Briefing Note

Prioritizing Adoption and Implementation of Quality Assured, Low-cost HIV Rapid Diagnostic Tests

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Purpose

This document describes how national HIV programs can adopt and implement quality-assured, low-cost HIV rapid diagnostic tests (RDTs).

Background

HIV testing is a gateway to HIV prevention and treatment services and accounts for a notable share of HIV health product budgets. There are currently dozens of quality-assured HIV RDTs on the market, including HIV professional use tests, HIV self-tests (HIVSTs), and HIV/syphilis dual tests. Some product offerings cost less than those currently procured by countries, offering an opportunity for countries to procure and implement more tests within a smaller funding envelope. The World Health Organization (WHO) has recently issued guidance on opportunities for countries to accelerate the adoption of low-cost, quality assured tests.[1]

WHO Guidance Update

WHO recommends the use of three-test algorithms for HIV diagnosis involving three consecutive reactive tests to confirm an HIV-positive result to ensure high accuracy and reduce the risk of misdiagnosis.[2] Verification studies are critical to confirm if the selected three-test algorithm can accurately diagnose HIV in its intended setting.[3]

[1] "Low-cost, quality assured HIV tests to sustain access to life-saving services", Departmental Update, WHO, published 7 May 2025, https://www.who.int/news/item/07-05-2025-low-cost--quality-assured-hiv-tests-to-sustain-access-to-life-saving-services
[2] "Consolidated guidelines on differentiated HIV testing services", Guidelines, WHO, published 19 July 2024, https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf?sequence=1
[3] "Optimizing HIV testing algorithms: a generic verification protocol for selecting appropriate HIV serology assays and assessing the level of shared false reactivity", Toolkit, World Health Organization, published November 2021, 9789240039162-eng.pdf

In its recent update, WHO encourages countries to adopt low-cost, quality assured HIV RDTs as the first test (A1) in their testing strategy. This includes allowing flexibility in conducting verification studies either during or after changes to the algorithm, and the adoption of multiple quality-assured A1 tests rather than only one A1 test. This guidance also applies to HIV/syphilis dual tests in antenatal care. WHO also urges countries to adopt low-cost, quality-assured HIVSTs especially in settings with limited health workers or testing capacity, and to consider HIVSTs as an alternative first test, particularly where service delivery gaps exist.

The Global Fund encourages national HIV programs to adopt and implement this guidance to generate savings and sustain lifesaving HIV testing services.

Key Considerations

Key considerations for national HIV programs are:

- **Supply and pricing:** Principal Recipients (PRs) can use Global Fund reference price and eligible product lists for decision-making and budgeting.[4,5] Adoption of lower cost A1 tests can generate the greatest savings. WHO has estimated that a country testing five million people annually could save nearly US$2 million by transitioning from a status-quo A1 test to a lower costing alternative.[6] Such savings can be reinvested in critical HIV activities.
- **Transition planning:** Countries should follow the standard practice of adequate planning for the phased introduction of new products while avoiding any risk of product wastage or stock shortfalls. This includes planning the phasing out of the old test (use of existing stocks and those in the pipeline) aligned with the procurement plan of new tests, time of placing orders, and delivery lead time.[7] In parallel, countries should update national policies and guidelines and streamline training plans and quality reference materials to account for new tests. Updates to health management information systems (HMIS) and logistics management information systems (LMIS) should not be forgotten.
- **Regulatory:** For products not yet registered, countries should assess regulatory considerations, including potential barriers, and facilitate importation waivers where required. Suppliers are encouraged to use streamlined regulatory filing processes, such

[4] "List of HIV diagnostic tests kits and equipment classified according to the Global Fund Quality Assurance Policy", The Global Fund, published 31 March 2025, https://www.theglobalfund.org/media/5ifod1fa/psm_productshiv-who_list_en.pdf
[5] "The Global Fund Pooled Procurement Mechanism Reference Pricing: RDTs", The Global Fund, version Q2 2025, revision 1, https://www.theglobalfund.org/media/2ffcrcra/psm_hivrdtreferencepricing_table_en.pdf
[6] "Adopting low-cost, quality-assured HIV tests to sustain access to life-saving services", webinar slides, World Health Organization, published 12 May 2025, https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/adopting-low-cost-hiv-tests-webinar-12may2025.pdf?sfvrsn=6ab91c81_3
[7] "Category and product-level procurement delivery planning guide: health and non-health products: indicative lead times", The Global Fund, Q3 2024, https://www.theglobalfund.org/media/10755/psm_categoryproductlevelprocurementdeliveryplanning_guide_en.pdf

as the WHO Collaborative Registration Procedure.[8] Once dossiers are filed by suppliers, national regulatory authorities should consider expedited review processes.

- **Verification studies:** Three-test algorithms and verification studies remain critical to avoid misdiagnosis of HIV.[9] Per WHO's guidance, countries can consider conducting verification studies for three-test algorithms (whether for single HIV or HIV/syphilis dual tests) concurrently with or after the adoption of lower-costing, quality-assured tests. Countries should assess their approach to verification studies in alignment with national policies and are encouraged to pursue flexibilities aligned with WHO's guidance. Verification study costs could be covered by the savings generated from the adoption of lower-costing tests. Recent verification studies can be used to support product selection.
- **Budgeting:** PRs can use grant funds to support the adoption and implementation of the new WHO guidance. PRs should work with Global Fund Country Teams and Country Coordinating Mechanisms to update the Health Product Management Template and budgets for transition-related activities.
- **Partnership support:** WHO country offices can support countries including providing technical assistance to expedite regulatory approvals and updates to national policies. Countries are encouraged to use existing coordination mechanisms to identify partners who may be able to support the transition to this guidance.

[8] "Annex 4: Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics", World Health Organization, https://cdn.who.int/media/docs/default-source/biologicals/ecbs/post-ecbs-collaborative-procedure-document-27-jan-2021.pdf?sfvrsn=d1e4dcf6_5&download=true

[9] "Preventing HIV misdiagnosis: implementation guide", World Health Organization, published 7 November 2024 https://www.who.int/publications/i/item/9789240092136