Integrated Screening in Antenatal Care

March 2026

This memo marks the second edition of CHAI's **Triple Elimination Series**, examining market-shaping strategies to strengthen programs to prevent vertical transmission of HIV, syphilis, and hepatitis B (HBV), collectively known as "triple elimination". It evaluates current approaches to integrated screening in antenatal care (ANC), maps the market landscape for emerging triple combination tests, estimates the potential integrated screening market size and timelines for new product introduction and scale, particularly in a rapidly changing global health financing landscape. The data and insights presented here draw on CHAI's implementation experience across sixteen countries and reflect progress as of September 2025.

Understanding LMIC market dynamics, country policies, and product preferences will be critical to ensuring rapid rollout of future integrated testing solutions and sustaining progress toward triple elimination efforts even amid recent funding decline.

Background

Vertical transmission (or mother-to-child transmission, MTCT) of HIV, syphilis, and HBV causes significant yet preventable infant morbidity, mortality, and stillbirths. Recognizing this, WHO established global targets for the elimination of all three infections, collectively referred to as Triple Elimination (TE). Achieving TE requires that pregnant women are consistently identified and linked to care for themselves and their newborn across all three diseases — making integrated screening during antenatal care (ANC) a critical entry point for elimination.

The burden of all three infections remains substantial. Globally, an estimated 120,000 infants are born with HIV and 700,000 congenital syphilis cases occur annually.[1] The burden of vertical HBV transmission is likely even greater than previously understood: a 2025 systematic review in The Lancet Global Health estimated 172,000 vertical HBV transmission events in the WHO African region alone in 2022, with the authors noting that the African region accounts for more new HBV infections annually than the rest of the world combined.[2]

While HIV testing and treatment coverage among pregnant women has steadily improved since 2015, screening for syphilis and HBV remains inconsistent or unavailable in many settings, limiting timely access to care and putting progress toward TE goals at risk. Integrated screening during ANC provides a practical solution by enabling pregnant women to be screened for all three infections at once.

Currently, countries rely on integrated workflows and multiple screening rapid diagnostic tests (RDTs) to deliver HIV, syphilis, and HBV screening through two main approaches:

1) **Three single HIV, syphilis, and hepatitis B surface antigen** (HBsAg) rapid diagnostic tests (RDTs)
2) A **dual HIV/syphilis RDT** alongside a **HBsAg RDT**

A third approach countries may consider in the coming years is a **triple combination test** - a single device that screens for all three infections simultaneously. Building on lessons learned from the introduction and scale-up of the dual HIV/syphilis test in ANC, a triple combination test has the potential to:

Expand access to simultaneous screening for the three infections	Accelerate progress toward vertical transmission elimination goals	Generate both system and service efficiencies due to integrated format

Integrated screening for HIV, syphilis, and HBV among pregnant women stands at a pivotal moment and is shaped by two key uncertainties: the level of available financing and the eventual price of triple tests.

On one hand, the diagnostic landscape is rapidly evolving. New triple combination tests are entering the market, offering opportunities to simplify testing, reduce missed infections, and improve maternal and newborn outcomes.

On the other hand, health systems are grappling with shrinking donor budgets and competing priorities, alongside already limited domestic financing for maternal health and infectious disease programs.

Sustaining progress toward TE screening goals will therefore depend on how effectively countries can navigate this shifting environment by aligning product selection, procurement strategies, and service delivery models to their specific needs and resources.

Key definitions throughout the memo

Triple Elimination (TE) refers to the elimination of vertical (also known as mother-to-child) transmission of HIV, syphilis, and hepatitis B

Integrated screening and care is a public health strategy to coordinate screening and care between multiple disease areas. In this memo, it refers specifically to HIV, syphilis, and hepatitis B in antenatal care settings.

Triple combination test refers to a rapid diagnostic test that screens for HIV, syphilis, and hepatitis B simultaneously, enabling comprehensive antenatal care screening with a single testing device or package.

Access CHAI's Dual HIV/Syphilis RDT market memo here:
https://www.clintonhealthaccess.org/report/dual-hiv-syphilis-rapid-tests-market-brief-sep-2025/

Market Assessment Process

To understand the evolving market and policy environment for integrated screening in ANC, CHAI conducted qualitative and quantitative analyses with **16 country programs** across Africa and Asia. These programs were selected for their progress in TE efforts.

The assessment draws on surveys completed by suppliers and CHAI country teams, informed by MoH program data and other nationally available sources. The surveys captured information on emerging triple combination test formats, national policies, procurement and testing trends, financing mechanisms, and anticipated screening demand. Country teams also provided insights on potential product introduction timelines and operational considerations for new diagnostic tools.

These inputs were combined with analysis of product pipeline developments, regulatory and WHO prequalification updates, and available pricing information to assess the evolving market landscape for integrated screening.

Findings are organized into three analytical components:

Focal Geographies

This analysis consists of data from: **Cambodia, Cameroon, Ethiopia, Ghana, India, Indonesia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia, Zimbabwe**

1 Current status
Global Screening Trends in ANC

Examines the **present landscape of integrated screening** across participating countries including national policies, coverage trends, test types in use (e.g., HIV/syphilis dual tests and single HBsAg tests), key suppliers, and financing mechanisms. The analysis highlights country progress towards TE screening goals utilizing various screening tools and integrated approaches.

2 Emerging products
And country preferences

Reviews the **emerging market for triple combination tests** using product pipeline data, WHO PQ and regulatory updates. It also draws on feedback from country teams regarding preferred product characteristics and potential use cases. This includes considerations of operational fit, price sensitivity, and readiness for adoption within existing ANC service delivery models.

3 Estimated uptake and impact

Models **anticipated introduction timelines and demand projections** for integrated tests under different financing, and pricing scenarios. Using country-level inputs, CHAI estimates potential annual test volumes and explores the expected public health and programmatic impact of scaling triple combination test use in ANC.

NOTE: This assessment does not represent all countries making progress toward TE. Responses reflect CHAI's assessment based on country-level data provided by CHAI country teams. Not all countries responded to every query; this is noted where applicable.

