FIND market and insights primer:
near-point of care molecular diagnostics in low-and middle-income countries

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Diagnosis for all

ACKNOWLEDGEMENTS

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ABBREVIATIONS

AMR	antimicrobial resistance
BSL	biosafety lab level
EIA	enzyme immunoassay
EID	early infant diagnosis
ELISA	enzyme-linked immunosorbent assay
EXW	ex-works
CLIA	chemiluminescence immunoassay
COGS	cost of goods sold
COVID-19	coronavirus disease 2019
HBV	hepatitis B virus
HCV	hepatitis C virus
HICs	high-income countries
HIV	human immunodeficiency virus
HPV	human papillomavirus
KOL	key opinion leaders
LICs	low-income countries
LMICs	low- and middle-income countries
LTA	long-term agreement
L0-4	level 0-4 health facility
MDR-TB	multidrug resistant tuberculosis
MDx	molecular diagnostics
MICs	middle-income countries
NAAT	nucleic acid amplification test
PCR	polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
POC	point-of-care
R&D	research and development
RDT	rapid diagnostic test
RTI	respiratory tract infection
RT-PCR	reverse transcription polymerase chain reaction
SLA	service level agreement
STI	sexually transmitted infection
TAM	total addressable market
TB	tuberculosis
UMICs	upper-middle-income countries
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Today, in our post-COVID-19 world, the concept of being diagnosed, from the patient or end-user perspective, has undergone a radical shift from centralized laboratories with large, fixed equipment run by highly trained technicians to enabling a result in the palm of a hand, done from the comfort of the end-user's home. Confirmatory disease testing can be done in decentralized settings with limited laboratory infrastructure. Leveraging the technological revolution spurred by COVID-19, a wave of innovation continues in the molecular diagnostics (MDx) industry bringing recent advances in speed, accuracy, and portability of testing closer to the patient, at or near their point-of-care (POC).

This market report focuses on near-POC MDx technologies appropriate for "Level 2 (L2)" facilities in low- and middle-income countries (LMICs)—i.e. district hospitals and near-patient laboratories. Simple-to-use diagnostics near the patient, with rapid results that can differentiate between multiple pathogens, have become a gold standard in the post-COVID-19 laboratory. Multiplexing, or the ability to test for multiple disease targets with a single sample, is transformative for patient management. At L2 health facilities, low, medium, and high multiplex MDx platforms can most efficiently be placed for diagnosis for clinical case management and ongoing surveillance needs.

Similarly, the near-POC MDx market has also demonstrated a slow adoption curve in LMICs over the decade (pre-pandemic), even with substantial funding. The expansion of the POC MDx footprint accelerated across most countries during COVID-19, with nearly twice the installed base of the market-leading platforms in 2021, compared to 2019.[1] However, as more MDx products attain regulatory approvals in HICs, ensuring LMICs have *timely* access to innovation is critical.

Market landscape: Over 80 near-POC MDx platforms exist, with at least 65 platforms on the market and 19 novel platforms in the pipeline, as of October 2022.[2] Although near-POC MDx platforms with very high multiplexing capacity may currently be considered complex and costly for the needs of L2 health facilities in LMICs, it is promising that there are new entrants, as well as existing technology in the market. With the appropriate go-to-market (commercialization) and product launch planning, along with affordable market prices, near-POC MDx platforms can evolve to adapt to service mounting disease needs in LMICs.

Procurement and distribution channels: The split between public and private markets for near-POC MDx technology differs by country, based on how healthcare services are accessed, the needs and willingness to pay, and the structure of market channels. The public market, in the form of governments' high-volume tenders for confirmatory disease testing, represents significant volumes but is more price-sensitive and requires more comprehensive

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[1] Source: FIND analysis of near-POC molecular diagnostics installed global base, pre-and post-pandemic.
[2] Source: FIND landscape of POC molecular diagnostic platforms.

service and maintenance network coverage; the routine surveillance market, owned by public referral laboratories, is an existing and secure smaller market, although still price-sensitive. The private market includes private laboratories, clinics, hospitals and even pharmacies, where regulations allow. The distributor's role cannot be understated in commercialization and the provision of after-sales services. Both direct and indirect distribution models are employed within the diagnostics industry. Countries with sizable middle and upper-middle-income population segments that access private market channels offer an opportunity to open and develop new markets for near-POC MDx multiplex technology.

Pricing: Currently, instrument and test cartridge pricing for near-POC MDx platforms, based on published ex-works (EXW) pricing, is US$10,000 to $72,000 for the instrument (depending on the number of modules) and $7.90 to $30 per test cartridge. It has been documented by Treatment Action Group and others that the EXW price could potentially be reduced to $5 per test cartridge.[3] Products can be compared using EXW pricing; however, it is critical to note that in the market, EXW pricing differs from what the buyer actually pays. Shipping, insurance, import fees, duties, and taxes must all be paid and are dictated by the Incoterms used between the buyer and the seller. In public health, long-term agreements are often negotiated at the EXW price, but for the buyer, the landed costs have been documented to be upwards of 50 to 100% more expensive.[4] This is not unique to MDx and is common among many laboratory (and health) products.

Cost structure: The costs of a near-POC MDx platform are comprised of the instrument, test cartridges, and service and maintenance. All near-POC MDx platforms in-market are closed-systems and, thus, subject to platform-specific installation, training, and service and maintenance costs.

Although the MDx instruments represent high capital expenditure for buyers, the perpetual costs of test cartridges comprise the dominant share of ongoing testing program costs. Overall, the three primary cost drivers that impact near-POC MDx test cartridge cost of goods are manufacturing scale, manufacturing location, and test cartridge complexity. Economies of scale from increasing volumes significantly decrease material costs by driving down the cost of reagents, as well as the direct and indirect costs by enabling a more automated process, reducing labour costs, and increasing efficiency. Shifting manufacturing to lower-cost labour environments can significantly decrease direct costs and ensure supply.

The service and maintenance support after the initial platform sale, provided by distributors, is a major cost component of near-POC MDx platforms. Cost drivers include the volume of platforms to be serviced, site distance and accessibility, the level of technical expertise required, the macroeconomic environment, and overall assessment of risk or uncertainty. Service and maintenance costs are usually built into all platform components: the instrument, the test cartridges, and service and maintenance agreements.

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[3] Advancing Access through Market Interventions: Lessons Learned from the GeneXpert Tuberculosis Test Buy-Down, Treatment Action Group, 2020
[4] Based on industry analysis across FIND, CHAI, and Market Access Africa.

Purchasing models: The high capital expenditure incurred to purchase an MDx instrument, and a common pain point faced by countries of unaffordable or inadequate service and maintenance coverage—especially after the initial few years of purchase covered under warranty—has led to the development of newer purchasing models. Potential solutions being demonstrated in the market include service level agreements, structured to be monitored according to key performance indicators, reagent rental agreements, also known as all-inclusive pricing agreements, and pay-per-result agreements.

Market potential: FIND estimates that 63.6 million tests represent the target addressable market per year, for near-POC MDx, at L2 health facilities in LMICs. This estimate includes tuberculosis (TB), flu and respiratory syncytial virus (RSV), hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human papillomavirus (HPV), chlamydia and gonorrhoea, and arboviruses (including dengue, yellow fever, and Zika virus). TB represents the largest market, with 28.1 million tests, followed by HPV at 14 million tests and HIV at 6.4 million tests. While in decline, the market for COVID-19 near-POC MDx represents an additional 33.8 million tests. This estimate considers the current epidemiology of select pathogens and recommended clinical protocols in up to three relevant use cases—screening or case finding, clinical management of disease, and surveillance—to estimate the annual testing need by disease. It also considers the clinical diagnosis and treatment guidelines from the World Health Organization and the current usage of non-MDx diagnostic alternatives, such as rapid diagnostic tests, microscopy and blood culture. This estimate is not a forecast or assessment of demand; it does not consider the willingness to pay, health system capacity, or health system efficiencies. It also does not include technology replacement outside of current guidelines (i.e. the share of overall testing attributable to other diagnostic types), and the current share of centralized testing is assumed to be constant.

Market barriers: The opportunity is in LMIC markets with fast-growing populations, increasing out-of-pocket spend, expansion of health insurance coverage, and overall, more informed consumers of healthcare services. However, market barriers exist, particularly information asymmetry between buyers and sellers. Manufacturers with promising technology are sometimes unfamiliar with the key stakeholders and how to commercialize their products in LMIC environments. Inadequate health system funding, siloed disease program management, unclear and lengthy product registration requirements, supply chain challenges and significantly higher costs of financing, procurement, and maintenance for LMICs, make new technology unaffordable, often incurring higher final prices than in HIC markets. Additionally, the POC MDx market, and especially the multiplex POC MDx market, are nascent—current guidelines, provider preferences, and system incentives can be outdated.

Market enablers: Working towards ensuring availability, awareness, and affordability of near POC MDx with multiplexing capabilities in LMICs is critical. Envisioning a healthy and competitive market that addresses both the supply and demand side market barriers will enable the market potential to be realized. Manufacturers can proactively engage buyers and policymakers on existing and new use cases, demand generation,

trade financing, and training solutions to make products widely available and affordable. Manufacturers can also continue technology development for MDx platforms that have an overall lower cost of the installed platform, greater flexibility to address multi-disease targets that correspond to local needs in lower-level health facilities, user systems with connectivity that supports data sharing and remote, lower-cost maintenance. Manufacturers must develop relationships with reputable regional or country distributors to encourage greater price transparency to the end-user; create new models to support distributor financing options; develop partnerships with private-sector channels; and continue to strive for disruption with an open-system model that can allow for flexibility of different test cartridges. Buy-side actors and healthcare providers need to shift from disease-centred to patient-centred approaches and financing; encourage the increasing country appetite to decentralize and diversify the existing MDx platform installed base;

develop a multiplex diagnostic strategy, policy, guidelines, and regulatory pathways in-country; and conduct both clinical and operational validation studies in-country to demonstrate the value of multiplexing, contribute to technology development, and support efficient registration processes.

Looking forward: The near-POC MDx market is likely to expand as disease testing needs diversify. Technological advances have enabled a vision towards multiplex molecular testing as a powerful, principal diagnostic test and surveillance tool. The implementation of relevant, affordable, and high-performance multiplex molecular POC testing will result in unprecedented changes in therapeutic decisions, management, and control of diseases. Today and in the future, countries, manufacturers, providers, and global health actors, across public and private sectors can work together to creatively develop scale-up pathways, change the paradigm, and make patient-centred diagnostics a reality.

INTRODUCTION

Leveraging the technological revolution spurred by COVID-19, a wave of innovation is underway in the in vitro diagnostics (IVD) industry. The IVD market can be described in different ways: by product type (instruments, reagents, and consumables); by technique (immunodiagnostics, clinical chemistry, molecular, haematology, and others); by setting (laboratories and point-of-care), by application (e.g. infectious diseases, cardiology, oncology); and by end-user (clinical laboratories, hospitals, physician offices, and increasingly, more consumer-centric retail options, such as e-commerce or pharmacies).

In particular, the molecular diagnostics (MDx)[5] industry has experienced dynamic change during and post the peak of COVID-19. This report focuses on defining different types of point-of-care molecular diagnostics (POC MDx) technology, and the role of multiplexing within this market.
The shift towards increasing access within near-POC settings means unprecedented patient, financial, and health system impact by enabling faster time to result, reducing loss-to-follow-up, and ultimately represents a critical push towards achieving universal health coverage. Molecular diagnostics have traditionally been centralized, i.e. concentrated in national or state-level referral labs, especially in low-and middle-income countries (LMICs). However, high-quality MDx can increasingly be offered closer to the patient. From a diagnostics perspective, true POC testing is conducted in the same place where the patient sample was collected ("sample-in-result-out"), and near-POC testing occurs in a laboratory close to the patient. The current norm of disease-specific diagnostic technology has to shift to testing for more ailments than ever before. This ability to test for multiple disease targets with a single sample is known as multiplexing and is transformative for patient management at lower-level health facilities and ongoing health threat surveillance. Simple-to-use diagnostics near the patient, with rapid results that can differentiate between multiple pathogens, has become a gold standard in the post-COVID-19 laboratory.

FIND and other global health actors continue to work with diagnostic manufacturers to develop and commercialize POC MDx platforms, specifically to meet the requirements for rapid disease detection in low-infrastructure LMIC settings, with compact and automated design for simplified test processing. A spectrum of technology solutions on the market is already capable of multiplex MDx, at or near-POC. Many novel platforms are in the late-stage pipeline, and some are available today.

The opportunity is in LMIC markets with fast-growing populations, increasing out-of-pocket spend, expanding health insurance coverage, and overall, more informed consumers of healthcare services. However, market barriers on both the supply and demand side must be addressed,

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[5] Molecular diagnostics (MDx) identify and analyse genetic sequences, biomarkers, and other molecules in a patient's DNA or RNA for markers of potential or future disease (e.g., for infectious agents like tuberculosis or COVID-19). Molecular diagnostic testing includes polymerase chain reaction (PCR) tests, loop-mediated isothermal amplification (LAMP), and clustered, regularly interspaced short palindromic repeat (CRISPR)-based assays. Source: John Hopkins Center for Health Security

particularly information asymmetry between buyers and sellers.

Cultivating greater transparency is a starting point. This report contributes towards this effort to catalyse dialogue on industry 'unknowns' and emerging trends in POC MDx in LMICs and usher in the next leap towards a more competitive and healthy market.

SCOPE AND PURPOSE

This report defines the different types of point-of-care molecular diagnostics (POC MDx) technology, including the technology landscape, forward-looking estimates of the near-POC MDx market and the role of multiplexing within this market.

True POC MDx is briefly explained in the Key Concepts section below. However, this type of technology is excluded from this report's market estimates and will be the subject of a stand-alone market analysis to be launched later in 2023. This report is intended to help industry and global health stakeholders understand the near-POC MDx market and growth potential in low-and middle-income countries (LMICs) at the Level 2 facility level.

As this report focuses on LMICs only, all calculations exclude HICs. The detailed methodology is available in the Annex and summarized in the Market potential section below

KEY CONCEPTS

Categories of point-of-care molecular diagnostic technologies

Different POC MDx platforms address different use cases.[6] No 'one size fits all' setting, application, or end-user solution exists. In this report, FIND has segmented the POC market into *near-POC*, *true POC, and instrument-free true POC* technology categories based on the level of laboratory infrastructure and skillsets required to use the diagnostic across various level health facilities (*Figure 1*).

This market report focuses on near-POC MDx technologies appropriate at an L2 facility level.

Specifically, the laboratory infrastructure requirements that determine suitability for L2 level include mains power (although it may be intermittent), an instrument size that can be placed benchtop, fully automated processing, a minimal number of steps for sample preparation, and a laboratory technician with one to two years of experience. As technologies get closer to the L1 or L0 healthcare levels, infrastructure requirements will lessen, and the requirements of laboratory technicians to operate the test will likely shift to the end-user being responsible for preparation, testing and waste disposal.

Figure 1 Point-of-care molecular diagnostic categories by setting and technology requirements.

	Instrument-Free True POC MDx	True POC MDx	Near-POC MDx	Centralized MDx
	Level 0 (L0) − Community	**Level 1 (L1) − Primary Care**	**Level 2 (L2) − District Hospital Lab**	**Level 3 (L3) − Reference Lab***
Setting	Community outreach Home testing	Primary care facility	Near-patient laboratory Referral/district hospital laboratory	Reference laboratory
Technology requirements for POC MDx	Battery powered Kits include disposable sample materials Integrated sample preparation Sample-in-result-out	Battery-compatible Kits include disposable sample materials Sample-in-result-out	Benchtop and automated 1-2 steps for sample preparation No dedicated molecular PCR lab required	N/A
Lab infrastructure	No instrument or mains power No water No lab equipment No temperature control	No mains power (unreliable) No or minimal lab equipment BSL-1 containment	Mains power (may be intermittent) Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge) BSL-2/1 containment	Mains power (reliable) High infrastructure facility BSL-2/3 containment
Test complexity applicable	RDT	True-POC PCR Basic microscopy RDT	Near-POC PCR ELISA with simple reader Microscopy RDT	Lab PCR ELISA/EIA/CLIA Fluorescence microscopy Culture (some) Sequencing (some)
Operator skill	Nurse/pharmacist Community health workers Self-testing (some cases) • Simple reagent/sample transfer	Nurse Trained laboratory worker • Minimal sample processing (≤ 3 steps)	Laboratory technician (1-2-year certification) • Sample processing with calibrated volumes (≤ 3 steps)	Science research specialist Laboratory technician (1-2-year certification)
Specimen capacity	Can process minimally invasive samples: fingerstick blood, nasal swabs, saliva, urine	Can process upper respiratory specimens; clinic may not have capacity for lower respiratory, venipuncture, plasma	Can process most BSL-2 specimens; depends on clinic sample capacity	Can process most BSL2/3 specimens
Test demand (throughput)	One-at-a-time testing (STAT test)	STAT test or end-of-day batch Up to 10 patients/day	STAT test or end-of-day batch May required random access Up to 50-100 patients/day	Up to hundreds of samples per run Random access
Desired time to result	Test results in <30 minutes While-you-wait results	Test results in 30-90 minutes While-you-wait or same-day results	Test results in 30-90 minutes Same-day or next-day results	Batch run; next-day test results Batch and return of results ≤ 2 weeks

*Note: Centralized MDx is also applicable to **Level 4** Reference Laboratories (with the ability to process and contain BSL-4 specimens.)

