Triple Test Considerations

Purpose: This guidance supports Ministries of Health, eVT stakeholders, and civil society advocates to navigate decisions about triple combination test prioritization within GC8 funding requests, translating the GC8 policy context into practical considerations for countries on their pathways towards triple combination test readiness.

1. Overview

What are triple tests and why do they matter?

Triple rapid diagnostic tests (RDTs) are single-use point-of-care tests that simultaneously detect **HIV, syphilis, and hepatitis B (HBsAg)** from one sample, typically within antenatal care (ANC) settings. They build on the success of dual HIV/syphilis RDTs by extending integrated screening to include hepatitis B—completing the clinical package required for triple elimination. They offer a clear set of advantages for integrated ANC delivery:

- **Close the HBV screening gap:** While HIV and syphilis testing in ANC are now widely scaled, hepatitis B screening remains significantly lower in many settings. Triple tests help normalize HBV testing as part of routine care rather than an add-on.
- **Reduce missed opportunities:** A single test at the first ANC visit ensures that all three infections are screened together, limiting drop-offs that occur when testing is fragmented across visits or platforms.
- **Improve efficiency and patient experience:** One test, one finger prick, and one workflow reduces provider burden, simplifies training, and shortens client wait times.
- **Enable earlier linkage to care:** Earlier identification supports timely interventions—ART for HIV, penicillin for syphilis, and prophylaxis for HBV—improving maternal and infant outcomes.
- **Strengthen integrated service delivery:** Triple tests reinforce ANC as a platform for integrated prevention, rather than parallel disease-specific programs.

For a broader overview of integrated ANC screening for triple elimination, including the programmatic case and implementation considerations, see CHAI's Integrated Screening for Triple Elimination Memo (2026).

At the same time, experience from dual HIV/syphilis RDT scale-up shows that realizing these benefits takes time and deliberate planning. As highlighted in CHAI's Dual RDT Market Brief (2025), scale-up across multiple countries took nearly a decade. Three lessons are particularly relevant for triple test introduction: policy and regulatory processes are often on the critical path and should begin early; introduction activities (procurement, training, and guideline updates) should run in parallel where possible; and early demand signaling—such as through GC8 applications—can shape supplier behavior and pricing.

Triple rapid diagnostic tests remain an emerging tool, and their introduction is most effective when aligned with country readiness, program maturity, procurement pathways, training capacity, and data systems. Countries may benefit from considering triple diagnostics not as a one-size-fits-all solution, but as part of a sequenced pathway toward strengthening integrated triple elimination programming.

What GC8 guidance says on integrated testing?

Program Essential 11 (PE 11) designates integrated testing for HIV, syphilis, and HBsAg at least once in pregnancy as a New Program Essential for GC8. This elevates triple screening from an optional integration opportunity to an expected standard of care.

Current guidance reflects both where countries are today and where they can go next: The Global Fund HIV Information Note **recommends dual HIV/syphilis RDTs plus standalone HBsAg testing** as the baseline approach at the first ANC visit.

At the same time, it **explicitly encourages countries to pursue efficiency gains through multiplex testing** — including triple combination tests that detect HIV, syphilis, and hepatitis B in a single test format.

This creates a clear opportunity within GC8:

- **Anchor investment in PE11:** Countries can justify integrated screening investments (including commodities, training, and systems strengthening) under a strong policy mandate.
- **Sequence adoption strategically:** Countries should determine adoption pathways that align with their readiness and health systems contexts.
- **Leverage a favorable product pipeline:** One triple test has already achieved WHO prequalification, with several others expected during the GC8 implementation period.
- **Deliver value for money:** In a constrained funding environment, triple tests offer a pathway to greater efficiency without expanding service scope, aligning with GC8 priorities on optimization and sustainability.

Why should planning for triple test transition start now?

Countries should plan for the introduction of, and transition to, triple combination tests during the GC8 application and early implementation phases. Early attention to product selection, procurement forecasting, and introduction planning can help ensure countries are well positioned to adopt currently available products and additional triple tests as they become available, while reducing the risk of delays due to misaligned enabling environments. For countries that are not yet prepared to introduce triple tests immediately, starting these conversations during GC8 planning can inform or strengthen future plans during GC8 mid-cycle revisions and reprogramming or for future GC9 allocation.

This guidance supports countries in navigating triple test decisions while maintaining continuity of services with existing products as the market matures during GC8 implementation.

2. Product landscape and anticipated timeline for emerging triple test products

A. Existing products

Currently, most 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 separate test kits: single HIV, syphilis, and hepatitis B surface antigen (HBsAg) rapid diagnostic tests (RDTs)
2. A dual HIV/syphilis RDT alongside a HBsAg RDT

These products are WHO prequalified, widely procured, and the foundation for most country programs today.