1 Current status

This section analyzes country progress toward TE, focusing on how policies, coverage, and test use have evolved across programs

A Policies and priorities impacting HIV, syphilis, and hepatitis B screening

TE specific

16/16 countries

- Have policies to eliminate vertical transmission of HIV, syphilis, and HBV
- Require pregnant women to be screened at least once for all three diseases

Other HIV, syphilis, HBV screening initiatives

13/16 of countries

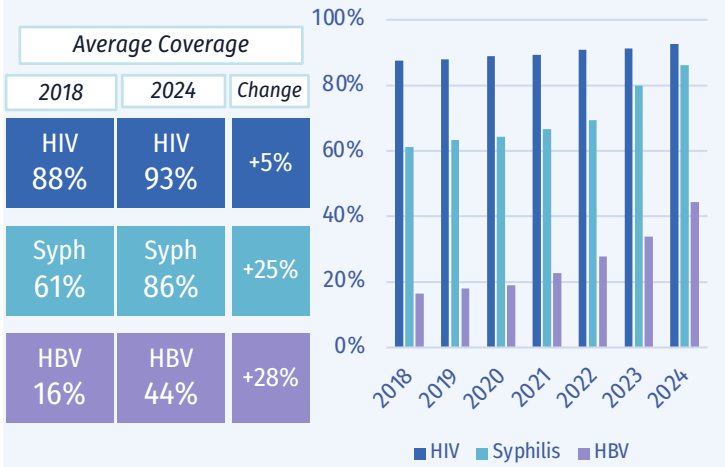
- Prioritize HIV, syphilis, and HBV screening for 1 or more additional key populations (men who have sex with men, trans & gender diverse people, sex workers, people who use and/or inject drugs, people in prison)

16/16 of countries

- Require screening of the three diseases for all blood donations

All 16 countries provided a response

B Screening coverage rates at ANC



HIV & syphilis coverage data was available from 15 countries; only 8 countries provided HBV coverage

C Test Types Used

14/16 countries Have a policy to use dual HIV/syphilis RDTs at ANC, **2/16** use single tests only

+56% increase in use of dual RDT Adoption of dual HIV/syphilis tests for ANC screening **rose from 20% to 76% between 2018 and 2024**

All 16 countries provided a response

D Primary RDT suppliers

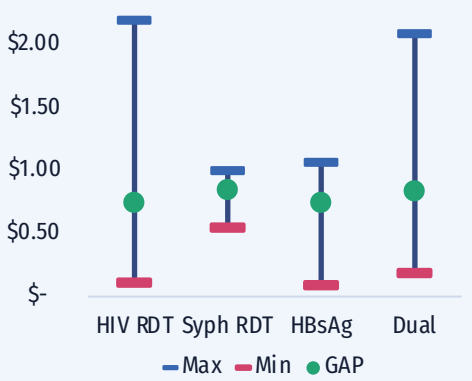
Supplier	# Countries supplied	Supplier	# Countries supplied
Abbott	13	MedSource	1
Abon	1	Meril Life	1
Bhat Biotech	1	OraQuick	1
Chembio	3	Premier	3
Diagnostar	1	SD Biosensor	4
INSTI	1	Trepo	1
Intec	2	Trinity	3
KHB	2	Viro Check	1

**Suppliers who offer tests across disease areas*

All 16 countries provided a response

E RDT Prices (US$)

GAP is a Global Access Price negotiated among suppliers, donors, and countries to support affordable, multi-country access.



All 16 countries provided a response

F Financing mechanisms

Historical procurement

7/13* of countries Procured at least 1 ANC screening commodity through **US Government** financing

12/13 of countries Procured at least 1 ANC screening commodities through **Global Fund** financing

8/13 of countries Procured at least 1 ANC screening commodities through **Domestic** financing

Only 13 countries provided a response

**US government financing primarily supported historical HIV RDT procurements*

Future procurement

14/15 of countries Will require Global Fund resources to support commodity procurement and programmatic activities

12/15 of countries Feel that TE screening approaches are unlikely to be deprioritized in future Global Fund applications

Only 15 countries provided a response

Takeaways

Policy & Coverage

Across the 16 countries, **policies supporting TE** are now in place, and countries are making steady progress toward achieving integrated screening targets using available diagnostic products with both **syphilis and HBV coverage improving by >25% in the last 6 years**. Most countries have adopted **integrated ANC testing workflows**, typically combining an HIV/syphilis dual test with a single HBsAg test. However, a few programs continue to rely on **three separate single tests** to achieve full screening coverage. While combination tests can streamline delivery and accelerate progress toward TE targets, countries remain focused on maximizing coverage with the resources already available.

Supply landscape

A **diverse mix of suppliers** currently supports ANC screening across countries, reflecting both healthy market competition and variation in available product quality, format, and price. Procurement decisions are often influenced by donor frameworks, national registration status, and supply reliability rather than price alone.

The **total cost of ANC screening commodities** varies considerably by country and test mix, typically ranging from **US$1.59 to US$2.35 per client** for complete HIV, syphilis, and hepatitis B screening when considering average GAP. Outside the GAP, costs can exceed US$3 per client due to differences in procurement mechanisms, order volumes, and distribution mark-ups.

Financing

Financing for ANC screening commodities remains largely dependent on external support. The **Global Fund** and **U.S. Government (USG)** are the primary funders in most countries, providing the bulk of HIV and syphilis testing commodities, with some overlap for HBV through maternal and newborn health programs. A smaller but growing share of countries are allocating **domestic resources,** however, these contributions remain limited and uneven. As donor funding plateaus and transitions accelerate, identifying sustainable domestic financing, supported by appropriate procurement, pricing, and market-shaping strategies will be critical to maintaining screening coverage and advancing TE goals.

Country Highlights

TE screening coverage is possible with existing commodities

While using single tests only, **Malawi** has achieved 80%+ coverage across HIV, syphilis, and HBV

Combination tests can be scaled rapidly:

In just two years, **Ethiopia** shifted 81% of first ANC HIV tests to dual HIV/syphilis tests.

2 Emerging products

Triple combination tests, now entering the market, are a key opportunity to integrate HIV, syphilis, and HBV screening, increasing coverage, streamlining workflows, and improving linkages to care. This section provides an overview of several anticipated products, country product preferences, service delivery considerations, evidence generation needs, and future use cases.

