FIND

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

Accelerating the Development and Uptake of Rapid Diagnostics to Address Antibiotic Resistance

October 13-14, 2022

LESSONS LEARNED FROM ABROAD THROUGH THE WHO'S ACCESS TO COVID-19 TOOLS ACCELERATOR PROGRAM

Bill Rodriguez
CEO, FIND

FIND SEEKS TO ENSURE

EQUITABLE ACCESS TO RELIABLE DIAGNOSIS AROUND THE WORLD

We connect countries and communities, funders, decisionmakers, providers, and product developers to spur diagnostic innovation and implementation 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

2021 STRATEGY: EXPECTED IMPACT

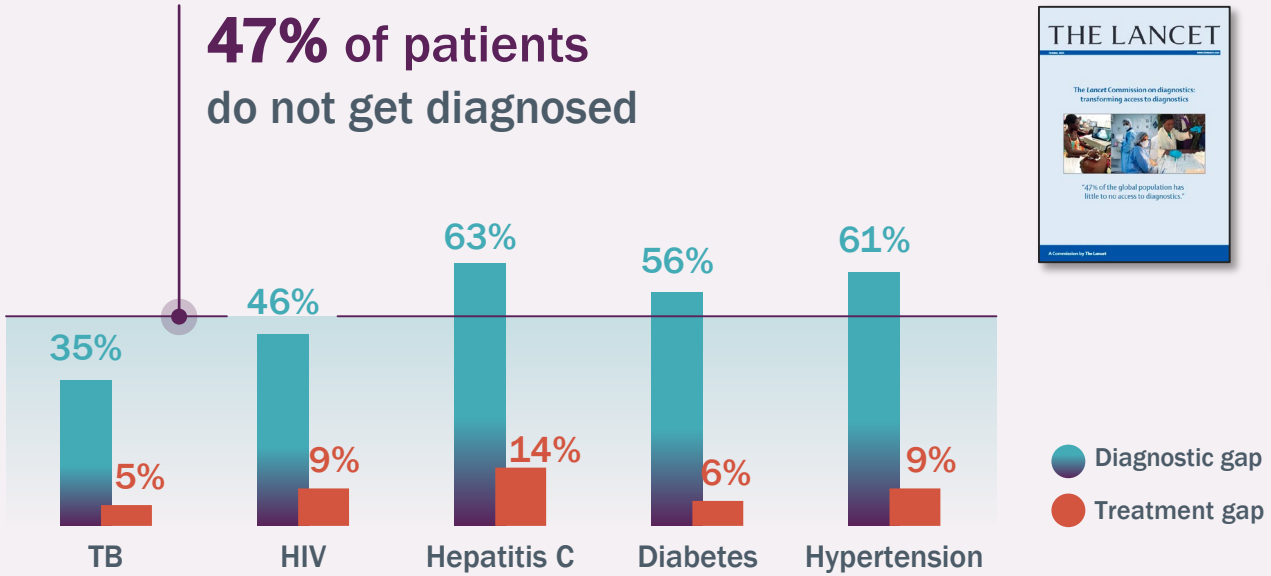
Save 1 million lives
through accessible, quality diagnosis

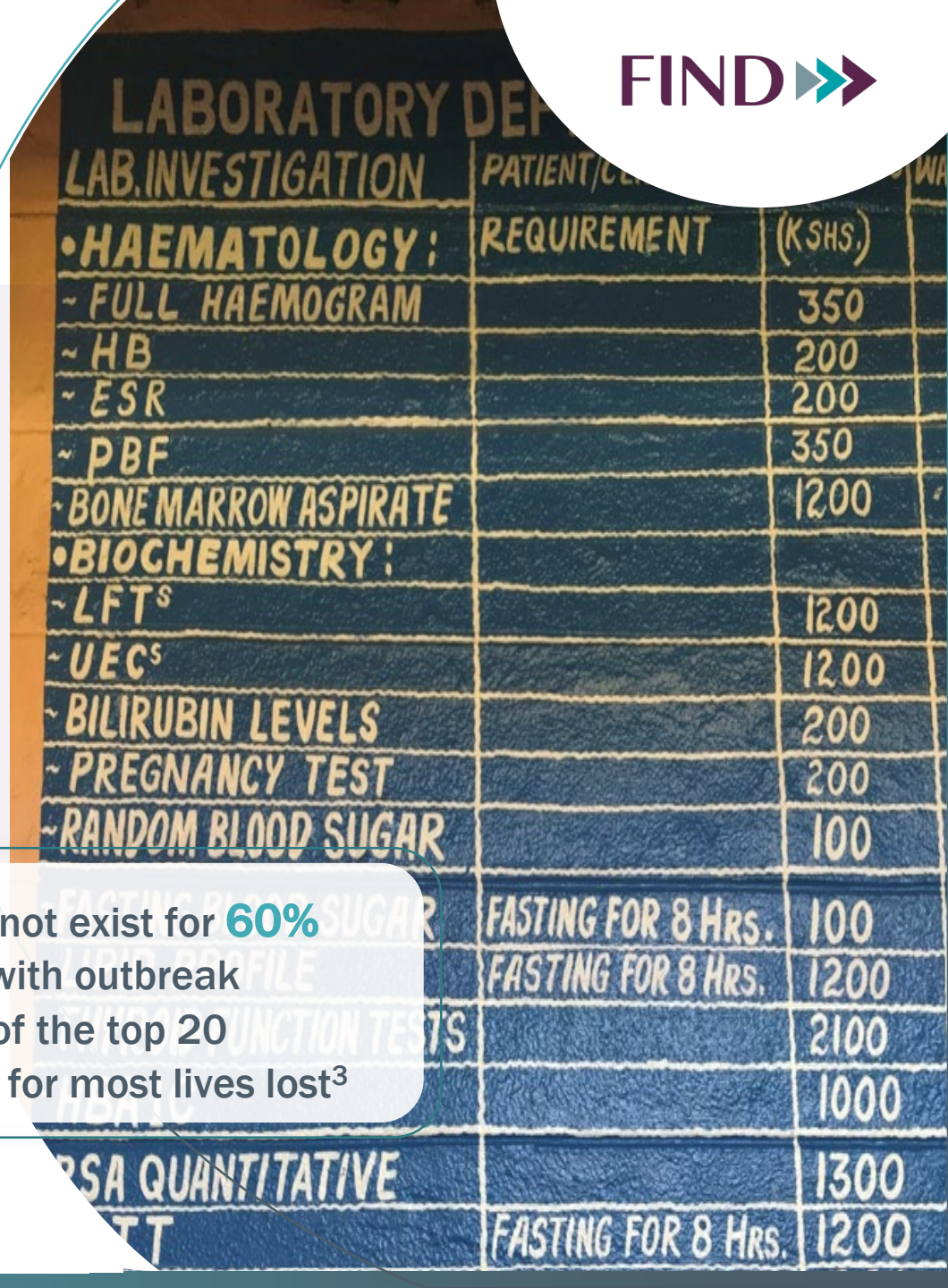
Save US$1 billion
in healthcare costs to patients and health systems

