Global Fund
RDT Consultation Meeting

December 11, 2023
Cape Town, South Africa
The Global Fund Procurement Strategy on Rapid Diagnostics Tests (RDTs) is currently under development and will be finalized after the meeting.

This document presents the Global Fund’s current intention, which is subject to change.

The data and information herein are provided for illustrative purposes and derive from a limited and preliminary analysis by the Global Fund.

The present document shall not be considered as the Global Fund’s representation or commitment of any kind.
Opening remarks

Hui Yang
Head, Supply Operations
Global Fund
Objectives of RDT Consultation
11 and 12 December 2023, Cape Town

1. **Bring together suppliers and partners** to share progress updates in HIV, Malaria and other Rapid Diagnostic Test (RDT) markets

2. Create a platform to share perspectives to inform ongoing and future RDT procurement strategies

3. Provide an **opportunity for face-to-face** meetings with individual suppliers and partners

4. Present the Global Fund’s Rapid Diagnostic Tests Procurement Strategy for 2024-2026 and obtain feedback from partners and suppliers

5. Engage with Regional manufacturers and provide visibly of Global Fund procurement activities in line with NextGen Market Shaping ambitions
## Agenda – 11 Dec 2023

### 8.30 – 9.00
**Registration & Welcome coffee**

### 9.00 – 10.00
**Welcome & Global Fund updates**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Duration</th>
<th>Speaker &amp; Role</th>
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<tbody>
<tr>
<td>9.00</td>
<td>Opening remarks</td>
<td>15m</td>
<td>Hui Yang / Head, Supply Operations – Global Fund</td>
</tr>
<tr>
<td>9.15</td>
<td>NextGen Market Shaping</td>
<td>25m</td>
<td>Ellie Marsh / Senior Manager, Strategy Procedure and Innovation – Global Fund</td>
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<tr>
<td>10.00</td>
<td>Pooled Procurement Mechanism (PPM)</td>
<td>20m</td>
<td>Lin (Roger) Li / Senior Manager, Direct Sourcing – Global Fund</td>
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### 10.00 – 10.15
**Coffee break**

### 10.15 – 12.00
**Disease and technical updates**

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<tr>
<th>Time</th>
<th>Session</th>
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<th>Speaker &amp; Role</th>
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<tbody>
<tr>
<td>10.15</td>
<td>Malaria Update</td>
<td>15m</td>
<td>Roopal Patel / Senior Disease Advisor, Technical Advice and Partnerships (TAP) - Malaria – Global Fund</td>
</tr>
<tr>
<td>10.30</td>
<td>HIV Update</td>
<td>25m</td>
<td>Celine Lastrucci / WHO HIV</td>
</tr>
<tr>
<td>10.55</td>
<td>TB Update</td>
<td>10m</td>
<td>Grania Brigden / Senior Disease Advisor, TAP – TB – Global Fund</td>
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<tr>
<td>11.05</td>
<td>WHO Prequalification</td>
<td>20m</td>
<td>Irena Prat / WHO PQ program</td>
</tr>
<tr>
<td>11.25</td>
<td>Global Fund QA and ERPD</td>
<td>20m</td>
<td>René Becker-Burgos / Specialist, Diagnostic Products Quality Assurance, HPM – Global Fund</td>
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### 12.00 – 13.00
**Lunch break**

### 13.00 – 14.30
**Innovation & Partners RDT Strategies**

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<th>Time</th>
<th>Session</th>
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<th>Speaker &amp; Role</th>
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<tbody>
<tr>
<td>13.00</td>
<td>Innovation pipeline</td>
<td>20m</td>
<td>Jeremie Piton / FIND</td>
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<tr>
<td>13.20</td>
<td>PMI sourcing strategy</td>
<td>20m</td>
<td>Christine Hershey / PMI</td>
</tr>
<tr>
<td>13.40</td>
<td>PEPFAR sourcing strategy</td>
<td>20m</td>
<td>Matthew Wattleworth / PEPFAR</td>
</tr>
<tr>
<td>13.50</td>
<td>UNICEF 2023-2028 Procurement Strategy</td>
<td>20m</td>
<td>Wandani Sebonego / UNICEF</td>
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<tr>
<td>14.10</td>
<td>Q&amp;A / Discussion 1</td>
<td>10m</td>
<td>All</td>
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### 14.30 – 15.00
**Coffee break**

### 15.00 – 17.00
**Global Fund RDT Procurement Strategy & tender timeline**

<table>
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<tr>
<th>Time</th>
<th>Session</th>
<th>Duration</th>
<th>Speaker &amp; Role</th>
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<tbody>
<tr>
<td>15.00</td>
<td>RDT Sourcing Strategy 2024-2026</td>
<td>60m</td>
<td>Azizkhon Jafarov, Mustafa al Samaraee / Global Health Technologies Team – Global Fund</td>
</tr>
<tr>
<td>15.40</td>
<td>Request for Proposals (RFP) Approach &amp; Timeline</td>
<td>30m</td>
<td>Kiraz Bulut / Legal Counsel (Institutional Matters), Legal Department – Global Fund</td>
</tr>
<tr>
<td>16.00</td>
<td>Q&amp;A / Discussion 3</td>
<td>30m</td>
<td>All</td>
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2. Global Fund Strategy (2023-2028)
NextGen Market Shaping

Ellie Marsh
Senior Manager, Strategy Procedure and Innovation
Global Fund
Equitable access to quality assured health products and innovations is critical to deliver on more resilient and people-centered integrated systems for health.

Health products remain the number one tool to address HIV, TB and malaria, and for ending the three diseases.
Evolution of the Global Fund’s Market Shaping partnership efforts

2002
- Individual initiatives to influence market shaping through grants

2007
- Board approves the first MSS

2011
- Beginning of pooled procurement (VPP) and introduction of PQR

2016
- PPM matures - strategic sourcing capabilities developed in-house
- PPM moves from offline processes to wambo.org

2018
- Enhanced efforts in supply chain, capacity building, and sustainability

2020
- COVID-19
  - >100% increase in value managed through PPM/wambo.org*
- Board approves updated MSS
- Board approves Global Fund 2023-2028 Strategy

2022
- In 2022
  - US $1.75 billion value through PPM/wambo.org
  - 83 countries
  - 1,611 orders
  - 5,600 shipments

NextGen Market Shaping
- A more end-to-end approach to delivering equitable access to quality-assured health products
- Builds on Global Fund & Partnership achievements and lessons-learned from COVID-19
- Introduces a dedicated focus on key impact areas, through strategic, enabling, and foundational interventions
- Involves co-creation of implementation roadmaps with partners
- Progress will be tracked against KPIs developed for the 2023-2028 Global Fund Strategy

With World Health Organization, recipients transition to ACTs from sub-optimal therapies

First global ARV and LLIN framework agreements

Integration of Supply Chain – creation of SSC

Ethiopia capacity building

First domestic financing transactions

Introduction of carton-less packaging for sustainability

ACT-A partnership & C19RM through PPM/wambo.org

*US$ 958M in 2019 versus US$ 2.2 billion in 2021

PQR = Price and Quality Reporting

VPP = Voluntary Pooled Procurement
Global Fund’s NextGen Market Shaping approach to drive equitable access to quality health products

<table>
<thead>
<tr>
<th>What we want to achieve</th>
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<tbody>
<tr>
<td><strong>Global</strong></td>
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<tr>
<td>1. Work with industry and partners to <strong>drive innovation that is accessible</strong> to LMICs</td>
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<tr>
<td>2. Secure supply that is <strong>affordable, available, quality and responsiveness</strong></td>
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<tr>
<td>3. Foster <strong>South-to-South collaboration</strong></td>
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<thead>
<tr>
<th>Strategic Interventions</th>
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<tr>
<td>1. Shape innovation and accelerate new product introductions at scale</td>
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<td>2. Promote capacity building for regional manufacturing</td>
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<tr>
<td>3. Drive environmentally sustainable procurement and supply chains</td>
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<table>
<thead>
<tr>
<th>Enabling Interventions</th>
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<tr>
<td>1. SMART partnership and <strong>co-creation of implementation roadmaps</strong></td>
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<tr>
<td>2. Integrate PPM/wambo.org and networked global and regional procurement platforms to drive further value through pooled mechanisms</td>
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<tr>
<td>3. Advance <strong>financing mechanisms</strong> to promote and sustain national procurement capacity (VFM)</td>
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<table>
<thead>
<tr>
<th>Foundational Interventions</th>
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<tbody>
<tr>
<td>1. <strong>In-country procurement capacity building and supply chain systems strengthening</strong></td>
</tr>
<tr>
<td>2. Advocate <strong>regulatory framework strengthening and harmonization</strong></td>
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<tr>
<td>3. <strong>Market surveillance</strong> for quality assurance and access</td>
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<tr>
<th>Regional</th>
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<tbody>
<tr>
<td>1. Leverage PPM / wambo.org procurement mechanism to collaborate with partners to build regional procurement capacities</td>
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<tr>
<td>2. Stimulate and sustain regional manufacturing capacity building</td>
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<thead>
<tr>
<th>National</th>
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<tbody>
<tr>
<td>1. Use grant investments and country partners to <strong>strengthen in-country supply chain systems</strong></td>
</tr>
<tr>
<td>2. Ensure quality assured health products will be distributed effectively and efficiently to communities and people we serve</td>
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The NextGen Market Shaping approach is reflected in GF’s sourcing strategies

The success of the NextGen Market Shaping approach is dependent on the contribution of, and partnership with, industry. This will require industry to:

- Responsive to Global Fund tenders
- Continue to invest in innovation targeted at the countries and communities the Global Fund serves
- Adopt sustainable, inclusive and equitable go-to-market approaches
3. Global Fund Pooled Procurement Mechanism (PPM)

Lin (Roger) Li
Senior Manager, Direct Sourcing
Global Fund
How we work
We raise funds and support programs

Countries make investment decisions

We review and approve grants

Local experts implement

Oversight in Action

- Local Fund Agents in each country monitor the implementation of grants.
- The Secretariat reports information to the Global Fund Board and the wider public.
Procurement Channels and Routes to Market

There are a number of procurement channels - with the Pooled Procurement Mechanism (PPM) representing around 60% total Global Fund health product spend.

1. Pooled Procurement Mechanism (PPM)
   - The Global Fund
   - Procurement Service Agent
   - Principal Recipient
   - Manufacturer
   - Long Term Agreements and Funds
   - Requisition in Wambo
   - Use funds / Transmit orders
   - Orders

2. National Procurement Mechanisms
   - The Global Fund
   - Procurement Entity
   - Principal Recipient
   - Manufacturer
   - Orders / Funds
   - Orders

3. Other Procurement Agents; Global Drug Facility (GDF / TB)
   - The Global Fund
   - Procurement Service Agent
   - Principal Recipient
   - Manufacturer
   - Funds
   - Orders
   - Orders
The GF Pooled Procurement Mechanism holds Framework Agreements (long term agreements with manufacturers for key product categories: ARVs, ACTs, LLINs and RDTs)

The Global Fund aggregates order volumes to leverage our spending power and achieve value-for-money:

- Competitive tenders to select manufacturers
- Stringent performance management through contract implementation

Procurement Service Agents:

- Liaise with framework agreement manufacturer
- Manage procurement for other categories and non-catalogue items where needed
- Provide logistics estimates and ensure delivery to country per the agreed incoterm
Since its creation, PPM/wambo.org has connected 531 PR users from 107 organizations in 83 countries (including 40 organizations from 27 countries for non-grant funded transactions).

Overall user satisfaction with the Wambo platform: 95%

Scale: 0 = Not satisfied at all to 10 = Fully satisfied

Tracked more than 6,000 shipments from shipping to delivery

- 2,498 by sea
- 3,116 by air
- 452 by road and rail

Count

- 79%
- 18%
- 3%

Volume

- 1,107 Bn
- 266 Mn
- 49 Mn

Overview PPM: More than 80 countries served in 2022 through PPM/Wambo

There are a number of More than 6,000 shipments of needed health products delivered despite global supply chain disruptions in 2022.
Overview PPM: USD 1.75 bn orders placed in 2022 through PPM/Wambo

PPM operates at a significant scale – largest LMIC buyer in many HIV and malaria categories

- **In 2022**, PPM processed 1,611 Purchase Orders **$1.75 bn** to more than 80 countries in all continents

- Largest category **ARVs** – enough to treat 7.3 million people on 1st line ART

- **ITNs** – in 2022, PPM procured **119 million bed-nets** including new generation innovative nets)

- **Diagnostics** including RDTs are a significant spend (including HIV rapid tests)
The Responsible Procurement Framework - realising our ambitions and achieving our goals.