Timeline

2025 | 2026 | 2027 | 2028

Triple combination test and WHO PQ timelines

- **July 2025:** Abbott ANC Panel receives WHO PQ
- **2027:** Intec Advance Quality Combo test expected to receive WHO PQ
- **2028:** SD Biosensor Standard Q Triple Test and bioLytical Truplex expected to receive WHO PQ

Product details

Additional suppliers are anticipated to enter the market over the next 3-5 years

The table below provides an overview of the key features differentiating the four triple tests that are either already available or expected to be among the first to market. Performance data reflect manufacturer-provided specifications unless WHO Prequalification Public Reports are available, in which case those are referenced. Sample size details are available in the referenced WHO PQ reports.

Pipeline of triple combination tests

NAME	ABBOTT ANC PANEL	INTEC ADVANCED QUALITY COMBO TEST	SD BIOSENSOR STANDARD Q TRIPLE TEST	bioLytical TRUPLEX
Total lanes	3	2	1	1
Sample volume	~250 µL capillary blood	~90 µL capillary blood	~20 µL capillary blood	~50 µL capillary blood
Buffer	1 buffer; 1 drop strip	1 buffer; 1 drop strip	1 buffer; 1 drop strip	1 buffer; 2 drops
Time to result	20-25 minutes	15-20 minutes	20-25 minutes	15 minutes
Sensitivity %/Specificity % (manufacturer provided)	Determine HIV Early Detect • p24 Antigen – 40-60%/100%[3] • HIV1/2Antibody – 100%/98%[4] Determine Syphilis TP – 100%/98.7%[5] Determine HBsAg2 – 100%/100%[6]	HIV1/2 – 100%/99.6% (n=1,329; 86 positive) Syphilis TP – 100%/100% (n=1,329; 86 positive) HBsAg- 99.3%/100% (n=300 samples; 150 positives)	HIV1/2 – 100%/100% (n=250 samples; 50 positives) Syphilis TP- 100%/100%(n=250 samples; 50 positives) HBsAg – 100%/100%(n=250 samples; 50 positives)	HIV1/2 – 100%/100% (n=381 samples; 51 positives) Syphilis TP- 100%/100%(n=381 samples; 35 positives) HBsAg – 100%/100%(n=381 samples; 3 positives)*
WHO PQ	Obtained July 10th 2025	Anticipated by Q4 2027	Anticipated by Q2 2028	Anticipated by Q4 2028
Price	Yet to be announced	Yet to be announced	Yet to be announced	Yet to be announced
Other considerations	Includes 4th generation HIV format; may require additional algorithm review	Lane 1 - Dual HIV/Syphilis Lane 2 – HBsAg		*Study enrollment is ongoing to be complete by March 2026

A Product preferences

16/16 of countries

Would consider the use of a **triple combination test** to achieve TE screening goals

- **7/16 countries** will consider a 3-lane combination test
- **10/16 countries** will consider a 2-lane combination test
- **13/16 countries** will consider a 1-lane combination test

More countries indicated openness to simpler test formats, with nearly twice as many countries open to a 1-lane test as to a 3-lane configuration. While interest in triple combination tests is high, **preferred test formats and configurations differ across countries**, reflecting variation in operational considerations and levels of ANC service integration. Countries emphasized the need for **early field evidence** to inform final product selection and adoption decisions, highlighting four key considerations:

- **Acceptability:** *How easy is the test for health care workers to use, read, and interpret?*
- **Performance:** *Do combined test lanes affect diagnostic accuracy?*
- **Efficiency:** *What will simplify service delivery and health systems?*
- **Affordability:** *What can domestic and donor budgets accommodate?*

B Combination test use cases

While facility-based ANC screening is expected to remain the primary entry point for triple combination tests, 13 countries noted that the market could expand to other priority populations as programs mature.

Seven countries would consider a quadruple combination test (HIV, syphilis, HBV, and hepatitis C) for ANC and beyond, extending to priority populations outside of pregnant women. With quadruple combination tests already available in research-use-only format, the product category is poised to evolve further — indicating broader potential use cases for integrated diagnostics.

Takeaways

Product readiness

Triple combination tests are nearing market entry, with the first WHO-prequalified product already available, creating an opportunity for countries to plan for triple combination test scale-up.

Country preferences

Interest in triple combination tests is high across all countries, with primary use anticipated in facility-based ANC screening and growing interest in expansion to other priority populations. Formats with fewer lanes and lower sample volumes are generally preferred.

Evidence for adoption

Early evidence on acceptability, performance, efficiency, and affordability will be essential to confirm optimal use cases, guide product selection, inform policy updates, and support procurement decisions. Without this, in a crowded marketplace, introduction could be slow.

3 Estimated uptake and impact

Inputs from 16 countries were used to map expected timelines from product registration to nationwide ANC integration, and to estimate annual test volumes under different pricing and financing scenarios.

A Estimated timeline from product approval to national scale-up

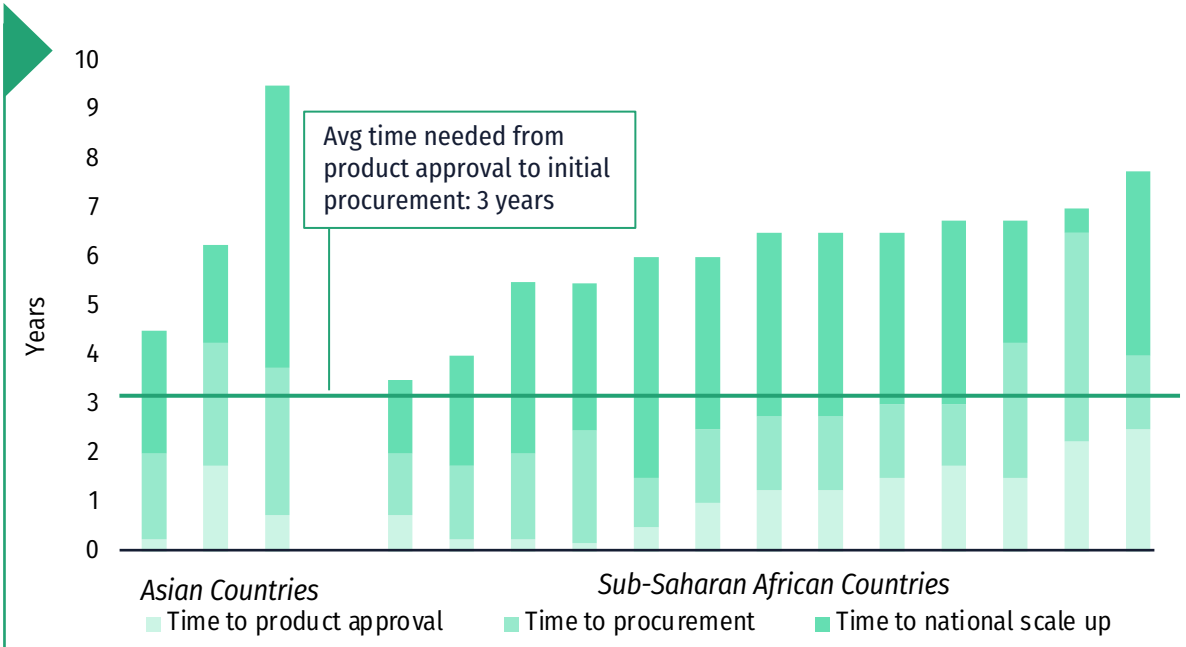
This section summarizes country-reported anticipated timelines for introducing triple combination tests. Bar segments represent each country's estimated timeline for each stage based on survey responses.

