

# STUDY ON THE AVAILABILITY AND AFFORDABILITY OF DIAGNOSTICS FOR COVID-19 AND MPOX IN LOW AND MIDDLE-INCOME COUNTRIES



MATAHARI



THE  
PEOPLE'S  
VACCINE

## IMPRESSUM AND ACKNOWLEDGMENTS

Date of Publication: January 2023

Author: Dr Fifa Rahman (Principal Consultant, Matahari Global Solutions)

Researchers: Dr Fifa Rahman and Dr Pedro Villardi (Matahari Global Solutions)

Suggested citation: People's Vaccine Alliance, 'Study on the Availability and Affordability of Diagnostics for COVID-19 and MPOX in Low and Middle-Income Countries' (2022)

The People's Vaccine Alliance (PVA) is a coalition of over 100 organisations, supported by Nobel Laureates, scientists, Heads of States and activists, working for a People's Vaccine, available free of charge to everyone, everywhere. PVA sought to analyse availability and accessibility of diagnostics for COVID-19 and MPOX in anticipation of discussions on an expansion of the TRIPS waiver, but also with the objective of understanding barriers to people in Low- and Middle-Income Countries accessing diagnostics considering regulatory mechanisms, supply chain barriers, as well as any policy barriers that prevent people in LMICs being able to access diagnostics when they needed it.

Matahari Global Solutions is a global health consultancy firm focusing on global health solutions with local relevance. Registered in Kuala Lumpur and with consultants based globally, our work has covered a wide range of global health issues, including pandemic response, transgender legal recognition and impact on access to healthcare, paediatric TB and impacts of advocacy, and the evaluation of multi-country HIV projects, across Africa, Asia, Eastern Europe and Central Asia, and Latin America.

Matahari Global would like to thank the People's Vaccine Alliance, in particular Julia Kosgei (Policy Advisor) who conceived the idea for this work and coordinated validation calls, and to Mohga Kamal-Yanni (Senior Health Policy Advisor) for her useful feedback and suggestions in the finalisation of this report.

This Report was informed by the experience and insights of numerous experts involved in access to affordable diagnostics. Our thanks to (listed alphabetically by surname):

Dr Ifedayo Adetifa	Director-General, Nigeria Centres of Disease Control and Prevention (NCDC)
Martin Auton	Senior Manager, Principal Recipient Services (Shaping Demand), Sourcing & Supply Chain Department, The Global Fund
Prof Brook K Baker	Senior Policy Analyst, Health GAP
Daniel Bausch	Senior Advisor, Global Health Security, FIND
Alexandra Bertholet	Deputy Director, Market Innovations, FIND
Willo Brock	Vice President, External Affairs, FIND
Stijn Deborggraeve	Senior Diagnostics Advisor, MSF Access
Devy Emperador	Senior Scientist, FIND
Dr Aytenew Ashenafi Eshete	Program Manager, Africa CDC
Dr Antonio Gomes Pinto Ferreira	Head of Diagnostics, Reagents Division & Laboratories, Bio-Manguinhos, Fiocruz
Dr Joe Fitchett	Senior Advisor for Biotechnology, Institut Pasteur de Dakar, Senegal
Dr Emma Hannay	Chief of Access, FIND
Arush Lal	Commissioner, Chatham House Commission for Universal Health
Dr Ramon Lemos Calaça	Specialist: Business Development, Bio-Manguinhos, Fiocruz
James Packard Love	Director, Knowledge Ecology International
Paul Molinaro	Chief of Logistics & Support, World Health Organization
Pascale Ondoa	Director of Science and New Initiatives, African Society of Laboratory Medicine (ASLM)
Jens Windahl Pedersen	Independent Consultant, Africa First Advisory
Irena Prat	Team Lead, In Vitro Diagnostics Assessment, Prequalification Department, WHO
Tatsiana Ptashnik	Contracts Manager   Malaria Prevention & Diagnostics, Health Technology Center, Supply Division, UNICEF
Mark Radford	Advisor, Impact Strategy & Projects, Global Access Diagnostics (GADx)
Dr Jilian Sacks	Technical Officer, COVID-19 Lab Team, Epidemic and Pandemic Preparedness and Prevention (EPP) Department, Health Emergencies Programme, WHO
Dr Ute Ströher	Technical Officer, In Vitro Diagnostics Assessment, Prequalification Department, WHO
Dr Toni Whistler	Laboratory and COVID-19 Diagnostics and Testing Specialist (US CDC Detailee), The Global Fund

## ABBREVIATIONS

<b>ACT-A</b>	Access to COVID-19 Tools Accelerator
<b>Africa CDC</b>	Africa Centres for Disease Control and Prevention
<b>AFRO</b>	Africa Regional Office
<b>AgRDTs</b>	Antigen Rapid Diagnostic Tests
<b>ARVs</b>	Anti-RetroVirals for HIV
<b>BARDA</b>	Biomedical Advanced Research and Development Authority (United States)
<b>C19RM</b>	COVID-19 Response Mechanism
<b>CE-IVD</b>	Certification for In-Vitro Diagnostics (European Union Directive IVDD 98/79/EC)
<b>CSOs</b>	Civil Society Organisations
<b>CBO</b>	Community-Based Organisation
<b>DRC</b>	Democratic Republic of Congo
<b>EUL</b>	Emergency Use Listing
<b>FCA</b>	Free Carrier terms (a price paid to a supplier that includes product delivery, handover, and clearance for export into the charge of a freight forwarder)
<b>FDA</b>	Food and Drug Administration (United States)
<b>FIF</b>	Financial Intermediary Fund (now known as The Pandemic Fund at the World Bank)
<b>HICs</b>	High Income Countries
<b>INGOs</b>	International Non-Governmental Organizations
<b>IP</b>	Intellectual Property
<b>IVD</b>	In-Vitro Diagnostics
<b>LMICs</b>	Low- and Middle-Income Countries
<b>MHRA</b>	Medical and Healthcare products Regulatory Agency (United Kingdom)
<b>MOH</b>	Ministry of Health
<b>NAT</b>	Nucleic Acid Testing
<b>NAAT</b>	Nucleic Acid Amplification Test
<b>PAHO</b>	Pan American Health Organization
<b>PCR</b>	Polymerase Chain Reaction
<b>PQ</b>	Prequalification (WHO)
<b>RDTs</b>	Rapid Diagnostic Tests
<b>SAATM</b>	Single African Air Transport Market
<b>SEARO</b>	South-East Asia Regional Office
<b>SRA</b> s	Stringent Regulatory Authorities
<b>TAG</b>	Treatment Action Group
<b>TB</b>	Tuberculosis
<b>WFP</b>	World Food Programme
<b>WHO</b>	World Health Organization
<b>WHO EUL</b>	WHO Emergency Use Listing Procedure
<b>WHO-PQ</b>	WHO Prequalification
<b>WTO</b>	World Trade Organization

## CONTENTS

<b>Impressum and Acknowledgments</b>	<b>2</b>
<b>Abbreviations</b>	<b>4</b>
<b>Introduction</b>	<b>6</b>
<b>Findings</b>	<b>9</b>
Regulatory barriers to timely diagnostics access	15
Intellectual property and technology transfer	18
Local production of diagnostics	23
Pricing of diagnostics: including differential pricing and transparency on prices	27
Supply chain challenges	30
Optimising procurement mechanisms	36
Impact of policies and guidelines on testing	40
Demand creation and testing literacy	43
<b>Recommendations</b>	<b>46</b>
<b>Conclusion</b>	<b>51</b>
<b>Annex: Diagnostics Procured by Global Health Agencies</b>	<b>52</b>
<b>Notes</b>	<b>53</b>

## TABLES AND FIGURES

<b>Figure 1</b>	
Regions where COVID-19 antigen rapid tests are manufactured	9
<b>Figure 2</b>	
Automated PCR Tests procured by the Supply Consortium in 2021	11
<b>Figure 3</b>	
Antigen RDTs procured by the diagnostics consortium broken down by region (July 2021)	12
<b>Figure 4</b>	
Types of MPOX tests in the market	13
<b>Table 1</b>	
Rapid Antigen Detection Tests that are included in WHO Emergency Use Listing	10

## INTRODUCTION

While there has been much publicised about the inequities in access to COVID-19 vaccines, dubbed in some outlets as ‘vaccine apartheid’<sup>1</sup> due to the overwhelming disparity in access between HICs and LMICs, relatively little has been written about diagnostics apartheid and the massive gaps in access faced by people living in and from LMICs. At time of writing, rapid self-tests are not available in most LMICs,<sup>2</sup> while throughout the pandemic, rapid self-tests have been available for free or at highly subsidised rates in HICs, including the United Kingdom, Canada, the United States, Switzerland, and Germany.

Alarming, in October 2021, the WHO reported that six in seven COVID-19 infections in Africa go undetected due to limited testing.<sup>3</sup> For MPOX, up to October 2022, people in remote regions of Africa continue to die of MPOX without access to testing, antivirals, or vaccines. In one article from the Democratic Republic of Congo, in the remote region of Tshopo in north-central DRC, there were 20 MPOX patients, including two who had died, with more than a dozen health workers testifying that there was a shortage of testing facilities. As a result, tracing the virus and close contacts of people with MPOX ‘nearly impossible’.<sup>4</sup>

Several countries have faced MPOX outbreaks for decades such as DRC, Central African Republic,<sup>5</sup> and Nigeria, but continue to have less testing than HICs that only recently have had outbreaks. According to WHO AFRO, while all African countries have PCR machines needed to test for MPOX ‘thanks to reinforced laboratory capacity in the wake of COVID-19, many continue to lack reagents and in some cases training in specimen collection, handling, and testing’.<sup>6</sup> Africa CDC continues to recommend, in its September 2022 outbreak brief, that countries establish laboratory diagnostic and genomic sequencing capacity for orthopoxviruses, including MPOX.<sup>7</sup> The same brief states that from August to September 2022, MPOX cases from DRC, Egypt, and Nigeria have increased by 50%, totalling 695 new cases in that period from these three countries alone.<sup>8</sup>

The barriers to accessing COVID-19 and MPOX tests exist in a larger diagnostics context – the need to optimise supply chains, the need to strengthen laboratory systems, reliance on foreign manufacturers, and the need to manage and diagnose infections that have been endemic for decades. Interviewees for this report described how government priorities in Africa at the time of writing had shifted away from COVID-19; and that self-tests had taken too long to reach countries in Africa. Amidst these concerns, there is ongoing work to revise country guidelines to integrate self-testing, to prepare community-testing guidelines, and to conduct training on self-tests, for example through Project Stellar, funded by the Global Fund,<sup>9</sup> and this is consistent with Africa CDC’s latest COVID-19 testing strategy that scale-up of Ag-RDTs, including self-testing, should be considered.<sup>10</sup> The strategy document further recommends integrated clinical evaluation of both TB and COVID-19 given overlapping symptoms – this will require streamlined procurement of both tests to ensure adequate supply, and training of health workers to ensure these are included as a matter of practice and priority.

Among the factors impeding access to rapid diagnostics, regulatory barriers have been singled out by global health procurers, with one stressing:

---

“Uptake was much lower than you would imagine because of (SRA approval) constraints. A lot of the frustrations around ‘where’s the testing’ came back to the issues around validation and registration of tests at both the country level and the global level with a set of similar barriers to jump through.”

This likely refers to WHO self-testing guidelines which were only released in March 2022,<sup>11</sup> and were a prerequisite for large procurers to purchase and deploy self-tests. Through the COVID-19 pandemic, while competition saw procurement prices for PCR tests reduce, costs to the consumer varied greatly, ranging from US\$11 in Kenya to US\$55 in Philippines – the latter costing approximately two days wages for the average Filipino.<sup>12</sup> These illustrate the need to both drive pricing down, to invest in pooled procurement to ensure consistent pricing and local production, and to prevent out of pocket spending by ensuring diagnostics are covered under universal healthcare initiatives.

Considering these realities, over the course of October–November 2022, we conducted a desk review of testing databases, available literature, and data from the COVID-19 diagnostics supply consortium to identify where tests were being manufactured, what prices tests were available for, and who was procuring them. In addition, in-depth interviews were conducted with 13 diagnostics experts across multiple global health agencies and government agencies, and written information was obtained from an additional four experts. Experts were interviewed guided by a semi-structured questionnaire covering the following themes: availability, funding for R&D (research and development) and production, affordability, procurement, regulation and delivery, intellectual property and technology transfer, and access to self-testing. Preliminary results were presented to the PVA Policy and Advocacy working group on 4<sup>th</sup> October 2022, attended by 20 experts who validated preliminary findings and made suggestions for improvement.

Overall, we found that availability and affordability of COVID-19 tests were constrained by slow regulatory processes, high prices, and conservative/non-timely policies around surveillance/epidemiological data collection value of PCR testing versus access value of rapid antigen tests. For MPOX, at time of writing while there are some rapid antigen tests on the market, there is an absence of evidence on sensitivity and specificity of these tests, and thus countries continue to rely on PCR tests that are often conducted in centralised laboratories which are located far away from communities that need them. Prices were influenced by procurement policies, the reliance on overseas suppliers of tests, insufficiently optimised supply chains, and in the case of automated GeneXpert PCR tests, intellectual property provisions that restrict competition for production of more affordable cartridges. Given that there are more than 40,000 GeneXpert systems installed in over 180 countries, it is essential that competition occur to ensure affordability and accessibility of tests.<sup>13</sup>

This report makes several recommendations, including:

- Increased investment for the local production of diagnostics along the entire pipeline, to reduce reliance on foreign supplies.
- Diversification of molecular platforms available to reduce reliance on patented technologies and monopolies, especially for near point-of-care platforms.
- Achieving a balance on testing policies/philosophies both at national and country level – i.e., molecular diagnostics are essential for surveillance/epidemiological data collection and trend mapping but in many environments, they remain out of reach during pandemic times, and rapid testing must be expedited as a matter of the right to health.
- Expansion of the WTO June 2022 TRIPS ministerial decision to include diagnostics, ensuring that during pandemic times, manufacturing of diagnostics technologies can be replicated and be made available at cheaper prices.

And while these findings are drawn from COVID-19 and MPOX data and insights, they are illustrative of barriers that will continue in any pandemic, irrespective of pathogen. At time of writing for example, Uganda is grappling with the Sudan variant of the Ebola virus without rapid tests for this strain and laboratories 'making do with mobile PCR test laboratories' that provide results in 4-6 hours.<sup>14</sup> While viral load for Ebola in the early stage of the disease may be too low for antigen rapid test detection, improved diagnostics strategies are necessary across the world. Rapid response in the next pandemic is dependent on ensuring improvements across the board and robust strategies on diagnostics.

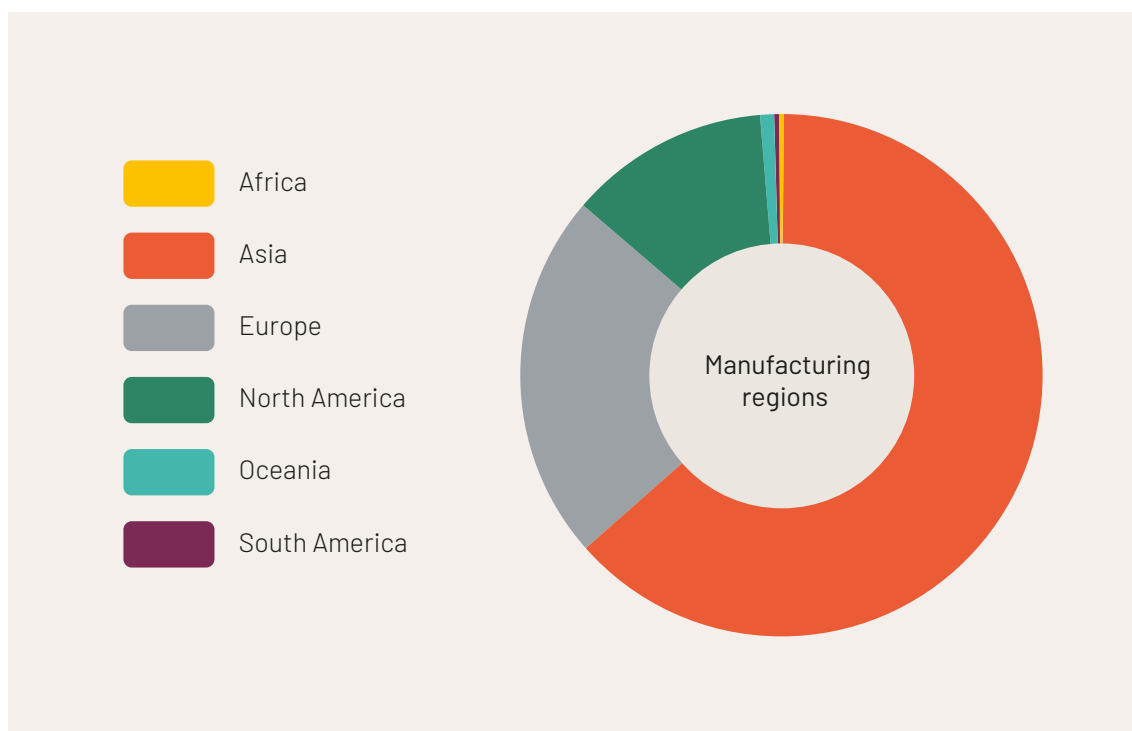


## FINDINGS

According to the FIND (the global alliance for diagnostics) COVID-19 test directory, there are 1,094 COVID-19 rapid antigen tests (cassette or strip tests) in the market with the majority manufactured in Asia (see Figure 1). As of 8<sup>th</sup> November 2022, 36 diagnostics products met WHO EUL requirements including ten (10) rapid antigen detection tests (manufactured by PMC, Abbott, SD Biosensor, Guangzhou Wondfo Biotech, and others), and three rapid antigen self-tests (see Table 1, below).<sup>15</sup> Of the large procurers, reference prices for professional use antigen RDTs at the Global Fund are between \$0.78-\$2.25, and for antigen RDT self-tests they are \$1.00-\$5.00. These prices are all “ex works”, meaning they do not include shipping and customs costs. Whereas the UNICEF Supply Division sets procurement of professional use antigen RDTs at US\$2.25 per test (Abbott), US\$2.20 (SD Biosensor), and US\$1.95 (PMC).<sup>16</sup> The types of tests procured directly correspond to diagnostics approved by the WHO EUL and to WHO guidelines.

