FIND

RAPID DEVELOPMENT OF RELIABLE DIAGNOSTICS FOR EMERGING INFECTIOUS DISEASES

Lessons learned from COVID-19

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FIND, THE GLOBAL ALLIANCE FOR DIAGNOSTICS

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 trials
- Governance: Board of Directors & Scientific Advisory Committee

2021 STRATEGY: EXPECTED IMPACT

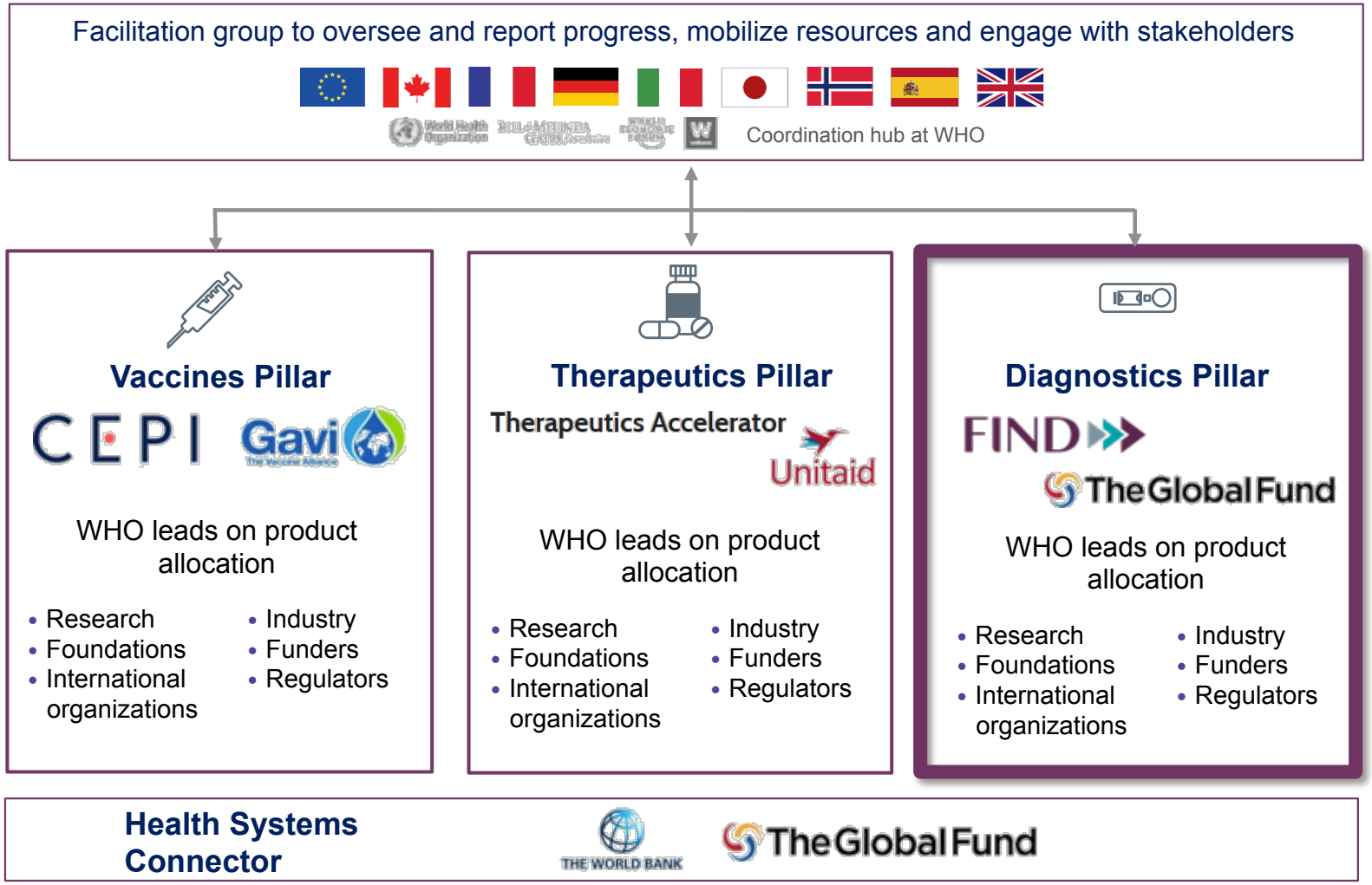
Save 1 million lives
through accessible, quality diagnosis

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

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

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

ACTaccelerator
ACCESS TO COVID-19 TOOLS



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DIAGNOSTICS FOR OUTBREAK-PRONE DISEASES

MANY SHARED CHALLENGES

WHO R&D BLUEPRINT PATHOGENS

Critical/important gaps across all, except for the three pathogens with recent high-profile outbreaks (Ebola, SARS, Zika, and now COVID-19) in which international focus/funding led to prioritized development of validated diagnostics

Overall, lack of focused support for research and development (R&D) in the absence of an event, prevents rapid detection of outbreaks, leading to increased loss of life and donor expenditure and the absence of sustainable diagnostic solutions

WHO Blueprint priority disease	Fatality rate	Recent outbreaks	Diagnostic need (red = critical, amber = important; green = remaining)	Diagnostic situation overview
CCHF	10–40%	Pakistan, 2010		• No established reference test • Very limited availability of commercial assays, with very low usage and limited performance data • No WHO prequalified diagnostic test
Filoviruses (Ebola and Marburg)	24–90%	West Africa, 2013–2016 and Democratic Republic of the Congo, 2017 & 2018 (Ebola); Uganda and Kenya, 2017 (Marburg)		• Recent high-profile outbreaks resulted in international focus and funding, which has enabled the development and introduction of critical diagnostics • Additional work is needed to improve current diagnostics, develop POC tests and ensure reliable availability • Additional work is also needed to ensure regulatory approval beyond WHO EUAL
Lassa fever	1–15%	Annual recurring outbreaks in West Africa		• No WHO-approved diagnostics and limited commercially available tests, none of which are easily deployable in the settings needed
MERS-CoV	~35%	Kingdom of Saudi Arabia, 2013–2018; South Korea, 2015		• Limited availability of validated assays, restricted to highly complex tests • Lack of POC diagnostics
SARS	~10%	Global, 2003		• Recent high-profile outbreaks resulted in international focus and funding, which has enabled the development and introduction of critical diagnostics • Additional work is needed to improve current diagnostics, develop POC tests and ensure reliable availability
Nipah and henipaviral diseases	~30%	Bangladesh, 2004		• No WHO-approved diagnostics and limited commercially available tests, none of which are easily deployable in the settings needed
Rift Valley fever	<1%	Republic of Niger, 2016		• No WHO-approved diagnostics and limited commercially available tests, none of which are easily deployable in the settings needed
Zika virus disease	Not fatal	South and North America, 2015–2016		• Recent high-profile outbreaks resulted in international focus and funding, which has enabled the development and introduction of critical diagnostics • Additional work is needed to improve current diagnostics, develop POC tests and ensure reliable availability • Additional work is also needed to ensure regulatory approval beyond WHO EUAL
Disease X	Not yet known			• Need for diagnostic platforms that can rapidly adapt and support diagnostics for unknown pathogens

