

Near point-of-care molecular TB testing at Mwami Rural Hospital, Zimbabwe.
Photo: ***Unitaid***

Multi-Country Demand Outlook for Near Point-of-Care (nPOC) Tuberculosis Diagnostics (2026–2030)

Projected nPOC testing uptake and the financing, implementation, and programmatic factors that will shape access to testing

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CLINTON HEALTH ACCESS INITIATIVE

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At a glance

771K [1]

people with TB undiagnosed or unreported in 2024 across 10 countries in focus

19M

projected nPOC tests a year by 2030 across the 10 countries

+17M

additional annual diagnostic tests that could be funded in 2030 if savings are reinvested

The problem. Access to molecular testing for tuberculosis (TB) remains uneven across high-burden countries, with testing concentrated in laboratories. Across the 10 focus countries in this outlook, an estimated 770,800 people with TB were undiagnosed or unreported in 2024, while 51 percent of notified TB patients were diagnosed clinically or by smear microscopy rather than with a molecular World Health Organization (WHO)-recommended rapid diagnostic test. Additionally, declining donor financing and uncertainty over future allocations are putting both existing testing volumes and expansion plans under pressure.

What changed. Near point-of-care nucleic acid amplification tests (nPOC-NAATs or nPOC tests) are molecular tests for TB detection that can produce results from a sputum or tongue swab sample in less than one hour. They run on battery-operated instruments that do not require specialized infrastructure for use or storage. These new nPOC tests are priced at less than half the cost of currently available molecular tests.

Two developments in the past year have reduced important barriers to nPOC test procurement and policy adoption. In July 2025, Pluslife's MiniDock MTB test received an Expert Review Panel for Diagnostics recommendation, enabling time-limited procurement through Global Fund-supported channels. In March 2026, WHO issued its first recommendations on a new class of nPOC tests for the initial detection of TB without simultaneous detection of rifampicin resistance at the peripheral levels of the healthcare system. The focus is now on implementation: how countries will deploy the technology, how quickly they can scale it, and what will be required to sustain testing.

What this outlook does. This demand analysis estimates how much nPOC testing is expected under different uptake scenarios through 2030 across 10 high-burden countries. Together, these countries account for 47 percent[2] of the global TB burden and 66 percent of the global molecular testing volume. The outlook models demand for the currently available nPOC test product profile, which matches the Pluslife MiniDock MTB test, while reporting results for the diagnostic class as a whole.

[1] WHO Global TB Database, 2024. Calculated as the difference between estimated TB incidence and new and relapse notifications across the 10 countries. Country program data may differ slightly from WHO estimates.

[2] World Health Organization. Global tuberculosis database. Available at: https://www.who.int/teams/global-tuberculosis-programme/data

Country testing data and 94 stakeholder interviews inform introduction timing, scale-up pace, substitution, and financing assumptions. Clinton Health Access Initiative (CHAI) modeled a base case and a reinvestment scenario. The **base case** follows a baseline projection of moderate growth in total testing and allows nPOC tests to substitute for existing tests. The **reinvestment scenario** holds the diagnostic commodity budget at its current level and uses savings from lower-cost substitution to finance additional testing.

What the outlook finds:

1. Across the 10 countries, nPOC testing could reach 19 million tests a year by 2030 under the base case, within a range of 15 million to 22 million. Total diagnostic testing is estimated at 46 million tests by 2030, with nPOC tests representing 41 percent of all diagnostic testing across the 10 countries, or 66 percent of all diagnostic testing when India is excluded. India's large smear microscopy volumes lower the aggregate share.

2. Most base-case nPOC testing demand comes from substitution. Country interviews indicate that early nPOC testing uptake will largely displace smear microscopy and existing molecular tests, so a rising nPOC test share does not by itself mean more patients are tested. Deployment to primary health centers can nevertheless improve access to molecular testing by bringing it closer to where patients first seek care.

3. Under the reinvestment scenario, savings from the transition to nPOC testing could fund an additional 17 million diagnostic tests in 2030. If the same diagnostic commodity budget is retained and savings are used to fund additional nPOC testing, total diagnostic testing could increase from 46 million tests under the base case to 63 million tests in 2030. nPOC test volume itself would nearly double, reaching approximately 34 million tests per year in 2030. Three-quarters of the additional nPOC volume is concentrated in countries where molecular tests are the primary method of TB diagnosis because nPOC testing primarily replaces higher-cost low-complexity NAAT (LC-NAAT) testing in these countries and generates savings. However, no country reported having such a reinvestment plan in place.

4. Introduction timing and site readiness shape uptake. Countries differ in when they expect to introduce nPOC testing and how quickly they expect to scale it. All 10 countries identify primary health centers as a deployment target, but they differ in the planned or expected sequence of deployment locations and in how quickly peripheral sites can be prepared. Stakeholders in every country emphasized that introducing a device alone is not sufficient. They pointed to four prerequisites: trained healthcare workers, functioning infrastructure and maintenance, reliable last-mile supply, and reporting systems that capture nPOC testing results.

Implication. A country's current test mix determines whether nPOC testing raises or lowers commodity costs. Placement and site activation determine whether deployment expands access to molecular testing, increases total testing, or supports earlier diagnosis. Increasing testing beyond the baseline projection will require demand mobilization and additional financing, including mechanisms to retain and reinvest savings.

1. Introduction

Most patients first seek care at facilities without on-site molecular testing. These patients may therefore receive less sensitive smear microscopy as the initial diagnostic test or be referred elsewhere for testing, which has the potential for loss of follow-up. Among the 4.3 million patients notified about a TB diagnosis across the 10 countries in 2024, nearly 2.2 million were diagnosed clinically or by smear microscopy rather than with a molecular test. In addition, the gap between estimated incidence of TB and notifications was approximately 770,800 people. Figure 1 shows that both gaps have narrowed since 2022 but remain large.

Low-complexity nucleic acid amplification test platforms such as GeneXpert have expanded molecular testing over the past decade, but access remains concentrated in facilities with laboratory infrastructure and trained laboratory personnel.

WHO's recommendation and early procurement through the Global Fund have moved nPOC tests from product evaluation to program design. Ahead of the eighth Global Fund grant cycle (GC8), countries and funders are deciding how many nPOC platforms and tests to procure, where to place devices, and how to finance site activation and continued operation.