11/16 of countries would be able to approve a new product and initiate procurement in **3 years' time** assuming current funding levels.

Countries require an estimated 3.5–9.5 years to progress from in-country product approval to national scale-up of triple combination tests.

The number and complexity of required activities vary by country, driving differences in how long approval, procurement, and scale-up processes take.

Targeted, catalytic actions from donors and suppliers—such as funding for validation studies and technical assistance, pricing interventions, and scale up financing—could accelerate these timelines and drive early access to triple tests.



Time to in-country product approval

Regulatory approval, MOH approval, in-country validation studies

0.25 to 2.25 years

Time to procurement

Algorithm revision, quantification, budget approval, site assessment, distributor and supply chain management plan

1 to 4.25 years

Time to national scale-up

Training and mentorship, M&E, distribution, quality assurance, post-market surveillance, demand generation

1.5 to 5.75 years

B Illustrative market dynamics and potential uptake and impact on integrated ANC screening

Country inputs provide visibility into anticipated timelines for triple combination test introduction and overall appetite for adoption. However, the future direction of the integrated screening market will depend largely on two key uncertainties: the level of available financing and the eventual price of triple tests. The scenarios that follow are not predictions, but illustrations of how different dynamics of funding and pricing could shape screening coverage, market size, and progress toward TE. Together, they highlight where funding reductions and pricing constraints may place TE gains at risk, and where affordable products and sustained financing could help mitigate those risks.

This analysis aimed to answer three key questions:

1. **What would it take to reach TE screening goals?**

   What are the **total test procurement volumes** and **budgets** required to achieve TE screening goals?

   Assumes appropriate funding to meet TE screening targets; countries scale screening coverage for all diseases in a linear fashion from 2025 to meet TE screening goals by 2030, and maintain through 2035.

2. **How will donor funding reductions affect progress?**

   How will donor cuts and funding uncertainty change **total test procurement volumes** and resulting **TE screening coverage**?

   Countries' donor-supported budgets experience a 15% cut in 2026 followed by a 50% donor cut in 2027. Budgets maintain 2027 levels until 2035; domestic contributions remain static year to year.

3. **As funding declines, what is required to recover?**

   Under donor cut scenarios, what **additional resources** are required to restore coverage and reach TE screening goals by 2030?

   Countries experience the same 2026 and 2027 donor cut, and rebound with donor or domestic funds to reach 2024 screening coverage levels by 2030, and achievement of TE screening goals by 2035.

Across all three questions, outcomes are assessed under different **product mix scenarios** and **triple combination test price points**

Methodology

Model inputs	Scenarios	Outputs
ANC population estimates	**Financing parameter** 1. **Funding Available:** Countries scale screening coverage to reach TE targets by 2030 and maintain through 2035 2. **Funding Cuts:** 15% cut in 2026, 50% cut in 2027; budget remain flat afterwards 3. **Funding Cuts With Rebound:** Funding declines initially in 2026 and 2027, but recovers to restore 2024 coverage levels by 2030 and TE goals by 2035	Test volumes
Country screening data		Resource needs
Procurement and pricing	**Product mix** 1. **Existing Screening Tools:** Continued use of single and dual tests 2. **Triple Combination Test Introduction:** Triple combination tests introduced alongside single and dual tests. Adoption based on country timelines	Screening coverage
Adoption timelines	**Triple combination test price range**	Progress toward TE

Key assumptions

The model uses structured assumptions on TE coverage targets, donor funding changes, and product transition patterns to estimate volumes and resource needs

- **TE screening goals** are 95% coverage for HIV and syphilis, and 90% for HBV.
- **HBsAg absorbs donor cuts.** Under funding reductions, single HBsAg testing is deprioritized over dual and single tests; HBV coverage only rebounds with introduction of the triple combination test.
- **Triple test uptake follows dual test experience.** Triple tests are introduced at 20% of HIV testing volume, scaling to 70% in year two and full replacement in year three, assuming adequate budget and guided by country input.
- **Countries continue transitioning from single to dual tests.** Single syphilis and HBsAg tests phase down to a minimum proportion; single HIV tests phase out entirely.
- **Retesting is excluded.** To produce a conservative market estimate, HIV, syphilis, and HBV retesting is not modeled.
- **The triple test price range (~US$1.00–$2.50)** reflects plausible market outcomes, from an optimistic scenario in which market shaping drive prices toward parity with existing dual products, to a premium scenario reflecting early-stage market dynamics and limited supplier competition. The range is intended to illustrate price sensitivity, not predict a specific market price.
- Additional model limitations are outlined in the Annex.

Key inputs:

This model draws on several key inputs provided by the 16 participating countries

Pregnant population estimates and first ANC attendance

607M *Pregnant women between 2025-2035*

92% *Average proportion of pregnant women attending 1st ANC visits*

Estimate of donor dependency, reflecting the proportion of screening commodities financed by external partners and the exposure to potential funding.

71% *Average share of HIV/AIDS expenditure financed by donors*

HIV, syphilis, and HBV screening coverage rates, including the **test mix** between single and dual tests.