B. Triple test product landscape

One WHO-prequalified triple test combining HIV, syphilis, and HBsAg detection is already commercially available and available on Wambo, with several additional products in development and expected to enter the market during the GC8 implementation period.

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 below. Sample 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
Sample application steps	1. Dispense fingerstick into sample tube 2. Invert 10 x 3. Remove foil covers from 3 x strips 4. Use 50 µL capillary to pick up sample 5. Dispense sample on to HIV sample pad 6. " on syphilis sample pad 7. " on HbsAg sample pad	1. Collect fingerstick blood with dropper 2. Dispense 1 drop into S1 well 3. Dispense 2 drops into S2 well	1. Collect fingerstick blood with 20 µL pipette 2. Dispense 20 µL into sample well	1. Collect fingerstick blood with 50 µL pipette 2. Dispense 50 µL into sample well
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)	Plasma samples Determine HIV Early Detect • p24 Antigen* – 42-59%/100%[1] (n=12 p24 specimens; 5 positives & n=22 p24 specimens; 13 positive) • HIV1/2Antibody – 100%/98%[2] (n=1119 samples; 682 positives) Determine Syphilis TP – 100%/98.7%[3] (n=570 samples; 270 positive) Determine HBsAg2 – 100%/100%[4] (n=514 samples; 201 positive)	Venous WB samples HIV1/2 – 100%/99.6% (n=1,329 samples; 86 positive) Syphilis TP – 100%/100% (n=1,329 samples; 86 positive) HBsAg- 99.3%/100% (n=300 samples; 150 positives)	Plasma samples 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)	Plasma samples 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**	$2.60 (Global Fund price)	Targeting <$1.50 (Indicative)	Targeting <$2.00 (Indicative)	Targeting $4.99 (Indicative)
Other considerations	Includes 4th generation HIV format; may require updated clinical algorithms and additional guidance for programmatic use	Lane 1 - Dual HIV/Syphilis Lane 2 – HBsAg		*Study enrollment is ongoing to be complete by March 2026

**p24 antigen figures reflect detection rates on commercial seroconversion panels per WHO PQ evaluation, not clinical specimens from acute HIV infection, and is not intended for programmatic characterization of acute HIV detection performance*

***Pricing figures reflect data presented at a Partner/Donor convening on triplex market access in Geneva on March 30–31, 2026. Indicative prices are subject to change as the market develops.*

1. 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
2. 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
3. WHO Prequalification of In Vitro Diagnostics Public Report: Determine Syphilis TP. PQDx 0485-013-00, version 5.0. Geneva: World Health Organization, October 2025
4. WHO Prequalification of In Vitro Diagnostics Public Report: Determine HBsAg 2. PQDx 0451-013-00, version 4.0. Geneva: World Health Organization, October 2025

Several product features are worth highlighting for country decision-making:

- **WHO prequalification status varies significantly across products.** The Abbott ANC Panel is the only product to have obtained WHO PQ to date (July 2025), meaning it is the only triple test currently eligible for procurement

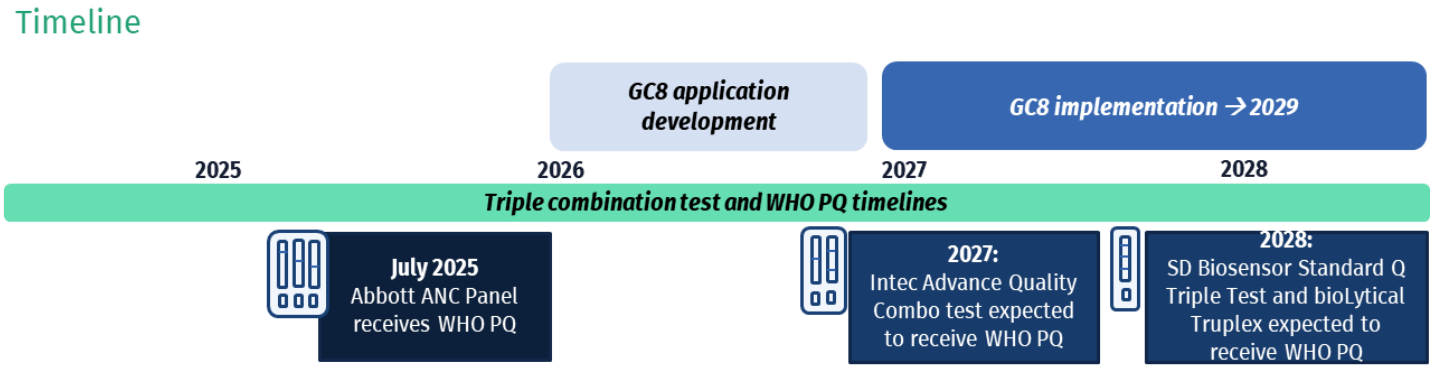
through Global Fund grants. The remaining three products anticipate WHO PQ between Q2 2027 and Q4 2028. Countries should factor these timelines into procurement forecasting and phasing strategies.