Source: Kelly-Cirino et al. https://gh.bmj.com/content/4/Suppl_2/e001179

COVID-19 has placed
testing in the spotlight

> “Test, test, test” — **Tedros Adhanom Ghebreyesus,** WHO

> “If we ask ourselves what has benefited us in this first phase of the spread of the virus, it is our high-test capacities, and the dense laboratory network” — **Angela Merkel,** Germany

> “If you don’t test, you won’t find” — **John Nkengasong,** Africa CDC

SUPPORTING CONTAINMENT IN A PANDEMIC

SARS-COV-2 TESTING PORTFOLIO

	Clinical diagnosis	Vaccine efficacy / seroprevalence	Surveillance
	Lab-based molecular testing	Lab-based antibody testing (ELISA, automated IA)	Sequencing Lab-based SNP detection
	Decentralized molecular testing platforms	Decentralized immunoassay platforms	
	Antigen rapid diagnostic tests (RDTs)	Antibody RDTs	

Improved access

Improved performance

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 2021: **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

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
Source: WHO EUL, Malaria Journal (all accessed 15 March 2021)

COMPRESSED TIMELINES FOR
FOR ALL TEST TYPES

PCR kits (lab-developed and commercial)

- **February 2020:** LDTs available
- **29 February:** first IVD test (CDC) obtained FDA EUA; 9 total with FDA EUA by end of April 2020
- **3 April 2020:** first WHO EUL test listed (Roche); 12 total by end of June 2020

Antibody tests

- **16 March 2020:** FDA published guidance permitting developers to market their tests without an EUA provided the test was validated, FDA was notified, and test reports included information about limitations; policy reversed on 4 May 2020
- **15 April 2020:** first lab-based test (ELISA) obtained FDA EUA
- **1 April 2020:** first RDT obtained FDA EUA

Point-of-care molecular tests

- **20 March 2020:** first test obtained FDA EUA (Cepheid Xpert), followed by 27 March 2020 (Abbott ID Now)
- **23 June 2020:** first WHO EUL test listed (Cepheid Xpert)

MOLECULAR TESTS FOR SARS-COV-2

Three main categories of molecular test for SARS-CoV-2; all are performed in labs and rely on sample collection/transport/result return systems to ensure decentralized access to testing

	Lab-developed tests (LDT)	Open, manual kits	Closed, proprietary tests & platforms
Test format and quality	• Lab develops their own testing protocol sourcing basic ingredients separately • Lab is responsible for verifying the accuracy of the test and ensuring consistent quality of testing	• Commercial company supplies a kit with all the basic ingredients and is responsible for ensuring their quality • Lab is responsible for ensuring consistent testing quality	• Commercial company supplies a test where all the basic ingredients are already combined, ensures accuracy and quality of the test and has built-in QC to enable monitoring of consistent test quality
Sample type & extraction	• Viral RNA has to be extracted separately then added to PCR test	• Viral RNA has to be extracted separately then added to PCR test	• Usually, extraction and PCR reaction are all integrated
Time to result	• Minimum 3–5 hours	• Minimum 3–5 hours	• Minimum 1 hour
Pros	• Usually the fastest to develop in a more experienced lab • Not reliant on a particular test supplier	• Compatible with a range of lab equipment • Can leverage existing personnel and infrastructure familiar with PCR	• Enables more automation ranging from high-throughput centralized testing to lower-throughput more decentralized testing; can leverage existing install-base and trained personnel, if available • More built-in QC, therefore higher confidence in quality of results
Cons	• Requires separate nucleic acid extraction • More prone to variability and requires QC and QA of test reagents and end-users	• Requires separate nucleic acid extraction • Requires well-trained staff and frequent proficiency testing to ensure quality	• Requires procurement of new machinery if no existing install-base or new space capacity
Example	• Charité protocol, CDC protocol	• TIB Molbio, Altona	• GeneXpert, Abbott ID Now, Molbio

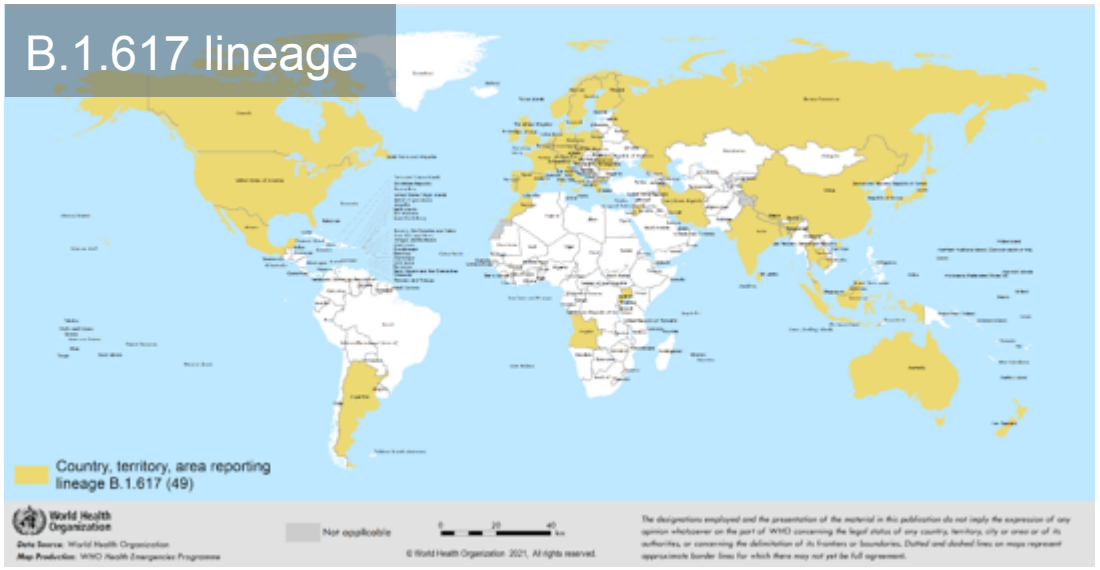
ANTIGEN AND ANTIBODY TESTS FOR SARS-COV-2

	Antigen (Ag)	Antibody (Ab) IgM or IgG; preferentially IgM & IgG
How does it work	• Directly detects the presence of the virus, indicating ACTIVE infection	• Detects the body's immune response to the virus, in the form of antibodies, which are present during ACTIVE infection and persist to indicate PREVIOUS infection
Most common uses	• Screen/triage patients who have ACTIVE infection and exclude individuals who are uninfected • May be considered to monitor active infection and recovery	• Identify people who have been exposed to the virus and have immunity* • Insufficient data on whether can be used to rule in or rule out ACTIVE infection ➢ A positive test in the presence of symptoms is likely consistent with COVID-19
Sample type	• Nasopharyngeal, nasal, or oropharyngeal swab; potentially, oral fluid and stool	• Finger stick blood, venous blood; potentially, oral fluid
Where & who performs	• Trained healthcare workers, wearing appropriate PPE in decentralized points of need	
Test formats and examples	• Lab-based: manual ELISA, automated immunoassay platforms • Decentralized: rapid diagnostic tests (RDTs)	• Lab-based: manual ELISA, automated immunoassay platforms • Decentralized: rapid diagnostic tests (RDTs)