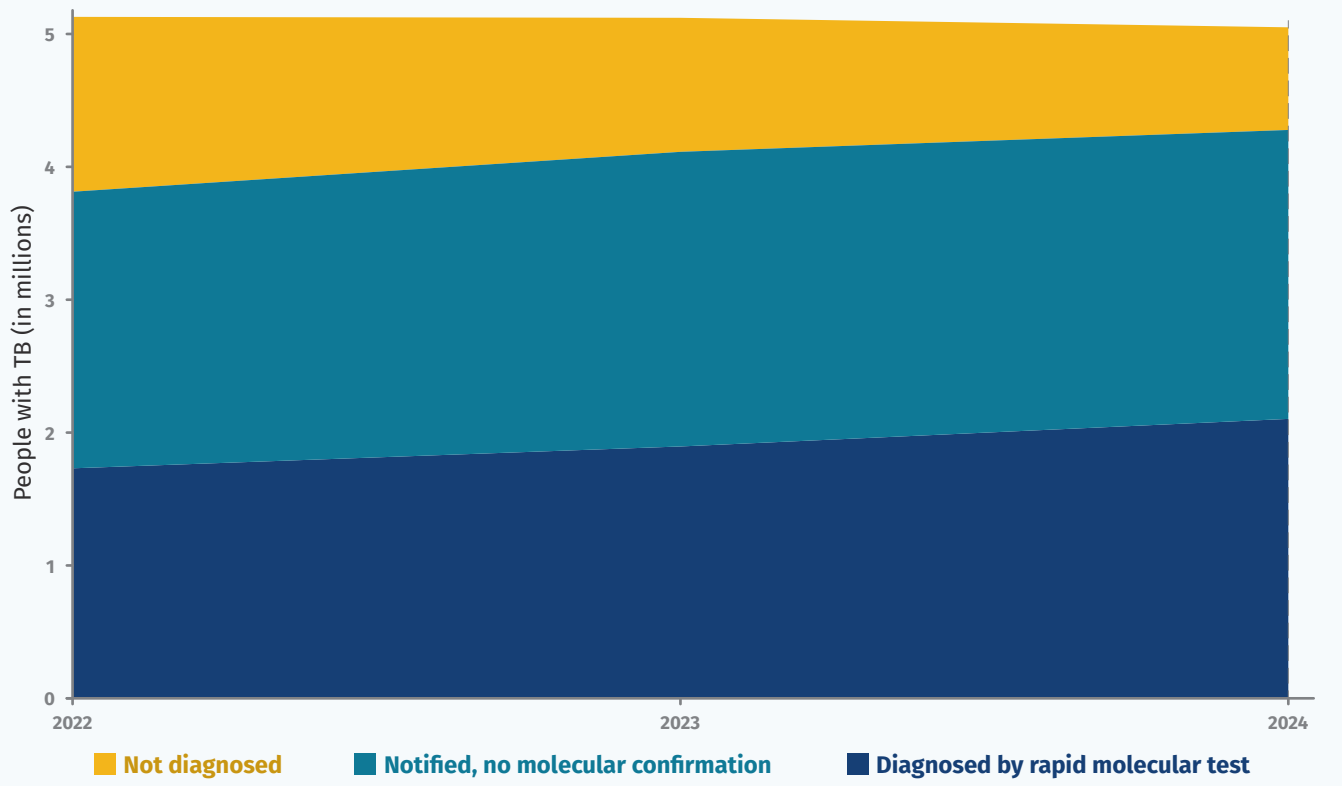


Figure 1. People with TB across the 10 countries, 2022–2024, by how they were diagnosed. The detection gap has narrowed, but 2.2 million people were still diagnosed clinically or by microscopy, and 770,800 were undiagnosed or unreported in 2024. Source: CHAI analysis of country program data and WHO Global Tuberculosis Report 2025.

Under the WHO recommendation, nPOC tests can be used in basic peripheral laboratories, including those that perform smear microscopy, as well as in health clinics, mobile units, and community sites without laboratories. They can be performed by healthcare workers with basic technical skills because they do not require laboratory procedures such as precision pipetting. As of August 2026, these tests cost approximately US$2.60 each, compared with approximately US$8 for an LC-NAAT cartridge. That cost advantage comes with a trade-off. Currently available nPOC assays have lower sensitivity than GeneXpert; however, their simpler operating requirements allow them to be placed closer to where patients first seek care. In addition, the results are available in approximately 30 minutes, compared with around 90 minutes for GeneXpert, potentially enabling diagnosis and treatment initiation during the same encounter and reducing pre-treatment loss to follow-up.

Whether nPOC test introduction improves access will depend on the type of facility where the tests are used. In country interviews, stakeholders described the three broad placement models presented in Figure 2.

At sites with existing molecular testing, nPOC tests can lower commodity cost and free up LC-NAAT capacity but do not by themselves extend access. At microscopy sites, nPOC tests replace a cheaper, less sensitive test; diagnostic quality improves, but commodity cost rises. At referral-dependent sites, nPOC tests bring first-line molecular testing on site, can shorten turnaround time, and can reduce the number of specimens that must be transported to a hub. Countries expect to combine these approaches, so similar nPOC test volumes can have different effects on cost and access.

Deployment to peripheral facilities also requires investment in site activation to ensure testing can be sustained. Section 4.1 sets out the operational requirements.

These placement decisions have implications for procurement, manufacturing capacity, and financing. The analysis that follows reflects country-level differences in healthcare system readiness, scale-up pace, and financing and provides an aggregate demand estimate across the 10 countries to inform procurement planning, pricing, and resource allocation.

Sites with on-site GeneXpert or other molecular platforms	Sites with smear microscopy	Sites that historically rely on referral
Molecular testing available on site	**Smear available on-site for diagnosis or treatment monitoring**	**Samples collected at these sites were sent to hub sites for testing**
• nPOC replaces existing molecular platforms • Cost per test falls • No additional patients reached; sensitivity drops • Frees existing platforms for drug susceptibility testing (DST)	• nPOC replaces diagnostic smear tests • Cost per test rises • Sensitivity improves • Referral pathway remains critical for DST	• Replaces specimen referral for initial testing • Cost per test falls • Reduces loss to follow-up and improves access • Referral for resistance testing still required • Requires higher investment in infrastructure, workforce, supply chain, and reporting

Only the third model lowers cost and expands access at the same time.

