Adopting low-cost, quality-assured HIV tests to sustain access to life-saving services

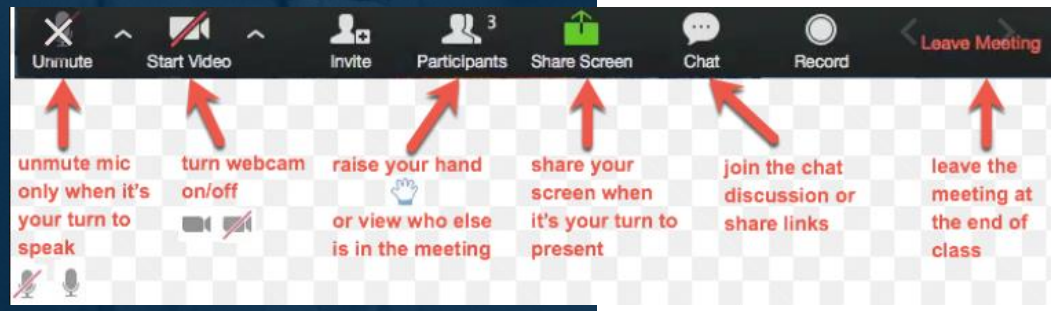
Adapting HIV testing services in the context of reduced and declining funding

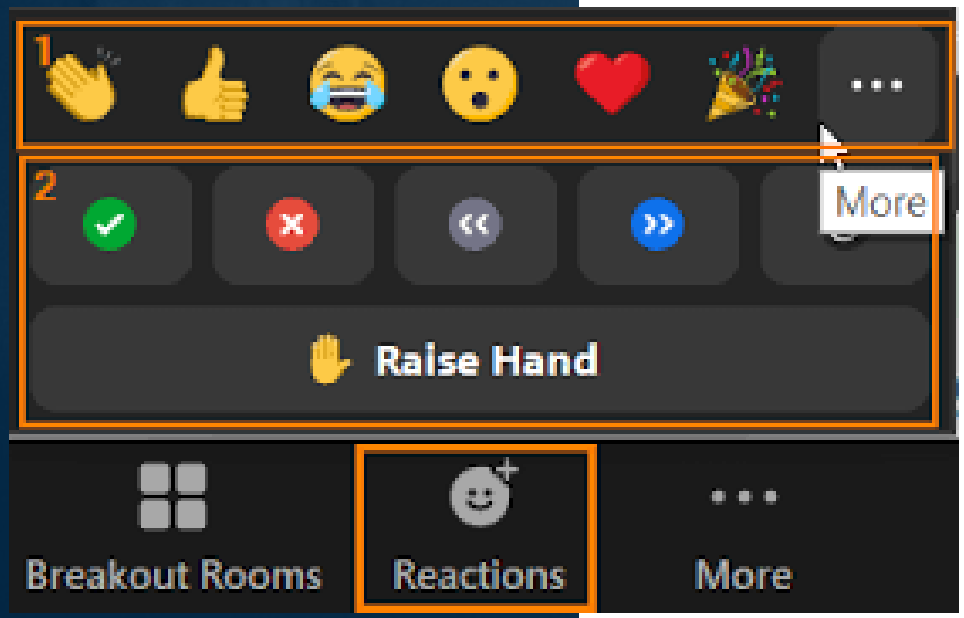
12 May 2025

Busi Msimanga, Celine Lastrucci, Cheryl Johnson
WHO/HQ
Global HIV, Hepatitis and STI, TPP

World Health Organization

Housekeeping rules





Introduce yourself

- Say hi in chat and update your name (name, country and affiliation)
- We will record for note keeping and sharing content internally.
- Slides will be shared after webinar.

We want to hear from you – but time is limited

- Ask questions ask in the Q&A or chat – or raise your hand
- Be concise and provide space for others to share and talk
- Stay muted and keep videos off unless presenting and speaking
- No AI bots for notetaking allowed

We are available for further follow-up

- Busi Msimang: msimangaradebeb@who.int
- Celine Lastrucci: lastruccic@who.int

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Webinar objectives

1. Provide update on some key opportunities for countries on cost-savings for HIV testing in response to reduced funding

2. Position countries to meet the moment and steps to accelerate strategic testing adaptations

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Today's programme

		Moderator: Aliza Monroe-Wise (WHO)
12:30 - 12:35	**Welcome Remarks**	Moderator: Aliza Monroe-Wise
12:35 – 12:55	**Prioritizing high quality low-cost diagnostics for impact and efficiencies**	Busi Msimang and Celine Lastrucci (WHO)
12:55 – 13:05	**Supporting countries towards faster and easier access to the low-cost HIV testing commodities**	Boniface Dongmo (WHO)
13:05 – 13:15	**Remarks from WHO prequalification team**	Susie Braniff (WHO- PQ)
13:15 – 13:30	**Remarks from Global Fund**	Marian Honu & Shaun McGovern (Global Fund)
13:30– 13:40	**Sharing country expériences: Pakistan and South Africa**	Rab Nawaz Samo (Pakistan) Nthabiseng Khoza (South Africa)
13:40– 13: 55	**Q &A**	Celine Lastrucci
13:55 – 14: 00	**Key messages and closing**	Aliza Monroe-Wise

Presentation outline

1. Recap of policy shifts in HIV funding
2. Quick review of key HIV testing guidance to date
3. Present key opportunities for savings for HIV testing
   - Low-cost HIV test kits and commodities
   - HIVST and reduced personnel
   - Introduce prioritization opportunities and forthcoming WHO implementation guidance

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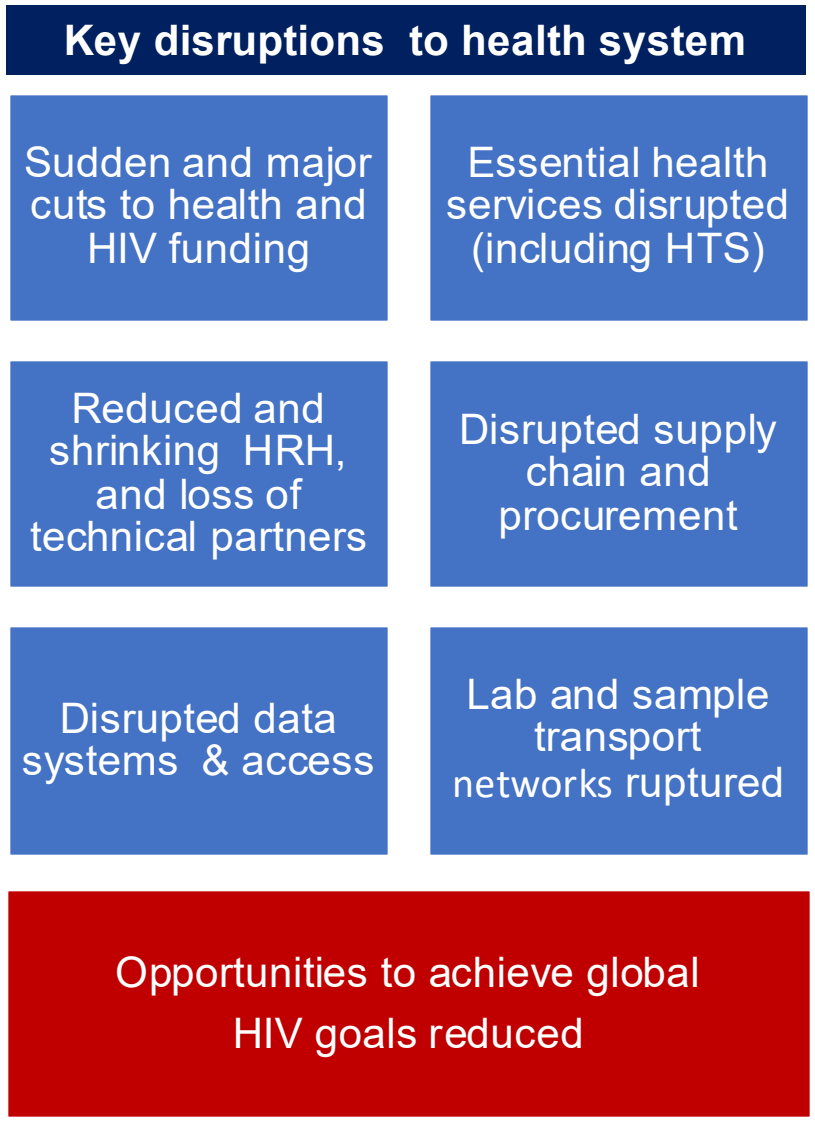
Reduced funding and policy shifts impact HIV services



Key findings from WHO rapid country assessments post policy and funding shifts:

- Substantial programme disruptions, but variable by country and region
- Many adopting '*integration of HIV into PHC*'
- Focusing adaptations to maintain ART for PLHIV
- Other areas such as **HIV testing and prevention** under review and/or being deprioritized
- Finding cost-savings is essential

It is critical to meet the moment and provide strategic insight and guidance

- Webinar focuses on some strategic adaptations for HIV testing services
- **More webinars and content coming**

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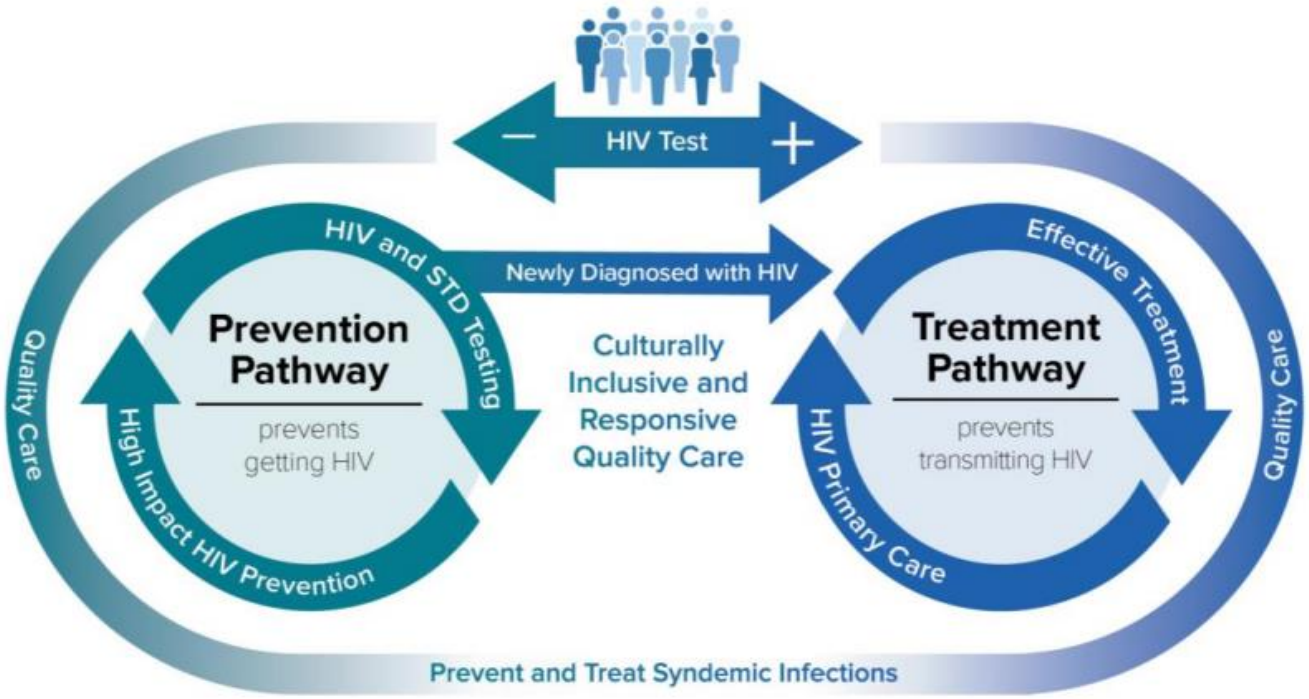
Guiding principles for HIV testing services