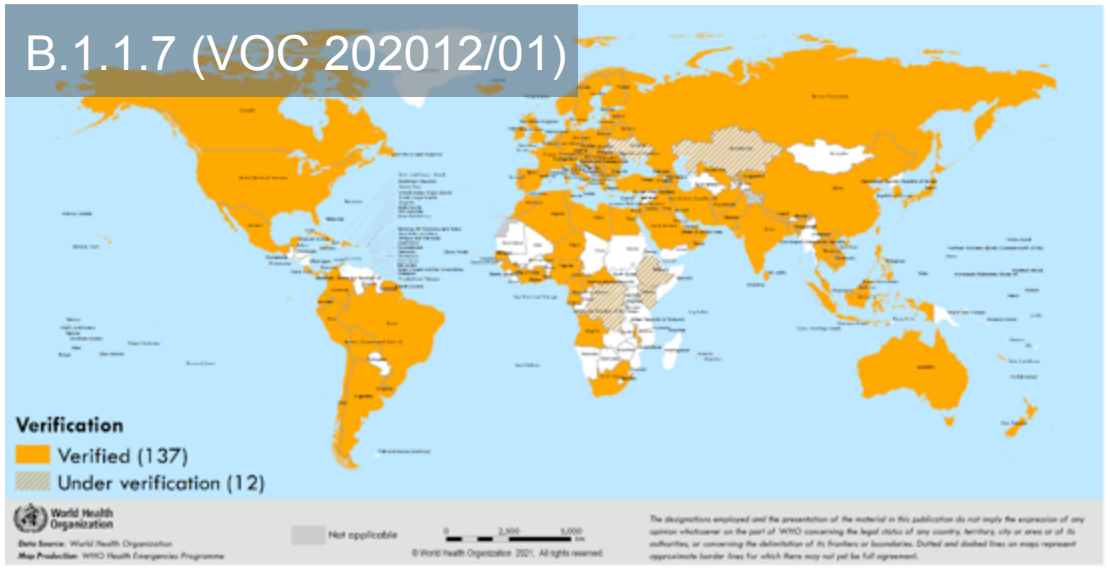
** Insufficient data on the duration/level of protection conferred by immunity*

SEQUENCING – VARIANTS OF CONCERN REPORTED GLOBALLY

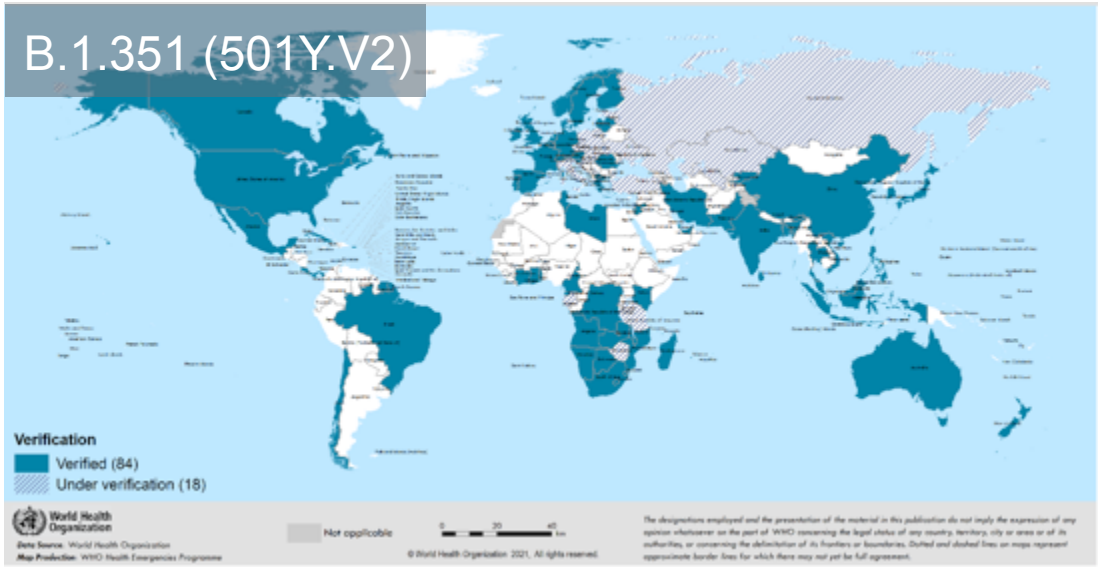
B.1.617 lineage



B.1.1.7 (VOC 202012/01)



B.1.351 (501Y.V2)



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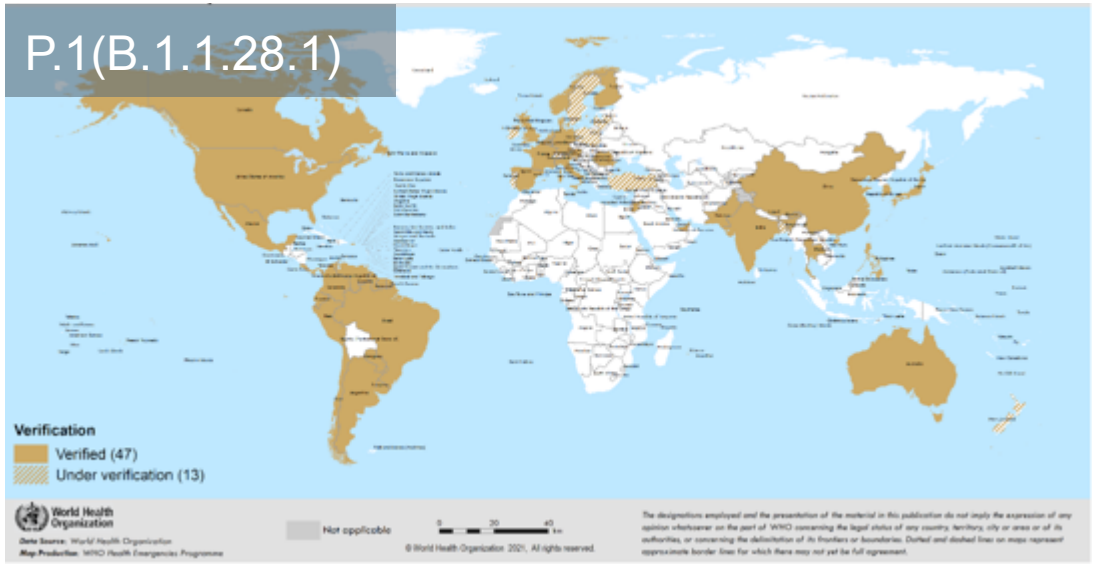


