Report on the latest breakthrough in the Dx Pillar

Brief to Member States

1st October 2020

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Development of diagnostics for COVID-19 has followed an accelerated timeline

- 31 Dec 2019: Cluster of "pneumonia of unknown cause" identified in Wuhan
- 11 Jan: **Genetic sequencing** shared
- 12 Jan: WHO first teleconference with Dx and lab network
- 13 Jan: WHO first protocol for PCR assay released
- 20 Jan: WHO screened manufacturers to produce requested kits
- 29 Jan: Production for requested kits started
- 2 Feb: **First dispatch of PCR Dx kits** to Regional and Country Offices
- 28 Feb: WHO Emergency Use Listing (EUL) procedure for PCR assays launched
- 3 Mar: Dx Consortium for COVID-19 established
- 15 Apr: First purchase orders under the Dx Consortium issued
- 24 Apr: COVID-19 **ACT Accelerator** launched

To date: **23 million tests procured** across partners (Global Fund, GDF/StopTB, PAHO, UNDP, Unicef, WHO) with **over 18 million in transit or delivered**

Testing is vital to containing the pandemic, but existing barriers mean we cannot reach everyone who needs a test today

Current PCR testing constrained by availability of tests, cost per test, need for lab infrastructure, need for scarce reagents, reliance on nasopharyngeal swabs

Many countries, particularly low- and middle-income countries (LMICs) have **struggled to scale testing and achieve the rapid turnaround times** required for epidemic control or case management

Earlier rapid antigen tests **failed to deliver satisfactory performance** (sensitivity / specificity)

WHO has released new interim guidance on the use of COVID-19 antigen RDTs

"Ag-RDTs that meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to a nucleic acid amplification test (NAAT)... can be used to **diagnose SARS-CoV-2** infection in a range of settings **where NAAT is unavailable or where prolonged turnaround times preclude clinical utility.**

… Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturer's instructions and within **the first 5-7 days following the onset of symptoms."**

Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

Antigen RDT use recommended where PCR is unavailable or where prolonged turnaround times of PCR preclude clinical utility

1. **Respond to suspected outbreaks** in remote settings, institutions and semi closed communities
2. **Support outbreak investigations,** helping to screen at-risk individuals and rapidly isolate positive cases
3. **Monitor trends in disease incidence in communities**, particularly for essential workers and healthcare workers
4. Where there is widespread community transmission, RDTs may be **used for early detection and isolation,** including asymptomatic contacts of cases

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Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

Multiple efforts underway to support Member States in the deployment of antigen RDTs

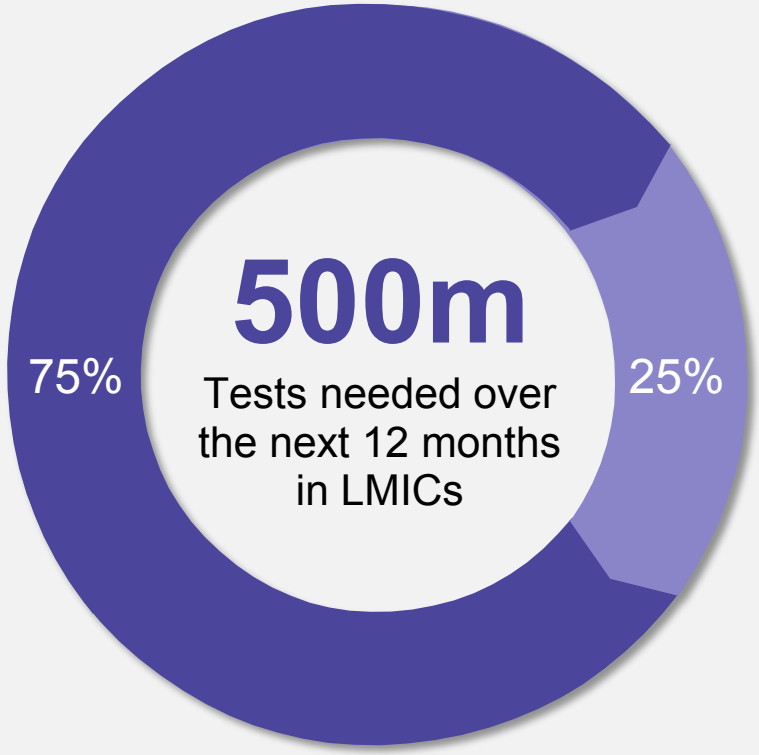
- **Briefings to regional bodies and groups** to raise the profile and urgency of tests deployment
- **Regulatory and registration support** to ensure products reaching market can be used in countries
- **Catalytic funding and country preparedness support** for governments to optimally implement tests and integrate them in health systems to increase uptake
- **Platforms to capture and share implementation data** and on-the-ground experiences to refine use cases