Baseline (2024) average testing coverage

92%	86%	44%
HIV	*Syphilis*	*HBV*

Baseline (2024) test type mix

51%	49%
Single-tests	*Dual-tests*

Single and dual test pricing estimates pulled from Global Access Pricing agreements.

$0.75	$0.85	$0.84	$0.75	*Price per test (US$)*
HIV	*Syphilis*	*Dual*	*HBV*	

Introduction and uptake timelines for dual and triple tests, based on country-reported anticipated pathways from product approval through national scale-up

Outputs

1 What would it take to reach TE screening goals?

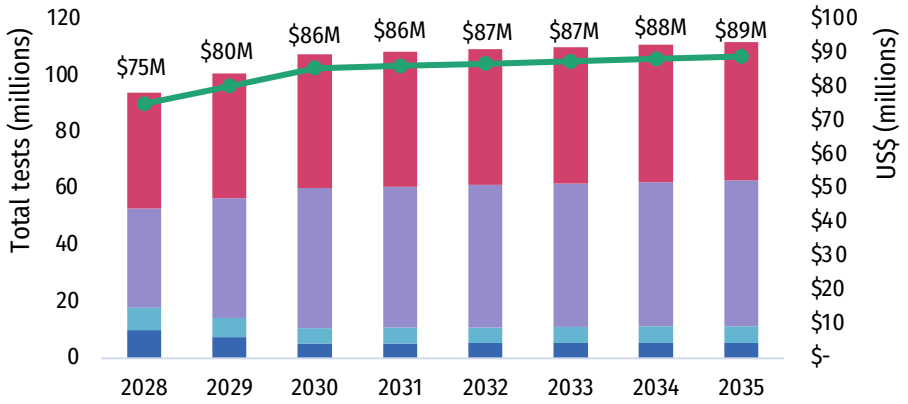
Total volumes & resource needs

Inputs from 16 countries indicate **triple test uptake to begin in 2028**. Estimated integrated screening volumes through 2027 do not vary by product mix scenarios. This is applicable in each set of early insights presented here.

Existing Screening Tools

99M Average annual single and dual test to be procured

US$78M Average annual resources for single and dual tests

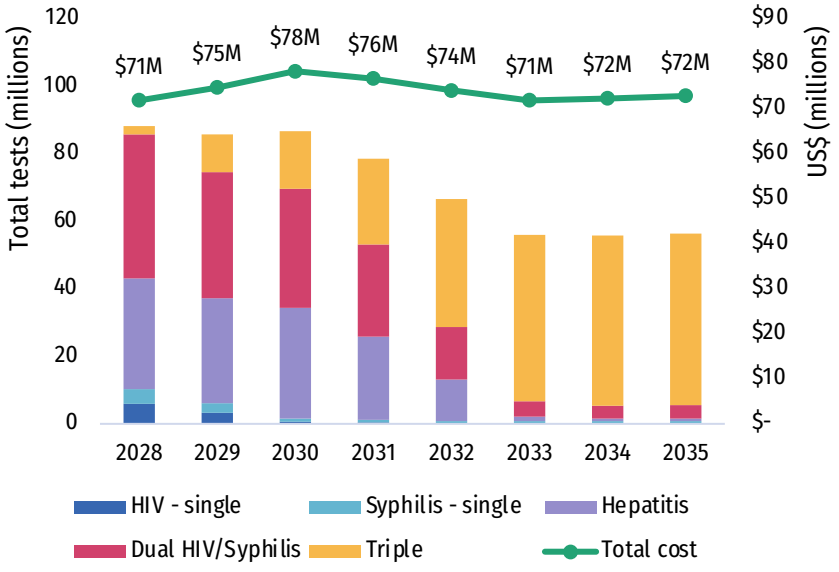


Triple Combination Test Introduction

73M Average annual single, dual, & triple combination tests to be procured

US$70M* Average annual resources for single, dual, & triple combination tests

*Average annual resource needs assume combination triple test price midpoint. Total resources will vary by triple test price—approximately US$58M at US$1/test versus US$77M at US$2.50/test

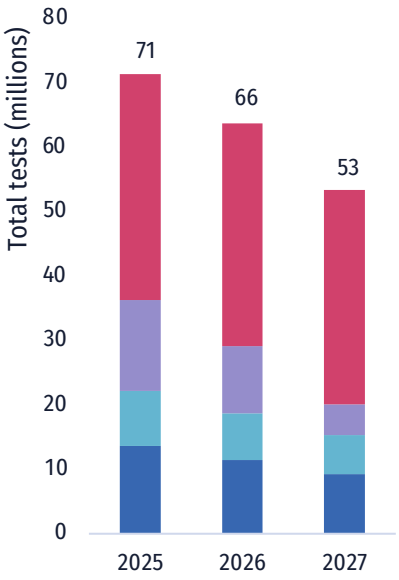


Takeaway: This scenario demonstrates that use of triple tests generates testing efficiency, reducing average annual procurement volumes by nearly 20% and annual average resource needs by ~10% to achieve and sustain TE screening goals.

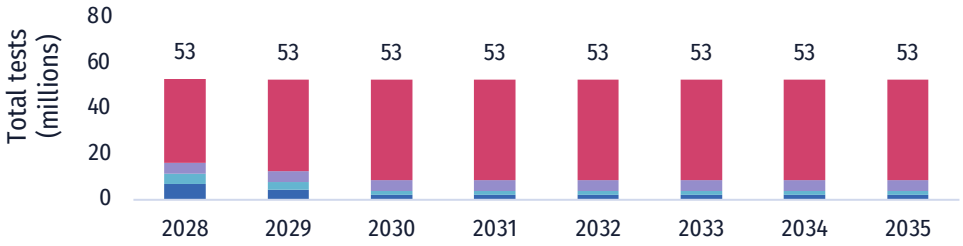
2 How will donor funding reductions affect progress?

Total tests

Donor cuts reduce annual screening funds from ~US$60M (2025) to ~US$44M (2027–2035), with domestic resources held constant. Volumes reflect estimated procurement within this constrained budget.