The OnSite COVID-19 Ag Self-Test Kit, manufactured by CTK Biotech Inc, is available for procurement through the UNICEF Supply Division. The product is offered at an FCA-based price (rather than ex-works price) of US\$1.30 - 1.95 per test.<sup>17</sup>

**FIGURE 1:** REGIONS WHERE COVID-19 ANTIGEN RAPID TESTS ARE MANUFACTURED



**TABLE 1:** RAPID ANTIGEN DETECTION TESTS THAT ARE INCLUDED IN WHO EMERGENCY USE LISTING

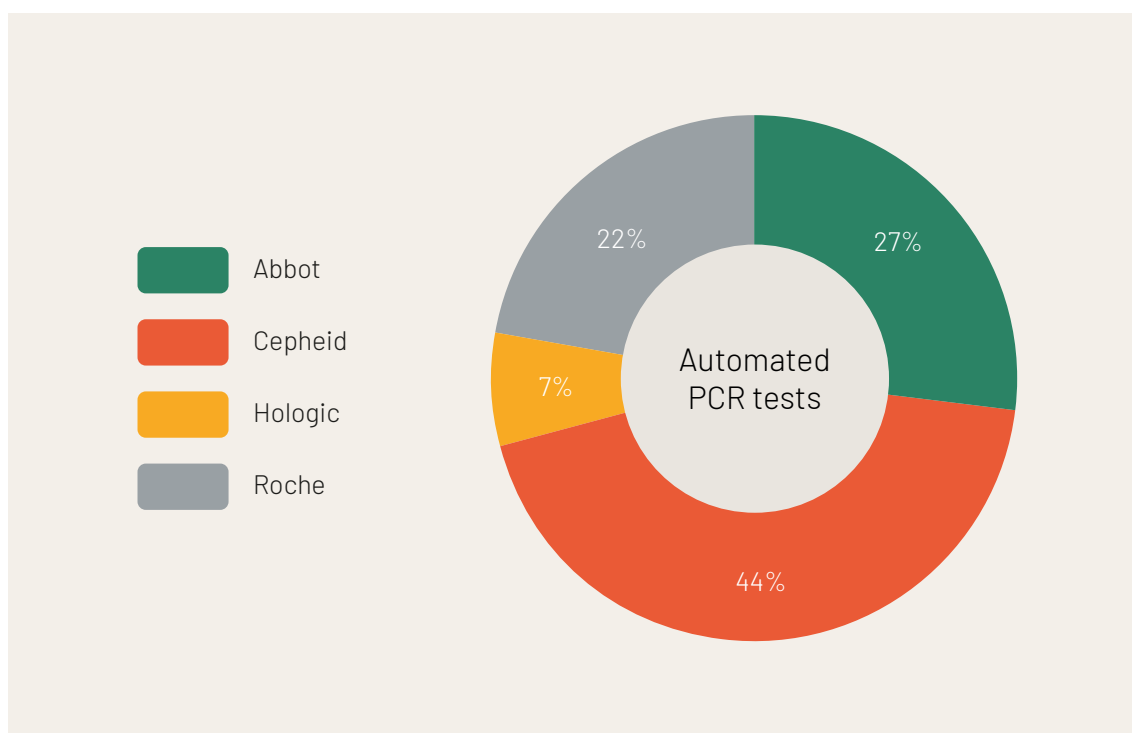
Date Listed	Manufacturer	Product Name
27 October 2022	Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag
11 August 2022	Artron Laboratories Inc.	Artron COVID-19 Antigen Test
18 July 2022	Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method
6 June 2022	Shanghai Kehua Bioengineering Co. Ltd.	Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)
13 May 2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test
4 April 2022	Acon Biotech (Hangzhou) Co. Ltd	SARS-CoV-2 Antigen Rapid Test (Flowflex)
1 February 2022	CTK Biotech, Inc.	OnSite COVID-19 Ag Rapid Test
17 March 2021	Premier Medical Corporation Private Limited	Sure Status COVID-19 Antigen Card Test
19 November 2020	Abbott Rapid Diagnostics Jena GmbH	Panbio COVID-19 Ag Rapid Test Device (NASAL)
2 October 2020	Abbott Rapid Diagnostics Jena GmbH	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)
22 September 2020	SD Biosensor, Inc	STANDARD Q COVID-19 Ag Test

There are 681 molecular tests for COVID-19 according to FIND's COVID-19 test directory, with 8 automated PCR tests (ranging from US\$10.00-US\$17.00, with the exception of the Biofire Respiratory Panel by BioMerieux at US\$107 per test) on Global Fund's Pooled Procurement Mechanism and 16 manual PCR tests. The COVID-19 pandemic saw the Global Fund – through its C19RM programme – scale up an installed base of over 10,000 GeneXpert devices for automated PCR testing, allowing a massive scale-up of COVID-19 molecular testing in LMICs.<sup>18</sup>

According to data from the WHO-led Diagnostics Supply Consortium, a procurement consortium linked to the Access to COVID-19 Tools Accelerator, approximately 44% of automated PCR tests procured in 2021 were manufactured by Cepheid, i.e., were tests used with GeneXpert machines (see Figure 2). Of all automated PCR tests procured by the Supply Consortium, a total of 6.34 million were delivered to 105 countries in 2021, an average of 60,380 tests per country over the year.<sup>19</sup> In the same period, 11.3 million manual PCR kits were delivered, 34% of which were BGI, 24% were

ThermoFisher, followed by TibMolbiol (3%) and 4.4M from other brands.<sup>20</sup> According to the WHO, the product mix reflects individual country requests, which in turn reflects their machine install base at the time. Supply Consortium data indicates that 66.06 million antigen RDTs have been delivered to 129 countries, with 45% of these countries located in the WHO AFRO region followed by 26% in the WHO PAHO region and SEARO (14%).<sup>21</sup>

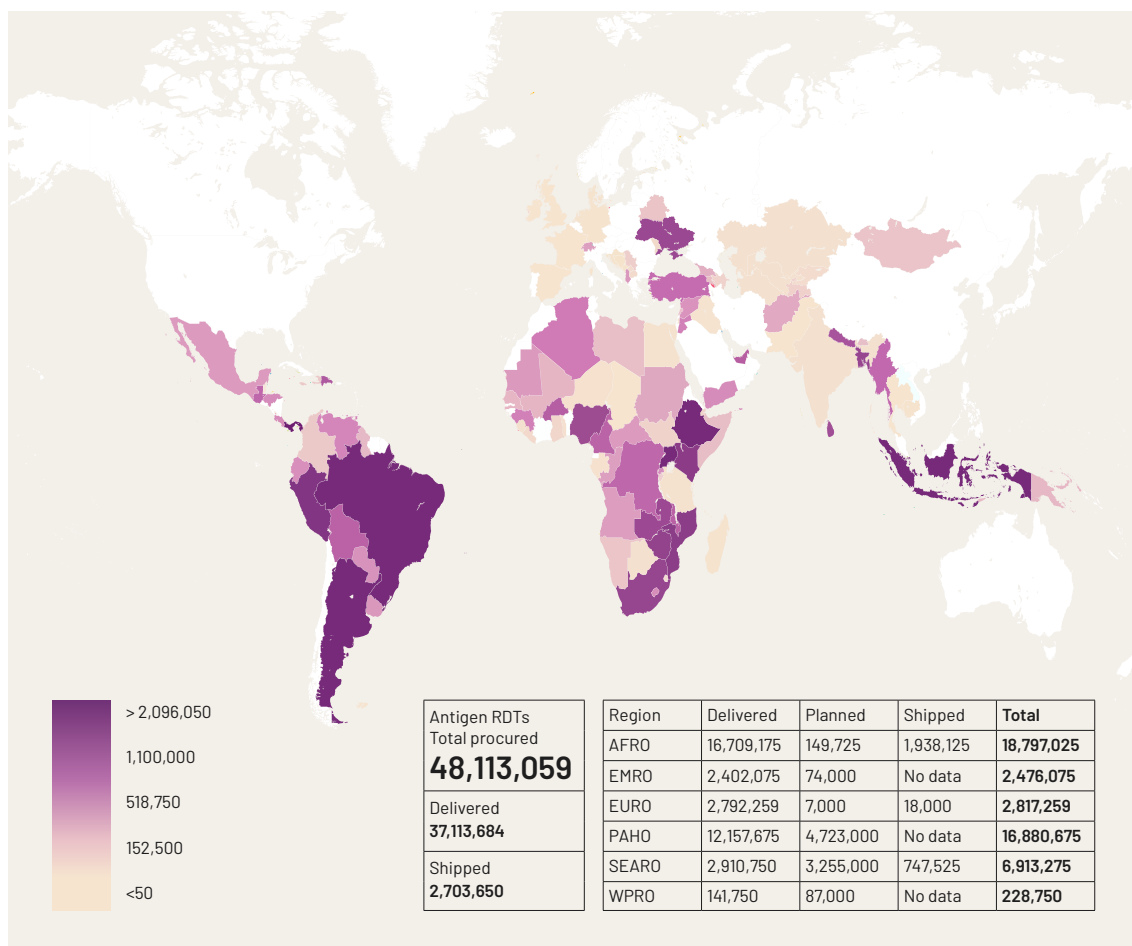
**FIGURE 2: AUTOMATIC PCR TESTS PROCURED BY THE SUPPLY CONSORTIUM IN 2021**



While over 16 million tests were delivered to the WHO AFRO region by July 2021, the below map (see Figure 3) is illustrative of the disparity in supply between various countries in each region – with Ethiopia receiving upwards of 2 million antigen rapid tests over the pandemic through to July 2021 versus Niger and Chad receiving lower volumes from the supply consortium at this time.

As WHO procurement occurs by request of member states who request specific products based on decisions made at country-level, this disparity may also reflect the fact that Niger and Chad had not expressed a demand for antigen rapid tests at that stage of the pandemic, i.e., the second half of 2021. It should be noted that at this time there were no restrictions in the allocation of antigen RDTs, hence Niger, Chad, and other countries could have requested antigen RDTs per their needs without a supply constraint.<sup>22</sup> These low volumes for countries like Niger and Chad may point to domestic policies preferring PCR – and also to WHO policy during mid-2021 that was still preferential towards PCR testing and was subsequently updated in October 2021 to be more permissive of rapid testing.

**FIGURE 3: ANTIGEN RDTs PROCURED BY THE DIAGNOSTICS CONSORTIUM BROKEN DOWN BY REGION (JULY 2021)**



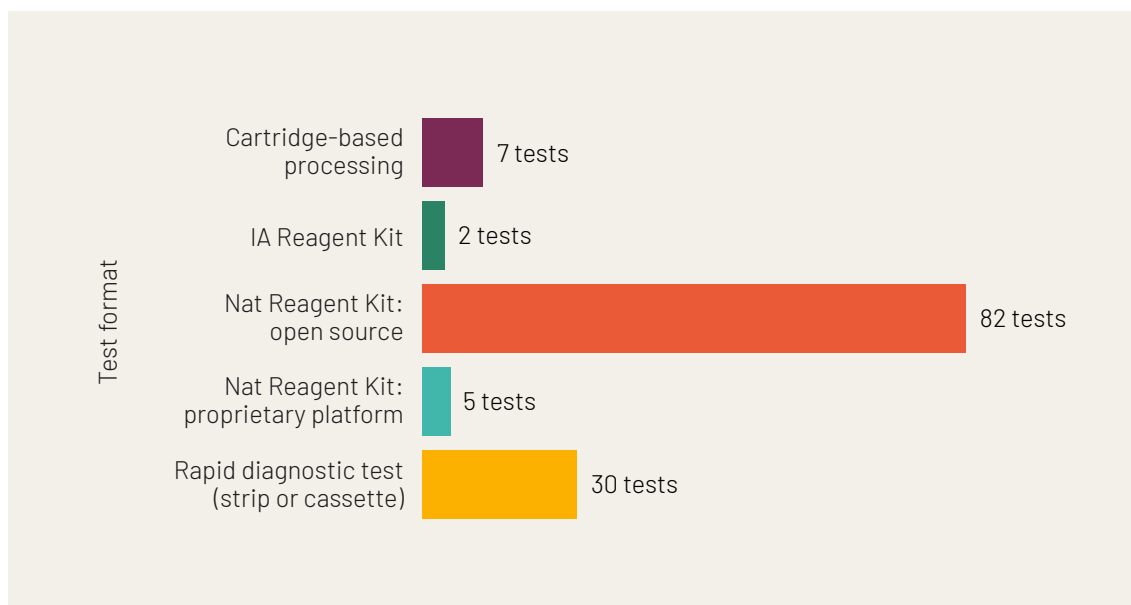
The June 2021 Global Fund COVID-19 update to the Board also describes ‘lower than anticipated demand’<sup>23</sup> of antigen RDTs at this time, with only \$62 million (9.3%) of total \$666 million in C19RM disbursements used for AgRDTs versus \$115 million (17.2%) for PCR tests.<sup>24</sup> Given that products procured by the Global Fund are also dependent on individual country requests and on WHO policies, this suggests a strong link between the WHO position on AgRDTs and country uptake.

For MPOX, there are 81 tests using open-source NAT reagent kits and 23 strip or cassette-based rapid antigen tests,<sup>25</sup> although none of the latter have been assessed by WHO. WHO PQ, in an interview with our team, stated that at time of writing there is insufficient evidence that antigen tests are sufficiently sensitive to detect MPOX with sufficient accuracy and that more data is needed.<sup>26</sup> A November 2022 report commissioned by Unitaid featured a number of MPOX rapid tests including the Oxford Orthopox Rapid Test and Tetracore Orthopox Biothreat Alert test, however both need further validation with human samples<sup>27</sup>

In practice, only laboratory PCR testing in reference centres is deemed valid/authoritative as at time of writing there are no prequalified point-of-care diagnostics tests. However, in January 2023, the WHO launched a public consultation process on target product profiles for MPOX diagnostics, including for MPOX antigen tests to be performed outside of healthcare facilities, within the community, including rural environments.<sup>28</sup> In June 2022, Cepheid announced a partnership to develop a MPOX test suitable for its GeneXpert machines.<sup>29</sup>

Given that there are over 40,000 GeneXpert systems installed over 180 countries, this would enable widespread deployment provided affordability of cartridges and reagents.<sup>30</sup>

**FIGURE 4: ANTIGEN RDTS PROCURED BY THE DIAGNOSTICS CONSORTIUM BROKEN DOWN BY REGION (JULY 2021)**



Our interviews indicate that at time of writing no information is available on procurement price differences between HICs and LMICs. However, based on FIND data, MPOX NAAT tests range between US\$5 to US\$40 per test,<sup>31</sup> which are not affordable for many LMICs.

Widespread and long-term access is dependent on price points reducing – and according to Mariângela Simão, the outgoing WHO Assistant Director-General for Access to Medicines and Health Products (quoted in *The Lancet*),<sup>32</sup> the WHO is working with manufacturers to develop rapid diagnostic tests for MPOX and to ensure they are accessible for LMICs.

Significant barriers exist as to the accessibility of tests in LMICs, and especially for those living in rural areas or areas with significant insecurity. Reagents specific to MPOX are often only available in central labs, meaning that persons living far from central labs are unlikely to receive diagnoses. According to Dan Bausch, Director, Emerging Threats and Global Health Security at FIND:

“(MPOX tests) are relatively centralised – there aren’t many labs that do it. So (accessibility) depends on where you are in the world and how centralised that is. If you’re in New York or London – that would be a different scenario compared to if you are in Bangui (Central African Republic), or even worse, 100 kilometres outside Bangui. And in worse case scenarios, there are considerable security issues combined with the fragility of supply pipelines and getting new reagents. These things are always a challenge and so these are major issues in accessibility of MPOX tests.”