To date, the Global Fund’s Supply Operations Department has put many of these principles into action through the adoption of a responsible procurement approach, yielding significant results:

- **Artemisinin EHS Compliance**: The Global Fund mitigated EHS risks and incentivized best practices by leveraging 3 year volume allocations.

- **Adoption of Standards**: Global Fund LTAs require suppliers to comply with international environment, health & safety standards. The number of insecticide-treated net manufacturers whose systems meet ISO standards for environmental management (14001:2015) and occupational health & safety (ISO 45001:2018) has increased by 19% since 2020.

- **Packaging Waste**: The Global Fund strives to reduce packaging waste across categories. For example, an estimated plastic waste reduction of 1,110 metric tons was achieved in 2020 via the elimination of the use of individual bags for ITNs.

Nevertheless, a systematic approach was needed to realize the Global Fund’s sustainability ambitions.

The Global Fund is building on our successes to date through the implementation of our “Responsible Procurement Framework” (RPF).

The RPF is -

- Based on the Triple-Bottom-Line framework.
- Developed in consultation with the UN informal Interagency Task Team on Sustainable Procurement in the Health Sector (SPHS).
- Endorsed by the Global Fund Management Executive Committee.
- A Secretariat-level operational guide for Global Fund sourcing; allowing buyers to identify, monitor, mitigate sustainability risks.

**Suppliers may be expected to** -

- Provide baseline sustainability & metric information.
- Strive to minimize the environmental impact of your activities*.
- Align with internationally recognized standards (e.g. ISO) where required.
- Support the Global Fund’s sustainability ambitions.

*For example, these can include (non exhaustive) reduction in GHG emissions, pollution during production, packaging waste.
Disease and technical updates

4. Malaria Update
5. HIV Update
6. TB Update
7. WHO Prequalification
8. GF QA and ERPD
Q&A / Discussion 1
Diseases update
Malaria

Roopal Patel
Senior Disease Advisor, Technical Advice and Partnerships (TAP) - Malaria Global Fund
1. Ensure optimal effective vector control coverage

2. Expand equitable access to quality early diagnosis and treatment of malaria, through health facilities, at the community level and in the private sector, with accurate reporting

3. Implement malaria interventions, tailored to sub-national level, using granular data, and capacitating decision-making and action

4. Drive towards elimination and facilitate prevention of reestablishment of malaria

5. Accelerate reductions in malaria in high burden areas and achieve sub-regional elimination in (a) select area(s) of sub-Saharan Africa to demonstrate the path to eradication

Progress against deaths is better, with more countries showing strong declines - here the challenges are more focal with a few key countries showing important reversals

Malaria cases are decreasing in some of the highest burden countries but most have strong increases

Source WHO estimates. Reference World Malaria Report 2022
Improving access and quality of diagnosis and treatment across all sectors.
- Engage private sector providers to drive parasitological testing before treatment
- Expand community platforms where access is low.
- For diagnostics, continued focus on availability, capacity for testing, ease of use, adherence to test results and accurate reporting and recording.
- Deployment of both microscopy and RDTs should be supported by a quality assurance programme
- Addressing *P. vivax* including G6PD testing for radical cure.
- Severe malaria and the continuum of care.

**Addressing biologic threats**

- Improved surveillance and mapping of drug resistance and Pfhrp2/3 gene deletions
- Prevention and mitigation of resistance – strategies to reduce selection pressure of current ACTs including diversifying 1st line treatments
- Availability and adoption of appropriate diagnostics based on surveillance and normative guidance
Deletion of Pfhrp2 and related hrp2 genes allow the parasite to escape from RDTs based on HRP2 antigens – major threat to early diagnosis and effective, prompt treatment as >80% of RDTs use in Africa are hrp2-only

- Limited surveillance to detect scale and scope of Pfhrp2/3 gene deletions to inform diagnostic selection.
- Malaria threat maps typically show percentage of pfhrp2 deleted samples amongst those tested and NOT all P. falciparum cases, national surveys of symptomatic, confirmed cases needed to determine prevalence of clinically significant deletions.
- Eritrea, Djibouti and Ethiopia have confirmed with national surveys, > 5% of false negatives due to pfhrp2/3 deletions
  - All three countries have switched/about to switch to non-HRP2 based RDTs
- Healthy market of Pfhrp2 based RDTs, appropriate for most settings but limited options for PLDH based RDTs with sensitivity to detect Pf with gene deletions.
- Normative guidance limited on reactive versus proactive response to risk of hrp2/3 gene deletions
Mitigating Diagnostic Biologic Threats

Global Fund:
- GC7: Increased support for surveys and surveillance for hrp2/3 gene deletions in coordination with PMI, BMGF and other partners
- Promote data sharing, to inform appropriate introduction of health products
- Promoting diverse and stable RDT market including addressing emerging needs

WHO:
- Review of guidance in response to emerging hrp2/3 gene deletions, potential risk-based transition to non-exclusive HRP2 RDTs
- Identify factors that put countries in Africa at increased risk of pfhrp2 deletions emerging
- pfhrp2 deletions having clinical impact
- pfhrp2 deletions spreading
- Supporting countries and aligning across partners for strong data sharing, to inform appropriate introduction of health products

Other partners, e.g. UNITAID, PATH, FIND, BMGF
- Promotion with suppliers of expanded availability and access of products that respond to biologic threats

Predicted concern impact of pfhrp2-deleted mutants.

Source: Watson et al eLife 6:e25008
Malaria Portfolio: Key Messages on GC7

Based on preliminary analysis of new grants to date, themes emerge throughout, particularly funding gaps

- Unprecedented fiscal pressure faced by countries and donors— in particular, low-income countries in Africa where malaria is concentrated
- Biologic threats, climate change and population growth all leading to increased costs of commodities and service delivery
- W1 saw gaps in essential services in Y3
- Led to TRP recommendation to fully fund ‘essential’ case management across GC7 including ACTs and RDTs
  - Vector control and seasonal malaria chemoprevention remain underfunded – struggle to maintain coverage means inability to innovate around delivery models or expanded deployment.

Insufficient program scope owing to funding challenges, prioritization decisions and/or bio-threats

The estimated malaria funding gap for Windows 1 and 2 is approximately US$1 billion to sustain essential services.
Malaria Portfolio: Key Messages

Category focus expected to continue toward case management with diagnostics, specifically malaria RDTs, continuing to play a key role

- Effective, quality case management is a major focus of the malaria strategy, beyond commodities including training, service delivery, supervision and health systems strengthening.

- Treatment and Diagnostics represent ~ 33% of the overall Malaria PPM Portfolio spend.
  - Diagnostic portfolio represented over 14% of the GF 2022 PPM spend of $1.75 billion

- The product portfolio is more mature driven by a less dynamic market however ensuring continued access to all required products and aligning with disease dynamics remains essential

PPM Malaria Portfolio Overview 2022 (Spend $)

- 67% Prevention & Vector Control
- 14% Diagnostic
- 19% Treatment

THE GLOBAL FUND
5. Diseases update HIV

Celine Lastrucci
WHO, Global HIV, Hepatitis and STI Programmes
Updated WHO testing recommendations and RDTs needs
New 2023 consolidate HIV Testing services guideline
Hepatitis and STIs testing WHO guidance

Céline LASTRUCCI, technical officer, HIV Testing Services (HTS)
WHO, Global HIV, Hepatitis and STI Programmes
GF RDTs stakeholders consultation - 11 dec 2023
**NEW**: HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation (conditional recommendation, low-certainty evidence)

Remarks
- HIVST-supported PrEP delivery may be an important tool to reach underserved populations.
- HIVST is an option to support PrEP delivery; its use should be driven by client needs and preferences.
- There is a range of PrEP options available for which HIVST use could be considered, including oral PrEP (daily or on-demand) and the dapivirine vaginal ring (DVR). HIVST can also be considered as part of post-exposure prophylaxis (PEP) implementation. Further research on the role of HIVST in implementing long-acting injectable prevention options, such as cabotegravir (CAB-LA), is needed.

**NEW**: HIV self-testing may be offered as an additional option for testing at facilities (conditional recommendation, low-certainty evidence).

Remarks
- HIVST does not replace provider administered testing. Individuals with a reactive self-test result should receive further testing from a trained provider using the full national testing algorithm.
- HIVST can replace risk screening tools* to optimize testing among those presenting at health facilities.

**NEW**: Caregiver-assisted testing using HIVST: There is insufficient evidence to support caregiver-assisted testing using HIVST kits currently. Therefore, prior to further implementation, challenges, concerns, and research gaps need to be addressed.

WHO does urge already recommended approaches to reach children
- EID
- index/family testing
- Indicator testing (eg testing in malnutrition clinics)
- Screening tools to screen in for testing clinical settings
WHO does NOT recommend using recency assays in HIV testing services

Recency testing for surveillance

WHO recommends use of recency assays in surveillance

- Utility of recency testing has been demonstrated in population-based surveys to measure HIV incidence
- Use of recency testing in programmatic settings should only be considered when existing HIV testing coverage of the population being studied is high, when a combination of assays including viral load can be delivered to reduce false recent results and analysis plans make appropriate statistical adjustments and infer population-specific trends in recent infection

- There are no WHO prequalified recency assays
  - No WHO prequalified recency tests in the pipeline or planned to be in the pipeline for WHO prequalification at this time.
  - No current pathway for recency testing to receive WHO prequalification as process reserved for recommended HTS interventions & diagnostic tests.

NO benefits of recency testing in routine HTS, 2023 HTS consolidated guideline

New WHO recommendation

HIV recency testing is not recommended as part of routine HIV testing services (conditional recommendation, low-certainty evidence)

Remarks

- This recommendation calls for excluding recency testing from routine HIV testing services. HIV testing services are defined as a package of services including brief pre-test information and post-test counselling; linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.
- Recency assays can, however, be used for surveillance of HIV incidence. WHO has published guidance on this in Using recency assays for HIV surveillance: 2022 technical guidance (https://apps.who.int/iris/rest/bitstreams/1486096/retrieve).
WHO recommends all countries currently using two consecutive reactive tests for an HIV-positive diagnosis to move forward using three consecutive reactive tests for an HIV-positive diagnosis. This is increasingly important as treatment-adjusted HIV prevalence and national HTS positivity continue to decline over time.