Empower countries
with diagnostic data to inform policy and care and achieve health goals

AMR TESTING IN GLOBAL CONTEXT

HALF THE WORLD LACKS ACCESS TO ESSENTIAL DIAGNOSTICS



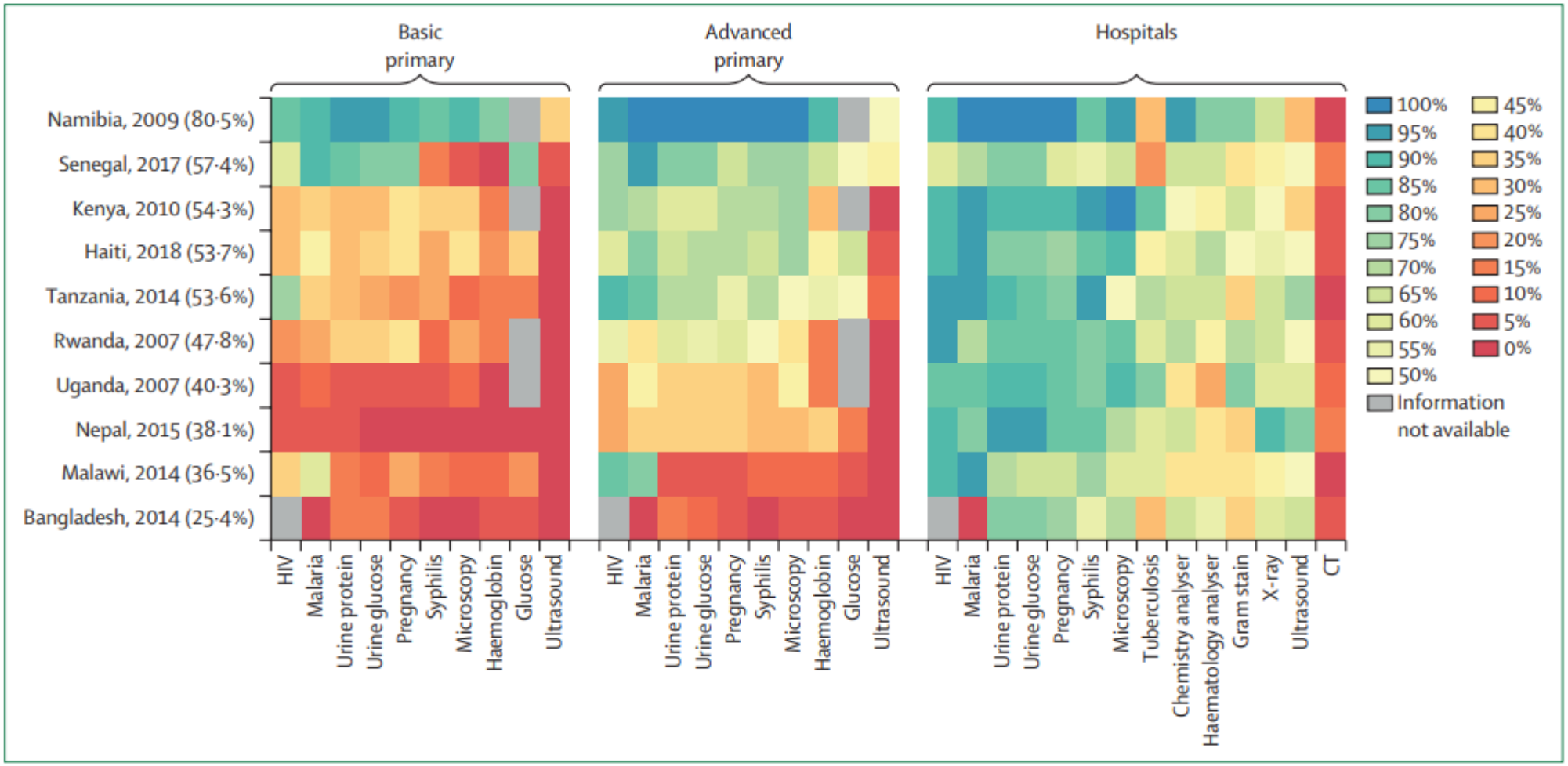


Basic diagnostic capacity is available in only **1%** of primary care clinics and **14%** of hospitals in some LMICs[1]

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

MAJOR GAPS IN AVAILABILITY OF ALL DIAGNOSTICS AT PHC LEVEL



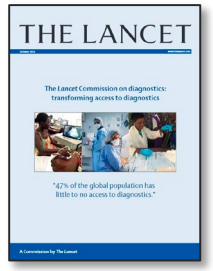


***Figure 3*: Availability of basic diagnostics by tier in ten low-income and middle-income countries in various years, 2007–18**

Source: *The Lancet* Commission on Diagnostics. Fleming et al. *Lancet* 2021;398(10315:1997–2050, https://doi.org/10.1016/S0140-6736(21)00673-5