- **Product formats differ in ways that matter for ANC workflows.** Sample volumes range from approximately 20 µL to 250 µL of capillary blood, and lane configurations vary. These differences have implications for health worker training, workflow adaptation, data capture, and result interpretation at the facility level.
    - **Note:** Evidence on provider preferences, ease of use, and real-world performance in ANC settings is currently limited but being generated and will emerge over the next 1-2 years. Countries should monitor this evidence as it develops, and factor it into product selection decisions where possible rather than relying solely on manufacturer promotion.

- **Sensitivity and specificity data are largely manufacturer-provided and based on limited sample sizes for some products.** Countries should monitor independent validation evidence as it becomes available.

- **The Abbott ANC Panel includes a 4th-generation HIV test**, Determine Early Detect, which can detect both HIV antigen (p24) and 1/2 antibodies. The antibody performance of the test is the same as the commonly used WHO PQ'd 3rd-generation RDTs, with high sensitivity and specificity. The antigen detection could potentially enable earlier identification of acute infection, and introduces important implementation considerations. Countries adopting this panel will need to review and update their national testing policies to define how p24 result will be used, address discordant results, define confirmatory testing pathways for suspected acute infections, and update counselling protocols for indeterminate results during the window period. These requirements add operational complexity which countries should weigh when considering adoption.

C. **Timeline graphic:**



While WHO PQ is the primary milestone enabling procurement, suppliers are also targeting GF ERPD, which would provide an additional pathway that may enable earlier procurement within the GC8 implementation period.

3. Planning for transition to triple tests for integrated ANC screening

The shift toward triple combination testing will be gradual and will look different across countries, depending on current testing approaches and system readiness. For most countries, this will involve a transition from existing integrated screening approaches (e.g., dual HIV/syphilis RDTs with standalone HBsAg testing) toward multiplex testing over time.

This section supports countries in making four interconnected decisions. These decisions need to be made in relation to each other - a procurement forecast that does not account for a planned product transition, or an introduction plan will create gaps difficult to close mid-implementation. This section is structured the following way:

- Decision 1: Should we plan to transition to triple testing for integrated ANC screening during GC8?
- Decision 2: Which product(s) should we select? (including "Product selection criteria")
- Decision 3: When can we realistically transition? (including "What introduction requires" and "Estimated introduction timeline")
- Decision 4: How do we budget and forecast procurement? (including "Budgeting for introduction activities", "Procurement forecasting across the transition" and "Risk")

Decision 1: Should we plan to transition to a triple test during GC8?

Most countries currently use dual HIV/syphilis RDTs alongside standalone HBsAg tests, or three individual tests. An initial decision is whether to maintain this approach or to plan to transition to a triple test during the GC8 period.

Countries will generally fall into one of three positions:

Position	Description	Recommended approach
Maintain and scale up current mix	Maintain and build strong existing workflows with dual + standalone HBsAg; limited capacity or appetite for transition to triple test	Procure existing single and dual products for full GC8 period to meet triple elimination screening targets; monitor triple test market and evolving evidence to inform potential introduction for GC9
Plan for introduction	Maintain current workflows in place while preparing for potential transition to triple tests during GC8 period	Procure existing single and dual products for early GC8 implementation; build in procurement flexibility and initiate triple test introduction planning as the enabling environment strengthens, additional evidence becomes available and/or more products enter the market.
Early adoption	Country has enabling environment to adopt triple test now	Plan transition activities based on operational context, cost considerations, and long-term implementation strategy

Decision 2: Which product(s) should we select?

This decision applies to countries in the "plan for transition" or "early adoption" positions.

Selecting an appropriate product mix involves weighing several factors that may vary across country contexts. Before outlining these criteria, two framing points are helpful to consider.

First, **WHO prequalification or GF ERPD is the baseline for product selection under GC8.** Only WHO PQ-listed products and those with GF ERPD are eligible for GF-financed procurement. The criteria below assume WHO PQ and/or GF ERPD as a given starting point.

Second, some important considerations — such as national regulatory approval timelines and supply security — are not included here because they do not guide *which* product to select, but rather *when* and *how* a transition can realistically happen. These are addressed in Decision 3.

