



ACT Accelerator Diagnostics Pillar

Member State Briefing

17 June 2021

#UnitedAgainstCoronavirus

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Multi-faceted approach by ACT-A Dx working groups has contributed to declining prices of dx tools

R&D Investments

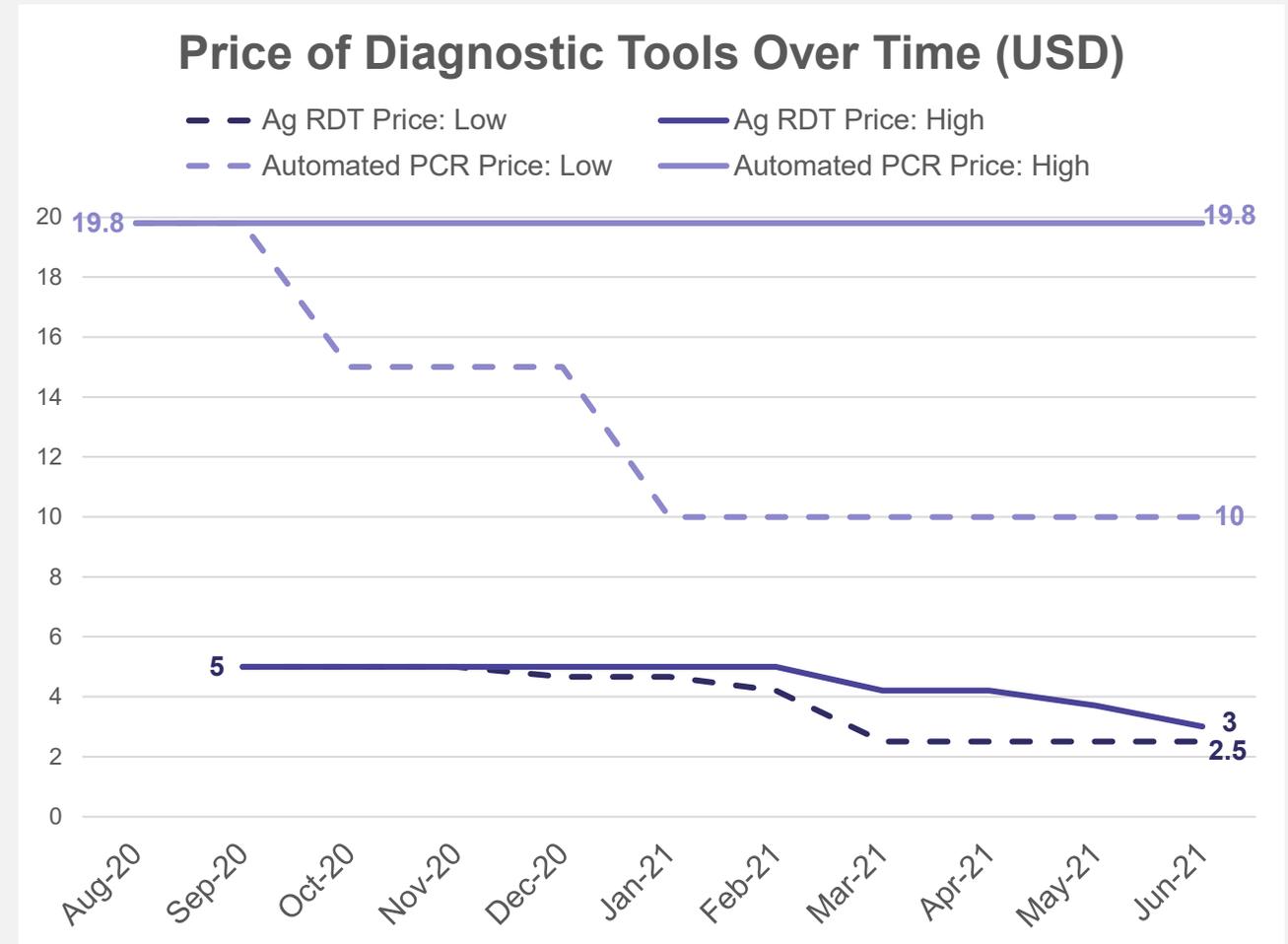
- Encouraging and guiding rapid development of Ag RDTs
- Investments in local manufacturing and increased efficiency to scale capacity

Market Shaping Interventions

- Coordinate negotiations across procurement organizations
- Invest in key suppliers and provide support for regulatory processes
- Increase number of high-quality suppliers in the market

Policy guidance and development

- Support to generate new policy guidance and rapid uptake of products to ensure adequate pull in the market



Source: Diagnostics Consortium for COVID data as May 31, 2021, Manufacturer pricing

