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### **Executive summary**

Diagnostics are fundamental to accurate detection of disease and critical to informing effective clinical care and selection of treatment. Yet access to diagnostic testing has remained poor and inequitable in many parts of the world. Approximately 47 percent of the global population has little to no access to diagnostics. This challenge is particularly evident in low- and middle-income countries (LMICs), where only 19 percent of patients have access to appropriate diagnostics at the primary health care level. This represents the single largest gap in the health care pathway (Fleming et al. 2021).

The COVID-19 pandemic continues to illustrate the criticality of appropriate and accessible diagnostics for a rapid response to new and existing diseases. At the same time, the pandemic has also highlighted the challenges in accessing quality-assured diagnostics, particularly for LMICs.

The 2021 Lancet Commission on Diagnostics analyzed existing gaps and barriers to appropriate diagnosis in LMICs. One major finding from this Lancet Commission is that local research and development (R&D), manufacturing, and distribution of diagnostics is limited, contributing to their lack of affordability in LMICs (Fleming et al. 2021).

To build on the Lancet Commission's body of work, PATH collaborated with Accenture to investigate access challenges within the diagnostics ecosystems in Latin America, Africa, and Southeast Asia. Market failures and market-shaping interventions needed for LMICs to close the existing diagnostics gap were identified through extensive desk research, one-on-one interviews with global health experts, and engagement with diagnostics manufacturers. This report aims to call attention to existing market failures across the diagnostics value chain, which includes R&D, manufacturing, procurement and distribution, and service delivery and user adoption.

Nine market failures were identified as key threats to diagnostic supply security: limited investment, insufficient workforce, deterring regulations, inefficient purchasing and procurement, operational inefficiencies, limited infrastructure and technology, high costs, low trust, and limited government and policy support.

Through the consistent and collaborative action of cross-sectoral stakeholders and players within this ecosystem, as outlined in the recommendations in this report, access to quality diagnostics in LMICs can be sustainably improved and expanded.



Global population with little to no access to diagnostics



Diagnostics gap in LMICs, the single largest gap in the care pathway



Deaths preventable in LMICs by reducing the diagnostics gap for six priority conditions



### Market failures in diagnostics ecosystems for LMICs

The diagnostics ecosystem is highly complex, layered, and interlinked with public, private, and global health systems, regulations, and stakeholders. Understanding the intricacies and nuances of existing market failures requires a structured assessment across the diagnostics ecosystem value chain (Figure 1).

FIGURE 1. The diagnostics ecosystem value chain



Each stage of the value chain involves multiple elements that must come together effectively to enable a sustainable ecosystem:

- Research and Development (R&D): Research, development and innovation activities aiding new product development, refinements, local customization, and knowledge sharing.
- 2. Manufacturing: Local manufacturing, customizing, and packaging of diagnostics products to be supplied through public and private distribution systems.
- 3. Procurement and distribution: Purchasing and procurement of finished products for tiered logistics and distribution services, including storage, cold-chain logistics, delivery, and coordination.

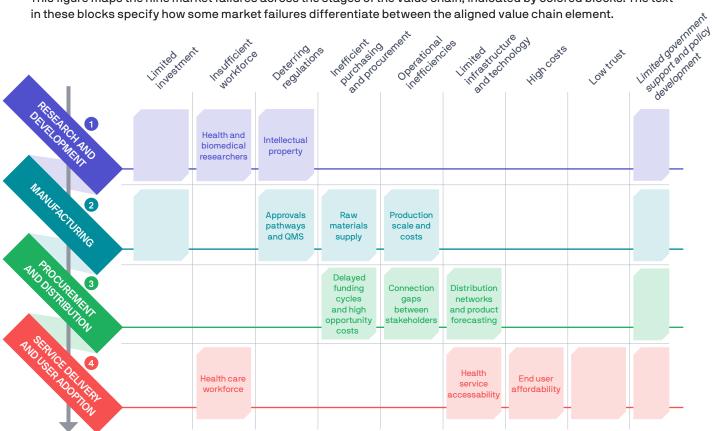


4. Service delivery and user adoption: Delivery of diagnostics services and uptake of diagnostics products by end users through out-of-pocket expenditures or public health system sales.