Product selection criteria:

Four criteria are most important for product selection: diagnostic performance, health worker considerations, and cost and value for money.

Criteria	What to assess	Country considerations
Diagnostics performance	How does the product perform in real-world ANC conditions? (facility and community-based?)	Current performance data is largely manufacturer-provided and based on limited sample sizes, particularly for HBsAg. Prioritize existing independent validation evidence ahead of product introduction where available and monitor peer country experience.
Health worker considerations	How does the product work for providers using it every day?	Sample volume, time for operation and to result, lane configuration, and result interpretation all affect usability in busy ANC settings. Engage health workers early in product selection where possible. Evidence on provider preferences is limited and emerging — monitor as it develops.
Cost	How does the cost of triple tests compare to other tests currently procured and used (dual HIV/syphilis + HBsAg or three single disease tests)?	Triple test list prices are not yet publicly announced for most products, except those that are commercially available. Prices should be listed on Wambo. The market is at an early stage with limited supplier competition, meaning prices are likely to be higher now than they will be as the market matures. The dual HIV/syphilis test market offers a useful precedent: prices dropped significantly as country demand signals became clear, more suppliers entered, and pooled procurement mechanisms aggregated volume. Countries should avoid locking into fixed long-term procurement commitments at this stage — procurement flexibility will be important as pricing evolves. Actively signaling demand now, through GC8 applications and country dialogues, can itself help shape market dynamics in favor of lower prices.
Value for money	What types of efficiencies are gained that might justify any price premiums?	A triple test can reduce the number of steps to screen a woman for all three diseases with fewer products to handle, less time at the point of care, and a support a simpler supply chain. However, the efficiency gains can depend on the product format and disease burden: a single-lane, low sample volume product offers the most streamlined workflow specifically for people with unknown HIV, syphilis, and HBV status, but potentially complicated if HIV status (or other) is known. This format is the newest and most similar to existing workflows, but training on result interpretation may take time.

Decision 3: When can we realistically transition?

This decision applies to countries in the "plan for transition" or "early adoption" positions.

What introduction requires:

Introducing a new testing product is not only tied to a procurement decision. It requires a structured set of activities across policy, training, supply chain, data systems, and community engagement to build a strong enabling environment for seamless product introduction and scale up, all of which take time to complete and will impact shifts in product volumes. Understanding what introduction requires, and how long it takes, is essential before a country can set a realistic transition date.

The table below outlines the key activity areas, with notes on budget considerations and where integration with existing programs could reduce costs.

Activity area	Key activities	Sequencing	Budget considerations	Integration opportunities
Planning for ANC guidelines	Define placement within ANC testing continuum, build quantification metrics for single/dual/triple tests	Informs sequencing of triples tests within existing ANC/EMTCT guidelines	MoH staff time	Conduct discussions with ANC/EMTCT TWGs
Policy and regulatory	Lab validation (if required for WHO PQ'd product); national algorithm verification and update (if required*); in-country product registration; updating standard treatment guidelines	Most likely first set of activities — serves as a gate for all other activities	MoH staff time; regulatory fee where applicable	Align with other planned lab validations and guideline updates to reduce standalone costs
Pilot (if needed)	Small-scale implementation at select facilities to test workflows, identify bottlenecks, and generate local evidence before national rollout	Directly after policy/regulatory confirmed; informs training content	Data collection, supervision costs	Target facilities where existing platforms are strongest; integrate with routine supervision
Health worker training	Update training materials; cascade training from national to facility level; refresher training	After pilot (if conducted); informed by pilot findings	Per diem, facilitation, printing costs	Integrate with ANC/PMTCT training cycles; use existing supervision structures

Supply chain preparation	Updating forecasting tools; adjusting procurement plans; transitioning stock from old to new products	Can run in parallel with training	Commodity costs should be broadly neutral if triple test pricing is equivalent to combined dual + standalone HBsAg cost. Transition management costs (temporary dual procurement and potential write-off of unused stock) are the key cost risks — see risk section below	Phase-in new products as current stock depletes to minimize waste
Data and reporting systems	Updating HMIS/DHIS2 data entry forms and registers to capture triple test results; staff orientation	Can run in parallel with training	IT/MoH data team time	Bundle with other HMIS updates in pipeline; request under RSSH M&E module
Linkage to treatment	Review and update referral and linkage pathways for HBsAg-positive, syphilis-positive, and HIV-positive women; confirm TDF commodity availability; confirm BPG availability and supply reliability for syphilis treatment in pregnancy; define post-delivery HBV management pathway and financing	Can run in parallel with training; must be confirmed before rollout	Commodity procurement (TDF, BPG); clinical protocol development; gap-financing for post-delivery treatment	Map against existing PMTCT linkage workflows; identify domestic or partner financing early
Quality assurance	External quality assurance and proficiency testing for new product; supportive supervision during transition period	Begins at rollout	QA consumables; supervision transport	Leverage existing QA mechanisms and supervision schedules
Community and demand side	Community mobilization and IEC materials updated to reflect triple testing	Can run in parallel with training	Materials development and distribution	Integrate into existing CHW programs and ANC demand creation activities