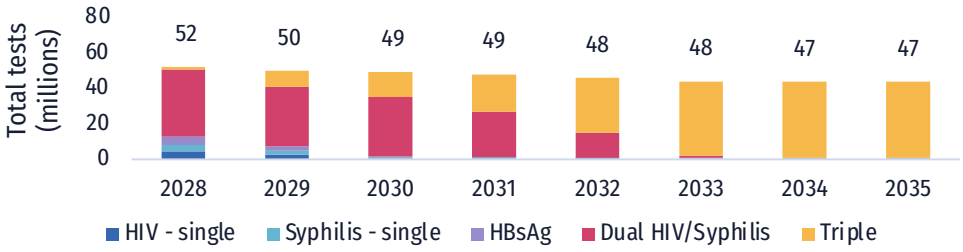


Existing Screening Tools



Annually, **53M single and dual tests can be procured** within anticipated resources in this financing scenario.

Triple Combination Test Introduction

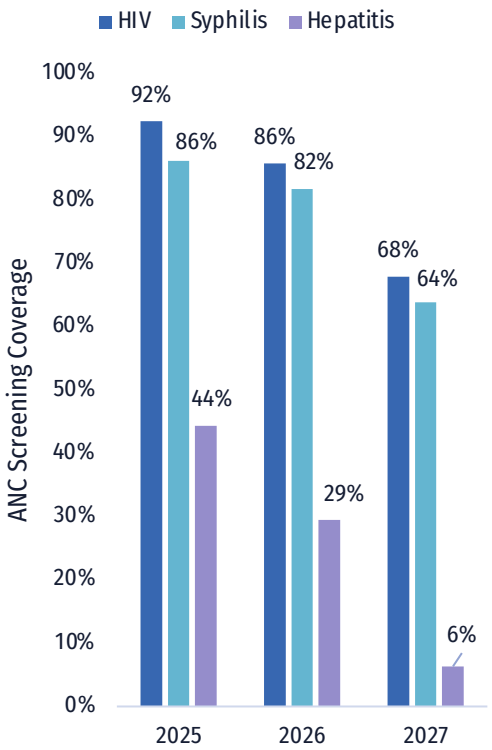


Triple combination test pricing dramatically shapes market size**.** This model assumes a US$1 price point for the triple combination test and **supports ~47M tests by 2035**, while ~US$2.50 limits volumes to ~20M within available budgets.

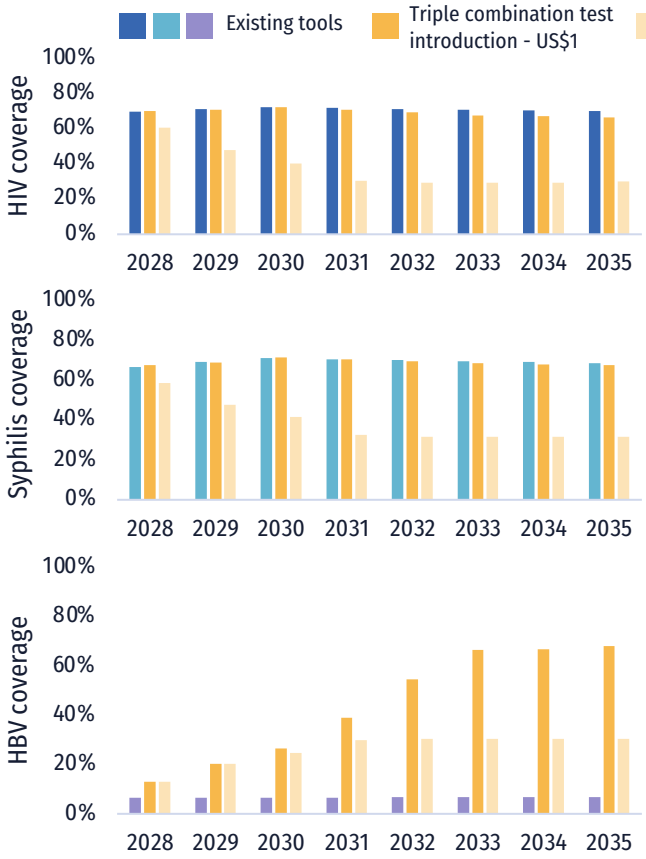
Takeaway: Constrained donor budgets may limit the ANC screening commodities market, reducing annual test volumes to approximately **53 million** under with existing screening tools and **~47 million** with triple combination test introduction and uptake, depending on the combination triple test price point. This represents a 25%-35% reduction of 2025 testing volumes.

TE screening coverage

Donor cuts leading to lower procurement volumes results in lower coverage for all three diseases, especially for HBV.



Figures below illustrate resulting screening coverage across product mix scenarios and triple combination test price point.



At US$1.00, triple combination tests maintain HIV and syphilis coverage closest to pre-cut levels. At US$2.50, however, the higher per-test cost means constrained budgets purchase fewer total tests, resulting in lower HIV and syphilis coverage than continuing with existing singles and duals alone.

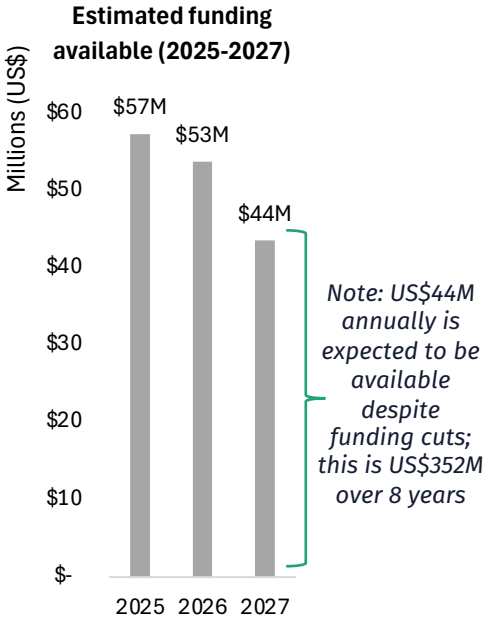
HBV is the exception. **Without triple combination tests, HBV coverage collapses under donor cuts and does not recover**. At any price point, triple combination tests are the only viable pathway to restoring HBV screening in this model.

Takeaway 1 - Coverage impact: Donor cuts significantly depress screening coverage, and although triple combination tests improve comprehensiveness, suboptimal pricing, in a financially constrained environment, further impacts screening coverage. Notably, this scenario assumes no recovery in donor financing — an assumption relaxed in Scenario 3, which models the targeted funding rebound needed to reignite progress toward TE screening goals.
Takeaway 2 - Pricing and market shaping: Triple test pricing will determine whether integrated screening expands the overall screening envelope or redistributes it. At current anticipated price points, constrained budgets may purchase fewer total tests, potentially reducing HIV and syphilis volumes in the near term. Alongside efforts to mobilize additional, dedicated resources for TE, proactive market shaping is essential to achieving a price point where all three programs benefit.