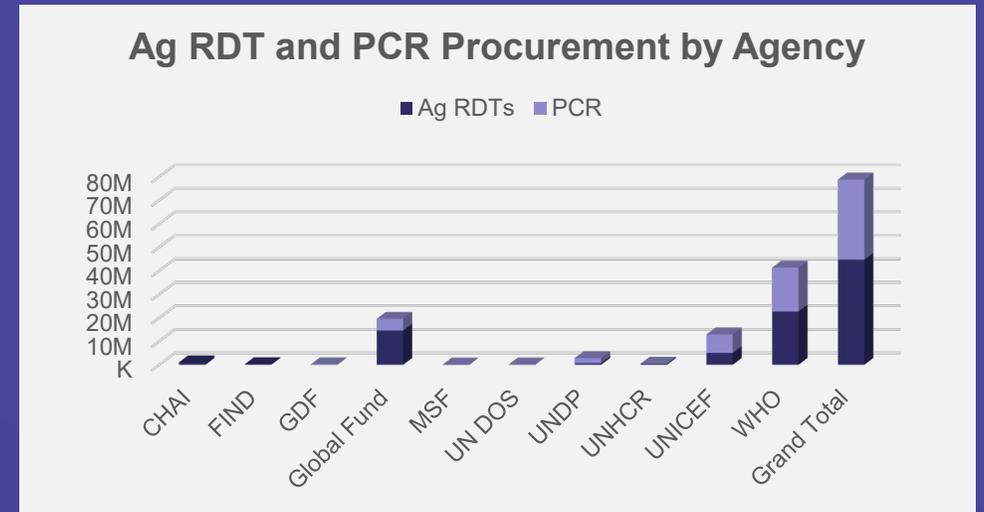
Dx Consortium supported procurement of over 80M tests to date¹...

Diagnostics Consortium for COVID has supported access to 80M diagnostic products across 175 countries and 6 regions to date

Globally, 36M molecular tests procured to date, with an additional demand of 2M reported..

...44.5M Ag RDT tests procured to date, with an additional 20.5M of demand reported

...opportunity to increase volumes with additional support



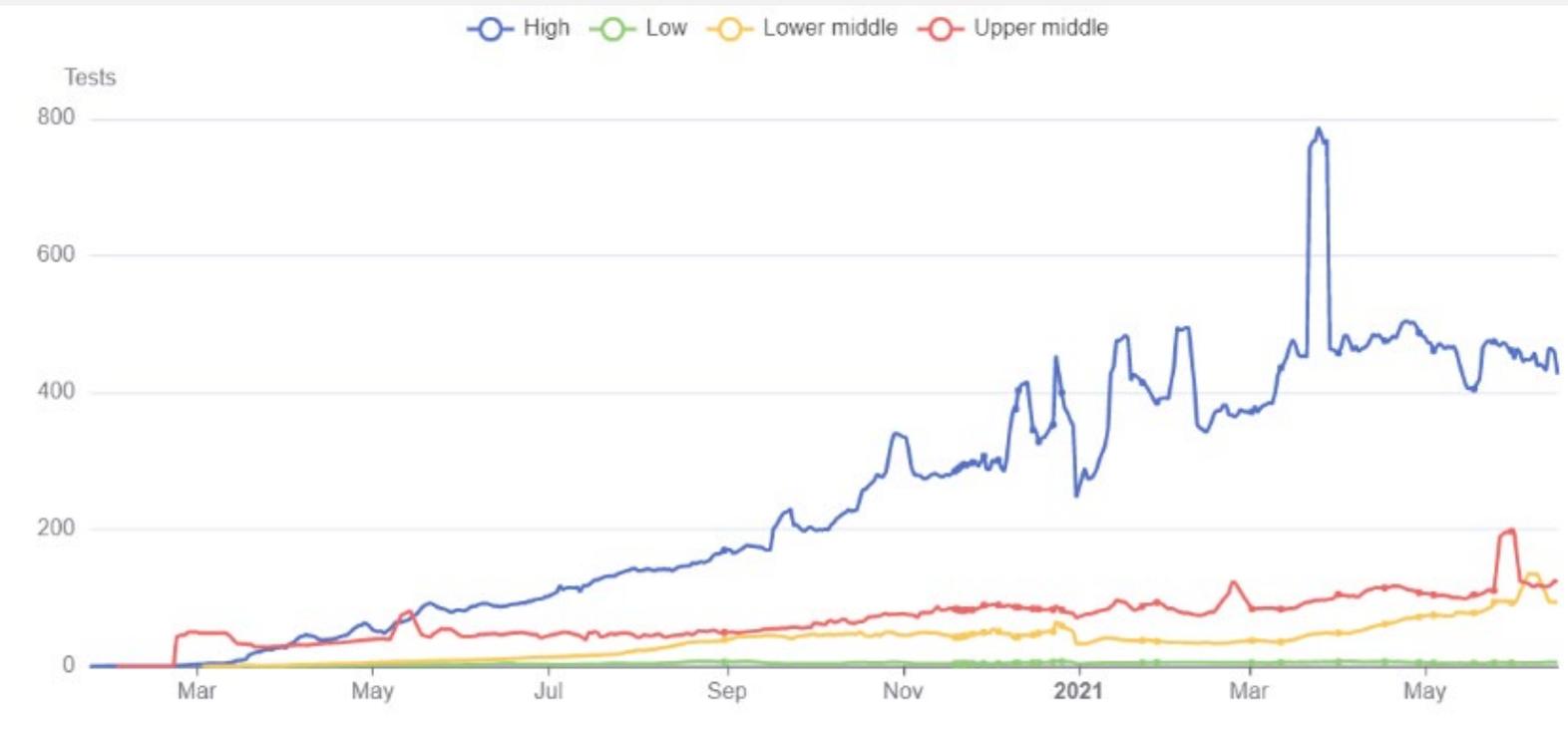
Source: Diagnostics Consortium for COVID data as 15 June 2021