Figure 2. Three nPOC test placement models and their implications for cost, access, and referral. Countries expect to use a mix of all three models. These are deployment choices rather than modeled scenarios; this outlook does not allocate volumes to individual sites. Source: CHAI analysis of 94 stakeholder interviews.

2. Approach

The outlook covers 10 countries: Cameroon, Côte d'Ivoire, India, Indonesia, Kenya, Nigeria, South Africa, Uganda, Viet Nam, and Zimbabwe. These countries were selected to represent a mix of high- and moderate-burden settings, countries with a range of experience adopting new diagnostics technologies, and a range of baseline molecular test adoption. Together, they account for 47 percent of global TB burden and 66 percent of global molecular testing volume.

Quantitative inputs included epidemiological and program baselines, historical testing volumes and mix, and national targets. Ninety-four interviews were conducted across the 10 countries.

Participants represented national TB programs, laboratories, implementing partners, and functions such as procurement, finance, regulatory affairs, and monitoring. The interviews informed assumptions on introduction timing, use cases, scale-up pace, target sites, substitution of existing diagnostic modalities, site readiness, and financing. Figure 3 shows how these inputs feed the model, which projects total diagnostic volumes, estimates nPOC testing uptake, and allocates nPOC test volumes across existing modalities.

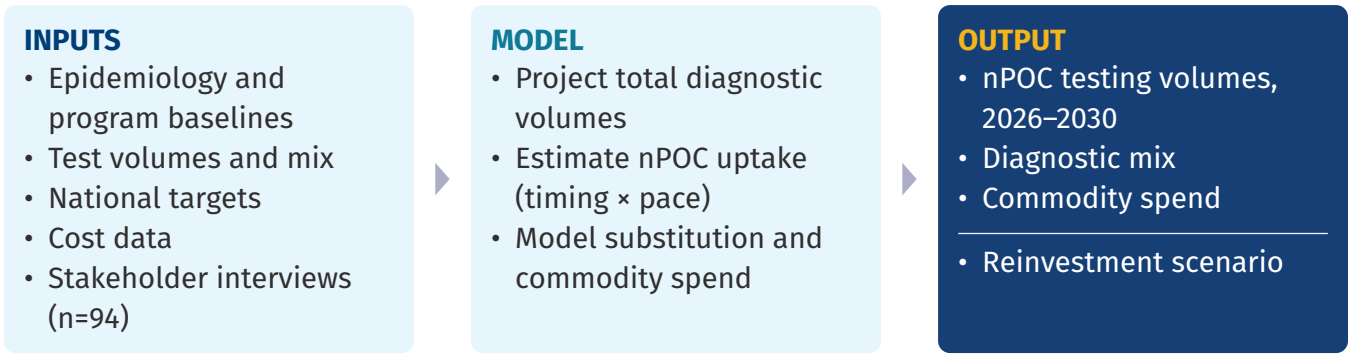


Figure 3. The model projects total diagnostic volumes, estimates nPOC testing uptake from introduction timing and scale-up pace, then allocates nPOC test volumes across existing modalities. The reinvestment scenario is run as a sensitivity analysis. The detailed methodology is provided in the Annex.

What this outlook covers

In scope

Testing volumes, diagnostic mix, commodity expenditure, and how reinvestment affects testing volumes.

Out of scope

Individual site placement, cost of scale-up (site preparation and activation), or epidemiological impact such as cases detected, treatment initiated, or health outcomes. The site activation requirements in Section 4.1 are drawn from the interviews, not from model outputs.

3. Projected nPOC demand and test mix, 2026–2030

3.1 Base-case scale

Under the base case, nPOC testing reaches approximately 19 million tests a year by 2030, within a range of 15 million to 22 million. This represents about 41 percent of all diagnostic testing across the 10 countries, and 66 percent when India is excluded. Figure 4 shows this trajectory against total diagnostic testing from 2025 to 2030.

Almost all of this volume comes from test substitution. The base case follows the baseline projection of moderate growth in total testing, so the proportion of nPOC tests increases by displacing existing tests rather than adding to total testing volume. The limits on uptake reflect financing, the feasible pace of program rollout, and site capacity rather than the scale of unmet diagnostic need.

Substitution includes deployment to primary health centers where nPOC testing replaces on-site microscopy or LC-NAAT performed after sample referral. Section 3.4 shows how reinvesting savings could increase total testing.

Because the model does not allocate projected volumes to individual sites, it does not quantify how much nPOC testing represents decentralized access rather than substitution at facilities already providing molecular testing.

Six countries also identify community or mobile outreach as a potential additional use case. This volume is not modeled separately. Outreach could reach people who are not currently tested and therefore generate additional volume, but it would depend on new financing. Programs reported that such activities are unlikely to increase as external funding shrinks.

