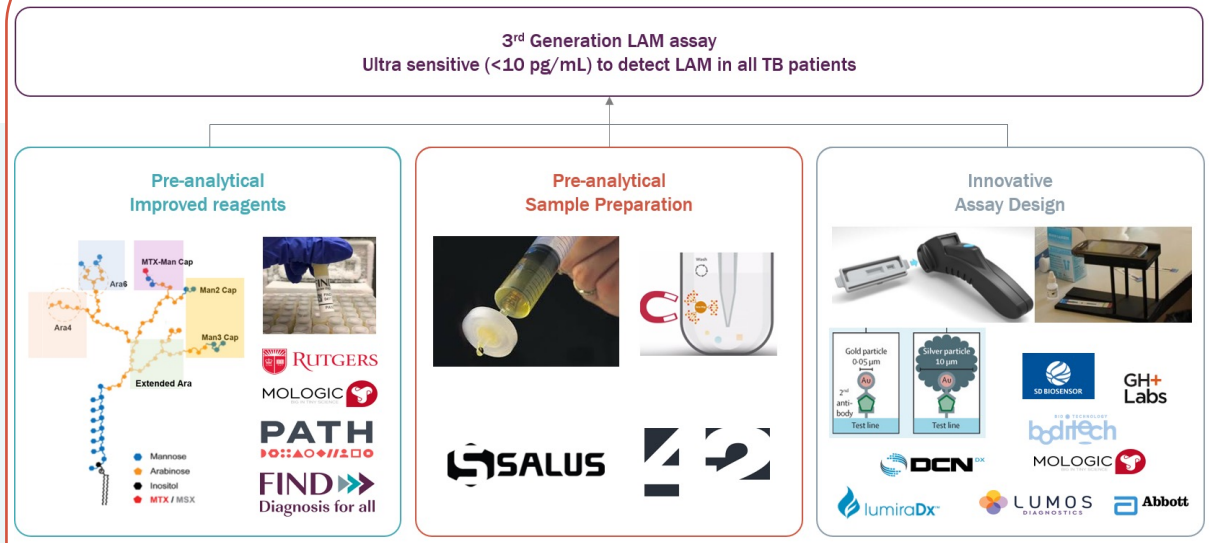


PLHIV (5 cohorts, n=1595)

	Sn [95% CI]	Sp [95% CI]
FujiLam	70.7 [59.0 – 80.8]	90.9 [87.2 – 93.7]
AlereLAM	34.9 [19.5 – 50.9]	95.3 [92.2 – 97.7]

HIV uninfected patients (n=372)

	Sensitivity (95% CI)	Specificity (95% CI)
FujiLAM	53.2% (43.9 to 62.2)	98.9% (96.7 to 99.6)
AlereLAM	10.8% (6.3 to 18.0)	92.3% (88.5 to 95.0)