* **National testing algorithms may require review and revision.** Countries considering introduction of triple tests may need to review and update existing HIV testing algorithms, many of which were designed around HIV-only or dual HIV/syphilis testing approaches. This review should clarify how triple test screening results will be incorporated into national ANC protocols, including confirmatory pathways for HIV, linkage to same-day treatment for syphilis, and appropriate follow-up testing and management for hepatitis B

Estimation transition timeline:

Countries should work through the following logic:

1. **Estimate how long each introduction activity will take** in their specific context, noting which activities must happen sequentially and which can run in parallel
2. **Identify the sequence of activities that determines the minimum time to transition readiness.** Policy and regulatory steps are almost always on the critical path since they gate everything else
3. **Map this against expected product availability.** When is WHO PQ, GF ERPD, and/or national registration confirmation anticipated, and when can supply realistically be secured? Refer to timeline graphic above.
4. **Work backwards** from the earliest realistic transition date to determine when preparation activities need to begin. In most cases, this means starting policy and regulatory steps well before a product is available.

Worked example
Country X wants to adopt a triple test with WHO PQ if confirmed in Q1, 2028.

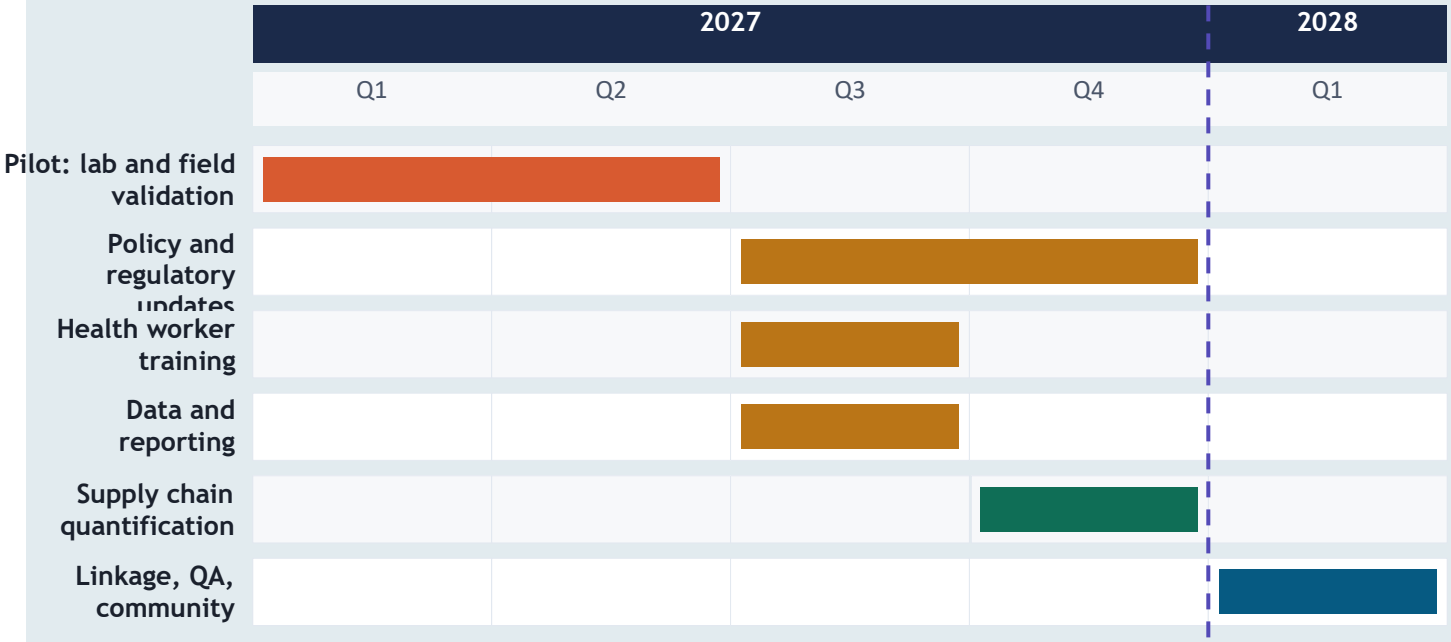
Steps 1 & 2: Activities, duration, and sequencing