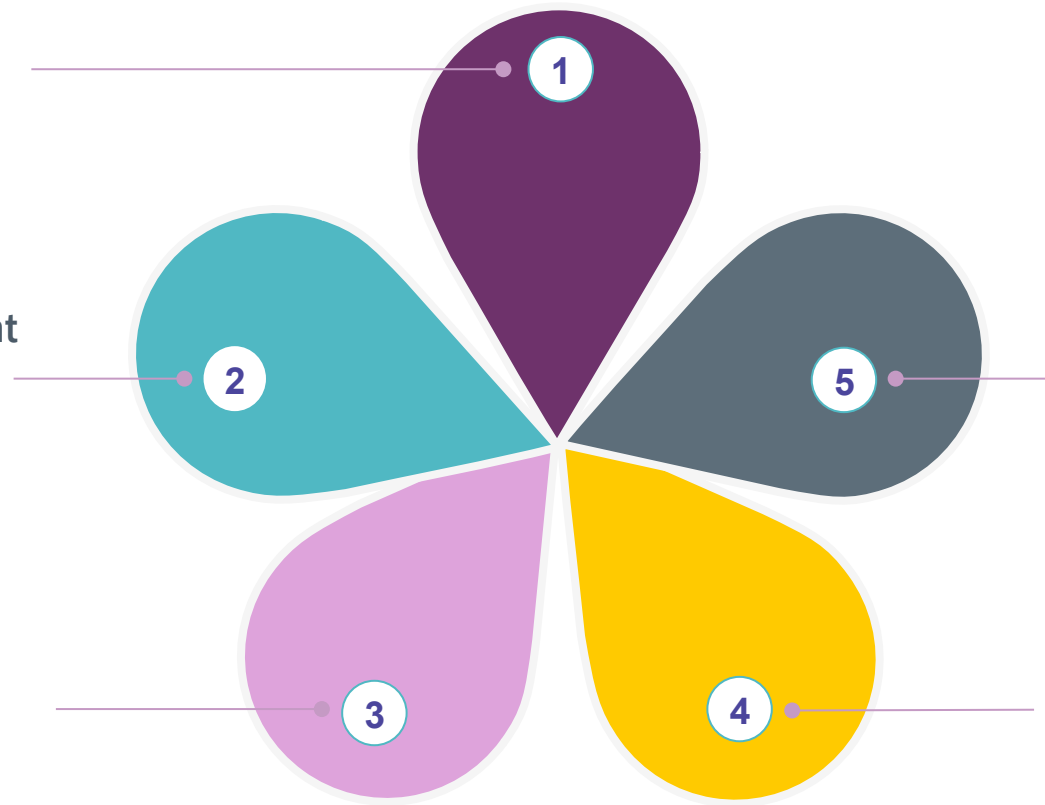
Source: WHO Weekly Epidemiological Update, 11 May 2021

WHO GUIDE ON GENOMIC SURVEILLANCE HIGHLIGHTS FIVE PRIORITY AREAS FOR SARS-COV-2

Sequencing programme framework
e.g. stakeholder engagement, resource mapping, technical and operational considerations

Sequencing capacity building
e.g. validate and compare different sequencing & data analysis strategies, training and technical support

Technology assessment / R&D
e.g. identify optimal NGS workflows to facilitate adoption in LMICs, improve and validate tools for rapid NGS data analysis

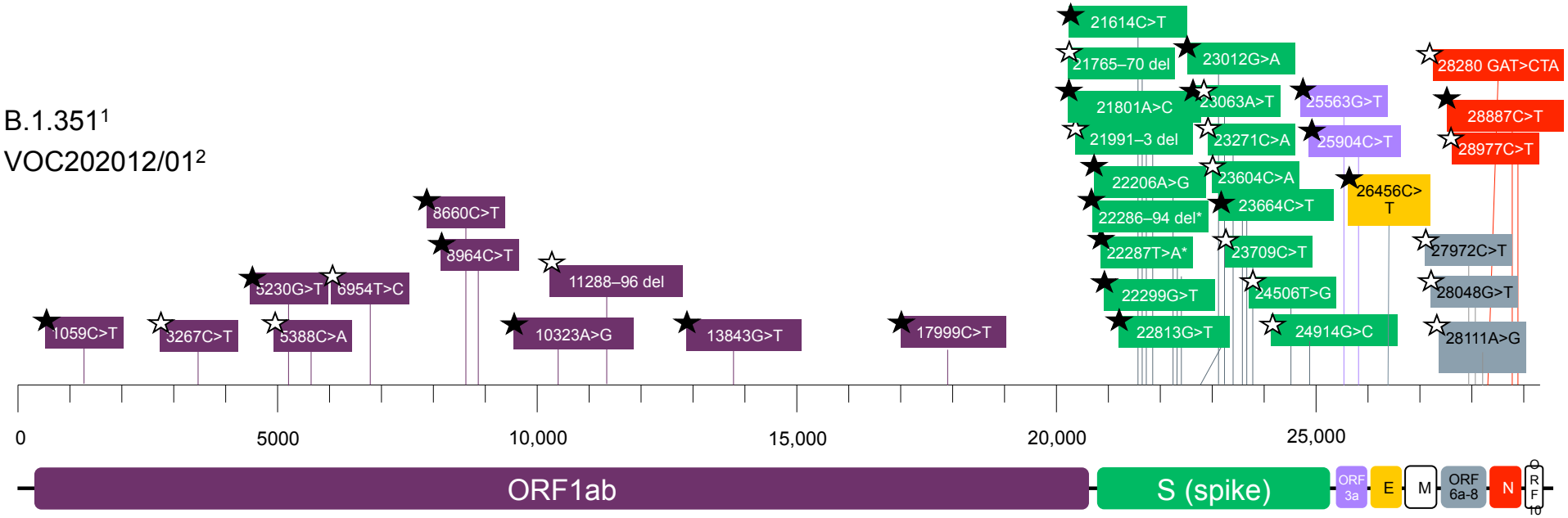


Advocacy & education
e.g. raise public awareness on value of sequencing, training and support for scientists to communicate findings effectively

Bioinformatics & data sharing
e.g. improve practices to facilitate rapid data sharing and set up data accreditation standards

IMPACT OF VOC MUTATIONS ON DIAGNOSTIC TARGETS

★ Mutations in B.1.351[1]
☆ Mutations in VOC202012/01[2]



Assays targeting ORF1a gene:
- Atila iAMP® COVID
- Wantai SARS-CoV-2
- BGI 2019-nCoV
- SARS-COV-2 R-GENE®
- AccuPower® SARS-CoV-2
- ExAmplar COVID-19
- VIASURE SARS-CoV-2
- DAAN 2019-nCoV
- EURORealTime SARS-CoV-2
- GeneFirst 2019-nCoV
- RADI COVID-19
- PerkinElmer® SARS-CoV-2
- Primerdesign Ltd. COVID-19
- Sansure 2019nCoV
- STANDARD M nCoV
- Allplex 2019-nCoV
- Kehua SARS-CoV-2
- TaqPath COVID-19
- ViroKey SARS-CoV-2
- Roche cobas® SARS-CoV-2
- Abbott Real*Time* SARS-CoV-2
- Hologic Aptima® SARS-CoV-2 and SARS-Cov-2 (Panther Fusion)
- TrueNat SARS-CoV-2

Assays targeting S gene:
- RealStar® SARS-CoV2
- RADI COVID-19
- TaqPath COVID-19

Assays targeting E gene:
- RealStar® SARS-CoV2
- AccuPower® SARS-CoV-2
- ExAmplar COVID-19
- RIDA GENE SARS-CoV-2
- STANDARD M nCoV
- Alllex 2019-nCoV
- Kehua SARS-CoV-2
- ModularDx SARS-CoV (COVID-19)
- Xpert Xpress SARS-CoV-2
- Roche cobas® SARS-CoV-2
- TrueNat SARS-CoV-2