- Ensure that the testing strategy has a positive predictive value ≥99% (PPV)
  - Meaning of the persons classified as HIV+, ≥99% will truly be living with HIV
  - PPV depends on positivity rate among testing population

- Quality assured assays, such as WHO prequalified, should be used:
  - **≥99% sensitivity**: fewer than 1 ‘false negative’ for 100 truly positive
  - **≥98% specificity**: fewer than 2 ‘false positive’ for 100 truly negative
  - Either rapid diagnostic tests (RDTs) or immunoassay (EIA, CLIA, ECL)
**Principles for the selection of HIV Testing Algorithms**

**WHO recommends to use only quality-assured products:** HIV assays that have undergone stringent regulatory assessments (product & manufacturing)

<table>
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<tr>
<th>Performance characteristics</th>
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<tr>
<td><strong>Highest sensitivity</strong></td>
<td>A1</td>
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<tr>
<td>(to rule in all positives [true + false])</td>
<td></td>
</tr>
<tr>
<td><strong>Highest specificity (&gt;A1)</strong></td>
<td>A2 and A3</td>
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<tr>
<td>(to rule out all false positives)</td>
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Correctness of the final HIV status is dependent on:
- Specificity of the individual products used (for A1, A2, A3), and
- Probability that any specimen that is falsely-reactive on the first assay (A1) is not also falsely-reactive on the second assay (A2) and third assay (A3) – **this can vary by region**

It is suggested to conduct a **verification study of the new testing algorithms** in order to:

1. Identify the **combination of products which have minimum possible common cross-reactivity** to reduce the risk of false HIV-positive diagnosis. (Note: *Products from the same manufacturer should not be used as part of the testing algorithm to minimize common cross-reactivity*)
2. Identify **flexible algorithms**: replacement tests in case of a "problem" with one of the selected tests, e.g. stock out, lot recall, etc. One for A1 and one for A2/A3
3. **Not intended to reevaluate sensitivity and specificity of individual products!**
### First verification studies results

#### Study outcomes in 3 countries (non exhaustive list):

<table>
<thead>
<tr>
<th>Country</th>
<th>CHAD (100 samples)</th>
<th>Cameroon (100 samples)</th>
<th>Mali (200 samples)</th>
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<tbody>
<tr>
<td><strong>SUPPORT RECEIVED</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Global fund</td>
<td>commodities+ running costs + HR</td>
<td>commodities+ running costs + HR</td>
<td>commodities+ running costs + HR</td>
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<tr>
<td>WHO</td>
<td>HR (consultant)+ remote technical support</td>
<td>HR (consultant)+ remote technical support</td>
<td>HR (consultant)+ remote technical support</td>
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<tr>
<td><strong>PREPARATION PHASE</strong></td>
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<td>procurement time (months)</td>
<td>16</td>
<td>7</td>
<td>15 *</td>
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<tr>
<td>tests selection, protocol and other tools development, ERB (months)</td>
<td>3</td>
<td>4</td>
<td>6</td>
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<tr>
<td><strong>SAMPLES COLLECTION PHASE</strong></td>
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<tr>
<td>sample collection duration (days)</td>
<td>5</td>
<td>7</td>
<td>10</td>
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<tr>
<td>sample characterisation duration (days)</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Nb sample collected</td>
<td>171</td>
<td>172</td>
<td>250</td>
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<tr>
<td>true positives</td>
<td>14 (8%)</td>
<td>15 (9%)</td>
<td>247</td>
</tr>
<tr>
<td>trues negatives</td>
<td>154 (90%)</td>
<td>147 (85%)</td>
<td></td>
</tr>
<tr>
<td>non conclusive</td>
<td>3 (2%)</td>
<td>10 (6%)</td>
<td>TBC</td>
</tr>
<tr>
<td><strong>VERIFICATION PHASE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>tests included in the study</td>
<td>6</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>total nb of tests performed</td>
<td>2400</td>
<td>3200</td>
<td>4800</td>
</tr>
<tr>
<td>Verification phase duration (days)</td>
<td>8</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>inter reader variability</td>
<td>0</td>
<td>0</td>
<td>TBC</td>
</tr>
<tr>
<td>invalid rate</td>
<td>0</td>
<td>0</td>
<td>0.5-2.5%</td>
</tr>
<tr>
<td>share false reactivity</td>
<td>1 test (1%)</td>
<td>4 tests (1 to 4%)</td>
<td>12 (0.25-1%)</td>
</tr>
<tr>
<td>share false reactivity</td>
<td>0</td>
<td>1 sample (3 tests)</td>
<td>4 samples (2 to 5 tests)</td>
</tr>
<tr>
<td><strong>TOTAL TIME operational phase (days)</strong></td>
<td>15</td>
<td>17</td>
<td>24</td>
</tr>
</tbody>
</table>

* 2 steps order because of additional tests included 6 months after initial order

#### How did the countries use the results (non exhaustive list):

<table>
<thead>
<tr>
<th>Country</th>
<th>share false reactivity identified</th>
<th>Does country changed A1</th>
<th>does the country change A2</th>
<th>does country change A3</th>
<th>HIV/syphilis dual test choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAD</td>
<td>NO</td>
<td>NO (training)</td>
<td>YES</td>
<td>YES</td>
<td>TBC</td>
</tr>
<tr>
<td>Cameroon</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO (decided to keep same test used as tie breaker before)</td>
<td>standard Q</td>
</tr>
<tr>
<td>Lesotho</td>
<td>NO</td>
<td>NO (training)</td>
<td>NO (training)</td>
<td>YES (decided to NOT keep same test used as tie breaker before)</td>
<td>1st response</td>
</tr>
<tr>
<td>Kenya</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES (decided to NOT keep same test used as tie breaker before)</td>
<td>standard Q</td>
</tr>
<tr>
<td>DRC</td>
<td>YES</td>
<td>NO (training)</td>
<td>NO (training)</td>
<td>YES (discontinued)</td>
<td>Bioline</td>
</tr>
<tr>
<td>Zambia</td>
<td>NO</td>
<td>YES</td>
<td>NO (training)</td>
<td>YES (no 3rd test before)</td>
<td>1st response</td>
</tr>
<tr>
<td>Mali</td>
<td>YES</td>
<td>YES</td>
<td>No (training)</td>
<td>YES (no 3rd test before)</td>
<td>1st response</td>
</tr>
<tr>
<td>Philippines</td>
<td>YES</td>
<td>not applicable (not using RDTs before verification study)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Sudan</td>
<td>NO</td>
<td>decision making process on going</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key testing messages from new HIV WHO testing guidelines

1. Select a strategic mix of **differentiated testing approaches** to fill the testing gaps

2. **Community based testing**, by trained providers will increase access and coverage, including for key populations

3. **HIV self-testing** should be expanded widely to allow greater access for people not testing in facilities and to increase ease of using oral PrEP, DVR and PEP

4. **Testing quality is critical. Avoiding misdiagnoses is critical**
   - Misdiagnoses have serious implications for people, programmes and public health
     - Misdiagnoses can be avoided by:
       • Using **Quality assured** product
       • Using the **serial 3 test strategy**
       • **Re-testing** prior to ART initiation
       • Conducting **verification studies**: the right tests in the right order
       • Instituting strong **quality management systems**

5. **Voluntary partner services**, including **Social Network Testing** may be used to increase HIV diagnoses and identify additional people with HIV

6. Use **Dual HIV/syphilis tests** in ANC and for KP

7. Think about **STI** and **viral hepatitis testing** alongside HIV testing

8. **Recency testing** adds complexity and costs in HTS and is **not recommended by WHO**
WHO guidelines on Testing Services

Other testing updates

- HIV algorithm verification toolkit (2021)
- Virtual intervention (policy brief 2022)
- Key populations (KP guideline 2022)
  - Optimal retesting frequency
  - Dual HIV/syphilis RDT

- Triple EMTCT: HIV, Syphilis, Hepatitis B
- Use of self-testing extended to Hepatitis C and Syphilis
- Trep/Non trep RDTs to improve active syphilis diagnosis
- Partners services extended to STIs and Hep-C
- Improving men uptake: Reaching men by testing in the workplace (including HIVST)
- Risk screening tools to optimize testing should be considered for screening “IN” those with symptoms & risks that might otherwise be missed (not screening “out”).

Self-testing and self-care becoming standard of care across many different areas
- HIVST
- HCVST
- C19ST
- Syphilis ST
- ST for pregnancy,
Key takeaways: STIs

SCALE UP

• Dual test is being taken up fast, market opportunity remains large
  o Greater uptake stimulating growing needs in syphilis testing, including non-treponemal RDTs or dual T/NT, and RPR/VDRL
  o Pooled procurement and increased volumes in ANC can increase affordability

• Self-collection of samples for STIs; pooled samples

URGENTLY NEEDED affordable & WHO PQ products

• New WHO recommendations coming for
  • syphilis self-testing (none in the market)
  • dual T/NT RDT ($$ and not PQ)
  • Evidence-based STI partner services: may increase volume

• Multiplex/dual/multipanel RDTs
  • e.g. combined HIV, HBV, Syp (T/NT) to support ETMCT

• RDTs for Ng/Ct

• Target product profiles for STIs POC tests: [Point-of-care tests for sexually transmitted infections: target product profiles (who.int)]
Key take aways: Viral hepatitis

Product pipeline needs support

• One new HCV WHO-PQ in November 2023
• No product with stringent regulatory approval yet for HbeAg or HCVcAg
• Strong interest to mobilize around HBV rapid testing through multiplex assays & self-testing (no PQe product available yet)
• Formal recommendations for testing of HDV (who to test and what assay to use) done in framework of HBV guidance update: Need for an RDT for HDV-serology+++; better options for EIA and NAT needed
• Liver function Tests remain important: POC would be interesting

Strategic planning for viral hepatitis testing

• For further scale up: Countries need support in developing cost-effective and adapted national testing strategies for HCV and HBV in different epidemiological contexts
  • WHO will develop further implementation guidance in 2023 for strategic country planning; this will include best practices from different countries and using different approaches
• Leverage the work under Global Fund, which has extended support to include HCV and HBV testing and treatment (independent of HIV status) in framework of HIV prevention programs in key populations and in triple elimination
Contributors

**WHO**: Rachel Baggaley, Cheryl Johnson, Alaleh Abadpour, Maggie Barr-DiChiara, Busisiwe Msimanga, Anne Bekelynck, Purvi Shah, Carlota Baptista Da Silva, Anna Elizabeth Monroe-Wise, Niklas Luhman, Funmi Lesi, Teodora Wi, Maeve B. Mello, Belen Dinku, Anita Sands, Michel Beusenberg, Heather Marie Schmidt, Michelle Rodolph

**UNAIDS**: Victoria Benaud and colleagues supporting GAM

Special thanks to all participating Ministries of Health, Academic Partners, Community Groups, UN agencies, and members of related WHO Guideline Development Groups

**Funders**: WHO receives grants supporting on testing services from Unitaid, the Bill and Melinda Gates Foundation, Global Fund and USAID

For more information on HIV testing services

- WHO HIV Testing Services Dashboard
- WHO HIV Testing Services Info App
- WHO HTS GL
5. Diseases update HIV

David Maman
Senior Disease Advisor, Technical Advice and Partnerships (TAP) - HIV Global Fund
Global Fund Strategy 2023-2028: END AIDS sub-objectives

1. Accelerate access to and effective use of precision combination prevention, with behavioral, biomedical, and structural components tailored to the needs of populations at high risk of HIV infection, especially KVP
   - Close gaps in HIV prevention coverage
   - **Accelerate access to and use of new HIV prevention options**
   - Evolve and expand the range of platforms for access to and delivery of people-centered HIV prevention

2. Provide quality, people-centered diagnosis, treatment and care, to improve well-being for PLHIV, prevent premature mortality and eliminate HIV transmission
   - Optimize diagnostic pathways
   - Differentiate and scale up quality HIV treatment services
   - Integrate services to prevent, identify, and treat advanced HIV disease, comorbidities, and coinfections
   - Evolve care pathways to strengthen therapeutic alliances between the people in care and the health and community systems
   - **Accelerate the introduction of diagnostics, therapeutics, technologies, and service delivery innovations**

3. Advocate for and promote legislative, practice, program and policy changes to reduce HIV-related stigma, discrimination, criminalization, other barriers and inequities and uphold the rights of PLHIV and KVP
Epidemiological Update & Consequences for HIV Testing

The proportion of people living with HIV who know their status was **86% in 2022*** (92% in Eastern and Southern Africa).

- **HIV testing positivity is decreasing**
  - All countries to adopt a **3-test algorithm** to keep a positive predictive value above 99% (HIV Program Essential)
  - The need for confirmatory A2 and A3 tests is decreasing -> **Countries need smaller packs if not individual packs for A2 & 3 or the possibility to buy buffer separately**

- **New strategies are needed for hard to reach, still undiagnosed populations:** HIV testing services include **HIV self-testing**, safe ethical index testing and social network-based testing (HIV Program essential)

- The **relative weight of Antenatal Testing & testing for Key Populations** in the total HIV testing mix will continue to increase
  - **Testing at ANC** responds to a logic of **elimination of Vertical Transmission**
  - **Key populations** are increasingly driving the HIV Epidemic
Key HIV Resources for Funding Requests
Updates for the 2023-2025 Allocation Period

HIV Information Note
The RSSH, TB and Malaria Information Notes are also available here.

Program Essentials
- Critical interventions needed to achieve outcomes and impact
- Program Essentials are key evidence-based interventions and approaches to address the ambitious goals set out in the HIV, TB, and Malaria global strategies.
- Elements recommended by technical partners (WHO, UNAIDS, Stop TB, RBM) and further described in their respective technical guidelines
- When part of national programs, Program Essentials will support countries to achieve their national targets. They can be funded by either The Global Fund or other sources.

Additional Resources
1. Technical Briefs
Technical Briefs will be published here. These resources will include additional detail on specific topics (HIV Service Delivery in COE, Health & Longevity, HIV, Human Rights and Gender Equality).