Critical since 1985, **Critical** today

WHO HTS 5Cs:

- Consent
- Confidentiality
- Counselling (education & information)
- Connection (linkage)
- Correct results

HIV testing is an essential gateway to prevention and treatment

Source: CDC, PEPFAR, WHO, IAS, BMGF, 2022

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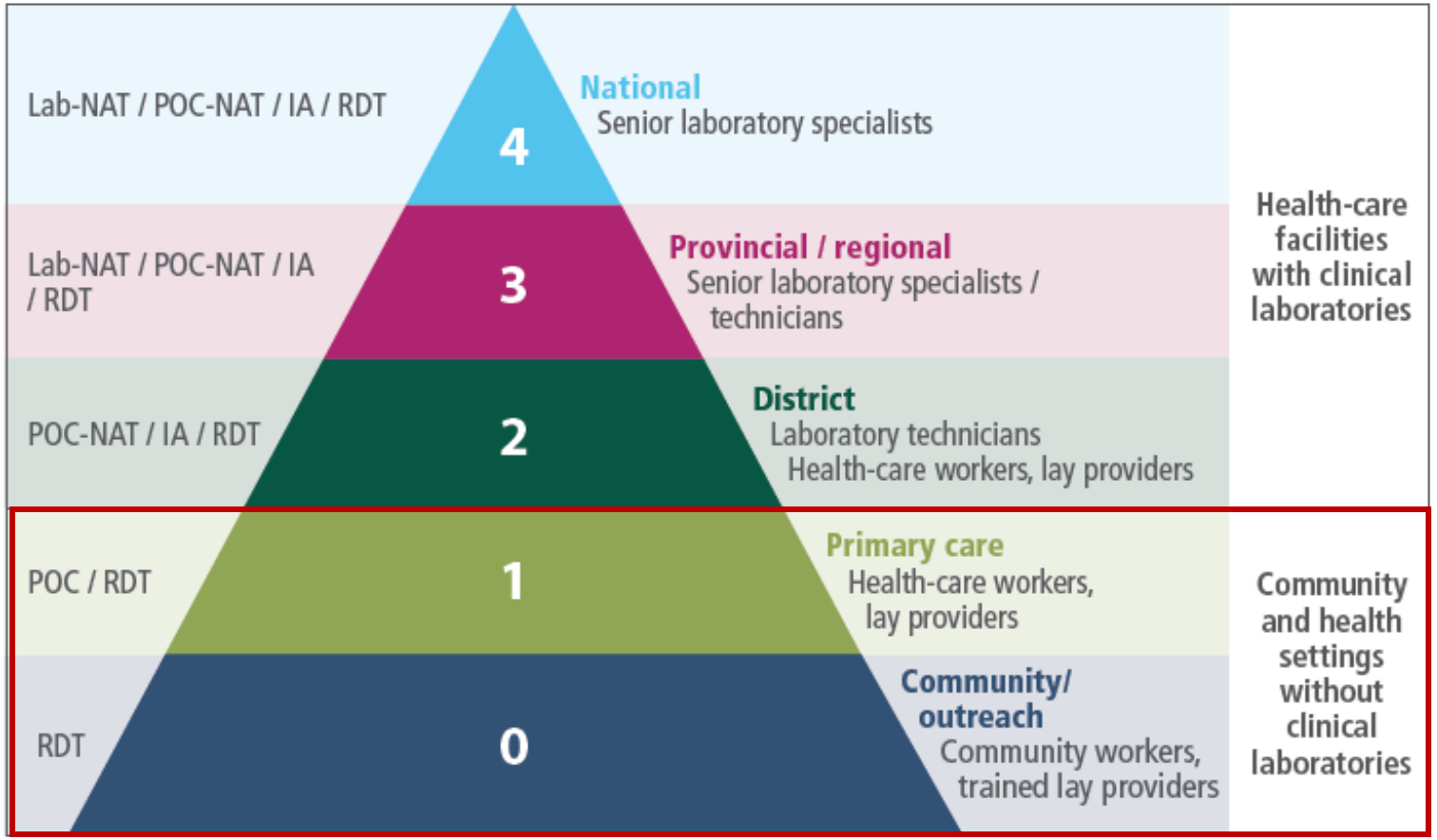
Rapid tests are the most common HIV tests



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.

+95% of all HIV testing worldwide is done at level 0 or 1 (health centres & community) with rapid tests

Self-testing growing here, 100+ country policies

Source: WHO, 2024: https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf

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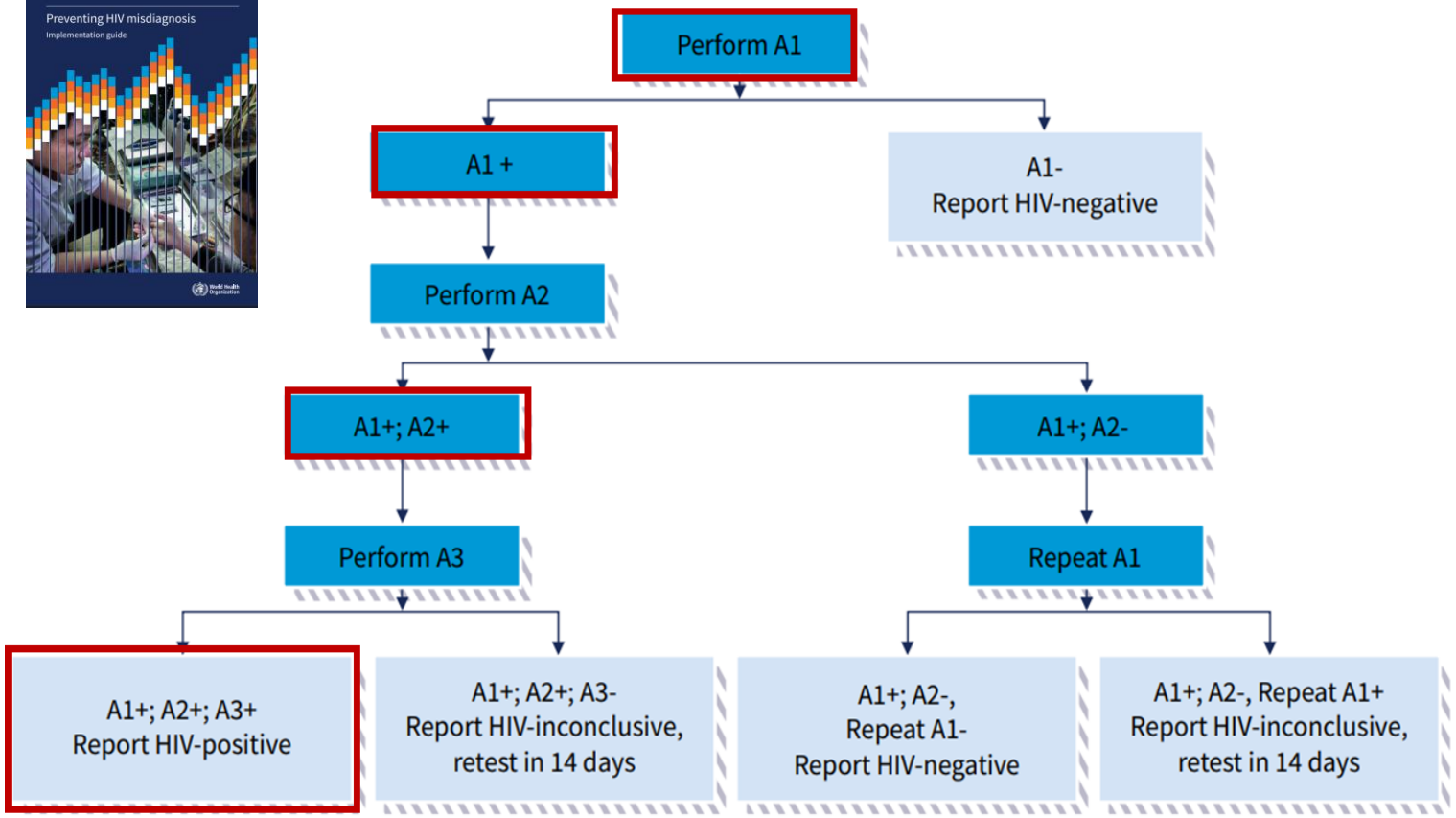
WHO recommendations for accurate diagnosis (>18 months)



A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test).

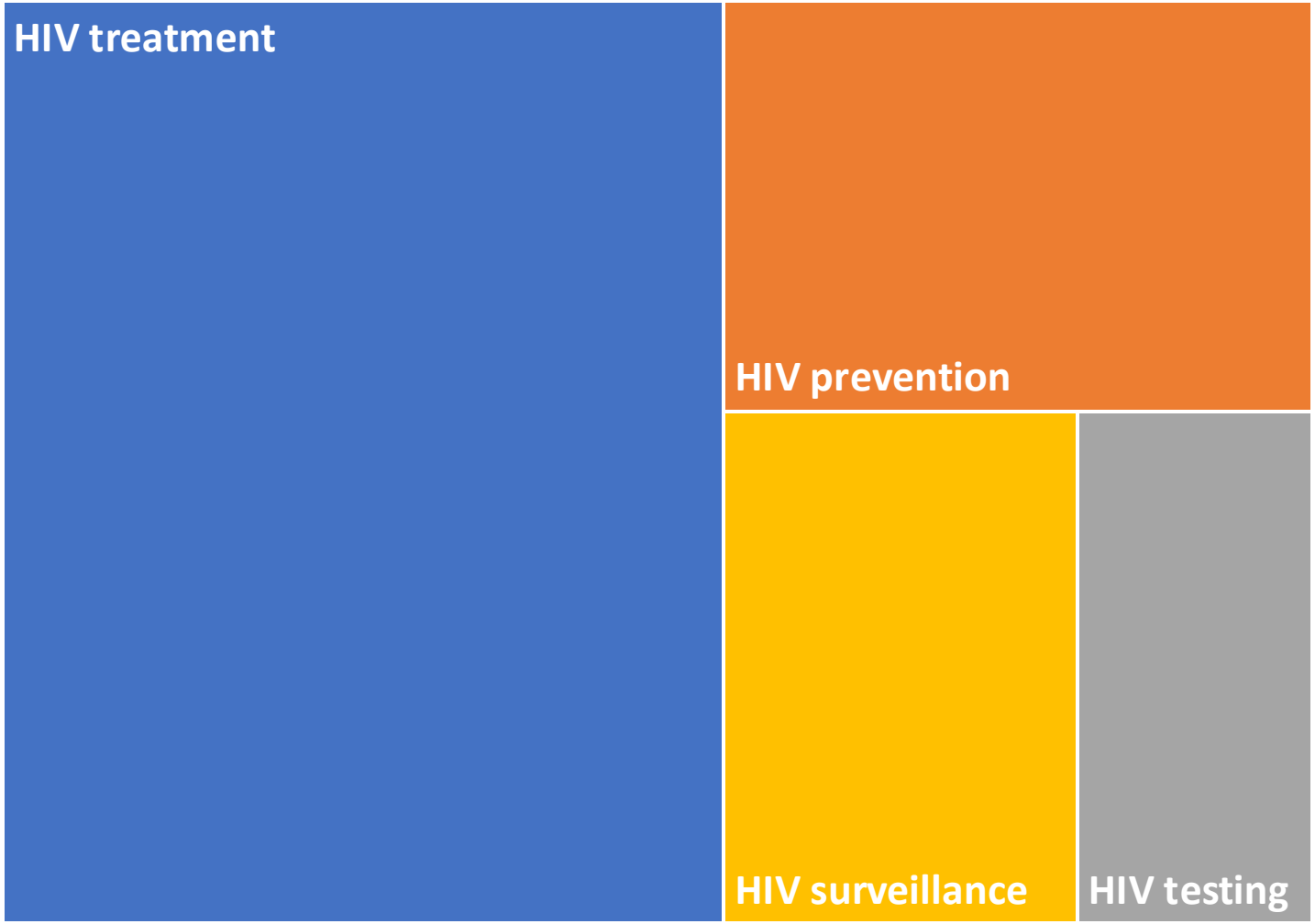
- WHO recommends simple and affordable 3-test strategy to ensure accurate diagnosis for all
- Quality **rapid tests**: affordable and enable same day diagnosis and ART
- Misdiagnosis, esp false positive diagnosis, is costly & difficult to resolve once ART is started
- Simple quality management systems (QMS) remain important
- Costs of life-long ART costs far exceed those of accurate testing