Market challenges in these value chain segments exist across LMICs, but it is important to differentiate gaps and nuances specific to Latin America, Africa, and Southeast Asia. Nine key market failures or challenges were identified and analyzed in detail. These market failures may appear in multiple value chain stages, as illustrated in Figure 2. Limited government support and policy development, for example, has been identified as a market failure that impacts each stage of the diagnostics value chain and is intertwined among descriptions of other market failures.

#### FIGURE 2. Market failures across the diagnostics value chain

This figure maps the nine market failures across the stages of the value chain, indicated by colored blocks. The text in these blocks specify how some market failures differentiate between the aligned value chain element.





#### Limited investment

Historically, the diagnostics sector has received insufficient attention in national or international health strategy plans and health expenditure budgets (Fleming et al. 2021). This is due to a myriad of factors stemming from the policy landscape. Traditionally, governments and donors have prioritized efforts to increase the accessibility of essential medicines and immunizations to close the treatment gap (K. A. Fleming et al. 2021). For example, out of almost 59,000 medicines, vaccines, and diagnostics in the health product pipeline since 1995, less than 2 percent have been diagnostics (WHO 2022). In the United States, federal investment in research to improve diagnosis amounted to US\$15-20M of the total US\$40B+ federal health research budget, less than 0.4 percent, in 2017 (SIDM n.d.). Bilateral and multilateral aid have similarly been insufficient and poorly aligned, as seen in 2020 aid for the COVID-19 response, when Latin America received only 7.7 percent of all development assistance despite recording over 34 percent of COVID-19 deaths in LMICs (Micah et al. 2021). This unreliable support directly limits funding for development of future-proof regulations and policies and R&D resourcing, which further exacerbates the issue (Brinkerhoff and Bossert 2014).

## Insufficient workforce: Health and biomedical researchers

The number of health and biomedical researchers in LMICs is dramatically lower than in high-income countries (HICs). In 2020, data from the World Health Organization (WHO) Global Observatory on Health R&D showed that HICs had 73 times more health researchers per million inhabitants than LICs and 7 times more than LMICs (Ciocca & Delgado 2017, WHO 2022). Limited and unsustained investment in academia, research, and innovation in LMICs results in limitations in training and career opportunities for R&D professionals. HICs often offer higher salaries and more professional

### Inadequate R&D investment limits innovation

Region: Africa

Africa comprises 15 percent of the world's population but bears 25 percent of the global disease burden and produces only 2 percent of the world's research output. Significant challenges that contribute to this include a lack of well-trained researchers despite existing pockets of excellence, limited career progression pathways, and poor research infrastructure, including a lack of access to scholarly tools such as scientific literature (Kasprowicz 2020).

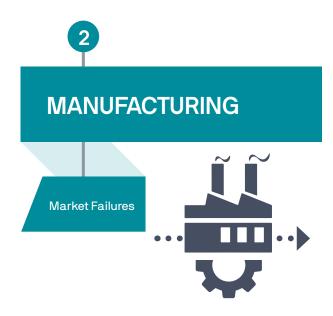
development opportunities, further perpetuating difficulty in hiring and retaining local researchers (Blackcock 2012, Cometto et al. 2013). This leads to product development being concentrated largely in HICs, especially through large-scale diagnostic manufacturers and well-established academic centers of excellence. This uneven distribution of R&D efforts and researchers limits in-country innovation, contributing to a lack of customized and acceptable diagnostics for LMIC needs.

"As a trained biomedical laboratory technician, I have the vision of having a local-based R&D laboratory to deal with the rampant tropical diseases. The constraint here is [a] source of funding to set up the state-of-the-art laboratory and a skilled labor force."

-Diagnostics distributor, Africa region

# Deterring regulations: Intellectual property

The capacity to translate scientific research into protected intellectual property (IP) differs across countries. Variable enforcement of IP rights in LMICs creates uncertainty for innovators and investors around the value of their IP, future protections, and hence monetization, further disincentivizing local investment and innovation. As a result, diagnostic products are often imported from HICs, which benefit from stronger IP protections. The reliance on overseas IP increases shipping and distribution costs, which are passed on to the end-user and ultimately contribute to limited affordability in LMICs (WHO 2011).



#### Limited investment

Manufacturers that are based in LMICs (local manufacturers) have limited growth opportunities due to lack of scalable and sustainable demand for diagnostic products in local and regional markets. This leads to low return on investment (ROI), limiting financial attractiveness for investors. Exceptions to this include countries with large domestic markets and country-first policy mandates, such as India and Brazil (WHO 2011). Loans to finance the upfront capital required for manufacturing are attached to high interest rates and become unattainable for many small and medium-sized manufacturers (Financing for Sustainable Development Report 2021). Without accessible and adequate financing, the cyclical issue of limited local manufacturing persists in LMICs.