Abbreviations: BSL, biosafety level lab. CLIA, chemiluminescence immunoassay. EIA, enzyme immunoassay. ELISA, enzyme-linked immunoassay. PCR, polymerase chain reaction. POC MDx, point-of-care molecular diagnostic. RDT, rapid diagnostic test, STAT, short turnaround testing.
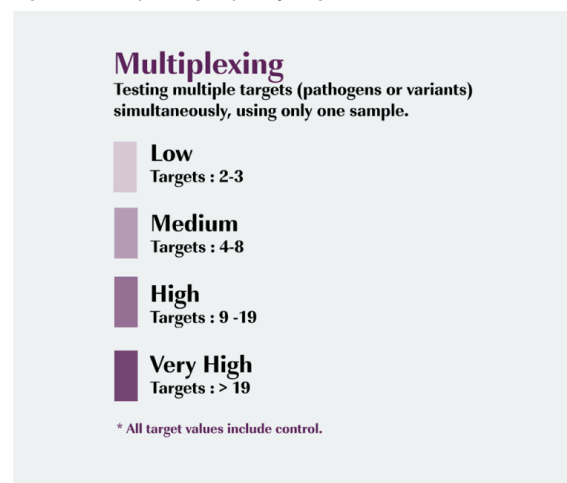
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[6] Use case: a specific situation in which a product or service could potentially be used.

Multiplexing, as applicable to categories of POC technology

A molecular diagnostics platform or instrument is considered 'multiplex' if it allows for the test of several targets (pathogens or variants) simultaneously, using only one sample. For this report, FIND has segmented multiplexing into **low multiplexing** (2 to 3 targets), **medium multiplexing** (4 to 8 targets), **high multiplexing** (9 to 19 targets), and **very high multiplexing** (20 or more targets), all including control, as summarized in *Figure 2*. Based on the multiplexing capacity, different MDx systems address different healthcare settings, use cases and client types, and price points vary drastically.

Figure 2 Multiplexing capacity segmentation.

To note, a multiplex test can **include testing for multiple targets within the same disease** (e.g., MDR-TB, which simultaneously detects three genes—*Mycobacterium tuberculosis* and drug-resistance against rifampicin [RIF] and isoniazid [INH]), and **testing multiple targets for multiple diseases** (e.g., a respiratory panel for COVID-19 [ORF1ab and N genes], Influenza A, Influenza B, and respiratory syncytial virus [RSV]).

Use cases for near-POC MDx multiplexing
Potential use cases for multiplexing could include (but are not limited to):

► **Diagnosis for clinical case management:** Multiplexing enables differential and confirmatory diagnosis for more efficient clinical case management—differentiating between two or more conditions with similar symptoms—improving the quality of care for patients.

► **Surveillance:** Multiplexing can serve disease surveillance programmes by enabling easier data collection and testing for a range of infectious agents of epidemic potential. The design of molecular reagents can allow for the rapid development of new tests to support emergency response for new pathogens. This results in quicker time for deployment for new tests than other technologies, such as rapid antigen testing.

Low, medium and high multiplex MDx platforms can most efficiently be placed in the near-POC setting for diagnosis and strengthened clinical case management, as well as for ongoing surveillance needs, as they are best located within small to medium-sized laboratories. Within the realm of multiplexing, low and medium multiplex testing panels are the cheapest, ranging from $7.90 up to $30 per test, and are broadly used in LMICs, for confirmatory testing of infectious diseases, with TB and HIV being the most frequently tested diseases using MDx. In the true POC settings within a primary care facility or at the community level, low multiplex MDx platforms can be most appropriate for high-performance screening and, in some cases, confirmatory testing.

Currently, very high multiplex testing panels—those with over 20 targets—are primarily used in HIC settings and range from $80 to $300 or

more per test for patients with severe conditions coming from emergency or intensive care units and for patients with unspecific symptoms, such as respiratory or gastrointestinal pain. Worldwide, this 'syndromic' panel testing for several potent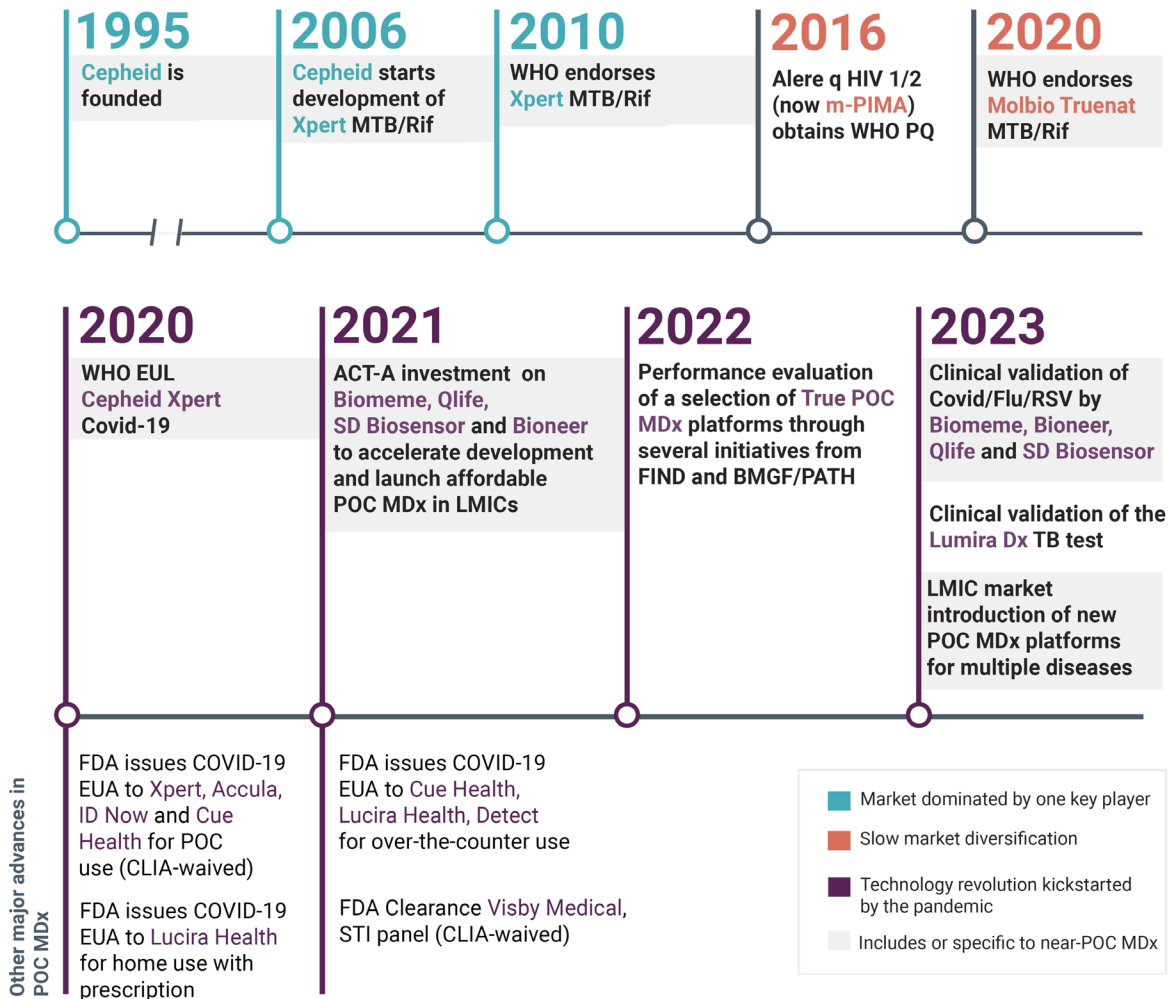ial respiratory or gastrointestinal pathogens has been the first application of high molecular multiplexing. However, innovations in the pipeline show promise in bringing a wider array of fit-for-purpose POC MDx technologies with high multiplexing capacity to the LMIC markets (see *Manufacturer landscape*).

BRIEF MARKET HISTORY

Between 1995 and 2016, the MDx market was dominated by a few large manufacturers—Abbott, Roche Diagnostics, and Cepheid. Very few market entrants were seen between 2016 and 2020, with the notable entry of Molbio (*Figure 3*).

COVID-19 accelerated the near-POC molecular diagnostic market expansion, with new market entrants and rapid technological innovation enabling testing diversification across a wide range of disease targets.

Figure 3 Near-POC MDx market evolution, with the report's focus on near-POC MDx outlined.

1995
Cepheid is founded

2006
Cepheid starts development of Xpert MTB/Rif

2010
WHO endorses Xpert MTB/Rif

2016
Alere q HIV 1/2 (now m-PIMA) obtains WHO PQ

2020
WHO endorses Molbio Truenat MTB/Rif

2020
WHO EUL Cepheid Xpert Covid-19

2021
ACT-A investment on Biomeme, Qlife, SD Biosensor and Bioneer to accelerate development and launch affordable POC MDx in LMICs

2022
Performance evaluation of a selection of True POC MDx platforms through several initiatives from FIND and BMGF/PATH

2023
Clinical validation of Covid/Flu/RSV by Biomeme, Bioneer, Qlife and SD Biosensor

Clinical validation of the Lumira Dx TB test

LMIC market introduction of new POC MDx platforms for multiple diseases

Other major advances in POC MDx

FDA issues COVID-19 EUA to Xpert, Accula, ID Now and Cue Health for POC use (CLIA-waived)

FDA issues COVID-19 EUA to Lucira Health for home use with prescription

FDA issues COVID-19 EUA to Cue Health, Lucira Health, Detect for over-the-counter use

FDA Clearance Visby Medical, STI panel (CLIA-waived)

Market dominated by one key player

Slow market diversification

Technology revolution kickstarted by the pandemic

Includes or specific to near-POC MDx

Historically, speed to market and scale-up for diagnostic products in HICs has taken up to five years. In LMICs, this scale-up timeline can take six times as long (*Figure 4*). Similarly, the near-POC MDx market has also demonstrated a slow adoption curve in LMICs over the decade (pre-pandemic), even with substantial funding. The

expansion of the POC MDx footprint accelerated across most countries during COVID-19, with nearly twice the installed base of the market-leading platforms in 2021, compared to 2019.[7] However, as more MDx products attain regulatory approvals in HICs, ensuring LMICs have *timely* access to innovation is critical.

Figure 4 Years to scale up for diagnostics, drugs, and vaccines in high-income countries (HICs) and low- to middle-income countries (LMICs).

* POC MDx adapted by FIND, derived from: Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Interventions, USAID, 2018. Source: Bill and Melinda Gates Foundation.

ACT : artemisinin-based combination therapy

Hib : Haemophilus influenza type b

LMIC : lower- and middle-income countries

POC MDx : Point of care molecular diagnostics

ARV : antiretroviral

HIC : high-income countries

ORS : oral rehydration solution

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[7] Source: FIND analysis of near-POC molecular diagnostics installed global base, pre-and post-pandemic.

MANUFACTURER LANDSCAPE

Over 80 near-POC MDx platforms exist, with at least 65 platforms in-market and 19 novel platforms in the pipeline, as of October 2022. Near-POC MDx tests generally include genomic material extraction capability combined with amplification and detection in the same consumable unit. Reverse Transcription-Polymerase Chain Reaction (RT-PCR) is the most common amplification method used; however, several platforms are compatible or are based on isothermal methods. Most near-POC MDx platforms demonstrate high multiplexing potential. However, several of the marketed solutions have, to date, a limited offering of tests.

A sub-set of the near-POC MDx landscape, including market leaders and newer platform entrants, is profiled in *Table 1*, based on products that have historically been procured for LMICs or more recent

technological entrants. Please note: the MDx platforms in *Table 1* do not represent a comprehensive list of regulatory-authorized/approved or commercialized tests for near-POC level. Instead, it is meant to provide a snapshot of the type of technology being discussed. The information provided on each platform below is publicly available from company websites.[8]

Although near-POC MDx platforms with very high multiplexing capacity—such as the BioFire FilmArray or SpotFire, Curetis Unyvero and Qiagen QIAstat-Dx platforms—may currently be considered too complex and costly for the needs of L2 facilities in LMICs, it is promising that the technology exists in the market, and will further adapt.

Table 1 Near-POC MDx platforms on the market, including their multiplexing capacity (non-exhaustive).

Instrument	TrueLab	GeneXpert	Standard M10	BioFire SpotFire	IRON qPCR	Vivalytic	Unyvero A50	QIAstat-Dx
Market stage[1]	In-Market			Market Launch Phase				
Manufacturer	Molbio	Cepheid	SD Biosensor	BioFire (bioMérieux SA)	Bioneer	Bosch Healthcare	Curetis	Qiagen N.V.
Manufacturer's country	India	USA	South Korea	France	South Korea	Germany	USA	The Netherlands
Max number of samples per run (modules) for near-POC	1, 2, or 4	2, 4 or 16	1 to 8	1, 2, or 12	2	1	2	1
Multiplexing capacity[2]	Low	High	High	Very High	Very High	Very High	Very High	Very High

[1] **Market stage:** Market Launch Phase (Early market presence, CE approved); In-Market (Evidence of procurement in LMICs).
[2] **Multiplexing capacity:** Low (2-3 targets), Medium (4-8 targets), High (9-19 targets), Very High (20+ targets); all ranges include control.

[8] Note: Information from manufacturers' RFP submissions to FIND is considered confidential and has not been used, unless overlapping directly with publicly available information.

MARKET ECONOMICS

To understand markets, global public health concepts are usually grouped into two categories - supply (manufacturer) and demand (in-country). The supply side encompasses elements such as cost structure and pricing strategy; the demand side seeks to explain the procurement process, payment models and in-country demand generation. This section provides a basic overview of the market's supply and demand side, including the most common procurement and distribution channels, pricing, and cost structure for near-POC MDx platforms in LMICs.

Procurement and distribution channels

Procurement for MDx can be within the public or private sector, and in both sectors, various distribution channels (direct and indirect) can be involved. Public and private sector procurement, payer, and distribution channels differ in LMICs and involve many stakeholders that work together to enable MDx product availability. Stakeholders include, but are not limited to, public sector buyers (government, donors, and other global health actors), private sector buyers, manufacturers, distributors, procurement agents, in-country logistics partners, end-users, and after-sales service technicians (*Table 2*).

Table 2 Stakeholders involved in procurement and distribution of laboratory products and services in LMICs (non-exhaustive).

Public sector buyers	Predominantly government entities using donor or domestic funding; buyers for the public sector can also include global health implementing organisations.
Private sector buyers	Typically hospitals, laboratories, and given the shift toward diagnostics available direct-to-consumer, may include wholesalers or pharmacy retail chains.
Distributors	Can cover regional, inter-country, or intra-country territory and typically have agreements (exclusive or non-exclusive) with manufacturers to sell and distribute their products in a given region or country. Distributors can also work with wholesalers, sub-distributors, brokers, or other types of 'middle' entities between the manufacturer, buyer, and end-user.
Procurement agents	Can be global or domestic and coordinate the purchasing process for the buyer, usually through tender or direct order.
In-country logistic partners	Support importation, shipping, distribution, and other related activities.
End-users	The operators and/or beneficiaries of the product, typically health facilities and laboratories.
After-sales service technicians	Provide servicing and maintenance of equipment and provide technical know-how, training, and repair. The technicians can sometimes work for the distributor or hold separate contracts with the laboratories.