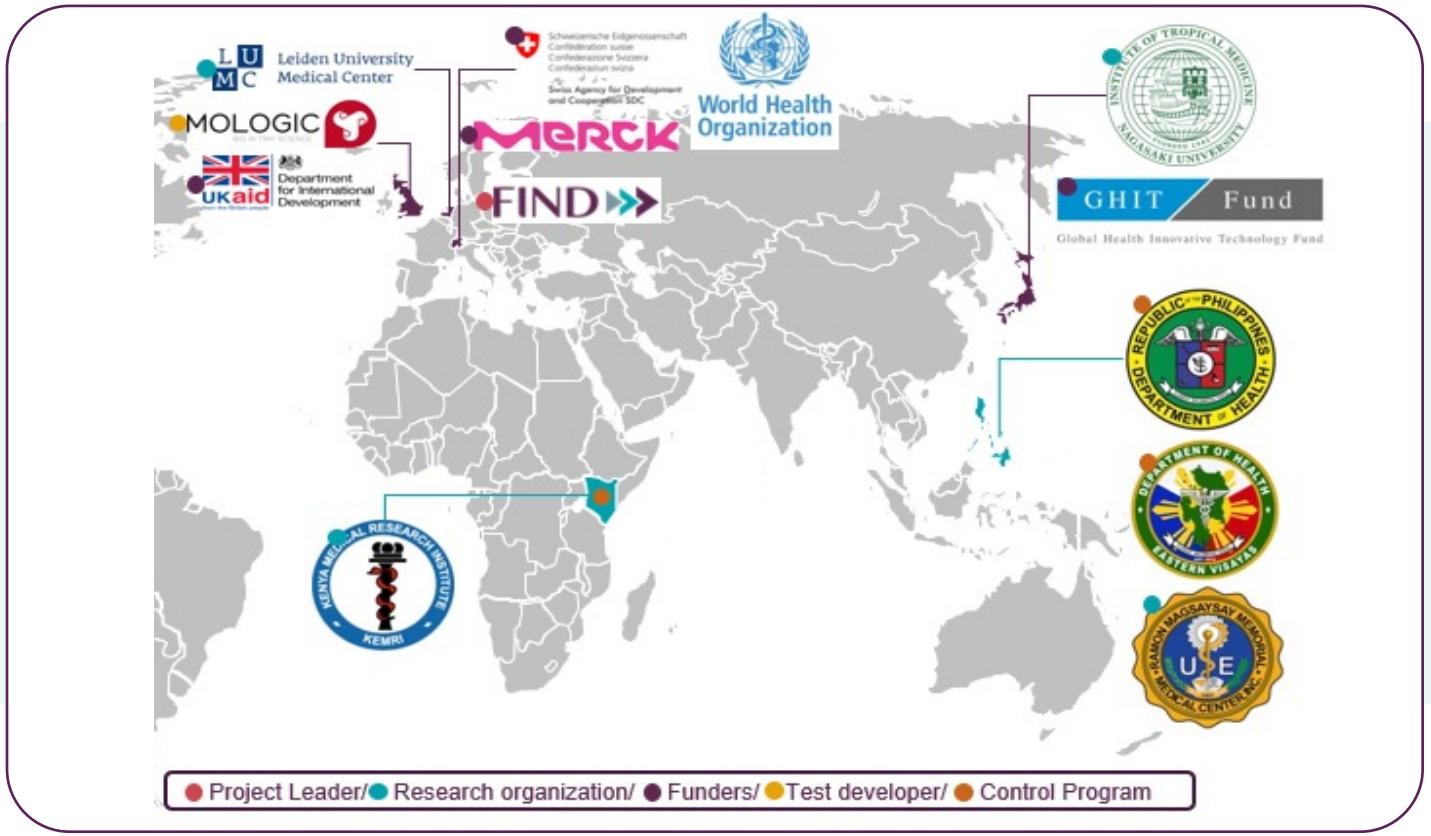


Third generation LAM tests now in development, finally putting accurate, affordable and accessible POC testing for TB within reach

Source: *Broger et al. J Clin Invest 2020; Broger et al, PLOS Med 2020*

JAPANESE COLLABORATION PIVOTAL TO ADVANCING RAPID TESTS THAT WILL SUPPORT SCHISTOSOMIASIS CONTROL & ELIMINATION

SUPPORTING NATIONAL PROGRAMMES TO MONITOR THE IMPACT OF MASS DRUG ADMINISTRATION CAMPAIGNS AND PRECISION MAPPING EFFORTS



GHIT grant approved July 2020

Consortium of 8 partners

In 2021, first field evaluations of prototype in Kenya and the Philippines (led by NUITM) yielded very encouraging results

Further development of the CAA RDT is required to meet the sensitivity targets, with a final field evaluation required prior to design-lock and transfer to manufacturing – planned for Q2/3 2022

FIND in collaboration with GHIT and the Merck Global Health Institute are developing an access strategy for the CAA RDT

Circulating anodic antigens (CAA) are secreted by all species of schistosomes that are of public health importance, making it a particularly suitable target for schistosomiasis diagnostics. A laboratory-based test for CAA is available; however, in order to achieve optimal sensitivity, the test requires complex sample processing steps and a reader for detection. This project aims to bring CAA testing out of the laboratory and into community settings, by developing it into an RDT.