Activity area	Details	Duration	Seq.
Pilot (if needed)	Lab and field validation	6 months	1
Policy and regulatory	Update national policy/algorithm	5 months	2
Health worker training	Develop and cascade training	3 months	2
Data and reporting	Update HMIS/DHIS2 forms	3 months	2
Supply chain	Update quantification and forecasting	3 months	3
Linkage / QA / Community	Review pathways, QA, IEC materials	Ongoing	4

Sequence: **1 = First (gates all others)** **2 = Parallel after pilot** **3 = After policy confirmed** **4 = Ongoing from rollout**

Steps 3 & 4: Map against availability and work backwards

To be ready for Q1 2028 product availability, pilots must begin in Q1 2027, followed by policy work by Q3, 2027, i.e., during GC8 application development.



Transition timing is rarely straightforward. The goal is to move early enough to realize the efficiency gains an integrated format offers, but not before the enabling environment is ready to support it.

Decision 4: How do we budget and forecast procurement?

This decision applies to all countries, regardless of positioning.

Budgeting for introduction activities

Countries planning for triple test transition need to budget for both product procurement AND introduction activities. Use the introduction activities table in Decision 3 to identify which cost categories apply to your context. Costs can often be integrated into existing budget lines (e.g., ANC training, supervision, data system updates) rather than requiring separate allocations.

- For countries in "maintain current mix" position: budget only for current product procurement. No introduction activity costs needed.
- For countries in "plan for transition" position: budget for current products for early implementation (Years 1-2) + introduction activities (Year 1-2) + procurement buffer for transition (Year 2-3)
- For countries in "early adoption" position: budget for triple test procurement + full introduction activities

Procurement forecasting across the transition

Forecasting procurement quantities of single, dual, and triple RDTs during a product transition requires:

1. **Baseline context:** Annual number of pregnant women to be tested at first interaction (use ANC attendance × testing coverage target), and known HIV prevalence. Also determine ANC retesting rate.
2. **Transition phasing:** Define the month/quarter when product transition begins and when it completes
3. **Calculate procurement volumes based on introduction plan:** Calculate quantities needed for each product during transition period ensuring that coverage target can be achieved across product mix
4. **Determine annual commodity volumes including buffer stock**. Add 10-15% buffer to manage transition uncertainty.
5. **Align financing mechanism:** Map each product and treatment commodity to its financing source (GF, domestic, USG, other) and confirm there are no funding gaps before finalizing procurement plans.

Note: Partner-developed quantification tools are available to support procurement forecasting (e.g., the Evidence Action quantification tool). Countries should review and adapt outputs accordingly.

Worked example - procurement forecast:

Step 1: Consolidate baseline context to define TE testing volumes

- 200,000 pregnant women attend ANC annually (ANC1 attendance)
- Testing coverage target: 95% → **190,000 women to be tested per year**
- GC8 implementation period: January 2027 – December 2029 (3 years)
- HIV prevalence among pregnant women: 5% ~**10,800 known HIV-positive women per year** may require a standalone syphilis test + HBsAg test rather than a triple test or dual test (as HIV status is already known at ANC1)*
- Note: Procurement figures should include additional volumes that align with national guidance for retesting in ANC. Retesting figures are not included in the calculated example below.

Step 2: Determine transition phasing to align with scale up plans

- Current products: dual HIV/syphilis RDT + standalone HBsAg test
- Planned transition: phased triple test rollout beginning Q1 2028, scaling across facilities through 2028 with all facilities offering triple test by end of Q4 2028 (this is an illustrative example, in some country contexts, transition may be faster or slower depending on enabling environment readiness, national registration timelines, product availability, and health worker training capacity

- **Detailed breakdown:**
  - **Q1 2027 – Q4 2027:** Current products only at all facilities — dual HIV/syphilis RDT + standalone HBsAg
  - **Q1 2028:** Triple test introduced at ~25% of facilities (early adopter sites with strongest platforms)
  - **Q2 2028:** Triple test scaled to ~50% of facilities
  - **Q3 2028:** Triple test scaled to ~75% of facilities
  - **Q4 2028:** Triple test at 100% of facilities — transition and scale-up complete
  - **2029:** Triple test at all facilities for full year

Step 3: Calculate procurement needs based on transition plan

Scale up	*Dual HIV/syphilis RDT*	*Single syphilis RDT*	*Single HBsAg RDT*	*Triple test*	*Total tests*
2028 Q1 (25% using triple test)	*38,125*	*2,500*	*35,625*	*9,375*	*47,500*
2028 Q2 (50% using triple test)	*26,250*	*2,500*	*23,750*	*21,250*	*47,500*
2028 Q3 (75% using triple test)	*14,375*	*2,500*	*11,875*	*33,125*	*47,500*
2028 Q4 (100% using triple test)	*2,500*	*2,500*	*0*	*45,000*	*47,500*

Step 4: Determine annual commodity volumes including buffer stock.