FIT-FOR-PURPOSE AMR RAPID TESTS

ADAPTED TO USE CASES AND TO HOW HEALTH CARE IS ACTUALLY DELIVERED

At home

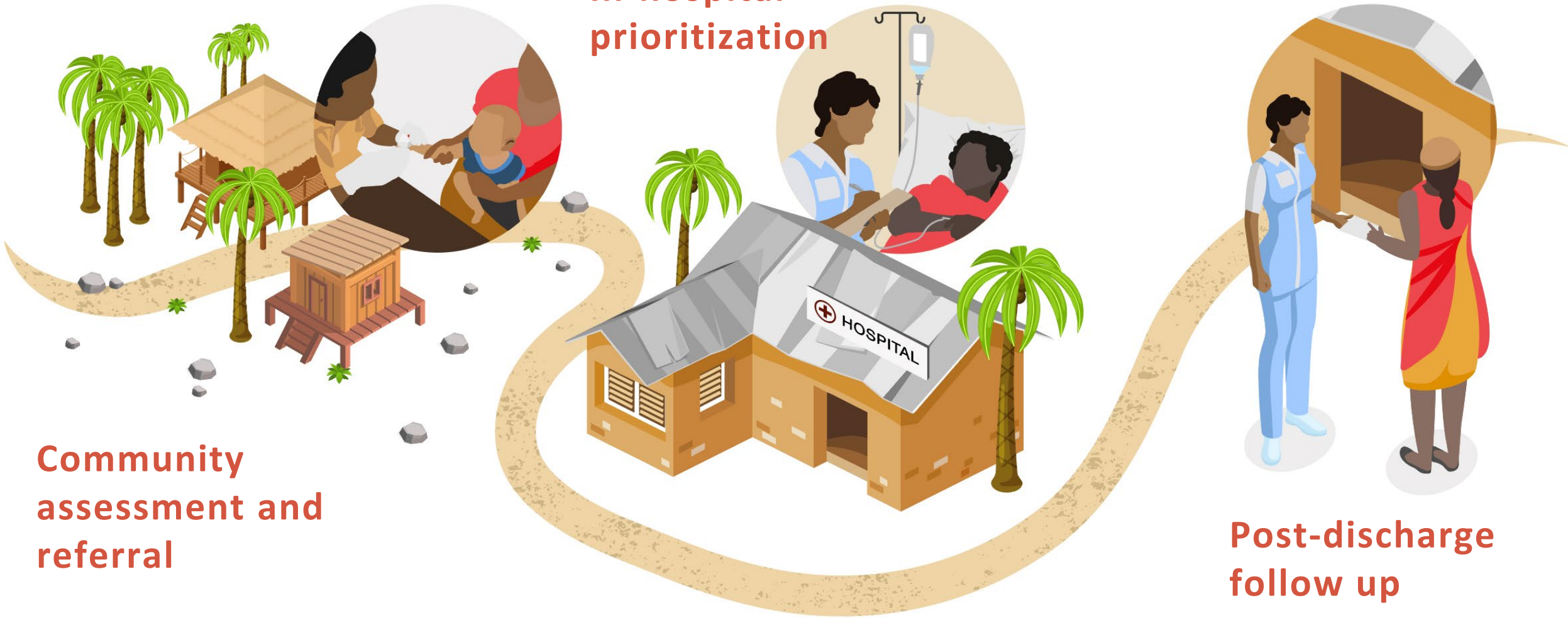
Primary care

District hospital

	Level 0 (L0)	Level 1 (L1)	Level 2 (L2)
Use setting	• Community outreach • At home testing	• Primary care facility	• Near-patient laboratory • Referral hospital laboratory
Testing infrastructure	• No mains power • No water • No lab equipment • No temperature control	• No mains power (unreliable) • Minimal lab equipment (may not support cold chain) • BSL-1 containment	• Mains power (may be intermittent) • Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge) • BSL-2/1 containment
Technologies required	**Self Tests**	**True POC**	**Near POC**

PATIENT CENTERED CARE

DIFFERENT NEEDS AT EACH STEP OF THE PATIENT JOURNEY



COVID-19 put
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,** PEPFAR (then Africa CDC)

THE ACT-ACCELERATOR PARTNERSHIP ENABLED

UNPRECEDENTED SPEED FOR BOTH DX SCALE-UP & NEW INNOVATIONS

lab capacity Feb–Jun 2020[2]

INNOVATION

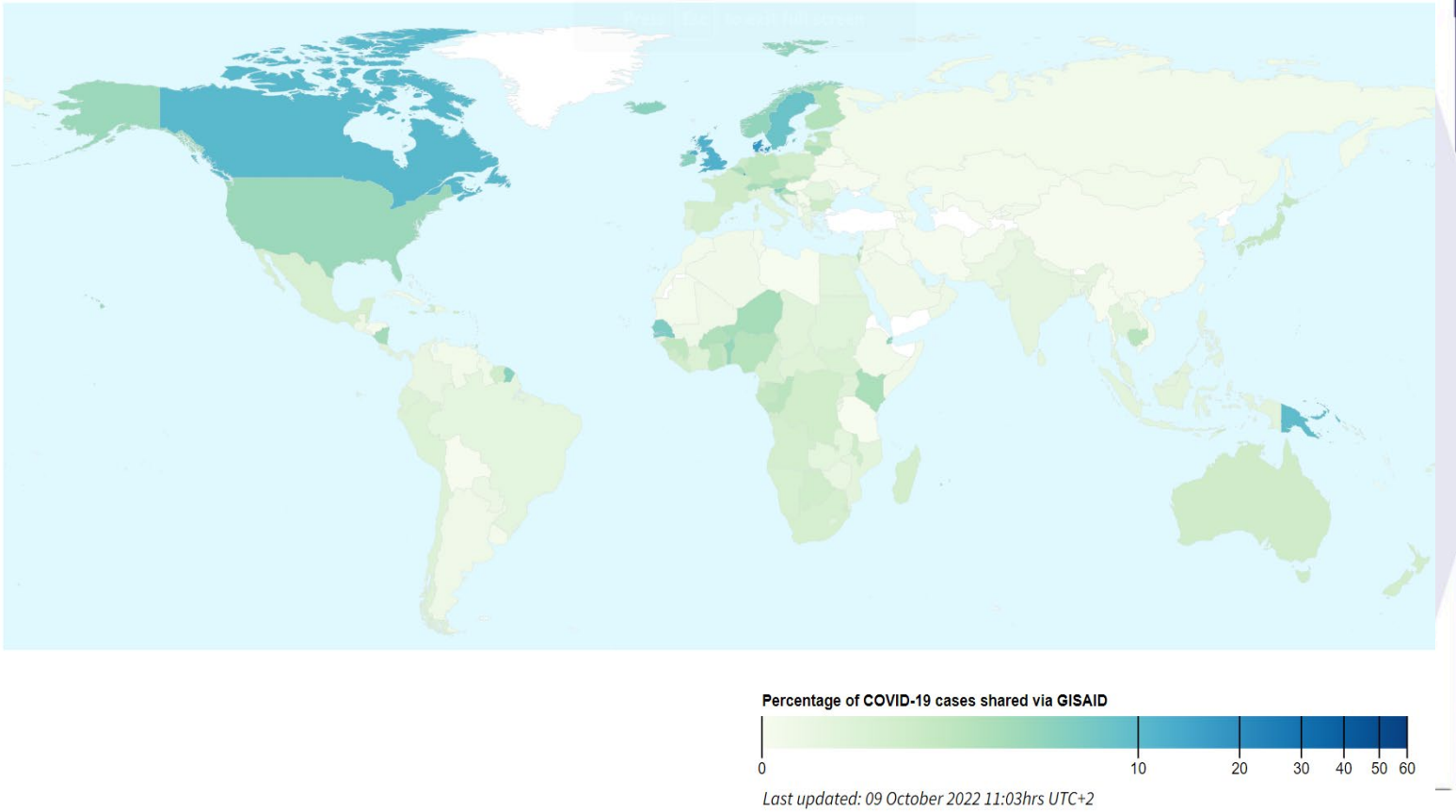
TB	5 years	TB-LAM in development
HCV	2 years	CAg in development
COVID-19	**64 days**	**236 days**