The following pages disaggregate key findings and a multitude of key barriers to availability and affordability of both COVID-19 and to a lesser extent MPOX diagnostics by theme, followed by a set of recommendations to governments, global health agencies, donors, and communities.

## REGULATORY BARRIERS TO TIMELY DIAGNOSTICS ACCESS

National regulatory authorities and institutions like the WHO PQ with a quality assurance mandate play an essential role in validating diagnostic tools for quality. During the pandemic, the Emergency Use Listing (EUL) was the mechanism through which validation occurred – with the ‘ultimate aim of expediting the availability of products to people affected by a public health emergency’.<sup>33</sup> According to Irena Prat, Team Lead for In-Vitro Diagnostics, at WHO PQ, EUL “is not aimed at ensuring the highest stringency of review as one would do in a normal situation outside a pandemic. But it is there to help us figure out which products are properly validated, and which manufacturers have a sufficiently robust quality management system in place so that when a patient is exposed to one of these products, we can be sure that the result given is the right one and that the patient can rely on that result in the context of a public health emergency.”

During the COVID-19 pandemic, regulators came under criticism. For example, one interviewee stated that ‘many regulators, even in higher income environments, ended up being unnecessarily slow and/or inconsistent in their approach’. In the case of WHO EUL, this resulted for example in “just a handful of tests being approved within any kind of useful timeframe, which in turn may have impacted on pricing of approved tests.”<sup>34</sup> Dr Aytenew Ashenafi Eshete, Program Manager in the Laboratory Systems and Networks Division for Africa CDC also said a big challenge was that many COVID test kits were not validated, and that ‘very few realtime PCR and point-of-care antigen tests’ have been approved by or received emergency use listing from WHO PQ. For MPOX, said Africa CDC, the challenges were different in that the tests on the market were specified only for research purposes, and thus were not suitable for wider public health use nor were they easily available on the market.

From a WHO perspective, challenges remain towards speedy assessment of quality diagnostics during pandemic times. Experts from WHO PQ told us that based on their experience through the pandemic, manufacturers continue to struggle in properly validating their products and in ‘submitting a compelling dossier for our review’.<sup>35</sup> This includes information that is of ‘such poor and summarised quality that we are not able to (adequately) assess and this leads to several rounds of requesting additional information’.<sup>36</sup>

WHO PQ is well-known for having a small, underfunded team. One report for example describes how the team is ‘heavily reliant on external consultants to perform essential work’ and that PQ staff ‘must manage essential work while facing increasing numbers of applications during the COVID-19 pandemic’.<sup>37</sup> These factors mean that the regulatory system as is delays access to diagnostics and is unsuited for speedy deployment of diagnostics during emergency periods such as during public health emergencies of international concern. One diagnostics expert interviewed for this report who said that ‘we have no clue whether MPOX rapid diagnostics tests work or not’ and that while WHO PQ was the main process for approval of these products, the under-resourcing of WHO PQ did not bode well for swift approval of rapid diagnostics.

The question then arises about the complementarity of WHO PQ and the so-called ‘stringent regulatory authorities’ (SRAs) like the United States FDA and Germany’s Federal Institute for Drugs and Medical Devices, the former of which authorised the Abbott BinaxNOW COVID-19 Antigen Self-Test on 31<sup>st</sup> March 2021,<sup>38</sup> a full year before WHO released guidelines on rapid antigen self-tests,

and with the latter authorising the use of three antigen self-tests in February 2021.<sup>39</sup> Given the speediness of SRAs in contrast to WHO PQ, test manufacturers may be reluctant to submit dossiers to WHO despite the reliance of many LMICs on their guidance and PQ approvals, suggesting the need to clarify and streamline procedures.

Few jurisdictions have emergency mechanisms for MPOX diagnostics, with the United States FDA only just opening up emergency authorisations in September 2022.<sup>40</sup> According to Devy Emperador, Senior Scientist at FIND, there are 'a few developers that have CE-IVD,<sup>41</sup> some with MHRA UK approval, and only one test with multiple country regulatory approvals."<sup>42</sup>

Dr Jilian Sacks, Technical Officer in the COVID-19 Lab Team at WHO stated that at time of writing, robust data on the validity and accuracy of these rapid tests from manufacturers was still forthcoming:

---

"In brief conversations I've had with a few manufacturers, it's clear that the global community is widely sharing sequencing information and given there is published data from before on this virus, companies were able to develop prototype products very rapidly but they haven't necessarily clinically validated these products. However if you ask a company when in the course of this disease can you use this product; I haven't seen any data from the companies to actually inform this."

Several interviewees spoke about the need for regional approaches, including well-funded regulatory authorities at the regional level to act speedily during pandemics, and for better regulatory harmonisation, including common evaluation protocols and common regulatory frameworks at the regional level. The African Medical Devices Forum was cited as a body that works predominantly as a harmonisation initiative doing important work – but that more work was needed. In discussing regulatory barriers during the validation meeting held on 4<sup>th</sup> October 2022, James Packard Love, Director at Knowledge Ecology International stated that it was imperative that countries invest in domestic regulation capacity and/or invest in building more global or regional capacity.

Dr Pascale Ondo, Director of Science and New Initiatives for the African Society of Laboratory Medicine (ASLM), however, emphasised, however, that regulatory barriers were only one aspect of the story on access. Notably, Ondo said:

---

"Even if diagnostics are regulated, that doesn't guarantee that these diagnostics are going to be available in a country because of issues such as supply chain and (workforce) challenges. Diagnostics networks and laboratories are underfunded and under capacity. And while it is difficult to give one reason, there is just not enough labs and workforce that can actually carry out tests."

This was echoed by an expert from the Global Fund, who stated that there remain many barriers within countries' own laboratory system infrastructures, including problems with specimen referral and with validation and verification<sup>43</sup> – illustrating that while regulatory barriers are significant, these issues exist within a larger diagnostics landscape; one that is underfunded and under-resourced.



**SUMMARY OF FINDINGS**

The regulatory environment currently does not provide for an optimal pandemic response due to multiple factors, including underresourcing at the WHO, poor quality of dossier submissions to the WHO, and the non-existence or poor reliance on regional regulatory bodies. Increased training to manufacturers on PQ/EUL procedures, streamlining of procedures, regulatory harmonisation, and increasing reliance and robustness of regional regulatory institutions is necessary to address these barriers before the next pandemic.

**RECOMMENDATIONS**

- Countries to allocate resources for domestic regulatory capacity or invest in regional regulatory capacity.
- Sharing and utilisation of results from SRAs (e.g., US FDA, EU) to support regulatory review and approvals in LMICs.
- WHO to develop more clarity on the impact of SRAs on its own PQ processes – similar to how it has done in the field of HIV with ARVs.
- Pending domestic capacity strengthening, establish clear policies of reliance on other SRAs where international processes are insufficiently agile.
- Additional training for manufacturers on WHO PQ/EUL procedures.
- Increased funding and more staffing for WHO PQ.

## INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

The patent for PCR with Taq polymerase was filed on 17 June 1987<sup>44</sup> and patents run for 20 years from date of first filing, meaning that the patent is now expired. While there are patents for PCR methods using modified primers filed in 2015, for example, patents for the basic technology have all expired and do not impede the ability for manufacturers to replicate the technology. Patents are a barrier to manufacture certain cartridges for molecular tests, such as the patent applying to the GeneXpert cartridge filed by Cepheid in December 2017, with an anticipated expiry date on 11 December 2037.<sup>45</sup>

There are further patents, including one that patents the universal docking bays and data doors featured on GeneXpert devices,<sup>46</sup> with anticipated expiry in September 2033. This means that there would be a patent barrier towards replicating the cartridge suitable for use in GeneXpert machines and in replicating the exact docking bays.

Relevant also are trade secrets that apply to certain diagnostics. An example provided by MSF Access Campaign<sup>47</sup> was trade secrets surrounding GeneXpert cartridges and the fact that there was no technology transfer or sharing of information that would enable LMIC manufacturers to replicate the cartridges. These facts, however, are specific to the GeneXpert technologies. According to one expert from Institut Pasteur Dakar, “A lot of people can make them (PCR tests and rapid tests). Some people make things better (than others) – but there’s so much competition and it shows that there’s not too much challenge in it.” These raise important questions about local production of tests to improve accessibility, described in the section on local production [below](#).

Given that there are more than 40,000 GeneXpert systems installed in over 180 countries,<sup>48</sup> there is an extensive reliance on these platforms and will continue to be for the lifetime of the applicable patents. When asked about what is needed for future pandemics vis-à-vis diagnostics platforms, WHO’s Chief of Logistics and Support described how interoperability of platforms would be key:

---

“On the manual PCR we as WHO were able to deploy fairly quickly, because we were using assays that were not platform specific. Interoperability is going to be key. And the more adaptable platforms we have, the better. GeneXpert is a fantastic innovation where you really need point of care diagnostics as fast as possible and it’s less messy and less risky to use. We had a lot of demand for it (during the COVID-19 pandemic). It is a very good platform for the Pacific Islands, for very rural parts of DRC, or Central African Republic. There’s no denying the innovation of (the platform), but it’s kind of a monopoly.”

According to RDT manufacturers we spoke to for this report, patents and trade secrets are less of an impediment to the manufacturing of rapid antigen tests – rather this is more dependent on know-how and supply of necessary components such as cassettes. According to Mark Radford, Advisor, Impact Strategy & Projects of Global Access Diagnostics, a social enterprise focused on delivering rapid diagnostics and reinvesting 100% of their profits to increase access to diagnostics, during the COVID pandemic trade secrets ‘were not a significant factor in limiting availability of

lateral flow tests to different geographies', but that the story was 'probably different' as regards molecular testing.

There are advancements in point-of-care molecular testing that are also subject to multiple patents. The Pluslife Integrated Nucleic Acid Testing Device: Mini Dock by Guangzhou Pluslife Biotech Co. Ltd is a handheld molecular diagnostic that can return results in 15 minutes, with 98.91% sensitivity and 100% specificity. The device can detect SARS-CoV-2 but has the potential for multi-pathogen detection. A patent application was filed on the in-vitro detection device and detection card on 17 June 2020 and is anticipated to expire on 17 June 2030.

MPOX assays are being developed by Chinese researchers using CRISPR technologies – and preprints indicate high selectivity and the ability to distinguish between MPOX and other orthopoxviruses. Given high unit prices of CRISPR technologies, these are likely to remain inaccessible to people in LMICs.<sup>49</sup>

Given poor accessibility of diagnostics in LMIC during the COVID-19 pandemic, handheld multiplex molecular diagnostics could be a game-changer for future pandemics, however patents are likely to restrict competition and ensure that prices remain artificially high.

For molecular diagnostics generally, a waiver of IP alone is insufficient to enable the engineering of cartridges and other components for use in GeneXpert machines. One diagnostics expert interviewed for this report stated:

---

"(On GeneXpert) – there are no generic products and there is no technology transfer. Because of trade secrets, you need more than the patent (waiver) to be able to reproduce the GeneXpert cartridge. It's an important point and I think it was a big mistake by the TRIPS waiver not to cover diagnostics."

Technology transfer was described by Dr Ifedayo Adetifa as needed 'across the board', and as affecting pricing of molecular tests and sequencing consumables particularly heavily. In Dr Adetifa's own words:

---

"Especially for reference labs and laboratory function, our perspective as the Nigeria CDC is that we need tech transfer for molecular tests as they cost an arm and a leg and are not readily available. The way trade agreements have worked out is that you might actually find the less resourced country is paying more than a richer country. For sequencing consumables, we probably pay more per genome than my colleagues elsewhere pay just because, for example, Illumina until recently had no presence on the continent. And they were no arrangements with African countries and others to really put together all the orders into large orders to put us in a better position to negotiate for preferential prices and to still make things available for when they are needed. There's a lot more that needs to be done in that area, because the platforms are proprietary."

In other words, tech transfer and subsequent local production can lower prices. Current high prices is attributed to multiple factors, including a lack of presence of HIC manufacturers and suppliers on

the continent, a lack of coordination between countries on pooled procurement, poor tech transfer, and the intellectual property that binds countries to arrangements with originator manufacturers.

A 2011 WHO report on increasing access to diagnostics through tech transfer stated that ‘transfer of health-related technologies has been credited with the potential to build health security, increase reliability of supply, decrease reliance on imports, lead to lower prices, and encourage development and production that is more suitable for local health needs.’<sup>50</sup> This is illustrated by Bio-Manguinhos Fiocruz in Brazil, who was able to produce their own molecular and rapid diagnostic tests, and to scale testing up during the COVID-19 pandemic. In an interview, Fiocruz experts described that technology transfer in the past was the reason why they were able to respond quickly to the pandemic and locally produce diagnostic tests. In the words of Dr Antonio Ferreira, Head of Diagnostics:

---

“We got to this level largely because of technology transfers in the past. In the past, we had to go after the companies (to get technologies). Nowadays, the companies come to us. Fiocruz and the Brazilian market are very attractive to the big players, they see us as having big potential.”

And while Bio-Manguinhos is able to respond quickly to pandemics via local competence on manufacturing and in processing tests, technology transfer and R&D partnerships continue to occur to increase competence via automation. Dr Ferreira describes this:

---

“We already had the technological basis to respond (in terms of diagnosis) to the pandemic, but we needed to sign agreements with partners to scale-up production (of rapid tests). Processing 100,000 tests/day is something we didn’t ordinarily do, and it was one of the things we conquered while facing COVID. We were able to establish partnerships that allowed us to incorporate competence and know-how and now we are investing in automation that will allow us to increase the scale even further. It was a process of absorbing know-how, but not exactly a straightforward process. For molecular tests, we had a partnership to supply inputs, but we were the ones who made the adaptations to reach 2-3 million tests/month. This without any external participation.”

The expertise inherent to Bio-Manguinhos Fiocruz created economic and public health value that could be replicated across other LMICs and regions. There is ongoing work funded by FIND and Unitaid to support technology transfer to LMICs with a Californian company, transferring technology to WAMA Diagnóstica in Brazil and Mologic and Bionote transferring technology to diaTROPIX at the Institut Pasteur de Dakar in Senegal, with the aim of commercialising tests under its own brand and producing 2.5 million rapid diagnostic tests per month by 2022.<sup>51</sup> At time of writing, diaTROPIX is building an expanded facility for both manual and semi-automated manufacturing processes in Mbao, approximately 28kms northeast of the original facility.<sup>52</sup> The WHO COVID-19 Technology Access Pool (C-TAP) also facilitated technology transfer from Spain’s National Research Council (CSIC) via a non-exclusive sublicense to allow companies to manufacture antibody tests, with BioTech Africa being the first company in Africa to collaborate with C-TAP to develop affordable COVID-19 surveillance devices.<sup>53</sup> Accompanied with facilitative trade agreements and streamlined distribution routes, these efforts are positive steps towards increasing test accessibility in Africa.

According to Dr Pascale Ondo, technology transfer is necessary as part of a national health security agenda – and the example of diaTROPIX should be replicated across Africa. In Dr Ondo's own words:

“(Technology transfer) is a gap to fill. I think that as long as the conversation stays focused on solving a problem of national or regional security and when you have an emergency and you need to have access to those to those medical products that are going to help you contain the threat, we can continue to focus on tech transfer. (We must address) the issue of trust in African locally made diagnostics so people really think that there's enough quality and reliability – and then surely it can be scaled up. I think there should be more diaTROPIX across the continent, and not necessarily on finished products. Sometimes, if you think about bacteriology testing, we need buffers and things that aren't completely finished diagnostic products but rather the commodities and the reagents that goes into the diagnostic – I think it would be really a big benefit if we could produce that on the continent. Beyond the fact that we would have diagnostics closer to the users (patients), the value chain is huge because you could create jobs and have a big impact on the local economy.”

#### SUMMARY OF FINDINGS

**Intellectual property.** Intellectual property provisions impede availability of certain PCR products such as GeneXpert cartridges, and access to handheld molecular diagnostics devices that may be gamechangers in future pandemics. Given that GeneXpert machines are widely available across HIV and TB-endemic countries, a waiver of the patents and trade secrets applicable to these machines could help increase accessibility, but this is dependent on supply of materials and available expertise in LMICs, and the willingness of Cepheid to share know-how.

Diversification of PCR platforms to reduce dependence on Cepheid for molecular diagnosis is necessary – however it remains likely in the near future that GeneXpert will remain dominant in many LMICs due it being the preferred diagnostic of large donors like the Global Fund (at least until competitors such as the TrueNat Molbio<sup>54</sup> gain more market share). As such, technology transfer and waivers of IP for GeneXpert technologies in particular would be valuable for allowing replication of more affordable generics.

IP is less of an impediment to accessibility and affordability of rapid antigen tests. These continue to be important to ensure point-of-care testing and the empowerment of communities to make decisions within their homes and communities about self-isolation, but access to them is impeded predominantly by regulatory barriers, price, and domestic conservatism on rapid testing versus molecular testing.