## Deterring regulations: Approvals pathways and quality management systems

Inefficient and fragmented regulatory systems across LMICs create barriers for local manufacturers to enter and scale up within these markets. Though some harmonization efforts are underway, the regulatory processes and requirements for product registration and sales across LMICs vary. In comparison to the expected ROI, manufacturers are expected to spend a disproportionate amount of time and money to file country-specific dossiers, navigate administrative processes, and in some cases, generate additional local clinical evidence. Local manufacturers often struggle to obtain, fund, and sustain sufficient technical expertise to consistently meet Good Manufacturing Practices and ISO manufacturing standards, inhibiting their ability to compete with the quality, consistency, and volumes of HIC market products (Zhan 2020). Inconsistencies in regulations and post-market monitoring also pose both real and perceived risks of quality assurance.

### Limited local production and high reliance on imports

Region: Latin America

In 2018, Brazil imported medical test kits, instruments, and apparatus used in diagnostics worth \$453 million, against exports of just \$12 million, indicating reliance on foreign manufacturers (WITS 2018).

# Inefficient purchasing and procurement: Raw material supply

Limited domestic availability of raw materials and products leaves diagnostics manufacturers in LMICs highly reliant on imports from HICs. Importations often come with higher costs, especially given local manufacturers' inability to buy at scale. During unstable times, including the COVID-19 pandemic, logistics issues with importation, such as grounded flights and travel restrictions, create bottlenecks for manufacturers, often rendering them unable to procure raw materials entirely (The Rockefeller Foundation 2020). During the first year of the COVID-19 pandemic, supplies of nitrocellulose membranes, sterile swabs, cassettes, and test reagents were all limiting factors for rapid diagnostic test (RDT) development, as the existing suppliers and international supply chains were limited in number and scope. Although some raw material suppliers have taken initiative to scale up production, rising prices of certain raw materials continue to impact diagnostics production capacity (Hannay et al. 2022).

"Economies of scale are absent in LMICs which are essential as there are a handful of large companies who are global monopolies, and it is nearly impossible to enter and compete with them without global, regional and national support."

-Medical relief organization representative, Global

## Operational inefficiencies: *Production* scale and costs

Local manufacturers who can overcome startup barriers still face issues in scaling production to the requisite level. Sustainable operations require appropriate infrastructure and technology, high utility rates of machinery, and predictable demand, all of which are a challenge in LMICs. Not having these leads to higher fixed costs and lower returns. Limited or fluctuating demand means manufacturers are unable to reap benefits from automation, for which the upfront costs would otherwise be sustainably amortized over a product's life cycle (K. A. Fleming et al., 2021).



# Inefficient purchasing and procurement: Delayed funding cycles and high opportunity costs

Procurement and distribution of diagnostics in LMICs rely on an especially complex network of actors, which can lead to high operational costs and financial risk. Governments are typically the largest buyers of diagnostics in LMICs, and government processes, budget cycles, and bureaucracy often cause funding disbursement delays, impacting the working capital available for distributors (Mugambi et al. 2018). This creates an imbalanced environment in which distributors must decide to delay fulfillment of orders or absorb the financial risk of fulfilling orders without upfront payment (Sourish Das 2020). A representative from an Africa-based diagnostics developer noted that a lack of coordination between large procurers and local governments for input waivers (i.e., tax credits) often leads to stock being stuck in warehouses for months, increasing the cost to manufacturers and distributors while reducing the usable shelf life of products. This creates inefficient distribution practices and assigns high opportunity costs to distributors already working in low margin businesses, where distribution costs can vary from 13 to 44 percent of product costs depending on the country and the product (Shretta 2015).

### Complex distribution networks increase timelines for service delivery

#### Region: Africa

Burkina Faso has 1 National Level Medical Store, 7 Regional Level Medical Stores, and 63 District Level Medical Stores, which when coupled with additional complexity from over a dozen other storage entities, cause communication and information gaps and delays in delivery of drugs and diagnostics by up to eight months (Schöpperle 2013).