Diagnostics Consortium for COVID

BMGF, CDC, CHAI, FIND, Global Fund, GDF, MSF, PAHO, UN-DOS, UNDP, UNHCR, UNICEF, Unitaid, USAID, WHO

Despite significant progress, equity gap remains

Daily tests/ 100k population by country income group¹



1. Due to data inconsistencies, we show a moving 7-day average.
2. Most recent rolling 7-day averages per 100,000 population. Source: FIND test tracker (as of 16 June 2021)

LMICs still testing at a fraction of HICs

Daily tests/ 100k population²

~x3 to x77 lower depending on income group



LICs, LMICs, UMICs (excl. China)

HICs

Efforts to understand and support member states needs expanded



Forums to understand needs and enable knowledge sharing and training:

- WHO Public Health Labs knowledge sharing webinars
- Country and regional roundtables
- Regional workshops for digital tools



WHO EUL and novel international standards:

- Ag RDTs and PoC NAT prioritized for WHO EUL
- WHO facilitated procedure introduced for streamlining in-country authorization/registration
- Development of 1st international standards for antigen tests



Practical support for capability building:

- Training & TA efforts
- Revised Essential Supplies Forecasting Tool to enable planning
- Prioritized efforts to enhance genomic surveillance and sequencing capabilities
- WHO External Quality Assessment: 3,300 panels distributed to 1809 laboratories from 101 countries



Guidance and evidence generation to support decision-making:

- Refreshed policy guidance for Ag RDTs
- Operational guidance and country checklist for RDTs



Expanded access to resources:

- Catalytic procurement to 175 countries
- Expanded access to funding through ACT-A fundraising efforts, including Global Fund's C-19RM

Regional forums to understand country needs and enable knowledge sharing



WHO Public Health Labs knowledge sharing webinar series

- Share individual countries experiences, lessons learnt and best practices
- Provide an additional forum to disseminate the latest WHO guidance



ACT-A Dx Country & Regional Roundtables

- Share relevant updates of what support ACT-A is offering to countries and how to access support
- Provide a listening forum for ACT-A to get feedback/input from countries on support needed, questions, challenges they are facing



ACT-A Regional Workshops on Digital Tools Matchmaking

- Support countries in the selection, implementation, and scale up of digital tools within their COVID-19 response by sharing knowledge and guiding development of an implementation plan.
- Provide a forum for countries to share best practices, challenges, and support needed for digital tools uptake and implementation.

WHO EUL pipeline for IVDs



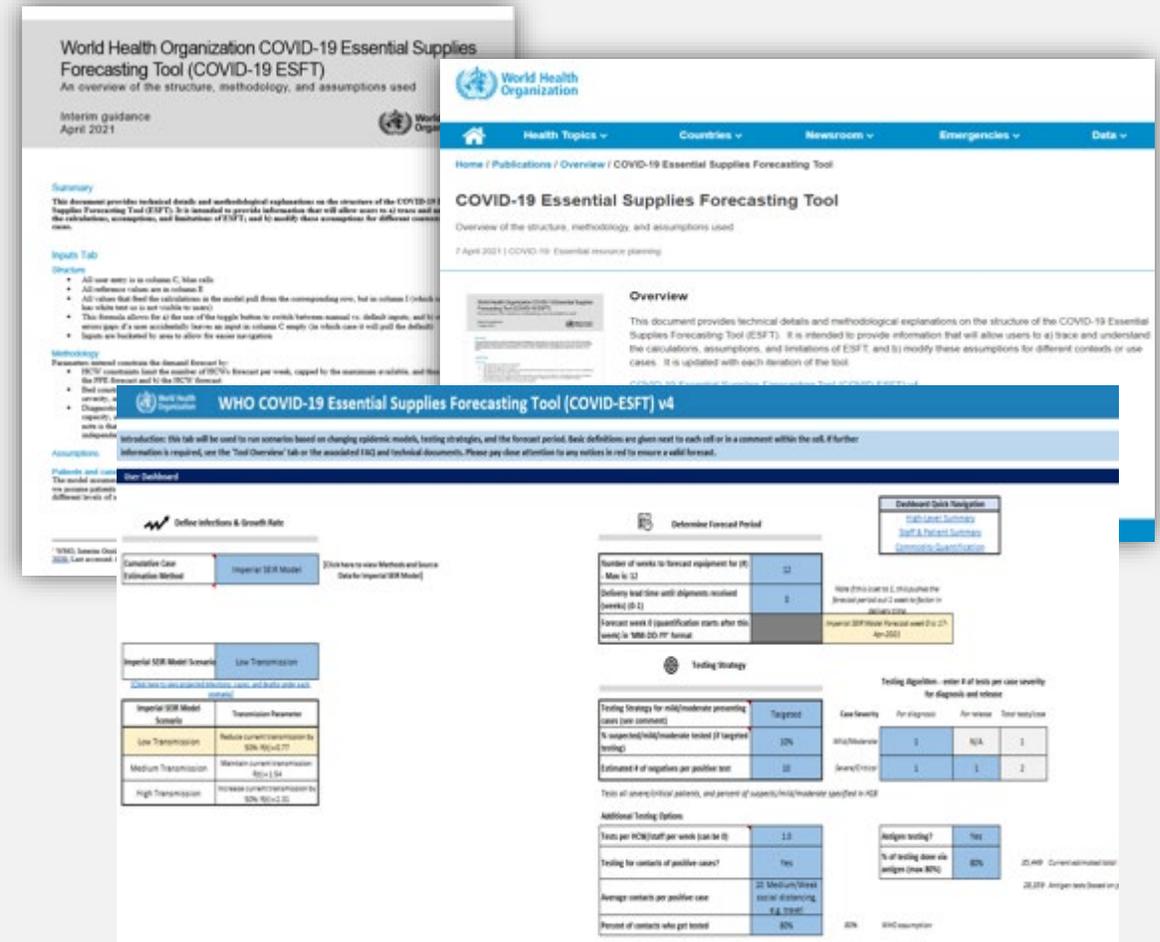
	Total	Test types		
		Nucleic acid	Antibodies	Antigen
Pre-submission interest	>200	<i>(split not available)</i>		
EOIs	145	64	41	40
Under assessment	71	17	28	26
EUL listed	28	23	1	4
EUL not accepted	40	24	9	7