2. Global Guidelines
Links to all key technical guidance documents are in footnotes of the HIV Information Note.
HIV Investment priorities for GC7

Program Essentials

- HIV Testing:
  - 3 test Algorithm
  - Self-Testing in the mix of HIV Testing Services

- Advanced HIV Disease: CD4, CrAg and TB LAM

Investment Priorities:

- From PMTCT to Integrated Approach towards **Triple Elimination of HIV, Syphilis and Hepatitis B**
  - More usage for Multi disease tests

- Dual HIV/Syphilis tests also for Key Populations

- With Hepatitis B comes the need of HBe Ag and with Syphilis TP, the need of non-TP testing

Looking Ahead:

- Triple RDT HIV/Syph/HBs Ag
- Tenofovir Urine test
6. Disease update

TB

Grania Brigden
Senior Disease Advisor, Technical Advice and Partnerships (TAP) – TB Global Fund
1. Finding & Treating all people with DS/DR-TB through equitable, people-centered approaches

2. Scale-up TB prevention, and emphasis on TPT and airborne Infection prevention & control

3. Improve quality of TB services across the care cascade, including management of co-morbidities

4. Adapting TB programs to respond to the evolving situation, including through rapid deployment of new tools and innovations

5. Promote enabling environments to reduce stigma, discrimination, human rights and gender-related barriers, address catastrophic costs

**Outcome**

At least 90% of people with TB identified and successfully treated

(>90% Treatment Coverage & >90% Treatment Success Rate)

**Impact**

90% reduction in TB deaths by 2030 (2015 baseline)

80% reduction in TB incidence by 2030 (2015 baseline)

TB no longer a public health problem: reduced financial burden on individuals, communities and alleviated health systems.

**Vision**

Healthier and more productive communities, free of Tuberculosis
**TB and Diagnostics**

- **Current TB diagnostic tests are not true point of care tests**

- **The current TB diagnostic network has issues with:**
  - Monopoly market until recently (Cepheid GeneXpert)
  - Majority of tests require lab infrastructure/electricity to run and/or recharge
  - Require sample that is difficult to obtain (Sputum/stool – for children)
  - Where is it POC (urinary LAM test) it is for a sub section of the at risk population.

**RD T for TB should ideally match POC requirements below.**

<table>
<thead>
<tr>
<th>Complexity</th>
<th>PoC</th>
<th>Near PoC</th>
<th>Low complexity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td>None</td>
<td>Maybe, preferable battery operated</td>
<td>Yes</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>None</td>
<td>None</td>
<td>Basic laboratory infrastructure needed (like electricity), but no special laboratory infrastructure</td>
</tr>
<tr>
<td>HR skill level</td>
<td>Unskilled</td>
<td>Basic Technical Skills (basic pipeting, precision not critical, etc)</td>
<td>Basic Technical Skills (basic pipeting, precision not critical, etc)</td>
</tr>
</tbody>
</table>
7. WHO Prequalification

Irena Prat

WHO PQ program
Update on Prequalification of in vitro diagnostics

11 December 2023
# Update on Prequalification of in vitro diagnostics

**Presentation outline**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>01</strong></td>
<td>Introduction to the prequalification assessment of IVDs</td>
</tr>
<tr>
<td><strong>02</strong></td>
<td>PQ Technical specifications</td>
</tr>
<tr>
<td><strong>03</strong></td>
<td>Collaborative registration procedure for IVDs</td>
</tr>
<tr>
<td><strong>04</strong></td>
<td>Specific information for RDTs</td>
</tr>
</tbody>
</table>
Update on Prequalification of in vitro diagnostics

Introduction to the prequalification assessment of IVDs
PQ of IVDs: aim & scope

Prequalification of IVDs began in 2010

- The aim of PQDx is to promote and facilitate **access** to safe, appropriate and affordable IVDs of **good quality**

- Focus is placed on **IVDs for priority diseases** and their suitability for use in **resource-limited settings**

- The **scope** of IVDs eligible for PQ continues to expand

- Currently 113 IVDs are prequalified

PQ List available at:

[Prequalified In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)]
PQ of IVDs: design

The PQDx programme is aligned with best international practice for IVDs

- ISO (and EN) standards
- GHTF/IMDRF guidance
- CLSI guidance
- Requirements of national regulatory authorities including: FDA, EU, TGA, HC, Japanese Ministry of Health, Labour and Welfare
What PQ does differently

Requirements are based on the same standards as GHTF/IMDRF

➢ PQ is aligned with internationally accepted practice

BUT assesses regulatory versions intended for the **global market**:

▪ Where a stringently reviewed versions exist, they are often not supplied to the global market

▪ RoW versions can differ from stringently assessed version
  - *site of manufacture, QC, labelling, key suppliers, composition, intended use…*

Reviews aspects of particular relevance for **resource-limited settings**

▪ Risk assessment, stability, flex studies, labelling, customer training & support

▪ Considers environmental & operational factors
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:

- Review of a product dossier
- Performance evaluation
- Manufacturing site inspection

Full assessment or Abridged assessment
Final prequalification outcome depends on:

- **Product dossier review**

- **Performance evaluation**

- **Manufacturing site inspection**

  - Final labelling review is conducted & the public report prepared
  
  - The product is added to the list of WHO prequalified IVDs
    
    - IVD is eligible for WHO and UN procurement & CRP
Post-PQ Activities

Ongoing requirements to maintain PQ listing

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
Update on Prequalification of in vitro diagnostics

PQ Technical specifications
PQ-IVD Technical specifications published in 2023

**TSS-18**
HbA1c point of care analysers for professional use

**TSS-19**
IVD medical devices for monitoring of blood glucose in capillary blood

**TSS-20**
IVD medical devices used for the qualitative detection of SARS-CoV-2 nucleic acid

**TSS-21**
SARS-CoV-2 antigen rapid diagnostic tests for professional use and self-testing

[Extranet WHO](https://extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series)
TSS 20 and TSS 21: SARS-CoV-2

- Published as part of transition from EUL to PQ

- Emergency Use Listing (EUL) is an extraordinary process intended to provide guidance to interested UN procurement agencies and NRAs of WHO Member States on IVD quality, safety and performance

- End of the PHEIC (May 5, 2023) triggered:
  - No new EUL submissions accepted
  - Cancellation of ongoing assessments (unless close to completion)
  - Start of transition phase (EUL → PQ)

- Q&A document available:
  - https://extranet.who.int/pqweb/sites/default/files/documents/IVD_Transitioning_FAQ_V2.pdf
TSS-22 Haemoglobin point of care analysers

- Expansion of PQ: non-communicable diseases (NCD), risk class B
- Technical consultation including 18 experts
- Public comment period: planned Q1 2024

TSS-23: RDTs to detect mycobacterial lipoarabinomannan (LAM) antigen

- Technical consultation (Jan 2024): approx. 15 experts
- Public comment period: planned Q1 2024
TSS under revision

TSS-3: Malaria rapid diagnostic tests, 2nd edition

- Technical consultation: June 2023
- Public comment period: planned Q1 2024

Scope of the revision:

- Format changes → align with IMDRF ToC chapter numbering
- Availability of WHO International Standard for Pf & Pv (analytical studies)
- Clinical evidence to support claim for the detection of parasites with HRP2/3 deletions (applicable to all IVDs that detect Pf non-HRP antigens, e.g. LDH)
Planned new TSS and TSS revisions

- TSS-4: In vitro diagnostic medical devices used for the detection of high-risk human papillomavirus (HPV) types in cervical cancer screening (mRNA, self-collection)
- TSS-6: Syphilis rapid diagnostic tests (self-testing)
- Open platform molecular tests (bridging studies)
- Sexually transmitted infections
  - TSS: Neisseria gonorrhoeae POC
  - TSS: Chlamydia trachomatis POC
- Tuberculosis
  - TSS: TB next-generation sequencing technologies for the detection of mutations associated with drug resistance in Mycobacterium tuberculosis complex
Update on Prequalification of in vitro diagnostics

Collaborative registration procedure for IVDs
Collaborative Registration Procedure (CRP)

Collaboration between NRA, Manufacturer and WHO

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: 90 days for NRA decision

**WHO PQ REPORTS SHARED**
- Dossier review & Change requests
- Site Inspection
- Performance Evaluation
CRP Roles and Responsibilities

The Manufacturer

• Submit an expression of interest to the NRA
• Provide consent for WHO to share PQ reports
• Submit product dossier to NRA

WHO

• Make reports available to NRA via secure transfer
• Provide advocacy and support to regulatory authorities

The NRA

• Treat WHO PQ reports as confidential
• Issue a national regulatory decision within 90 days
NRAs participating in CRP for IVDs

As of October 2023

Rwanda, Nigeria, Mauritania, Uganda, South Africa, Ethiopia, Tanzania, Kenya, Bhutan, Namibia, Malawi, Eritrea, Burundi, Gabon, Togo, DR Congo, Senegal, Zanzibar, Mozambique, Ivory Coast, Cameroon, Ghana, Thailand, Yemen, Cabo Verde, Togo, Angola, Zimbabwe, Botswana, Comoros

As of October 2023
Update on Prequalification of in vitro diagnostics

Specific information for RDTs
Specific information for RDTs

- TSS updates: ensuring compliance
- Upcoming new TSS / PQDx expansion plan

Performance evaluations:
- New panel for HIV serology assays under development
- Development of protocol for HIV urine tests and parallel revision of protocol for HIV oral fluid tests
- Revision of other HIV serology protocols (serum/plasma and capillary blood)
- New panel for « main » protocol for HIV tests on serum and plasma and HIV-syphilis dual tests
- Align analytical panels with above
- Protocol revision planned for Q1 2024, once panel fully characterized
Specific information for RDTs cont’d

Malaria:
Collection of new specimens with *P. falciparum* hrp2/3 deletion in Africa planned for 2024

Revision of protocol in parallel with revision of TSS requirements scheduled for 2024

- Hrp2/3 deletion panels
- Addition of *P. vivax* international standard
Performance evaluation laboratories – list

• 15 listed laboratories
  https://extranet.who.int/prequal/vitro-diagnostics/prequalified/performance-evaluation-laboratories

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Country</th>
<th>Date of Listing</th>
<th>Laboratory Option List</th>
<th>Analyte(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotechnology and Genetic Laboratory Instituto Nacional de Saude (INS)</td>
<td>Mozambique</td>
<td>9 Jun, 2022</td>
<td>Option 1</td>
<td>HIV NAT (quantitative) HIV NAT (qualitative - EID)</td>
</tr>
<tr>
<td>CDC Division of Global HIV/TB International Laboratory Branch Viral Load and Early Infant Diagnosis Team</td>
<td>United States</td>
<td>10 Sep, 2018</td>
<td>Option 1 Option 2</td>
<td>HIV NAT (quantitative) HIV NAT (qualitative - EID)</td>
</tr>
<tr>
<td>Central Public Health Laboratories Kampala</td>
<td>Uganda</td>
<td>8 Apr</td>
<td>Option 1</td>
<td>HIV NAT</td>
</tr>
</tbody>
</table>

Download list as CSV file
Prequalified RDTs

Chart Title
ACCESS TO QUALITY ASSURED IVDS: PUTTING THE PIECES TOGETHER
THURSDAY 14 DECEMBER 2023 - 7.00 TO 9.00AM

Updates on initiatives that support access to quality assured IVDs, with a focus on the African region. Followed by interactive panel discussion.

Laboratory professionals, IVD regulators and product manufacturers are welcome.