Year / Period	Dual HIV/syphilis RDT			Single syphilis RDT	Single HBsAg RDT	Triple test	Total tests for integrated ANC screening
2027	190,000*	10,000	180,000	–		370,000	
2028	78,750	10,000	71,250	108,750		268,750	
2029	–	10,000	10,000	190,000*		200,000	
2027-2029 Total	258,750	30,000	261,250	288,750		838,750	

***Note**: Dual HIV/syphilis RDT and triple test volumes are calculated against total women to be tested (190,000) without deducting known HIV-positive cases (~10,000). In practice, known HIV-positive women do not require the HIV component of a dual or triple test and would receive standalone syphilis and HBsAg tests instead. However, since coverage targets are applied to the total ANC population and it is not possible to know in advance which women within the 95% target will be known HIV-positive, procuring dual and triple tests against the full target volume is the practical approach. This means dual and triple test volumes are slightly overstated — offset by the standalone syphilis and HBsAg tests procured separately for known HIV-positive women*

Additional quantification considerations

Annual coverage across product mix should achieve target TE coverage i.e. 95% for HIV, 95% syphilis, and 90% HBV

Additional standalone syphilis and HBsAg tests may be needed for known HIV positive cases and other testing timepoints

Retesting requirements should be factored into total volumes

	Dual HIV/syphilis RDT	Single syphilis RDT	Single HBsAg RDT	Triple test
2027-2029 Total	261,250	30,000	253,750	308,750
Buffer (15%)	39,188.00	4,500.00	38,063.00	46,313.00
Grand total	300,438	34,500	291,813	355,063

Step 5: Align financing mechanisms:

Financing source

Product	Global Fund (GC8)	USG	Domestic financing	Other
Dual HIV/syphilis RDT	50%	50%		
Single HBsAg RDT	75%		25%	
Single syphilis RDT	100%			
Triple test	100%			

Risks

The table below maps key risks that may affect a country's ability to introduce a triple test during the GC8 implementation period. For each risk, a brief description and suggested mitigations are provided. Countries should use this table to inform introduction planning.

Risk area	Description	Mitigation
Treatment cascade risk	Improved HBsAg testing coverage through triple test introduction will identify more HBsAg-positive women than current programs — creating downstream demand for TDF prophylaxis during pregnancy and post-delivery HBV management. If treatment pathways and commodity procurement are not prepared in advance, women identified through improved testing may not receive the care they need.	Map treatment cascade capacity before scaling up testing. Confirm TDF procurement is included in the GC8 budget under the Treatment, Care and Support module. Identify domestic or partner financing for post-delivery HBV management — not financed by GF under GC8 — before finalizing the application. Include BPG availability check for syphilis treatment alongside HBsAg-positive pathway planning.
Regulatory and timing risk	Delays in WHO prequalification during the GC8 implementation period could affect introduction timelines and require interim product mix or phasing strategies. National registration requirements add further time beyond WHO PQ and are often overlooked in transition planning.	Build flexibility into grant procurement language to allow product substitution when WHO PQ is confirmed. Initiate national registration process early — ideally before WHO PQ is formally confirmed where regulatory pathways allow. Include a contingency procurement plan for current products if transition is delayed.
Affordability and value-for-money risk	If triple tests are priced above the combined cost of dual tests plus standalone HBsAg, countries may need to identify offsetting efficiencies or optimize grant allocations to enable adoption. Market pricing for products yet to be commercially available is not yet confirmed, creating uncertainty for GC8 budget planning.	Seek indicative pricing from suppliers early. Model total cost per woman tested — not unit price — to assess value for money. Factor in supply chain and training efficiencies that an integrated format generates. Signal demand clearly through GC8 applications to encourage competitive pricing.
Enabling environment risk	Introduction planning activities — including algorithm updates, health worker training, HMIS updates, and supply chain preparation — take time and must happen before transition can begin. If any of these stalls, the transition timeline slips regardless of product availability.	Use the introduction planning table in this module to map sequencing and duration of all activities and identify the critical path. Build preparation activities into the GC8 workplan and budget from grant start — do not wait for WHO PQ confirmation to begin.