**Technology transfer.** For molecular tests, and especially for GeneXpert devices and cartridges which are widely available across many LMICs, technology transfer remains extremely relevant. However, given the low likelihood of the manufacturer sharing

technology, long-term strategies towards diversification of automated PCR technologies is necessary to prevent overreliance on these tools. The FIND and Unitaid initiative to facilitate antigen RDT technology transfer to LMIC manufacturers is a positive example of how technology transfer initiatives can lead to robust and sustainable local production activities.

### RECOMMENDATIONS

#### Intellectual property

- Diagnostics to be covered in future pandemic-related TRIPS waivers.
- In moulding the 'new public health order', Africa CDC to include discussions of a new TRIPS order taking into account diagnostics and the widespread availability of GeneXpert machines, as well as future use of handheld molecular diagnostics.

#### Technology transfer

- Countries to identify opportunities for technology transfer between established actors and potential local manufacturers.
- Countries to seek partnerships with LMIC-based manufacturers receiving technology transfer for diagnostics in their regions.
- Countries and global health agencies/initiatives to emphasise technology transfer as an essential component of pandemic aid, including through investments on local production of pandemic tools in The World Bank Pandemic Fund and other related aid.

## LOCAL PRODUCTION OF DIAGNOSTICS

The majority of LMICs remain heavily reliant on foreign suppliers for supply of raw materials, semi-finished products, and finished diagnostic products related to both molecular and rapid antigen tests. However, COVID-19 and low access to testing has exposed the need for local or regional production of diagnostics to ensure rapid deployment during pandemics. In the words of one diagnostics expert interviewed for this report:

---

“Many countries are dependent on a few suppliers which are located in the North... we know there is a lot of potential for local industry development in Africa and there’s a lot of political will. I think there’s important momentum to change the market with more local production of diagnostics to improve access but also sustainability.”

Pascale Ondo, Director of Science and New Initiatives at the African Society of Laboratory Medicine (ASLM), also pointed to ‘the gap that needs to be filled’ vis-à-vis local production of diagnostics and stated that local production of a simple test like a rapid diagnostic test for malaria could be a gamechanger for detection, if not a profitable endeavour.

For MPOX, Nigeria CDC pointed out that they had been working on MPOX for many years, but that the pipeline for diagnostics only expanded when the most recent outbreak reached the West. According to Dr Ifedayo Adetifa, more predictable supplies in the future depends on investments in local production:

---

“What happened with the more recent outbreak is suddenly the pipeline for diagnostics expanded, by perhaps 10-20-fold in terms of products that were suddenly in development or were becoming available. The challenge that (COVID-19 and MPOX) have in common is that it is not enough to keep pointing fingers to manufacturers and the dependence on supply chain mechanisms outside one country. The absence of domestic manufacturer of laboratory consumables or domestic development of laboratory consumables at any point in time during the COVID-19 pandemic (is problematic) and understandably so for the first few waves. Then to be able to come up with something that domesticates your testing and reduces your expense or makes for a more resilient or predictable supply should have followed. We and many countries in the Global South were unable to do that. And that’s a lesson that we need to take forward to make sure that we’re not in that kind of position again.”

A Médecins Sans Frontières Access Campaign report has mapped existing sites for local manufacturing in Africa and Latin America - ranging from local assembly of semi-finished products to local production of finished diagnostics - including diaTROPIX in Senegal, Astel Diagnostics in Uganda, Kenya Medical Research Institute (KEMRI) in Kenya, Bio-Manguinhos (Fundação Oswaldo Cruz/Fiocruz) in Brazil, CapeBio Technologies and Lateral Flow Laboratories (South Africa) and Moroccan Foundation of Advanced Research Science and Innovation / Moldiag (Morocco).<sup>55</sup> The same report, however, pointed to the lack of enabling policies that prevented local production from truly flourishing. Notably, that governments often do not plan for the use and integration of locally produced diagnostics, including volumes for purchase, even when quality standards are met,

meaning that manufacturers are uncertain about how big the potential market is for diagnostics, particularly if it is a local manufacturer competing with imported products.<sup>56</sup>

In discussing diagnostics products from Africa, while welcomed, interviewees suggested that more needed to be done to ascertain why prices remained inconsistent, with some African products costing more than products imported from outside Africa. In the words of Dr Aytenew Eshete, Program Manager at Africa CDC:

---

“Local production is a great concept. Many African countries have started to produce COVID-19 testing kits and even testing kits for other emerging and reemerging diseases. This is great, but sometimes prices are really high compared to those produced outside Africa, and other times the cost is really low. We need to really look in depth at the cost issue and determine the reasons why there’s such a difference.”

Other established manufacturers in LMICs, however, while possessing the technical expertise to manufacture tests for COVID-19, still faced challenges in responding to the scale of demand for testing at the peak of COVID-19. Dr Ramon Lemos Calaça, Business Development Specialist at Fiocruz in Brazil, described how supply of raw materials impacted their manufacturing capabilities:

---

“The biggest difficulty for us was to find quality supplies for the antigen tests, and for the molecular test, any suppliers. At the beginning of the pandemic there was huge competition for the inputs and raw materials. It was something we needed to act in a timely manner. Eventually we were able to get the inputs and develop our own molecular kits for COVID-19. So once we had the technological part in place, we also had to rapidly scale up production. Initially we had the capacity of producing 20,000 reagents per week and we scaled it up to 500,000 per week in something like two and a half months – it was a huge transformation for us. We solved the issues with the molecular tests first. And then we had to face something not entirely unexpected – we had the test kits, but we didn’t yet have the capacity to perform the tests.”

Fiocruz underwent a remarkable process of transition and adaptation to meet test demand and continue to work to optimise manufacturing processes to be able to increase their scale of production and response. According to Dr Antonio Ferreira, Head of Diagnostics at Bio-Manguinhos Fiocruz, partnerships were established to optimise competencies, and further investments in automation are being made to be able to respond more quickly in future pandemics:

---

“Processing 100,000 tests per day is something we didn’t ordinarily do, and it was one of the things we conquered while facing COVID. We were able to establish partnerships that allowed us to incorporate competence and know-how. We are now investing in automation that will allow us to increase the scale (of production). It was a process of absorbing know-how, but not exactly a straightforward process. In the molecular production part, we had a partnership to supply inputs, but we were the ones who made the adaptations to reach 2–3 million tests per month. This without any external participation.”



In discussions with Fiocruz, the increasing reliance on domestic expertise and supply was evident, and with it the increasing competence and future production plans in other disease areas. Notably, according to Dr Lemos, in the pipeline are tests for cancer, cardiovascular conditions, and other diseases prevalent in the Brazilian population.

According to MSF Access, local production of diagnostics in LMICs continues to be 'stymied by a lack of funding'.<sup>57</sup> This was echoed by Dr Ifedayo Adetifa, Director-General of Nigeria CDC, who told us that a lack of local production of diagnostics in Nigeria was the 'consequence of decades of insufficient funding of R&D and insufficient investments in the whole research ecosystem.'<sup>58</sup>

Data from the MSF report indicates that local production is funded from a variety of different sources. Life Assay Diagnostics in South Africa, focused predominantly on brucellosis, COVID-19, leptospirosis, and typhoid, received start-up funding from the Department of Science and Technology, and thereafter loans and grants from BMGF Grand Challenges, FIND, and other private industry.<sup>59</sup> Whereas Astel Diagnostics in Uganda, focused on COVID-19 and Ebola, receives partial funding from the French government.

Interviewees indicated that the landscape for funding for local production of MPOX tests was vastly different from COVID – with the need to 'hunt for financing'. Dr Antonio Ferreira, Head of Diagnostics at Fiocruz, illustrated how public funding was essential to ensure the country could respond swiftly to new public health challenges:

---

"(For MPOX) there will be no private involvement and the funding will be 100% public. For MPOX, we are working with the resources that we already have, because it is our institutional mission: to work in the front line to give the SUS (Sistema Único de Saúde – Brazil's public health system) and the country tools to face the new diseases."

This testimonials from Fiocruz are illustrative of a few things – among them that substantial investments into local production in LMICs and reducing dependence on external suppliers allows for more agile response to pandemics and new public health challenges, and that more stable investments into the full pipeline of diagnostics tools remains necessary and much needed.

Work is underway in Africa to increase local production not just of finished diagnostics products, but also reagents and plastics needed for cartridges and pipette tips. In the words of Dr Ifedayo Adetifa, Director-General of Nigeria CDC:

---

"We're supporting work being done in the Nigerian Institute for Medical Research (NIMR) to validate any products they have with our archive of samples. Our bio-repository has samples that can be used for test validation for MPOX and all of the other conditions that we are looking at. In that way, we are working with and happy to work with developers of diagnostics to validate their test products. We believe that this is an area of growth that requires more players in the country to work on tests and other related consumables for laboratory diagnostics. This also includes production of plasticware (materials). I was in Kenya for part of the pandemic and there's a nice factory somewhere on the coast that had begun to make a lot of the plasticware that was required, and

(they) were reliable. Just with (manufacture of) the pipette tips and all the stuff that you need, you can save yourself quite a bit of heartache and save your foreign exchange reserves by just being able to make those in country and also benefit from the consequences (such as) the economic benefits, employment, more taxes, and even the possibility of increase of foreign exchange from exports to neighbouring countries. So that's an area of growth that needs more players."

At time of writing, there are no quality assured MPOX rapid tests available in the market. According to FIND, interviewed for this report, a handful of test developers for both MPOX RDT and molecular diagnostics have begun work on the development of MPOX tests. While our research did not find MPOX-specific incentives for MPOX rapid test development, according to FIND, entities such as BARDA in the United States have provided incentives for medical countermeasures on smallpox as part of biosecurity activities which in turn have also supported further development of medical countermeasures for MPOX.<sup>60</sup>

#### **SUMMARY OF FINDINGS**

LMIC procurement of diagnostics is marked by an overreliance on foreign diagnostics. However, there are positive examples in LMICs, including via the expertise to produce diagnostics locally at Bio-Manguinhos in Brazil and diaTROPIX in Senegal, the latter of which is currently expanding manufacturing facilities with a 2023 completion date. Local production brings massive public health value through increased pandemic preparedness and surveillance capacities, but also economic value through job creation, local sourcing, and enhanced industrial capacity.

#### **RECOMMENDATIONS**

- Governments, donors, and development banks should offer more funding to support the full pipeline of diagnostics production.<sup>61</sup>
- To increase regional coordination efforts towards pooled procurement strategies.
- To foster South-South cooperation, for example from Bio-Manguinhos and diaTROPIX transferring know-how and technology to other LMICs.
- Governments and regional bodies to streamline distribution channels and ensure consideration of local diagnostics production in trade agreements currently being negotiated, including those being negotiated by the Economic Community of West African States (ECOWAS).

**PRICING OF DIAGNOSTICS:  
INCLUDING DIFFERENTIAL PRICING AND TRANSPARENCY ON PRICES**

Data indicated that due to competition, prices of COVID-19 tests have reduced compared to the beginning of the pandemic. At time of writing, many manual PCR tests range from US\$5-10 and automated PCR tests range from US\$10-15. Experts interviewed for this report, however, universally raised that pricing of tests was not optimal to achieve equitable access, illustrating how in some contexts there is a large difference in price between procurement price and costs to the final customer. Examples from a 2021 article in Health Affairs is testament to this – where patients seeking a test in Philippines were on average quoted a cost of US\$55 for a PCR test (two days' wages for an average Filipino) and in Kenya \$11 – meaning that a PCR test remained out of reach for the 37% of Kenyans living in extreme poverty (living on less than US\$1.90 a day).<sup>62</sup> In addition, one expert interviewed for this report stated that while the ACT-Accelerator did result in reduced prices over time, that prices of COVID-19 AgRDTs in Europe and other HICs remained lower than prices in Africa,<sup>63</sup> raising questions about affordability and the role of local production and supply costs in future pandemics.

Dr Jilian Sacks, Technical Officer for COVID-19 in the WHO Emergencies Programme stated that 'good strides' had been made in ensuring development of products that are fit-for-purpose, including simple self-tests and that there no longer were the technological barriers in access to COVID-19 tests that are seen in access to MPOX tests. Sacks said, however, that "access barriers certainly include affordability and figuring out how public health systems will integrate COVID-19 testing within their overall budgets, how donors will prioritise funding for COVID-19 and in the future, how individuals will prioritise paying out of pocket for COVID-19 tests, and how without right-priced products, affordability will continue to be a barrier".

Large procurers, like the Global Fund, who deployed millions of PCR and rapid antigen tests during the COVID-19 pandemic both through the C19RM and as part of the Access to COVID-19 Tools Accelerator, engaged in essential negotiations with manufacturers to reduce prices and to expand countries included in pooled procurement deals. Martin Auton, the Senior Manager, Principal Recipient Services (Health Product Demand) in the Global Fund's Sourcing & Supply Chain Department, said that "we saw differential pricing in the automated PCR space where with Abbott and Roche, there were a lot of negotiations to move beyond a list of about 10 or 12 (countries) to broaden that and they needed a lot of pushing to extend their scope. In the RDT space, we don't see a lot of differential pricing, but we also don't see a lot of the best possible pricing rates."

Dr Aytenew Ashenafi Eshete, Program Manager in the Laboratory Systems and Networks Division for Africa CDC, illustrated how budgets factored in during acute periods of the pandemic, particularly for Member States that did not have the necessary primers to do the tests:

---

“The pack procured (by Africa CDC) consists of 96 PCR tests but deducting positive and negative controls you end up with about 92 tests at approximately US\$5–6 per test. (Budgets) have to include extraction kits and primers, because initially some Member States did not have primers to do the tests and they were quite expensive. But because most diagnostics manufacturers manufacture PCR testing for COVID and other diseases as well – so we’ve observed competition among them and (therefore) price reductions. And we select them based on price, quality, sensitivity and specificity, and what pathogen is picked up.”

Dr Aytenew also stated that the GeneXpert cartridges were “more expensive than we expected”, raising important questions about future TRIPS waivers and TRIPS-related decisions for production (see section on IP [above](#)) but also on local production and diversification of PCR platforms.

Price reductions were possible as a result of competition and through pooled procurement mechanisms, such as the WHO Diagnostics Consortium (established at the request of the UN Secretary-General in support of the UN Crisis Management team in February 2022).<sup>64</sup> When ACT-A was established in April 2020, it was agreed that supply chain and procurement-related matters would be addressed through the Consortium. According to one diagnostics expert interviewed for this report, the WHO diagnostics Consortium “pooled procurement demand, and also pooled negotiations with suppliers” to lower prices, although cautioned that even lower prices would have been ideal.<sup>65</sup> With MPOX, however, there remains no pooling mechanisms for tests procurement.<sup>66</sup>

Affordability, and budgetary limitations within LMICs for diagnostics, combined with insufficient social safety nets for those requiring to self-isolate as a result of testing positive, also affected demand of tests. Mark Radford, Advisor, Impact Strategy & Projects of Global Access Diagnostics, a social enterprise and manufacturer, stated: “A big limiting factor in one African setting I observed was the demand barrier, i.e., relatively low demand for testing, linked perhaps on the one hand to budgetary and capacity limitations for health infrastructures, but also to the challenges of offering safety nets around the considerable negative externalities for individuals of testing positive for the disease. For future pandemics I think this is an issue that needs to be thought about carefully by the donor community, policy makers and others and needs to be more effectively addressed if we want testing to be more universally accepted.”

#### SUMMARY OF FINDINGS

Through the COVID-19 pandemic, competition enabled price reductions, however prices remain suboptimal for widespread LMIC access. At acute phases, and with enabling policies, more competition would have helped reduce prices to enable equitable access for LMICs. Poor transparency remains on cost-of-goods and customer pricing for both MPOX and COVID-19 tests and there is no one database that lists these, nor government procurement prices. This is a significant information gap. Pricing of GeneXpert cartridges can be influenced by transparency on cost-of-goods, but also on ensuring generic production of cartridges. Low demand for testing was influenced by a multitude of factors including affordability and the lack of social safety nets for those who did test positive.

#### RECOMMENDATIONS

- In line with the 2019 WHO transparency resolution<sup>67</sup> recommendation for Member States to 'take appropriate measures to publicly share information on the net prices of health products', regional and national bodies to establish user-friendly databases displaying net prices of diagnostics products.
- Countries to adopt comprehensive strategies on price reductions for diagnostics, including local policies towards funding of local production, partnerships on technology transfer, price transparency, optimising trade routes, etcetera.