In LMICs, there are typically two distribution channels through which MDx products (and, in general, diagnostic platforms) are sold to the buyer:

► **Direct distribution**: Manufacturers sell directly to the buyer/consumer. In this channel, the manufacturer controls all aspects of distribution.

► **Indirect distribution:** Manufacturers sell to various intermediaries or third parties (distributors, wholesalers, and retailers) that then sell the product to the buyer/consumer. This is very common in the diagnostics industry and allows companies to focus on their core business while outsourcing distribution to a local expert that knows the environment.

The distributor's role cannot be understated in commercialization, including navigating the often complex importation and logistics requirements and providing after-sales services. A critical component of any launch strategy in LMICs involves recognising the distributors' role (either within the company, through a direct approach, or outsourced to a third party through an indirect approach). Manufacturers have different exclusivity agreements with distributors depending on specified criteria (e.g. geographies). Some manufacturers have their own subsidiaries that act as distributors and vertically integrate them into their business.

Public and private sector procurement

Public procurement of MDx platforms most commonly occurs via both distribution channels:

► Donor-funded procurement orders are placed directly with manufacturers by global procurement agents in accordance with pre-established framework agreements.

► Donor or domestic-funded procurement by governments through a tendering process (which may or may not involve global or domestic procurement agents, wholesalers, importers, and other actors, depending on the country's tendering process and requirements).

Private sector procurement, local tenders, and urgent gap-filling of MDx platforms most commonly occur via indirect distribution channels. To note, when distributors bid directly on tenders, they typically do not have access to the price negotiated at a global level, thus further inflating the landed costs to the buyer. Additionally, the manufacturer may not have visibility into what the distributor or sub-distributors are selling or the price points and inclusions.
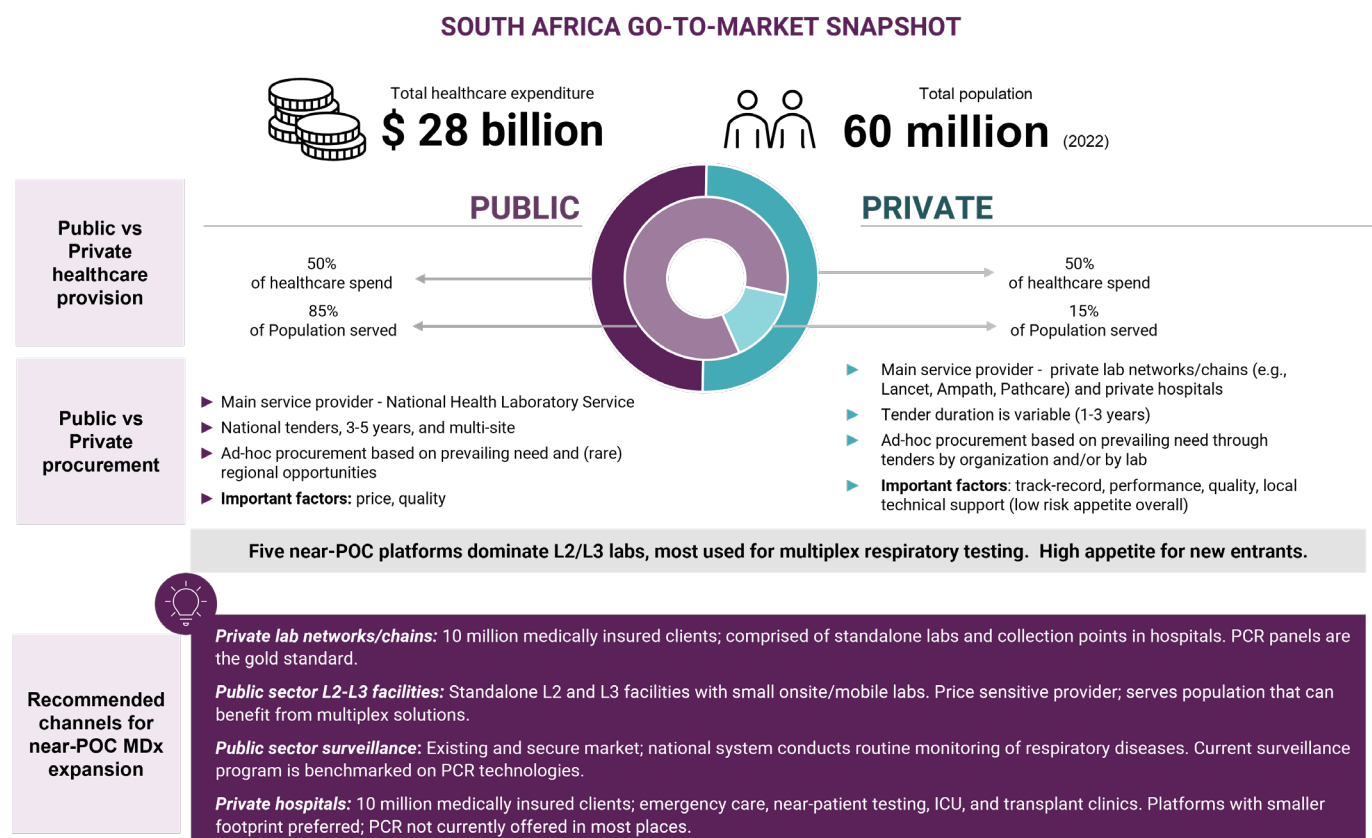
Private sector distribution channels for near-POC MDx platforms include hospitals, laboratories, and potentially large pharmacy retail chains. These players will likely have the required infrastructure such as main power, benchtop, temperature control and lab equipment, and trained lab workers to conduct testing. While not included in the scope of the near-POC focus of this report, it is important to note that newer channels exist for POC MDx technology at L1 levels. This includes the opportunity to establish innovative pathways in the private sector to enable decentralization of diagnosis—such as through workplace/employer testing models and home-visiting sample collection services, or even via clinics via a pharmacy, as has become commonplace in many countries post-COVID-19.
Overall, the public and private market opportunities differ by country and region based on how healthcare services are accessed, the need and willingness to pay, and the structure of market channels. The

public market, in the form of governments' high-value tenders for confirmatory disease testing, represents significant volumes but is price-sensitive and requires more comprehensive service and maintenance network coverage; the routine surveillance market, owned by public referral laboratories, is an existing and secure smaller market, although still price-sensitive.

Countries with sizable middle and upper-middle-income population segments who access private market channels, including private laboratory and hospital chains, offer an opportunity to open and develop new markets for POC MDx technology, especially for multiplexing. For example, a snapshot of South Africa's market potential for near-POC MDx is below (*Figure 5*).

Figure 5 South Africa Go-To-Market Snapshot.

SOUTH AFRICA GO-TO-MARKET SNAPSHOT

Total healthcare expenditure
$ 28 billion

Total population
60 million (2022)

PUBLIC — **PRIVATE**

Public vs Private healthcare provision

50% of healthcare spend
85% of Population served

50% of healthcare spend
15% of Population served

Public vs Private procurement

► Main service provider - National Health Laboratory Service
► National tenders, 3-5 years, and multi-site
► Ad-hoc procurement based on prevailing need and (rare) regional opportunities
► **Important factors:** price, quality

► Main service provider - private lab networks/chains (e.g., Lancet, Ampath, Pathcare) and private hospitals
► Tender duration is variable (1-3 years)
► Ad-hoc procurement based on prevailing need through tenders by organization and/or by lab
► **Important factors**: track-record, performance, quality, local technical support (low risk appetite overall)

Five near-POC platforms dominate L2/L3 labs, most used for multiplex respiratory testing. High appetite for new entrants.

Recommended channels for near-POC MDx expansion

Private lab networks/chains: 10 million medically insured clients; comprised of standalone labs and collection points in hospitals. PCR panels are the gold standard.

Public sector L2-L3 facilities: Standalone L2 and L3 facilities with small onsite/mobile labs. Price sensitive provider; serves population that can benefit from multiplex solutions.

Public sector surveillance: Existing and secure market; national system conducts routine monitoring of respiratory diseases. Current surveillance program is benchmarked on PCR technologies.

Private hospitals: 10 million medically insured clients; emergency care, near-patient testing, ICU, and transplant clinics. Platforms with smaller footprint preferred; PCR not currently offered in most places.

Based on market research by Market Access Africa and FIND, 2022.

Pricing (including Incoterms)

Instrument and test cartridge pricing for near-POC MDx platforms is outlined in *Table 3*, based on published ex-works (EXW) pricing and utilized by procurement agents for the public sector in LMICs. Prices are often negotiated globally via Access Agreements or Long-Term Agreements (LTAs) between R&D partner, the procurement agent (or funding agency) and manufacturer. As additional manufacturers enter the market, there is potential for further price reduction as competition increases, and manufacturing costs can be reduced as multiplexing capabilities reach scale.

Products can be compared using EXW pricing; however, it is critical to note that EXW pricing differs from what the buyer actually pays. Shipping, insurance, import fees, duties and taxes must all be paid and are dictated by the Incoterms used between the buyer and the seller. Incoterms specify when the transfer of goods happens in a transaction, along with the risk, and dictate the party that must pay the relevant premium (*Figure 6*). In public health, LTAs are often negotiated at the EXW price, but for the buyer, landed costs have been documented to be upwards of 50-100% more expensive *(Figure 7)*. This is not unique to MDx and is common among many laboratory (and health) products.

Table 3 Ex-works pricing (USD) for common near-point-of-care molecular diagnostic platforms in LMICs.
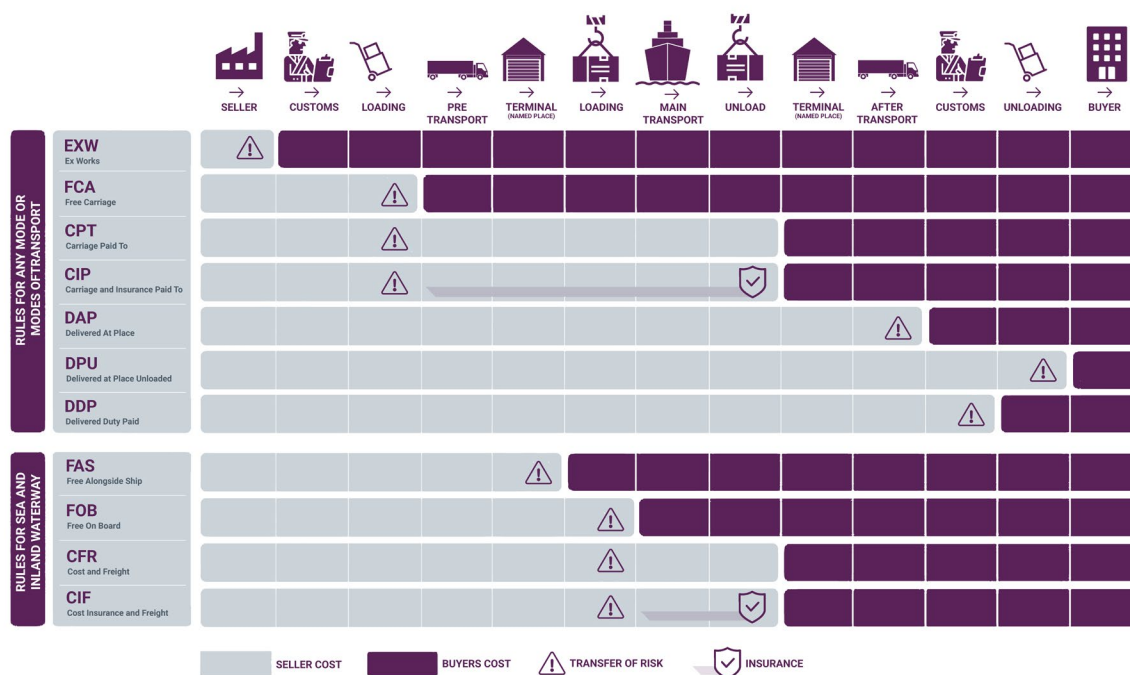
Instrument	• **$10,000−19,000** (1 to 4 modules) • **$19,000−72,000** (16 modules)
Test Cartridge	• **$5*−15:** single and low multiplexing (1-3 targets for one disease) • **$15−30:** medium to high multiplexing (4-9 targets to test for two to four diseases)

1. *5 USD target price point, as documented in Advancing Access through Market Interventions: Lessons Learned from the GeneXpert Tuberculosis Test Buy-Down, Treatment Action Group.
2. Source: Global Drug Facility Diagnostics, Medical Devices & Other Health Products Ordering List 2023; African Society for Laboratory Medicine Diagnostic Pricing Database.
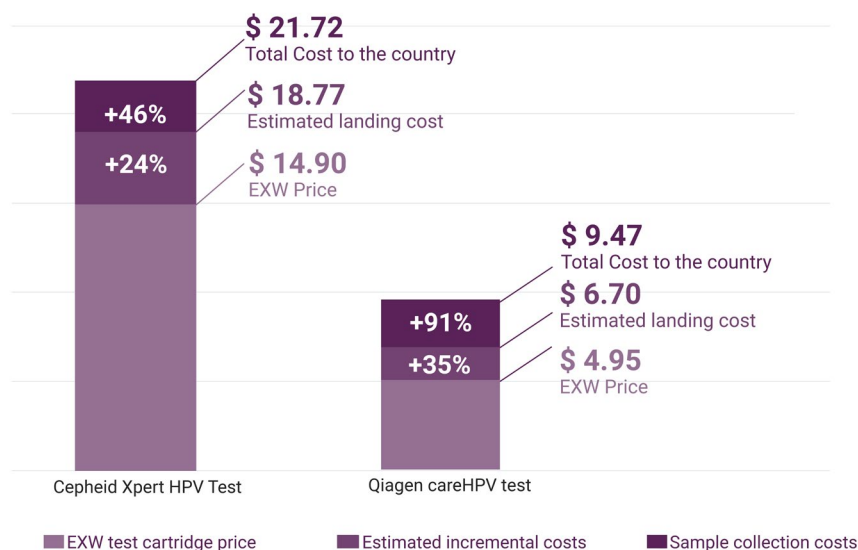3. Note: Ranges include Cepheid GeneXpert and Molbio TrueLab platforms.

Figure 6 Incoterms overview

Source: Incoterms 2020

Figure 7 Comparison between ex-works and estimated landing cost of HPV test cartridges in LMICs, indicative estimates, USD.

1. Source: CHAI Analysis; Affordability and Accessibility of IVDs in LMICs, 2022. Geographic scope includes: Africa (Eswatini, Kenya, Lesotho, Nigeria, Rwanda, South Africa, Uganda) & Asia (Cambodia, Indonesia).

2. Estimated landing cost includes supply chain and distributor costs including: customs clearance, freight, logistics and local distribution, distributor and agent fees, and import duty and taxes.

Cost drivers of the near-POC MDx technology[9]

The costs of a near-POC MDx platform are comprised of the instrument, test cartridges, and service and maintenance. These components represent a combination of capital and operational expenditure for the buyer or end-user (e.g. a disease program in the Ministry of Health or a private hospital group), as outlined in *Table 4*. All near-POC MDx platforms in-market are closed-systems,[10]

and thus, subject to platform-specific installation, training, and service and maintenance costs. Fixed and variable costs are treated differently from an accounting perspective, with variable costs expensed when incurred versus fixed costs depreciating over time. For smaller buyers of this type of technology, it is likely that they will need additional modalities of financing to enable the initial capital payment required.

Table 4 Near-point-of-care molecular diagnostic cost categories from the buyer/end-user perspective.

Fixed and Capital expenditure (Capex)	• Instrument • Infrastructure upgrades to health facilities required
Variable and operational expenditure (Opex)	• Test cartridges • Distribution and supply chain • Platform service and maintenance • Human resources (healthcare workers including laboratory technicians)

Instrument and test cartridges

For both the instrument and test cartridges, end-user prices commonly comprise six main components, each with specific optimization levers (*Figure 8*). These consist of the cost of goods sold (COGS), segmented into materials and manufacturing, corporate expenses, including sales and marketing and R&D expenses, the manufacturer margin, warehouse and shipping, and the distributor mark-up.