3 As funding declines, what is required to recover?

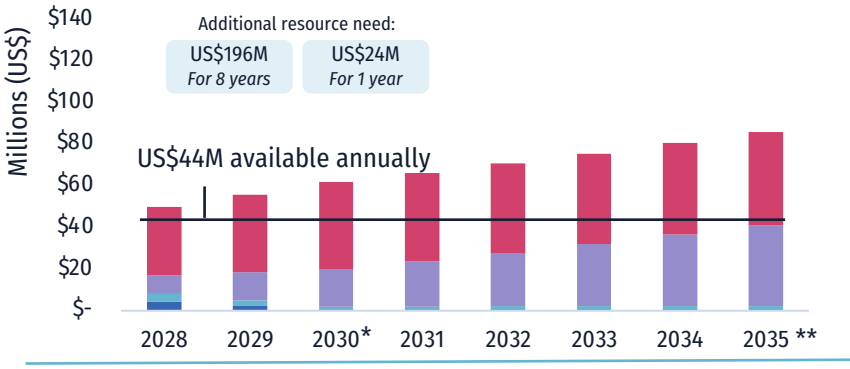
Resource needs

Figures below illustrate resource need across product mix scenarios and triple combination test price point to meet 2024 TE coverage rates in 2030, and TE screening goals by 2035.



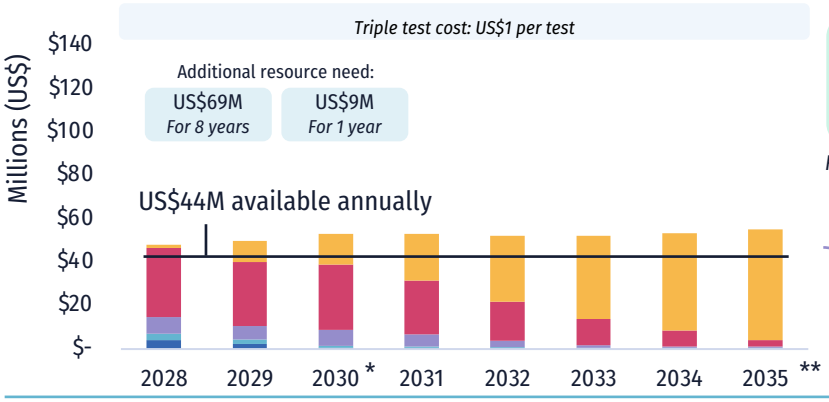
Due to donor cuts, the market size is estimated at **~191M dual and single tests, approximately 64M tests per year** resulting in the following screening coverage rates in 2027:

HIV	69%
Syphilis	66%
HBV	8%



Existing screening tools

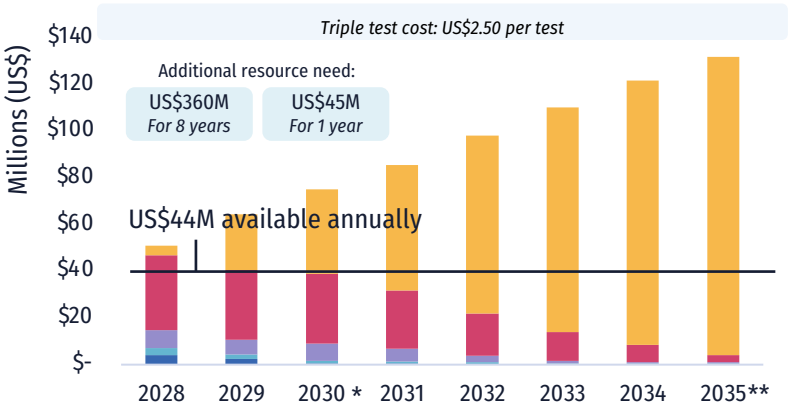
To reach TE screening goals, **678M single and dual tests are needed over 8 years,** approximately 84M tests per year



Introduction and scale up of triple combination tools

Resource needs for single, dual and triple tests based on country-reported introduction and scale-up timelines

Lower per-test cost offsets increasing volume, keeping annual resource needs stable



Triple combination tests reduce the total volume needed to reach TE goals by roughly one-third, from 678M to **462M tests over eight years**; approximately 58M tests per year.

HIV - single | Syphilis - single | Hepatitis | Dual HIV/Syphilis | Triple combination test

* Resources needed to achieve baseline (2024) TE screening coverage

HIV	93%
Syphilis	87%
HBV	50%

** Resources needed to achieve TE screening goals by 2035

Takeaway: Additional resources will be required to regain TE screening momentum following significant donor cuts and achieve TE screening goals. Triple tests can reduce both the volume and cost of achieving TE goals — from 678M to 462M tests and from US$196M to as low as US$69M in additional funding needed over eight years. Realizing these gains depends on achieving an optimal triple combination test price through proactive market shaping. While triple combination tests improve efficiency these benefits are realized gradually as countries transition from single and dual tests.

Takeaways

This analysis reveals that the future of integrated screening hinges on two variables: the trajectory of financing and the price at which triple tests enter the market. Across all three scenarios, three themes emerge clearly:

Coverage is tied to financing stability

Declines in donor-supported budgets could result in immediate and sustained reductions in screening coverage across all three infections, most notably for HBV. In the absence of new tools, HBV coverage may not recover under these conditions

Test affordability enables scale

Lower-priced triple combination tests could enable higher procurement volumes and support coverage recovery, while higher price points may constrain the ANC commodities market and limit the gains that triple combination tests can achieve, even with strong interest and adoption.

Reaching TE needs sustained investment

Resource needs depend heavily on both the price of triple tests and the trajectory of funding. Affordable pricing helps narrow the overall resource needs, whereas higher pricing combined with prolonged donor cuts pushes TE targets further out of reach.

These findings underscore that future coverage, market size, and program impact will depend on **stable financing and the affordability of triple combination tests** as countries plan for introduction and scale-up

Looking forward

Integrated screening is at a critical inflection point. Countries have strong policies, rising coverage, and clear demand for more efficient tools — but progress toward TE is increasingly threatened by tightening donor budgets and uneven domestic financing.