Workshop Agenda

- Welcome & Opening Remarks (WHO)
- Stakeholder updates (PEPFAR/USAID, UNITAID, The Global Fund)
- Expert Review Panel for Diagnostics (The Global Fund)
- PQ Assessment of IVDs (WHO)
- The Collaborative Registration Procedure (NRA)
- HIV Testing Algorithms (WHO)
- Post-market Surveillance (WHO)
- Panel discussion with audience Q&A

Come early for Breakfast from 6.30 am

René Becker-Burgos
Specialist, Diagnostic Products Quality Assurance, HPM
Global Fund
Decision point: GF/B50/DP06:

Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products

and Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment
### KEY CHANGES TO EXISTING POLICIES

<table>
<thead>
<tr>
<th><strong>i</strong></th>
<th>Approval of the amended and restated Quality Assurance Policy for Pharmaceutical Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ii</strong></td>
<td>Approval of the amended and restated Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment</td>
</tr>
<tr>
<td><strong>A</strong></td>
<td>Revise the QA Policy for Diagnostics Products into a <strong>consolidated QA Policy for Medical Devices</strong></td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Expand the eligibility criteria for products to include health products that are <strong>authorized for use by a WLA</strong></td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Expand the list of products eligible for procurement in emergencies to include those <strong>approved pursuant to the WHO Emergency Use Listing procedures</strong> or other emergency procedure set up by an SRA / WLA</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Describe the <strong>risk-based approach</strong> the Secretariat will take for handling quality-related concerns that have been identified on specific orders</td>
</tr>
<tr>
<td><strong>E</strong></td>
<td><strong>Update to ensure consistency</strong>, support and guide implementation of the Policies.</td>
</tr>
</tbody>
</table>

### Delegate authority to the Secretariat to make non-material adjustments to the quality assurance policies, in consultation with the Strategy Committee Chair and Vice Chair, and to report back to the Strategy Committee and Board
<table>
<thead>
<tr>
<th><strong>What are the key changes for IVDs?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Former QA POLICY Framework</strong></td>
</tr>
<tr>
<td><strong>Reference</strong></td>
</tr>
<tr>
<td><strong>QA Diagnostic Products Policy (2017)</strong></td>
</tr>
<tr>
<td><strong>Product applicability</strong></td>
</tr>
<tr>
<td>For all Diagnostic Products (IVDs plus others)</td>
</tr>
<tr>
<td><strong>General quality standards (section 7)</strong></td>
</tr>
<tr>
<td>Quality Management System requirements (ISO 13485 or equivalent)</td>
</tr>
<tr>
<td><strong>Additional Quality Requirements (section 8)</strong></td>
</tr>
<tr>
<td>IVDs with respect to HIV, tuberculosis and malaria and to Hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient management of these diseases</td>
</tr>
<tr>
<td>Prequalified by the WHO Prequalification Programme</td>
</tr>
<tr>
<td>Or</td>
</tr>
<tr>
<td>WHO Global TB programme recommendation</td>
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<tr>
<td>Or</td>
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<tr>
<td>Authorized for use by Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as high risk)</td>
</tr>
<tr>
<td>Or</td>
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<tr>
<td>After assessment by Expert Review Panel</td>
</tr>
</tbody>
</table>

| **NEW QA POLICY Framework**          |
| **Reference**                        |
| **QA Medical Device Policy (2023)**  |
| **Product applicability**            |
| For all Medical Devices (including In-Vitro Diagnostics) |
| **General quality standards (section 7 & 8)** |
| Quality Management System requirements (ISO 13485 or equivalent) |
| **Additional Quality Requirements (section 10)** |
| IVDs with respect to ... |
| Prequalified by the WHO Prequalification Programme |
| Or |
| WHO Global TB programme recommendation/Rapid Communications |
| Or |
| Authorized for use by Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (Class C & D) |
| Or |
| Authorized for use by WHO Listed Authority (WLA) |
| Or |
| After assessment by Expert Review Panel |
| In case of Public Health Emergencies of International Concern (PHEIC) |
| Approved under the WHO Emergency Use Listing (EUL) |
| Or |
| Under SRA/WLA Emergency procedures |
More available on Global Fund website


Diagnostic Products

Implementers of Global Fund-supported programs must ensure the diagnostic products they purchase meet our partnership’s quality standards.

Our Quality Assurance Policy for Diagnostic Products applies to all durable and non-durable in vitro diagnostics, imaging equipment and microscopes used in Global Fund-supported programs for diagnosis, screening, surveillance or monitoring purposes.

- Quality Assurance Policy for Diagnostic Products download in English [Download]

We promote best practices in the procurement of diagnostic products, including:

- Complying with World Health Organization guidance on storage and distribution
- Ensuring that products are used by appropriately trained and suitably qualified persons only
- Using best efforts to participate in suitable external quality assessment programs
- Using best efforts to organize calibration and maintenance of relevant equipment
- Using best efforts to develop systematic reporting of product defects

The cost of quality assurance and quality monitoring measures must be included in grant budgets. Those responsible for the procurement of diagnostic processes (in most cases, the Principal Recipient) should ensure they observe all applicable laws and regulations. In addition, World Health Organization guidelines or national guidelines should serve as the basis for the selection of particular products.

Eligibility of Products

In accordance with our quality assurance policy, implementers have four options when selecting which in vitro diagnostic products to purchase. They can choose products that meet one of the four options:

- List of HIV Diagnostic Test Kits and Equipments Classified According to the Quality Assurance Policy
  download in English
- List of Rapid Diagnostic Test Kits for Malaria Classified According to the Quality Assurance Policy
  download in English
- List of SARS-CoV-2 Diagnostic Test Kits and Equipments Eligible for Procurement: COVID-19
  download in English
- List of TB Diagnostic Tests Classified According to the Quality Assurance Policy
  download in English
Indicative next steps before following ERPD, before a test can be procured using Global Fund funds

**Pathways to GF procurement**

- WHO PQ
- ERPD
- SRA¹

**ERPD assessment & procurement implication**

- Risk category 1 & 2: Eligible
- Risk category 3: Limited eligibility on exceptional basis²
- Risk category 4: Not eligible

**Next steps**

- Manufacturer enters direct/indirect contracting arrangement with GF (see next slide)
- Product listed on wambo.org
- Countries review of national HIV testing algorithm
- If product is selected as part of algorithm, countries place orders through wambo.org
- Manufacturer continues ongoing improvement to manufacturing and quality assurance, potentially with support from partners
- Manufacturer may re-submit a complete new EOI after substantial improvement

---

1 SRA is not possible for HIV RDTs for self testing (see QA Policy)
2 Procurement permitted if no alternatives that can meet programmatic and/or operational requirements
ERPD is hosted by WHO, initiated by the Global Fund

Global Fund’s role includes:

• prepares and circulates the invitations for EoI in close collaboration with UNITAID and partners,

• manages the receipt of product questionnaires as sent by manufacturers,

• forwards complete questionnaires and associated documents to WHO for review,

• notifies manufacturers of the outcome of the ERPD’s review of their respective submissions,

• maintains on the website an up-to-date list of diagnostics submitted and/or eligible for procurement as per QA policy, based on ERPD advice

WHO role’s role includes:

• arranges the timely review of the product questionnaires,

• assess data provided in the submissions, draft the corresponding quality risk assessment reports, and allocate each product questionnaire to the appropriate risk category; the data for each product will be reviewed at least by two assessors,

• reports the conclusion on the acceptability or non-acceptability for procurement of each product,

• provides advice on measures to mitigate identified risks
Global Fund, Unitaid and PEPFAR, supported by WHO, are piloting the use of the Expert Review Panel to accelerate approval of HIV rapid tests manufactured in Africa

What do we hope to achieve?

1. To accelerate equitable access to quality assured HIV rapid diagnostic tests (RDTs) manufactured in Africa
2. To incentivize manufacturers to conduct sustainable, end-to-end manufacturing of HIV RDTs in Africa within the next 10 years, as a step in the pathway to securing an uninterrupted supply of RDTs in Africa

What is the Expert Review Panel for Diagnostics (ERPD)?

1. Group of independent experts, convened by WHO, that reviews the potential risks and benefits associated with the use of diagnostic products that may have a high public health impact but have not yet undergone a stringent regulatory assessment
2. Favorable ERPD risk rating can result in time-limited addition to the list of eligible products for procurement by countries using grant funds
3. ERPD assessment does not replace WHO PQ / Stringent Regulatory Assessment (SRA) but provides an interim solution for a time-limited period in anticipation of the completion of a stringent review process
Manufacturers must meet the following criteria and submit the following documents in order to be eligible for ERPD review

**Criteria**

1. **Regulatory status:** Product is under review by WHO PQ or SRA, or manufacturer submits a Letter of Commitment to apply to WHO PQ or SRA

2. **Quality Management System (QMS) status:** Product is manufactured at a site compliant with ISO 13485:2016 or equivalent management system

3. **Intent to expand manufacturing steps:** Manufacturer provides a signed Letter of Intent indicating its intent to expand the manufacturing steps for the product in African sites to end-to-end manufacturing within the next 10 years.

4. **Manufacturing in the African Union:** Product is at least partially manufactured in one of the 55 Member States of the African Union (AU)

**Documentation**

1. **Cover letter**

2. **Letter for regulatory status,** either from WHO Prequalification of In-Vitro Diagnostics Program, or a SRA or – in the absence of such a confirmation letter – a Letter of Commitment from the manufacturer

3. **Quality Management System (QMS) status** documents

4. **“Letter of Intent”** to expand manufacturing steps conducted in Africa


Unique to this GF/ERPD/Adhoc 24/08-2023
ERPD call

See call for EOI for details
More available on ERP on Global Fund website


Opportunities for Evaluation

Manufacturers are invited to submit their products for Expert Review Panel evaluation. Invitations are published as either semi-annually Round calls with a submission deadline or Ad-Hoc with no specified deadline. We regularly publish all invitations on our Updates page. The continued Ad-Hoc invitations are also found in the drop down lists below.

Opportunities for Evaluation of Medicines

Opportunities for Evaluation of Diagnostic Products

Update: Expression of Interest (EOI) for HIV rapid diagnostic tests manufactured in Africa (09/ERPD/Adhoc 28/09-2023)
download in English

Malaria Rapid Diagnostic Tests for Infections of Pf only, Pf/Pv or Pan (09/ERPD/Adhoc 23/09-2023)
download in English

Diagnostic tests for Hepatitis B, Hepatitis C, and combined HIV, Hepatitis B and C (09/ERPD/Adhoc 22/10-2022)
download in English
Innovation & Partners RDT Strategies

9. FIND Innovation pipeline
10. PMI sourcing strategy
11. PEPFAR sourcing strategy
12. UNICEF 2023-2028 Procurement Strategy

Q&A / Discussion 2
DIAGNOSTIC INNOVATION PIPELINE AT POC

Jérémie Piton, PhD
11 December 2023, Cape Town
In partnership with WHO, other global health agencies and the G20/G7, we are driving progress towards **universal health coverage** and **global health security**

- Established in 2003 as a product development & delivery partnership
- Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member
FIND STRATEGIC PRIORITIES TO
TO STRENGTHEN HEALTH SYSTEMS AND MAXIMIZE IMPACT

Responding to countries’ priorities

- Support packages tailored to country / regional needs for sustainable uptake and impact
- Strong partnership with MoH to influence policy on critical regional global health priorities

Multiplex point-of-care molecular test launch

Identifying multiple pathogens from a single test enables health systems to be structured around patients, not diseases

Primary care and patient-centered diagnostics

Accessible diagnosis and health management where patients seek care is critical to Universal Health Coverage

Regional diagnostic manufacturing

Manufacturing RDTs closer to those who need them ensures sustained, secure and affordable supply

Disease surveillance

Reliable, connected and optimized networks provide essential early warning systems and track disease elimination

Equitable access to reliable diagnosis around the world
Kary Mullis’ first thermocycler
Disclaimer: The product depicted in this slide (Cobas system by Roche Diagnostics) was selected to represent a product class. The selection does not represent endorsement or recommendations on any particular product by FIND.
TB Lab tech in Kenya, photo from 2016

Malaria LAMP testing in Peru, photo from 2015

TB lab tech in India, photo from 2017

Ebola Xpert training in DRC, photo from 2015

HAT LAMP testing, photo from 2012

Disclaimer: The products depicted in this slide (Gene Xpert by Cepheid and HAT LAMP by Eiken) were selected to represent a product class. The selection does not represent endorsement or recommendations on any particular product by FIND.
Today, new innovations mean high-quality testing is getting closer and closer to the point-of-care where people can most readily access it.
**Key Requirements for New LFA**

**To make a transformational impact**

- **Use cases**: clinical diagnostic, self-testing
- **Data Capture**: Visual reading and manual reporting
- **Targets**: Antigens, Antibodies,
- **Materials**: Gold particle, Latex nanobeads,
- **Sample type**: Blood, swab, urine
- **Price**: Low price
TO MAKE A TRANSFORMATIONAL IMPACT

**Use cases**: clinical diagnostic + self testing, mass testing,

**Data Capture**: manual and Digital,

**Disease**: COVID-19

**Targets**: Antigens, Antibodies

**Increased Performance**: Gold particles, Latex nanobeads, Quantum dots,

**Manufacturing**: Regional manufacturing,

**Sampling methods**: Non invasive, self sampling

**Price**: Lower price

** Readers**: branded readers

Lateral flow test engineering and lessons learned from COVID-19. Budd et al., 2023 Nature reviews Bioengineering
TO MAKE A TRANSFORMATIONAL IMPACT