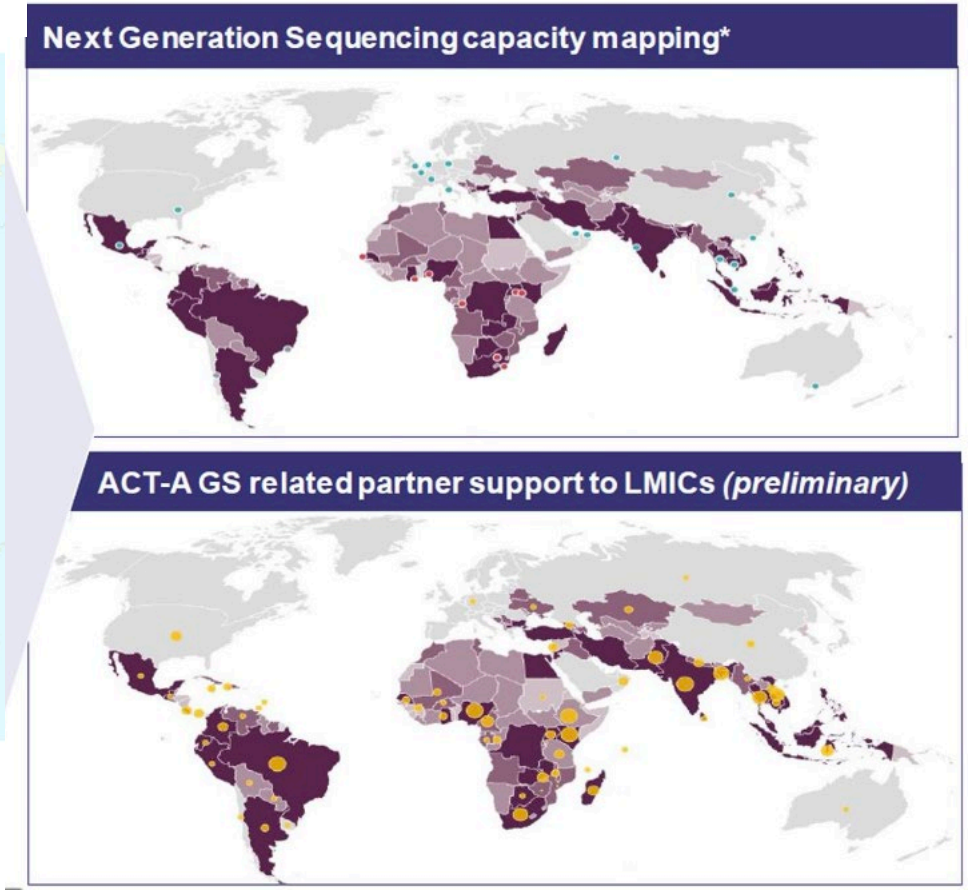
1. FIND. COVID-19 test tracker. www.finddx.org/covid-19/test-tracker (accessed 18 Sept 2020)
2. Rahman F. *The Malaysian Response to COVID-19*. Report prepared for DNDi, 15 June 2020. www.europeanpharmaceuticalreview.com/article/125084/the-malaysian-response-to-covid-19-building-preparedness-for-surge-capacity-testing-efficiency-and-containment/ (accessed 18 Sept 2020)

THE ACT-ACCELERATOR PARTNERSHIP ENABLED

GLOBAL GENOMIC SURVEILLANCE

As of Sept 2022, 13+ million viral genome sequences from human cases of COVID-19 shared by 215 countries and territories via GISAID since 10 Jan 2020





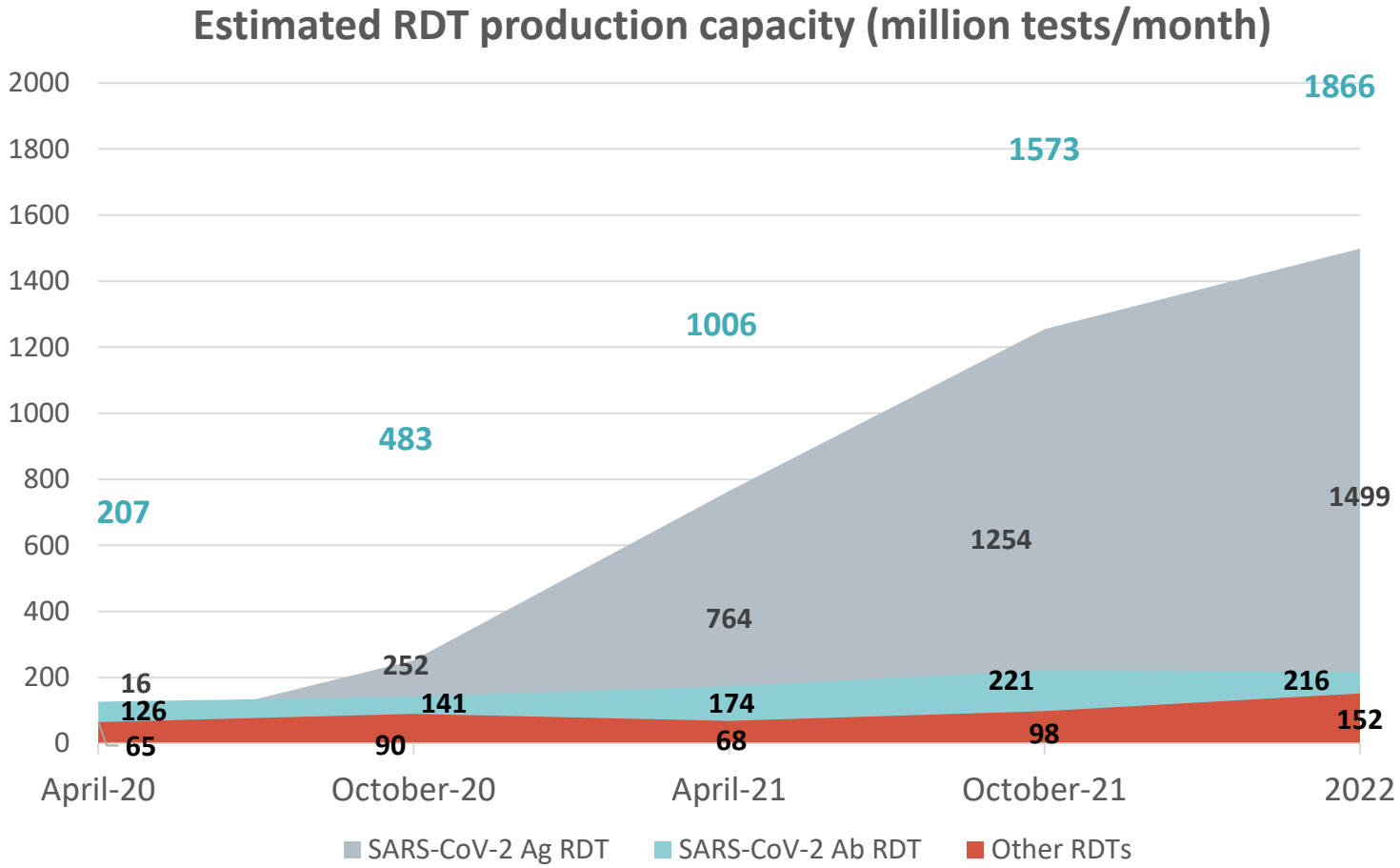
https://www.finddx.org/covid-19/covid-19-genomic-surveillance/

PRESSURE-TESTED THE DIAGNOSTICS ALLIANCE CONCEPT

The **Diagnostic Pillar** has been **co-convened by FIND and the Global Fund**, with participation from **a coalition of 50 standing partners** across 3 working groups.