The COGS is driven by volume, size, availability, and complexity of materials, as well as the manufacturing location and level of automation (see *Table 5*). Corporate

expenses are impacted by demand, competition, product complexity, and organization and size. Warehouse and shipping costs are driven by location, mode of transport, and incoterms, with a reduction in costs if manufacturing is close to end-users (e.g. in Africa), in countries with competitive freight costs (e.g. Europe and the US) or for products that have a smaller physical footprint. The distributor mark-up is impacted by the extent of distributor responsibilities, site accessibility, and distance for serving requirements, labor cost and level of uncertainty risk (see *Table 6*)

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[9] Based on molecular diagnostic-focused costing analysis conducted by FIND and Advention Business Partners in 2022-2023. Information from manufacturers' RFP submissions to FIND is considered confidential and has not been used, unless overlapping directly with publicly available information.
[10] Closed systems exist as packages of pre-analytic automation, analytic phase instrumentation, and post-analytic systems from a single vendor. The accompanying hardware and software are designed specifically to integrate with that vendor's other instrumentation and applications. (LabCE)
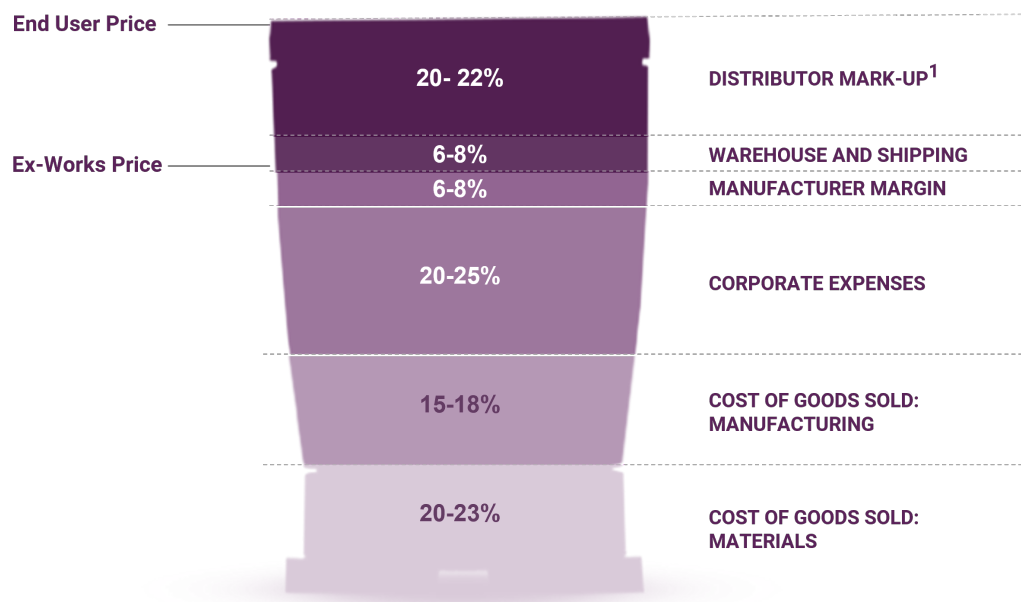
Figure 8. Components of an end-user price

End User Price

20- 22% — DISTRIBUTOR MARK-UP[1]

Ex-Works Price

6-8% — WAREHOUSE AND SHIPPING

6-8% — MANUFACTURER MARGIN

20-25% — CORPORATE EXPENSES

15-18% — COST OF GOODS SOLD: MANUFACTURING

20-23% — COST OF GOODS SOLD: MATERIALS

[1]*Range quoted is at minimum*

Table 5. Cost drivers of near-point-of-care molecular diagnostic test cartridge COGS, from highest to lowest impact.

Impact	Cost drivers on test cartridge COGS	Definition	COGS impacted	Cost implications on COGS for manufacturers
+	Manufacturing scale	Impact on contractual volumes negotiated with manufacturer.	• Materials • Packaging • Direct costs • Indirect costs	• Limited impact for large/mature players • High impact for developing players (with automation); costs decrease at one million tests per year.
	Manufacturing location	Impact of shifting manufacturing location.	• Direct costs	• High impact with moves to countries with lower labour wages (e.g., South Asia), as labour costs are a significant share of total manufacturing costs.
	Cartridge complexity	Impact of simplifying the type of cartridge and number of components.	• Materials • Direct costs • Indirect costs	• PCR cartridges range from 2 to 6 components; the more components, the higher cost.
	Reagents sourcing strategy	Make or buy strategy regarding reagents (mainly enzymes).	• Materials • Direct costs • Indirect costs	• In-house development of reagents reduces variable costs, but requires high investment.
	Plastic components size	Impact of change to cartridge dimensions.	• Materials	• The larger the cartridge size, the higher the material, packaging and shipping costs.
	Additional elements	Addition of extra components to perform additional steps (e.g. treatment of sample).	• Materials • Packaging	• Adding steps increases test costs, with the added chip being the most expensive.
	Sourcing of plastic components	Make or buy strategy regarding plastic components.	• Materials • Direct costs • Indirect costs	• Adding preparation components (e.g. buffer/pipettes) increases tests costs.
–	Complexity of reagent production process	Difference between lyophilization and dry-down reagent process.	• Direct costs • Indirect costs	• Lyophilization is more expensive than the dry-down reagent process, but limited impact as reagent production is a minor share of total manufacturing costs.

Manufacturing scale

Economies of scale from increasing volumes significantly decrease material costs by driving down the cost of reagents, as well as the direct and indirect costs by enabling a more automated process, reducing labour costs, and increasing efficiency. Reagent costs depend on local availability (high in North America, Europe, and Asia; low in Africa).

Manufacturing costs are closely linked to test design and automation. Overall, costs reduce most significantly when transitioning from a highly manual to a more automated process and to countries with lower wages. For smaller players, the impact of additional volume on costs is high as they gradually move from a manual to a semi-automated and fully automated process. On the other hand, large/mature players with manufacturing capacity in the multi-millions would see minimal savings by increasing their volumes, as they already benefit from an automated process.

Manufacturing location

Shifting manufacturing to environments with lower labour costs, such as India, China, or Vietnam, significantly impacts direct costs and ensures supply.

Service and maintenance

A major cost driver of the near POC MDx devices is the service and maintenance support after the initial platform sale, often provided by distributors. The major cost drivers of service and maintenance costs for the distributors are outlined in *Table 6.* The cost of service and maintenance is usually built into all platform component end-user pricing: the instrument, the test cartridges, and the service and maintenance agreements.

► **Instrument** purchase includes warranty costs for one to two years, not including in-country service visits, and is typically included in the instrument cost.

► **Test cartridges** include both manufacturer and distributor-related costs that

Table 6 Cost drivers of service and maintenance for near-point-of-care molecular diagnostic platforms.

Cost drivers on MDx service and maintenance	Definition	Cost implications for distributors
Volume of platforms to be serviced	Number of platforms/sites to service.	For a decentralised MDx model at L2 facilities: • More devices have higher total servicing needs • Multiple sites, longer site distance and more difficult/remote terrain increases transport costs
Site distance and accessibility	Physical distance and transport requirements to access sites.	
Level of technical expertise required	Impact of the product complexity on the technical skillsets required to address service requests.	• The more complex the MDx system, technician (HR) costs increase.
Complexity of platform components	Impact of the number and technical complexity of platform components.	• The greater the number of platform components for repair or replacement, the higher the cost provision.
Response time terms	Impact of the maximum time period between service request and response.	• The more demanding the response time terms (e.g. 24 hours), the higher the cost.
Platform payment model	Outright payment vs flexible payment models over time.	• For more flexible payment models, the higher the cost provision for risk management.
Macroeconomic environment	Security, inflation, foreign exchange risks including currency devaluation.	• With destabilization or higher risks, the cost provision increases.
Overall assessment of risk/uncertainty	The level of risk the distributor takes on to deliver on the service terms.	• All-inclusive service and maintenance agreements will have higher costs built in, to account for unexpected uncertainty/risks.

contribute to MDx platform service and maintenance.

► **Separate service and maintenance agreements**, ranging from coverage on discrete responsibilities to comprehensive/all-inclusive needs, are purchased on an ongoing basis and are typically structured in one-to-three-year contracts.

Innovative procurement models, including service and maintenance

The most common procurement model for near-POC MDx platforms is separate purchases of the instrument, test, individual warranties for an initial period (one to two years), and service level agreements (SLAs) for ongoing service and maintenance needs.

However, given the high capex incurred to buy an instrument, and a common pain point faced by countries of unaffordable or inadequate service and maintenance coverage—especially after the initial few years of purchase covered under warranty— newer purchasing models have emerged. These are being demonstrated in market[11] as potential solutions to improve accountability for the manufacturer and/or distributor, enable buyers to have more flexibility to switch platforms, and can also lessen risk in terms of test volumes for manufacturers. These models include:

► **Service level agreements**, structured to be monitored according to key performance indicators with the costs of service and maintenance added as a surcharge to test prices across a volume commitment of tests (e.g. demonstrated by Cepheid's AccessCare). These agreements do not cover instrument installation/placement.

► **Reagent rental agreements** or **all-inclusive pricing agreements** that distribute the costs of installation/placement, in addition to service and maintenance costs, over a volume commitment of tests, through an added surcharge to test prices (demonstrated by USAID).

► **Pay per result**, in which programs pay per actionable result (not including failed/invalid results (demonstrated by the South Africa National Health Laboratory Service).

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[11] Meeting Report: Roundtable on Access to Multi-disease Molecular Diagnostics (June 2, 2022), Treatment Action Group, MSF Access Campaign

MARKET POTENTIAL

FIND has estimated the size of the near-POC MDx market. **This market size estimate represents the target addressable market (TAM)[12] for near-POC MDx, for L2 health facilities in LMICs.**
A summary of what this market size estimate includes (*Figure 9*), and its

methodology, is below. This is followed by the market size outputs with the relevant key assumptions by disease area. The detailed methodology is available in Annex A.

Figure 9. What the near-point-of-care molecular diagnostics market size estimate is and is not.

What this market estimate is:

► The target addressable market is expressed as the current number of tests per year by disease that near-POC MDx platforms can address when placed at Level 2 health facilities or near-patient laboratories in LMICs.

► It considers the current epidemiology of select pathogens and recommended clinical protocols in up to three relevant use cases—screening or case finding, clinical management of disease, and surveillance—to estimate the annual testing need by disease.

► It considers the current epidemiology of select pathogens and recommended clinical protocols in up to three relevant use cases—screening or case finding, clinical management of disease, and surveillance—to estimate the annual testing need by disease.

What this market estimate is not:

► This is not a forecast or assessment of demand; it does not consider the willingness to pay, health system capacity, or health system efficiencies.

► It does not consider dynamic disease transmission and/or country disease strategies.

► It does not consider current procurement volumes or preferences for specific MDx products in the public or private sectors of the countries included.

► It does not consider technology replacement outside of current guidelines (i.e. the share of overall testing attributable to other diagnostic types such as rapid diagnostic tests, microscopy, and blood culture). The current percentage of centralised testing is assumed to be constant.

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[12] The total addressable market (TAM) refers to the total available market, and the size of the financial opportunity a particular product offers.

Methodology

This market estimate was calculated in two main steps:

1. **Quantify the total need for MDx:** estimate by disease, considering current incidence and prevalence, treatment guidelines, clinical use cases, the donor funding landscape, and global disease strategies for control or elimination. For countries with expected donor funding, molecular testing was assumed to expand in the near term via increasing case detection, as well as an increasing share of molecular tests versus syndromic or microscopy testing.

2. **Estimate the share of MDx that can occur at L2 health facilities (near-POC):** by disease based on two indicators of current testing practices: the level of laboratory system centralization and health spend per capita.

   ► Note: the assumption for the percentage of MDx testing at L2 health facilities was further validated with published and grey literature and both interviews and a survey of Key Opinion Leaders (KOLs).

The near-POC MDx market size estimate was developed over two steps.

Step 1: Data Framework Development, Data Collection, and Country Archetype Reference Development

Data was collected in the following structure:

► **Disease data, by country:** Diseases incidence and prevalence rates and progress on WHO targets data were collected using WHO, UNAIDS and IHME Global Burden of Disease, 2019 estimates.

► **Current country health spend:** From the WHO Global Health Expenditure Database.

► **Facility data for L2 health facilities by country:** Data was collected for health spend per capita by country and density of L2 health facilities (district hospitals and provisional hospitals), using the WHO Global Health Observatory (health facilities per 100,000 population, 2013). This number of district/rural hospitals includes estimates from both the public and private sectors per 100,000 population. Wherever data was unavailable, it was supplemented with literature research. If needed, the median of the quartile (quartiles created based on normalized health care spending) was considered a proxy.

Countries were classified into **four archetypes** based on their healthcare spend per capita and the density of L2 health facilities per 100,000 population (*Table 7*). Archetypes were formed based on a composite normalized score from these two datasets. The rationale for these two key parameters is below:

► **Healthcare spend**: this parameter is a direct factor in the adoption of MDx instruments to replace microscopy or other means of diagnosis.

► **Density of L2 health facilities:** as L2 health facilities are considered the ideal setting for the near-POC platforms, as discussed in the report, this parameter indicates the extent of decentralization of the health system, compared to centralization.

Table 7 Country archetype overview.

Archetype	Total health spending, per capita (compared to median)	Density of L2 health facilities* per capita (compared to median)	Example countries
A	Higher	Higher	South Africa, Brazil
B	Higher	Lower	Peru, Thailand
C	Lower	Higher	Kenya, Viet Nam
D	Lower	Lower	India, Zambia

For disease areas with limited literature or KOL inputs on testing practices (centralized vs decentralized; MDx testing vs other testing types), this archetype analysis was deployed to estimate missing data points and assess the share of total testing needs feasible, given current practice, at L2 health facilities. The model structures the lower-income countries (LICs), LMICs, and upper-middle-income (UMICs) into archetypes based on their health spend and level of decentralization of health facilities and estimates the level of testing need for near-POC MDx.

Step 2: Near-POC MDx Testing Estimates

Use cases for near-POC MDx have been developed based on the clinical and surveillance needs by syndrome or pathogens from a literature review and a KOL survey on current testing practices in each country archetypes.

All estimations present the most realistic (leaning towards conservative) assumptions. The target addressable market was determined by combining patient population estimates with the use cases determined. A top-down estimation approach was adopted for each disease area, followed by adjustments to each disease's market size based on enabling and limiting factors identified that are unique to each disease.

Country and disease inclusion

75 LMICs are included in this market estimate, representing 90% of the total LMIC population. Out of 136 LMICs, 61 were excluded from the market estimate. In all cases, World Bank classifications have been used. The breakdown of the countries excluded is as follows:

► Thirty-three are small states, including islands.

► Twenty-four are fragile/conflict countries, as classified by World Bank. Note: Although Nigeria, Ethiopia, and the Democratic Republic of Congo are classified as fragile/conflict countries, they *are included* in the market estimate as all three have significant populations, are recipients of donor funding, and have substantial out-of-pocket

expenditures in the private sector, which can drive uptake of near-POC MDx.

► Four countries are considered special cases. Russia was added to the fragile/conflict states list and removed from scope. Kosovo and American Samoa were excluded due to limited data availability. Bulgaria was assessed as out of scope as it demonstrates characteristics more closely associated

with a high-income market as part of the European Union economy.