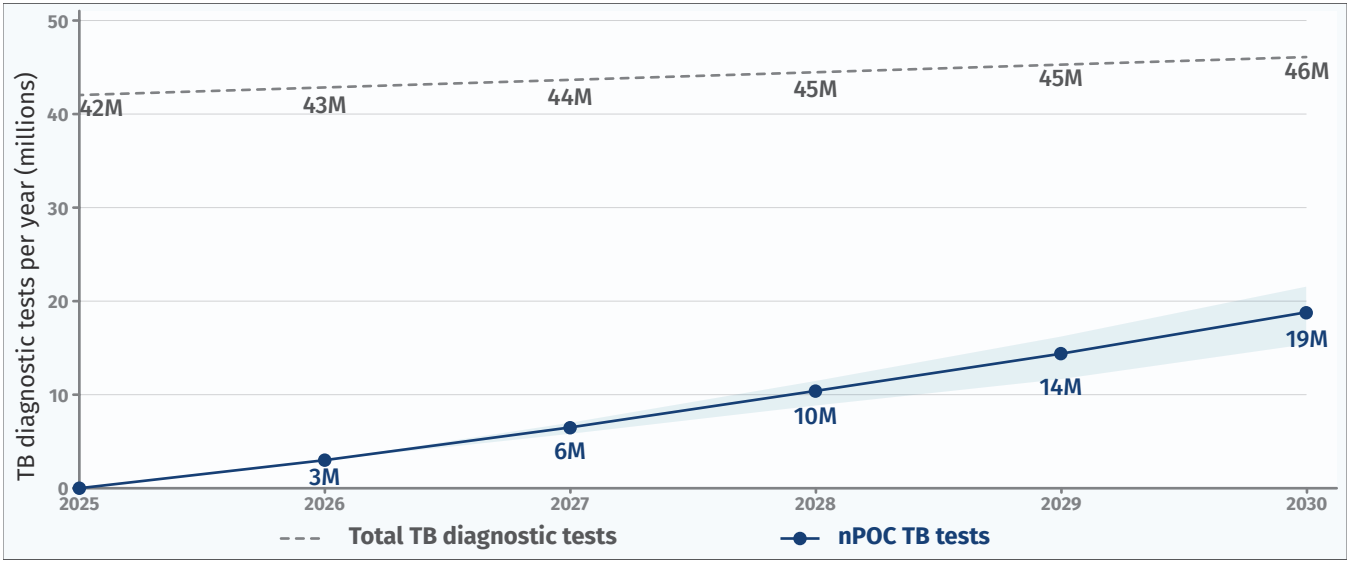


Figure 4. Base-case nPOC testing uptake against total diagnostic testing for the 10 countries, 2025–2030. The band reflects constrained and accelerated uptake assumptions, not a confidence interval. Source: CHAI analysis.

3.2 Timing and pace differ sharply

Two factors explain most country-level variation: when nPOC testing is introduced and how quickly programs scale thereafter. Based on these factors, the 10 countries fall into four groups:

- **Early start, fast scale.** Four countries where policy commitment, financing, and implementation readiness support early introduction and rapid scale-up. These countries generate most of the early volume.
- **Early start, moderate scale.** Two countries where procurement is progressing, but site readiness and implementation capacity are expected to limit the pace of rollout.
- **Later start, moderate scale.** Three countries where regulatory timelines and financing uncertainty are expected to delay introduction and constrain subsequent scale-up.
- **Later start, fast scale.** India alone, where introduction depends on regulatory pathways and the availability of a domestically manufactured product, but scale-up could proceed rapidly once these conditions are met.

The size of India's diagnostic system makes its introduction timing and subsequent scale-up the largest country-level source of uncertainty in this outlook.

Early market uptake is already visible. As of August 2026, several countries have received initial shipments under the Global Fund Early Adopter mechanism, and two countries (Indonesia and Zimbabwe) have begun nPOC testing. Growth is expected to be staggered among the countries rather than simultaneous. These groupings reflect conditions at the time of country engagement and may change as GC8 grant-making, regulatory decisions, and procurement plans become clearer.

3.3 Test mix evolution and cost implications

The 10 countries fall into two broad groups based on their current testing mix, as shown in the Figure 5. In six of the countries (Côte d'Ivoire, Indonesia, Nigeria, South Africa, Uganda, and Zimbabwe), molecular testing is the primary method for TB diagnosis, with LC-aNAAT accounting for 70 percent of total diagnostic volume.

In the remaining four countries, smear microscopy accounts for more than one-third of diagnostic testing in each country: approximately 74 percent in India, 70 percent in Cameroon, 49 percent in Viet Nam, and 35 percent in Kenya. Across these countries combined, smear accounts for approximately 72 percent of testing, reflecting India's large share of total testing volume.

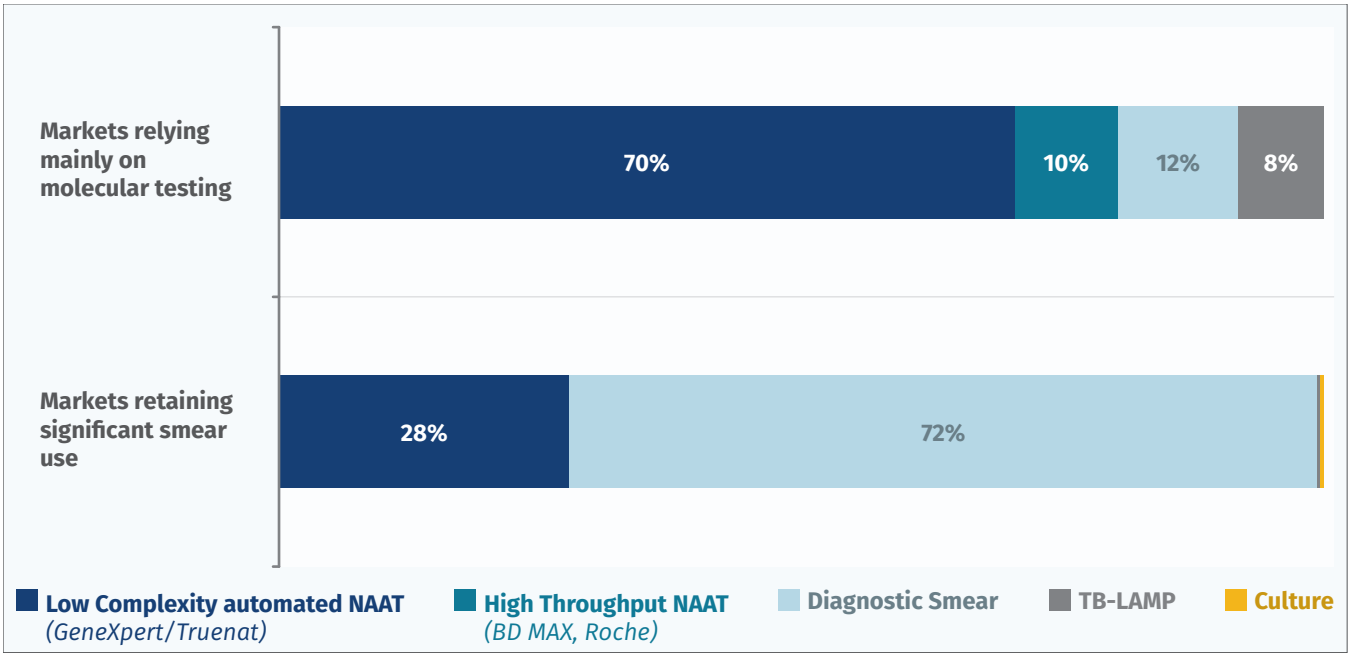


Figure 5. Current diagnostic mix across 10 countries, grouped by baseline. Smear volumes are diagnostic only; testing for treatment monitoring is excluded. Baseline years: India 2023, Indonesia 2025, all others 2024. Source: CHAI analysis of country testing-volume data.