4th-generation HIV test line and associated client management risk	Discordant results — where the antigen line is reactive, but the antibody line is not — cannot be confirmed without laboratory-based NAT or 4th-gen EIA, which are not routinely available in ANC settings. Updating testing policies and procedures for these cases will be critical for testing quality and client management.	Train health workers on discordant result protocols and counselling for indeterminate results. Countries can assess operational complexity and additional diagnostic needs and whether this is feasible/beneficial (see below for additional 4th generation HIV test considerations

4. Considerations on 4th generation HIV testing

Currently only one WHO-prequalified triple test (Abbott ANC Panel) includes the Determine HIV Early Detect, a 4th-generation HIV rapid diagnostic test (RDT) that detects both p24 antigen and HIV antibodies. Countries considering adoption of this panel should weigh both its potential advantages and key implementation considerations as part of product selection.

A. What is a 4th-generation HIV RDT?

Fourth-generation HIV RDTs are designed to detect HIV infection earlier than standard antibody-only (3rd-generation) tests by also detecting p24 antigen — a marker present during the acute phase of infection before antibodies develop. This could allow for earlier diagnosis during the short window between infection and antibody response with a highly sensitive test.

B. What does the evidence say?

The available evidence highlights both the strengths of the antibody component and important considerations related to the antigen component in real-world use:

- **Strong antibody detection performance.** The antibody component of the Determine HIV Early Detect performs comparably to high-quality 3rd-generation RDTs, with 100% sensitivity and 99% specificity based on WHO prequalification data. This antibody performance is the basis for the product's WHO PQ status.
- **Narrow window for antigen-only detection.** The period during which p24 antigen is detectable is relatively short, and only two weeks earlier than a 3rd generation test[1], however in many sub-Saharan African settings, the average time from infection to diagnosis is ~2.5 years[2]. Given this, population-level improvements in screening due to antigen detection may be limited in routine ANC testing contexts
- **Implications for discordant results.** In cases where antigen is detected in the absence of antibodies, results cannot be confirmed using standard HIV testing algorithms. This would require repeat testing or additional confirmatory testing, depending on national guidelines and available laboratory capacity.
- **Evolving evidence on programmatic value.** Recent systematic reviews (preprint) synthesizing available data across multiple settings confirm strong antibody performance but highlight mixed evidence on whether the addition of antigen detection translates into meaningful incremental benefit in routine use. Reported sensitivity

1 Cohen MS et al. The Detection of Acute HIV Infection. *Journal of Infectious Diseases*. 2010;202(S2)
2 Giguère, K., Eaton, J. W., Marsh, K., Johnson, L. F., Johnson, C. C., Ehui, E., … Maheu-Giroux, M. (2021). Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000–20: A modelling study using survey and HIV testing programme data. The Lancet HIV, 8(5), e284–e293. https://doi.org/10.1016/S2352-3018(20)30315-5

for acute infection varies by specimen type and population, with generally lower performance observed in fingerstick or whole blood samples commonly used in ANC settings.

Study	Scope	Key findings	Link
Should Ag/Ab RDTs be used to detect acute HIV infection? (2025)	All Ag/Ab RDTs — 53 studies across 24 countries	Pooled sensitivity for acute HIV infection: 48% overall; 33–35% with fingerstick/whole blood (standard in ANC); 25% among PrEP users. Concluded Ag/Ab RDTs miss more than half of acute cases and evidence does not support prioritizing over antibody-only alternatives	medRxiv preprint
Should WHO-prequalified 4th-generation Ag/Ab RDTs be used to detect acute HIV infection? (2026)	WHO-prequalified 4th-generation products specifically — 31 studies from 19 countries	Higher p24 antigen sensitivity reported than the 2025 review: pooled sensitivity of 74–77% specifically in plasma and serum specimens among cases with high viraemia (≥1,000,000 copies/mL) whereas a 52% sensitivity was reported across all samples without a VL cut-off. P Pooled sensitivity is 62% in three studies amongst risk populations.	medRxiv preprint

C. Programmatic considerations for adopting a triple test platform containing 4th-generation HIV testing

Countries considering triple test formats that include 4th generation HIV testing should assess how test features align with national priorities, health system capacity, and implementation context:

- Current algorithms do not account for p24 antigen RDT result which may impact or require change to results interpretation, operational workflow, and/or clinical decision-making.

- **Considerations related to the 4th-generation HIV component.** Incorporating antigen detection may introduce additional considerations for training, counselling, and management of discordant results, particularly in settings with limited access to confirmatory testing. At the same time, its potential value will depend on country-specific epidemiology, testing patterns, and program priorities.

- **Integrated triple testing as a key advantage**. The panel enables simultaneous screening for HIV, syphilis, and hepatitis B in a single test, which can streamline ANC workflows, reduce missed testing opportunities, and support more integrated service delivery.