WHO recommends serology (RDT/EIA) tests for diagnosis and does not recommend routine HIV testing using recency, WB/IB, NAT (RNA or DNA). (reserve NAT for early infant diagnosis (EID) and clinical management of PLHIV)

**This guidance and messaging is focused on testing for those >18 months of age and who receive serology testing through rapid tests or enzyme immunoassays*

Source: WHO 2024, https://iris.who.int/bitstream/handle/10665/379478/9789240092136-eng.pdf; WHO 2019; Eaton 2019; Eaton 2017

Understanding HIV programme costs



HIV testing is generally <10% of previous national HIV budgets*

Testing is *'small, but mighty'* service that **enables access to**:

- life-saving treatment
- high impact prevention
- simple and routine surveillance

Illustrative figure based on data and reporting from UNAIDS 2022; *5-7% of budgets in many African countries due to wide-scale RDT use

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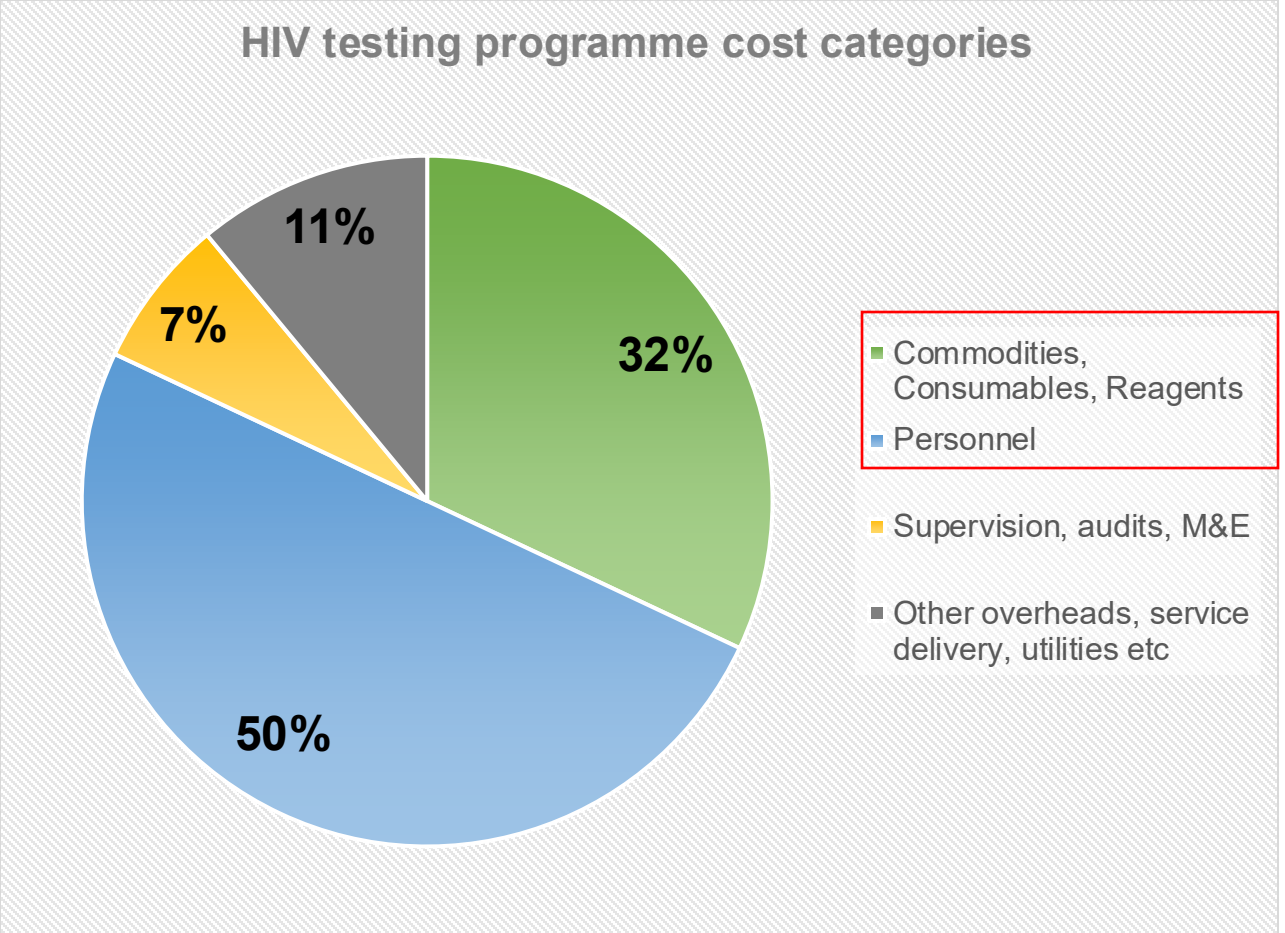
Understanding HIV testing costs



+1 billion HIV RDTs were procured in 101 LMICs 2015-2023.

18% increase in HIV RDTs procured from 2021 to 2023*.

Main HIV testing costs are personnel (**testers**) and commodities (**test kits**)

Focusing on these two areas is a strategic way to cut costs

**This represents much of large procurers and donor resources not direct procurement figures from EIC/WHO report 2024.*

Graph is illustrative and adapted from Vyas et al 2020 https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-05446-5

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Strategic opportunity for cost-savings

#1. Shifting to low-cost HIV test kits and commodities

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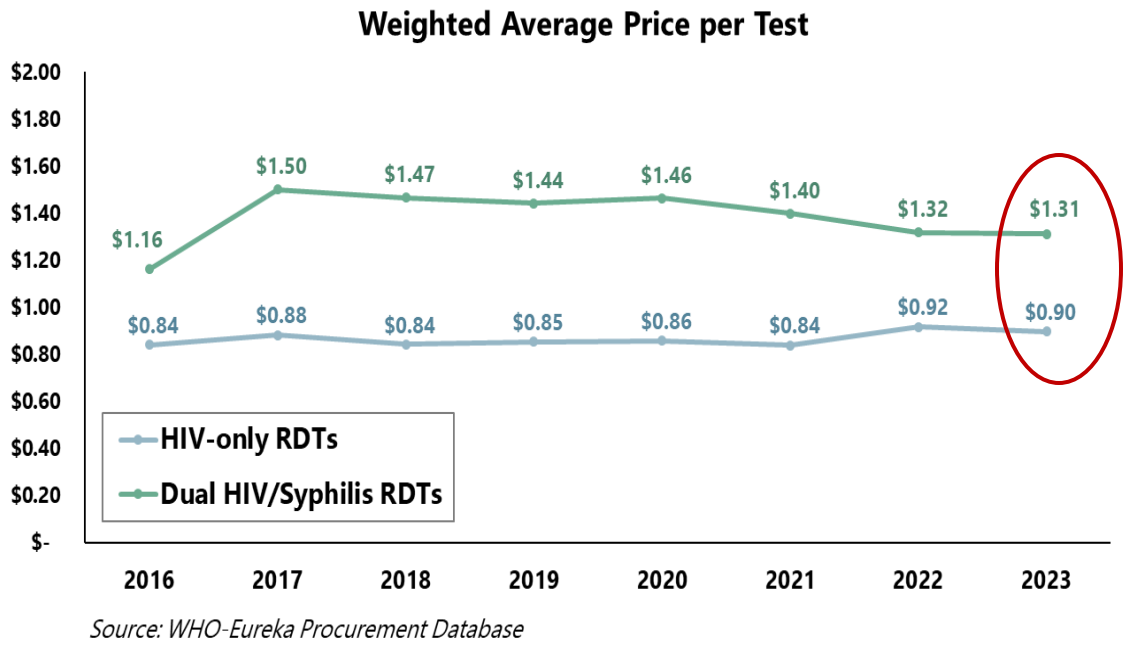
Average weighted price of HIV tests remains high, yet low-cost quality-assured options are available



Source: WHO-Eureka Procurement Database

Average weighted price of HIV tests:

- HIV RDT: $0,90
- HIV/syphilis RDT: $1,31
- HIVST: $2,00

Yet, lower cost quality-assured tests exist

Current opportunities in the WHO catalogue

- **HIV RDT:** +21 PQ'ed ($0,53-$2,79)
  - 5 manufacturers have tests **<$0,70-0,75** (**Premier, Meril, SD Biosensor, Abon** and **Trinity**)
  - 4 manufacturers have tests **<$0,70** (**Wantai, Wondfo, KHB** and **InTec**)
  - All with A1 characteristics
- **HIV/Syph RDT**: 3 PQ'ed ($0,90-$0,95)
  - **SD Bionsensor, Abbott (SD Bioline)** and **Premier**
- **HIVST**: 7 PQ'ed ($1-$3,29)
  - 2 manufacturers have tests **<$1,50** (**Wondfo** and **Abbott)**

**Note price information includes cost of accessories per WHO sources and catalogue as of 5 May 2025*
Reference information: EIC/WHO 2024, WHO catalogue 2025; WHO tool kit 2021; Global Fund 2025