Even where policy has moved past smear microscopy, programs still use it for initial diagnosis in certain circumstances. Some programs revert to microscopy for first-line diagnosis when molecular commodities are unavailable; in one country, stakeholders expect facilities to fall back on microscopy if nPOC testing is priced above the level domestic insurance reimburses. Diagnostic smear volumes may therefore persist even where national policy favors molecular testing.

These shares describe testing volume rather than the distribution of facilities. Even in countries relying primarily on molecular testing, many sites have no molecular testing on site.

Across the 10 countries, commodity expenditure falls even as volume rises. Under the base-case mix, average commodity cost per test drops from roughly US$4.47 in 2025 to US$3.60 in 2030, and total commodity expenditure falls by about 12 percent relative to 2025.

Test volumes grow by about 10 percent over the same period under the baseline projection, with or without nPOC tests. These figures were modeled at an nPOC test price of US$3.60. The price had fallen to around US$2.60 by August 2026, meaning that potential commodity savings would be greater at the lower price, all else being equal.

Although aggregate commodity expenditure falls, budget implications vary by country. In countries relying primarily on molecular testing, replacing LC-NAAT with nPOC testing reduces average commodity cost per test and generates the savings represented in the reinvestment scenario. In countries retaining significant smear use, moving from microscopy to nPOC testing raises commodity cost per test, and budgets may therefore need to increase in the short term. Expanding molecular testing access in these settings requires additional financing rather than relying on savings from substitution.

3.4 Reinvestment and where additional volume occurs

The base case assumes that savings are not reinvested in additional testing, and that total commodity expenditure is instead reduced. If these savings are reinvested in testing, nPOC test volumes could nearly double from about 19 million to approximately 34 million tests by 2030, within a range of 29 to 39 million. Figure 6 compares nPOC test volumes under the base case and the reinvestment scenario. Total testing rises from 42 million tests in 2025 to 46 million in 2030 under the base case. Under the reinvestment scenario, holding the latest diagnostic commodity budget constant at US$186 million could support approximately 63 million tests in 2030. This represents an additional 17 million tests a year relative to the base case.

The additional volume is not evenly distributed. nPOC test volume in countries relying primarily on molecular testing rises from around 10 million to 22 million tests, while the volume in countries retaining significant smear use rises from around 9 million to 12 million. Roughly three-quarters of the increase is concentrated in the countries with a high current share of existing molecular tests because nPOC testing primarily replaces higher-cost LC-NAAT testing in these countries, opening up funding for additional tests. Figure 7 shows 2030 nPOC test volume by the two groups under the base case and the reinvestment scenario.

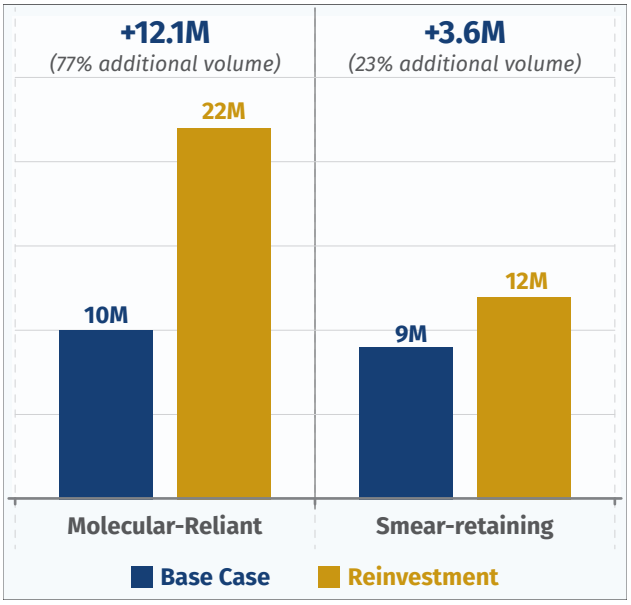


Figure 7. nPOC test volume in 2030 by diagnostic baseline, base case compared with reinvestment. Roughly three-quarters of the additional nPOC volume under the reinvestment scenario comes from countries relying primarily on molecular testing. Source: CHAI analysis.

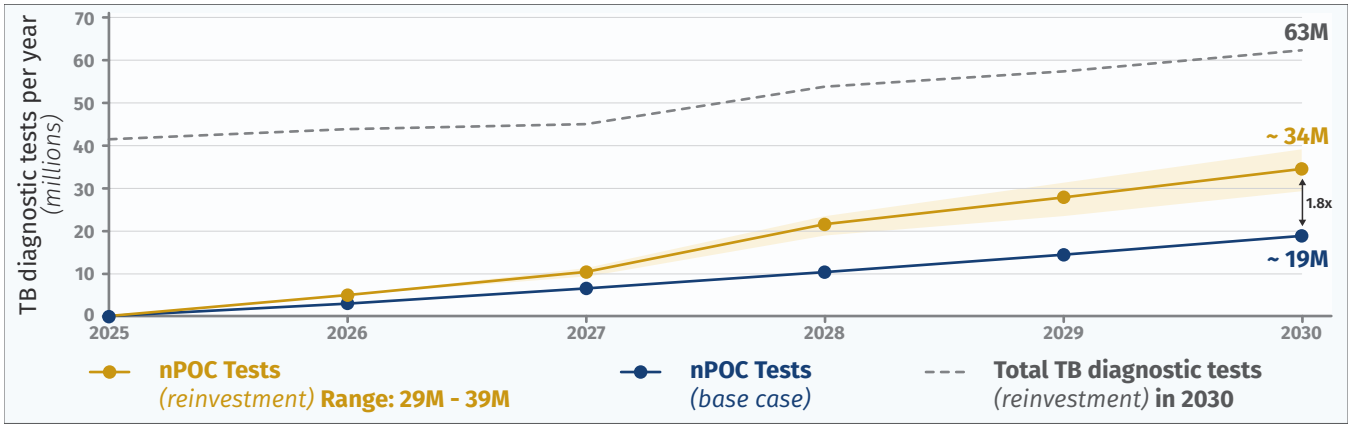


Figure 6. Projected nPOC test volume under the base case and the reinvestment scenario, shown alongside total diagnostic testing under the reinvestment scenario. No country described a mechanism for retaining and reinvesting savings in additional testing; this is a modeling assumption about what could be achieved within the same commodity budget, not a plan currently proposed by country programs. Source: CHAI analysis.