WHO's Essential Supplies Forecasting Tool, version 4 (ESFT v4) can support country procurement planning & needs

- The WHO COVID-19 Essential Supplies Forecasting Tool (ESFT) assists governments, partners, and other stakeholders to forecast the necessary volume of:
 - personal protective equipment,
 - diagnostic equipment,
 - consumable medical supplies,
 - biomedical equipment for case management,
 - essential drugs for supportive care and treatment of COVID-19.

- The tool provides the user with a choice among several epidemiological methods for forecasting COVID-19 cases.

- Version 4 offers several updates, including:
 - inclusion of a new pharmaceutical's module including corticosteroids and anticoagulants,
 - inclusion of antigen rapid diagnostic tests,
 - and a new case forecasting option using data from Imperial College
- A separate dashboard updated bi-weekly sharing aggregate forecast of the potential global demand over a 12-week period



WHO COVID-19 Essential Supplies Forecasting Tool (COVID-ESFT) v4

Defence Forecast Period

Number of weeks to forecast equipment for (E)	12
Defence lead time until shipments received (week) (D-L)	0
Forecast week 0 (quantification starts after this week) in WHO DD FY Annual	2020

Testing Strategy

Testing Strategy for mild/moderate presenting cases (per country)	Targeted	Case severity	For diagnosis	For release	Total tests/case
% symptomatic/mild/moderate tested (if targeted testing)	33%	Mild/Moderate	1	N/A	1
Estimated # of swabs per positive case	10	(Severe/Critical)	1	1	2

To meet the challenge of new variants, ACT-A Dx is prioritizing sequencing and surveillance



Launched in April 2021, the **ACT-A Dx Genomic Surveillance working group** is co-led by the WHO and the Rockefeller Foundation and focused on improving genomic surveillance to better control this pandemic and future major events.

Country / regional objectives

- Sequencing and bioinformatics **capacity strengthening**
- Leveraging NGS capacity map to **identify gaps; tailor interventions** in priority countries

Global objectives

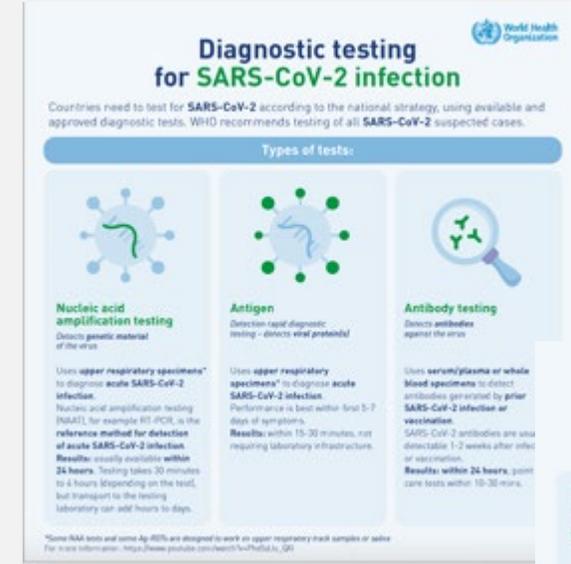
- Availability of **integrated bioinformatics**; data systems and tools
- **R&D/ innovation** for rapid and automated data analysis and sharing
- **Market shaping and supply chain** management interventions

Updates in progress from WHO on technical and operational guidance on Ag RDTs

Interim guidance: Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays
WHO (currently under revision)

SARS-CoV-2 Antigen Rapid Detection Rapid Diagnostic Testing - Training package
WHO-FIND

SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide, including readiness checklist
WHO/FIND