## SUPPLY CHAIN CHALLENGES

As the virus broke in January 2020 – the WHO worked towards ensuring assays were being set to countries globally to enable sequencing and molecular testing, with first batches of assays dispatched in early February. This was enabled also by the rapid development of PCR tests by companies like TIB Molbiol<sup>68</sup> in January 2020. In an interview for this report, Paul Molinaro, the WHO Chief of Logistics and Support described those critical few weeks:

---

“The sequence was transmitted probably that first week of January 2020. By the 21st or 22nd (of January), it looked like there was a viable assay from TIB Molbiol. We were moving faster than EUL and PQ here, and (our decision) was based on that being sent to independent labs for verification, coming back, seeming positive, and being given the go-ahead (for deployment to countries) by the WHO technical team. Then we were able to do some limited contracts and send out first batches of assays around the 2nd, 3rd, 4th, 5th, and 6th of February (2020). Because it was just a powder, there was no sensitivity, we essentially couriered those with DHL. We sent that off the following month to about 60-70 countries. They were small amounts but the idea was to at least get it into the hands of numbers of countries essentially as a readiness measure for countries to be able to identify if a case occurred.”

As cases rose, there was an unprecedented demand in molecular testing supplies across the world. In one May 2020 research article describing testing mobilisation for African countries, researchers described how ‘restricted supplies of test reagents and consumables are making it difficult to mobilise capacity’ and how manufacturers of PCR platforms (including Roche, Abbott, and Cepheid) were not able to scale up production quickly enough.<sup>69</sup> This was further exacerbated by hoarding practices by rich countries. The Director-General of Nigeria CDC, Dr Ifedayo Adetifa, told us:

---

“There were global shortages of reagents and laboratory consumables across the board – including basic diagnostics, PCR, to consumables required for genomics surveillance and sequencing. There was a physical distortion to supply chain logistics across the world. And then there was also, for want of a better description, a monopoly or nationalisation of existing consumables and richer countries buying up everything in far excess of what they required at any time, which then meant that even others who had their own funds could not procure in a timely manner.”

This did not just apply to African countries, but also to countries like Brazil. As Dr Ramon Lemos, Specialist for Business Development at Bio-Manguinhos Fiocruz told us:

---

“(At the start of the pandemic) there was a competition across the world among all the countries that needed the tests. So whether molecular or antigen or serological, we were all in the same situation. The biggest difficulty for us was to find quality suppliers of the antigen test and any suppliers for molecular tests.”

Bio-Manguinhos Fiocruz eventually was able to self-manufacture both molecular and antigen tests, however this was not the case for many, if not most, LMICs. While antigen RDTs and semi-finished products are being manufactured at KEMRI in Kenya, diaTROPIX in Senegal, and other key locations on the continent, increased local production is needed and various other supply chain barriers need to be resolved. As one author described, optimised supply chains on diagnostics would reduce costs related to import levies, distribution and freight charges, reduced foreign currency expenditure, and reduced number of intermediaries and geographical distance.<sup>70</sup> In addition, supply chain barriers include limitations on forecasting and quantification of tests needed, inventory management, and redistribution.<sup>71</sup>

At the WHO, supply challenges arose with country requests for automated PCR tests. For example, countries that requested GeneXpert COVID cartridges were often countries that had a strong Global Fund presence due to GeneXpert use for HIV and TB diagnosis, and internal procedures meant that it was difficult for WHO to transfer funding to the Global Fund for supply of these tests. These challenges were added to by differential pricing for automated PCR tests discussed elsewhere in this report. Paul Molinaro, WHO Chief of Logistics & Support illustrated these challenges:

---

“It became apparent that it was very difficult to transfer funding between buyers. So if I had the funding and I had a country or MOH wanting access to Cepheid, it was very difficult to me to give the funding to Global Fund as a transaction and buying on behalf of everyone or anyone who needs it, notwithstanding the specific issues (related) with scarcity and some of the commercial games (companies) were playing in terms of allocation and pricing and where they were sending the tests. It was quite a complicated game.”

Interviewees welcomed supply chain streamlining through local production (discussed in more depth above) but noted that some tests made in Africa were more expensive than those imported from China. Dr Aytenew Ashenafi Eshete, from Africa CDC, illustrated this:

---

“With local production accessibility and proximity might be good, but cost can be a bit challenging perhaps due to some components that require bringing from outside into Africa. A study needs to be done on this.”

In September 2020, the ACT-Accelerator pledged to make 120 million affordable antigen RDTs available for procurement for LMICs through a partnership with Abbott and SD Biosensor.<sup>72</sup> Forecasting and quantification, or rather the inability of countries to adequately predict how many antigen RDTs they were planning to procure, resulted in tensions between large procurers and manufacturers during the pandemic. This erroneously manifested as a perception that LMICs were not interested in COVID antigen RDTs. As one large procurer told us:

---

“When the RDTs came there actually wasn’t a supply constraint. Countries were struggling with budgets and weren’t able to indicate to us what volumes they wanted. So there was a very strong tension between us telling the supplier we’ll buy this amount (of RDTs) but knowing we only really had money for a quarter or third of it. There were lots of tensions and pressures from the manufacturer – and the funded demand wasn’t there to step up to the agreed volumes.”

In an interview for this report, Nigeria CDC confirmed that it wasn’t possible to estimate volumes of antigen RDTs needed – and attributed this to the differential behaviour of the virus in Nigeria. In the words of Dr Ifedayo Adetifa, Director-General at Nigeria CDC:

---

“Lots of plans were made early in the pandemic based on assumptions of the number of cases that we were likely to have based on Western models. But for some unknown reason COVID-19 behaved differently here. While there was evidence that it was clearly a highly transmissible virus and there was widespread transmission through the community, as we saw with antibody tests, we simply did not have as many cases of severely ill and hospitalised cases as projected. This meant that we had to change our assumptions so that we didn’t have an excess of RDT supply.”

This points to a few things. Given WHO findings that six in seven COVID-19 infections go undetected in Africa, it remains clear that there was an undersupply of diagnostics to Africa. Based on testimony for this report, this co-existed with constrained budgets and countries that were underprepared for a pandemic of this magnitude. There is a need, therefore, for more robust and inclusive country negotiations and discussions, established pandemic protocols for pooled procurement, and agreed processes for forecasting and quantification in peacetime or the time between pandemics.

Several interviewees raised flights and distribution channels as a key supply chain issue. Dr Pascale Ondo told us that in addition to local production, more direct distribution channels were needed to ensure uptake of African products:

---

“Some (diagnostics companies) don’t have representatives in Africa. If you take a country like São Tomé and Príncipe, for example, there are not many flights that go there. You would have to take a flight from Africa up to Portugal then back down to São Tomé. This is an issue.”



By April 2020, approximately 80% of all regular flight routes were restricted as airlines shut down movements due to a lack of passengers. Given that approximately half of global air cargo is carried through passenger aircraft,<sup>73</sup> deployment of pandemic tools became extremely challenging. According to Paul Molinaro, WHO's Chief of Supply & Logistics, deployment of pandemic commodities occurred not through regular passenger routes as many were shut down during the pandemic. Infrastructure and capabilities of Ethiopian Airlines and facilities in Addis positioned the airline as a strategic choice. Molinaro stated:

---

"We were chartering dedicated aircraft where passenger seats had been removed and using Addis as the hub for this. They had the capacity to consolidate this in Addis and the assets to move beyond Addis."

Africa CDC highlighted flight access as a key challenge, although also spoke to partnerships with airlines and storage hubs that enabled efficient distribution. In the words of Dr Aytenew Ashenafi Eshete:

---

"Africa CDC has a hub in Addis Ababa using the WFP (World Food Programme) storage hub. Once the kits have been procured and arrive at this hub in Addis, they are distributed to the different member states. Of course, flight access is one of the challenges, but most of the time Ethiopian Airlines supports us. Other African airlines also transport reagents, but there definitely are issues on transporting realtime PCR as they need -20 centigrade and very few African airlines have such capacity."

The prominence of Ethiopian Airlines as the main carrier for COVID-19 commodities cargo was also raised by Dr Ifedayo Adetifa of Nigeria CDC, who spoke about supply chain challenges for reagents:

---

"Supply chain challenges applied mostly to reagents because generally the multichannel pipettes and all those other things are commodities that we will have available. In a situation (like COVID-19) where we had to expand testing and open many more labs, we had to purchase all of these reagents. Then they were affected by more of the supply chain disruptions such that nobody could predict when items finally arrive at a port. In the case of Africa, Ethiopian Airlines became the major source of air cargo across borders. But that meant that they were serving many countries and often they could there were delays in (obtaining timely supplies)."

Paul Molinaro, Chief of Logistics and Support for WHO, confirmed heavy reliance on Ethiopian Airlines for diagnostics logistics, but crucially described the extensive and innovative solutions undertaken by the WHO to ensure tests reached countries across the globe during a time of unprecedented demand:

---

“For diagnostics we were quite reliant on Ethiopian Airlines because we could bring (the tests) to one place and then move them around subsequently quite easily. WFP would charter (Ethiopian Airlines) through Addis, and we would set up essentially milk runs. So that one flight would go and if we had control over it, it would go and do up to five country drops and come back (to port). And then another one the next day to three different country drops and come back. It was very difficult in the beginning until the airlines began to switch some of their networks back on. It wasn’t the biggest issue. (Getting tests to countries) was doable but would take time. And it wasn’t just Africa. We had to do very special things for the Caribbean. We had to do a lot for the Pacific Islands, we used Fiji, Brisbane, and got into Iran with Emirati government aircraft, as well as donated aircraft from UAE and Qatar Airways. And so, it was a whole bunch of different options that we had of which Ethiopian Airlines in Africa was one, and a good one. But if you have 180 countries on the globe all asking for the same thing at the same time, it’s very difficult to keep everyone happy.”

These testimonies illustrate the remaining complexities with supply chain – ranging from the dependence on automated PCR from one supplier, to shut down flight networks that prevent commodities delivery during a public health crisis – and point to the need for larger discussions – including with corporations and within the context of free trade deals – on streamlining supply routes, improving flight paths, and equipping planes with infrastructure that can improve health across the African continent. At time of writing, 17 African countries (Cabo Verde, Côte d’Ivoire, Cameroon, Ethiopia, Ghana, Kenya, Morocco, Mozambique, Namibia, Nigeria, Rwanda, Senegal, South Africa, Togo, and Zambia) are piloting the Single African Air Transport Market (SAATM),<sup>74</sup> which may improve cargo transport across these countries and have a ripple effect to neighbouring countries that are outside the SAATM.

### **SUMMARY OF FINDINGS**

The beginning of the pandemic saw countries across the world compete for access to PCR testing and quality rapid testing supplies. Countries with manufacturing capacity, such as Brazil, adapted to increase local production for local supply, reducing reliance on foreign manufacturers. However, this was an anomaly, with many countries relying on foreign products. Supply chain is hence inextricably linked with local production, but also on ensuring more direct transport links and having visibility on volumes needed.

### **RECOMMENDATIONS**

- Countries to conduct comprehensive assessments on supply chain blockages and where streamlining could occur – and include supply chain in national diagnostics strategies with key milestones and action points, including on discussions with airlines, development of local production facilities, and improving forecasting and quantification to ensure transparency and visibility on test volumes.
- Countries to consider collaborating on pooled procurement and building free trade supply chains, removing trade barriers and tariffs between countries and using stronger market and purchasing power to reduce corporate negotiation strength and becoming a more important trade partner.
- To initiate inter-agency discussions to coordinate storage and supply chain between vaccines, diagnostics, and relevant therapeutics with experienced actors in the Middle East and Africa that have also been able to connect origins in Asia with countries in Africa and invest in storage, climate control and supply chain.
- Manufacturers of newer diagnostics technologies (and vaccine development) should focus on a need for less climate control for their technologies (with proof of success in the polio vaccine and upcoming innovations on handheld PCR platforms).

## OPTIMISING PROCUREMENT MECHANISMS

There were several procurement mechanisms that operated through the COVID-19 pandemic. The WHO-led Diagnostics (Supply) Consortium operated as one of the working groups under the diagnostics pillar of the ACT-Accelerator, and included UNICEF, Global Fund, and ACT-Accelerator CSOs<sup>75</sup> participating in biweekly calls. By October 2021, UNICEF through its Supply Division procured millions of tests for the ACT-Accelerator, with 8.74 million PCR tests and 6.87 million Ag-RDTs procured from 17 manufacturers for 82 countries, reaching a total value of US\$120.98 million. In total, the ACT-Accelerator deployed 161 million tests across 181 countries from Q1 2022 to Q3 2022,<sup>76</sup> although due to various factors (including less donor interest in funding testing), undertesting in LMICs was prevalent.

As discussed, elsewhere in the report, a volume guarantee was meted for the procurement of 120 million Abbott and SD Biosensor rapid antigen tests in September 2020, and demand for these tests struggled to reach agreed volumes. In May 2020, in a call with the Supply Consortium, the New York-based organisation Treatment Action Group raised several questions as regards whether the Supply Consortium had undertaken assessments to determine global need versus supply of diagnostics. A written answer to the Treatment Action Group stated the following:

---

“The Consortium has not yet undertaken this type of assessment. The Consortium’s efforts have focused on LMICs and negotiating with suppliers to secure availability of molecular diagnostic test kits for COVID-19 for use on platforms already available in LMICs, including those manufactured by Cepheid, Abbott, Roche, and Thermo Fisher. The Consortium agrees to take forward an assessment of global supply vs. need, and to update this assessment on a regular basis or as necessary to inform its ongoing work.”

While our research did not interrogate whether such assessments existed, a global health procurer interviewed for this report detailed tensions with the manufacturers in being able to pay for what was agreed:

---

“(These deals) bring some value through advocacy in securing some commitment from manufacturers, but may or may not be necessary, and sometimes may be a little bit counterproductive, even. They came up with a number and none of the buyers were financially committed to be able to write a cheque at the end of the day... the number of RDTs (agreed upon) was well above the amount of funding that was out there at that time, and countries were also struggling with their finances. It was many multiples of what could be afforded.”

There were suggestions in interviews that the deal could have more strategically engaged the Global Fund’s COVID-19 Response Mechanism (C19RM), which at time of writing has dispensed more than US\$4.3 billion to 131 countries.<sup>77</sup> This may also point to the failure of the ACT-Accelerator to adequately value and engage LMICs and intelligence about where they were on procurement and what funds they were ready to commit. Poor LMIC involvement and engagement was cited as a ‘strategic mistake’ inherent to the architecture of the ACT-Accelerator in an October 2022 external evaluation.<sup>78</sup>

This may also have been combined with competencies related to country-level forecasting and quantification of local needs, as discussed in the supply chain section of this report. In the words of one diagnostics expert:

---

“(Countries) can’t just order commodities without some kind of prediction on how much they plan to commit or procure in the next year. There are tools available to do that. But if you have never done it as a country it takes time to get up to speed to do it.”

Testimony from Africa CDC also spoke to the challenges with surveillance and quantifying demand and coming up with figures for pooled procurement volumes. In the words of Dr Aytenew Ashenafi Eshete:

---

“At the start of the pandemic, countries didn’t know how many people were infected. That was one of the big challenges – to quantify the demand of countries, because we don’t know the exact how many people have been infected, what are the capacity of countries and so on. In the beginning, around February 2020, we capacitated and provided member states with accumulators and started to procure reagents and receiving donations from different parts of the globe. They started to do tests (with these initial supplies). After that, we began to understand about (levels of) demand in the countries themselves after a year. And as the first wave, second wave and third waves came, countries started to ask us and let us know the amount of testing kits that they needed and based on their requests from the Minister of Health we would support them based on their demands.”

For future pandemics, robust forecasting and quantification will be needed to prevent bottlenecks as experienced in this pandemic. The WHO COVID-19 Essential Supplies Forecasting Tool<sup>79</sup> (latest version 15 February 2022) is a useful tool for quantification – and similar adapted tools will be useful in future pandemics. While it was not the objective of this report to examine procurement within countries, one 2018 source reported health facilities lacking market and institutional power to influence procurement, and the lack of procurement training available to health facility workers in Tanzania and Kenya,<sup>80</sup> making it difficult for authorities at the national level to aggregate needs.

One expert consulted for this report stated that the PAHO Strategic Fund offers an ‘excellent – and largely overlooked – model for what such mechanisms could look like. It goes beyond traditional pooled procurement by also offering robust technical cooperation because it is Member State-focused and housed in a multilateral organisation.<sup>81</sup> The Strategic Fund was touted as having successfully mitigated ‘COVID-19 related supply chain disruptions and major stockouts – while continuing its existing work to improve demand forecasting, support quality assurance and primary health care, and ensure affordability of medications to maintain health services’ through the locking in of affordable prices which were significantly less than usual via a variety of long-term agreements with pre-contracted suppliers.<sup>82</sup>

Africa CDC procurement occurred through the Africa Medical Supplies Platform, which was developed under the leadership of African Union Special Envoy Strive Masiyiwa, specifically created to create an agile platform to support procurement of quality COVID-19 testing supplies.<sup>83</sup> Dr Aytenew Ashenafi Eshete described its creation:

---

“We follow the Africa CDC procurements guidelines and procurement can be very complicated. Due to the onset of the COVID-19 pandemic, the Africa Medical Supplies Platform was established to expedite the process and procurement of any kind of testing kits (and other materials), so any Member State can go on to the website and make a purchase. Essentially manufacturers communicate with Africa CDC, we review the data, and after that evaluation, we communicate with the Africa Medical Supplies Platform to upload the name of the company and types of test kits. Then Member States can access them for procurement.”