4. Implications for decision making and priority setting

4.1 For countries

Match placement to the intended outcome

Section 1 sets out how placement shapes cost and access. For countries, the practical question is which objective to prioritize: expanding access, improving diagnostic quality, reducing commodity costs, or freeing up existing capacity. Although all 10 countries identify primary health centers as a deployment target, they differ in the priority and pace they assign to decentralization. Figure 8 shows the sites that countries identify as deployment targets under their priority use cases. In one country, the national TB program ranks peripheral placement first, while the laboratory department prioritizes complementing existing laboratory hubs.

In another, a senior laboratory stakeholder cautioned against decentralization because technicians are unevenly distributed and human resource allocations are difficult to change. In some countries, reducing the cost of diagnosis ranks above expanding testing to peripheral facilities.

Several countries have developed plans specifying target facility tiers, device numbers, and start dates in 2026. Three stated 2030 device targets ranging from 220 to 3,000, although the largest depends on financing that is not yet secured. Three others provided neither device estimates nor dates, while one tentatively indicated introduction in 2028, a timeline stakeholders described as theoretical without secured funding. These remain high-level plans rather than confirmed procurement and may change as financing decisions are made.

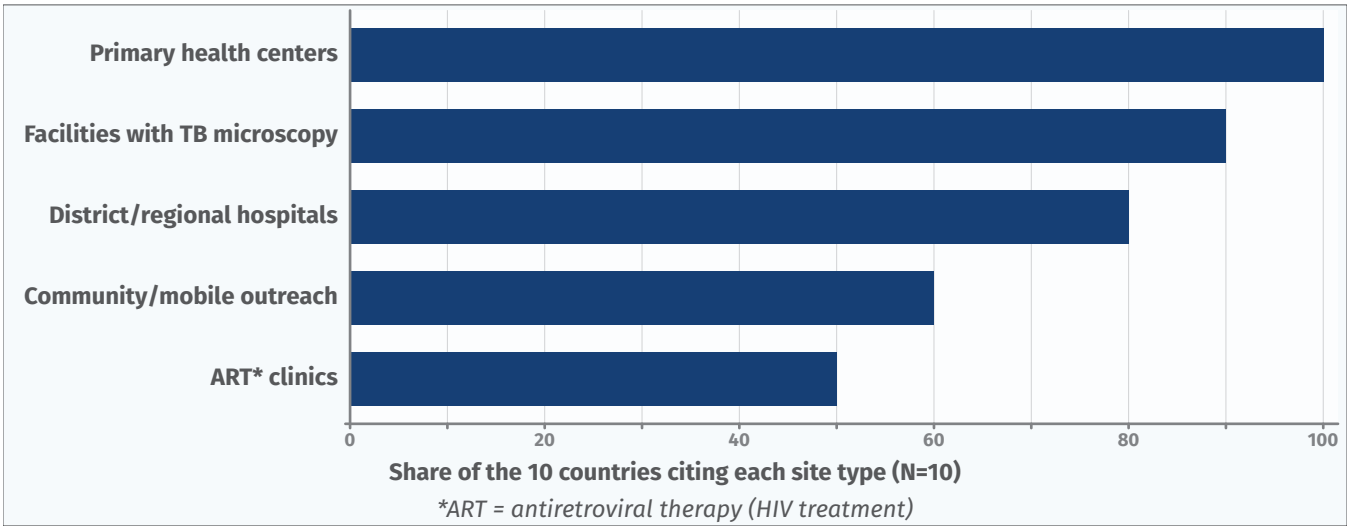


Figure 8. Sites that countries identify as deployment targets for nPOC testing under their priority use cases. The figure provides a qualitative indication of intent from the 94 interviews, not a modeled input. Source: CHAI analysis of 94 stakeholder interviews.

Experience with GeneXpert deployment shows that decentralization targets can outpace the infrastructure, workforce, and recurrent financing available to support them, resulting in devices becoming concentrated at higher-level facilities. nPOC test deployment could face similar constraints unless site readiness is addressed alongside procurement.

Currently available nPOC assays do not detect rifampicin resistance. Peripheral deployment therefore requires a pathway linking first-line testing with resistance testing. Under one possible model, nPOC testing is performed where the patient presents, treatment begins on the initial result, and specimens from patients with positive results are referred for resistance testing.

At referral-dependent facilities, this model could reduce the number of specimens transported to a testing hub because only positive specimens would require referral. This requires reliable systems for transporting specimens, returning resistance results, and adjusting treatment where necessary. This is particularly important in settings where existing systems are under strain. In at least two countries, culture and drug-susceptibility testing capacity is concentrated in a small number of national laboratories and is exposed to the same financing pressures as the broader diagnostic system.

Financing also constrains the scale of deployment. Given the commodity costs used in this analysis, South Africa's target of five million tests a year would be difficult to finance under the current platform mix. Reinvesting savings from lower-cost nPOC testing, as illustrated in Section 3.4, could help narrow this gap.

Activation determines whether decentralization results in sustained testing

Stakeholders in all 10 countries emphasized that placement must be accompanied by site activation to sustain testing once devices arrive. Figure 9 shows the four activation domains raised most consistently across the 94 interviews.