SPOTLIGHT ON BURULI ULCER

GHIT INVESTMENT SUPPORTING DEVELOPMENT OF THE FIRST-EVER RAPID TEST FOR BURULI ULCER

WHO DTAG highlights Buruli ulcer as one of the 4 skin-NTDs that urgently needs new diagnostics to facilitate treatment

Early, accurate diagnosis and treatment can prevent painless infections becoming deep ulcers that lead to permanent disability

With partners we have developed the first-ever RDT for Buruli ulcer, made possible by leveraging two innovations: monoclonal antibodies specific for mycolactone; and magnetic plasmonic nanoparticles

An RDT for Buruli ulcer will be key to:

- Meet the WHO NTD 2030 targets
- Enhance diagnosis at primary health centres and community levels
- Reduce turnaround time for result confirmation (1 hour instead of 1+ weeks)
- Improve early treatment following early confirmation
- Improve treatment monitoring and test of cure

FUTURE OPPORTUNITIES & POTENTIAL COLLABORATIONS

ACCELERATED BY COVID-19 ADVANCES

CAD, artificial intelligence & machine learning

Quality diagnosis in areas without specialist healthcare workers

Mobile devices & connectivity

Reach the hard-to-reach; enable real-time monitoring of health status

Next-generation technologies (genomics, CRISPR)

Sequencing for disease surveillance and rapid response

Wearables & home-use tools

Self-monitoring, early detection and ambulatory management

Manufacturing & tech transfer for LMICs

Build on COVID-19 capacity to enable affordable and accessible tests for NTDs, TB and malaria

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COVID-19 & DIAGNOSTICS

ACT-ACCELERATOR DIAGNOSTICS PILLAR IS

WORKING TO HARNESS INNOVATION, SECURE ACCESS & DEPLOY AFFORDABLE, QUALITY POINT-OF-CARE TESTS

ACTaccelerator
ACCESS TO COVID-19 TOOLS

To break chains of transmission

To enable targeted public health interventions and treatment

To inform epidemiological surveillance

To detect novel variants

Gradual roll-out of vaccines and continued threat of novel variants mean that **widespread, affordable, and accurate testing remains critical to global COVID-19 response**

SPEED OF COVID-19 ANTIGEN RDT INTRODUCTION HAS BEEN UNPRECEDENTED COMPARED WITH ANY OTHER RDT

Dec 2019: Cluster of "pneumonia of unknown cause" identified in Wuhan

Early January 2020: **Genetic sequencing** shared

July 2020: **FIND/Unitaid issue EOI** to bring lower cost Ag RDTs with regionalized manufacturing to LMICs

Mid September 2020: WHO releases **interim guidance** on the use of rapid antigen tests

End September 2020: **WHO issues EUL:** first rapid point-of-care reader-free Ag test[1] **120m volume guarantee** for LMICs announced under ACT-A

October 2020: **Countries start using** rapid antigen tests in healthcare settings and beyond, together with PCR

November 2020: **WHO issues EUL:** first rapid point-of-care reader-free Ag test **with easier sample collection** (nasal)[2]

January 2021: **FIND/Unitaid announce first EOI agreement:** with PMC, bringing Ag RDTs price down to **US$2.50 per test**

Within 6 months of EUL listing: **over 30 million Ag RDTs have been procured** across Dx Supply Consortium partners only[3]

Example: malaria RDT timeline

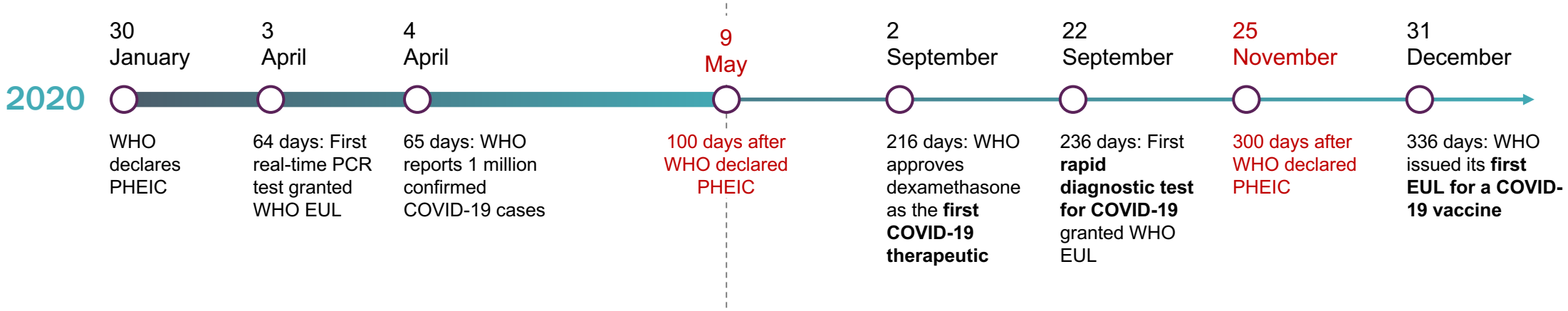
- **Early 1990s** – Emergence of malaria RDTs into largely unregulated markets and with uncertain performance
- **1999** – WHO first meeting on rapid diagnostic testing
- **Early 2000s** – Rapid expansion in number of products
- **2002** – Development of coordinated effort to quality control RDTs pre- & post-purchase
- **2018** – WHO requirement for RDTs to be pre-qualified