WHO leads on regulatory, policy, product procurement, and allocation

GLOBAL RDT PRODUCTION CAPACITY SKYROCKETED FROM OCTOBER 2020 TO MID-2022, MAINLY DUE TO SARS-COV-2 AG RDTS



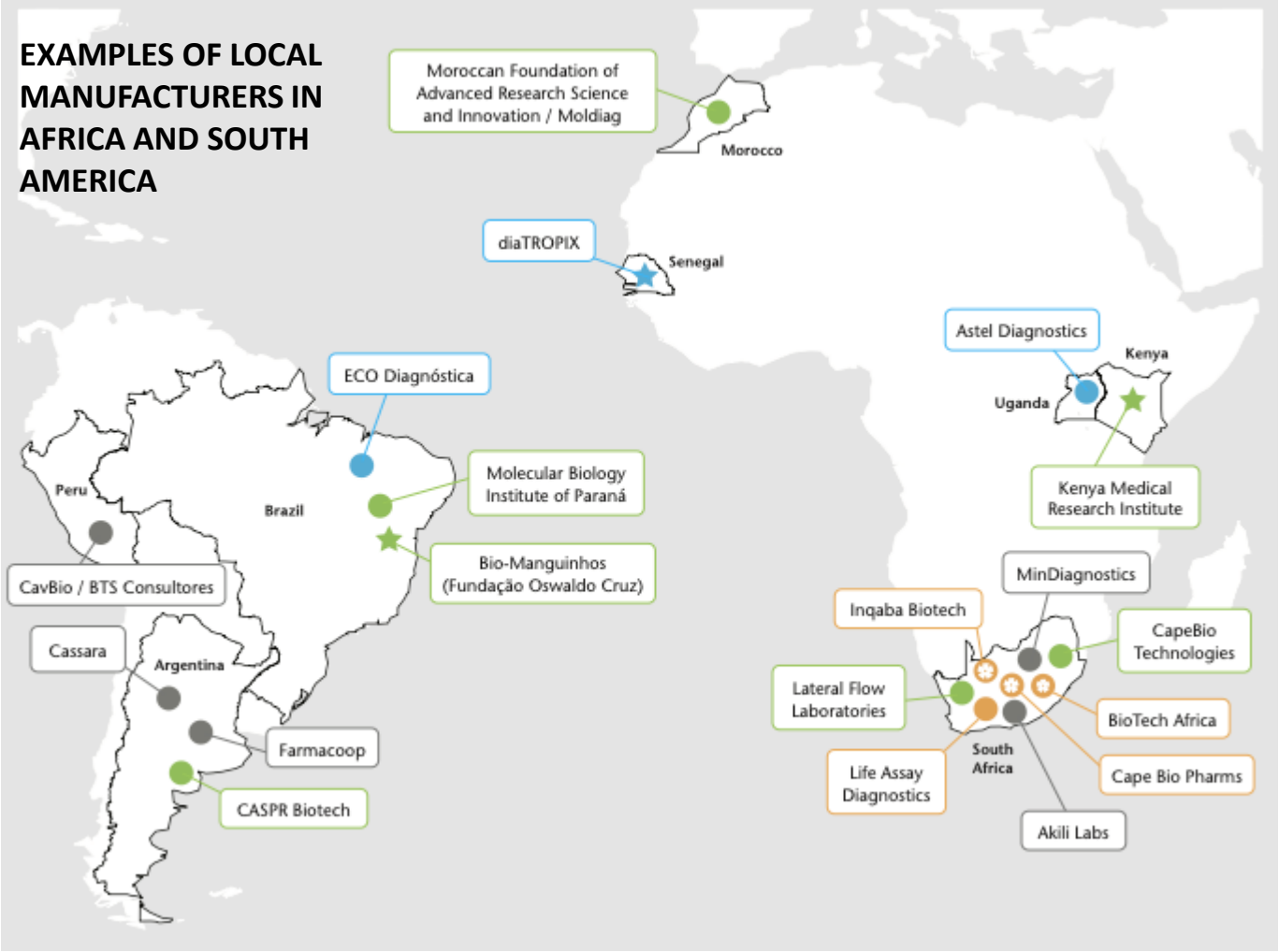
4X growth in total mfg capacity from Oct '20 – Apr '22

Capacity is concentrated in China & ROK

Source: Confidential manufacturer interviews N=17, April 2021. Estimated production capacity based on theoretical capacity when the facility is run at its maximum

EXPANSION AND DIVERSIFICATION OF LOCAL PRODUCTION IS NEEDED TO MEET THE GLOBAL NEEDS

EXAMPLES OF LOCAL MANUFACTURERS IN AFRICA AND SOUTH AMERICA



★ Non-profit or public manufacturer

❁ The finished product is a test component, not a complete diagnostic test

Level of local production

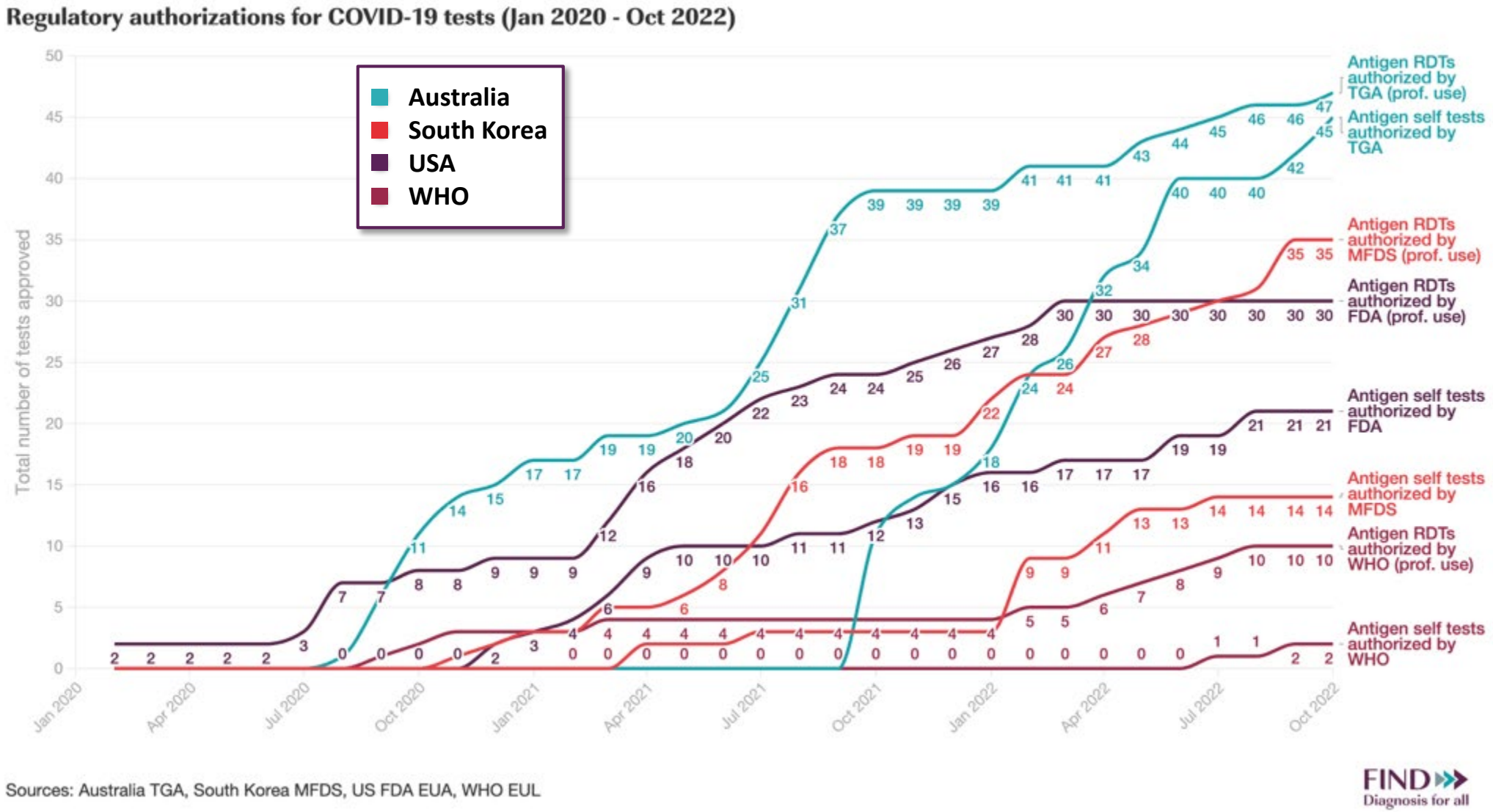
1. Local assembly of semi-finished products
2. Local production of finished products
3. Local production of finished products and some raw materials
4. Local production of finished products and some raw materials and/or local innovation