Antigen rapid tests are an easy-to-use, affordable complement to molecular testing

Antigen rapid tests

- ⊕ Rapid turnaround: under 30 min
- ⊖ Lower accuracy
- ⊕ Administered at point-of-care or home settings
- ⊕ Can be scaled with appropriate funding
- ⊕ More affordable

Used for early detection, patient management and surveillance



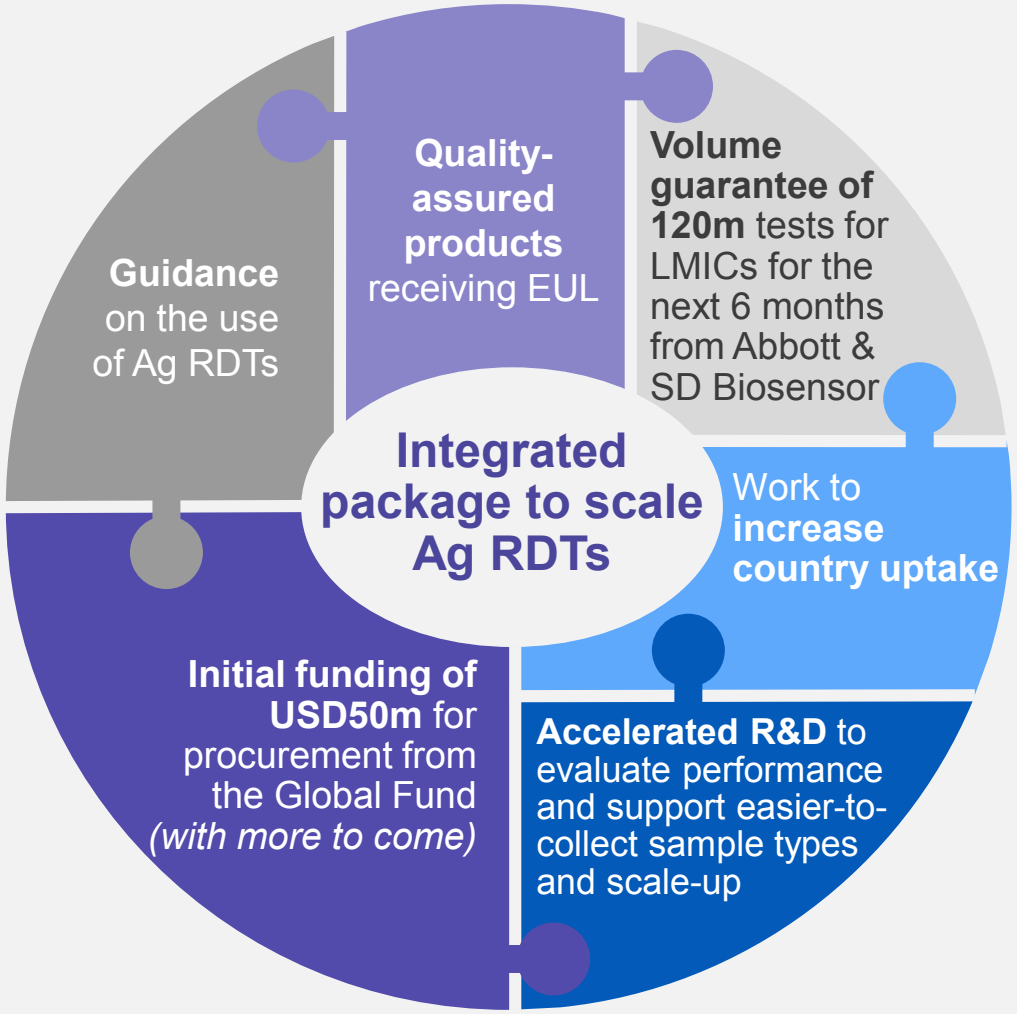
Molecular tests (or PCR)

- ⊖ Slow turnaround: often 48h+
- ⊕ High accuracy
- ⊖ Require labs & trained health workers
- ⊖ Challenging to rapidly scale in LMICs
- ⊖ More expensive

Used for patient management

Note: The estimated test split was informed by the necessary trade-off between testing accuracy, speed to result, ease of use and affordability and was calculated based on four use cases (triage and confirmation of symptomatic severe cases, triage and confirmation of symptomatic mild cases, triage of asymptomatic at risk cases and surveillance of asymptomatic cases). For patient triage, it is assumed that a split of 85% RDT (preferably Ag) and 15% molecular will be used; for surveillance, it is assumed that only antibody RDTs are used; antibody RDTs can be substituted with ELISA.