**Key Requirements for New LFA**

**Targets**: Antigens, Antibodies, Molecular

**Eco-friendliness**: Packaging, less plastic

**Increased Performance**: Gold particle, Latex nanobeads, Quantum dots, Fluorescence, Nanodiamonds, enzymatic nanoparticles

**Use cases**: self testing, clinical diagnostic, surveillance

**Data Capture**: Digital, automatic connection to healthcare systems, Post market Surveillance

**Challenging Disease**: TB, NG/CT, Schistosomiasis, AMR, Vaccine preventable disease (YF, Mening, Cholera, Measles)

**Targets**: Antigens, Antibodies, Molecular

**Multiplex**: Multi-pathogen, Multi-markers, Resistance, Pan-virus, disease X

**Increased Performance**: Gold particle, Latex nanobeads, Quantum dots, Fluorescence, Nanodiamonds, enzymatic nanoparticles

**Manufacturing**: Innovation, Regional manufacturing,

**Stability**: Increase stability at higher temperature

**Sampling methods**: Non invasive, self sampling

**Use cases**: self testing, clinical diagnostic, surveillance

**Data Capture**: Digital, automatic connection to healthcare systems, Post market Surveillance

**Challenging Disease**: TB, NG/CT, Schistosomiasis, AMR, Vaccine preventable disease (YF, Mening, Cholera, Measles)

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**Manufacturing**: Innovation, Regional manufacturing,

**Stability**: Increase stability at higher temperature

**Sampling methods**: Non invasive, self sampling

**Eco-friendliness**: Packaging, less plastic

**Price**: Lower price

**Readers**: Universal readers,

**Sample prep**: Sample prep, urine concentrator

FLUORESCENT NG ASSAY DEVELOPED BY FIND AND DCN AND EVALUATE IN SOUTH AFRICA CLINICS

Symptomatic men

Performance

Sensitivity: 96% (91% – 98%)
Specificity: 97% (90% – 99%)

Symptomatic women

Performance

Sensitivity: 92% (78% – 97%)
Specificity: 96% (92% – 98%)

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<thead>
<tr>
<th>TPP</th>
<th>Minimal requirement</th>
<th>Optimal requirement</th>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>&gt;80%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Specificity</td>
<td>&gt;95%</td>
<td>&gt;98%</td>
</tr>
</tbody>
</table>
CT/NG
MOLECULAR TEST ON LFA FORMAT

https://www.accessdata.fda.gov/cdrh_docs/reviews/K200748.pdf

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.
FILL CRITICAL GAPS ACROSS DIFFERENT HEALTHCARE SETTINGS

Technologies suitable to testing infrastructures

**Near POC**
- Basic lab equipment requirements
- Benchtop/desktop units, mains power
- Semi-automated testing processes

**True POC**
- No laboratory equipment requirements
- Portable, battery-operated devices
- Kits including disposable sample materials
- Fully automated testing process

**Instrument free POC**
- No instrument or power requirements
- Kits including disposable sample materials
- Fully automated testing processes

Increasing accessibility
PRE-PANDEMIC
LIMITED TOOLS, MAINLY IN HOSPITALS

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.
THE DELUGE
THE COMING EXPLOSION IN NEW POC DIAGNOSTIC TECHNOLOGIES

Connected diagnostics and interoperable systems for data management, data aggregation and data sharing for surveillance

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.
THE POC MOLECULAR DX DEVELOPMENT PIPELINE HAS THE POTENTIAL TO TRANSFORM HEALTHCARE DELIVERY IN LMICS

Near POC pipeline:
- 80 novel platforms
- Competitive characteristics compared to Cepheid
- Strong multi-pathogen, potential for syndromic testing

True POC pipeline:
- >30 platforms
- Mostly based on isothermal amplification; costs now below US$5
- Growing market penetration

Instrument free POC pipeline:
- >10 platforms in development; 3 on the market
- Test costs still high
- Commercialization mostly limited to the US

Disclaimers:
- Landscape and development stage assessment conducted based on the COVID-19 test offering for each platform. Data last updated on Q4-2022
THE POC MOLECULAR DX DEVELOPMENT PIPELINE HAS THE POTENTIAL TO TRANSFORM HEALTHCARE DELIVERY IN LMICS

Near POC pipeline:
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- >10 platforms in development; 3 on the market
- Test costs still high
- Commercialization mostly limited to the US

Disclaimer: Data last updated on Q4-2022. The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.
Proprietary assays developed by platform manufacturer only

Addition of new tests subject to market opportunities (limited interest for niche markets)

High reliance on one provider increases risk of product shortage

Development of specific panels/kits possible by ‘local’ developers

Addition of new tests facilitated to address local health priorities

Development of validation & biobanking protocols and reference & QA/QC panels

Requires partnerships & innovative financing
CONCLUSION: KEY REQUIREMENTS FOR NEW DIAGNOSTIC TOOLS
TO CLOSE THE GAP AT POC (MOLPOC AND LFA)

**POINT-OF-CARE (POC)**
Usable where people live and seek care (incl. communities and primary care settings)

**MULTI-PATHOGEN**
Able to identify multiple diseases in one sample (incl. outbreak-prone pathogens)

**AFFORDABLE**
Pricing structures adapted to LMICs

**ACCURATE**
Robust and highly sensitive results

Progress towards universal health coverage and global health security

Improved performance

Improved access
Thank you!

TOGETHER, we can ensure that everyone who needs a test can get one.
Invitation
Regionalizing Diagnostics Value Chains: The path to expanded, equitable access

Official Satellite at the ASLM conference co-hosted by Unitaid, FIND, ASLM, and partners, followed by a cocktail. Please RSVP here to attend.

Date: 12 December 2023
Time: 17:30 – 19:00
Venue: Cape Town International Convention Centre (CTICC), South Africa
MEETING REPORT AVAILABLE

BUILDING FOR SUSTAINABILITY:
Accelerating Regional Manufacturing
For Diagnostics
A FIND & Unitaid Consultation with Diagnostics Manufacturers
15 - 16 April, 2023

Background

The global health community is in agreement about the urgent need to establish resilient health systems worldwide, especially following the COVID-19 pandemic, which highlighted the inadequacy of access to health technologies due to their manufacturing being concentrated in a small number of regions. While these consolidate manufacturing facilities have been critical in securing essential commodities during the low or non-emergency period, they have also highlighted the need to diversify manufacturing networks to ensure redundancy and resilience in the event of future pandemics or crises. This diversification is critical to ensuring that health needs can be met in low and middle-income countries (LMICs) that are frequently underemphasized.

Together, FIND and Unitaid are committed to supporting efforts to create an ecosystem that enables diversified, manufacturing-based diagnostics that meet the needs of LMICs, with a sustainable and resilient approach to diagnostics. The growing consensus is that ensuring the availability of diagnostics is crucial to achieving global health goals.

Meeting objectives

On 15th and 16th April 2023, FIND and Unitaid convened a meeting with 22 diagnostic manufacturers from 10 countries, representing diverse geographical regions in Africa, Asia, the Americas, and Europe. These manufacturers varied in their maturity, product offering, size, and approach to UHC markets. The primary objective of the meeting was to foster cross-regional collaboration, to exchange technology transfer, and manufacturing partnerships for diagnostic technologies related to UHC health priorities. The long-term vision is to ensure all regions are adequately prepared for potential pandemics and endemic diseases while simultaneously establishing a sustainable and resilient ecosystem in LMICs for regional manufacturing of rapid diagnostics.

The outcome of this weeklong convening of diagnostic manufacturers successfully brought together various stakeholders to discuss strategies for strengthening regional research and development (R&D) and manufacturing networks for health technologies. Access to priority areas, recommendations were made by manufacturers, as outlined in this document, providing concise actions that should be considered for establishing an enabling ecosystem that supports the sustainable regional production of diagnostics in LMICs.


FIND & Unitaid will open a call to accelerate & strengthen regional IVD supply in LMICS

- Register to be notified when EOI is open for submissions

Potential future funding and matchmaking opportunities for

Regional supply strengthening projects to meet unaddressed regional priority public health IVD needs

Matchmaking/partnership requests to strengthen the regional IVD supply base

Professional services covering specialized expertise and services that may be essential to regional IVD supplier(s)
## HEALTH PROGRAMME

### Disease Target

<table>
<thead>
<tr>
<th>Health Programme</th>
<th>Disease Target</th>
<th>Product Development Phase</th>
<th>Non-IVD Products</th>
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<tr>
<td></td>
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<td>Phase 0 Concept</td>
<td>Phase 1 Feasibility</td>
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<td>Antimicrobial Resistance</td>
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<td></td>
<td>Multi-Disease</td>
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**NOTES:**
- Rapid Diagnostic Test
- Molecular POC
- Instrument
- Reagents
- Hematology Test
- Clinical Chemistry Test
- Accessory
- Digital Tool
- Other

---

**THROUGHOUT 2023 THERE WERE 14 NON-IVD PIPELINE PRODUCTS**

- Throughout 2023 there were 14 non-IVD pipeline products.
U.S. President’s Malaria Initiative
Malaria RDT Procurements

Lisa Hare & Christie Hershey
Malaria Supply Chain Branch
USAID/U.S. President’s Malaria Initiative
December 2023

Global Fund RDT Stakeholder Consultation Meeting
OUTLINE

1. U.S. President’s Malaria Initiative
2. Historical Malaria RDT Procurements
3. Malaria RDT Sourcing Process
4. HRP2 Deletions
5. Contacts
PMI COUNTRIES & FUNDING

PMI HAS INVESTED APPROXIMATELY $9 BILLION IN HELPING PARTNER COUNTRIES FIGHT MALARIA AND STRENGTHEN HEALTH SYSTEMS
PMI’S HISTORICAL MALARIA RDT PROCUREMENTS

Procure ~ 99 million malaria RDTs per year

1. 95% HRP2 Pf
2. 1% HRP2/pLDH Pf/Pv
3. 4% HRP2/pLDH Pf/Pan (no longer procuring)

First pLDH/pLDH Pf/Pv tests procured in 2022/2023

Mostly 25 packs, but a recent increase in 10 packs for HRP2 Pf and HRP2/pLDH Pf/Pv
PMI’s Malaria RDT Sourcing Process

- PMI’s malaria RDT sourcing events are conducted by our procurement service agent, currently the Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM) project led by Chemonics

- Best Value Criteria in Allocations for FY2024:
  - Total Landed Cost
  - Supplier Performance
  - Innovation (non-HRP2 based tests)
  - African/Regional manufacturing
  - Registration Coverage
PMI’S PERSPECTIVE ON HRP2 GENE DELETIONS

- Targeted support for surveillance, testing through therapeutic efficacy studies
- Support partner countries to review data and update policies
- Procurement of pLDH RDTs in areas with >5% prevalence of deletions in those patients presenting with symptomatic malaria
- Consider non-HRP2 based tests to be a necessary tool for malaria control
RDT TASK FORCE

- Review evidence and work on alignment across procurers
- Concerns about increase in *hrp2* gene deletions but limited data to guide decisions
- Potential development of a risk-based approach to prioritize surveillance and guide procurement of pLDH tests
- Potential shift to proactively diversify RDTs by procuring pLDH tests before demonstrating the 5 percent threshold
  - Promote innovation and investment in non-HRP2 tests
  - Increase demand and potentially lower cost
  - Requires approaches to limit impact on individual country malaria budgets
  - Given combined HRP2/pLDH tests there may no longer be the need to tradeoff detection due to sensitivity issues vs. deletions
CONTACTS FOR PMI RDT PROCUREMENTS

Lisa Hare, Chief Malaria Supply Chain Branch
lhare@usaid.gov

Christie Hershey, RDT Procurement Lead
chershey@usaid.gov
THANK YOU
Overview

- Diversifying RTKs market (African manufacturing)
- Procurement history of RTKs
- PEPFAR funding dynamics
- Order processing and flow
- Key takeaways
Why is African Based Manufacturing Important?

During the COVID surge in 2020, African countries had very limited access to RTKs, drugs, and medical supplies, as countries limited exportation and products were hoarded by manufacturing countries.