● Level of local production unknown

Source: MSF Access Campaign Issue Brief, Local diagnostics to meet local health needs, 8 July 2021 https://msfaccess.org/improve-local-production-diagnostics

BUT COVID-19 ALSO SHOWED THAT

GLOBAL REGULATION IS A BARRIER TO TESTING



Sources: Australia TGA, South Korea MFDS, US FDA EUA, WHO EUL

FIND
Diagnosis for all

BUT COVID-19 ALSO SHOWED THAT

GAPS PERSIST IN PROCUREMENT & COUNTRY UPTAKE

ACTaccelerator
ACCESS TO COVID-19 TOOLS

Diagnostic goals

All countries able to deploy **affordable, quality tests**

LMICs supported to establish **effective test, trace, isolate strategies** and **surveillance**

Minimal disruption of **core health services**

Diagnostic priorities

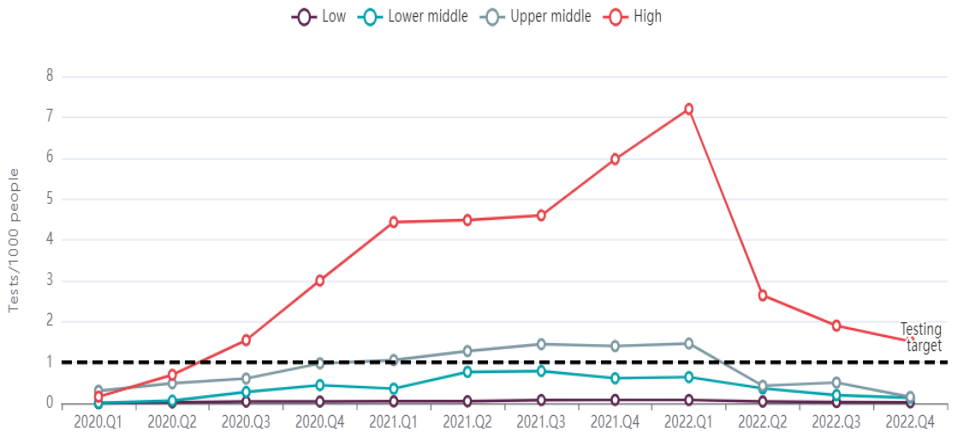
Scaled availability of affordable tests

Equitable access to tests

Rapid, effective country uptake

Diagnostic reality

Tests conducted per 1000 individuals



Testing rate per 1000 individuals per day Q1 20' to Oct 22'[1]

LIC: 0.02 **LMIC: 0.14** **UMIC: 0.15** **HIC: 1.51**

1. FIND. COVID-19 test tracker. www.finddx.org/covid-19/test-tracker (accessed 18 Sept 2020)

BUT COVID-19 ALSO SHOWED THAT

THE PATIENT JOURNEY NEEDS TO BE AT THE CENTER OF DX STRATEGY

POC PLATFORMS FOR SEPSIS AND 'BACTERIAL VS. VIRAL' TRIAGE

NanoEntek

- **NanoEntek,** FREND system
- **Multiplexing capacity:** Low
- **TAT:** <3 min
- **Technology:** Immunoassay
- **Panels:** PCT, hsCRP, others
- **Development status:** FDA platform, CE and FDA tests

abionic

- **Abionic**, abioSCOPE system
- **Multiplexing capacity:** Med (<13)
- **TAT:** 5-8 min
- **Technology:** Immunoassay
- **Panels:** sepsis (pancreatic stone protein, CRP, hsCRP, PCT)
- **Development status:** Platform is FDA registered and CE marked

MeMed

- **MeMed,** Key Platform
- **Multiplexing capacity:** Low
- **TAT:** 12 min
- **Technology:** Chemiluminescent immunoassay
- **Panels:** TRAIL, IP-10, and CRP signature
- **Development status:** BV test (Bacterial vs. Viral for peds to adults) is CE-IVD, FDA approved

Inflammatix™

- **Inflammatix** platform
- **29 m-RNA host response markers**
- **TAT:** 5-8 min
- **Technology:** Molecular
- **Panels:** InSep (presence, type, severity), ViraBac test (bacterial vs. viral)
- ***In development***