Diseases included in this market size estimate are outlined in *Table 8*. To note, antimicrobial resistance (AMR), malaria, and other STIs, such as syphilis, are not included in this near-POC MDx market sizing, with further details in their respective sections below. Although hepatitis B virus (HBV) is considered an STI, it has been categorized under the hepatitis disease area

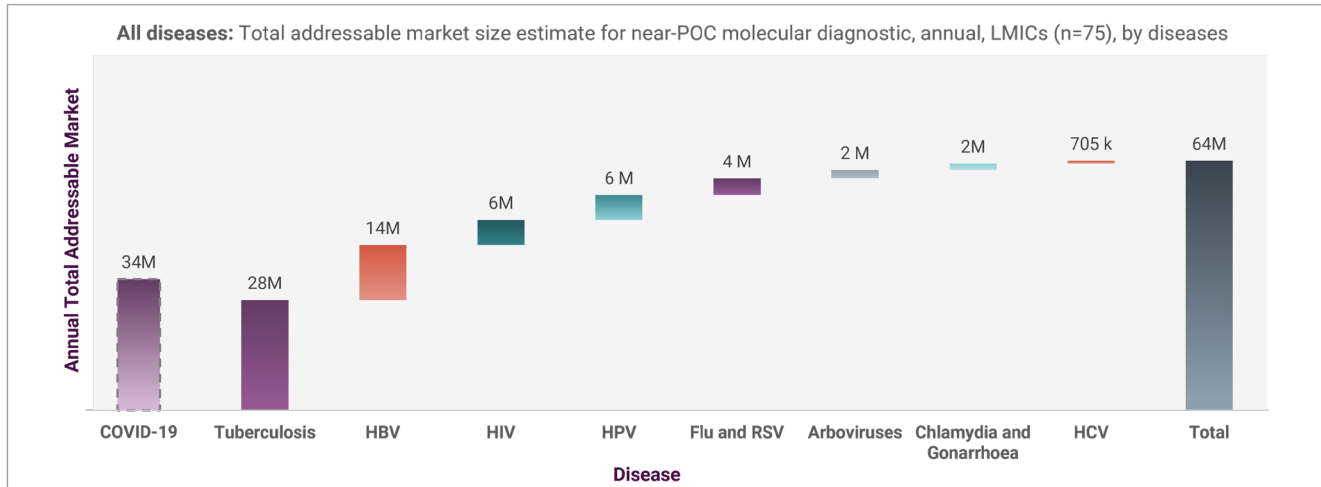*Table 8 Diseases included for the near-point-of-care molecular diagnostics market size estimate.*

Disease area	Disease
Respiratory	Tuberculosis (TB)
	Flu (A and B) and respiratory syncytial virus (RSV) (combined)
	COVID-19
Hepatitis	Hepatitis B virus (HBV)
	Hepatitis C virus (HCV)
Sexually Transmitted Infections	Human immunodeficiency virus (HIV)
	Human papillomavirus (HPV)
	Chlamydia and gonorrhoea (combined)
Arboviruses	Dengue, yellow fever, and Zika virus (combined)

Market potential, by disease

FIND estimates that 63.6 million tests represent the target addressable market (TAM) per year, for near-POC MDx, at L2 health facilities in LMICs (*Figures 10 and 11*). This estimate includes TB, flu and RSV, HBV, HCV, HIV, HPV, STIs (chlamydia and gonorrhoea), and arboviruses (dengue, yellow fever, and Zika virus). TB represents the largest market, with 28.1 million tests per year, followed by HBV at 14 million tests and HIV at 6.4 million tests. Separately, COVID-19 testing is currently estimated at
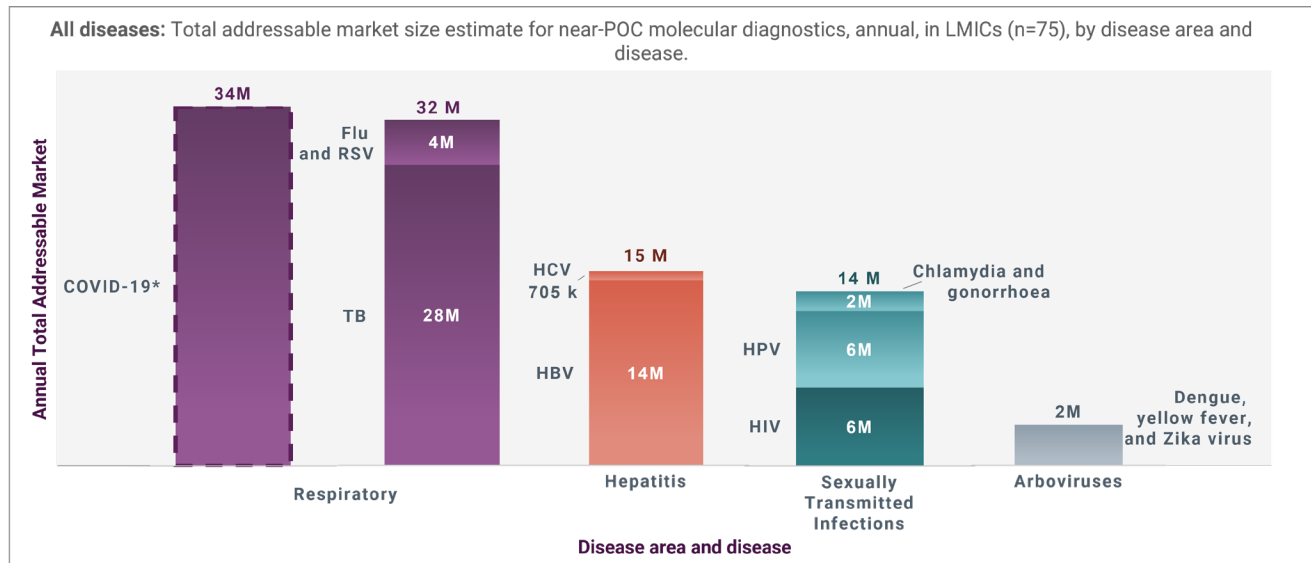
33.8 million tests, but this is expected to continue to decline dramatically in the near term if no other variants of concern are identified.

30

Figure 10 Total addressable market size estimate for near-point-of-care molecular diagnostics, annual, in LMICs (n=75), by disease.

All diseases: Total addressable market size estimate for near-POC molecular diagnostic, annual, LMICs (n=75), by diseases

*COVID-19 testing volumes are presented separately, as they are expected to continue to decline.

Figure 11 Total addressable market size estimate for near-point-of-care molecular diagnostics, annual, in LMICs (n=75), by disease area and disease.

All diseases: Total addressable market size estimate for near-POC molecular diagnostics, annual, in LMICs (n=75), by disease area and disease.

*COVID-19 testing volumes are presented separately, as they are expected to continue to decline.

For the diseases in scope, it is key to assess the current maturity of the demand for MDx testing and growth potential (*Figure 12*). For the near term, COVID-19 is considered a mature market that will see a decline in the absence of new variants that cause greater morbidity or mortality (while the market is shrinking, it is sensitive to changing epidemiological factors and country policies). On the other hand, the market for TB MDx is growing, with the highest-burden middle-income countries focused on rapid case finding and preventing further resistance, as per WHO guidelines. The HIV MDx market is attributed to viral load testing and early infant diagnosis (EID) testing and is expected to grow.

Arboviruses, flu and RSV, and STI MDx markets are in their infancy; despite wide demand, supply is currently limited and will gradually form a more significant proportion of total MDx testing demand. Similarly, hepatitis (HBV and HCV) and HPV markets are nascent but are expected to grow with increased investment by global and national disease programs.

East Asia and Pacific (33%, including China), Sub-Saharan Africa (31%) and South Asia (26%, including India) account for the majority of the near-POC MDx test market for the diseases in scope (*Figure 13*).

Figure 12. Market maturity and growth trend expected by disease area.

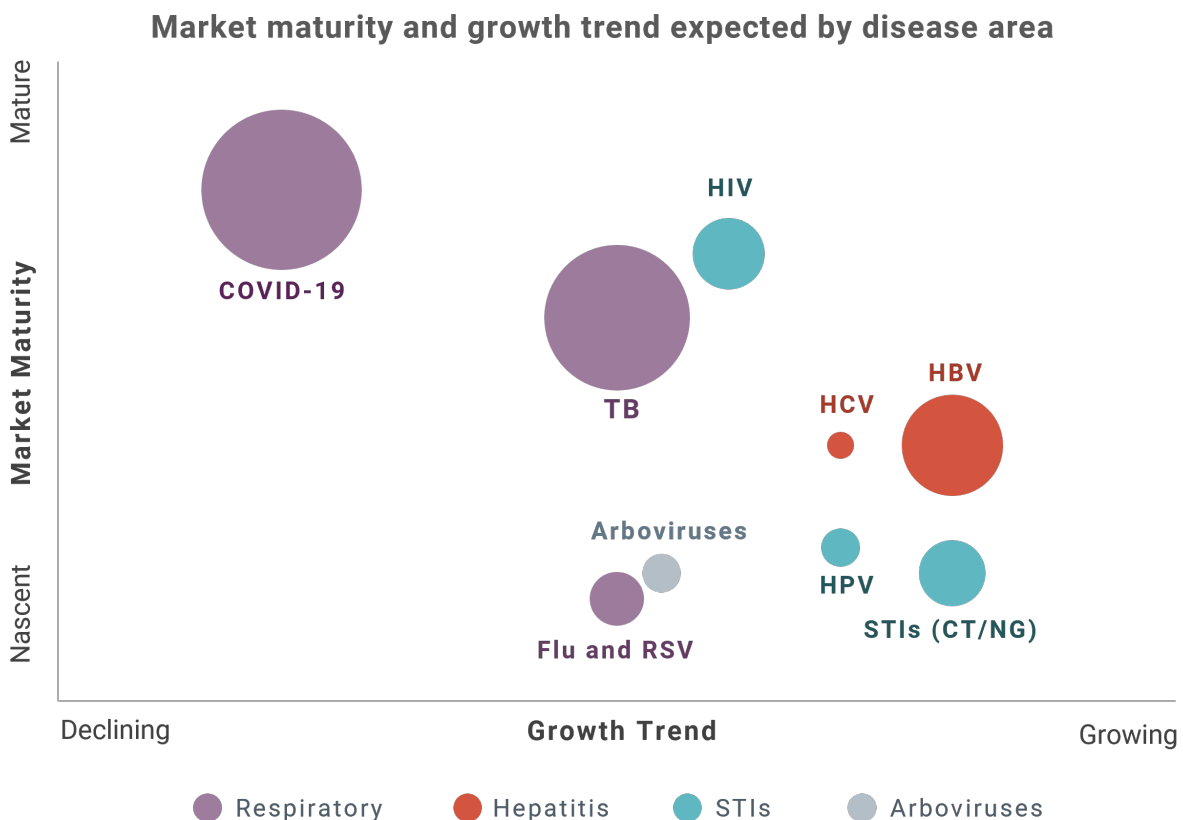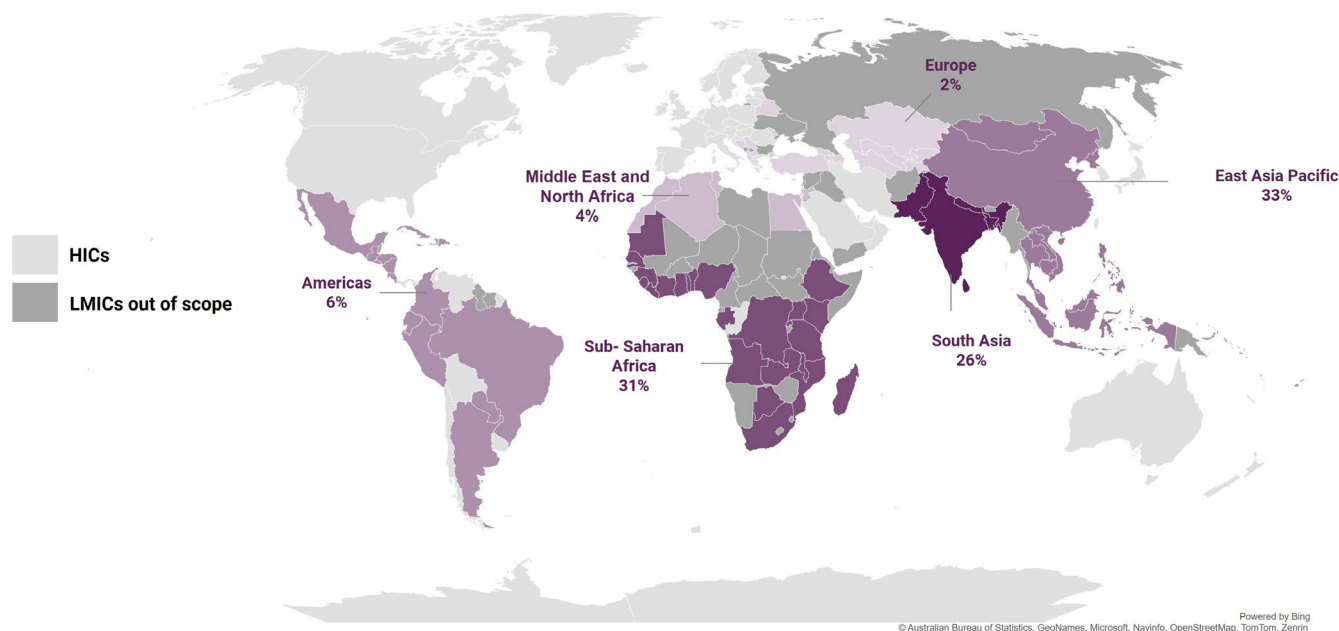Market maturity and growth trend expected by disease area

Figure 13 Total addressable market size estimate for near-point-of-care molecular diagnostics, annual, in LMICs (n=75), by region (as classified by the World Bank).
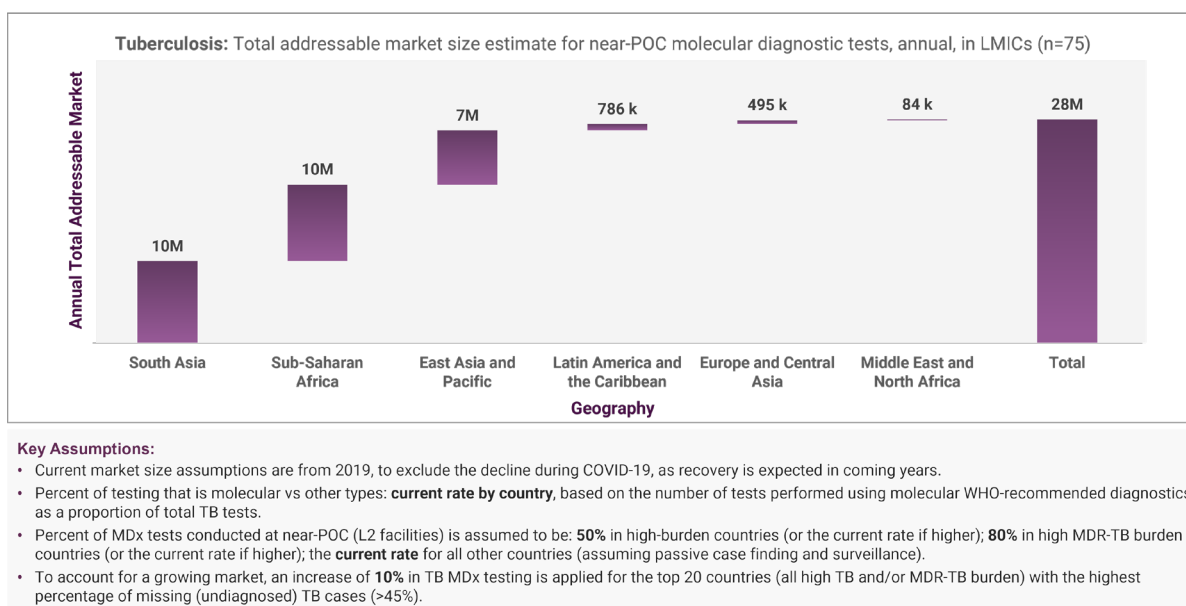

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Respiratory: tuberculosis

Tuberculosis (TB) represents an estimated 28.1 million tests, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 14)*. TB is the largest market of the diseases included in this market size estimate. India, South Africa, Indonesia, China, Bangladesh, and the Democratic Republic of Congo represent 60% of TB's total addressable market.

Figure 14. Tuberculosis, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- Current market size assumptions are from 2019, to exclude the decline during COVID-19, as recovery is expected in coming years.
- Percent of testing that is molecular vs other types: **current rate by country**, based on the number of tests performed using molecular WHO-recommended diagnostics as a proportion of total TB tests.
- Percent of MDx tests conducted at near-POC (L2 facilities) is assumed to be: **50%** in high-burden countries (or the current rate if higher); **80%** in high MDR-TB burden countries (or the current rate if higher); the **current rate** for all other countries (assuming passive case finding and surveillance).
- To account for a growing market, an increase of **10%** in TB MDx testing is applied for the top 20 countries (all high TB and/or MDR-TB burden) with the highest percentage of missing (undiagnosed) TB cases (>45%).

TB is a highly contagious respiratory disease and one of the top ten causes of death worldwide. More than 80% of TB cases occur in 30 countries, of which 90% are emerging economies classified as LMICs.[13] Early diagnosis is an important component in the strategy to achieve a global TB case reduction of 90% by 2030. WHO recommends rapid and sensitive MDx tests for TB and TB drug resistance detection.

The TB MDx market is enabled by increased test demand expected from countries with high TB and multidrug-resistant TB (MDR-TB) burden, as well as a recovery of test volumes to pre-pandemic levels in coming years, supported by 'TB Recovery Plans' from national TB programmes across countries.