***Abon – owned by Abbott*
*** SD Bioline – subsidiary of Abbott*

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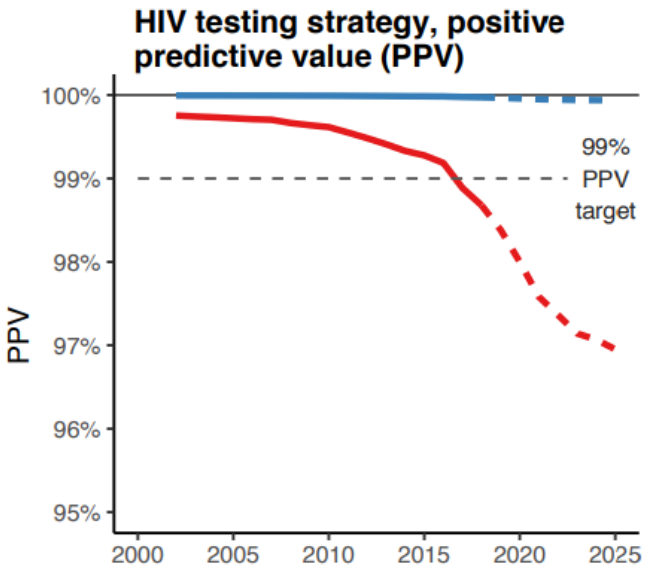
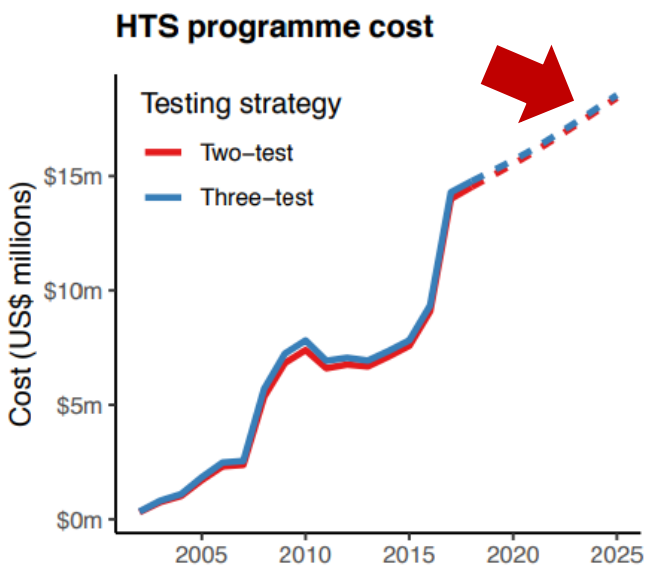
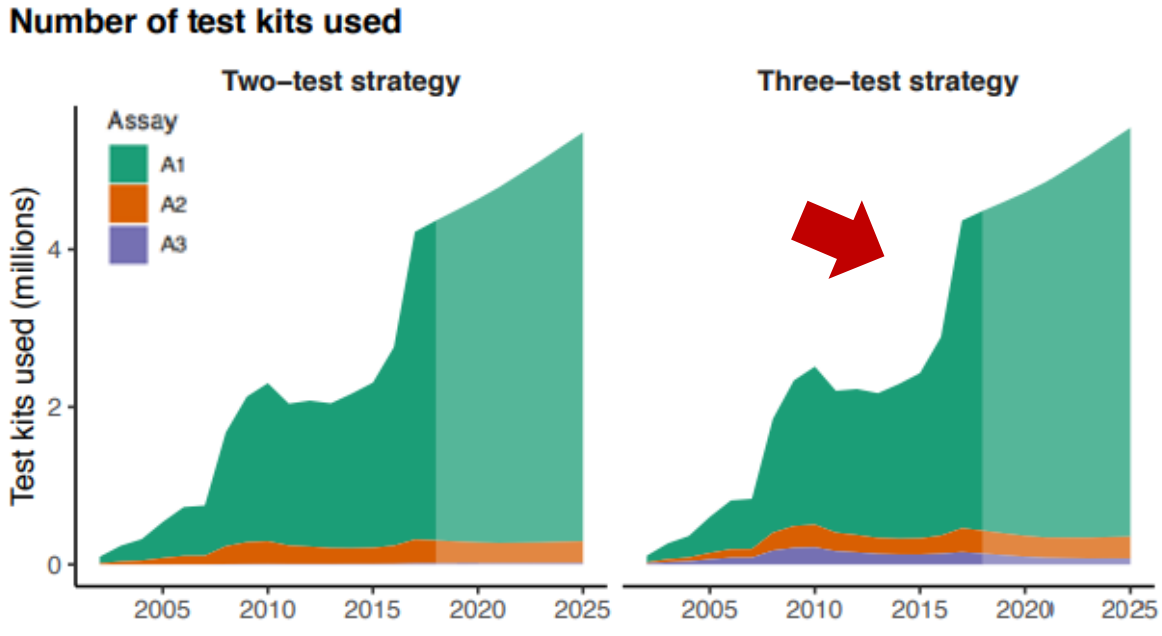
Focusing on adopting a low-cost first test (A1) in algorithm will have greatest impact on savings







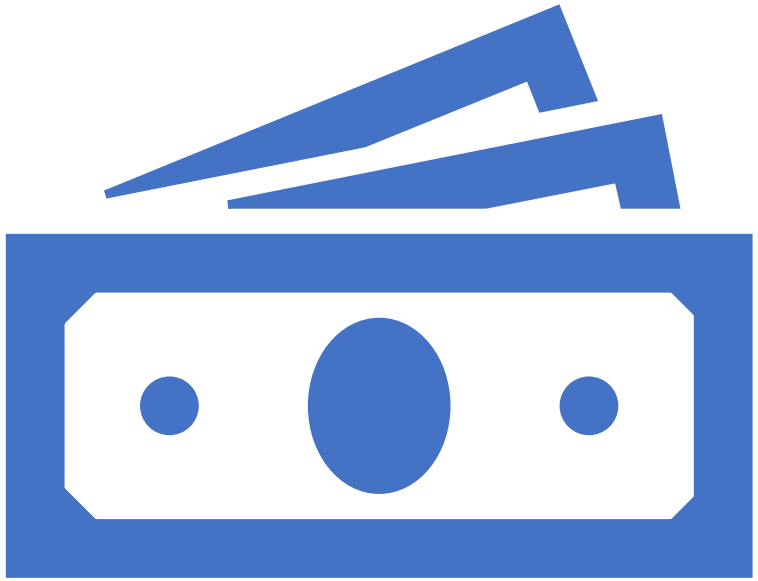
3-test strategy remains best buy

- Removing 3rd test does not lead to sufficient savings (cost virtually the same)
- Avoiding misdiagnosis and cost of unnecessary lifelong ART remains critical for countries

Strategic savings by focusing on first test

- Cost of the first test drives HIV testing programme costs
- Changing to low-cost delivery and test kits (A1) will lead to greatest saving

Example of savings:
HIV testing for 5 million people annually



Status quo A1 HIV RDT

- $0.90 costs US$4,5 million

Low-cost A1 HIV RDT

- $0.53* costs US$2.65 million

Savings gained

- US$1.85 million savings
- 41% instant decrease in annual costs

Could be used to maintain testing coverage and reinvest in lifesaving services

*: *lowest cost RDTs with accessories as per May 2025 WHO catalogue*

Note this is a simplified and illustrative example based on costs in previous slides

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NextGen Market Shaping Strategic Initiative Overview

WHO already working to address challenges with improving HIV testing algorithms and adopting low-cost quality-assured products

1 **Title**

2 Heterogeneity of false reactivity profiles of HIV assays while optimizing national HIV
3 testing algorithms: findings from a multi-country analysis.

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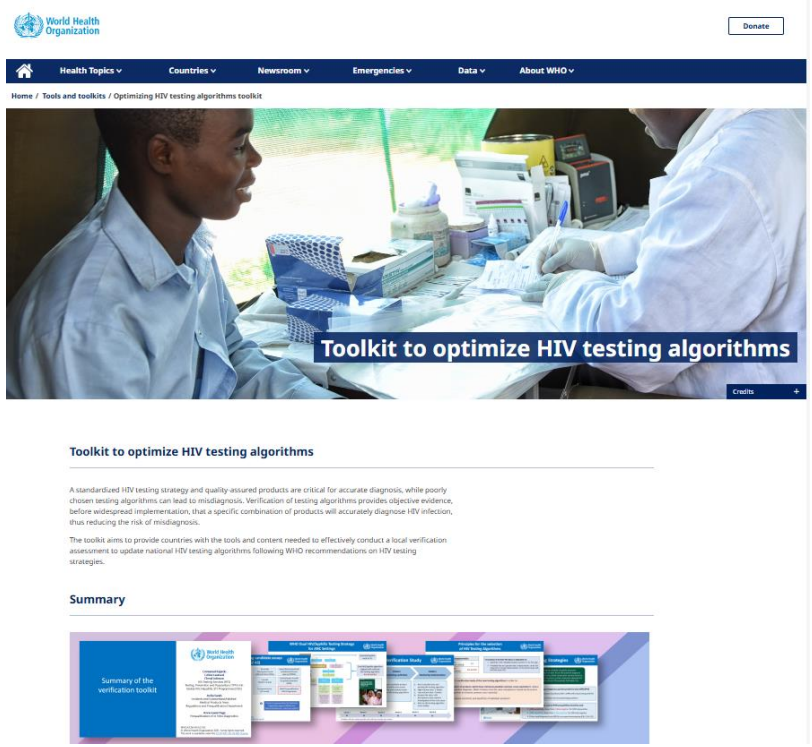
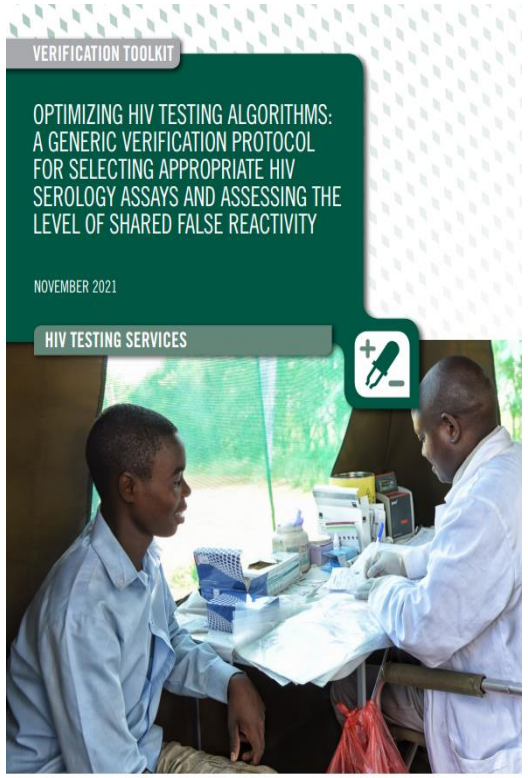


Source: Accrombessi et al 2025: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5068987; WHO/Global Fund 2025; WHO 2020; WHO 2023

What are WHO verification studies?



- **Operational path to adopt WHO recommendations through a rapid assessment of tests to be included in national algorithm**
  - **Simpler and quicker:** negative samples only and practical sample size – more streamlined than lengthy accuracy studies of individual tests
  - **Complementary:** leverages (and does not duplicate) performance evaluations, eliminates risk of shared false reactivity (which leads to misdiagnosis)
  - Quickly **increases flexibility** and potential opportunities for **interchangeability**
- **Key adaptations for 2025**
  - Complete verification study and collect data **in parallel or after** new algorithm selected and implementation started
  - Evaluate **several low-cost A1** options while maintaining existing **A2/A3**
  - Adopt and roll-out streamlined **training and simplified QMS activities**
- **WHO already supporting many countries**
  - **Affordable and co-funding available** in many countries, especially when switching to low-cost tests
  - **Increased HQ, and partner, support available** along with ongoing efforts to **mobilize resources**

Source: WHO 2021, https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkit

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Simple WHO quality management systems (QMS) testing tool kit

WHO's QMS toolkit for non-lab settings*
- Simple, multi-disease tools - essential activities where QMS is donor-funded (e.g. RTCQI+)
- Continue to prioritize pushing industry to cover more QA/QC and training costs

WHO QMS tool kit coming end-May 2025

Optimized and sustainable QMS priorities

Decentralize tasks
- Local simplified + streamlined training + competency-based assessments (eg: by site supervisor)
- Regional/district lab staff conduct annual site visits (site prioritization)

Simplify documentation
- Update SOPs and aids annually or when tests change

Simplified or periodic testing prior to ART initiation or deprioritize
- Single RDT (not full algorithm before ART), periodic instead of routine, and/or only low performing sites/testers
- Deprioritize if not feasible or no funds

External quality assessment (EQA)/PT scheme
- Frequency: 1x per tester, 1x per year
- Use ISO-certified, or local dried tube specimens (DTS), or blinded site samples

External quality control/use of known positive and negative samples (QC)
- Frequency: new batches, new staff, or following test exposure to environmental conditions
- Use commercial sample or local DTS or site-characterized and stored samples

- M&E: collect testing data, core indicators on-site analysis (Number of tests, %pos, %invalid, % inconclusive)
- Occurrence management and PMS: in case of unexpected results, conduct root cause analysis and action PMS