Assays targeting N gene:
- Atila iAMP® COVID
- Wantai SARS-CoV-2
- SARS-CoV-2
- SARS-COV-2 R-GENE®
- VIASURE SARS-CoV-2
- DAAN 2019-nCoV
- EURORealTime SARS-CoV-2
- GeneFirst 2019-nCoV
- PerkinElmer® SARS-CoV-2
- Sansure 2019nCoV
- Allplex 2019-nCoV
- Kehua SARS-CoV-2
- Xpert Xpress SARS-CoV-2
- TaqPath COVID-19
- Abbott Real*Time* SARS-CoV-2
- **Rapid antigen RDTs**

** Mutation and deletion at same site disputed. 1. Tegally H et al. medRxiv 2020. doi: 10.1101/2020.12.21.20248640; 2. Public Health England. www.gov.uk/government/publications/investigation-of-novel-sars-cov-2-variant-variant-of-concern-20201201 (Accessed 4 January 2021)*

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FIND INDEPENDENT EVALUATIONS

HIGH-QUALITY STUDIES THROUGHOUT THE

DIAGNOSTICS LIFECYCLE, FROM DISCOVERY TO IMPLEMENTATION

Design lock

Stringent regulatory approval and/ or pre-qualification

Global policy

National regulatory verification

National policy approval

Discovery & research | **Development** | **Validation & verification** | **Demonstration** | **Variable country-level assessment**

- Feasibility
  - Proof of principle
- Analytical performance
  - Human factors & usability
- Analytical validation, stability, transport stress, shelf life (manufacturer)
- Risk, novelty, intended user & intended use
  - Clinical performance verification (comparison), usability, test cost
- Pre-qualification risk-based approach (evidence of safety, quality, and performance for use in LMICs including: benefits and risks, and operational utility of the IVD)
- Evidence weighted decision making
  - GRADE & EtD assessment using PICO framework
  - Implementation requirements
  - Public consultation
- Lab suitability (correct and appropriate use; competency; maintenance & disposal)
  - Health technology assessment
  - Cost of testing

Quality assurance – GXP; FIND is ISO 13485 certified

FIND INDEPENDENT EVALUATIONS TO SUPPORT USE OF COVID-19 TESTS

www.finddx.org/covid-19/sarscov2-eval

Antibody rapid test study sites:
- Barcelona Institute for Global Health (IS Global) (Spain)
- BIOASTER Technology Research Institute (BIOASTER) (France)
- Boston Children's Hospital (BCH) (USA)
- Centre Hospitalier Universitaire Vaudois (CHUV) (Switzerland) – manual ELISA only
- Liverpool School of Tropical Medicine (LSTM) (UK)
- Ospedale San Raffaele (OSR) (Italy)
- Universidad Peruana Cayetano Heredia (UPCH) (Peru)
- Universidade Federal do Rio de Janeiro (UFRJ) (Brazil)
- University of the Witwatersrand (Wits) (South Africa)
- Washington University in St. Louis (WUSTL) (USA)

Antigen rapid test study sites:
- Apollo Hospitals Chennai and New Delhi (India)
- Centre for the AIDS Programme of Research in South Africa (CAPRISA) (South Africa)
- Charité – Universitätsmedizin Berlin (Germany)
- Liverpool School of Tropical Medicine (LSTM) (UK)
- King George's Medical University (KGMU) (India)
- Translational Health Science and Technology Institute (THSTI) (India)
- Universidad Peruana Cayetano Heredia (UPCH) (Peru)
- Universidade Federal do Rio de Janeiro (UFRJ) (Brazil)
- University of Cape Town (UCT) (South Africa)
- University Hospital Heidelberg (UKHD) (Germany)
- University Hospitals of Geneva (HUG) (Switzerland)
- University of Sao Paulo (USP) (Brazil)
- University of the Witwatersrand (Wits) (South Africa)

Molecular test study sites:
- Translational Health Science and Technology Institute (THSTI) (India)
- University Hospitals of Geneva (HUG) (Switzerland)

FIND INDEPENDENT EVALUATIONS

MOLECULAR TESTS

EXAMPLE DATA COLLECTED

	Company	Product name	Product number	Gene target	Verified LOD (copies / reaction)	Avg Ct (lowest dilution 10/10)	Clinical sensitivity (50 positives)	Clinical specificity* (100 negatives)	Lot No.	PCR platform**	Supplier recommended Ct cut-off
1.	**altona Diagnostics**	RealStar® SARS-CoV-2 RT-PCR Kit 1.0	821003/ 821005	E	1–10	35.45	92% (95%CI: 81, 97)	100% (95%CI: 96, 100)	023567	BioRad CFX96 deep well	None; any signal can be considered positive
				S	1–10	35.99	92% (95%CI: 81, 97)	100% (95%CI: 96, 100)			
2.	**Atila BioSystems Inc.**	Atila iAMP COVID-19 Detection (isothermal detection)	iAMP-COVID-100-RUO	ORF1ab	50–100	N/A	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	COVID20200320	BioRad CFX96 deep well	Any signal is considered positive (isothermal)
				N	1–10	N/A	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			
3.	**Beijing Wantai Biological Pharmacy Enterprise Co. Ltd**	Wantai SARS-CoV-2 RT-PCR Kit	WS-1248	ORF1ab	1–10	36.20	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	nCoVP20200305	BioRad CFX96 deep well	≤40
				N	1–10	37.12	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			
4.	**BGI Health (HK) Co. Ltd**	Real-time Fluorescent RT-PCR kit for detection 2019-nCOV (CE-IVD)	MFG030010	ORF1	1–10	32.43	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	6220200305	Roche LightCycler 480	≤38
5.	**bioMérieux SA**	ARGENE® SARS-COV-2 R-GENE®**[b]**	423720 (CE-IVD) 423717	N	10–50	36.44	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	1007989610 1007947520	BioRad CFX96 deep well	Any signal considered as positive