Emerging themes

The continuing spread of MDR-TB is one of the most urgent and difficult challenges facing global TB control. Multiplex TB test panels that detect TB pathogens and drug resistance are critical to address this.

There is a need for non-sputum samples to reduce the reliance on existing sputum-based testing. Collecting sputum-based samples remains a major barrier to improving TB case detection, considering that individuals with paucibacillary TB (including children) and those with HIV are less capable of producing sputa.[14]

Respiratory: COVID-19, flu, and RSV

Flu (inclusive of Flu A and Flu B) and RSV represent an estimated 4.2 million tests, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 15*). China, India, Brazil, Mexico, and South Africa represent 70% of the total addressable market for flu and RSV. However, individual country behaviours and system incentives that drive MDx testing are dynamic and subject to change in these markets.
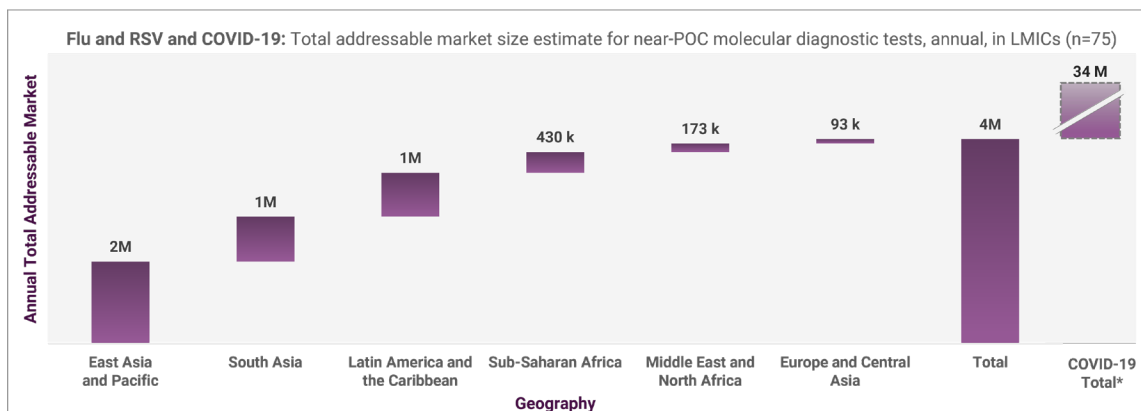
The flu and RSV market is enabled by the rate of severe disease and the emergence of respiratory variants as factors that could increase demand.

The market for COVID-19 MDx testing has been estimated based on the WHO minimum testing rate of one person tested per 100,000 population per week, which was then adjusted for an adherence expectation and rate of testing at near-POC L2 health facilities compared with centralized testing. In total, 33.8 million tests per year are estimated as the need. However, it is observed that most countries are not complying with this minimum testing need, especially with declining fatality rates and lack of motivation to confirm a diagnosis in the general population, resulting in COVID-19 testing volumes that continue to decline.

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[13] Global tuberculosis report, 2021, World Health Organization
[14] The Epidemiological Importance of Subclinical Tuberculosis. A Critical Reappraisal, Am J Respir Crit Care Med, 2021.

Figure 15. Flu and RSV and COVID-19, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Flu and RSV and COVID-19: Total addressable market size estimate for near-POC molecular diagnostic tests, annual, in LMICs (n=75)

Key Assumptions (for flu and RSV):
- Only testing for moderately severe and hospitalized cases of lower respiratory tract infections are included; upper respiratory tract infections are assumed to be non-severe and not included.
- Estimated percent of testing that is molecular vs. other types: **20-60%,** depending on the country archetype (Key Opinion Leader survey).
- Estimated percent of MDx tests conducted at near-POC (L2 facilities): **10-20%,** depending on the country archetype (Key Opinion Leader survey).

*COVID-19 test volumes are considered separately, as they are expected to continue to decline.

Emerging themes

A key trend is emerging, enabled by MDx technology and the effects of the pandemic, in moving away from opportunistic syndromic management, which increases the risk for AMR, and shift to etiological diagnosis, where the specific pathogen causing the illness is identified.

Historically, limited public resources to meet population health needs in emerging economies have meant that screening and case management for respiratory infections relies on the syndromic diagnosis approach. This refers to diagnosing and treating a patient based on symptoms most associated with a particular illness and relies on clinical judgment and empirical treatment rather than laboratory confirmation. However, given the level of overlap in symptoms for different respiratory pathogens—fever, cough, breathing problems, rashes—an accurate differential diagnosis based on symptoms alone is difficult. The risks are then of over-treatment or under-treatment of patients, a significant driver of emerging antimicrobial

and treatment resistance, which has profound implications for population health management. In the case of flu A/B, RSV, and also COVID-19, MDx is necessary to provide a differential diagnosis. This has not historically been equitably accessible to populations in emerging markets due to limited resources, infrastructure, and trained healthcare workers. In recent years, during the COVID-19 pandemic, due to the improved availability and awareness of MDx technology, there has been a significant shift in health-seeking behaviours.

Hepatitis: hepatitis B virus

HBV represents an estimated 14 million tests, in terms of the total addressable market for near-POC MDx, at the L2 level in LMICs (*Figure 16)*. China, India, Nigeria, Indonesia, and Egypt represent 65% of the total addressable market for HBV.

Chronic HBV infection remains a major cause of liver disease globally, and in 2019, HBV resulted in an estimated 820,000 deaths, mostly from cirrhosis and liver cancer.[15]
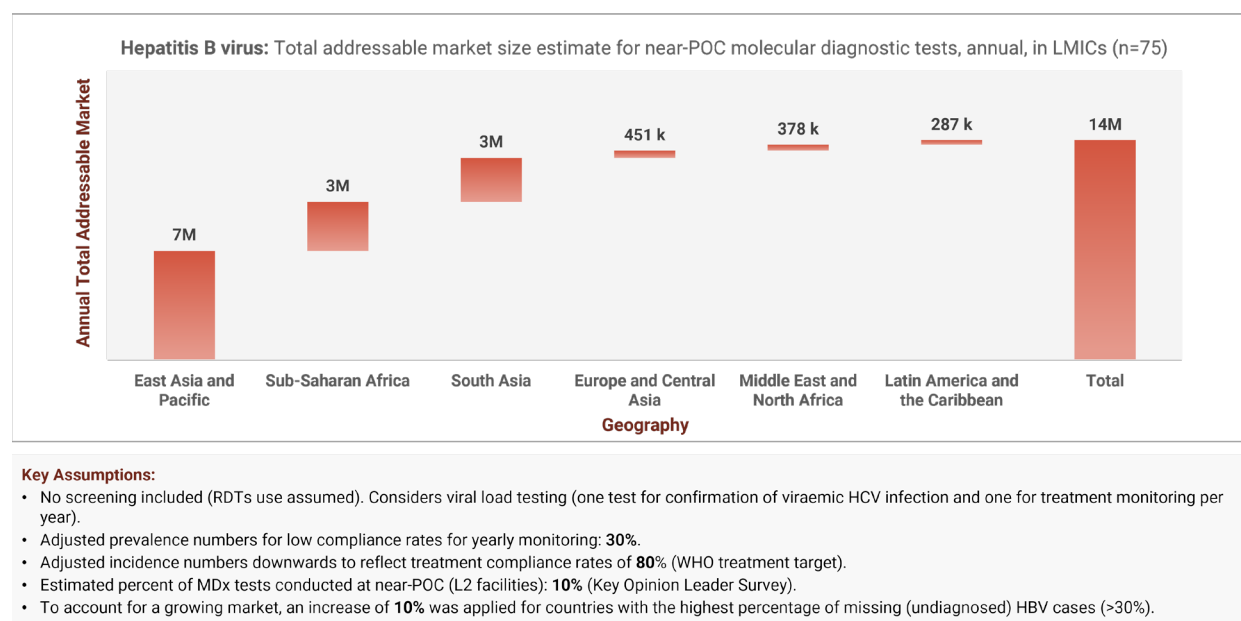
The testing and treatment algorithm for HBV remains complex. No case screening using near-POC MDx was included, given current guidelines which recommend using a single quality-assured serological diagnostic tool (i.e., laboratory-based immunoassay or RDT) for hepatitis B surface antigen (HBsAg) screening. For this market size estimate, two use cases were considered, in accordance with WHO guidelines[16]:

1. Viral load monitoring to inform treatment decisions for new cases, and
2. Monitoring of disease progression for existing patients and new patients.[17]

Emerging themes

HBV testing and treatment uptake is lagging despite high morbidity and mortality. Many factors contribute to this significant gap in access, including limited awareness and lack of funding for a public program. However, some countries have started to expand HBV testing and treatment by building on the foundation of their HCV program. India has now expanded its HCV infrastructure to screen and treat patients for HBV. Similarly, Rwanda has scaled up its viral HCV program to include HBV testing. Prioritising quality, accessible HBV viral load testing can facilitate market expansion in high-burden countries.

Figure 16. Hepatitis B virus, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- No screening included (RDTs use assumed). Considers viral load testing (one test for confirmation of viraemic HCV infection and one for treatment monitoring per year).
- Adjusted prevalence numbers for low compliance rates for yearly monitoring: **30%**.
- Adjusted incidence numbers downwards to reflect treatment compliance rates of **80**% (WHO treatment target).
- Estimated percent of MDx tests conducted at near-POC (L2 facilities): **10%** (Key Opinion Leader Survey).
- To account for a growing market, an increase of **10%** was applied for countries with the highest percentage of missing (undiagnosed) HBV cases (>30%).

[15] Hepatitis B Fact Sheet, World Health Organization.
[16] Hepatitis B Diagnosis Guidelines, World Health Organization.
[17] HCV Market Intelligence Report 2021 and Preliminary HBV Market Insights, CHAI

Hepatitis: hepatitis C virus

HCV represents an estimated 0.7 million tests, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 17)*. India, China, Nigeria, Egypt, and Pakistan represent almost 50% of the total addressable market for HCV. Despite India and China being the largest country markets, Sub-Saharan Africa is the biggest estimated regional market. Overall, this market size is sensitive to health spending per capita and financing to HCV programs globally.

WHO estimated that in 2019, approximately 290,000 people died from HCV, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). Antiviral medicines can cure more than 95% of persons with HCV infection.[18]
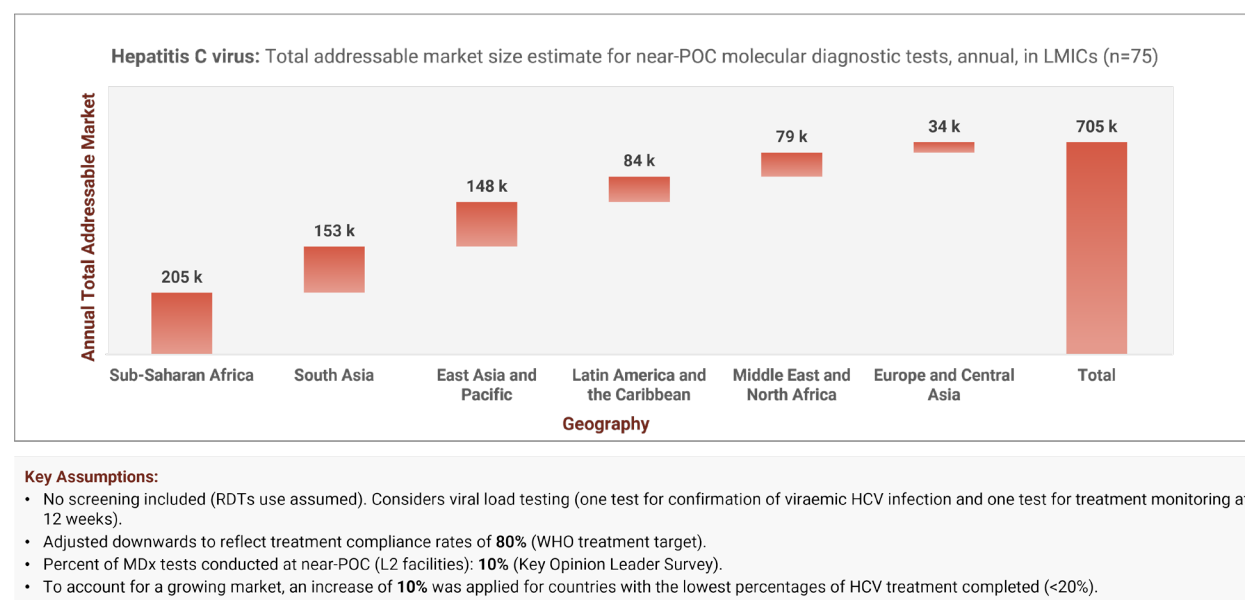
The HCV MDx test estimate was developed similarly to the HBV estimate. No case screening using MDx was included, and the use cases considered consist of viral load testing to inform treatment decisions and annual viral load monitoring.

Emerging themes

Hepatitis is a severely underdiagnosed disease in LMICs. WHO estimates that up to 90% of people with HBV and 80% with HCV are unaware of their infection worldwide. The market for testing is expected to grow rapidly, driven by factors such as increasing awareness about HBV and HCV, the rising prevalence of the disease, and the availability of advanced diagnostic, treatment, and prevention options. Additionally, hepatitis is a key external funding priority, under HIV and associated infections, for multilateral and bilateral funders. Key donors such as Gavi, PEPFAR, and the Global Fund for HIV, TB, and Malaria (The Global Fund) support product introductions for innovations in LMICs.

Figure 17. Hepatitis C virus, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- No screening included (RDTs use assumed). Considers viral load testing (one test for confirmation of viraemic HCV infection and one test for treatment monitoring at 12 weeks).
- Adjusted downwards to reflect treatment compliance rates of **80%** (WHO treatment target).
- Percent of MDx tests conducted at near-POC (L2 facilities): **10%** (Key Opinion Leader Survey).
- To account for a growing market, an increase of **10%** was applied for countries with the lowest percentages of HCV treatment completed (<20%).

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[18] Hepatitis C fact sheet, World Health Organization.

HIV

HIV represents an estimated 6.4 million tests per year, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 18*). South Africa, Nigeria, Tanzania, Uganda, and Kenya represent 60% of the total addressable market for HIV.
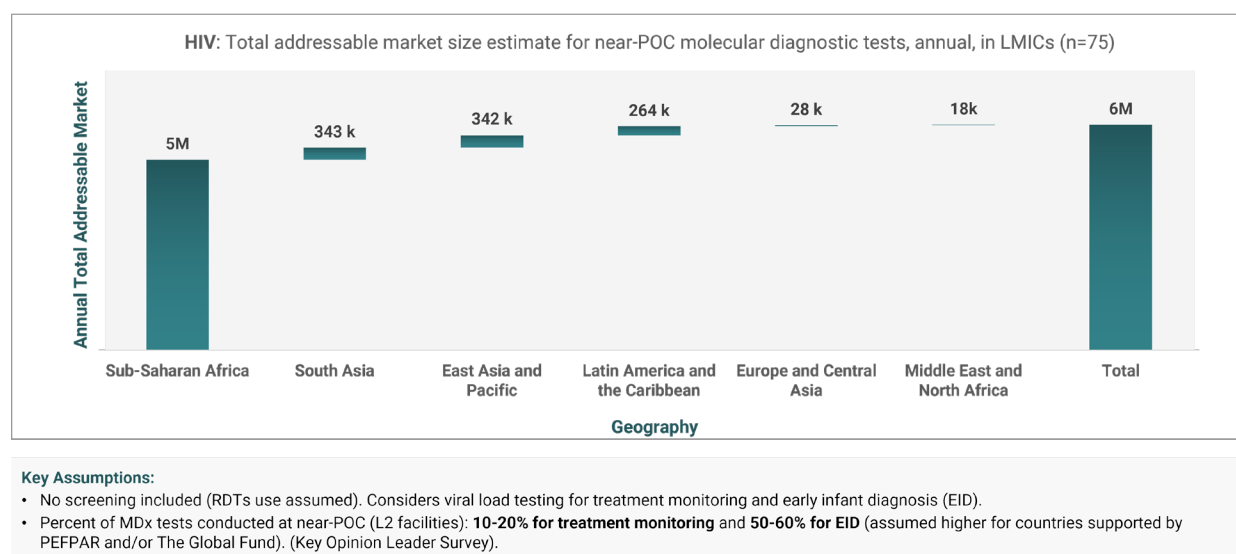
HIV remains a major global public health issue, having claimed 40 million lives so far with ongoing transmission in all countries globally, with some countries reporting a resurgence in new infections. In 2021, 650,000 people died from HIV-related causes, and 1.5 million people acquired HIV. There is no cure for HIV infection. However, with access to effective HIV prevention, diagnosis, treatment and care, including for opportunistic infections, HIV infection has become a manageable chronic health condition, enabling people living with HIV to lead long and healthy lives.[19]

For this market estimate, two major use cases were considered: viral load testing for treatment monitoring and early infant diagnostics. No market is assumed for HIV screening of key populations. A key enabling factor towards the HIV testing market is the level of global health funding by PEPFAR and The Global Fund.