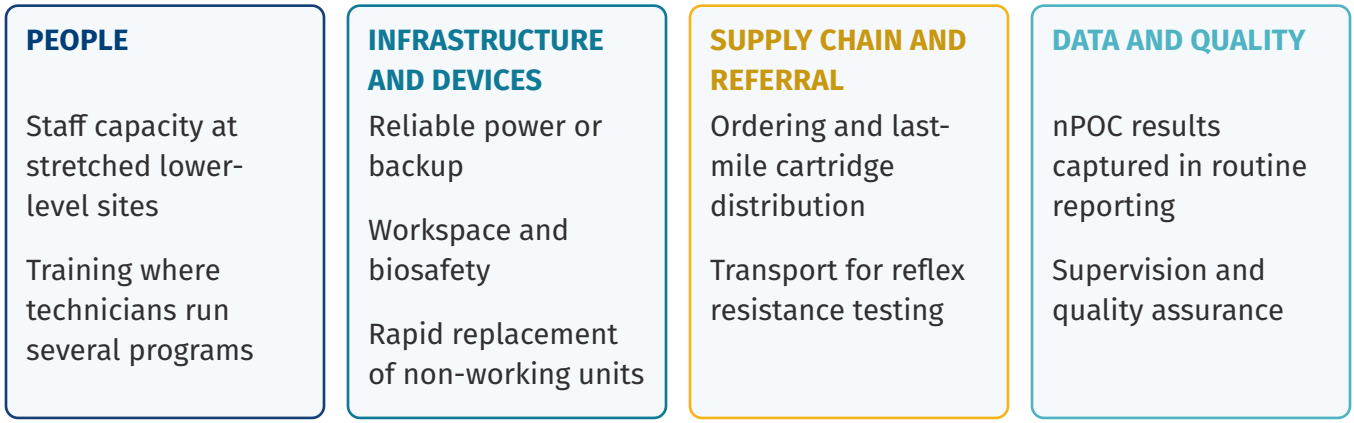


Figure 9. The four activation domains (people, infrastructure and devices, supply chain and referral, and data and quality) were raised most consistently across the 94 interviews. They were cited in countries with mature molecular networks and in countries where molecular access remains limited. What varied was mainly the severity of each constraint. Supply chain was the exception: the one country with a centralized laboratory network reported stock-outs as rare. Source: CHAI analysis of 94 stakeholder interviews.

The barriers are primarily operational and financial. Stakeholders did not identify running the test itself as a major difficulty, and in two countries they expected adoption to be smoother than the GeneXpert rollout because the devices are simpler to use. The larger challenge is how quickly peripheral facilities can be prepared to sustain testing.

Among the nine countries with a defined initial deployment sequence, five plan to begin at peripheral facilities, prioritizing low-volume, hard-to-reach, or microscopy-only sites. Two of these stated explicitly that existing GeneXpert capacity would remain in place. Three countries plan to begin where laboratory space and trained staff are already available, while one plans to introduce multiple use cases concurrently. The remaining country had not defined an initial sequence at the time of engagement.

The pace of site activation contributes to the range around projected uptake, with countries planning a more gradual rollout generally falling in the lower half of that range. Peripheral-first deployment also tends to prioritize facilities where infrastructure, staffing, and supply systems are most constrained. Activation should therefore be costed from the first phase of rollout. A minimum package would cover the following:

- **People.** Initial and refresher training as well as sufficient staff capacity where technicians already cover several programs.
- **Infrastructure and devices.** A power assessment and reliable backup supply, appropriate workspace and biosafety, and a defined maintenance and repair pathway.
- **Supply chain and referral.** Ordering and last-mile cartridge distribution, together with transport of positive samples for resistance testing.
- **Data and quality.** Routine reporting of nPOC testing results, supervision, and quality assurance.

Procurement plans should include explicit budget lines for this activation package from the outset, regardless of the placement model.

4.2 For funders

Financing decisions determine whether savings from substitution reduce diagnostic expenditure or support additional testing. Several countries described how a lower unit price would allow them to meet existing procurement or testing targets within a fixed donor budget, and one country set a price threshold that would qualify nPOC tests for domestic insurance reimbursement. Retaining and redirecting savings to additional testing is a different ask, one no country has built a mechanism for yet.

Such a mechanism would need to retain savings within the diagnostic budget and give the responsible institution both the authority and the incentive to use them for additional testing. Where budgets are not capped, the binding constraint may be the evidence needed to justify additional expenditure.

Funders will need to tailor their support to the constraint limiting uptake in each country. In four countries, lowering the unit cost of testing could bring program targets within existing budgets. In five countries, site readiness is the principal constraint, meaning that financing devices and commodities alone will not accelerate uptake unless infrastructure and activation needs are also addressed. In one country, the priority is generating evidence that nPOC testing reduces the cost per case diagnosed. Funding strategies should therefore combine commodity financing with targeted investment in site activation and evidence generation, depending on the country context.

Allocations under GC8 will materially influence whether nPOC testing uptake in constrained countries accelerates or stalls beyond 2027.

Domestic financing matters too. In some countries, reimbursement caps remain below the cost of molecular testing, and adding a new test to insurance coverage is a slow process. Devices can be in place but remain underused if recurring consumable costs have no dedicated funding line.

4.3 For manufacturers

Across scenarios and uptake assumptions, projected nPOC test volume in 2030 spans approximately 15 million to 39 million tests. Manufacturers should therefore phase capacity investments against staggered country introductions and test their plans across the projected range rather than treating its upper bound as committed demand. Regulatory and manufacturing developments in India could materially change the timing and scale of demand. Additional market entrants may increase price competition, but dividing demand among more suppliers may also affect the volumes and prices that each manufacturer can sustain.

Procurement barriers were raised in most countries, although their form varied. High distributor markups were considered a critical barrier in one market and led another to procure through pooled mechanisms. Elsewhere, barriers included product-registration requirements, customs delays, and decentralized procurement processes that had not yet resulted in purchases. Stakeholders raised concerns about maintaining a reliable supply of tests across dispersed sites, which may limit utilization even where devices are installed.

Manufacturers must consider more than the ex-works price of the test. Distribution, service, and maintenance should be treated as part of the commercial offer rather than as downstream arrangements left for countries to resolve. Commercial terms should make the total delivered cost transparent across procurement routes; define responsibilities for registration and importation, training, last-mile supply, maintenance, and repair or replacement; and provide a service model proportionate to the cost of the instrument and expected utilization at peripheral sites. Distribution arrangements need to limit excessive markups while supporting viable local service. Commercial models developed for higher-cost centralized platforms may not be appropriate for large networks of low-volume peripheral sites.

4.4 For interpreting access and impact

Test volume alone cannot demonstrate whether nPOC testing has improved access. Deployment plans and routine monitoring should distinguish whether nPOC testing is extending molecular testing to people or facilities not previously reached, shortening the diagnostic pathway, reducing commodity costs, or relieving existing capacity constraints. Effects on cases detected, treatment initiation, and health outcomes are not modeled in this outlook and will require separate evaluation.

5. Key developments that would shift the outlook

This outlook reflects conditions at a specific point in time. Six developments could change the timing, scale, or composition of projected demand and indicate when the outlook should be updated.

