HIV/Syphilis Dual-RDT Market Brief



September 2025

This brief marks the inaugural edition of CHAI's **"Triple Elimination Series,"** examining market-shaping strategies to prevent vertical transmission of HIV, syphilis, and hepatitis B (collectively known as "triple elimination"). It focuses on the introduction and scale-up of dual HIV/ syphilis rapid diagnostic tests (RDTs) and details CHAI's collaboration with global and country-level partners to build an enabling environment for their adoption. The data and insights presented here draw on CHAI's implementation experience across six countries and reflect progress as of June 2025.



Understanding the key enablers in HIV/syphilis dual RDT scale-up can inform rapid rollout of future multiplex testing solutions, supporting integrated testing strategies to advance triple-elimination efforts and sustain progress toward testing goals even amid funding decreased and shifting priorities.

Background

Each year, <u>vertical</u> (<u>mother-to-child</u>) <u>transmission of HIV and syphilis</u>, <u>cause significant yet preventable infant morbidity</u>, <u>mortality</u>, <u>and stillbirths—particularly in sub-Saharan Africa</u>. Syphilis alone remains a leading cause of stillbirths, with congenital cases rising globally.

While HIV testing and treatment coverage among pregnant women has steadily improved since 2015, screening for syphilis remains inconsistent, limiting timely access to care.

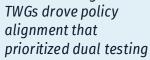
Dual HIV/syphilis-RDTs offer a practical solution to efficiently and effectively address the screening gap. Despite these tests having WHO-PQ for over a decade and global recommendations for their routine use, adoption and uptake was slow until substantial efforts were undertaken by CHAI and partners to establish an enabling environment.

Enabling environment pillars

The introduction and scale-up of HIV/syphilis dual RDTs was made possible through a combination of global and national level actions that shaped the enabling environment and gradually converged to support uptake. Viewed holistically, these pillars can be grouped into three categories—policy & evidence, product & market readiness, and financing & implementation.



Policy Change & Stakeholder Coordination + Advocacy National and global TWGs drove policy





Early Evidence

Data demonstrated feasibility, impact, and value



Country Pilots

Real-world pilots built confidence in the usability of format, feasibly of implementation, and generated early demand



Algorithm Revision

Testing process updated to include new product



Robust Product Pipeline

Multiple suppliers ensured competition and a secure supply



Stringent Regulatory Authority Approval

Enabled widespread confidence in procurement of quality-assured tests



Market Intelligence

Demand forecasting across uptake scenarios reduced uncertainty and enhanced planning



Affordable Pricing

Established competitive pricing agreements and installed a volume guarantee to unlock-introduction



Catalytic Financing and Procurement

Early investments accelerated introduction and reduced risk for manufacturers, donors, and governments



Implementation Planning

Structured scale-up plans enabled system readiness and faster uptake across all tiers of the health system

Policy & Evidence

Product & Market Readiness

Financing & Implementation

The 10-year uptake story

2014: Global Fund allows

for dual procurement per

The scale-up of HIV/syphilis dual RDTs took nearly a decade, with timelines varying widely across countries.

While WHO pre-qualification and accompanying Global Fund procurement eligibility allowed for product introduction, widespread adoption and scale up began after the 2017 WHO informational note. This helped countries move from pilots to policy updates, algorithm changes, and procurement planning. Some scaled quickly, while others took more time—highlighting that success depended not just on tools, but on coordinated and sustained action.

Timeline

Enabling environment largely absent Key pillars established, paving the way for scale 2013 2014 2015 2016 2017 2018 2020 2021 2022 2023 2024 Global enabling environment

2017: WHO informational 2019: WHO Normative note* guidance

> 2018: Early cost-effectiveness evidence 2018: PEPFAR endorses dual tests in

2022: Targeted advocacy at IAS COP planning

Country pilots

Guideline/Algorithm revisions

2024: WHO expanded

guidance

*The 2017 WHO informational note for use of dual RDTs for pregnant women and other key populations catalyzed in-country activities to establish policy, public procurement, and implementation planning

2013: First dual RDT with WHO PQ

WHO PQ

2018: Early market intelligence

2021: Two more dual RDTs secure WHO PQ and CHAI/MedAccess **Pricing agreements**

CHAI supported 6 Ministries of **Health** to prepare for and plan for dual RDT introduction and scale up: India, Ethiopia, Kenya, Nigeria, South Africa, and Uganda

2018: Gates catalytic financing for early country pilots supported by CHAI

2020: GiveWell grant to Evidence Action for dual-RDT implementation support

Implementation planning

Catalytic financing and procurement

The successful uptake of HIV/syphilis dual RDTs relied on critical sequencing between global and country-level actions. Global efforts, such as normative guidance, product prequalification, and market-shaping, often served as prerequisites for national adoption. In turn, country pilots and algorithm revisions were necessary to finalize country policies which opened doors for further implementation planning, procurement, and generate d demand - reinforcing global investments. Understanding these interdependencies is essential for accelerating future scale-up of integrated diagnostics.