Supporting African Based Manufacturing of RTKs:

- Aligns with USAID’s broader strategy to support economic development
- Improves the continent’s self-reliance and expands economic opportunity
- Enhances platform for pandemic preparedness and response
- Supports supply chain diversification
- Supports strengthening and development of regional regulatory bodies
- Increases resiliency and growth throughout the region

The collapse of global cooperation and a failure of international solidarity have shoved Africa out of the diagnostics market. Over 70 countries have restricted exports of medical goods.

CDC Africa
May 2020

https://www.thenewhumanitarian.org/news/2020/05/18/Africa-coronavirus-test-kits
PEPFAR has announced procurement targets to support African Based Manufacturing of RTKs

- PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of $20 million.

- PEPFAR will make key adjustments to its procurement policies to better support emerging African manufacturers to scale-up over time.

- PEPFAR will explore additional regulatory pathways to ensure proper approvals for quality- assured HIV products for purchasing, and over time, will contribute to strengthening of regional regulatory mechanisms on the continent.

https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/
PEPFAR GHSC-RTK has delivered over 320 million RTKs since 2016 with Nigeria, Tanzania, Zambia, Uganda and Mozambique as largest recipients.

<table>
<thead>
<tr>
<th>Country</th>
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<td>Nigeria</td>
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</tbody>
</table>

GHSC-RTK Tests delivered and in pipeline: LOP through FY2023-Q2
322.7 million tests total
PEPFAR GHSC-RTK has procured and delivered over 50 million total tests in FY23
PEPFAR GHSC-RTK Brands (2022-2023)

GHSC-RTK Tests delivered by brand: 2020 thru FY2023-Q4

- Determine, 73.1%
- OraQuick ST, 6.5%
- Bioline, 5.1%
- Uni-Gold, 3.3%
- Bioline Duo, 2.2%
- Alere Combo, 2.2%
- STAT-PAK, 1.9%
- Wantai, 1.8%
- SD Biosensor Combo, 1.5%
- Asante Recency, 1.1%
- 7 Others, 0.8%
<table>
<thead>
<tr>
<th>Country of Manufacture</th>
<th>Amount</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>$28,021,088</td>
<td>63.7%</td>
</tr>
<tr>
<td>United States</td>
<td>$6,655,524</td>
<td>15.1%</td>
</tr>
<tr>
<td>Thailand</td>
<td>$5,388,668</td>
<td>12.2%</td>
</tr>
<tr>
<td>Ireland</td>
<td>$1,772,992</td>
<td>4.0%</td>
</tr>
<tr>
<td>Korea</td>
<td>$1,527,499</td>
<td>3.5%</td>
</tr>
<tr>
<td>China</td>
<td>$410,105</td>
<td>0.9%</td>
</tr>
<tr>
<td>India</td>
<td>$171,534</td>
<td>0.4%</td>
</tr>
<tr>
<td>Canada</td>
<td>$46,670</td>
<td>0.1%</td>
</tr>
</tbody>
</table>
PEPFAR funding dynamics - 101

- PEPFAR strategic priorities determined
- Funding levels determined at the country level (COP process)
- Treatment targets established - associated testing requirements/needs, all while balancing programmatic implementation
- Volumes and timing of deliveries established (SPT)
  - Brands established by national testing algorithms
  - Donor and local funding levels established and validated
- Overall COP budgets approved (FAST - FY Oct-Sept)
- Congressional approvals and funding released
- RTK budgets allocated to RMI (PEPFAR PSA for RTKs)
- Procurements initiated at established intervals within SPT
PEPFAR funding dynamics - 101

- PEPFAR strategic priorities determined
- Funding levels determined at the country level (COP process)
- Treatment targets established - associated testing requirements/needs, all while balancing programmatic implementation
- Volumes and timing of deliveries established (SPT)
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- Congressional approvals and funding released
- RTK budgets allocated to RMI (PEPFAR PSA for RTKs)
- Procurements initiated at established intervals within SPT
HIV self test kit procurement surged during COVID

- Smaller market segment in comparison to clinical use products (donor procured)
- Private sector market segment could be considerable
- Private sector strategies required

HIVST procured per year

FY23 data includes both procured and pipeline order

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>FY20</th>
<th>FY21</th>
<th>FY22</th>
<th>FY23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sum</td>
<td>1,751,000</td>
<td>1,569,750</td>
<td>4,158,993</td>
<td>2,001,750</td>
</tr>
</tbody>
</table>
RMI - Order processing and flow

Lead Time Breakdown

Client

Inquiry
Quotation

Quotation Process

Process Lead Time
Commodity RFQ: 2 days
Freight Forwarder RFQ: 3 days
Quote Preparation: 1 week
Total: 2 weeks

PO Process

Process Lead Time
PO Preparation: 3 days
USAID Approval: 1 week
Order Placement: 2 days
Total: 2 weeks

Production/Ordering Process

Process Lead Time
Production: 6-8 weeks
QA Sampling: 1 week
Freight Quote/AWB: 1 week
Total: 8-10 weeks

Shipping / Logistics

Process Lead Time
IW: 2-4 weeks (DRC: 10-12 wks)
Pick up: 1 week
Shipping: 2 weeks
Total: 4-7 weeks

Delivery – CMS/Regional Warehouse/IPS

Customs (1-2 wks)

Airport (CIP)
RMI - Order processing and flow
Key takeaways

- PEPFAR has established targets for local/regional manufacturing
- Budget allocations are established annually at each country level
- RMI is PEPFAR’s centralized procurement mechanism
- Brands of products are determined by national algorithms
- Self test market is limited in the donor space - significant opportunity in the private sector space

Questions?
UNICEF 2023 – 2028 PROCUREMENT STRATEGY FOR RAPID DIAGNOSTICS FOR HIGH - RISK DISEASES

Wandani Sebonego
UNICEF Supply Division
Goal

- Every child including adolescents survives and thrives with access to quality health care
- Every child including adolescents lives in a safe, sustainable climate and environment
  - Clean air
  - Safe water
  - Healthy food

Strategy Specific Objectives

- Secure access to quality assured rapid diagnostics for high-risk diseases (malaria, HIV, Syphilis, viral hepatitis and cholera)
- Reduce negative environmental impacts of RDTs procured and delivered by UNICEF
- Secure sustainable and equitable prices
- Secure access to new and innovative RDTs
- Shape a diverse and resilient supplier base for supply security
UNICEF 2023 – 2028 PROCUREMENT STRATEGY FOR RAPID DIAGNOSTICS FOR HIGH-RISK DISEASES

▪ Approach

  • Collaborate with partners, governments, civil societies, regulators and manufactures to ensure
    ✓ quality primary health care
    ✓ Sustainability agenda

  • Sustainable procurement
    ✓ Technical
    ✓ Commercial
Securing access to quality assured rapid diagnostics for high-risk diseases

- Quality and Regulatory requirements
  - Test Devices
    - QMS requirement: ISO 13485 certified
    - Regulatory compliance: WHO pre-qualified
  - Kits accessories (alcohol swabs, lancets and specimen transfer devices)
    - QMS requirement: ISO 13485
    - Regulatory Compliance: GHTF founding members
Procurement Strategy Pillars

▪ Reduce negative environmental impacts of RDTs procured and delivered by UNICEF
  • Local production and procurement agenda
  • Product packaging considerations
  • Freight considerations: Air vs Road vs Sea

▪ Shape a diverse and resilient supplier base for supply security
  • New products and suppliers
  • Local manufacturing (Africa)
Technical and Commercial Evaluation Criteria

- Technical Evaluation Criteria (documentary evidence)
  - WHO PQ public report
  - Valid ISO 13485 (test device and accessories)
  - Valid regulatory documents
  - Certificate of sterility, COA
  - Labelling and packaging requirements
  - Shelf life

- All submitted documents will be verified through relevant authorities

- Commercial weighted evaluation criteria
  - Price and volume 65%
  - Sustainability criteria 35%
Temperature tolerance of existing RDTs

> 40 C degree environments
RDTs temperature tolerances ≤ 30 vs ≤ 40

- HIV ≤ 30°C
- HIV ≤ 40°C
- Malaria ≤ 30°C
- Malaria ≤ 40°C
- HBV ≤ 30°C
- HBV ≤ 40°C
- HCV ≤ 30°C
- HCV ≤ 40°C
- Syphilis ≤ 30°C
- Syphilis ≤ 40°C
- HIV/Syphilis ≤ 30°C
- HIV/Syphilis ≤ 40°C
- Cholera ≤ 30°C
Global Fund RDT Procurement Strategy 2024-2026 & tender timeline

13. GF RDT Sourcing Strategy 2024-2026
14. Request for Proposals (Approach and timeline)
Q&A / Discussion 3
RDT PPM Procurement
Highlights 2020-2023

Mustafa al Samaraee
Lead Diagnostic, Direct Sourcing
Global Fund
## All-RDT/ Global Fund RDT scope

The Rapid Diagnostics Test portfolio covers several product segment and type of tests used in the fight against AIDS, Tuberculosis and Malaria

<table>
<thead>
<tr>
<th>Malaria RDT (MRDT)</th>
<th>HIV RDT (HRDT)</th>
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<tbody>
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<td>❖ Plasmodium falciparum (P.f)</td>
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<td>❖ Cryptococcus</td>
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<td>❖ G6PD</td>
<td>❖ CD4 RDT</td>
<td>❖ TB LAM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>❖ Other: Gonorrhea, Chlamydia, Cryptosporidiosis, Pregnancy (hCG)</td>
</tr>
</tbody>
</table>
All-RDT/ 1.1 Bn tests procured since 2020

Big gap in price between the different RDT types

- From 2020 to Sep 2023 Global Fund procured **818 million Malaria RDT**, worth **US$ 219M**
- **270 million HIV RDT** worth **US$ 273M** procured during same period
- Despite high HIV RDT volumes, spend remains high comparing to Malaria RDT

**VALUE**
US$518M worth of RDTs procured...

- **$273 M** 53% HIV RDT
- **$219 M** 42% Malaria RDT
- **$25 M** 5% Other RDT

**VOLUME**
...for 1.1Bn tests

- **818M tests** 73%
- **270M tests** 24%
- **27M tests** 3%

Data Source: Global Fund Procurement Service Agent
All-RDT/ $518M procured since 2020
Demand across 78 countries with lion’s share in few countries

PPM supplied RDTs to 78 countries* across all continents from 2020 to Sep 2023, …


... and 12 countries accounted for 80%

Data Source: Global Fund Procurement Service Agent
**All-RDT/ Strengthening supplier performance**

While supplier OTIF* performance was adversely affected by the COVID-19 pandemic, our efforts and commitment to improve performance has yielded significant results.

- **COVID-19** had a **significant negative impact** on the availability of all RDTs, especially the Malaria RDTs due to supply chain challenges and **deprioritization** in favor of more **profitable tests**.

- **Supplier Performance** has significantly increased for the **Malaria RDT**, above the target since Q3 2022, due to several measures taken by the Global Fund including:
  - Intensified communications with suppliers
  - Supply base diversification
  - More frequent updates regarding forecasts
  - Performance improvement plans for low performance

- **Improved performance** for HIV and Other RDT categories remain **below target**, mainly due to limited supplier diversification

---

*Supplier OTIF is a key performance indicator (KPI) comparing supplier purchase orders delivered “On Time in Full” (OTIF) against total number of Supplier Purchase Orders. The KPI measures when Supplier has fulfilled their obligations to the PSA regarding the Committed Delivery Date.*

Data Source: Global Fund Procurement Service Agent
Malaria RDT/ Demand remains high

Covid-19 impacted Malaria programs, as evidenced by the demand dip in 2021

1. Global Fund demand is cyclical by nature of the funding Grant Cycles, yet
   • Higher demand in 2020 was a mitigation measure against future anticipated supply constraints
   • Lower volumes in 2021 owing to the pandemic
   • Steady demand recovery in 2022
   • 2023 total volume is expected to be around 200M tests

2. PPM volume procured indicates
   • The share of P.f only tests is reducing from almost 80% in 2020 to 74% of in 2023
   • P.f/P.v demand grew from 7.2M tests in 2020 to 17.8M as of Sep 2023
   • P.f/Pan decreased in 2023
   • Demand for pLDH based tests remains low

Data Source: Global Fund Procurement Service Agent
Malaria RDT/Tests procured in 45 countries

Nigeria, DR Congo, Uganda, Mozambique and Tanzania, who gather over half of malaria cases worldwide, also represented over 50% of global MRDT demand

PPM served 818M tests to 45 countries*, ...