COMMERCIALIZED PLATFORMS WITH BLOOD CULTURE ID/AMR PANELS

HIGH-MULTIPLEXING NEAR-POC MOLECULAR PLATFORMS

BIOFIRE BY BIOMÉRIEUX

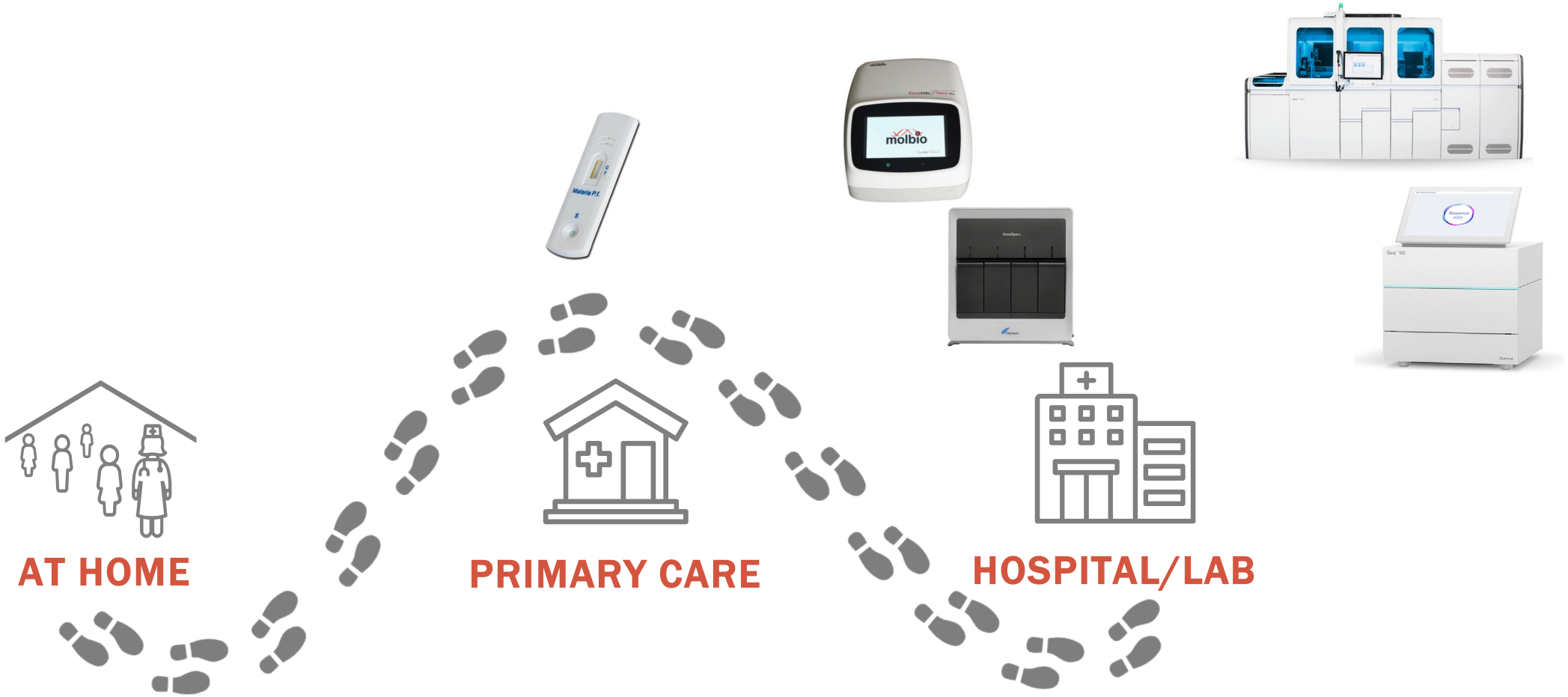
- **Multiplexing capacity:** High (~100)
- **Sample processing:** fully integrated
  Technology: PCR
- **Panels:** Commercial BCID panel and other syndromic panels
- **Price:** High

GenMark Dx

- **Multiplexing capacity:** High (72)
- **Sample processing:** integrated
- **Technology:** DNA hybridization/array
- Panels: Commercial BCID panels (Gram+/Gram-) and other syndromic panels
- **Price:** High

THE COMING DELUGE

PRE-PANDEMIC



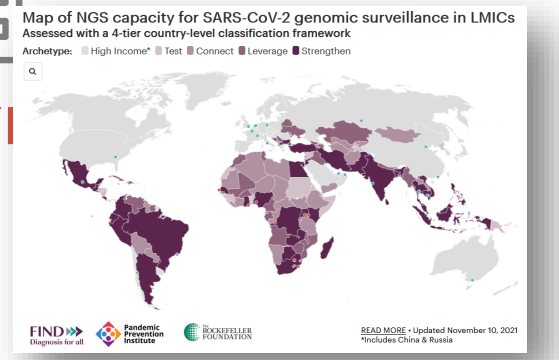
THE COMING DELUGE

COVID-19 DRIVEN INNOVATION

AT HOME

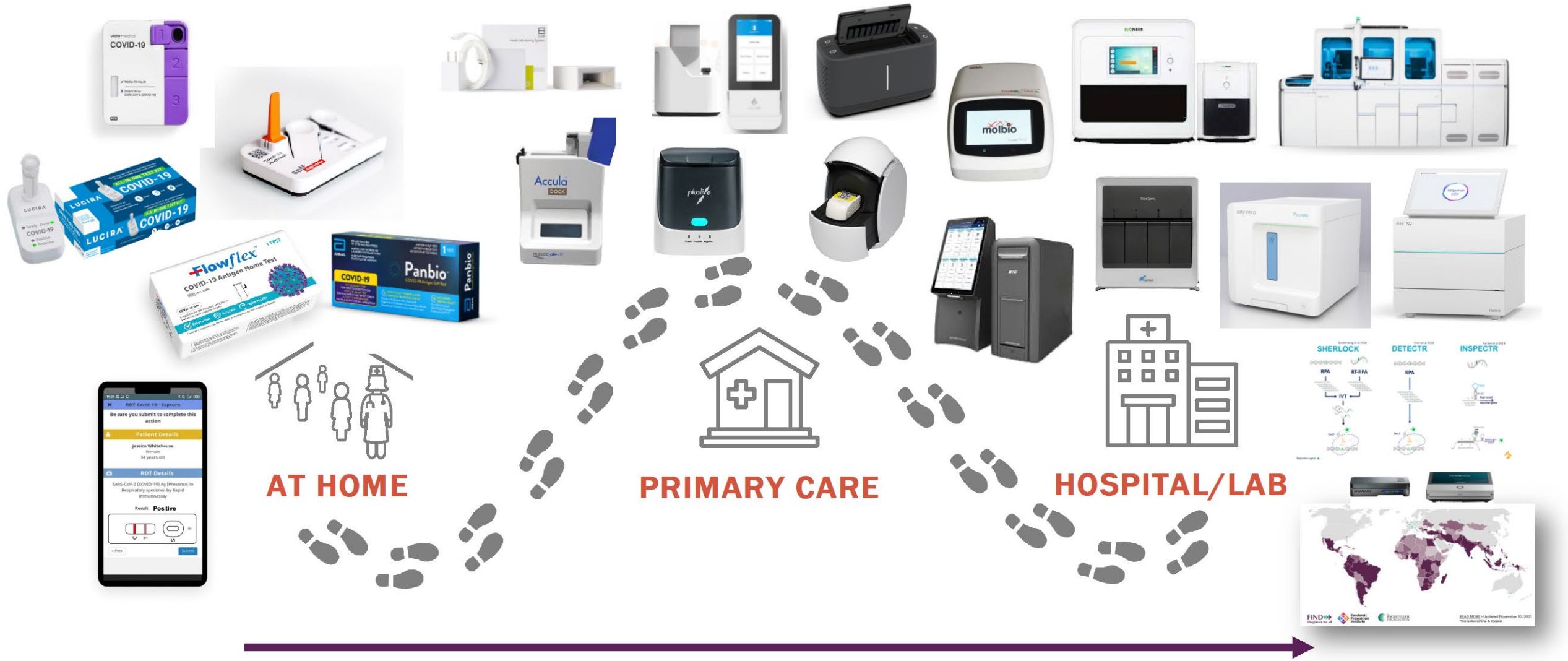
PRIMARY CARE

HOSPITAL/



Connected diagnostics and interoperable systems for data management, data aggregation and data sharing for surveillance