Country pillar details



Policy & evidence

6/6 countries updated national guidelines to enable dual **RDT** adoption

Time to policy update: 1-5 years | Average: 2.5 years

Country pilots

4/6 of countries

Pilot timelines ranged from 3-19 months; not all countries required a pilot despite new test format; pilot evidence was critical for national and global advocacy

Algorithm revision

6/6 of countries

Algorithm review required 3-24 months with pace depending largely on MOH resources, priority and process; all policy updates were contingent on completion of algorithm revision



Financing & implementation

Implementation planning

6/6 of countries such

as, integrated strategic planning and evidencebased advocacy (both global and national), to stakeholder coordination, data tool integration, health worker training, LIMS alignment, updated quantification, and national rollout preparation

Catalytic financing and procurement

4/6 of countries

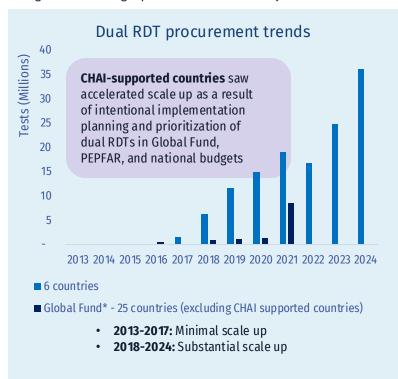
Prioritized dual test in Global Fund budgets between GC5 and GC6 allocations

3/6 of countries

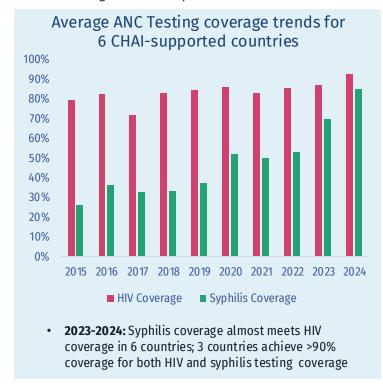
Included dual RDTs in national budgets by 2023

Impact

Establishing the enabling environment for the HIV/syphilis dual test led to tangible results across countries. The following figures highlight increased procurement volumes, improved syphilis testing coverage, and qualitative accounts of greater testing efficiency through integrated screening. Uptake acceleration clearly follows the establishment of the enabling environment pillars.



***NOTE:** Data is from Global Fund Price and Quality Reporting: Transaction Summary; downloaded July, 2025. Data from 2022-2025 is incomplete and was excluded from the analysis



Service delivery efficiencies

6/6 of countries

Indicated efficiencies at the point of service delivery



Fewer blood draws for patients and HCWs



Faster time to diagnosis



Improved patient experience



Reduced missed testing

System efficiencies

6/6 of countries

Indicated efficiencies across the health system



Simplified provider training



Waste reduction



Streamlined program planning and monitoring

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Integrated reporting



patient tested

Looking forward

This brief highlights the key enabling environment pillars that were essential to effectively introduce and scale dual HIV/syphilis testing across multiple countries. As uptake of the dual RDT expanded, countries saw improved testing coverage and greater efficiency in ANC screening service delivery, leading to a projected reduction in congenital syphilis. These lessons now serve as a blueprint for future diagnostic product introductions.

Considering the significant changes in health resourcing, sustained global collaboration will be critical to accelerate the adoption of next-generation combination diagnostics, including triple tests for HIV, syphilis, and hepatitis B. Early investments in policy alignment, market shaping, and financing will help minimize delays between product availability and uptake. Lessons from the dual RDT experienc e underscore the importance of clearly owned, flexible, country-led approaches that integrate planning, service delivery, and program monitoring. By aligning demand, supply, and financing stakeholders were able to drive faster adoption of the dual-RDT. As the diagnostics landscape continues to evolve, applying these insights will be key to achieving triple elimination goals more efficiently and equitably.