www.finddx.org/covid-19/sarscov2-eval

Objectives

- Verify analytical sensitivity
- Determine clinical performance

Study design

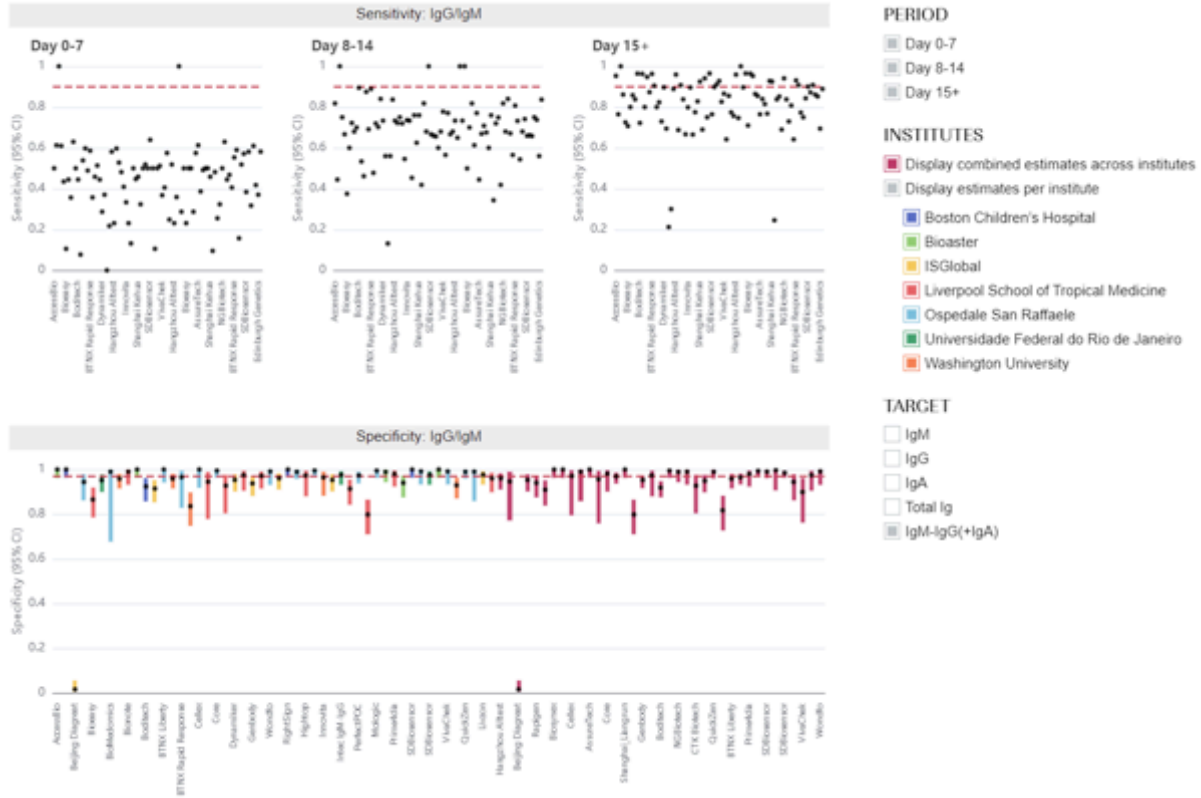
- Retrospective study using remnant, clinical samples

Status

- Conducted between Feb and Aug 2020 (Europe, Asia)
- Total # tests included: N = 22 manual PCR, N = 2 platform-based tests
- Ongoing work to assess performance against new VOCs

ANTIBODY TESTS

SENSITIVITY & SPECIFICITY ESTIMATES OBTAINED



www.finddx.org/covid-19/sarscov2-eval

Objective

- Determine clinical performance

Study design

- Retrospective study using remnant, clinical samples

Status

- Conducted from Q2 2020 to Q1–2021 in 10 sites (Europe, N America, S America, Africa)
- Total # tests included: N = 35 RDTs, N = 16 ELISAs

ANTIGEN RDTS

EXAMPLE RESULTS: STANDARD Q COVID-19 AG TESTS (SD BIOSENSOR)

Clinical performance

Country	Brazil	Germany	Switzerland
Clinical Sensitivity (95% CI); N	88.7% (81.3, 93.4); 106	76.6% (62.8, 86.4); 47*	89% (83.8, 92.7); 191
Sensitivity days ≤7, N	90.7% (83.3, 95.0); 97	80% (64.1, 90.1); 35	89.8% (84.4, 93.4); 176
Sensitivity Ct ≤33, N	91.9% (84.9, 95.9); 99	87.8% (74.5, 94.7); 41	91.8% (86.9, 95); 183
Sensitivity Ct ≤ 25, N	95.9% (86.3, 98.9); 49	100% (84.5, 100); 21	97.2% (92.9, 98.9); 141
Clinical Specificity (95% CI), N	97.6% (95.2, 98.8); 294	99.3% (98.6, 99.6); 1216	99.7% (98.3, 99.9); 338
Invalid rate (%, n/N)	0%, 0/400	0%, 0/1263	0%, 0/529

Note:40/47 positives were tested using Roche, 5/47 positives were tested using Seegene and 2/47 were tested using TibMolbiol.

Analytical performance

	Lowest dilution detected	Corrected concentration	Viral Copy equivalence	Supplier-reported LOD
Analytical Sensitivity	**5.0 x 10^3 pfu/ml** ~ 7.14 x 10^3 $TCID_{50}$/ml	**7.58 x 10^2** pfu/ml	**1.15 x 10^6 copies/ml** applied to test	1.25 x $10^{3.2}$ $TCID_{50}$/ml ~ **1.39 x 10^3 pfu/ml**

Note: corrected concentration accounts for volume of dilution that is absorbed onto the swab and then diluted into the proprietary extraction buffer.

www.finddx.org/covid-19/sarscov2-eval

Objectives
- Verify analytical sensitivity
- Determine clinical performance

Study design
- Prospective study

Status
- Ongoing in 9 sites (Europe, South America, Africa, Asia)
- Total # tests included: N = 23

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THE ANTIGEN RDT SUCCESS STORY

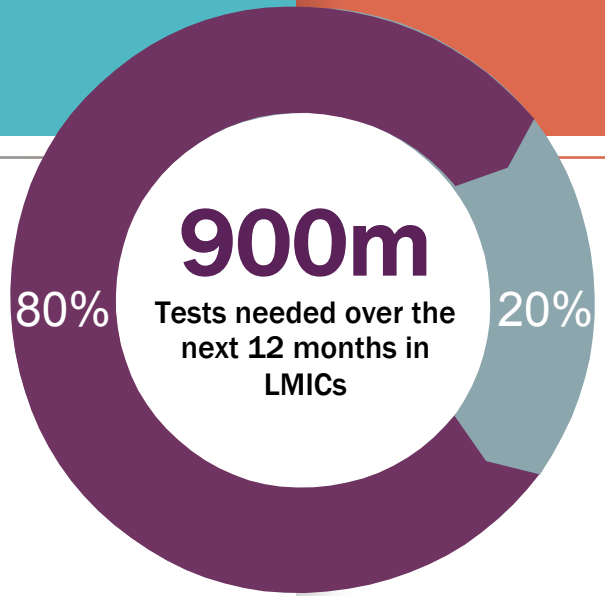
ANTIGEN RDTS ARE AN

EASY-TO-USE, AFFORDABLE COMPLEMENT TO MOLECULAR TESTING

Antigen RDTs

Used for early detection, patient management and surveillance

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



Molecular tests (PCR)

Used for patient management

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

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.