Africa CDC worked actively throughout the pandemic to secure supplies for Member States, whether through purchases or donations and through established cooperation agreements, approaching Qiagen (Germany) and BioPerfectus (China) for PCR tests and donations from BGI Genomics (through Africa-China cooperation agreements).<sup>84</sup> Africa CDC also procured tests through UNICEF, however these processes required 2-3 months lead time.

For MPOX, there is no centralised sharing of information for MPOX procurement, complicating the ability to secure volume discounts. This is compounded by an uncertain trajectory of the emergency, with cases decreasing in many geographies at time of writing. While commercial test kits are beginning to be available, there is limited information of accuracy and quality with many countries in the WHO Americas, Southeast Asia, and Western Pacific regions preferring to use their own lab-developed tests.<sup>85</sup> Given these factors, at time of writing, pooled procurement for lower prices is unlikely to be a major priority for affected countries and global health agencies.

#### **SUMMARY OF FINDINGS**

Pooled procurement for COVID-19 rapid diagnostics was complicated by difficulties in forecasting and quantification of demand – pointing both to the need for better and more robust forecasting for future pandemics and certainty of domestic financing for future pandemic response. At the global level, volume guarantees did not correlate to projected estimates of country demand, therefore ensuring better coordination across procurers, funders – such as Global Fund’s C19RM, and LMIC representatives are vital to ensure success.

#### **RECOMMENDATIONS**

- Countries to adopt and adapt the use of more robust forecasting tools within planning for future pandemics to ensure pooled procurement can occur more effectively.
- Capacity building for health facility staff involved in procurement to facilitate national aggregation of needs.
- Future global pandemic countermeasures platforms to ensure that LMIC expertise is at the table – this could be via specific structures like LMIC expert councils to validate and contextualise decisions made by agencies.
- Regional bodies to conduct South-to-South best practice learning exercises, including on the viability of the PAHO Strategic Fund in other regions.

## IMPACT OF POLICIES AND GUIDELINES ON TESTING

There are several institutional policies – whether at the international or national levels – that affect affordability and accessibility of diagnostics. At the international level, WHO recommendations and guidelines translate into whether large procurers like the Global Fund and UNICEF can deploy certain tools. At both the international and national levels, philosophies as regards surveillance and the emphasis on PCR to achieve this can ignore access priorities for those in rural communities, elderly persons, mobile populations, and persons with disabilities, who may not be able to travel to laboratories and to wait for long periods for the return of a PCR result. Brook K Baker, Senior Policy Analyst at Health Gap, who was instrumental in advancing COVID test-and-treat discussions in the ACT-Accelerator, illustrated precisely this:

---

“The WHO and many LMIC governments have evidenced a regrettable preference for PCR tests over antigen rapid diagnostic tests based on their greater accuracy and linkages to disease reporting registries. However, PCR tests are significantly more expensive; depend on expensive laboratory equipment, a highly trained workforce, and specimen collection and transportation to central facilities; and often result in serious delays in reporting results to patients and clinicians. Thus, the theoretical early-detection and accuracy benefits of PCRs tests evaporate when compared to the pragmatic benefits of highly affordable and accurate Ag RDTs that produce actionable results in 15-30 minutes. When those Ag RDTs are also made available for community and self-testing by populations that have received treat-to-treat health literacy training, incentives to test, to take health precautions, and to connect to care for treatment are all greatly enhanced.”

WHO Guidelines were described as ‘critical’ for access and deployment of in-vitro diagnostics. Yet the WHO was slow in developing, revising, and clarifying use cases for Ag RDTs at the community level. Self-testing guidance was delayed until March 2022. Despite wide-spread, highly successful self-testing programs for HIV, malaria, and more recently hepatitis C, a time-consuming process of evidence generation addressing acceptability and implementation of self-testing was initiated to develop the self-testing guidelines – perhaps an inappropriate process for a fast-moving pandemic. According to one interviewee, some WHO staff evidenced a ‘troubling distrust of patients’ ability to self-test responsibly’, with poor understanding that ‘self-testing was obviously the best use for connecting patients to rapid assessment, care, and treatment’. Another diagnostics expert told us:

---

“(WHO Guidance) is critical. So many countries still look to – and will adopt – the WHO recommendation in their national strategies. It is the whole attitude of countries to look to WHO recommendations and even Global Fund procurement is based on WHO-recommended tests. It’s a chicken-and-the-egg story.”



The reliance on WHO guidance to deploy self-tests and waiting for them meant that in many respects at time of writing, diagnostics priorities had shifted. Dr Pascale Ondo, in an interview with our researchers, stated that country priorities were now focused on other diseases that are endemic to their contexts:

---

“What are the diagnostic priorities in Africa? The diagnostic priorities are certainly to manage your priority diseases, which at this point in Africa is not necessarily COVID-19. If you take countries like Nigeria and Mali, and ask them to invest in COVID self-tests, there will be a consideration of whether that is the right investment. The reality of countries is that they now have other fish to fry.”

Shifting priorities away from COVID-19 and particularly from COVID-19 self-tests was echoed also by Africa CDC, who stated:

---

“Some countries are really hesitant to (adopt) self-testing. In some (other) countries, they put self-tests in the community pharmacies (while others) put them in hospitals. The purpose of course is that people can self-tests and present for healthcare services in case of a positive result – and these issues are still under discussion. We need more advocacy and mobilisation on self-testing and integration of self-tests within routine healthcare services.”

Future guideline development within the context of public health emergencies of international concern also need to take into account domestic assessments that countries may need to carry out to contextualise deployment of self-tests. In other words, norm-setting agencies must include these considerations in timelines for equitable access of tools. Dr Ifedayo Adetifa, Director-General of Nigeria CDC, described some of these internal assessments that need to inform domestic strategies:

---

“The question is: are people going to be comfortable enough to self-test? We needed to gather data on acceptability and ease of testing. We have worked in collaboration with a few partners to generate those data. And then of course there’s the bit about how you manage the waste because we’ll have all these cartridges and the facemasks that are thrown everywhere. As a country we have taken these actions to try to find the answers to those questions before formally rolling out self-testing as part of our national strategy.”

One diagnostics expert interviewed for this report emphasised that while responsible waste disposal was important, access for communities was paramount, asking: “Did we really pause for pregnancy testing, HIV self-testing, malaria testing, etc. because of proper disposal concerns?”

In Brazil, Bio-Manguinhos Fiocruz stated that at present there is little momentum on self-testing, although work was in progress to understand MOH needs on this. In the words of Dr Ramon Lemos:

---

“(Self-tests production) is one of the things we are planning, and to understand demands from the MOH and from State Secretariats to supply the “Farmácia Popular”<sup>66</sup> Program (FPP). It is not difficult for us to manufacture and supply these tests, but the MOH needs to demand it and presently there is no public policy in place or in discussion.”

It can be argued that this is less an illustration of the lack of value of rapid self-tests, but rather that by the time regulatory agencies finally issued guidelines on COVID self-testing and therefore enabling donor agencies to procure self-tests for LMICs, the world had begun to deprioritise COVID. HICs, in contrast, relied on domestic expertise to validate and deploy self-tests. This points to the need for several reforms for the next pandemic – that WHO invest in bigger teams for regulatory approvals during emergency periods, for countries to increase domestic regulatory expertise, to rely more on regional regulatory expertise, or to use data from other stringent regulatory authorities.

In tandem with policies that preferred PCR to antigen RDTs, another barrier that emerged was the absence of income support for people in LMICs that tested positive and were not able to generate income. This policy oversight reduced the impetus for individuals, and especially those working in informal settings, from actively self-testing or accessing government-offered PCR tests. Additionally, poor access to effective novel antivirals may also drive poor uptake of tests.<sup>87</sup> This is discussed in more detail in the demand creation section below.

#### SUMMARY OF FINDINGS

Enabling policies are necessary for diagnostics uptake. Firstly, policies that prioritise PCR even though the majority of communities live far from laboratory services reduces ability for disease detection and protection of communities. Secondly, delayed WHO guidelines prevented the adoption of self-tests at country level at times when they would have been most useful, i.e., during acute phases of the pandemic. Thirdly, the lack of income support and social safety nets were seen as a significant factor for low uptake of tests in LMICs and especially so for those in informal settings. Experts have pointed to poor access to novel antivirals as a crucial factor for poor diagnostics uptake, although more research is needed on community perceptions in this regard.

#### RECOMMENDATIONS

- Rights-based testing approaches. This may require a shift in philosophies from prioritising PCR at all costs (which may restrict availability only to those close to laboratories and health facilities) to a pragmatic balance between PCR access and rapid antigen tests to ensure widespread access and self-empowerment in communities about their own healthcare – or investments in new handheld/point-of-care PCR platforms.
- Expedited guideline processes internationally to ensure timely deployment of rapid diagnostics.
- Countries to invest in domestic pandemic funds to ensure income protection for those requiring self-isolation, incorporated within national diagnostics strategies.

## DEMAND CREATION AND TESTING LITERACY

As discussed elsewhere in this report, demand for COVID-19 rapid antigen tests in Africa was 'lower than anticipated' at acute phases of the pandemic,<sup>88</sup> despite six in seven COVID-19 infections in Africa going undetected.<sup>89</sup> While this is attributed fundamentally to certain policies preferring PCR over antigen RDTs and WHO AgRDT guidelines that were relatively rigid compared to many of those in HICs, it may also relate to insufficient demand creation at the community level. In the words of Dr Alexandra Bertholet, Deputy Director of Market Innovations at FIND:

---

"What we're seeing now is that the demand (for AgRDTs) isn't there. The point about advocacy groups getting more involved in diagnostics is a big lesson we can learn from COVID. Because if you look at the demand side, it just hasn't materialised for COVID self-tests. We have quality assured suppliers coming to us saying we have a million extra tests that we can't sell, can you help? and countries won't take them. And another thing that wasn't clear was countries' self-testing policies. Officially, there are only a handful of countries that have self-testing policies."

In June 2022, FIND and Unitaaid announced a US\$2 million investment for 21 in-country advocacy partners across 19 LMICs 'to develop and implement advocacy strategies that will improve uptake of test-and-treat approaches to combat COVID-19'. Given that only a quarter of Paxlovid courses go to LMICs,<sup>90</sup> and that test-and-treat programmes in LMICs are heavily reliant on the use of AgRDTs,<sup>91</sup> these advocacy programmes constitute essential investments to increase uptake. One of the grantees, the CBO Shifa Foundation in Pakistan, for example, conducted dialogues with communities to increase demand of testing across Islamabad, including in J Salak<sup>92</sup> in central Islamabad and Golra Sharif in the west of the city.<sup>93</sup> While these efforts are welcome, it is arguable that advocacy and community-based demand creation remained relatively neglected up to 2022 and early investments are needed in the next pandemics.

A major barrier that has emerged through the literature is the failure of both national governments and international guidelines to account for those in informal employment who could not necessarily afford to self-isolate upon a positive test and lose income from self-isolation. This was documented, for example, in one August 2022 research report examining access to COVID-19 diagnostics in 14 countries<sup>94</sup> where safety nets and income protection were raised as a key barrier to diagnostics uptake. In the words of Mark Radford, Advisor, Impact Strategy & Projects for Global Access Diagnostics:

---

"In terms of my own personal observations, a big limiting factor I saw in an African setting was actually a demand barrier (relatively low demand for testing), linked perhaps on the one hand to budgetary and capacity limitations for health infrastructure, but also to the challenges of offering safety nets around the considerable negative externalities for individuals of testing positive for the disease. For future pandemics I think this is an issue that needs to be thought about carefully by the donor community, policy makers and others and needs to be more effectively addressed if we want testing to be more universally accepted."

Dr Emma Hannay, the Chief Access Officer at FIND, echoed this sentiment, stating that ‘enforced isolation’ as the result of a positive diagnosis can have socioeconomic implications; and that policymakers needed to account for these implications in designing future domestic pandemic countermeasures:

---

“From a public health standpoint, diagnosing infectious disease is critical: as well as being the first step for people to access the care they need, diagnosis ensures that measures can be taken to break chains of transmission, and that epidemiological data are accurate. However, for individuals it is not always so simple. As we saw with COVID, a positive diagnosis can have consequences, such as enforced isolation, which in some cases can be the difference between working to feed your family that day or not. As we saw with HIV – and other diseases including now MPOX – certain diseases can have a particular stigma attached to them, which can have profound social implications. It is therefore imperative that public health policy makers consider the full impact of the policies they make, not just on public health but on individuals. Where necessary, these policies must be supported by financial and social support. It is essential that diagnosis is set up as a positive first step back to health, not a tragedy that people seek to avoid.”

Based on these, demand for testing for diseases requiring isolation are inextricably linked with income generation – and governments must adapt and prepare for upcoming pandemics with social protection funds, and especially in consideration of those working in the informal sector and those who do not have regular salaries.

For MPOX, which has existed in several LMICs for much longer than it has in HICs, innovative approaches have been taken to increase demand, uptake, and use of MPOX tests. For example, in Nigeria, communities and healthcare facilities have mistaken MPOX for chickenpox, resulting in recommendations to test for MPOX where chickenpox is suspected and the need to decentralise testing to different laboratories across the country. In the words of Dr Ifedayo Adetifa, Director-General of Nigeria CDC:

---

“(MPOX) is being mistaken for chickenpox, another common illness associated with a rash in a significant number of cases and our laboratory results confirm this given that our suspected case samples test positive for MPOX and VZV (varicella zoster virus)<sup>95</sup> in almost equal proportions. This is not surprising given that older children and adults commonly come down with chickenpox because we do not have a vaccination programme. Now, we are working on reviewing case definitions to ensure that any case suspected to be chickenpox should have samples collected to test for MPOX. In addition to reviewing case definitions to improve surveillance, we need to ensure testing is decentralised. All MPOX testing in previous outbreaks was centralised to the reference lab in Abuja and that was okay at the time for the number of cases that were occurring. With the increased number of suspected cases and confirmed cases we are seeing now; we have expanded testing to our laboratory in Lagos in the southwest to serve the southern part of the country. In addition, we intend to decentralise some more to bring testing closer to people and to reduce the transit time for sample or specimen referrals. And the final bit is ensuring we have stable sources and options for consumables. I have just signed off on an alternative source of consumables, just to make sure we have backup and to reduce the risk of stockouts.”

Our work did not conduct an in-depth examination on CBO advocacy for demand generation and testing literacy in MPOX in Nigeria and other countries where MPOX is endemic. One article describes how a small group of volunteers in Adamawa State in northeast Nigeria worked to spread awareness of the disease and brought suspected cases in rural areas to the attention of health authorities for medical intervention,<sup>96</sup> however it is unclear how widespread these groups are across the country and across other African countries responding to MPOX emergencies. While decentralisation of laboratories is one step towards ensuring increased accessibility, investments in community-led advocacy and testing literacy can help increase community awareness of accessibility to testing and should be invested in.

Poor access to effective novel antivirals may have also compromised uptake of testing for individuals and communities. In a 2022 Lancet Global Health article, Emily B Wroe and colleagues stated that 'a global push for test and treat should focus on antigen rapid diagnostic tests and self-testing, for which demand will be amplified by the availability of effective treatments.'<sup>97</sup> At time of writing, only a quarter of Paxlovid orders will go to LMICs.<sup>98</sup>

#### SUMMARY OF FINDINGS

There have been insufficient investments on community-led advocacy, compromising demand creation and testing literacy within communities in LMICs. In addition, sluggish adoption of self-tests policies at the global level inhibited the ability for LMICs to respond as rapidly as HICs.

#### RECOMMENDATIONS

- Global health agencies to invest in and place priority on advocacy and community-led demand creation in LMICs earlier in pandemics, to ensure equitable uptake, affordability, and rights-based approaches in access to pandemic tools.
- A mapping exercise to be conducted on community led MPOX interventions in LMICs, including on investments into their work and salarizing of community health workers.
- Countries – in planning for next pandemics – to build income protection funds as a crucial measure in diagnostics uptake strategies, and to prioritise those in the informal sector.