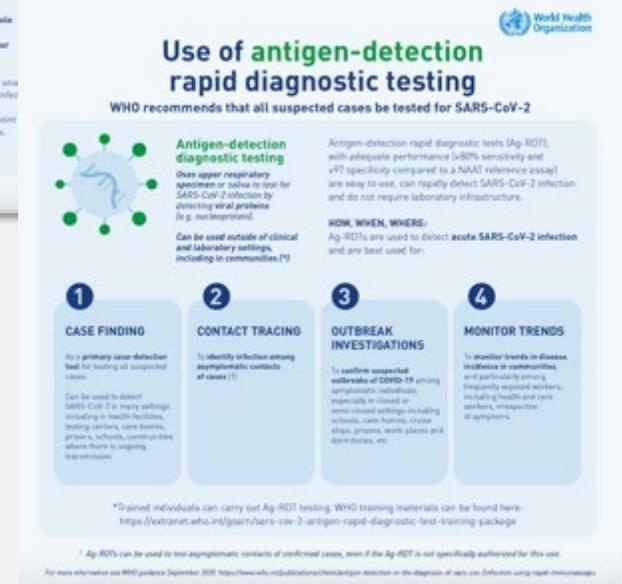
Diagnostic testing for SARS-CoV-2 infection

Countries need to test for SARS-CoV-2 according to the national strategy, using available and approved diagnostic tests. WHO recommends testing of all SARS-CoV-2 suspected cases.

Types of tests:

- Nucleic acid amplification testing**
Detects genetic material of the virus.
Uses upper respiratory specimens* to diagnose acute SARS-CoV-2 infection. Nucleic acid amplification testing (NAAT), for example RT-PCR, is the reference method for detection of acute SARS-CoV-2 infection. Results: usually available within 24 hours. Testing takes 20 minutes to 4 hours (depending on the test), but transport to the testing laboratory can add hours to days.
- Antigen**
Detection rapid diagnostic testing - detects viral proteins.
Uses upper respiratory specimens* to diagnose acute SARS-CoV-2 infection. Performance is best within first 5-7 days of symptoms. Results: within 15-30 minutes, not requiring laboratory infrastructure.
- Antibody testing**
Detects antibodies against the virus.
Uses serum/plasma or whole blood specimens to detect antibodies generated by prior SARS-CoV-2 infection or vaccination. SARS-CoV-2 antibodies are only detectable 1-2 weeks after onset of infection. Results: within 24 hours; point care tests within 10-30 mins.

*Some NAAT tests and some Ag-RDTs are designed to work on upper respiratory tract samples or saliva. For more information: <https://www.who.int/news/item/14-05-2020>



Use of antigen-detection rapid diagnostic testing

WHO recommends that all suspected cases be tested for SARS-CoV-2

Antigen-detection rapid diagnostic tests (Ag-RDT), with adequate performance (≥80% sensitivity and ≥97% specificity compared to a NAAT reference assay) are easy to use, can rapidly detect SARS-CoV-2 infection and do not require laboratory infrastructure.

HOW, WHEN, WHERE:
Ag-RDTs are used to detect acute SARS-CoV-2 infection and are best used for:

- 1 CASE FINDING**
As a primary case-detection tool for testing all suspected cases.
Can be used to detect SARS-CoV-2 in many settings including in health facilities, testing centers, care homes, prisons, schools, community centers where there is ongoing transmission.
- 2 CONTACT TRACING**
To identify infection among asymptomatic contacts of cases (1).
- 3 OUTBREAK INVESTIGATIONS**
To perform targeted outbreaks of COVID-19 among symptomatic individuals, especially in closed or semi-closed settings including schools, care homes, prisons, ships, prisons, work places and dormitories, etc.
- 4 MONITOR TRENDS**
To monitor trends in disease incidence in communities, or if particularly among frequently exposed workers, including healthcare care workers, irrespective of symptoms.

*Trained individuals can carry out Ag-RDT testing. WHO training materials can be found here: <https://extranet.who.int/gpam/sars-cov-2-antigen-rapid-diagnostic-test-training-package>

* Ag-RDTs can be used to test asymptomatic contacts of confirmed cases, even if the Ag-RDT is not specifically authorized for this use. For more information see WHO guidance September 2020: <https://www.who.int/docs/default-source/coronavirus/updates-on-diagnosis-of-sars-cov-2-infection-using-rapid-immunoassays.pdf>