WHO TARGET PRODUCT PROFILE (TPP) FOR ANTIGEN RDTS

KEY FEATURE	ACCEPTABLE	DESIRABLE
Target use setting	Outside laboratories	Self-administered, or by trained lay workers
Clinical sensitivity	≥80% (initially >70%)	≥90% (initially >80%)
Clinical specificity	≥97%	≥99%
Specimen type	NP, OP, nasal (mid-turbinate), sputum	Nasal (anterior nares), saliva/oral
Time to result	≤40 mins	≤20 mins
Test kit stability	12 mos at 4–30°C	18–24 mos at 4–40°C
Need for equipment	Handheld or benchtop	Not required

Source: WHO Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0. First published 31 July 2021; revised 28 September 2021

For a point-of-care test for suspected COVID-19 cases and their close contacts, to diagnose acute SARS-CoV-2 infection in areas where reference assay testing is unavailable, or turnaround times obviate its clinical utility

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Time to result	≤40 mins	≤20 mins
Test kit stability	12 mos at 4–30°C	18–24 mos at 4–40°C
Need for equipment	Handheld or benchtop	Not required

FIND independent evaluation of products that have received WHO EUL

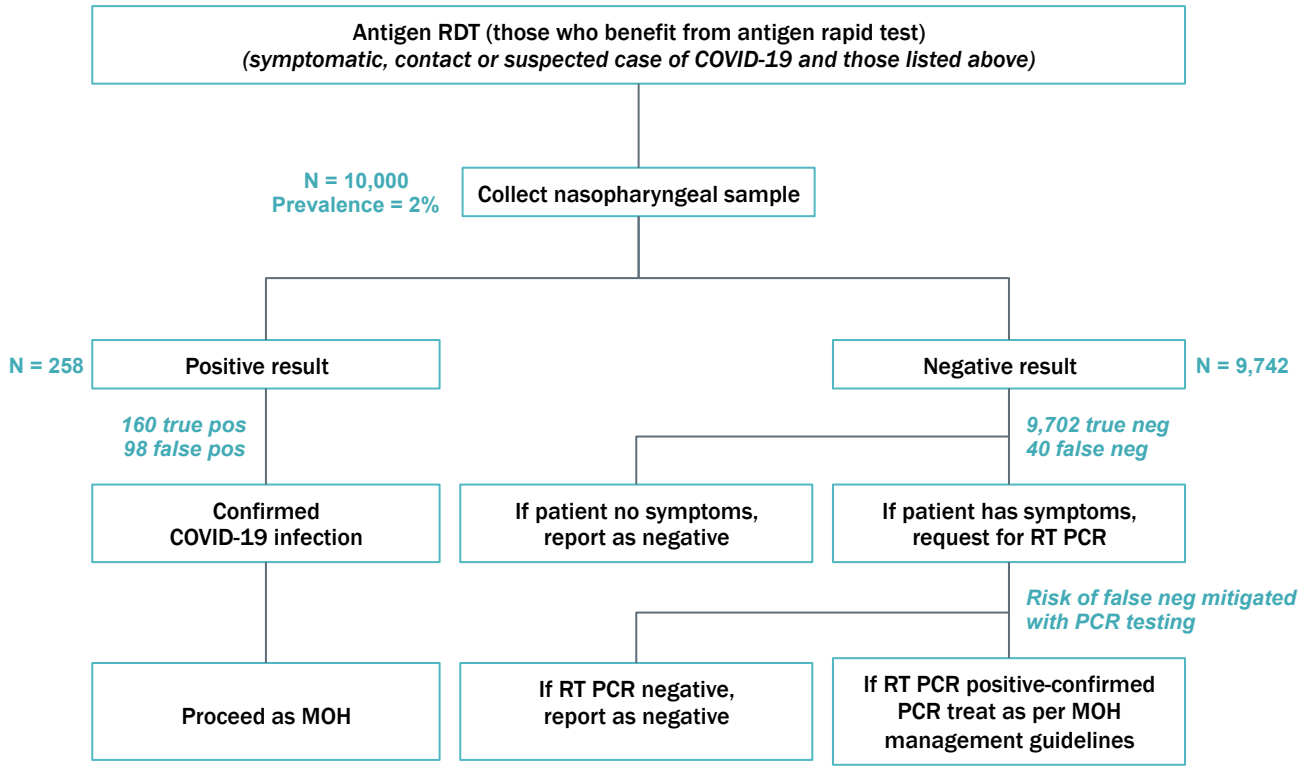
TEST	CLIN. SENS. %	CLIN. SPEC %.
Abbott (Panbio)	85-91 [88-93]	>99
SD Biosensor (STANDARD Q)	77-89 [88-92]	>99
PMC (Sure Status)	91 [94]	>97

Only studies from same sites included (CH, DE). Range provided for various sites. [#] denotes sensitivity for Ct<33. Only specimens under EUL included. Detailed reports can be found at: www.finddx.org/sarscov2-eval-antigen/

Source: WHO Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0. First published 31 July 2021; revised 28 September 2021

ANTIGEN RDTS AS SCREENING TOOLS IN DIAGNOSTIC ALGORITHMS

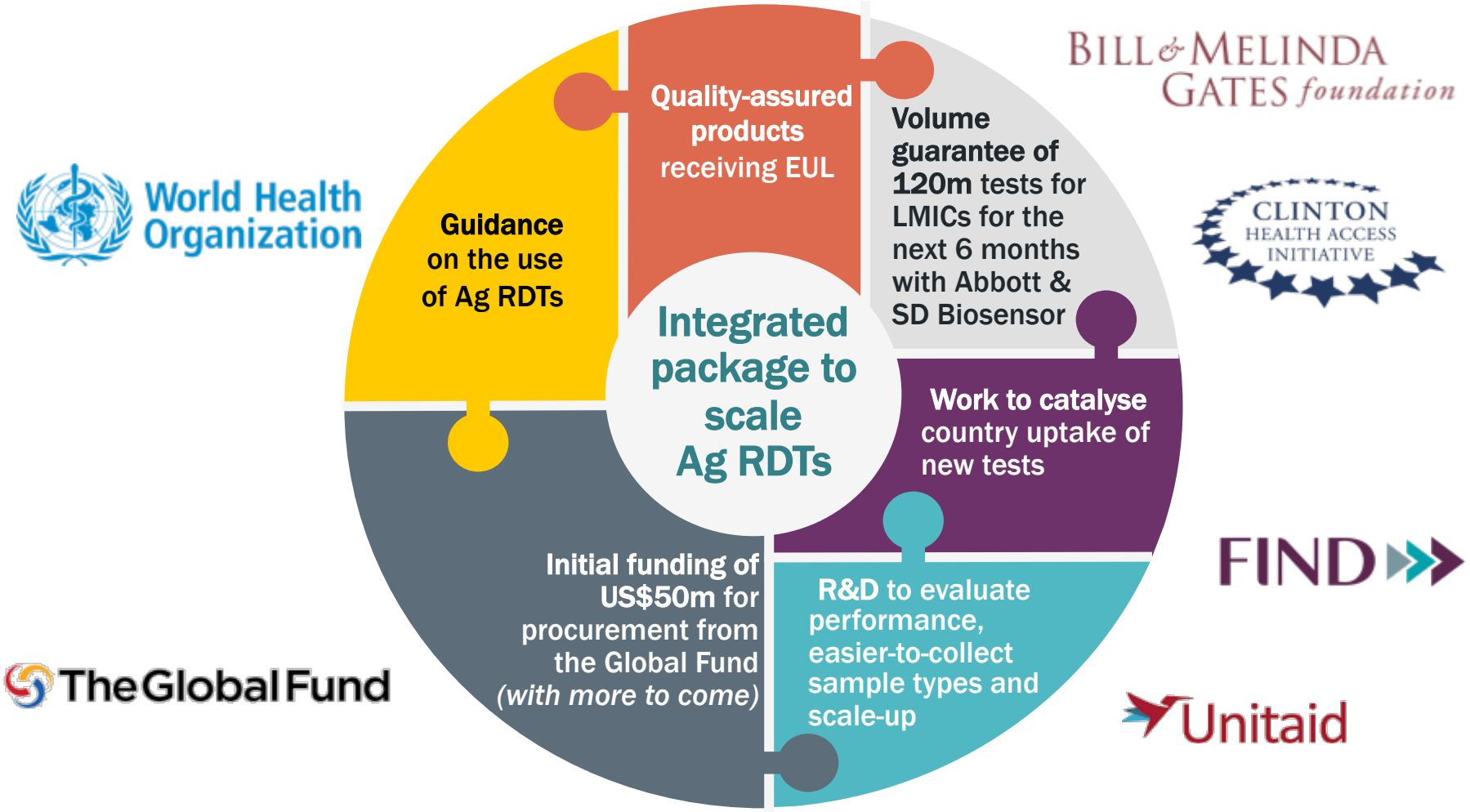
TESTING ALGORITHM FOR ANTIGEN RDT



- With Ag RDT screening and PCR confirmation, most of the positives (2%) can be identified early, isolated, and treated
- 97% of the population can resume economic activity
- Serial testing could mitigate false positivity challenge
- Alternate testing strategies entail a long time to result leading to ineffective follow-up action and high costs[1]