Emerging themes

Although significant recent investments in improving the diagnostic networks, centralized laboratories, and sample collection networks have been made in most HIV high-burden settings, clear improvements in access to infant testing and treatment initiation of infants have not increased at the same rate. Substantial challenges and barriers remain. In 2019, only 60% of infants received an HIV test within the first two months of age.

Figure 18. HIV, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- No screening included (RDTs use assumed). Considers viral load testing for treatment monitoring and early infant diagnosis (EID).
- Percent of MDx tests conducted at near-POC (L2 facilities): **10-20% for treatment monitoring** and **50-60% for EID** (assumed higher for countries supported by PEFPAR and/or The Global Fund). (Key Opinion Leader Survey).

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[19] HIV/AIDS Fact Sheet, World Health Organization.

A recent systematic review of laboratory-based, standard-of-care infant testing found that the mean turnaround time from sample collection to the results received at the clinic was 44.5 days. In addition, in a subset of studies, 15% of infants living with HIV had died between infant testing and ART initiation. Considering this, the opportunity for near-POC MDx testing for EID is expected to increase.

HIV viral load testing in people living with HIV is the preferred monitoring approach by WHO.

It allows early detection of treatment failure and guides treatment decisions, such as adherence counselling or regimen change. Decentralized viral load testing will improve clinical outcomes for people living with HIV. Various studies have demonstrated the feasibility of this.[20] In addition, with the push by UNAIDS towards the 2025 target of 95% of all people receiving antiretroviral therapy will have viral suppression, the decentralized HIV VL market is expected to grow.
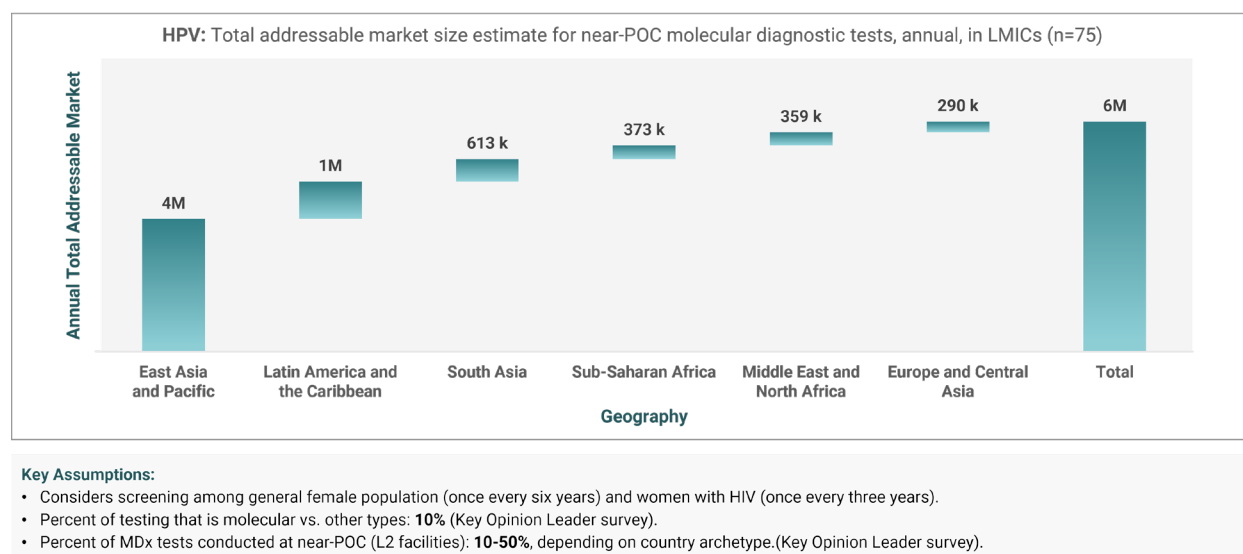
HPV

HPV represents an estimated 6.3 million tests per year, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 19*). China, India, Brazil, Indonesia, and Mexico represent 70% of the total addressable market for HPV. Cervical cancer is the fourth most prevalent type of cancer in women worldwide, and HPV is the main cause of more than 95% of cervical cancers.[21] The WHO guideline recommends using a DNA-based HPV test (i.e. an MDx test) as the preferred method for

HPV (i.e., cervical cancer) screening. This market estimate focuses on the need for screening among the general female population and women with HIV/AIDS.

Emerging trends

As the most common viral infection affecting the reproductive system, the prevention, diagnosis, and treatment of HPV infection has garnered significant international public health attention, with the elimination of

Figure 19. HPV, total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- Considers screening among general female population (once every six years) and women with HIV (once every three years).
- Percent of testing that is molecular vs. other types: **10%** (Key Opinion Leader survey).
- Percent of MDx tests conducted at near-POC (L2 facilities): **10-50%**, depending on country archetype.(Key Opinion Leader survey).

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[20] Implementation of CD4 and viral load testing in decentralized, remote, and resource-limited settings, UNITAID.
[21] Cervical cancer fact sheet, World Health Organization.

cervical cancer forming part of the global public health strategy recommended by the WHO. The market is enabled by targets by WHO to eliminate cervical cancer b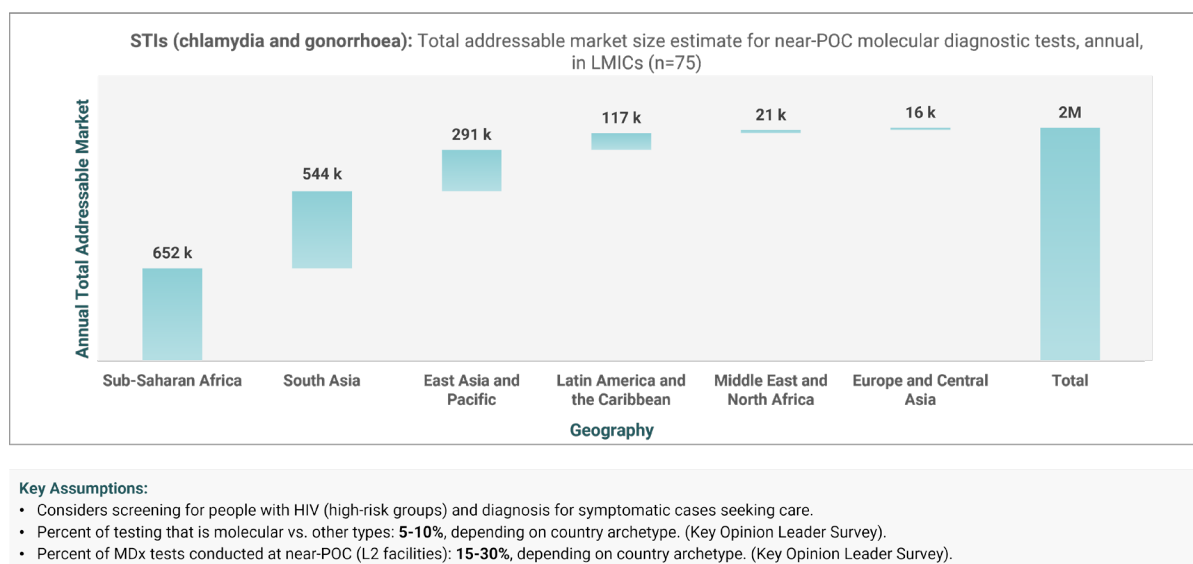y 2030, specifically to test 70% of eligible women at least twice in their lifetime.[20] According to KOLs, HIV donors are expanding their focus towards HPV diagnostics, increasing the potential market opportunity.

STIs: chlamydia and gonorrhea

Chlamydia and gonorrhoea represent an estimated 1.6 million tests per year, in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 20*). India, China, South Africa, Nigeria and Tanzania represent 65% of the total addressable market for chlamydia and gonorrhoea. For this market size estimate, "STIs" focus on chlamydia and gonorrhoea. HIV, HPV, and HBV have individual sections, and syphilis is not included due to the range of RDTs with high sensitivity and specificity available at POC, limiting the need for near-POC MDx in resource-limiting settings.

Figure 20. STIs (chlamydia and gonorrhoea), total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

STIs (chlamydia and gonorrhoea): Total addressable market size estimate for near-POC molecular diagnostic tests, annual, in LMICs (n=75)

Annual Total Addressable Market / Geography

- Sub-Saharan Africa: 652 k
- South Asia: 544 k
- East Asia and Pacific: 291 k
- Latin America and the Caribbean: 117 k
- Middle East and North Africa: 21 k
- Europe and Central Asia: 16 k
- Total: 2M

Key Assumptions:
- Considers screening for people with HIV (high-risk groups) and diagnosis for symptomatic cases seeking care.
- Percent of testing that is molecular vs. other types: **5-10%**, depending on country archetype. (Key Opinion Leader Survey).
- Percent of MDx tests conducted at near-POC (L2 facilities): **15-30%**, depending on country archetype. (Key Opinion Leader Survey).

Emerging trends

Although syndromic management (relying on symptoms and clinical algorithms for diagnosis) is simple and cost-effective, most STIs are asymptomatic. Thus, WHO recommends that countries enhance syndromic management by gradually incorporating laboratory testing to support diagnosis. In settings where quality assured MDx tests are available, it is recommended to treat STIs based on laboratory tests. AMR of STIs—particularly gonorrhoea—has increased rapidly in recent years and has reduced treatment options. The Gonococcal AMR Surveillance Programme (GASP) has shown high rates of resistance to many antibiotics, including quinolone, azithromycin and extended-spectrum cephalosporins, a last-line treatment. As resistance is expected to rise, there is a growing need to develop

multiplexing tests that detect both pathogen and drug resistance in relevant geographies. HIV and other STIs have high co-prevalence, often share socio-behavioural elements, especially in vulnerable populations, and require integrated and multifaceted

approaches to engage those at greatest risk of HIV and other STIs in any interventions to increase testing, treatment, and prevention. Due to the common population at risk across multiple STIs, public health programs can benefit from multiplex STI panels.

Arboviruses: Dengue, yellow fever, and Zika virus

Arboviruses, comprising dengue, yellow fever, and Zika virus in this market size estimate, represent an estimated 2.1 million tests per year in terms of the total addressable market for near-POC MDx, at L2 health facilities in LMICs (*Figure 21*). India, China, Brazil, Indonesia, and Mexico represent 65% of the total addressable market for these arboviruses.

Arthropod-borne viruses (arboviruses) such as dengue, yellow fever, chikungunya and Zika virus are all current public health threats in tropical and sub-tropical areas where approximately 3.9 billion people live. The frequency and magnitude of outbreaks of these arboviruses, particularly those transmitted by Aedes mosquitoes, are increasing globally, driven by the convergence of ecologic, economic, and social factors.

Emerging trends

The market is expected to be led by dengue virus volumes, as current serologic assays (e.g. IgM and IgG ELISAs) cannot be used by diagnosis during the early symptomatic phase. In addition, infection with flaviviruses induces cross-reactive antibodies, which are a challenge for serological diagnosis.[22] Therefore, a specific diagnostic method for acute dengue virus infection is of great interest, and MDx has become an important tool that can be used for early and specific detection of dengue virus. Climate change also leads to increases in global temperatures and erratic precipitation patterns, contributing to the expansion of mosquito-borne arboviruses and the populations of the mosquitos that vector them.

Figure 21. Arboviruses (dengue, yellow fever, and Zika virus), total addressable market size estimate for near-point-of-care molecular diagnostic tests, annual, in LMICs (n=75).

Key Assumptions:
- Considers percentage of mild-moderate, and severe cases requiring diagnosis.
- Percent of testing that is molecular vs. other types: **15-50%**, depending on country archetype. (Key Opinion Leader Survey).
- Percent of MDx tests conducted at near-POC (L2 facilities): **15-50%**, depending on country archetype. (Key Opinion Leader Survey).

[22] Magnitude of Antibody Cross-Reactivity in Medically Important Mosquito-Borne Flaviviruses: A Systematic Review, Infection Drug Resistance, 2021.

Malaria (not included in market size estimate)

Malaria is excluded from near-POC MDx market size estimate, as microscopy and quality-assured microscopy remain the gold standard of malaria detection and disease management. Based on expert discussions, the immediate use case for MDx methods for malaria are in surveillance (mapping the prevalence of malaria) by ministries of health and academics (to increase the power of surveys in low-transmission settings). The use case for diagnosis using MDx is limited for case diagnosis or management.

More sensitive diagnostic tools should be considered only in low-transmission settings per WHO. Using nucleic acid amplification test (NAAT)-based methods should not divert resources away from malaria prevention and control interventions. Thus, there is a need to develop low-cost molecular tests for malaria that health systems can adopt.

Antimicrobial resistance (not included in market size estimate)

The Global AMR R&D Hub[23] conducted a detailed analysis of patient needs and market potential for priority health technologies addressing AMR. The study revealed that antibiotic resistance is a major concern and extends horizontally across all pathogens regardless of the spectrum of infectious diseases caused. To address this issue, the analysis developed need profiles for two diagnostics, which aim to reflect some of the highest and most acute unmet needs for new products in the field of AMR. Pathogens in the analysis address diseases and/or syndromes caused by the pathogens listed on *WHO's Global Priority Pathogens List of Antibiotic-Resistant Bacteria and M. tuberculosis* (focusing on the 'critical' pathogens).

The first diagnostic need profile, Dx1 (bacterial vs "other"), is designed to differentiate between bacterial and non-bacterial pathogens. The lack of such a diagnostic has long been considered a bottleneck in the ability to move beyond syndromic diagnosis. This diagnostic is envisioned as a rapid, low-cost product, accessible to resource-limited countries or settings—a true-POC test.

The second diagnostic need profile, Dx2 (ID/susceptibility), informs physicians about the nature of the causative bacteria and what antibiotics those bacteria are susceptible to. Dx2 (ID/susceptibility) will only be used to diagnose critically ill hospitalized patients. It is envisioned to be rapid, low-cost, and accessible to resource-limited countries or settings as a near-POC test with high sensitivity and specificity. It would have a wide panel of identification (prioritized pathogens) for direct detection of multiple target bacterial pathogens from lower respiratory samples (bronchoalveolar lavage or endotracheal aspirates), volatile organic compounds – (includes urine, faeces, sweat, or exhaled breath), or blood.

The study indicates that hospitalized patients with all-cause pneumonia and bloodstream infections, eligible for Dx2 (ID/susceptibility), are estimated at 24 million in LMICs. The demand and uptake for these diagnostics will be highly

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[23] Estimating Global Patient Needs and Market Potential for Priority Health Technologies Addressing Antimicrobial Resistance, Global AMR R&D Hub.

dependent on the cost they are made available to LMICs. The target addressable market is estimated at 12 million tests per year, assuming at least a 50% capture of patient need at near-POC L2 hospitals in the initial years after the launch of such diagnostics.

The availability of these envisioned diagnostics would revolutionize the treatment of infected patients worldwide. It would avoid unnecessary antibiotics and enable widespread and early capture of patients before they become critically ill. The cost of these diagnostics is a critical factor in their adoption and widespread use in LMICs, however, the success of these diagnostics would greatly benefit the healthcare system by improving patient outcomes and reducing healthcare costs associated with treating antibiotic-resistant infections.

MARKET BARRIERS

The near-POC MDx market faces challenging factors, on both the supply and demand sides representing market barriers, and particularly information asymmetry between buyers and sellers across these market aspects. (*Figure 22*).

Figure 22. Point-of-care molecular diagnostic market barriers on both the supply and demand sides.

Supply-side barriers:

► Manufacturers, especially small and medium-sized developers of promising technology, are sometimes unfamiliar with the key stakeholders and how to commercialise their products in LMIC environments.

► The POC MDx market, and especially multiplexing in this context, is nascent—current guidelines, provider preferences, and system incentives can be outdated.