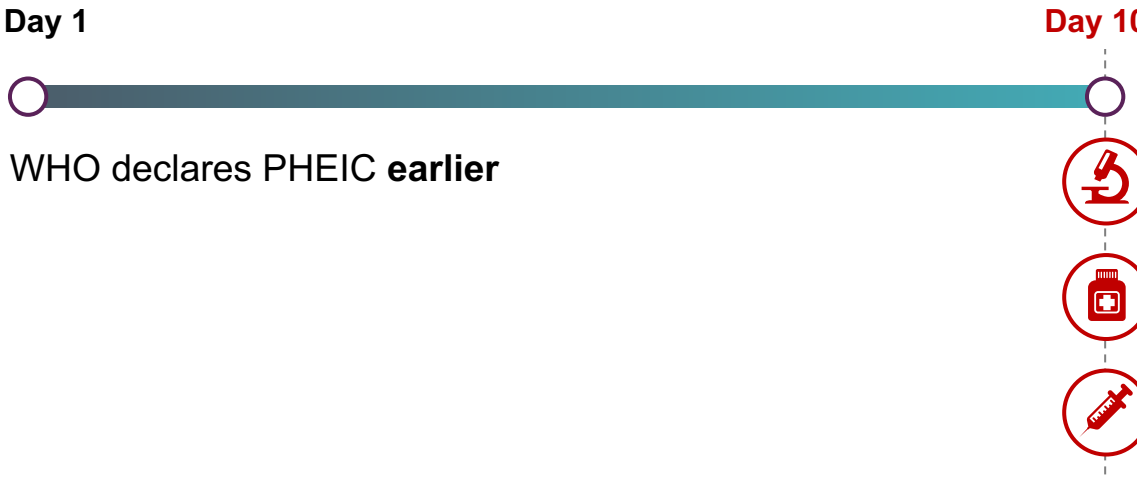
Source: 1. SD Biosensor STANDARD Q COVID-19 Ag Test; 2. Abbott Panbio COVID-19 Ag Rapid Test Device (NASAL); 3. Global Fund, GDF/StopTB, PAHO, UNDP, Unicef, WHO; https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open; Cunningham J, et al. Malar J 2019;18:387. All accessed 15 March 2021

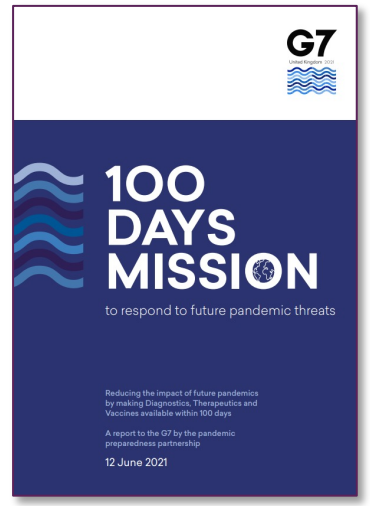
ACT-A, ACT-Accelerator; Ag, antigen; EOI, expression of interest; EUL, emergency use listing; LMIC, low- and middle-income countries; PCR, polymerase chain reaction; PMC, Premier Medical Corporation; RDT, rapid diagnostic test

LESSONS FOR THE FUTURE

CRITICAL NEED FOR A QUICKER RESPONSE







EUL, emergency use listing procedure; PCR, polymerase chain reaction; PHEIC, public health emergency of international concern.

G7 100 Days Mission to respond to future pandemic threats.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/992762/100_Days_Mission_to_respond_to_future_pandemic_threats_3_.pdf

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Together, we can ensure that everyone who needs a test can get one

THANK YOU

..and the many partners and other donors who make the work of FIND possible