**Tool kit was developed over 18-months with internal and external experts and was an official project of the WHO Dx Task Force to strengthen Dx capacity.*

WHO strategy for rapid algorithm change for impact

1 **Immediately update national HIV testing algorithms and policies**

- **Adopt new lower cost A1** (first test in algorithm) within WHO recommended 3-test strategy
- **Keep existing A2/A3** (second and third tests) to ease country transition
- **Place orders as soon as possible** with prices at or below those in WHO catalogue, pooled procurement and Wambo or if lower cost available via direct procurement agreements
- **Employ country waivers for WHO PQ products** to provide immediate access to products (work on local registration in parallel or shortly after introduction)
- **Collect data in parallel or after algorithm transition** per WHO toolkit with low-cost candidate products (this will ensure competition, flexibility and help achieve lower price points in longer-term)
- **Adopt streamlined training & QMS activities** and work on industry funding for QA/QC and training

2 **Additional HIV testing commodity adaptations for savings**

- Only use **serial testing algorithm** with HIV RDTs or EIA (stop parallel testing, which is more expensive)
- **Discontinue use of recency assays, NAT (RNA or DNA), WB/LIA for routine HIV testing and diagnosis** (>18 months of age) **and question Ag/Ab RDT**
- **Switch to lower cost quality-assured HIVST option (≤ $1.50)**
- As countries with partners to drive prices down further (e.g. set-up coordinated procurement across countries, data and tool sharing, flexible algorithms)

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Strategic opportunity for cost-savings

#2. Shifting to HIV self-testing and adapting to fewer testing staff

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Prior to funding cuts, HRH was limited

Global health reporting has been showing challenges with growing gaps in human resources for health (HRH)

Policy shifts and reductions in funding have exacerbated these gaps

Reports indicate some HIV testing cadres have been frozen, unpaid or are in process of being eliminated

Multiple countries, particularly in east and southern Africa, report HIV testing is down ≥30%

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HIV self-testing (HIVST) - a critical approach and adaptation

HIVST could lead to savings if replacing provider testing

- WHO recommends facility-based self-testing (2024)
- HIVST filled important gaps during COVID-19, especially in facilities
- HIVST provides flexibility – enables triage model
- HIVST can fill gaps in work force and save health worker time

Additional adaptations can further enhance savings

- Continue task-sharing testing wherever incomplete
- Revamp delivery to include pay for virtual services, convenience models, private sector, workplace, and pharmacy for population segments and settings where feasible

Source: WHO 2024, WHO 2021, WHO 2023, WHO 2015

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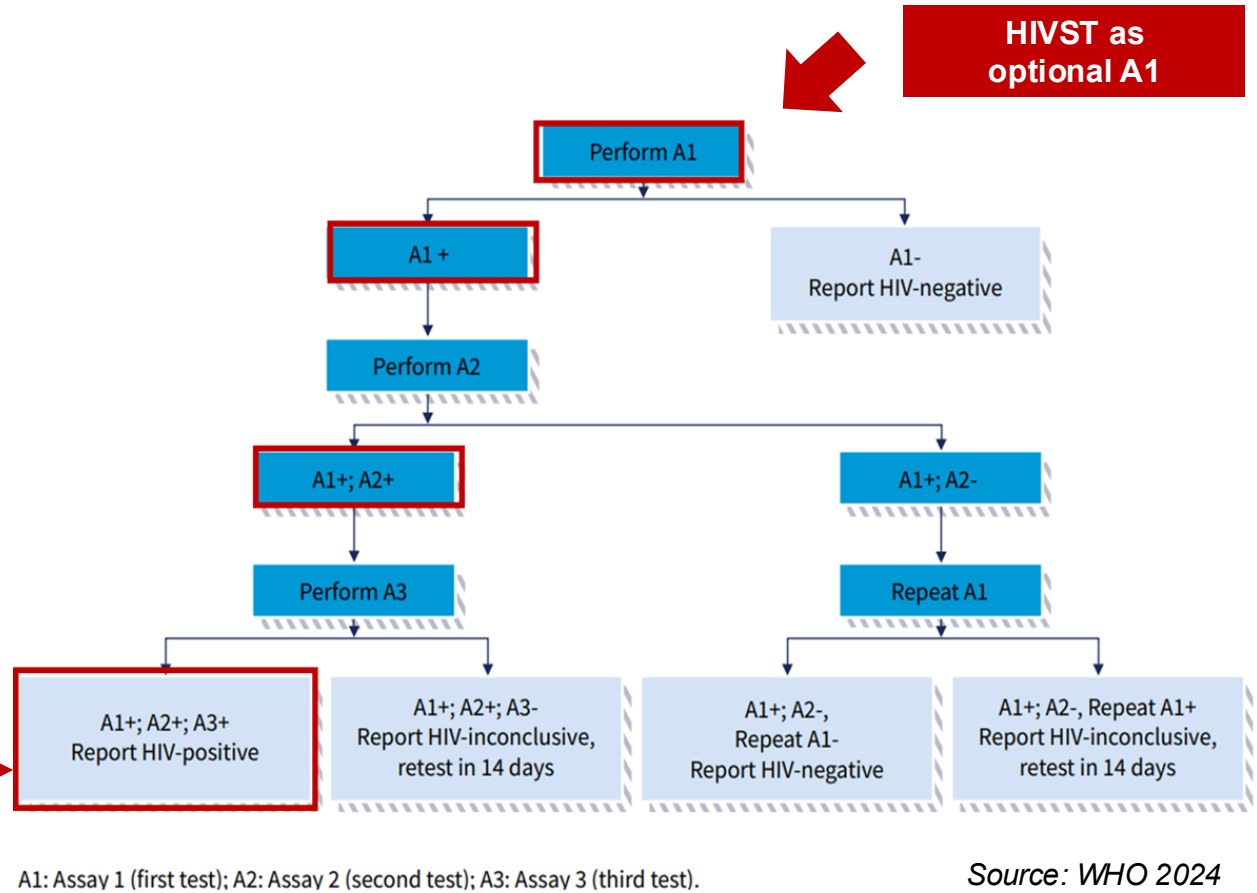
Countries already using HIVST to address ongoing disruptions

HIVST is recommended as a "test for triage"

- Countries need flexibilities now due to limited HRH capacity and stock-outs
- When needed (awaiting stock) use HIVST as A1
- Prioritize quality-assured HIVST kits
- Prioritize confirming all reactive self-test results with available A2 and A3 (per WHO 3-test strategy)
- Do not start ART based on a single reactive test
  - Substantial risk of misdiagnosis and unnecessary ART initiation

Adapted HIV testing strategy implementation considerations



A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test).

Source: WHO 2024

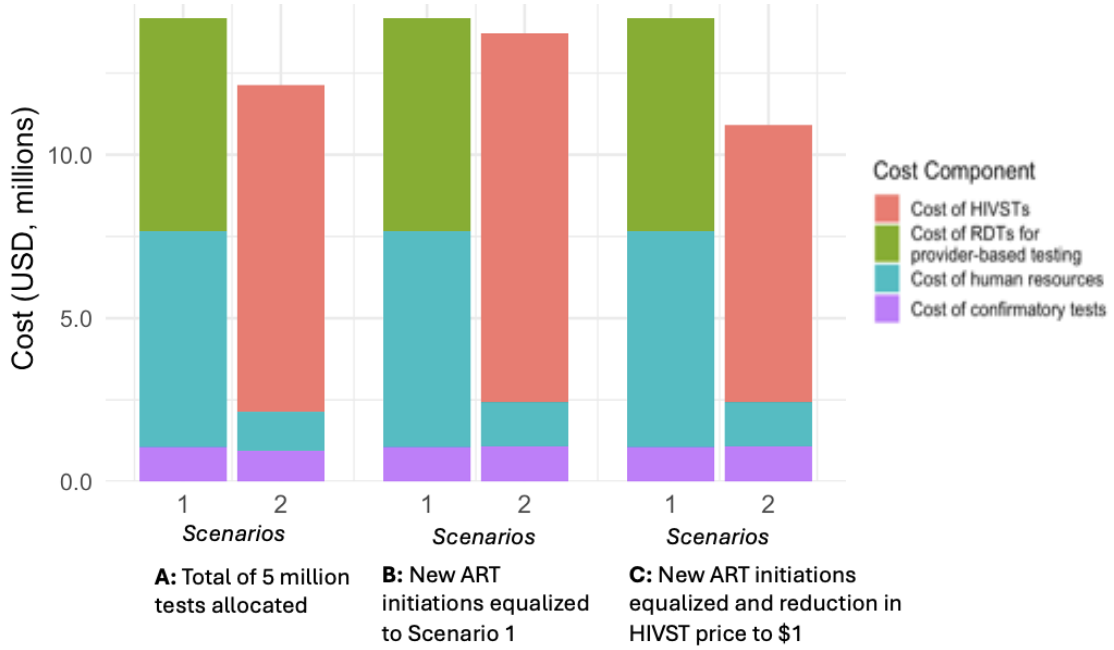
WHO already recommends facility-based HIV self-testing, expanded use could lead to more savings

Modelling on the cost-effectiveness of using HIVST in facilities to fill HRH gaps shows:

- **At least 15% cost-saving – up to 23% savings if using $1 WHO PQ HIVST**
- **Up to 85% reduction in staff-time**
- **If considering local economic impact (putting $$ toward jobs versus commodities)**
  - Return of investment (ROI) is the same at $1.50 but is favorable with high ROI at $1
- **Cost of change and scale-up?**
  - Costs still 1.5–3.0% lower, and total staff-time for testing still falls by 40% and 80% respectively, when considering scale-up costs

Preliminary results

Total cost, by component, of HIVST vs provider-testing scenarios



Country-facing calculator in development for local planning for optimal savings for HRH and HIVST

Source: WHO 2024, Nichols, Edun, Imai-Eaton, Bernsteyn, Johnson 2025 in preparation; for copy of the country calculator that is in beta-testing email johnsonc@who.int

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Key WHO actions on HIV testing commodities

💰 **Cut costs without cutting quality**

- Stick to the 3-test strategy to avoid misdiagnosis and unnecessary treatment.
- Discontinue other complex and costly testing practices and products (e.g. use simple RDT)
- Focus on adopting lower cost tests: HIV RDTs: ≤ $0.70, Dual HIV/syphilis RDTs: ≤ $0.95, HIV self-tests (HIVST): ≤ $1.50

🚀 **Support rapid country transition**

- Focus on switching out A1 for greatest and most immediate savings
- Use policy waivers to accelerate importation and implementation
- Push industry to fund training and QA/QC in new agreements and tenders.

🤝 **Coordinate for bigger impact in longer-term**

- Share data and experiences with WHO to inform updates to operational guidance
- Work with key partners to increase access to low-cost HIV tests

Key WHO actions on HIVST to address gaps

🤝 **Support flexibility to maintain testing services**

- Support policies that include the use of HIVST to avoid additional disruption
- Highlight benefits of HIVST: it's flexible, fills staffing gaps, allows private sector use and worked well as critical adaptation during COVID-19

💰 **Optimize resources to maintain testing services**

- Review staffing plans and HIVST data to find right balance based on country needs and gaps due to reduced personnel and testers
- Review and use WHO country calculator (for details contact johnsonc@who.int)
- Share HIVST data with WHO to help update guidance

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More WHO guidance soon

HTS adaptations

Optimized delivery

- Task sharing & self-testing
- Simple integrated testing models
- Focused facilities
- Virtual interventions & AI
- Pharmacy & private sector

Streamlined retesting

- Stop general “window period” testing
- Optimizing re-testing (avoid over-testing in KPs and pregnant women)
- Simplified testing and/or self-testing for PEP/PrEP
- Annual testing for most key populations

Quality & Accurate

- 3-test strategy
- Simple low-cost tests
- Simple QMS
- Easy and rapid verification studies

Targeted testing

- Simplified & reduced
- Sick & symptomatic clients
- Pregnant women & partners
- Index clients and risk networks
- Geographic prioritization

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WEBINAR SERIES

TEST. ADAPT. DELIVER.
HIV Testing Services in a Shifting Landscape

Navigating change, driving innovation and delivering impact in HIV testing services and beyond.