Demand-side barriers:

► Disease-focused funding, procurement, and program management siloes in the public sector; current MDx systems are 'owned' by specific disease programs (e.g., TB). A lack of clear ownership and strategy for diagnostics within a country's health system results in sub-optimal or haphazard diagnostics deployment.

► Unclear and lengthy product registration requirements, along with supply chain challenges slow uptake of new technology.

► Higher costs of financing, procurement, and service and maintenance in LMICs—especially those considered fragile markets or with smaller populations—make new technology unaffordable and often incur higher final prices than in HIC markets. An increased test cost for multiplexing poses a barrier to affordability in both public and private sectors.

► Misalignments of funding capacity, ownership, and decision-making exist between centralised (e.g. national government payers, national lab network) and end-users at the decentralised levels of the health system (L2 hospitals and labs, patients).

MARKET ENABLERS

Working towards ensuring availability, awareness, and affordability of near POC MDx with multiplexing capabilities in LMICs is critical. Envisioning a healthy and competitive market that addresses market barriers on both the supply and demand side will enable the market potential to be realized (*Figure 23*).

Figure 23. Point-of-care molecular diagnostic market enablers on both the supply and demand sides.

Supply-side enablers (for manufacturers):

► Continue technology development for POC MDx platforms that have:
  • Greater flexibility to address multi-disease targets corresponding to local needs in lower-level health facility environments.
  • Lower overall cost of the installed MDx platform, including instrument, test cartridge, and the supply chain requirements needed (e.g. temperature during transport and storage requirements).
  • A smaller physical footprint.
  • Simple-to-use user interfaces and systems that support remote distance and connected tools for ongoing and lower-cost maintenance.
  • Broader connectivity options for data sharing between end-users and government/health provider administration, to help inform policymaking and pandemic preparedness.

► Develop relationships with regional or country distributors to:
  • Encourage greater transparency of prices along the supply chain and mark-ups to the end-user.
  • Share new product information in an efficient manner that competitively positions innovative products, allowing distributors to test new products in their markets.
  • Develop new models to support distributor financing options (e.g. pre-payment, trade finance support, leasing models).

► Proactively engage with buyers and policymakers on existing and new use cases, demand generation, trade financing, and training solutions to make products widely available and affordable.

► Develop partnerships with private sector channels, including private hospitals, laboratories, and pharmacy chains, that encourage innovative distribution models, such as integrating multi-disease screening in workplace or pharmacy retail environments.

► Continue to strive for disruption with an open-system model that can allow for the flexibility of different test cartridges and open-source consumables and supplies.

Demand-side enablers (for countries and global health actors):

► For buy-side actors and healthcare providers, shift from disease-centred to patient-centred approaches and financing to enable integrated diagnostics, patient management, care, and surveillance systems.

► Increase appetite in-country from public buyers to decentralise and diversify their existing MDx platform installed base to mitigate risk and pain points experienced along the supply chains for test cartridge and consumable shortages during the pandemic.

► Develop a multiplexing diagnostic strategy, policy, guidelines, and regulatory pathways in-country, taking advantage of the need to utilise the expanded MDx platform installed base for other purposes, as COVID-19 testing demand has drastically declined.

► Conduct clinical validation studies in-country to support more efficient registration processes.

► Conduct operational validation studies in-country, with healthcare providers, to demonstrate the value of multiplexing and contribute to technology development for appropriate use cases. Compare POC MDx, and multiplex POC MDx, to existing alternative diagnostic types to quantify the cost of transitioning to new technology and to help develop the 'investment case', especially for public sector buyers.

LOOKING FORWARD

As testing shifts away from COVID-19 needs, and test developers add more multiplexing capabilities to their menus, the near-POC MDx market is likely to expand. Technological advances have enabled a vision towards multiplex molecular testing as a powerful, principal diagnostic test, and surveillance tool.

In LMICs, the entry of a diverse spectrum of near-POC MDx platforms enables better clinical case management. In the private sector, new markets can be unlocked with private laboratories, hospitals, and even pharmacy chains, especially for the multiplexing use cases and those with the ability to pay. As more people seek care in the private sector and it expands, competition will drive prices down and potentially free resources from a much-constrained public sector. In the public sector, there is significant potential to fulfil

open appetite from governments seeking competitive choices on quality and cost. Additionally, multi-disease surveillance systems exist in LMICs and continue to be highly relevant, with opportunities to build onto the gold-standard PCR testing that is utilized as continuous disease threats emerge.

The implementation of relevant, affordable, and high-performance multiplex molecular POC testing will result in unprecedented changes in therapeutic decisions, management, and control of diseases. Today, and going forward, countries, manufacturers, providers, and global health actors, across public and private sectors can work together to creatively develop scale-up pathways, change the paradigm, and make patient-centred diagnostics a reality.

Annex A

Near-point-of-care molecular diagnostics market size methodology
Note: All sources are available in Annex B: References.

TB

To estimate the market size for near-point-of-care molecular TB testing, the number of TB cases reported and notified in 2019 was divided by the estimated positivity rate per country. The reference year selected was 2019 to exclude the adverse effect of the COVID-19 pandemic on TB testing and case notification. An assumption was made that the market is expected to grow by 10% for the top 20 countries with the highest number of missing TB cases. The near-POC molecular tests share of the total testing market was then calculated using WHO data on mWRD (Molecular WHO Recommended Diagnostics) tests conducted as a proxy.

The final estimated near-POC molecular rate was adjusted according to WHO classification of high-priority countries. These countries also receive international donor funding, so an increase in near-POC molecular testing is expected. For countries with MDR, the near-POC molecular rate is estimated at 80% or the current rate, whichever is higher. For high-burden countries, the near-POC molecular rate is estimated at 50% or the current rate, whichever is higher. For other countries, the current rate is used.

Due to the availability of high-quality data from the WHO TB Report, archetypes-based estimates were not performed for TB estimates, unlike other disease areas.

COVID-19

To estimate the market size for near-POC molecular COVID-19 testing, the caseload in the previous year (March 2022–2023) was multiplied by the tests per positive case reported by countries. This calculation provided an estimate of the total number of tests conducted annually and an understanding of the testing capacity and overall testing strategy in countries. The expectation of increasing or decreasing tests was estimated using the change in fatality rate over time. Reported fatality rates were correlated with testing rates and expected awareness of COVID-19 testing in the population.

As per WHO, a minimum testing rate of one person tested per 1000 population per week should be maintained. The minimum testing need per country was estimated using population numbers and compared to the expected testing rate calculated in the previous step. It was noted that most countries did not comply with the minimum testing need in the past year. Therefore, a prudent measure of adherence to the WHO-prescribed minimum testing rate was taken. A 90% adherence rest for Archetype 'A', guided by high health spend, was assumed; similarly, 80% was assumed for Archetype 'B', 70% for Archetype 'C', and 60% for Archetype 'D'.

Based on this calculation, the expected testing rates and expected minimum testing need adherence were compared, and the higher number of the two was selected.

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Through a KOL survey, an expected percentage of molecular versus other types of testing rates was elicited per archetype. A 60% molecular versus other types of testing rate was estimated for Archetype A, 30% for Archetype B, 15% for Archetype C, and 20% for Archetype D. Another estimate received through this KOL survey was the percentage of molecular testing estimated above, i.e. what percentage is done at near-POC versus centralized testing, based on current testing practices in the country. From this, 20% was estimated for Archetype A, 10% for Archetype B, 10% for Archetype C, and 10% for Archetype D for respiratory pathogen testing (excluding TB).

Hence, despite being top-down or need-based, these estimates are prudent and consider current testing practices in the countries based on current health spend, donor funding, and current health system design and capacity.

Flu and RSV (combined)

The target addressable market for Flu and RSV was estimated using a syndromic approach. This involved examining the symptoms reported by patients to the healthcare system, which were categorized into Upper Respiratory Tract Infections (URTI) and Lower Respiratory Tract Infections (LRTI). URTIs were considered non-severe and not included in the target market calculation. LRTIs were divided by age group, and the percentages of asymptomatic or non-severe cases, severe cases, and hospitalized cases were determined. Only severe and hospitalized cases were assumed to require diagnostics.

A KOL survey elicited an expected percentage of molecular tests versus other tests (such as rapid tests) per archetype. A

molecular rate of 60% was estimated for Archetype A, 30% for Archetype B, 15% for Archetype C, and 20% for Archetype D.

Another estimate received through the survey was the percentage of molecular testing estimated above at near-POC versus centralized testing, based on current testing practices in the country. For respiratory pathogen testing (excluding TB), 20% was estimated for Archetype A, 10% for Archetype B, 10% for Archetype C, and 10% for Archetype D.

HBV

No demand for near-POC molecular diagnostics for case screening is assumed, given the current guidelines that recommend using a single quality-assured serological diagnostic tool (i.e. laboratory-based immunoassay or RDT) for hepatitis B surface antigen (HBsAg) screening. For this estimation, two use cases were considered: i. Viral load monitoring to inform treatment decisions for new cases, and ii. monitoring of disease progression for existing patients and new patients. According to WHO guidelines, following a positive HBsAg serological test, using quantitative or qualitative nucleic acid testing (NAT) to detect HBV DNA is recommended as the preferred strategy to guide whom to treat or not treat. WHO guidelines recommend one quantitative viral load test every year to monitor disease progression. However, compliance with this recommendation is low in LMICs. Per expert interviews, 30% testing of HBV-prevalent cases is assumed. To adjust for low treatment compliance rates in LMICs, 80% (WHO treatment target) is assumed to be a realistic measure. The caseload estimated from IHME 2019 global disease burden and the percentage diagnosed and treated from the Polaris Data

Observatory were obtained. Countries with less than 30% of cases diagnosed were adjusted to increase the market size upwards by 10%. This increase in market size is sensitive to funding for HBV programs. The KOL survey obtained an expected percentage of testing done at near-POC versus centralized testing, based on current testing practices in the country archetypes. Across all country archetypes, 10% near-POC versus centralized testing was estimated.

HCV

No demand for molecular Near-POC diagnostics for case screening is assumed, similar to HBV estimates. According to WHO guidelines, the preferred strategy for diagnosing viraemic infection after a reactive HCV antibody serological test result is to use quantitative or qualitative NAT to detect HCV RNA. Nucleic acid testing for qualitative or quantitative detection of HCV RNA should be used as a test of cure at 12 weeks after the end of treatment.

The caseload estimated from IHME 2019 global disease burden was obtained, and it was assumed that there would be two tests for each case incidence in a year. The percentage diagnosed and treated data from Polaris Data Observatory was also obtained. Countries with less than 20% treatment completion rates were adjusted to increase the market size upwards by 10%. However, this increase in market size is sensitive to funding for HCV programs. To realistically adjust this market size, the WHO target of 80% treatment was used due to low treatment compliance rates in LMICs. The KOL survey obtained the expected percentage of testing done at near-POC versus centralized testing based on current

testing practices in the country archetypes. Across all country archetypes, 10% of testing was expected at near-POC versus centralized testing.

NG/CT

For this market size estimate, STIs (other than HIV and HPV) focus was on gonorrhoea (NG) and chlamydia (CT). NG/CT markets are evaluated considering rising AMR, especially for gonorrhoea, resulting in reduced treatment options. Syphilis is not included in the estimation because a range of RDTs with high sensitivity and specificity is available at the point of care. Because of the generally good performance of syphilis RDTs, there is a limited need for near-POC tests in resource-limited settings.

Common assumptions are considered for the estimation of target addressable market (of NG/CT) due to the common presentation of symptoms. IHME GBD, 2019 estimates for NG/CT were used. Based on the literature (see *References*), 44% are estimated to be symptomatic infections. Out of this, 66% are estimated to present to care based on Primary Market Research (PMR) conducted by FIND. A sizeable percentage of cases presenting with symptoms are treated with a syndromic approach. However, considering the growing number of NG strains with antibiotic resistance and the growing push towards antibiotic stewardship to avert AMR, health systems will require a move towards etiological case management.

To estimate the market size, countries were scored and grouped based on the caseload of NG/CT patients seeking care and country health spend and a composite scoring was created. A third group of countries reporting

high resistance to gonorrhoea drugs was also created. The estimated etiological diagnostics for each group were determined using PMR estimates. 40% etiological diagnosis for countries reporting high resistance was assumed, 20% etiological diagnosis for countries with above median composite score was assumed, and 14% etiological diagnosis for countries with below composite score was assumed.

Other than diagnosis, the annual screening recommended for all sexually active persons living with HIV was considered an additional use case. Data on people living with HIV was obtained from WHO and supplemented with a literature search wherever unavailable. Countries were segregated into two groups based on the number of HIV diagnostics and counselling facilities per 100,000 population. For countries with an above-median number of these facilities, a screening rate of 50% was assumed, and for countries with a below-median number of facilities, a screening rate of 40% was assumed based on expert interviews.

Hence, a total need was calculated, including case management and screening need for NG/CT diagnostic or screening.

HIV

To estimate the near-POC molecular testing market for HIV, two major use cases were identified: treatment monitoring and EID. Viral load testing is required to confirm that antiretroviral therapy is successfully suppressing viral load. For HIV-exposed infants, virological testing for HIV as early as possible is recommended so that antiretroviral therapy (ART) can be started immediately and morbidity and mortality are

prevented. No market is assumed for HIV screening of key populations.

The number of newborns requiring EID testing was estimated using the estimated "number of pregnant women who require ART" from UNAIDS. The March 2021 guidelines for HIV prevention, infant diagnosis, antiretroviral initiation, and monitoring recommend a NAT test within 0-2 days of birth for HIV-exposed infants or children. If the first test is negative, a repeated NAT at 4-6 weeks and another at nine months are recommended. The required number of tests has been estimated using this algorithm and positivity rates from research papers.

For viral load monitoring, it is assumed that two tests per year will be conducted for new infections and one viral load test every year. The KOL survey estimates that 10% of molecular testing will occur at near-POC locations, while the rest will be centralized. For EID tests, it was estimated that 50% would be performed at near-POC locations due to substantial challenges and remaining barriers to access. Finally, these percentages were adjusted for countries supported by PEPFAR and The Global Fund (adjusted upwards by 10% in near-POC versus centralized). A 20% share for viral load testing and a 60% share for EID testing was assumed for these countries.

HPV

To estimate the market size for near-POC molecular tests for HPV, the focus has been on the demand for screening among the general female population and women living with HIV. As per WHO guidelines, the general female population aged 30−64 should be screened regularly with a valid HPV test every five to ten years. Our

estimates assume a screening frequency of every six years. For women living with HIV, the recommended screening interval is every three to five years in the age range from 25 to 64, with most countries adopting a screening frequency of every three years. One test every three years for this patient group is assumed.

Using data from the World Bank and the Our World in Data, data is obtained on the size of the female population within the relevant age range and the percentage of HIV prevalence in the total population. To estimate the number of HPV tests required for women with HIV infection, key patient groups were women receiving ART and women hospitalized for HIV. Based on PMR, the hospitalization rate of people living with HIV was assumed to be 4%.

The KOL survey elicited an expected percentage of molecular tests versus other tests (such as rapid tests) per archetype. A molecular rate of 10% was estimated for all country archetypes. Another estimate received through the survey was the percentage of molecular testing estimated above at near-POC versus centralized testing, based on current testing practices in the country. For this, 50% was estimated

for Archetype A, 40% for Archetype B, 25% for Archetype C, and 10% for Archetype D.

Arboviruses
Owing to limited data availability, the market has been estimated using data for the dengue fever virus, yellow fever virus and Zika virus using IHME GBD estimates. From the literature, the percentage of severe and mild-moderate cases were retrieved. 40%, 45% and 30% were assumed to be percentages of cases requiring diagnostics (and not treated syndromically) for dengue, yellow fever and Zika virus, respectively. A test positivity rate was then assumed to calculate the volumes of tests required.

The KOL survey elicited an expected percentage of molecular versus other testing rates per archetype. From this, 50% was estimated for Archetype A, 30% for Archetype B, 15% for Archetype C and 15% for Archetype D. This also considers the declining sensitivity of molecular tests post five days of onset of treatment. Another estimate received through these surveys was the percentage of tests done at near-POC versus centralized testing, based on current testing practices in the country. From this, 50% was estimated for Archetype A, 30% for Archetype B, 15% for Archetype C and 15% for Archetype D.

ANNEX B: REFERENCES

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