Source: Country MOH guidelines, representative of most national guidelines for COVID-19 testing;
1. Further evidence generation is required for data-driven advocacy

ACT-ACCELERATOR ENABLED ACCESS PACKAGE OF TWO WHO-APPROVED ANTIGEN RDTS BY SEPTEMBER 2020



ACT-ACCELERATOR EOI

IMPROVE ACCESS TO ANTIGEN RDTS FOR LMICS

Accelerating development and market entry of improved, quality-assured SARS-CoV-2 antigen RDTs for expanded use in LMICs

Rapidly creating the supply conditions (manufacturing capacity, diversity of supplier base, affordability) to meet the needs of LMICs

EOI FOLLOWED A COMPRESSED TIMELINE

FIRST CONTRACTS FINALIZED IN DECEMBER 2020

100+ applications received

1. 30+ reviewed by independent panel of external experts
2. 5–7 discussed in detail by Investment Committee
3. 4 finalists with signed contracts

INVESTMENTS REFLECTED TWO EOI GOALS

Initial investments finalized: US$2.50/test including price matching agreement and larger supplier base in Q1 2021

Short-term: investments in R&D and tech transfer agreements for lower-cost tests; continued utility improvements with shift to nasal & clearer temperature stability

Global supply of $2.50/test starting Q1 2021, with volumes available of 20M tests/month by Q3 2021

Premier Medical Corporation (PMC)
Investment in manufacturing capacity expansion and automation to scale up low-cost production in exchange for ensured access pricing and test volume for LMICs

Long-term: strengthening local manufacturing capacity & support for product transfer

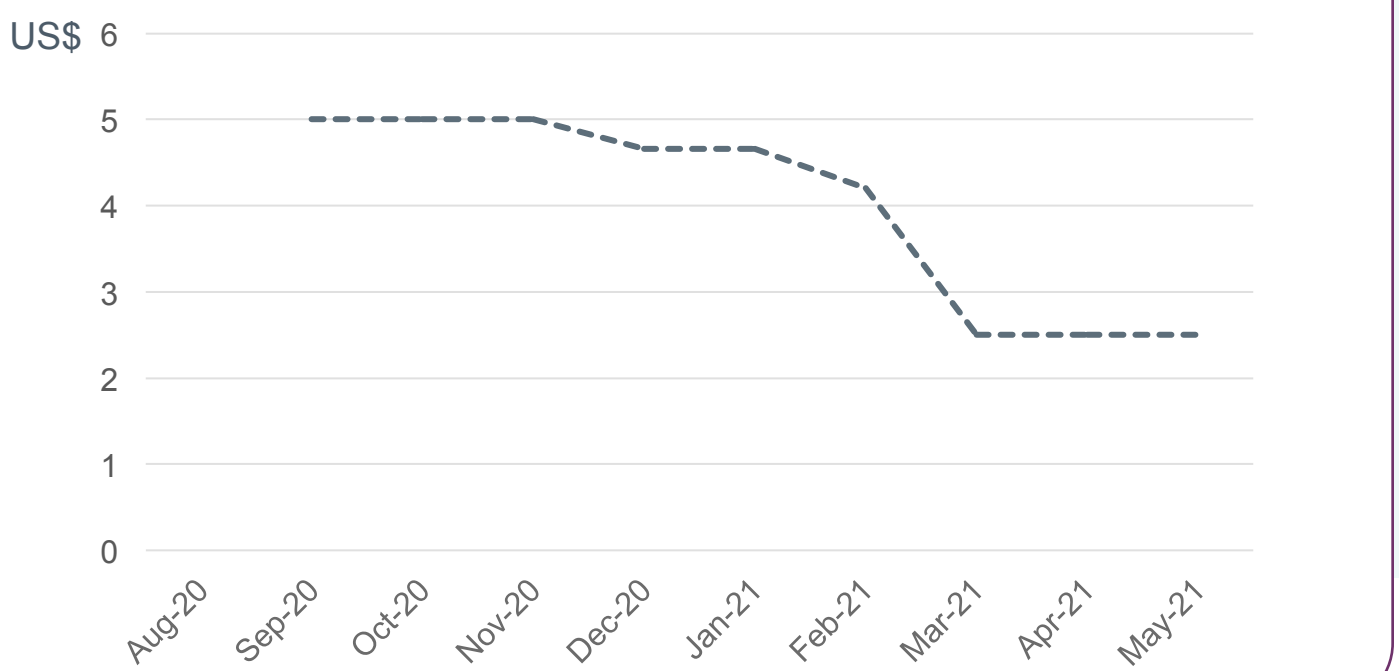
Capacity expansion to 80M tests/year (LMICs)

Partnership between established US RDT developer and local Brazilian manufacturer for tech transfer, focusing on LatAm region

Partnership between West African manufacturer and British manufacturer for technology transfer

ACTIVE INTERVENTIONS HAVE LOWERED THE PRICE OF QUALITY-ASSURED ANTIGEN RDTS FOR LMICS

PRICE OF QUALITY-ASSURED* ANTIGEN RDTS OVER TIME



WHO Emergency Use Listed

Source: Diagnostics Consortium for COVID data as 27 April 2021

R&D investments

- Investments in local manufacturing and automation to increase efficiency to scale capacity

Market-shaping interventions

- Coordination negotiations across procurement organizations
- Investments in key suppliers and support for regulatory processes increased 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

MAIN RESEARCH TOPICS REMAINING FOR ANTIGEN RDTS

Technology R&D

- Less invasive sample types to increase access
  - *Is there enough Ag in saliva?*
  - *Is it complexed with antibodies?*
- Impact of VOCs in performance
  - *Is there selective pressure for N mutations at immunodominant epitopes?*
- Need for standards to enable performance comparisons, lot release, and in-country QC
- Improved shelf-life to facilitate implementation in harsher environments (e.g. >30°C)
- Improved analytical sensitivity (better antibodies, novel detection schemes)

Implementation studies and operational research

- Evidence generation in-country to support policy development
- Frequent testing with antigen RDTs to enable a robust test-trace-isolate strategy and support lifting restrictions
- Expanded use cases in non-traditional healthcare settings (border crossings, pharmacies, workplaces)

FIND

THANK YOU