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HIV testing services are in crisis due to funding reductions, with rapid funding shifts prompting changes and interruptions in service delivery. Ensuring testing services remain accessible is critical to sustaining HIV treatment and prevention outcomes. More than ever, evidence-based guidance is critical to the prioritization, focusing, and planning of services across countries and regions.

This webinar series presents the latest evidence-based innovations, tools, and guidance in HIV testing services. It features experts sharing global guidance, country implementation experiences, practical toolkits, and strategies for maintaining quality and access in a rapidly evolving landscape. Topics include HIV testing in pregnancy, virtual-space interventions, self-testing, network-based approaches, and testing in prevention. Whether a policymaker, implementer, or researcher, this series offers valuable insights to strengthen HIV responses worldwide.

Each session will be conducted with simultaneous interpretation in English and in French.

DATE & TIME	SESSION
May 12, 2025 12:30 pm - 2 pm CAT/CET	**Prioritizing High-Quality, Low-Cost Diagnostics to Sustain HIV Testing Services**
May 15, 2025 2 pm – 3:30 pm CAT/CET	**Elimination: Maximizing the Impact of HIV Testing for Pregnant and Postpartum Women**
June 12, 2025 2 pm – 3:30 pm CAT/CET	**Operationalizing Facility-Based HIV Self-Testing: Launch of the Implementation Toolkit and Training Modules**
June 26, 2025 2 pm – 3:30 pm CAT/CET	**Launching of Budgeting and Resource Planning Guidance for Implementing Virtual Interventions as Part of HIV Responses**
July 9, 2025 2 pm – 3:30 pm CAT/CET	**Closing the Gaps: Launch of a Network-Based Testing Toolkit to Expand HIV, Hepatitis, and STI Testing Reach**
August 7, 2025 2 pm – 3:30 pm CAT/CET	**Innovating with HIV Self-Testing for Impact in Southern Africa: Lessons Learned from the STAR (Self-Testing Africa) Initiative**
September 4, 2025 2 pm – 3:30 pm CAT/CET	**Supporting PrEP Access: HIV Self-Testing in Uptake and Scale-Up**
October 9, 2025 2 pm – 3:30 pm CAT/CET	**Advancing Testing Quality: Launch of the WHO Management System Toolkit for Non-Laboratory Settings**
November 13, 2025 2 pm – 3:30 pm CAT/CET	**Delivering HIV Testing Services in a Changing Environment: Planning, Prioritization, and Maintaining Access**

For more information about this webinar series, visit our webpage.

Save the date!

- More content available and coming soon
- More WHO webinars on strategic adaptations for efficiency and savings for HIV testing
  - Next webinar is on Thursday **15 May**
  - Register here
- WHO operational guidance coming end-May 2025
- **Need more support?**
  - Connect with the testing team
    - johnsonc@who.int

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Acknowledgements

WHO HQ

Global HIV, Hepatitis, STI - TPP

HTS Team

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Supporting countries towards faster and easier access to the low-cost HIV testing commodities

Strategic opportunities and economic impact for savings on HIV testing commodities

Boniface Dongmo Nguimfack
WHO HQ

World Health Organization

How can WHO and Partners support the process

WHO and Partners can support countries in achieving faster and easier access to **low-cost HIV testing commodities** in several impactful ways:

- **Policy and Regulatory Guidance**
- **Prequalification and Quality Assurance**
- **Technical and Procurement Assistance**
- **Capacity Building and Implementation Support**

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Adopting low-cost, quality-assured HIV tests to sustain access to life-saving services

BRANIFF, Susie Remarks

WHO HQ Prequalifications Unit

World Health Organization

Prequalification of in vitro diagnostics

Dr Susie Braniff
IVD Assessment Team
Prequalification Unit
World Health Organization

World Health Organization

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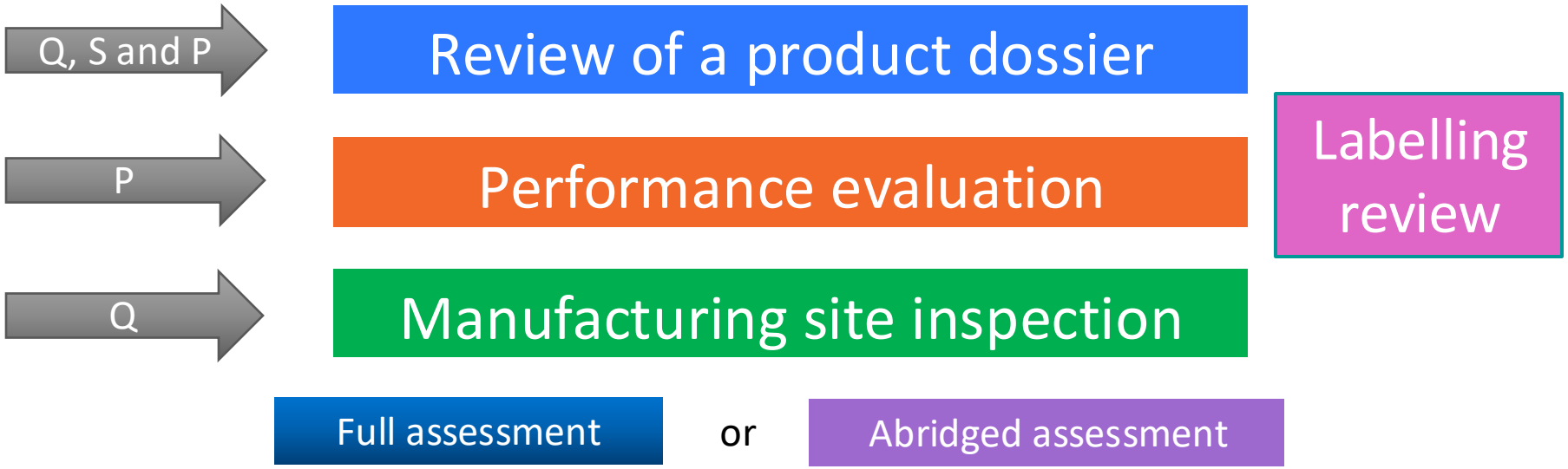
PQ assessment components

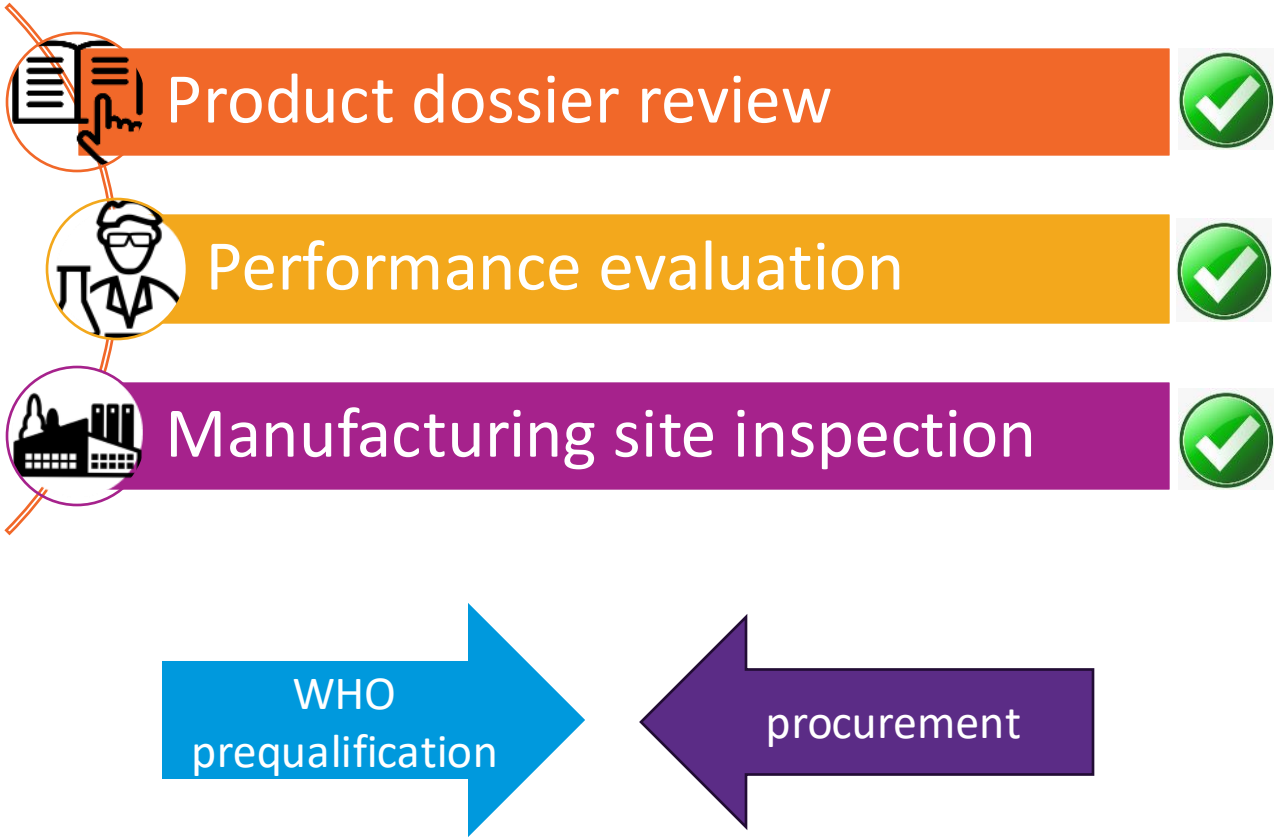
- A comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements
- The prequalification assessment process includes three components:



Prequalification decision

Final prequalification outcome depends on meeting requirements in all assessment components

- The public report prepared
- The product is added to the list of WHO prequalified IVDs
  - IVD is eligible for WHO and UN procurement & CRP
  - IVD is eligible for procurement by organizations relying on PQ listing