The emerging generation of triple combination tests presents a timely opportunity to protect this progress, streamline service delivery, and close persistent coverage gaps for syphilis and HBV. Realizing this will require coordinated action across evidence generation, financing, and implementation planning to ensure countries can introduce and scale triple tests rapidly and affordably.

Key takeaways

1. Integrated screening is already happening. Across the 16 focus countries, countries are actively screening for HIV, syphilis, and HBV within ANC platforms using existing tests. This foundation of integrated service delivery demonstrates both feasibility and country demand—and provides the infrastructure upon which triple combination tests can scale.

2. Triple combination tests offer a high-impact, efficiency-driven pathway to sustain and expand screening coverage across HIV, syphilis, and HBV
They simplify workflows, reduce overall test volumes, and improve comprehensive screening even under constrained budgets.

3. The market opportunity extends well beyond ANC
All countries plan to use triple combination tests beyond pregnant women, and many would consider expanded combination tests that include HCV alongside HIV, syphilis, and HBV, indicating broader applications for future integrated diagnostics and expanded market opportunities.

4. Countries are ready for new product adoption, but timelines remain long without catalytic action
Even with strong policy environments, national scale-up takes 3.5–9.5 years; early donor and supplier investments can significantly accelerate uptake. Countries should plan for resources prioritized to support new product introduction activities within upcoming financing opportunities like Global Fund Grant Cycle 8 and USG MOU.

5. Pricing will be a decisive factor for market size, coverage outcomes, and feasibility
Lower-cost triple combination tests (~US$1.00) significantly reduce resource needs and enables recovery of coverage with modest additional investment; higher prices (~US$2.50) constrain test volumes, worsens screening coverage levels for HIV and syphilis, and limits screening coverage rebound for HBV.

6. Donor funding cuts pose a significant and measurable risk to HIV, syphilis, and especially HBV screening
Without triple combination tests, HBV coverage is unlikely to recover to pre-donor cut levels; triple tests are critical to mitigating long-term declines.

7. Strategic coordination across policy, evidence, pricing, and financing will determine success: Achieving the full potential of triple combination tests will require coordinated action across stakeholders — from global normative guidance and regulatory pathways to country-level procurement planning and domestic financing commitments. Sustaining screening coverage is a shared responsibility across donors, governments, and suppliers; no single actor can drive this transition alone.

Annex

References

1. Country guidance for planning triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus programs. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2025. License: CC BY-NCSA 3.0 IGO
2. Matthews PC, et al. Vertical transmission of hepatitis B virus in the WHO African region: a systematic review and meta-analysis. The Lancet Global Health, 2025
3. WHO Prequalification of In Vitro Diagnostics Public Report: Determine HIV Early Detect. WHO reference number: PQDx 0243-013-00, version 9.0. Geneva: World Health Organization, September 2025
4. WHO Prequalification of In Vitro Diagnostics Public Report: Determine HIV Early Detect. PQDx 0243-013-00, version 9.0. Geneva: World Health Organization, September 2025
5. WHO Prequalification of In Vitro Diagnostics Public Report: Determine Syphilis TP. PQDx 0485-013-00, version 5.0. Geneva: World Health Organization, October 2025
6. WHO Prequalification of In Vitro Diagnostics Public Report: Determine HBsAg 2. PQDx 0451-013-00, version 4.0. Geneva: World Health Organization, October 2025

Market Size Estimation Assumptions and Methodology

Inputs:

- Number of women currently pregnant: calculated based on country team inputs and the percent of pregnant women who attend 1st ANC visit
- Number of pregnant women who attend 1st ANC visit: calculated from the percent pregnant women who attend 1st ANC visit and number of women currently pregnant
- HIV, syphilis, HBV coverage volumes and rates in ANC were calculated first using inputs from country teams and estimated ANC volumes. Where data was unavailable, calculations were made based on historical trends from data
- Dual HIV/syphilis screening coverage and volumes in ANC: calculated from country teams. Where data was unavailable, calculations were made based on historical trends from data or an assumption of linear scale up from dual introduction year to known 2024 dual usage
- Change rates of female population ages 15-49 and percent of women age 15 to 49 currently pregnant: historical trend rate is calculated for the change in % women age 15-49 currently pregnant by calculating the average of the historical change year over year from 2018-2024. This rate is then applied, year over year, to project population estimates from 2025-2035

Assumptions:

- When additional budget cuts must be made after the HBsAg budget is already reduced to $0, the dual test takes the remaining cut. In countries where the dual test is not procured, single HIV and syphilis RDTs take the cut based on the proportion each disease area comprised of the previous year's budget

Model Limitations

- Model inputs were provided by CHAI country teams informed by nationally available data sources, including MoH program data. Responses reflect CHAI's best assessment and do not represent official MoH positions. Not all countries were able to respond to every query; gaps are noted where applicable.
- While the 16 countries represent a significant share of the HIV, syphilis, and HBV burden, findings may not be generalizable to all LMIC settings pursuing triple elimination
- Financing scenarios are illustrative, not predictive. The three financing scenarios model possible funding trajectories based on current trends but do not reflect confirmed donor commitments or budget decisions. Actual funding levels may differ from those modeled.
- Triple combination test pricing is assumed, not confirmed. The modeled price range of ~$1.00–$2.50 reflects plausible market outcomes but no triple test has announced pricing at the time of publication. Actual pricing will depend on supplier decisions, volume commitments, and procurement mechanisms.
- Product transition assumptions are simplified**.** The model assumes a uniform triple combination test uptake trajectory (20% → 70% → 100% over three years) informed by dual test experience. In practice, the pace and sequencing of transition will vary by country based on regulatory, procurement, and programmatic factors.
- The model assumes single HBsAg testing is the first commodity deprioritized when donor funding is reduced. While this reflects observed patterns in several countries under Global Fund Cycle 7 reprioritization, it may not apply uniformly across all settings.
- The model assumes countries scale screening coverage in a linear fashion toward TE targets. Actual coverage trajectories are likely to be uneven, influenced by subnational variation, health system capacity, and competing priorities.
- The model only estimates commodity costs and does not account for broader programmatic costs such as training, supply chain, quality assurance, or health information system investments required to support triple test introduction and scale-up.