THE COMING EXPLOSION IN NEW POC MOLECULAR PLATFORMS



Connected diagnostics and interoperable systems for data management, data aggregation and data sharing for surveillance

FIND INVESTMENT PORTFOLIO – MULTIPLEXED PLATFORMS

	LEVEL 1-2 PLATFORMS		LEVEL 2 PLATFORMS	
	Biomeme	Qlife	SD Biosensor	Bioneer
Value to Market	Rugged, molecular platform suited for Level 1 settings	Multi-analyte system suited for Level 1 settings	Late-stage platforms offering competition, multiplexing capacity and expanded test menu (AMR, TB) in near term	
Multiplexing	27	8	12	40
In Market	COVID/Flu	COVID, CRP	COVID	HIV/HCV/HBV VL
Pipeline	STI, bacterial vs viral, food, water	COVID IgG-IgM, ALAT, PKU	TB, Zika/Dengue/ChikV, HIV/HCV/HBV VL	COVID, TB, STI, AMR
Funded activities	**Activity 1:** COVID/Flu Dev. and V&V **Activity 2:** System Optimization **Activity 3:** Manufacturing optimization	**Activity 1:** COVID/Flu Dev. and V&V **Activity 2:** System Optimization	**Activity 1:** COVID validation **Activities 2-3:** COVID/Flu/RSV development and V&V **Activity 4:** Manufacturing optimization and COGS reduction (automation)	**Activity 1:** COVID/Flu/RSV development and V&V **Activity 2:** Manufacturing optimization and COGS reduction (automation)
Endpoint	Q1'23: SRA submission of COVID/Flu test in ISP platform	Q1'23: SRA submission of COVID/Flu test	Q3'23: SRA submission of COVID/Flu/RSV	Q3'23: SRA submission of COVID/Flu/RSV
Commitment	$10.96-13.77/test (EXW, COVID/flu)	$9.98-14.98 ("all-in", COVID/Flu)	$9.98 (EXW, COVID) $14.98 (EXW, COVID/Flu/RSV)	$14.38 ("all-in", COVID/Flu/RSV)
Funding	$3,800-6,500 (EXW, instrument)	$500 (COGS, instrument)	$10,000 (EXW, instrument)	$10,000 (COGS, instrument)
	$5.5M	$3.45M	$6M	$6M

FIND INVESTMENT PORTFOLIO – TRUE POC (LEVEL 1) PLATFORMS

	INTRUMENT-FREE			INSTRUMENTED		
	Self-Diagnostics	Philmedi	Biocrucible (*)	Pluslife	Co-diagnostics	Sherlock Biosci. (*)
Value to Market	Potential for low-cost and multiplexing in an instrument-free test system	Early stage, but with relevant pipeline and potential for low-cost and multiplexing	Experienced team with approach to lowest-cost disposable	Lowest-cost, proven performance, real potential for multiplexing	Potential for broad sample type and volume & integrated sample prep	Proof-of-concept for CRISPR
Multiplexing	4	In development	None	7	6	5
In Market	COVID-19	None	None	COVID-19	None	None
Pipeline	STI	COVID-19, Malaria, TB, HIV	COVID-19	STI, HIV, HPV	COVID-19	COVID/Flu/RSV, STI (NG/CT)
Funded activities	COGS reduction of multiplexed product	V&V of COVID-19 test, and transfer to manufacturing	Proof-of-concept Gen2 device (lower cost and improved usability)	HPV 16/18/45 cartridge development	V&V of COVID-19 test	Platform development and verification of respiratory panel
Target COGS	<$5	< $10	<$2/test <$30/instrument	$2/test (achieved)	TBC	$5-15/test
Funding	$350K	$250K	$250K	$350K	No funding	$200K

* Companies are at early stage and still pursuing both an instrumented and an instrument-free version of their product

COVID-19 EXPERIENCE, CAN THIS BE APPLICABLE TO AMR?

CHALLENGES

Developers:

- Slow access to samples
- Lack of clear product requirements
- Insufficient regulatory harmonization

Demand and uptake:

- Complex global problem requiring collaboration across clinicians, epidemiologists, politicians
- Limited evidence to inform testing policy
- Market underprepared

SUCCESSES

Collaboration between academia and industry[3,4]

- Automated PCR tests available in 64 days from PHEIC
- Rapid diagnostic tests approved in 236 days

Increase demand from Governments, increasing manufacturing capacity and capabilities[5,6]

- Reduced costs for diagnostics
- Routinely updated guidance on test use and efficacy
- Increased access globally, including for LMICs where spread of genomic variants were tracked

LMICs, lower- and middle-income countries.

1. Venkatesan, P. (2020). COVID-19 diagnostics—not at the expense of other diseases. The Lancet Microbe, [online] 1(2), p.e64; 2. Ondoa, P., et al. (2021). Transforming access to diagnostics: how to turn good intentions into action? The Lancet, [online] 0(0). Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02182-6/fulltext; 3. Vandenberg, O., et al. (2020). Considerations for diagnostic COVID-19 tests. Nature Reviews Microbiology, 19(171–183); 4. G7 Pandemic Preparedness Partnership (2021). 100 Days Mission to respond to future pandemic threats. [online] gov.uk. Available at: 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; 5. WHO (n.d.). Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries. [online] www.who.int; 6. ACT now, ACT together 2020-2021 Impact Report", World Health Organization, April 2021.

WILL WE RISE TO THE CHALLENGE OF AMR?

While trillions have been spent to fight COVID-19 in just 4 months...[1]

US$12 trillion/year
have been lost in global production in 2020

US$10 trillion
have already been spent in stimulus packages and other support measures

US$40 billion is needed to tackle AMR over the next 10 years...[2]

US$3 trillion/year
will be lost in global production between 2016 and 2050[1]

US$40 billion
investment is needed over the next 10 years to tackle AMR

[1] *Ziyad Cassim, Borko handhiski. The $10 trillion rescue: how governments can deliver impact. https://www.mckinsey.com/~/media/McKinsey/Industries/Public%20Sector/Our%20Insights/The%2010%20trillion%20dollar%20rescue%20How%20governments%20can%20deliver%20impact/The-10-trillion-dollar-rescue-How-governments-can-deliver-impact-vF.pdf*

[2] *O'Neill J. Tackling drug-resistant infections globally: final report and recommendations. Review on antimicrobial resistance, 2016*

FIND

Thank you

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