## RECOMMENDATIONS

The public health emergencies of international concern, COVID-19 and MPOX, generated several key lessons on, inter alia, the need for more agile regulatory processes for rapid tests, the need for local production in LMICs, the value of CBO-led advocacy to create demand and increase testing literacy, and the need to streamline supply routes. Based on the above findings, we make the following recommendations:

### LMIC COUNTRY GOVERNMENTS

- To establish **robust multiyear integrated diagnostics country strategies** in view of the upcoming 2023 WHO diagnostics resolution. These should include, inter alia, planning for income protection for those in the informal sector for future pandemics, local production, regional collaboration on regulatory processes, and community-led advocacy, demand creation, expertise on quantification and forecasting, and testing literacy.
- To allocate resources for **domestic regulatory capacity** or invest in regional regulatory capacity.
- Pending domestic capacity strengthening, to **establish clear policies on reliance of other SRAs** where international processes are insufficiently agile.
- To ensure **inclusion of diagnostics in future pandemic-related TRIPS waiver discussions**.
- To **identify opportunities for technology transfer** between established actors and potential local manufacturers, and **to seek partnerships with LMIC-based manufacturers** receiving technology transfer for diagnostics in their regions.
- To **foster South-South cooperation**, for example from Bio-Manguinhos and diaTROPIX **transferring know-how and technology** to other LMICs.
- To **streamline distribution channels** and ensure consideration of **local diagnostics production in trade agreements** currently being negotiated, including those being negotiated by the Economic Community of West African States (ECOWAS).
- To adopt and adapt the use of more **robust forecasting and quantification tools and processes** within planning for future pandemics to ensure pooled procurement can occur more effectively, and capacity building for health facility staff involved in procurement to facilitate national aggregation of needs.
- To advocate for the inclusion and equal intellectual partnership of LMICs within **future global pandemic countermeasures platforms** to prevent poorly-contextualised global responses – this could be via specific structures like LMIC expert councils to validate and contextualise decisions made by global health agencies.

- **Rights-based testing approaches.** This may require a shift in philosophies from prioritising PCR at all costs (which may restrict availability only to those close to laboratories and health facilities) to a pragmatic balance between PCR access and rapid antigen tests to ensure widespread access and self-empowerment in communities about their own healthcare – or investments in new handheld/point-of-care PCR platforms.
- To build **income protection funds** as a crucial measure in diagnostics uptake strategies and in pandemic planning strategies, and to prioritise those in the informal sector.
- To conduct **comprehensive assessments on supply chain blockages for diagnostics** and where streamlining could occur – and include supply chain in national diagnostics strategies with key milestones and action points, including on discussions with airlines, development of local production facilities, and improving forecasting and quantification to ensure transparency and visibility on test volumes.
- To consider **collaborating on pooled procurement and building free trade supply chains**, removing trade barriers and tariffs between countries and using stronger market and purchasing power to reduce corporate negotiation strength and becoming a more important trade partner.
- In line with the 2019 WHO transparency resolution<sup>99</sup> recommendation for Member States to ‘take appropriate measures to **publicly share information on the net prices of health products**’, regional and national bodies to establish user-friendly databases displaying net prices of diagnostics products.
- To adopt **comprehensive strategies on price reductions for diagnostics**, including local policies towards funding of local production, partnerships on technology transfer, price transparency, optimising trade routes, etcetera.

### REGIONAL BODIES

To establish/**strengthen regional regulatory processes** to ensure rapid, optimal, and equitable access to diagnostics in communities.

- In moulding the ‘new public health order’, Africa CDC to include discussions of a **new TRIPS order taking into account diagnostics** and the widespread availability of GeneXpert machines, as well as future use of handheld molecular diagnostics.
- To increase **regional coordination efforts towards pooled procurement strategies**.
- To **foster South-South cooperation**, for example from Bio-Manguinhos and diaTROPIX **transferring know-how and technology** to other LMICs.
- To **streamline distribution channels** and ensure consideration of **local diagnostics production in trade agreements** currently being negotiated, including those being negotiated by the Economic Community of West African States (ECOWAS).
- To adopt **comprehensive strategies on price reductions for diagnostics**, including local policies towards funding of local production, partnerships on technology transfer, price transparency, optimising trade routes, etcetera.

### DONOR GOVERNMENTS/ DEVELOPMENT BANKS/HICS

- To increase **funding allocations and political support for WHO PQ processes** and staffing, as well as regional regulatory processes.
- To fund experts to provide **training to manufacturers** on PQ/EUL procedures.
- To **emphasise technology transfer as an essential component of pandemic aid**, including through investments on local production of pandemic tools in The World Bank Pandemic Fund and other related aid.
- Governments, donors, and development banks should offer **more funding to support the full pipeline of diagnostics production**.<sup>100</sup>
- To build **income protection funds** as a crucial measure in diagnostics uptake strategies and in pandemic planning strategies, and to prioritise those in the informal sector.
- In line with the 2019 WHO transparency resolution<sup>101</sup> recommendation for Member States to ‘take appropriate measures to **publicly share information on the net prices of health products**’, regional and national bodies to establish user-friendly databases displaying net prices of diagnostics products.



## WHO

- To establish a **diagnostics focal point staff position at the WHO headquarters** to drive an agenda for diagnostics affordability and accessibility and to ensure a robust implementation of the 2023 WHO diagnostics resolution.
- To increase staffing and funding allocation to the **Prequalification Department** in parallel with streamlined procedures to ensure more agile regulatory responses during public health emergencies of international concern, while maintaining robustness and quality of evaluations.
- **Expedited guideline processes** to ensure timely deployment of rapid diagnostics.
- To **develop more clarity on the impact of SRAs on its own PQ processes** – similar to how it has done in the field of HIV with ARVs.
- To ensure that **future global pandemic countermeasures platforms integrate LMIC expertise** – this could be via specific structures like LMIC expert councils to validate and contextualise decisions made by global health agencies.
- To **fund CSO engagement** in WHO diagnostics-related processes, whether via the upcoming WHO CSO Commission or other CSO-led efforts.
- **Rights-based testing approaches**. This may require a shift in philosophies from prioritising PCR at all costs (which may restrict availability only to those close to laboratories and health facilities) to a pragmatic balance between PCR access and rapid antigen tests to ensure widespread access and self-empowerment in communities about their own healthcare – or investments in new handheld/point-of-care PCR platforms.

## GLOBAL HEALTH AGENCIES

- To fund experts to provide **training to manufacturers** on PQ/EUL procedures.
- To invest in and place priority on **advocacy and community-led demand creation in LMICs earlier in pandemics**, to ensure equitable uptake, affordability, and rights-based approaches in access to pandemic tools.
- To fund a **mapping exercise on community led MPOX interventions in LMICs**, including on investments into their work and salaried of community health workers.
- To initiate **inter-agency discussions to coordinate storage and supply chain** between vaccines, diagnostics, and relevant therapeutics with experienced actors in the Middle East and Africa that have also been able to connect origins in Asia with countries in Africa and invest in storage, climate control and supply chain.
- To support the adoption of **comprehensive strategies on price reductions for diagnostics** at country level and as organisational strategies, including local policies towards funding of local production, partnerships on technology transfer, price transparency, optimising trade routes, etcetera.

### SRAS

- SRAs (e.g., US FDA, EU) to **share results** to support regulatory review and approvals in LMICs.

### CSOS/CBOS/INGOS

- INGOs to facilitate **training of manufacturers on WHO PQ/EUL procedures**.
- To advocate for **inclusion of diagnostics in future pandemic-related TRIPS waiver discussions**.
- To advocate for the inclusion and equal intellectual partnership of LMICs and CSOs within **future global pandemic countermeasures platforms** to prevent poorly-contextualised global responses – this could be via specific structures like LMIC expert councils to validate and contextualise decisions made by global health agencies, and for robust CSO representation and funding.
- INGOs to fund **a mapping exercise on community led MPOX interventions in LMICs**, including on investments into their work and salaried of community health workers.

### MANUFACTURERS

Manufacturers of newer diagnostics technologies (and vaccine development) should **focus on a need for less climate control for their technologies** (with proof of success in the polio vaccine and upcoming innovations on handheld PCR platforms).

- Manufacturers to commit to **sharing know how and transferring technology** during pandemics.

## CONCLUSION

Lessons from both COVID-19 and MPOX indicate that LMICs faced inequitable access to diagnostics due to multiple cross-cutting and systemic factors, including regulatory barriers, insufficient demand creation, intellectual property and trade secrets impeding development of proprietary molecular diagnostics platforms, an overreliance on patented platforms, insufficient local production, supply chain barriers, and insufficient investment in community led demand creation and testing literacy. Given the multitude of factors affecting diagnostics affordability and accessibility, and leveraging upon a WHO resolution on diagnostics set for a World Health Assembly discussion in 2023, it is time for international actors and country governments to create robust multiyear strategies on diagnostics to ensure more affordable tests, more agile pandemic responses, and greater access for individuals and communities in LMICs.

(THIS TABLE CONTAINS PARTIAL FIGURES WITHIN EACH ORGANISATIONS' SUPPLY CATALOGUES)

Procurer	Manufacturer (Product Name)	Type of Diagnostic	Price per test (\$USD) (if available, indicated FCA/EXW)
WHO (via Diagnostics Consortium)	BGI	Manual PCR	\$4.70 <sup>102</sup>
	ThermoFisher	Manual PCR	\$5.02
	Abbott (Panbio COVID-19 Ag Rapid Test Device (NASAL))	Rapid antigen test (professional use)	\$2.25 <sup>103</sup>
	Abbott (Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL))	Rapid antigen test (professional use)	\$2.25
	SD Biosensor (STANDARD Q COVID-19 Ag Test)	Rapid antigen test (professional use)	\$2.20
	Premier Medical Corporation (Sure Status COVID-19 Antigen Card Test)	Rapid antigen test (professional use)	\$1.95
	CTK Biotech Inc. (OnSite COVID-19 Ag Rapid Test (nasopharyngeal/nasal))	Rapid antigen self-test	\$1.20
	Cepheid (GeneXpert)	Automated PCR	\$14.90 <sup>104</sup>
UNICEF	Cepheid (GeneXpert)	Automated PCR	\$15.22 <sup>105</sup>
	Abbott (Panbio COVID-19 Ag Rapid Test, kit)	Rapid antigen test (professional use)	\$2.25 FCA
	SD Biosensor (STANDARD Q COVID-19 Ag Test)	Rapid antigen test (professional use)	\$3.00
	CTK Biotech Inc. (OnSite COVID-19 Ag Self-Test Kit)	Rapid antigen self-test	US\$1.30 - 1.95 FCA
Global Fund	BGI	Manual PCR	\$3.80 <sup>106</sup> EXW
	ThermoFisher	Manual PCR	\$5.02 EXW <sup>107</sup>
	Abbott (RealTime SARS-CoV-2 RT-PCR Kit)	Automated PCR	\$10.00 EXW <sup>108</sup>
	Manufacturer not specified (SARS-CoV-2 Rapid Antigen Diagnostic)	Rapid antigen test (professional use)	\$0.62-2.25 EXW
	Manufacturer not specified (SARS-CoV-2 Rapid Antigen Diagnostic Self-Test)	Rapid antigen self-test	\$0.65-4.50 EXW

## NOTES

- 1 Zain Rizvi, 'Vaccine Apartheid' Public Citizen (29 November 2021) < <https://www.citizen.org/article/vaccine-apartheid/>> accessed 2 November 2022; OHCHR, 'UN Expert urges States to End Vaccine Apartheid' (14 June 2022) < <https://www.ohchr.org/en/press-releases/2022/06/un-expert-urges-states-end-vaccine-apartheid>> accessed 2 November 2022; Simar Singh Bajaj and others, Vaccine Apartheid: Global Cooperation and Equity (2022) 399(10334) The Lancet P1452-1453
- 2 Matahari Global Solutions, 'Mapping Access Gaps in COVID-19: Results from 14 Countries and Territories' (August 2022) < <https://itpcglobal.org/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-COVID-19.pdf>> accessed 2 November 2022
- 3 WHO AFRO, 'Six in seven COVID-19 infections go undetected in Africa' (14 October 2021) < <https://www.afro.who.int/news/six-seven-covid-19-infections-go-undetected-africa>> accessed 2 November 2022
- 4 Djaffar Al Katanty and Edward Mcallister, 'In Africa's MPOX outbreak, sickness and death go undetected' Reuters (31 October 2022) < <https://www.reuters.com/business/healthcare-pharmaceuticals/africas-MPOX-outbreak-sickness-death-go-undetected-2022-10-31/>> accessed 2 November 2022
- 5 WHO Central African Republic, 'MPOX in Central African Republic' (13 October 2016) < <https://www.afro.who.int/news/MPOX-central-african-republic>> accessed 2 November 2022
- 6 WHO AFRO, 'Establish laboratory diagnostic and genomic sequencing capacity for orthopoxviruses, including MPOX' (30 June 2022) < <https://www.afro.who.int/news/bolstering-MPOX-laboratory-testing-africa>> accessed 4 November 2022
- 7 Africa CDC, 'Outbreak Brief #9: MPOX in African Union Member States' (9 September 2022) < [https://africacdc.org/wp-content/uploads/2022/09/AfricaCDC\\_MPOXBrief9\\_09Sep22.pdf](https://africacdc.org/wp-content/uploads/2022/09/AfricaCDC_MPOXBrief9_09Sep22.pdf)> accessed 4 November 2022
- 8 Africa CDC, 'Outbreak Brief #9: MPOX in African Union Member States' (9 September 2022) < [https://africacdc.org/wp-content/uploads/2022/09/AfricaCDC\\_MPOXBrief9\\_09Sep22.pdf](https://africacdc.org/wp-content/uploads/2022/09/AfricaCDC_MPOXBrief9_09Sep22.pdf)> accessed 4 November 2022
- 9 The Global Fund, 'Project Stellar: Supporting the COVID-19 Response' (4 March 2022) < [https://www.theglobalfund.org/media/11815/covid19\\_c19rm-project-stellar-briefingnote\\_en.pdf](https://www.theglobalfund.org/media/11815/covid19_c19rm-project-stellar-briefingnote_en.pdf)> accessed 4 November 2022
- 10 Africa CDC, 'Revised COVID-19 Testing Strategy: Transitioning from Emergency Response to Integration into Routine Healthcare Services' (August 2022) p. 11 < <https://africacdc.org/download/revised-covid-19-testing-strategy-second-edition-june-2022/>> accessed 4 November 2022
- 11 WHO, 'Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing: Interim Guidance' (9 March 2022) < [https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self\\_testing-2022.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1)> accessed 4 November 2022
- 12 Alison Connor, Nisha Hariharan, and others, 'Access To COVID-19 Testing In Low- And Middle-Income Countries Is Still Critical To Achieving Health Equity' Health Affairs (27 October 2021) < <https://www.healthaffairs.org/doi/10.1377/forefront.20211026.483412>> accessed 4 November 2022
- 13 Cepheid, 'Cepheid and BioGX Announce Collaboration to Develop MPOX PCR Test for the GeneXpert® System' (27 June 2022) < <http://cephheid.mediaroom.com/2022-06-27-Cepheid-and-BioGX-Announce-Collaboration-to-Develop-MPOX-PCR-Test-for-the-GeneXpert-R-System>> accessed 4 November 2022
- 14 Henry Kyobe Bosa, 'Uganda's Ebola Outbreak is a Test of What We've Learned from COVID' New York Times (3 November 2022) < <https://www.nytimes.com/2022/11/03/opinion/uganda-ebola-trust.html?smid=nytcore-ios-share&referringSource=articleShare>> accessed 4 November 2022
- 15 WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2 (last updated 8 November 2021) < [https://extranet.who.int/pqweb/sites/default/files/documents/221108\\_EUL\\_SARS-CoV-2\\_Approved\\_IVDs.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/221108_EUL_SARS-CoV-2_Approved_IVDs.pdf)> accessed 15 December 2022
- 16 UNICEF Supply Division, < <https://www.unicef.org/supply/media/11136/file/Premier-Medical-Sure-Status-COVID-19-Ag-Card-Test-Product-Reference.pdf>> accessed 30 September 2022; UNICEF Supply Division, 'Product reference notes for rapid antigen tests to diagnose SARS-CoV-2' < <https://www.unicef.org/supply/documents/product-reference-notes-rapid-antigen-tests-diagnose-sars-cov-2>> accessed 6 December 2022
- 17 UNICEF, 'Onsite COVID-19 Antigen Self-Test Kit Reference Note' < <https://www.unicef.org/supply/media/14286/file/Onsite-COVID-19-Antigen-Self-Test-Kit-Reference-Note.pdf>> accessed 4 November 2022
- 18 The Global Fund, COVID-19 Situation Report #39 (Reporting period 13 February 2021 – 25 February 2021)(p. 3) < [https://www.theglobalfund.org/media/10655/covid19\\_2021-02-26-situation\\_report\\_en.pdf](https://www.theglobalfund.org/media/10655/covid19_2021-02-26-situation_report_en.pdf)> accessed 30 September 2022
- 19 Supply Consortium data, provided by Dr Jilian Sacks, Technical Officer, COVID-19 Lab Team, WHO (via email, 10 November 2022)
- 20 Ibid
- 21 Diagnostics Supply Dashboard (8 March 2022)
- 22 Feedback from Dr Jilian Sacks, Technical Officer, COVID-19 Lab Team, WHO (via email, 10 November 2022)
- 23 The Global Fund, 'C19RM Monthly Update to the Board' (24 June 2021), p. 24 < [https://www.theglobalfund.org/media/11136/covid19\\_2021-06-24-board\\_update\\_en.pdf](https://www.theglobalfund.org/media/11136/covid19_2021-06-24-board_update_en.pdf)> accessed 28 November 2022
- 24 Ibid, p. 23
- 25 FIND MPOX Test Directory < <https://www.finddx.org/mpx-test-directory/>> accessed 3 October 2022
- 26 Interview with Ute Ströher, Technical Officer, WHO PQ (via Zoom, 22 September 2022)