# Operational inefficiencies: Communication gaps between stakeholders

Public, private, and development sector organizations involved in the diagnostics supply chain often have several tiers, layers, and intermediaries. These tend to work as separate functions, leading to poor and irregular communication, information silos, and a lack of accountability. The resulting environment with limited oversight and harmonization of Good Distribution Practices further hinders the development of a coordinated and efficient distribution system needed for a sustainable diagnostics ecosystem (Yadav 2015).

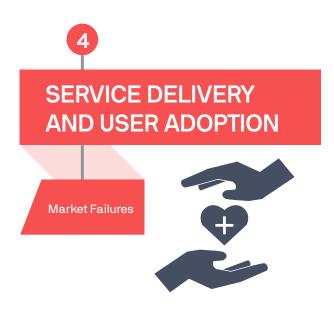
# Improper forecasting and requisitioning leading to stockouts and supply-demand fluctuation

#### Region: Latin America

A study conducted in rural antenatal clinics and community-based settings in Guatemala showed that nearly half of the women who came for HIV, syphilis, and hepatitis B virus testing services did not get tested, as stockouts occurred in part due to the lack of information management systems and improper requisitioning (Kuupiel 2019).

#### Limited infrastructure and technology: Distribution networks and product forecasting

Market sustainability is further limited by infrastructure and technology gaps in the last mile of distribution processes in LMICs. Most private diagnostics distributors and wholesalers tend to focus on urban and high-profit regions, leaving the harder-to-reach areas for government distribution (Yadav 2015). Owing to manual and paper-based approaches for information management at the procurement, distribution, and service delivery stages of the value chain, diagnostics distributors are unable to capture real-time consumption data to analyze trends and develop accurate demand forecasts. This inhibits their abilities to streamline supply chains and enable the timely dispatch of diagnostics at the right volumes, leading to product wastage (Fritz et al. 2021). Common forecasting methods utilize historical procurement and consumption patterns, past experience of procurers, or rough needs assessments given missing or inconsistent receipt of data. These methods are less accurate than real-time data gathering in predicting the inherently variable and evolving demand of diagnostics in LMICs, leading to inefficient or underinformed planning for procurement and distribution (Engel et al. 2016).



### Insufficient workforce: *Health care* workforce

Estimates indicate that there is a need for an additional 840K to 1M workers to support diagnostics testing and medical imaging globally. There is little standardized data available from LMICs, but estimates in sub-Saharan Africa have shown that most countries have less than 1 pathologist and 5 radiologists per million population (K. A. Fleming et al., 2021). This implies both an overburdened and insufficient workforce to effectively operate complex diagnostics devices and procedures or provide subsequent health services.

#### High costs: End-user affordability

WHO estimates that up to 90 percent of populations in LMICs access diagnostic services through out-of-pocket payments (WHO, 2017a). As LMICs are characterized by low disposable incomes, the general population is often unable to afford diagnostic services. This leads toward the tendency to seek diagnostic services only when symptoms become severe, which results in late disease identification (WHO, 2011). Coupled with higher end-user costs patients may face due to the inefficiencies described in previous sections, the result is lower sustained product demand. As income levels continue to apply downward pressure to demand, sales and user adoption are negatively impacted.

#### Limited infrastructure and technology: Health service accessibility

A large proportion of populations in LMICs lack access to diagnostic products and services based on social, economic, and geographic determinants. Greater availability of diagnostic services is seen in urban areas and, especially, for people of higher

#### Inadequate workforce capacity and skill

#### Region: Southeast Asia

In Indonesia, the most persistent challenge during the pandemic was the unequal distribution of trained diagnostic workers across the 34 provinces. Even when the logistics support chain was addressed and equipment/reagents were made available, the lack of trained staff hindered laboratories from reaching their maximum outputs. The non-availability of diagnostic workers frequently led to diagnostic errors (Aisyah 2021).

socioeconomic status. In addition to the distribution challenges in rural areas, where a large proportion of LMIC populations live, health care facilities are sparsely distributed and suffer from limited access to stable electrical supplies, clean water, reliable internet connections, and systems needed for transporting specimens (Welland 2017). Further, up to 20 percent of health centers in LMICs do not have a refrigerator or cold rooms to store diagnostic samples, and many do not have sufficient capacity (M. Fleming et al. 2021). These limitations significantly hinder accessibility and uptake of diagnostic services in LMICs.