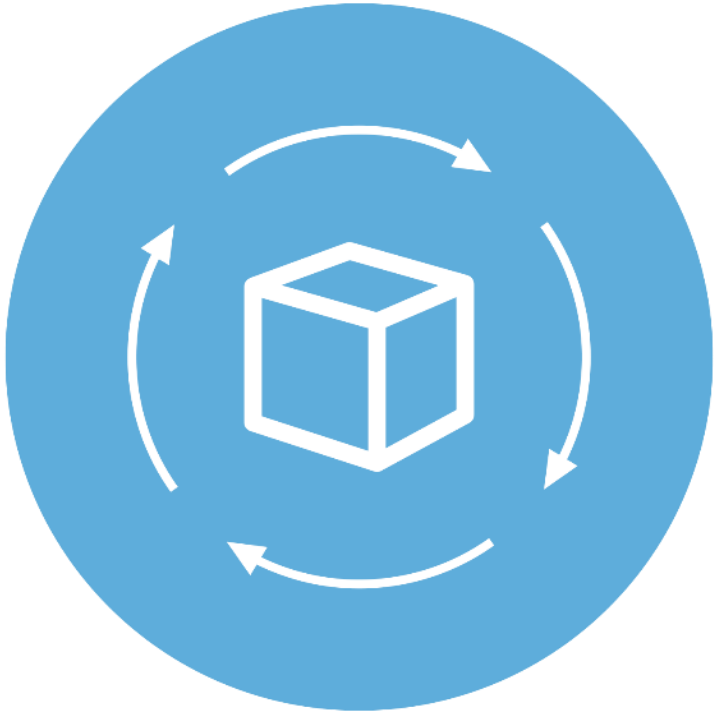


Post-PQ Activities

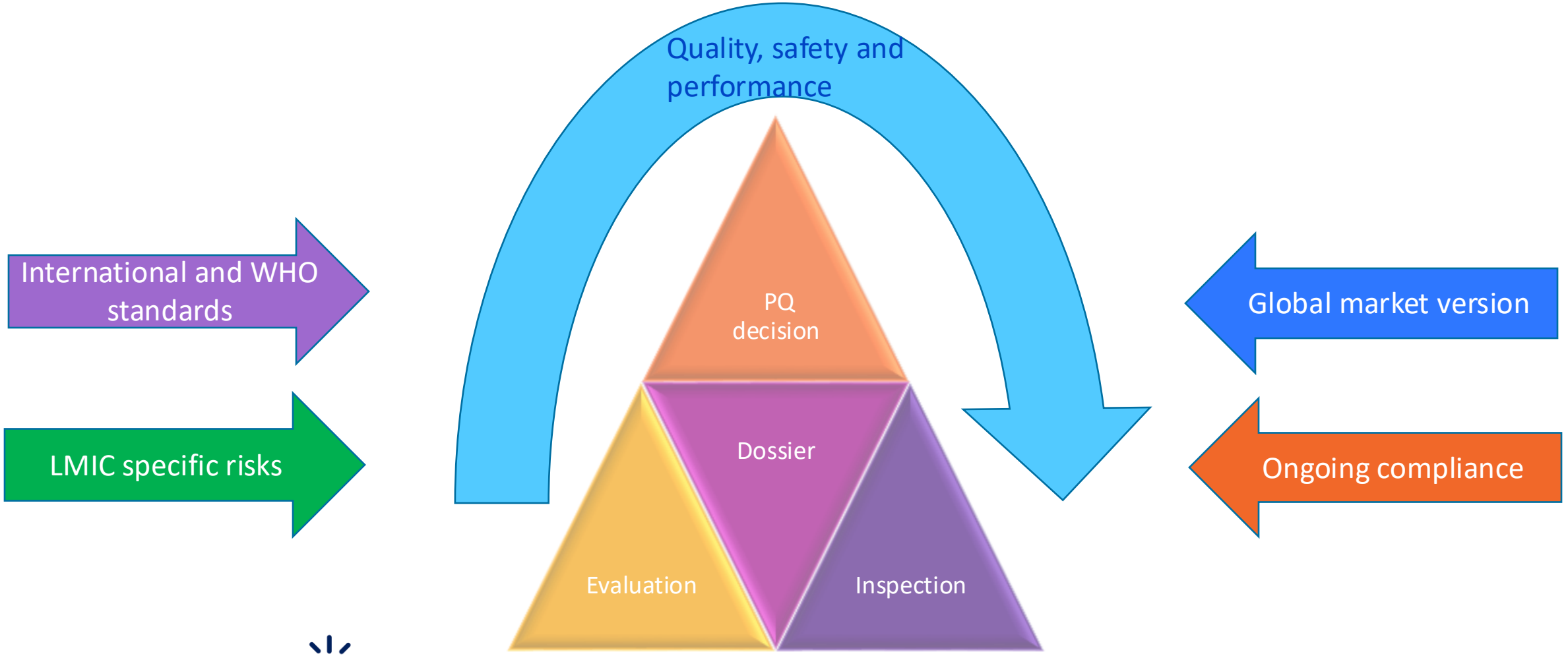
Ongoing requirements to maintain PQ Listing

The manufacturer must comply with:

- Commitments to PQ
- Annual reporting
  - Sales data, complaints, Field Safety Correction Notices
- Change reporting
- Post market surveillance obligations
- Ongoing compliance with TSS
- Routine site inspections



Prequalification assessment in a nutshell



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Prequalified HIV RDTs

- **21** HIV RDTs for professional use
  - 17 different manufacturers
- **7** HIV RDTs for self-testing
  - 7 different manufacturers
- All PQ-ed IVDs meet PQ requirements
- ALL IVDs accepted for PQ assessment meet minimal performance characteristics defined by WHO

WHO PQ-ed HIV RDTs

Product Name	Manufacturer	Intended Users
CheckNOW HIV SELF TEST	Abbott Rapid Diagnostics Jena GmbH (former Alere Technologies GmbH)	Self Testing
HIV SELF TEST BY URINE – Human Immunodeficiency Virus (HIV) type-I urine antibody diagnostic kit (colloidal gold)	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Self Testing
Insti HIV Self Test	bioLytical Laboratories Inc.	Self Testing
Mylan HIV Self Test	Atomo Diagnostics Ltd	Self Testing
Oraquick HIV Self Test	OraSure Technologies, Inc.	Self Testing
Surecheck HIV Self-Test	Chembio Diagnostic Systems, Inc	Self Testing
Wondfo HIV Self-Test	Guangzhou Wondfo Biotech Co., Ltd	Self Testing

WHO Collaborative registration to leverage PQ listing for national registration purposes

Product Name	Manufacturer	Intended Users
ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum /Plasma)	ABON Biopharm (Hangzhou) CO.,LTD	Professional Users
Asante HIV-1/2 Oral Fluid Test	Sedia Biosciences Corporation	Professional Users
Bioline HIV1/2 3.0	Abbott Diagnostics Korea Inc. (Formerly Standard Diagnostics, Inc.)	Professional Users
Determine HIV Early Detect	Abbott Diagnostics Medical Co., Ltd. (Formely "Alere Medical Co. Ltd.")	Professional Users
Determine HIV-1/2	Abbott Diagnostics Medical Co., Ltd. (Formely "Alere Medical Co. Ltd.")	Professional Users
Diagnostic Kit for HIV(1+2) Antibody (Colloidal Gold) V2	Shanghai Kehua Bioengineering Co., Ltd.	Professional Users
DPP HIV 1/2 Assay	Chembio Diagnostic Systems, Inc.	Professional Users
DPP HIV 1/2 Assay (oral fluid)	Chembio Diagnostic Systems, Inc.	Professional Users
First Response HIV 1-2.O Card test Version 2.0	Premier Medical Corporation Private Limited	Professional Users
HIV 1/2 STAT-PAK	Chembio Diagnostic Systems, Inc.	Professional Users
INSTI HIV-1/HIV-2 Antibody Test	bioLytical Laboratories Inc.	Professional Users
MERISCREEN HIV 1-2 WB	Meril Diagnostics Pvt. Ltd.	Professional Users
ONE STEP Anti-HIV (1&2) Test	InTec Products, Inc.	Professional Users
One Step HIV1/2 Whole Blood/Serum/Plasma Test	Guangzhou Wondfo Biotech Co., Ltd	Professional Users
OraQuick HIV 1/2 Rapid Antibody Test	OraSure Technologies, Inc.	Professional Users
Panbio HIV Verification Test (former name : Maxure HIV-1/2)	Abbott Rapid Diagnostics Jena GmbH (former Alere Technologies GmbH)	Professional Users
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Professional Users
STANDARD Q HIV 1/2 Ab 3-Line Test	SD Biosensor, Inc.	Professional Users
SURE CHECK HIV 1/2 Assay	Chembio Diagnostic Systems, Inc.	Professional Users
TrinScreen HIV	Trinity Biotech Manufacturing Ltd	Professional Users
Uni-Gold HIV	Trinity Biotech Manufacturing Ltd	Professional Users

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Collaborative Registration Procedure

Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

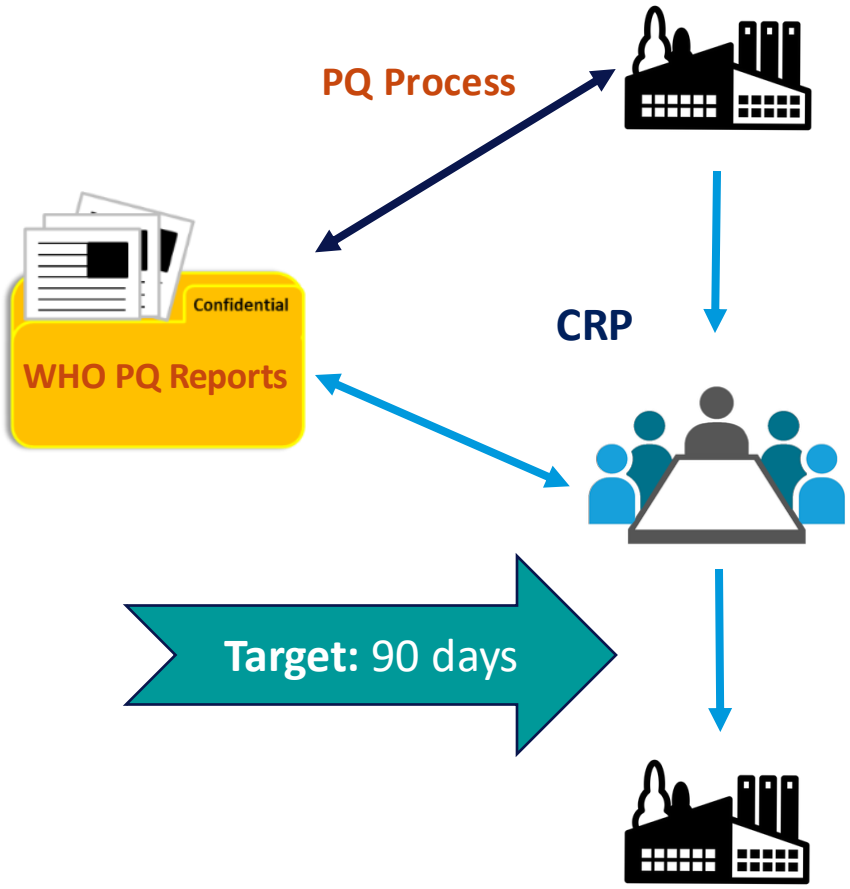
PRINCIPLES

- Voluntary for Mx of prequalified IVDs
- Product sameness must be guaranteed
- Confidentiality of data shared
- Target timeline: **maximum 90 days** for NRA decision

WHO PQ REPORTS SHARED

- Dossier review & Change requests, Site Inspection, Performance Evaluation

37 NRAs have agreed to participate in the CRP



Website link: Regulation and Prequalification

Thank You

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Adopting low-cost, quality-assured HIV tests to sustain access to life-saving services

Marian Honu & Shaun McGovern

Global Fund - Remarks

THE GLOBAL FUND

Leveraging HIVST to minimize the impact of RDT stock out
Experiences from Sindh Province (Pakistan)

DR. RAB NAWAZ SAMO
M.B.B.S (Dow), MSc Epidemiology (Aga Khan), MPS
National program Officer-Sindh
United Nations Development Program

Outline

- 1st RDT stock out in Q-4 2024
- How we managed continuity of testing services by leveraging HIVST as A1 test.

Program Overview

- UNDP Pakistan is the Principal Recipient (PR) for Global Fund's grant for HIV since July 2021
- Implementing HIV prevention services through partnerships with government, NGOs, and community-based organizations (CBOs).
- Providing HIV prevention services to MSM, TGs, FSWs.

ROUTINE TESTING APPROACH FOR HIV

- We follow 3- serial RDT algorithm for HIV diagnosis*
- A1 & A2 performed in the community (outreach/DICs).
- HIV reactive individuals are referred to ART centers for confirmation by using the full algorithm.