C19RM Status of Awards Submissions and Pipeline



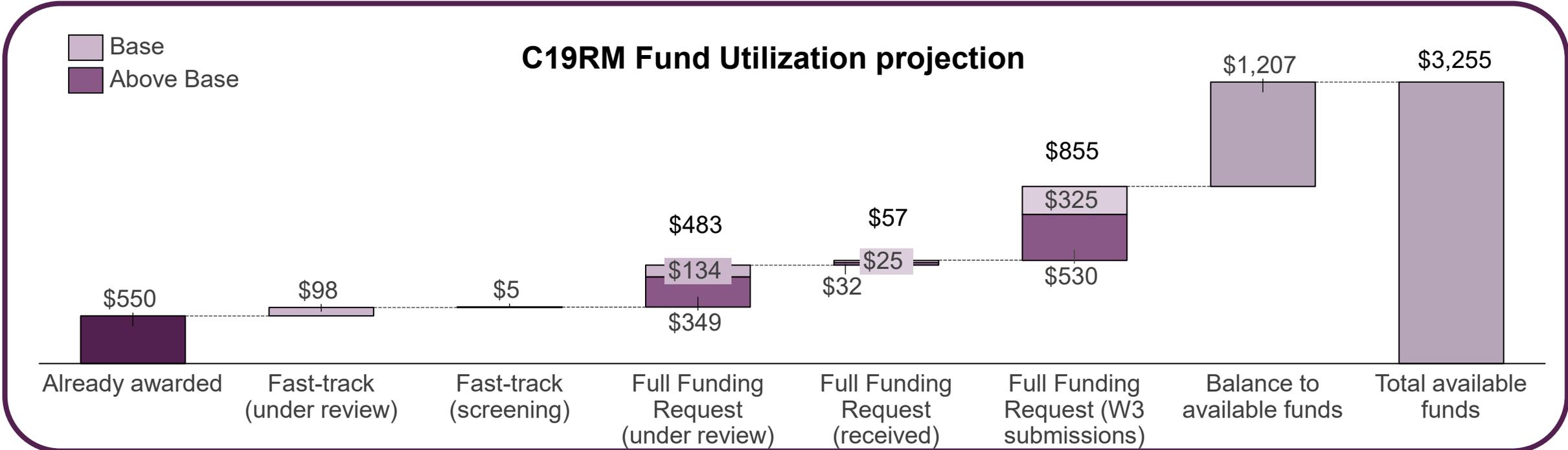
17% or US\$550 million of C19RM 2021 funding is awarded to 27 countries and 1 multicountry for a portfolio average of 8.3% of HTM allocation.

US \$134 million was awarded for 2 Full Funding requests (1 is pending board approval before its confirmed).

US \$416 million was awarded via Fast-track Funding Requests.

In addition, **20% or US\$643 million is submitted or under review** for potential C19RM 2021 funding (**US\$103 million** under Fast-track; **US\$159 million Base** and **US\$381 million Above Base** under Full Funding Request).

In addition, for Window 3 we have just received 24 funding requests for **US\$325 million Base** and **US\$530 million Above Base**. This means that over US\$1.5 billion is currently in the pipeline.



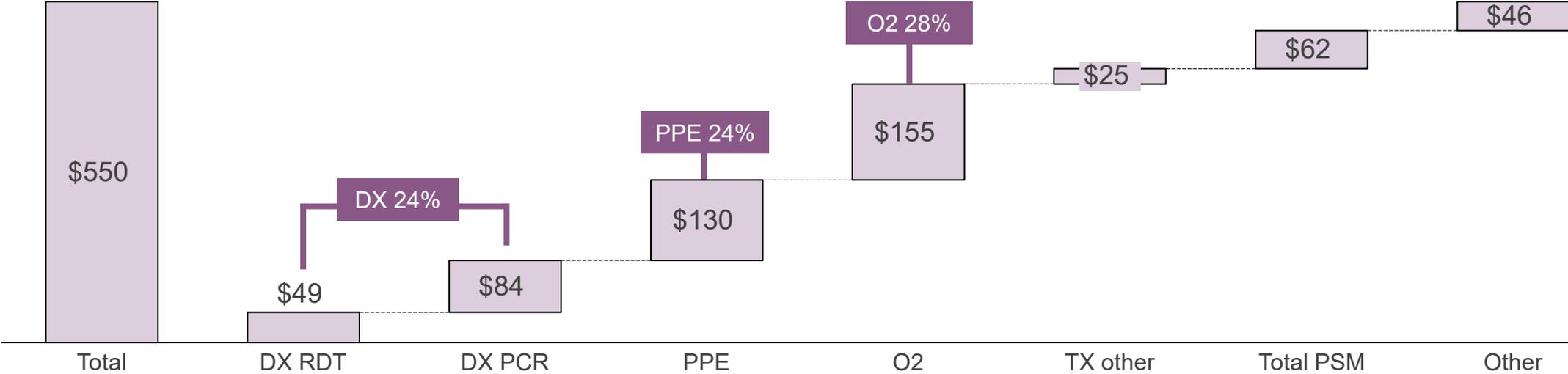
All values in the charts are in US\$ million and rounded

C19RM Award by Health Products



Health product investments are more equally balanced across the key Health Products
Over **50%** of awards to date are expected to come via Wambo.