- **India.** If a domestically manufactured product enters the market, its arrival could materially increase aggregate demand across the 10 countries; without such a product, this outlook assumes that uptake in India remains limited.
- **GC8 allocations and grant-making.** Once GC8 allocations are confirmed and the resulting grants are developed, country budgets and procurement plans will provide a clearer indication of whether, when, and at what scale countries intend to procure nPOC tests. They will also show whether site activation is funded and whether savings can be retained and reinvested in additional testing.
- **Early implementation results.** Early evidence on placement, site activation, supply continuity, device uptime, utilization, and completion of resistance-testing referral pathways will show whether the uptake assumptions are realistic. Performance and feasibility evidence will also inform policy and domestic financing decisions.
- **Competitive entry.** The timing, regulatory approval, and pricing of additional products could affect country choices and the pace of adoption.
- **The private sector.** Private-sector demand could be substantial but is not well quantified. Realizing this potential would require clearer evidence on market size and purchasing channels, together with appropriate engagement strategies.
- **Sample pooling at existing molecular testing sites.** Sample pooling could lower commodity costs and increase effective NAAT capacity at sites already providing molecular testing, potentially reducing the rationale for replacing existing NAAT platforms with nPOC testing at those locations. Wider adoption could therefore shift nPOC test deployment toward peripheral facilities without on-site molecular testing. Sample pooling is not reflected in this outlook.

The outlook should be updated as these developments clarify or change country plans and the assumptions underlying projected uptake. nPOC testing is only part of the diagnostic landscape. The diagnostic mix is shifting among smear microscopy, LC-NAAT, and high-throughput platforms. A broader outlook across diagnostic technologies would provide a stronger basis for future market planning than an assessment of nPOC testing alone.

Annex: Methodology and limitations

A.1 Countries included

The exercise covered 10 high-burden countries across Africa and Asia. Together, they represent approximately 47 percent of estimated global TB burden and 66 percent of global molecular testing volume, based on WHO Global Tuberculosis Report 2025 estimates and country testing-volume data. Countries were classified according to their current national diagnostic test mix (Table A.1).

Those in which smear microscopy accounted for at least one-third of the total diagnostic testing were classified as retaining significant smear use; the remaining countries, where LC-NAAT accounted for most diagnostic testing, were classified as relying primarily on molecular testing. These classifications were used to set assumptions about which existing tests nPOC tests would replace.

Country	Region	Diagnostic baseline
Cameroon	Africa	Retains significant smear use
Côte d'Ivoire	Africa	Relies primarily on molecular testing
India	Asia	Retains significant smear use
Indonesia	Asia	Relies primarily on molecular testing
Kenya	Africa	Retains significant smear use
Nigeria	Africa	Relies primarily on molecular testing
South Africa	Africa	Relies primarily on molecular testing
Uganda	Africa	Relies primarily on molecular testing
Viet Nam	Asia	Retains significant smear use
Zimbabwe	Africa	Relies primarily on molecular testing

Table A.1. Countries included, with the diagnostic baseline used to set substitution assumptions. Baselines describe each country's dominant national testing mix, not uniform access within a country.

A.2 Data and stakeholder engagement

Model inputs reflect data available as of March 2026. Quantitative inputs comprised epidemiology and program baselines, historical test volumes and mix, national testing targets, and cost and commodity data.

Ninety-four interviews were conducted across the 10 countries, covering national TB programs, laboratory networks, implementing partners, procurement and financing institutions, and technical experts.

Interviews provided information on diagnostic priorities and barriers, intended use cases, readiness, and financing and informed assumptions about deployment and substitution. Assumptions were reviewed through multiple rounds of country engagement and technical review.

Baseline diagnostic figures reflect the most recent year of national data available: India 2023, Indonesia 2025, all other countries 2024. Sputum smear microscopy volumes are diagnostic only; smear performed for treatment monitoring is excluded.

A.3 Model steps

Step 1. Total country testing volumes were projected through 2030 using historical testing patterns, epidemiological trends, program targets, and budget considerations.

Step 2. Uptake trajectories were built in two stages. Introduction timing was based on confirmed procurement where available and otherwise on stakeholder input and expected regulatory processes. Scale-up pace was set by scoring each country on healthcare system readiness, financing, national program support, and inclusion in a Global Fund Strategic Initiative. The two dimensions together produce lower-bound, base, and upper-bound uptake curves.

Step 3. Projected nPOC test volumes were allocated across existing testing modalities to estimate diagnostic mix and commodity expenditure. Substitution assumptions differ by baseline. Countries were classified as relying primarily on molecular testing where LC-NAAT accounts for the majority of current diagnostic volume. Across this group, LC-NAAT represents approximately 70 percent of total diagnostic volume and smear microscopy 12 percent. Countries retaining significant smear use were those where smear microscopy accounts for at least one-third of total testing; across this group, smear microscopy represents a volume-weighted share of approximately 72 percent. In the first group, nPOC testing is modeled as displacing LC-NAAT. In the second, it displaces a mix of smear microscopy and LC-NAAT.

A.4 Scenarios

Base case. Deployment under current assumptions on adoption, country-level healthcare system readiness, and financing. Total testing follows the baseline projection of moderate growth, while savings from substitution reduce commodity expenditure rather than finance additional tests.

Reinvestment scenario. A budget-neutral sensitivity analysis in which savings from substituting more expensive molecular testing fund additional testing volume, holding total commodity expenditure constant. The scenarios are not competing predictions. They show how projected volumes change under different financing decisions.

A.5 Limitations

1. Outputs depend on assumptions regarding adoption, deployment, diagnostic substitution, and financing. The treatment of substitution has the largest effect on the results.

2. The analysis reflects information available at the time interviews and country reviews were conducted. Regulatory, procurement, financing, and market conditions may have changed since.

3. The reinvestment scenario is a sensitivity analysis rather than a projection. It assumes savings are fully retained and reinvested in additional testing, which is a deliberate policy choice and not an automatic outcome. No country described such a mechanism.

4. Outputs are expressed as testing volumes. A test performed is not the same as a patient diagnosed or started on treatment, and one patient may account for more than one test. Estimates measure testing activity and access to molecular diagnosis, not patients diagnosed or treated.

5. The model incorporates healthcare system readiness at the country level when setting the pace of scale-up, but it does not assess readiness or activation requirements at individual deployment sites. Activation requirements in Section 4.1 are drawn from the stakeholder interviews and are qualitative evidence, not model outputs.

6. Deployment plans, device counts, and uptake classifications reflect country positions at the time of engagement. Several are expected to change once GC8 allocations are confirmed and procurement plans are finalized.

7. Results are presented in aggregate across the 10 countries and by diagnostic baseline. They should not be interpreted as country-level projections.

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