#### Low trust

Low trust and usage of health technologies, such as diagnostics, are impacted by prior experiences with varying quality of products, cultural differences, and othering that may be experienced by minority ethnic patients during encounters with health care personnel (Alpers, 2016). According to WHO, approximately 10 percent of medical products circulating in LMICs are either substandard or falsified (WHO, 2017b). Further, preferences for traditional medicine in rural and in some indigenous and low-income areas contribute to low demand for modern medicine approaches (Alpers, 2016). This can result in resistance to the adoption of new technologies and equipment in diagnostics and health care (James et al., 2018). Overall, these factors decrease demand, with more significant impact to locally manufactured diagnostics. To ensure supply security of diagnostics and promote local autonomy in LMIC markets, it is critical to support holistic investment and strengthening of each component of the diagnostics value chain.

# Toward improved supply security for quality diagnostics

LMICs in Latin America, Africa, and Southeast Asia are witnessing a steep growth in the demand for diagnostic products, as shown in Figure 3. Southeast Asia is the fastest growing market with an anticipated compound annual growth rate (CAGR) of 8.6 percent (PwC, 2021). Despite the discussed market failures, the COVID-19 pandemic has highlighted the need for as well as the existing capabilities of domestic development of diagnostics in LMICs. For example,

the COVID-19 pandemic spurred investments in localization of vaccine manufacturing to help mitigate market failures. The need and opportunity for local diagnostic manufacturing will require investment and intervention throughout the entire value chain. Several opportunities emerge for policymakers, donors, private companies, and other global health stakeholders (Figure 4) to collectively close the diagnostics gap, as noted below.

FIGURE 3. Global in vitro diagnostics (IVD) market size and growth by geography (2018–2024) (PWC, 2021).

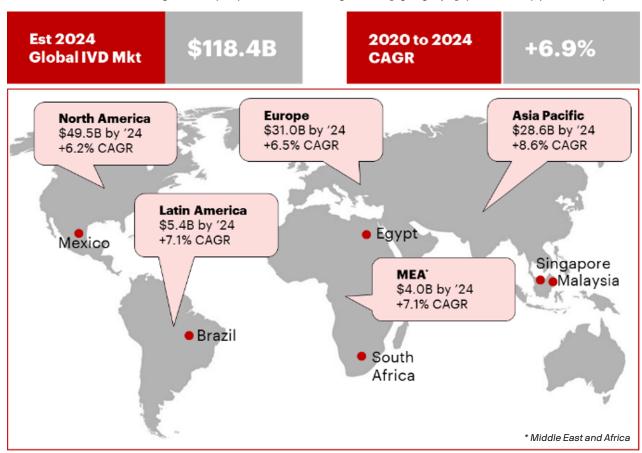


FIGURE 4. Diagnostics ecosystem stakeholders and their roles to improve diagnostic supply security in LMICs



### Regional coordination of supply and demand

### Establishment of local or regional diagnostics manufacturing hubs







Investment in local diagnostics manufacturing can help mitigate overreliance on imports, build local capacity, and spur local demand. Doing so requires increased investment from development financial institutions (DFIs) and commercial investors. Government support is required through enabling policies and incentives, trade enablement, and financial and technical assistance. Given the increased focus on localization in the donor community, manufacturers in these countries should be ready to articulate investment opportunities and returns to capitalize on potential investor interests. Local manufacturer communities of practice should also be established to share best practices and lessons learned.

#### **Enabling pooled procurement**







Coordination and aggregation of demand, both for raw materials and finished product, would allow manufacturers and regional procurers to achieve lower prices through improving operational efficiency. Governments must develop and implement policies and practices to improve communication and coordination. Pooled procurement is one mechanism that should be better leveraged, particularly for non-

# Pooled procurement to reduce supply and demand fluctuations for locally produced diagnostic products

Region: Latin America

The Organization of Eastern Caribbean States Pharmaceutical Procurement Services (OECS PPS) procures an 840-item product portfolio including a diverse range of pharmaceutical and non-pharmaceutical items. It is a self-financing public sector monopsony, or buyers' cartel, that covers its operating cost from a modest surcharge imposed upon subscribing Member States.

The OECS PPS achieves price benefits of greater than 20%, allowing a broad community of small-volume markets to secure reliable supply at fair prices. It has consistently achieved annual cost savings of approximately US\$4 million reinforcing the procurement services as an excellent cost-benefit model of economic and functional cooperation between OECS Member States (Barton et al. 2022, OECS 2022).