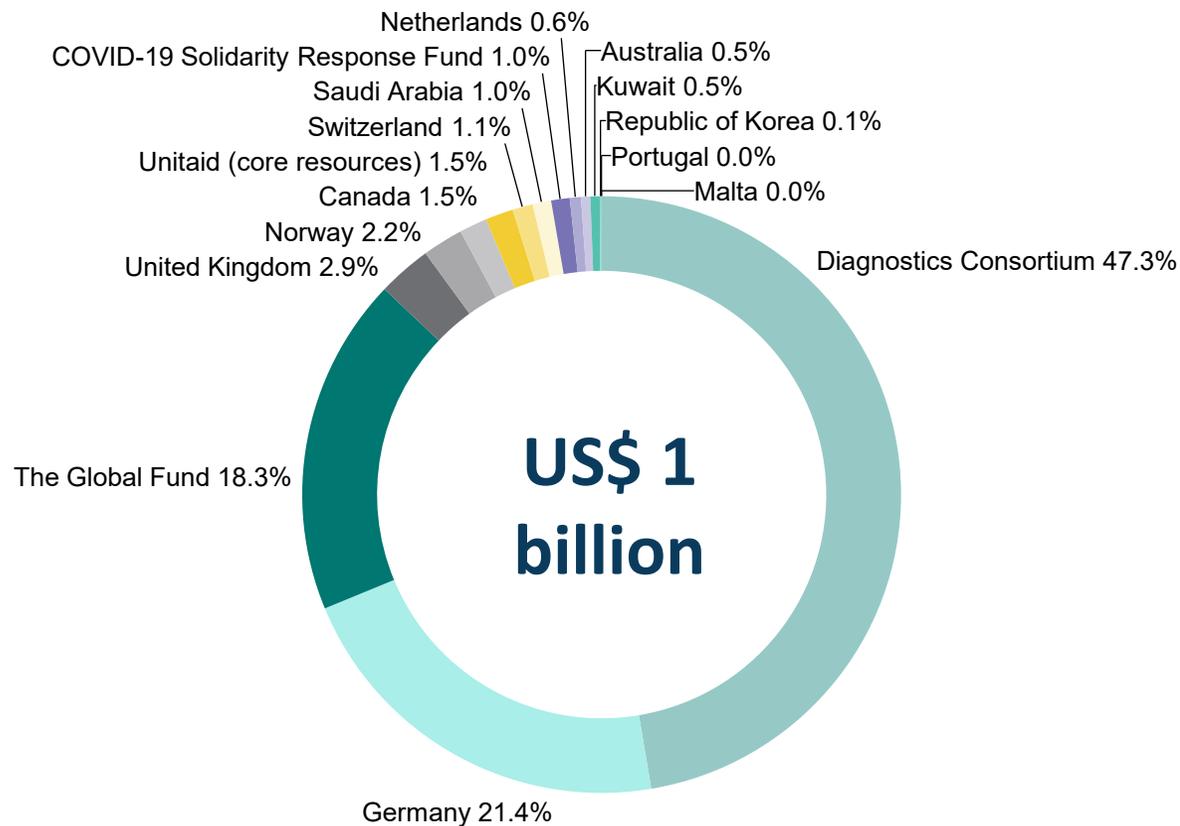
C19RM Awards by type



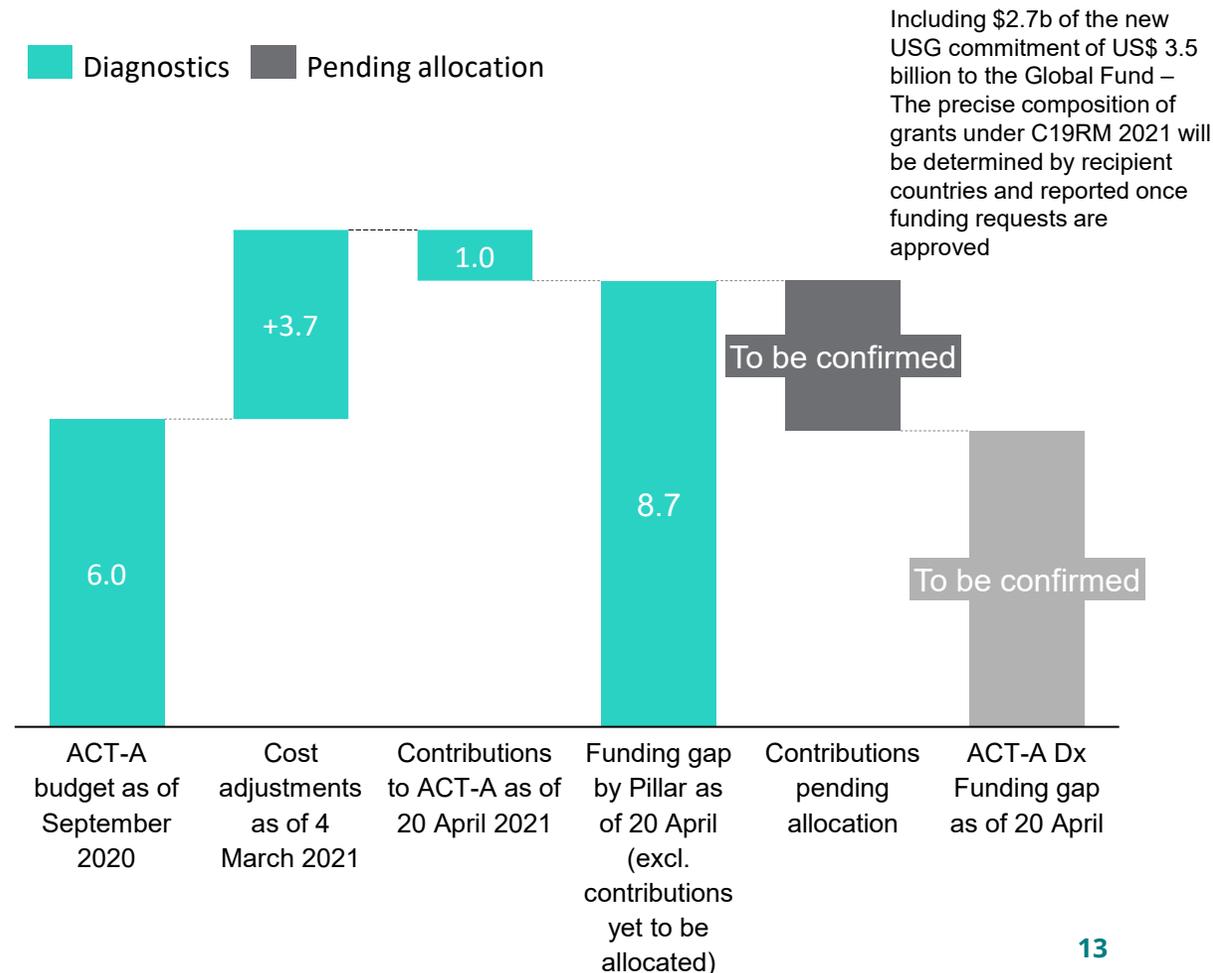
* All values in the charts are in US\$ million and rounded