ACT-A Dx package to launch & scale Ag RDTs is a great win for the wider ACT-A Partnership



Beyond the first rapid antigen test EUL listed and the second expected soon, there is a strong pipeline of new products being developed globally

- Significant innovations on usability, particularly with easier-to-collect sample types and self-collection

- Increased performance of instrument-free tests, with enhanced digital integration of data

- Lower cost products that can be scaled quickly

Reminder: What do we want to deliver by mid-2021?

R&D

- **Target Product Profiles** to guide test development published
- Well-performing **antigen rapid diagnostic tests (RDTs)** & **point-of-care molecular tests** developed
- Non-proprietary **test result reader app and solution for integration** developed

Market Readiness

- Regionalized production incl. in LMICs & mechanism set up to make **RDTs affordable and available**
- **Adapt EUL process for in-vitro diagnostics (IVDs) according to Member State needs**

Supply

- **500m tests** procured

Country Preparedness

- **Country support to implement guidance, studies and training packages to optimize use of tests**
- Country **policies and uptake in integrated testing strategies** driven in 50+ countries
- 10,000 **health care workers** trained; with 5,000 by end 2020

All countries able to deploy **affordable, quality point-of-care tests**

Significant number of LMICs have been supported to put in place **effective test, trace, isolate strategies**

Disruption of **core health services** minimized

$1.7B needed to reach 2020 Dx milestones

	Main milestones by end of 2020	Organization	Total ask *$US million*	Funding gap for 2020 *$US million*
1	Develop 2-3 affordable, well-performing Ag RDTs, leveraging existing regionalized production capacity	FIND / Unitaid	200	162
2	Support development of 1-2 affordable, well-performing point-of-care molecular tests	FIND / BMGF*	90	90
3	Design market interventions to make 3-5 well-performing antibody and antigen RDTs available and affordable ensuring they achieve EUL	WHO / FIND / Unitaid	40	4
4	Develop non-proprietary test result reader app and interoperability solution to integrate with diagnostics	WHO / FIND / BMGF*	30	28
5	Maintain and continue to update open access resources (e.g., biobanking)	FIND	30	21
6	Create mechanism to aggregate demand from 20+ countries	FIND	10	10
7	Procure 85m tests to cover immediate LMICs need; 500m for 12 months	Dx Consortium / Supply Working Group partners	5,000	1,131
8	Strengthen laboratories in 20+ countries	WHO / Global Fund	400	182
9	Conduct operational research, incl. innovative delivery models, to support country policies	WHO / FIND / Unitaid	150	70
10	Train 5,000 Healthcare Workers and lab technicians in 20+ countries	WHO / FIND / Global Fund	50	22
		Total	**6,000**	**1,720**

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1. WHO, Global Fund, CHAI, UNICEF, Unitaid, BMGF, World Bank, Africa Union, WFP, UN bodies, FIND, amongst others.

* BMGF is conducting self-funded activities to accelerate the development of POC molecular tests and to integrate digital solutions in diagnostics.

In summary

- More and better testing is vital to fighting COVID-19 – both ***before*** we have effective therapeutics and vaccines, and ***when*** we have them
- Availability of high-performing rapid antigen tests to complement PCR tests is a significant milestone
- ACT-A Dx is supporting the rapid deployment of high-performing rapid antigen tests in LMICs with a comprehensive package, including guidance, volume guarantees, initial procurement funding, capacity building and training
- For ACT-A Dx to fulfil its mission, continuing to accelerate the development of diagnostic tools and ensuring they are made accessible to all, including by providing 500 million tests for LMICs by June 2021, $6 billion is required

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Appendix

In addition to the Ag RDTs package, what else have we achieved since launch?

1. Procured 19m molecular tests and 8m sample collection kits
2. Refreshed product pipeline for molecular tests and landscape on sample collection
3. Kicked-off work for the development of a non-proprietary digital solution
4. Refined modelling of health and economic impact of diagnostics
5. Developed map of partners in-country implementation activities across regions
6. Provided online training to 18,000+ participants including health and social care workers across 100+ countries

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Note: data as of 23 September 2020