Global Fund markets, given the development sector's historical successes with this market intervention.

#### Standardizing regional regulations and standards



Cooperation at regional levels to build regulatory agencies, such as the African Medicines Agency or Association of Southeast Asian Nations Medical

### Strengthening regulatory capacity through regional harmonization

Region: Africa

The ZaZiBoNa collaborative medicines registration initiative was established in 2013 by Zambia, Zimbabwe, Botswana, and Namibia, but any South African country may voluntarily participate. The initiative was formed to address regulatory challenges, such as huge backlogs of product applications, high staff turnover, long registration times, inadequate financial resources, and limited capacity to assess certain products such as biologicals and biosimilars. Manufacturers apply to register their product in countries individually and request assessment by ZaZiBoNa, which assigns countries to conduct reviews. WHO is responsible for quality assurance of the final reports. Post assessment, ZaZiBoNa makes a recommendation to the countries, who make the final decision to register or reject products based on country-specific requirements. This regional harmonization helps reduce regulatory workload, accelerate registrations of required products, build mutual trust and confidence in regulatory collaboration, and improve information sharing and networking (Sithole 2020).

Device Directive, support unification of standards for product registration, distribution, and post-market surveillance. This level of harmonization maintains autonomy and accountability while facilitating cross-country regulatory compliance. Harmonization also supports manufacturers in optimizing the design of required studies to generate data for local validation, providing advanced visibility to country-specific product customization requirements and enabling manufacturers to appropriately build time and resources into their commercial launch strategies. National regulatory agencies could also consider reconciling policies to recognize product and facility approvals from WHO-recognized stringent regulatory authorities.

Sharing of supply and demand data through regional or disease vertical consortiums





During the COVID-19 pandemic, global health actors procuring diagnostics in LMICs shared data on pricing and volumes of diagnostics purchased. National governments could establish systems for the sharing of similar data at local and provincial levels within their own countries and between neighboring countries to

support price transparency. These same mechanisms could be deployed to coordinate transfer of diagnostics between regions based on fluctuations in supply and demand.

## Workforce capacity, training, and retention

Strengthening and increasing local capability development opportunities







Enhanced and expanded training of local R&D and manufacturing workforces are necessary to increase the size of the workforce addressing upstream supply chain workforce gaps. Training should cover production and regulatory requirements, standard operating procedures focused on quality management systems, and after-sale support. Expanding job scopes and supportive training of priority diagnostics and digital literacy for community health workers and other non-physician health care workers could support filling downstream workforce gaps, improving service delivery and linkages to diagnostic testing.

Implementing policies to retain health care workers in LMICs and decrease HIC reliance on foreign-born health care workers





LMIC governments should focus on retention strategies beyond wage increases, such as improved working and living conditions for health care workers. Ministries of health and academic institutes in LMICs can build partnerships with training, education, research, and medical institutions from other LMICs, HICs, and/or private-sector players to support science and health workforces. HICs should follow the WHO global code of practice on international recruitment of health personnel and not hire from countries with poor health care worker-to-population ratios where appropriate (Cometto et al. 2013).

#### Knowledge networks and markets

Enabling technology transfers across countries







Diagnostic companies producing quality products with relevant applications in LMICs could enter into technology transfer agreements with local manufacturers to increase production capacity and expand product access. Additionally, academic

### Technology transfer to build local capacity for infectious disease diagnostics

#### Region: Latin America

The Oswaldo Cruz Foundation (Fiocruz), a
Brazilian scientific institution for R&D affiliated
with the Ministry of Health, is one of the world's
most successful recipients of technology
transfer for infectious disease diagnostics. It
has developed and produced in vitro diagnostics
(IVDs) independently and in collaboration with
international commercial partners.

One partnership of note, Fiocruz has signed a series of technology transfer agreements with Chembio Diagnostics, which has given Fiocruz access to a second-generation lateral flow test platform, the proprietary Dual Path Platform (DPP), a rapid immunoblot for serologic HIV infection confirmation, and associated reagents. Fiocruz's technology transfer process includes access to technical documentation, personnel training, and exchange visits among other activities, in exchange for a minimum quote of purchases by Fiocruz from Chembio with the understanding that once the technology transfer process was complete, royalties would be paid (WHO 2011).

institutions and R&D incubators developing diagnostics can seek commercial and manufacturing partners in LMICs who are well positioned to supply diagnostics to such markets. In the short term, technology transfers of commercial or near-commercial technologies enable local manufacturers to build commercial capacity and a revenue stream. Over time, this may spur longer term investments in local R&D capacity-building.