A1: *Early determine,* A2: *Uni gold,* A3: *SD Bio line*

Stock out

- Program faced acute shortage of 1st RDT in Q4-2024 due to quality concerns.
- Mishandling of the shipment during transportation by the manufacturer.
- All stock was quarantined and put on hold

*Storage temperature required: 2-30°C (36-86°F)

ALTERNATIVE STRATEGY

- The priority was the continuity of the testing services in the country.
- Alternative arrangements for A1.
- Discussions with CMU, WHO, UNAIDS, & PACPs
- Agreed to use HIVST stock to ensure continuity of testing services (program and donation from WHO)
- Started using HIVST as the 1st Test (administered by service providers)

Guidelines

Clear guidelines were developed and circulated to all CBOs

Criteria for using HIVST as A1

- Individuals presenting with clinical signs of HIV infection.
- Individuals who request PrEP
- Partners of HIV positive individuals

Next Steps

All individuals who were reactive on HIVST, were referred to referral laboratory for the confirmation as per national algorithm.

Impact of HIVST Adaption in Sindh Province (Oct-2024)

From 11th Oct to 29th Oct 2024 (15 working days)

Target for HIV Testing	HIVST Kits	HIVST Kits Used	HIVST Reactive	Referred to Lab	HIV Confirmation	Initiated ART	Denial	Expected Diagnosis
4000	2370	1317 (56%)	28 (2.1%)	25	22 (88.0%) (+VE) 03 (12.0%) (-VE)	22 (100%)	03	35

Conclusion

- HIVST was found feasible approach for continuity of testing services during stock outs.
- Has potential to fill the testing gaps during stock outs.
- HIVST is a feasible and convenient approach.

Is HIVST scalable approach to routine testing?

Discussion Point

Is HIVST scalable approach to routine testing?

Thank you

LOW-COST QUALITY-ASSURED HIV TESTS TO SUSTAIN ACCESS TO LIFE SAVING SERVICES

THE SOUTH AFRICAN EXPERIENCE

PN Khoza

12 May 2025

BACKGROUND: PROCUREMENT PROCESS

- National Tender: 3 years: funded domestically. All Test kits are WHO prequalified.

- Three A1s procured: SD Biosensor, One step Anti-HIV1/2, Meriscreen
- Only one A2: Diagnostic Kit for HIV (1+2)
- Only one A3: Abon HIV 1/2/0 Triline
- Annual testing between 16 and 18 million tests

- Two HIVST RDTs procured: OraQuick and Wondfo (500,000 each over 3 years)

- Two Dual HIV/Syphilis: First Response Combo card and Std-Q
- Dual HIV/Syphilis testing in ANC: Average testing frequency is 3-4 per pregnancy due to late visits even though there are 8 BANC visits allowed.

WHAT INFLUENCES LOWER PRICES?

- **Lower Prices influenced by:**
  - volumes within the tender with average price @R8 ($0.40) – annual tests 16-18 million
  - SD Biosensor (0.38USD), One Step Anti-HIV1/2 (0,41USD), Meriscreen HIV 1-2 (0.41USD)
  - **Price includes** pre-market surveillance, shipment into the country, warehousing in country and transport to provincial depots
  - A1 price lower than the WHO catalogue price and the pooled GF procurement system

- Flexibility for Global Fund to procure through national tender for PRs/SRs at these low prices

- The 3 A1s allow for inter-changeability and for risk management (stockouts)

- Selection of three A1s encourages lower price competition

PROCUREMENT PROCESS

- Two Self Tests (1 million tests over 3 years from government) – smaller volumes

- OraQuick: (3.1USD) and Wondfo (1.63USD) - (500,000 each over 3 years)
- Prices higher that WHO catalogue low prices
- Blood-based test is much cheaper (yet same performance)

- Dual HIV/syphilis: First Response (1.0USD) and Std Q (1.1USD)
- Prices comparable with WHO catalogue

- Country has adopted implementing 3-test algorithm since April 2025
- Started the verification study process (with NICD and WHO) after transitioning to 3-test strategy

THANK YOU

Annex

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Annex

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WHO catalogue prices, May 2025

No.	Product name	Manufacturer	Clinical Sensitivity (%)	Clinical Specificity (%)	Price per test
1	MERISCREEN HIV 1-2 WB	Meril Diagnostics Pvt. Ltd.	99.4	99.9	US$ 0,74
2	STANDARD Q HIV 1/2 Ab 3-Line Test	SD Biosensor, Inc	100	99.3	US$ 0.72
3	First Response HIV 1-2.O Card test (Version 2.0)	Premier Medical Corporation Private Limited	100	100	US$ 0,75
4	ONE STEP Anti-HIV (1&2) Test	InTec PRODUCTS, INC	100	100	US$ 0.55
5	One Step HIV1/2 Whole Blood/Serum/Plasma Test	Guangzhou Wondfo Biotech Co., Ltd	100	100	US$ 0.68
6	Genie Fast HIV 1/2	Bio-Rad	100	98.5	EUR 1.2
7	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	Shanghai Kehua Bio-engineering Co., Ltd	100	100	US$ 0.70
8	Determine HIV Early Detect	Abbott Diagnositcs Medical Co. Ltd.	100	99.4	US$ 0.9
9	DPP HIV 1/2 Assay	Chembio Diagnostic Systems Inc.	100	99.9	US$ 2.75
10	OraQuick HIV 1/2 Rapid Antibody Test	OraSure Technologies, Inc.	99.1	99.8	US$ 3.0
11	Rapid Test for Antibody to HIV (Colloidal Gold Device)	Beijing Wantai Biological Pharmacy Enterprise Co.	100	98.5	US$ 0,53
12	SURE CHECK HIV 1/2 Assay	Chembio Diagnostic Systems Inc.	99.8	99.9	US$ 2.1
13	ABON HIV 1/2/O Tri-Line HIV Rapid Test Device	ABON Biopharm (Hangzhou) Co. Ltd.	100	99.7	US$ 0.71
14	INSTI HIV-1/HIV-2 Antibody Test	BioLytical Laboratories, Inc.	100	99.7	US$ 2,79
15	Bioline HIV-1/2 3.0	Abbott Diagnostics Korea Inc	100	99.7	US$ 0.82
16	Uni-Gold HIV	Trinity Biotech Manufacturing Ltd.	99.8	99.9	EUR 0.71
17	HIV 1/2 STAT-PAK	Chembio Diagnostic Systems Inc.	99.5	100	US$ 1.2
18	Determine HIV-1/2	Abbott Diagnositcs Medical Co. Ltd.	100	98.9	USD$ 0.90
19	Geenius HIV 1/2 Confirmatory Assay	Bio-Rad	100	97.3	EUR 17.5
20	TrinScreen HIV	Trinity Biotech Manufacturing Ltd.	100	100	USD$ 0.75
21	Panbio HIV	Abbott Rapid Diagnostics Jena GmbH	100	99,7	US$ 1,2

Source: WHO catalogue 2025; WHO tool kit 2021

Key background and terminology

What is a quality-assured HIV test?

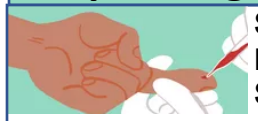
- **Test shown to meet performance and quality standards** by a recognized and responsible regulatory authority and/or WHO prequalification
- **Test meets minimum international standards**
  - Minimum 99% sensitivity and 98% specificity
  - Can be used together to achieve ≥99% positive predictive value
- **Additional resources**
  - **WHO PQ Reports:** https://extranet.who.int/prequal/vitro-diagnostics/prequalification-reports
  - **WHO PQ TSS**: https://iris.who.int/bitstream/handle/10665/341653/9789240020801-eng.pdf
  - **Global Fund QA Policy for IVDs**: https://www.theglobalfund.org/media/hc5hxug2/psm_qa-medical-devices_policy_en.pdf
  - **GHTF**: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf
  - **IMDRF**: https://www.imdrf.org/

What does A1, A2, A3 mean?

- **A1 = First test in testing strategy and algorithm**
  - These tests are optimized for sensitivity to ensure they detect a high number of people with HIV
  - These tests “rule in” potential infection
  - After A1, confirmatory testing is essential
- **A2/A3= Second and third test in testing strategy and algorithm**
  - These tests are optimized for specificity to ensure that the people diagnosed truly have an HIV infection
  - These tests “rule out” HIV infection
  - 3-tests have been shown to be needed based on current HIV epidemic to achieve minimum positive predictive value for all people being tested
- **Additional resource**
  - WHO 2024: https://www.who.int/publications/i/item/9789240096394

In vitro diagnostic medical devices (IVDs) for HIV testing services

1 Rapid diagnostic tests



Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: 5-10 per 5-15 min
Price per test: ~$0.44-$3.00
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 23-90 days
Where: Virtually anywhere (PHC & Community level, as well as higher level facilities and labs)
Who: Virtually anyone (trained lay providers, HCW, lab techs etc)
Storage: Generally, no electricity or refrigeration needs

2 Self-test

Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: Vast, but variable by distribution approach
Price per test: ~$0.95-5.00; but can be quite costly in high-income countries & the private sector
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 23-90 days
Where: Virtually anywhere (PHC & community level etc)
Who: Most anyone (videos/demonstrations can help users)
Storage: No electricity or refrigeration needs

3 Other simple assays & Immunoassays

Steps: Moderate to complex
Results: ~30 min–3hrs, turnaround time varies by setting generally next day
Specimen: Serum, plasma

Throughput: 9 per 15-30 min to 90 per hr (varies with batching)
Price per test: Highly variable (>$1.00-24)
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 18-45 days; WB & Line Immunoassays can be longer
Where: Health facilities (some PHC, but mostly higher-level facilities and labs as some assays need automation
Who: Trained facility staff and lab techs only etc
Storage: Electricity and refrigeration needs

4 Nucleic acid testing (NAT)

Steps: Moderate to Complex
Results: ~1hrs–4hrs, turnaround up to 35 days (varies by setting), turnaround time not same day
Specimen: Plasma & DBS (RNA and TNA)

Throughput: Widely variable by device (8-384 per 8hr shift)
Price per test: $22-85 (not including $$$ device)
Performance: Data must support Dx claim (%PA) - WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 10-33 days
Where: Health facilities (some PHC, higher level facilities & labs)
Who: Highly trained facility staff and lab techs only etc.
Storage: Electricity and (mostly) refrigeration needs

Factors for product selection

Operational characteristics for consideration:

- Test purpose (aid for diagnosis, diagnosis, monitoring)
- Specimen type
- Detection type
- Time to result
- Storage and stability
- Staff and skill level
- Equipment and consumables required
- Quality control (internal/external)

Additional considerations

- Aims and population
- Contributing to best algorithm and programme need
- Programme & public health impact
- Implementation and feasibility
- Price and service costs
- Training needs
- Support and supervision

Source: WHO, 2024, Fajardo/WHO 2025 forthcoming

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Recency testing in routine HTS programmes is not recommended

Guidance recommends **against** recency testing in routine HTS

Evidence review:

- No study showed clear evidence of effectiveness or clinical benefit
- **Variable acceptability**, with many finding intervention unacceptable
- **Uncertain effects on social harm**
  - Concerns remain such as fear of stigma, conflict among community members, dissatisfaction with services and increased intimate partner violence were reported by providers and clients.
- **Need to prioritize limited HTS resources** toward impactful approaches
  - **Limited feasibility** due to requirements for substantial resources, time, planning, training and monitoring
  - **High costs** as does not replace diagnostic testing and requires additional tests and service costs (test kits, VL, implementation).
  - **Concerns about reduced equity** due to diversion of funds

What is recency testing?

Assay used within an algorithm to estimate if HIV infection occurred in past 1-year

No WHO PQ recency assays

Guidance on recency for surveillance still supported where resources available

World Health Organization

Source: WHO 2024; WHO/UNAIDS, 2022