- 27 Unitaid, Overview of MPOX Antivirals and Diagnostics Landscape (November 2022), <https://unitaid.org/assets/Overview-of-mpox-antivirals-and-diagnostics-landscape-03-2022.pdf>
- 28 WHO, Draft for Public Consultation: Target Product Profiles for tests used for MPOX diagnosis (January 2023), [https://cdn.who.int/media/docs/default-source/documents/health-topics/monkeypox/mpxv-ivds-tpps\\_v0-2023-01-16.pdf?sfvrsn=7ad34d5b\\_1](https://cdn.who.int/media/docs/default-source/documents/health-topics/monkeypox/mpxv-ivds-tpps_v0-2023-01-16.pdf?sfvrsn=7ad34d5b_1)
- 29 Cepheid, 'Cepheid and BioGX Announce Collaboration to Develop MPOX PCR Test for the GeneXpert® System' (27 June 2022) accessed 4 November 2022
- 30 Cepheid, 'Cepheid and BioGX Announce Collaboration to Develop MPOX PCR Test for the GeneXpert® System' (27 June 2022) <http://cephid.mediaroom.com/2022-06-27-Cepheid-and-BioGX-Announce-Collaboration-to-Develop-MPOX-PCR-Test-for-the-GeneXpert-R-System> accessed 4 November 2022
- 31 Data requested from FIND (Devy Emperador, Senior Scientist FIND, via email, 4 October 2022)
- 32 Vijay Shankar Balakrishnan, 'Collaborating to improve MPOX diagnostics' The Lancet Microbe (September 2022) <[https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(22\)00256-7/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(22)00256-7/fulltext)> accessed 4 November 2022
- 33 World Health Organization, 'Emergency Use Listing' <<https://www.who.int/teams/regulation-prequalification/eul/>> accessed 3 October 2022
- 34 Interview with Mark Radford, Advisor, Impact Strategy & Projects, Global Access Diagnostics (via email, 3 October 2022)
- 35 Interview with Irena Prat, Team Lead for In-Vitro Diagnostics, WHO PQ (via Zoom, 22 September 2022)
- 36 Interview with Ute Ströher, Technical Officer, WHO PQ (via Zoom, 22 September 2022)
- 37 Duke Global Health Innovation Center and Global Health Technologies Coalition, 'Navigating Complexity to Improve Global Access: Supporting a More Efficient and Effective World Health Organization Prequalification Program' (August 2022) <<https://www.ghcoalition.org/documents/pdf/Navigating-complexity-to-improve-global-access-supporting-a-more-efficient-and-effective-WHO-prequalification-program.pdf>> accessed 3 October 2022
- 38 U.S. FDA, Letter to Angela Drysdale, VP, Regulatory Affairs, Abbott Diagnostics Scarborough, Inc., on the Emergency Use Authorization EUA210264 (4 April 2021) <<https://www.fda.gov/media/147251/download>> accessed 28 November 2022
- 39 Reuters, 'Germany approves three COVID home test kits to help chart way out of lockdown' (February 24, 2021) <<https://www.reuters.com/business/healthcare-pharmaceuticals/germany-approves-three-covid-home-test-kits-help-chart-way-out-lockdown-2021-02-24/>> accessed 28 November 2022
- 40 Conor Hale, 'Here we go again: FDA opens up emergency authorizations to MPOX tests' Fierce Biotech (8 September 2022) <<https://www.fiercebiotech.com/medtech/here-we-go-again-fda-opens-emergency-authorizations-MPOX-tests>> accessed 6 November 2022
- 41 CE marking indicates that an IVD device complies with the European In-Vitro Diagnostics Devices Directive (IVDD 98/79/EC) and that the device may be legally commercialised in the EU. <<https://www.emergobyul.com/services/europe/european-ce-marking-vitro-diagnostic-ivd-medical-devices>> accessed 6 November 2022
- 42 Interview with Devy Emperador, Senior Scientist, FIND (via email, 4 October 2022)
- 43 Interview with Toni Whistler, Laboratory and COVID-19 Diagnostics and Testing Specialist (US CDC Detailee), The Global Fund (via Zoom, 29<sup>th</sup> September 2022)
- 44 Kary B Mullis and others, 'Process for amplifying, detecting, and/or cloning nucleic acid sequences using a thermostable enzyme' <<https://patents.google.com/patent/US4965188>> accessed 30 September 2022
- 45 Carla María McDowell-Buchanan and Daniel Clemens, 'Integrated immuno-pcr and nucleic acid analysis in an automated reaction cartridge' (Filed 11 December 2017) <<https://patents.google.com/patent/EP3551766B1/en?q=Integrated+immuno-pcr+and+nucleic+acid+analysis+in+an+automated+reaction+cartridge&oq=Integrated+immuno-pcr+and+nucleic+acid+analysis+in+an+automated+reaction+cartridge>> accessed 30 September 2022
- 46 Ron Chang and others, 'Universal Docking Bay and Data Door in a Fluidic Analysis System' (Filed 5 September 2013) <<https://patentscope.wipo.int/search/en/detail.jsf?docId=W02014039703>> accessed 30 September 2022
- 47 Interview with Stijn Deborggraeve, Diagnostics Advisor Infectious Diseases, MSF Access (via Zoom, 27<sup>th</sup> September 2022)
- 48 Cepheid, 'Cepheid and BioGX Announce Collaboration to Develop MPOX PCR Test for the GeneXpert® System' (27 June 2022) <<http://cephid.mediaroom.com/2022-06-27-Cepheid-and-BioGX-Announce-Collaboration-to-Develop-MPOX-PCR-Test-for-the-GeneXpert-R-System>> accessed 4 November 2022
- 49 Priyom Bose, 'On-site ultrasensitive MPOX viral testing using CRISPR/Cas12a' (18 October 2022) <<https://www.news-medical.net/news/20221018/On-site-ultrasensitive-MPOX-viral-testing-using-CRISPRCas12a.aspx>> accessed 6 November 2022
- 50 WHO, 'Increasing Access to Diagnostics Through Technology Transfer and Local Production' (2011) <<https://www.who.int/publications/i/item/9789241502375>> accessed 7 November 2022
- 51 Unitaid, 'FIND and Unitaid invest to support technology transfer and boost local production of COVID-19 rapid tests in low- and middle-income countries' (July 2021) <<https://unitaid.org/news-blog/find-unitaid-technology-transfer-covid-19/#en>> accessed 7 November 2022
- 52 Interview with Dr Joe Fitchett, Senior Advisor for Biotechnology, Institut Pasteur de Dakar, Senegal (via Whatsapp, 7 November 2022)
- 53 Medicines Patent Pool, 'New agreement under C-TAP aims to improve global access to COVID-19 testing technologies' (16 June 2022) <<https://medicinespatentpool.org/news-publications-post/new-agreement-under-c-tap-aims-to-improve-global-access-to-covid-19-testing-technologies>> accessed 7 November 2022

- 54 The Truenat from Molbio (also a WHO recommended test for TB) is gaining more and more attention, and USAID is funding rollout of the system in Africa.
- 55 MSF Access, 'Local Diagnostics to Meet Local Health Needs' (8 July 2021) p. 4 <<https://msfaccess.org/improve-local-production-diagnostics>> accessed 3 November 2022
- 56 Ibid p. 6
- 57 Ibid, p. 2
- 58 Interview with Dr Ifedayo Adetifa, Director-General Nigeria CDC (via zoom, 11 November 2022)
- 59 MSF Access, Online Supplement 1  
Overview of diagnostics manufacturers involved in technology transfer to or local production in low- and middle-income countries - Excel Spreadsheet (accessed 3 November 2022)
- 60 Interview with Devy Emperador, Senior Scientist, FIND (via email, 4 October 2022)
- 61 MSF Access, 'Local Diagnostics to Meet Local Health Needs' (8 July 2021) p. 5 <<https://msfaccess.org/improve-local-production-diagnostics>> accessed 3 November 2022
- 62 Alison Connor, Nisha Hariharan, and others, 'Access To COVID-19 Testing In Low- And Middle-Income Countries Is Still Critical To Achieving Health Equity' Health Affairs (27 October 2021) <<https://www.healthaffairs.org/doi/10.1377/forefront.20211026.483412>> accessed 4 November 2022
- 63 Feedback from Professor Brook K Baker, Senior Policy Analyst, Health Gap (via email, November 2022)
- 64 WHO, 'COVID-19 Supply Chain System: Requesting and receiving supplies' (30 April 2020) <<https://www.who.int/publications/m/item/covid-19-supply-chain-system-requesting-and-receiving-supplies>> accessed 15 November 2022
- 65 Interview with Stijn Deborggraeve, Diagnostics Advisor Infectious Diseases, MSF Access (via Zoom, 27<sup>th</sup> September 2022)
- 66 Interview with Dan Bausch, Director, Emerging Threats and Global Health Security, FIND (via Zoom, 28<sup>th</sup> September 2022)
- 67 WHO, 'Improving the transparency of markets for medicines, vaccines, and other health products' (May 2019) <[https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf)> accessed 7 November 2022
- 68 TIB Molbiol <<https://www.tib-molbiol.de>> accessed 17 November 2022
- 69 Matthew M Kavanagh and others, 'Access to life-saving medical resources for African countries: COVID-19 testing and response, ethics, and politics' (2020) 395 The Lancet 1735-38, 1736
- 70 Faith Mangwanya, 'Shortening the supply chain of rapid point of care diagnostics through local production and assembly in African low-income countries' (9 July 2022) <<https://www.linkedin.com/pulse/shortening-supply-chain-rapid-point-care-diagnostics-local-mangwanya/>> accessed 9 November 2022
- 71 Desmond Kuupiel and others, 'Supply chain management and accessibility to point-of-care testing in resource-limited settings: a systematic scoping review' (2019) BMC Health Services Research
- 72 WHO, 'Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries' (28 September 2020) <<https://www.who.int/news/item/28-09-2020-global-partnership-to-make-available-120-million-affordable-quality-covid-19-rapid-tests-for-low-and-middle-income-countries>> accessed 9 November 2020
- 73 Interview with Paul Molinaro, Bill Heaney, 'How air passenger traffic impacts cargo capacity' AirCargoNews (19 August 2022) <<https://www.aircargonews.net/freight-forwarder/how-air-passenger-traffic-impacts-cargo-capacity/>> accessed 25 November 2022
- 74 Wole Oyebeade, 'Nigeria, 16 others begin test-run of single air transport market treaty' The Guardian Nigeria (25 November 2022) <<https://guardian.ng/business-services/nigeria-16-others-begin-test-run-of-single-air-transport-market-treaty/>> accessed 28 November 2022
- 75 Represented by Zahedul Islam from Alliance for Public Health.
- 76 WHO, 'ACT-Accelerator Outcomes Report, 2020-22' (14 December 2022) <<https://www.who.int/publications/m/item/act-accelerator-outcomes-report-2020-22>> accessed 15 December 2022
- 77 The Global Fund, 'COVID-19' <<https://www.theglobalfund.org/en/covid-19/response-mechanism/>> accessed 10 November 2022
- 78 Open Consultants, 'External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)' (10 October 2022) <<https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-act-a>> accessed 10 November 2022, p. 26
- 79 WHO, 'WHO COVID-19 Essential Supplies Forecasting Tool (COVID-ESFT) v4.1' (15 February 2022) <[https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential\\_forecasting-2022.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential_forecasting-2022.1)> accessed 10 November 2022
- 80 Maureen Mackintosh and others, 'Rethinking health sector procurement as developmental linkages in East Africa' (2018) 200 Social Science & Medicine 182-189
- 81 Feedback from Arush Lal, Commissioner, Chatham House Commission for Universal Health (via email, 9 November 2022)
- 82 Arush Lal, Christopher Lim, and others, 'Minimizing COVID-19 disruption: Ensuring the supply of essential health products for health emergencies and routine health services' The Lancet Regional Health: Americas (6 December 2021), DOI: <https://doi.org/10.1016/j.lana.2021.100129>
- 83 Africa CDC, 'Revised COVID-19 Testing Strategy: Transitioning from Emergency Response to Integration into Routine Healthcare Services' (August 2022) p. 11 <<https://africacdc.org/download/revised-covid-19-testing-strategy-second-edition-june-2022/>> accessed 4 November 2022
- 84 Interview with Dr Aytenew Ashenafi Eshete, Program Manager, Africa CDC (via Zoom, 23 September 2022)

- 85 Interview with Dr Jilian Sacks, Technical Officer, COVID-19 Lab Team, WHO (via Zoom, 28 September 2022)
- 86 A program where medicines and diagnostics are subsidized by the government and provided in public and private pharmacies. Emmerick, I.C.M., do Nascimento, J.M., Pereira, M.A. et al. Farmácia Popular Program: changes in geographic accessibility of medicines during ten years of a medicine subsidy policy in Brazil. *J of Pharm Policy and Pract* 8, 10 (2015). <https://doi.org/10.1186/s40545-015-0030-x>
- 87 Emily B Wroe and others, 'Test and treat: a missing link in the global fight against COVID-19' (2022) 10(2) *The Lancet Global E181-E182* DOI:[https://doi.org/10.1016/S2214-109X\(21\)00568-4](https://doi.org/10.1016/S2214-109X(21)00568-4)
- 88 The Global Fund (supra note 20)
- 89 WHO AFRO (supra note 3)
- 90 Gareth Iacobucci, 'Covid-19: "Grotesque inequity" that only a quarter of paxlovid courses go to poorer countries' *BMJ* 2022;379: o2795 <doi: <https://doi.org/10.1136/bmj.o2795>> accessed 28 November 2022
- 91 U.S. Government, Administration for Strategic Preparedness & Response, 'Test to Treat' < <https://aspr.hhs.gov/TestToTreat/Pages/default.aspx>> accessed 28 November 2022
- 92 Shifa Foundation on Twitter (22 November 2022) <<https://twitter.com/ShifaFoundation/status/1594957570426404864>> accessed 28 November 2022
- 93 Shifa Foundation on Twitter (16 November 2022) <<https://twitter.com/ShifaFoundation/status/1592785751384936448>> accessed 28 November 2022
- 94 Matahari Global Solutions, 'Mapping Access Gaps in COVID-19: Results from 14 Countries and Territories' (August 2022) <https://itpcglobal.org/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-COVID-19.pdf> accessed 10 November 2022
- 95 The virus that causes chickenpox.
- 96 Eric Domo, 'Angels of hope battle monkeypox in Nigeria' *Gavi* (20 June 2022) < <https://www.gavi.org/vaccineswork/angels-hope-battle-monkeypox-nigeria>> accessed 28 November 2022
- 97 Emily B Wroe and others, 'Test and treat: a missing link in the global fight against COVID-19' (2022) 10(2) *The Lancet Global E181-E182* DOI:[https://doi.org/10.1016/S2214-109X\(21\)00568-4](https://doi.org/10.1016/S2214-109X(21)00568-4)
- 98 Oxfam International, 'Just a quarter of Pfizer's COVID-19 Treatment Orders will go to developing countries' (21 November 2022) <<https://www.oxfam.org/en/press-releases/just-quarter-pfizers-covid-19-treatment-orders-will-go-developing-countries>> accessed 6 December 2022
- 99 WHO, 'Improving the transparency of markets for medicines, vaccines, and other health products' (May 2019) <[https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf)> accessed 7 November 2022
- 100 MSF Access, 'Local Diagnostics to Meet Local Health Needs' (8 July 2021) p. 5 <<https://msfaccess.org/improve-local-production-diagnostics>> accessed 3 November 2022
- 101 WHO, 'Improving the transparency of markets for medicines, vaccines, and other health products' (May 2019) <[https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf)> accessed 7 November 2022
- 102 Updated pricing from Dr Jilian Sacks, Technical Officer, COVID-19 Lab Team, WHO (via email, 6 December 2022)
- 103 WHO, 'Emergency Global Supply Chain System (COVID-19) catalogue' (20 August 2022) < <https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue>> accessed 15 December 2022
- 104 GeneXpert Pricing <<https://www.finddx.org/pricing/genexpert/>> accessed 13 December 2022
- 105 UNICEF Supply Catalogue, 'Xpert Xpress CE-IVD SARS-CoV-2 kit/10T' < <https://supply.unicef.org/s0003892.html>> accessed 13 December 2022
- 106 The Global Fund, 'Pooled Procurement Mechanism Reference Pricing: COVID-19 diagnostics' (4<sup>th</sup> October 2022) <[https://www.theglobalfund.org/media/10233/covid19\\_diagnosticsreferenceprices\\_table\\_en.pdf](https://www.theglobalfund.org/media/10233/covid19_diagnosticsreferenceprices_table_en.pdf)> accessed 13 December 2022
- 107 Ibid
- 108 Ibid





MATAHARI



THE  
PEOPLE'S  
VACCINE