#### Encouraging open access and knowledge sharing











Encouraging or mandating open science principles and access requirements through public and private funding agreements for diagnostics R&D can foster sharing and collaboration and decrease financial barriers to accessing knowledge. Through creative deal structuring in product development partnerships, such as geography-specific licensing and price points, diagnostics innovators can also find appropriate ways to openly license technologies and share know-how globally to enable the regional diversification and expansion of diagnostics production and supply capacities.

### Establishment of intellectual property clearinghouses to fill supply gaps





Patent pools and clearinghouses should be explored as mechanisms for the philanthropic sharing of intellectual property (OECD 2011). The World Bank recommended a value-chain based approach for all essential health commodities through which companies, who are normally competitors, collaborate using clearinghouses (Evenett et al. 2021, Findlay & Hoekman 2020, World Bank & World Trade Organization 2022). Diagnostic manufacturers who are unable to satisfy demand for their product can share IP and report bottlenecks through a clearinghouse, along with qualifications a contract manufacturer must meet to receive their IP. Producers that meet specifications agree to produce the diagnostic products for an agreed-upon time. In addition to facilitating IP sharing to fill supply gaps, those governing the clearinghouse would have insight on supply-demand bottlenecks and can share this information back with governments and other purchasers to implement relevant market interventions.

#### Medicines patent pool

#### Region: Global

The Medicines Patent Pool (MPP) increases access to and facilitates development of essential medicines by signing licensing and accessibility agreements from patent holders. The MPP has currently signed agreements with 15 patent holders across the HIV, HCV, and COVID-19 treatment and technology spaces (Medicines Patent Pool n.d.).

#### Logistics and information management

Facilitating third-party logistics (3PL) service agreements and utilizing interoperable information management systems





LMICs need systemic solutions to solve the logistics infrastructure gaps in diagnostics. Implementing service agreements between public health systems and 3PL providers can be an efficient and affordable solution to product delivery and standardization across regions. 3PL providers use sophisticated analytics tools and technologies for decision-making to ensure on-time order fulfillment, route optimization, and shipment visibility. Increased data collaboration and open sharing through the deployment of multistakeholder information management systems can

vastly improve coordination and demand-supply management to enable a sustainable market. Use of these tools could help optimize distribution of diagnostic products, potentially reducing shipping costs, accelerating deliveries, and improving access.

#### Innovative financing and funding

#### Establishing incentives to de-risk market entry







Advanced market commitments (AMCs) incentivize investment in R&D for technologies that may have a small viable market by establishing sufficient demand for a final product. Donors participating in an AMC can negotiate tail prices for products after the commitment has been met, so that the cost remains accessible. Similarly, a donor can enter into a volume guarantee agreement with a manufacturer to establish a set price and volume available per year for a health product and to collaborate to ensure product registration, commercialization, and post-market surveillance. In this way, the manufacturer agrees to produce enough of the product and sell that volume at an agreed-upon price each year and, if that volume is not met, the donor will either purchase or provide payment for the remainder (MedAccess 2022). AMCs and volume guarantees should be established in parallel to product development partnerships that support local diagnostics developers and manufacturers to avoid risk of excluding small and medium-sized businesses that do not have the interim capital for R&D and manufacturing necessary to get the product to market.

### Volume guarantee to secure supply of quantitative point-of- care G6PD test

#### Region: Global

Individuals with glucose-6 phosphate dehydrogenase (G6PD) deficiency who take the leading treatment of P. vivax malaria, 8-aminoquine, are at risk of a severe blood disorder if the drug if not administered at a correct dose. WHO recommends conducting a G6PD deficiency test prior to administering treatment to reduce risk of mis-administering the treatment. MedAccess has entered into a volume guarantee deal with SD Biosensor to secure access to and continue to increase adoption of the STANDARD G6PD test for LMICs (MedAccess 2022).