US\$1 BILLION FUNDED FOR DX PILLAR SO FAR, BRINGING THE FUNDING GAP TO US\$ 8.7 BILLION FOR 2021

ACT-A Dx contributors as of 20 April 2021

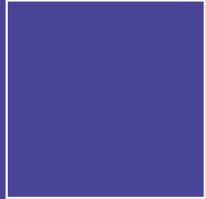


ACT-A Dx funding gap for 2021 as of 20 April 2021





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Appendix: EUL facilitated procedure and IS for Ag RDTs

WHO EUL facilitated procedure



New risk-based approach mechanism for WHO EUL in vitro diagnostics similar to the WHO Collaborative Registration Procedure (CRP) - i.e., *Participants, sameness of product and confidentiality of information*

Aim: to provide a convenient means for NRAs wishing to enhance listing/authorization of IVDs by taking advantage of WHO EUL assessment outcome



Differences with CRP:

Information to be shared with the NRAs; under the EUL-FP the **dossier and QMS (desk review) assessment reports are shared**

Timelines are shortened i.e., **5 days instead of 30 days for sharing reports and 15 days of regulatory decision instead of 90 days**

Scope of products: **limited to SARS-CoV2 IVDs**

Roll out from 15 June 2021: Information to the Regional Advisors was shared on 31 May 2021 for wider dissemination to key stakeholders, webinar for manufacturers was conducted on 1 June and webinar for NRAs is planned on 15 June 2021.

Developing 1st international standards for SARS-CoV-2 Antigen Tests



Background

- More than **200 SARS-CoV-2 Ag tests commercially available** or in development¹.
- More than **100 regulatory approved** SARS-CoV-2 Ag tests worldwide



Intended use of the IS

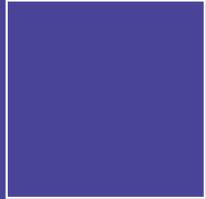
- **Comparative evaluation** of SARS-CoV-2 antigen tests
- **Evaluation of analytical sensitivity** (determining LOD in IU)
- **Calibration of secondary references** for SARS-CoV-2 antigen
- **Other regulatory and QA activities** (post-market surveillance, EQA)



Project timelines

- **Proposal endorsed by ECBS in Dec 2020**
- Sourcing and characterizing materials during Jan-Apr 2021
- Feasibility study evaluating different SARS-CoV-2 antigen preparations as potential candidates: Apr-Jun 2021
- **Interim working standard available** (via NIBSC catalogue): **July/Aug 2021**
- Main collaborative **study to evaluate candidate IS in Q4 2021**
- **Final report submitted to ECBS in Q4 2021** for establishment of the IS

¹ Source: FIND SARS-CoV-2 Diagnostic Pipeline: <https://www.finddx.org/covid-19/pipeline>



Appendix: ACT-A Dx Pillar priorities for 2021

ACT-A Dx refreshed priorities and goals for 2021

Dx Pillar Priorities

Objectives & deliverables (Jan 2021)

1	Secure equitable access to tests	Procure and deploy 900 M tests , including molecular tests, AgRDTs, and expansion of sequencing capabilities
2	Stimulate rapid & effective country uptake	Deploy novel products, generate operational research, and support testing strategies Strengthen testing infrastructure and sequencing capacity Build capabilities and provide technical assistance and training for healthcare and community workers
3	Drive development and at-scale availability of affordable, digitally-integrated tests	Support market entry , product registration, and EUL process Develop 2 rapid, \$1 tests for professional and self-testing , including expanded use settings Develop multi-pathogen platforms and sequencing solutions to detect novel variants Develop non-proprietary test reader app and interoperability solution Establish buyers' consortium and distribution network