### Expanding distributors' capacities and product offerings through supply trade finance mechanisms







Traditional trade finance mechanisms, including credits, guarantees, and insurance, are essential to international trade as they reduce risk associated with cashless transactions and allow companies to continue operations and maintain cash flows during export and import of goods. Trade finance is particularly vital to small and medium enterprises (SMEs) with limited cashflow, but, despite accounting for approximately 80 percent of employment in LMICs, SMEs face the greatest difficulty in accessing these mechanisms (World Trade Organization 2016). Expanding access to supply chain finance products, such as pre-shipment, post-shipment/ post-acceptance, and distribution financing for SMEs could address diagnostic distribution operational inefficiencies and risks related to delayed payments (Asian Development Bank 2022).

#### A call to action

There is a critical need to improve quality diagnostic access in LMICs. End-to-end investments must be made to strengthen local manufacturing capacities, demand-planning, workforces, quality assurance, and partnerships. All stakeholders in this ecosystem have a role to play, with commitment needed across LMIC and HIC governments, regional authorities, local and global manufacturers, procurers, distributers, academia, the development sector, and other global health actors. With appropriate action and collaboration, access to quality diagnostics in LMICs can be sustainably improved and expanded to ensure greater global health equity.

If interested in engaging with PATH to support this call to action or to learn more, please contact the team at <a href="mailto:dxsupplysecurity@path.org">dxsupplysecurity@path.org</a>.

### **Appendix**

#### Methodology

A three-pronged approach was undertaken to understand key challenges, root causes, and potential interventions across Latin America, Africa, and Southeast Asia through:

- Extensive desk research on existing literature (i.e., published reports, articles, and thought papers) to identify and understand prevailing market failures in the three focus regions.
- 2. One-on-one interviews with key stakeholders in global health organizations (including the Global Fund; Global Access Diagnostics; United Nations Development Programme; Clinton Health Access Initiative; MSF (Médecins Sans Frontiers); Becton, Dickinson and Company; SD Biosensor; CostCare Medical Supplies; Halteres Associates LLC; University of Cambridge) to refine findings.
- 3. Engagements with 22 local diagnostics manufacturers and distributors along with leveraging expertise from Accenture subject matter advisors to understand on-ground challenges and possible recommendations.

#### Scope

- Lack of funding and the policy landscape may lead to market failures and impact diagnostic supply security at various stages of the value chain. Although funding and policy market failures and proposed recommendations were incorporated throughout this report, the failures play a much deeper role than what is outlined here due to the fragmentation of political ecosystems between countries and at the international level.
- Proposed solutions relating to last-mile infrastructure, including investment in roads, internet connectivity, power, and clean water, were excluded from this analysis. Market failures related to infrastructure and other environmental and geographic characteristics. while key considerations for patient access to quality diagnostics and health care overall, fall more broadly under the social determinants of health and were left out of the market failures scope of this paper.
- Solutions to address the low trust that many end users, including both patients and health care workers, have toward modern health technology, including diagnostics, is also out of scope for this paper. Low trust stems from both cultural and colonial histories and prevalence of counterfeit products in LMIC markets. Interventions targeting these failures would be on the individual, instead of market level, and focus more on adoptability than accessibility.
- Although recommendations for financing diagnostics expansion through public-private partnerships were included, an analysis of integrating diagnostics into national health insurance schemes was not conducted.

#### Acknowledgments

This is a PATH report based on a joint analysis carried out by Accenture and PATH. The views expressed in this report do not necessarily reflect the position of PATH, Accenture, or other organizations.



PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with

expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Through PATH's unique capabilities in health systems strengthening and convening partnerships across sectors and borders, PATH aims to improve market access for high-quality, cost-effective diagnostics that meet local and regional needs. With experience across health areas and technology platforms, PATH Diagnostics has proven approaches to support developers and manufacturers in bringing valuable insights and tools to market. PATH's objective is to work toward bringing equity in health by enhancing capabilities and resources at the regional and local level.



Accenture Development Partnerships **accenture** (ADP) is a mission-driven consulting practice working with the world's

largest NGOs, foundations, donors, companies, and governments to create social impact in over 120 countries. It focuses on helping to strengthen organizations and enhance their programmes—leveraging our capabilities in business strategy, digital innovation, and the development of cross-sector partnerships. ADP's Global Health Practice helps clients build the capabilities and solutions they need to create sustainable health impact for people in the developing world. Accenture has been working towards closing the health equity gap, with a focus on shaping stronger ecosystems that provide equitable access and improved patient outcomes across industries and functions.

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