... and 10 countries accounted for 80% of the volumes

Data Source: Global Fund Procurement Service Agent
Malaria RDT/ Market dynamics

Supplier base for malaria tests have notably increased

- Malaria rapid tests remain the **main malaria diagnostic tool**. Other technologies will likely address specific use cases with unique value.

- The Malaria rapid tests market consistently shows **high demand**. Demand continues to concentrate on the HRP II type of tests.

- Over the last 3 years, the pool of **WHO approved malaria rapid tests suppliers has expanded** contributing to healthy market and supply security. However, the pool of suppliers with pLDH based tests is limited.

- There is an emerging risk of increasing **HRPII gene deletion**. However, certainty of gene deletion scale and location is yet to be determined. This may lead to increased demand for the pLDH tests in the coming years.

- The production capacity of WHO-prequalified malaria RDT suppliers has increased exponentially during the pandemic. However, larger **suppliers tend to prioritise manufacturing of other types of tests** over malaria rapid tests.

- Malaria rapid test **prices have increased** but remain **stable** for the last couple years.
HIV RDT/ 270M tests procured since 2020
Combo and Self-Test share increased steadily to one third of total demand by Sep 2023

- **270 Million HRDT tests**, worth US$ 273M in total, was procured through PPM from 2020 to Sep 2023

- Demand share of **HRDT Professional** tests remains **predominant** but steadily **reducing** from over 90% in 2020 to about two thirds by Sep 2023

- **HIV Syphilis combo** test demand **grew** 313% from 3.8M tests in 2020 to **11.8M** as of Sep 2023

- **Self-Test** demand **grew** 473% from 1.9M tests in 2020 to **9.0M** as of Sep 2023

Data Source: Global Fund Procurement Service Agent
HIV RDT/Tests procured in 75 countries

Tanzania, Uganda, Mozambique, and Nigeria each had over 20M+ tests procured and together represented over half of PPM worldwide demand

PPM served 270M tests to 75 countries*,…


… and 11 countries accounted for 80% of volumes

Data Source: Global Fund Procurement Service Agent
HIV RDT/ Market dynamics – HIV Professional

Cost remains high compared to similar tests

• Demand for HIV tests have diversified as combo tests and self-tests integrated into the HIV programs. Overall, demand for HIV professional tests remain high (above 60% of all HIV RDT).

• HIV professional rapid tests cost remains high compared to other similar tests, despite high volumes due to concentrated demand around a preferred set of products related to product selection practices.

• As a result, HIV professional market limited ability to ensure supply security and healthy competition.

• Combo tests demand is growing. Over 40 countries are in process of adopting the dual test.

• Increase in dual test share is also related to decreasing prices.

• Expected demand from countries for a triple combination tests HIV, HBs Ag, Syphilis.
HIV RDT/ Market dynamics – HIV Self-Test
More options available but demand remain concentrated

• **Demand** for HIV self-tests **significantly increased** and more countries planning to order self-tests. However, forecast volumes are largely **stalling** due to high cost and lack of diversity between oral and blood-based test.

• Increased number of **WHO PQ-ed ST** with **lower-cost**. Yet, weighted average **price** for HIVST remains **substantially higher** than professional test and more affordable tests are needed to reach ST full potential.

• Despite increased interest and procurement in **blood-based test** **supply security** is still at risk in short term due to **concentrated demand on oral-based**.

• Currently **one WHO PQ HIV ST manufacturer in Africa**.
Other RDT/ US$ 25M procured since 2020

Syphilis and Hepatitis B (HB) together represent about 90% of total demand of tests

ORDT volume procured through PPM from 2020 to Sep 2023 offer following observations:

- **Sustained strong demand growth** from 1M test in 2020 to 6M in Sep 2023 of Hepatitis B (HB) tests with total 12 Million tests worth US$ 11M

- **Stable demand** of ~3M Syphilis test per year with total 11 Million tests worth US$ 7M, and of ~300k Hepatitis C (HC) tests with total 1.1 Million tests worth US$ 1.1M

- **Tuberculosis** cyclical demand over the period with total 882k tests worth US$ 3.2M

- Over **100K CD4 tests** procured in 2022 and 2023

- **Six countries** (Malawi, Ethiopia, Mozambique, Uganda, Burkina Faso and Haiti) represent **80% of total 27M ORDT tests procured**

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**Data Source:** Global Fund Procurement Service Agent

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RDT Procurement Strategy
2024 – 2026

Scope & Forecast

Aziz Jafarov
Manager, Direct Sourcing, Global Sourcing Health Technologies
Global Fund
The Rapid Diagnostics Test portfolio covers several product segment and type of tests used in the fight against AIDS, Tuberculosis and Malaria.

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Malaria RDT/ GC7 Volume Forecast
Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

CONTEXT

• **Preliminary forecast** based on Health Product Management Tools submitted as part of the GC7 Funding Request

• 3-year forecast totals close to **600 millions** of Malaria RDT tests.

• Overall forecast of GC7 **similar to GC6 volumes**

• Volumes **driven by** demand for MRDT **P.f only**

• **2026 demand likely to increase** due to potential savings at the end of the cycle
HIV RDT/ GC7 Volume Forecast

Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

**CONTEXT**

- **Preliminary forecast** numbers are based on Health Product Management Tools submitted as part of the GC7 Funding Request
- The overall number of planned RDTs is relatively stable for GC7 (as a comparison to GC6)
- Total 3 years forecast amounts 184 millions of test
- Volumes are driven by demand for Professional test
- Stable demand of Self-Test across the years

**PRELIMINARY FORECAST**

<table>
<thead>
<tr>
<th>Year</th>
<th>HIV/Syphilis Combo</th>
<th>ST</th>
<th>Pro</th>
</tr>
</thead>
<tbody>
<tr>
<td>2024</td>
<td>48M</td>
<td>7M</td>
<td>13M</td>
</tr>
<tr>
<td>2025</td>
<td>63M</td>
<td>9M</td>
<td>17M</td>
</tr>
<tr>
<td>2026</td>
<td>73M</td>
<td>9M</td>
<td>20M</td>
</tr>
</tbody>
</table>
Other RDT Volume Forecast

Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

CONTEXT

- **Preliminary forecast** numbers are based on Health Product Management Tools submitted as part of the GC7 Funding Request
- Total 3 years forecast amounts **35 millions of tests**
- Increase in **Syphilis demand** from 3M test in 2024 to 5M in 2026
- Increased demand of CD4 tests compared with previous cycle: addition of ‘new’ countries ordering large volumes
- **Cryptococcus** tests accounts for: 250k tests year 1; 300k tests year 2 and 200k tests year 3 (included in “Other tests” category)

PRELIMINARY FORECAST

PPM ORDT demand forecast 2024 to 2026 in Millions of test

- **Hepatitis B (HB)**
- **Tuberculosis**
- **Syphilis**
- **CD4**
- **Other tests**

* Other tests: Cryptococcus, Hepatitis C (HC), Gonorrhea, Chlamydia, Cryptosporidiosis, Pregnancy (hCG)
RDT Procurement Strategy
2024 – 2026

Strategy & Objectives

Aziz Jafarov
Manager, Direct Sourcing, Global Sourcing Health Technologies
Global Fund
RDT Strategy Evolution

The RDT Procurement Strategy has evolved in cycles, building on learnings as well as disease specific dynamics.

Spot RFP Approach (Prior to 2019)
- Purchase Order agreement implemented
- Spot tenders pricing approach
- Performance management matrix set up

Performance Based Approach (2019 - 2023)
- Long-Term Framework Agreement implemented
- Rigorous supplier performance implemented
- Market Shaping intervention including MRDT interchangeability
- Strengthened QA policy with WHO PQ requirements

Value Creation through SRM (2024 - 2026)
- Key principles of supplier relationship management (SRM) applied
- Performance management matrix enhanced to enable decision-making
- More direct engagement with suppliers

RDT Procurement Strategy cycles

Prior to 2019 | 2019-2023 | 2024-2026
--- | --- | ---
Spot RFP Approach | Performance Based Approach | Value Creation Through SRM
Broad Value Consideration

Strategic Objectives

THE GLOBAL FUND
# The 5 Strategic Objectives for 2024 - 2026

<table>
<thead>
<tr>
<th>Objective</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Ensure Equitable Access to RDTs: Affordability and Availability</strong></td>
<td>Maintain competitive &amp; sustainable pricing through diversified supply base and value delivery</td>
</tr>
<tr>
<td><strong>2. Secure RDTs supply chain including by incentivising Regional Manufacturing</strong></td>
<td>Improve supply chain for responsive and agile RDTs delivery</td>
</tr>
<tr>
<td><strong>3. Supply Quality-Assured RDTs</strong></td>
<td>Ensure access to quality-assured health products through strict Quality Assurance (QA)</td>
</tr>
<tr>
<td><strong>4. Encourage environmentally sustainable RDTs</strong></td>
<td>Drive sustainable procurement and supply chains in line with NextGen Market Shaping ambitions</td>
</tr>
<tr>
<td><strong>5. Accelerate the introduction of the innovative RDTs at scale</strong></td>
<td>Enable product introduction and innovation to ensure optimal care for people we serve, cost reduction and reduced environmental impact</td>
</tr>
</tbody>
</table>
Objective 1 Ensure Equitable Access to RDTs: Affordability and Availability

Maintain competitive & sustainable pricing through a diversified supply base

Affordability: Competitive and Sustainable pricing

- GF will continue to support and maintain competitive and sustainable markets
- Cost will remain a key element of the sourcing strategy to ensure an optimal use of resources
- Continue to broaden the definition of “Value” beyond pricing and looking for opportunities to add value beyond product costs
- Increasing supplier accountability including Most Favoured Nations implementation

Availability: Diversified Supply Based

- Continue with multi-year agreements aligned with strategic objectives
- Ensure the inclusion of new market entrants supplying existing and innovative RDTs.
Objective 2 Secure RDTs supply chain including by incentivising Regional Manufacturing

Promote regional manufacturing and improve supply chain for responsive and agile RDTs delivery

A. Incorporate previous tender cycles & Covid-19 pandemic learnings, and with a stronger focus on supplier accountability & supply chain robustness
   • Strategy will continue to ensure the reliable supply of all required RDTs through resilient and diversified supply base
   • Deepen partnership with suppliers to proactively understand and mitigate supply challenges, including challenges related to upstream supply security, to maintain high delivery performance
   • Improving overall lead times through robust forecast periodically communicated with suppliers
B. Promote local and regional manufacturing
   • Encourage regional RDT manufacturing closer to end users to improve access and diversify the supply base
   • Continue to promote geographic diversification & promote local manufacturing and capability building
   • Consider regional manufacturing as evaluation criteria in RDT tender
Objective 3 Supply Quality-Assured RDTs

Ensure equitable access to Quality-Assured health products through strict Quality Assurance (QA)

- **Product Quality is essential** to ensure that quality assured RDTs are sourced and delivered to the people we serve

- Global Fund Quality Assurance (QA) eligibility requirements will continue to ensure that health products are available at internationally recognized quality standards

- **Framework Agreement** proposed under RDT Procurement cycle 2024 – 2026 will continue to include a strong QA section at its core

- Quality Assurance will also continue to be an integral part of our supplier review process and focus on quality updates and topics impacting supply
Objective 4  Encourage environmentally sustainable RDTs

Drive sustainable procurement and supply chains in line with NextGen Market Shaping ambitions

- Supply Operations is piloting a Responsible Procurement Framework which embeds sustainability principles and practices into our sourcing activities

- This Framework was developed in response to the challenges of Climate Change and supports the implementation of the Global Fund Supplier Code Of Conduct

- Through the RDT Procurement cycle 2024-2026, suppliers will be encouraged to
  - Continuously strengthen sustainability credentials and practices throughout their manufacturing and supply chains, and share baseline information to measure our impact
  - Minimize environmental impact of distribution, delivery, and at end-user level through enhanced planning, adapting transport routes, reduce packaging etc.
  - Implement projects to address environmental impact of manufacturing RDTs
  - Leverage innovations to further reduce packaging and shipping costs
Objective 5 Accelerate the introduction of the innovative RDTs at scale

Enable equitable access to innovations to ensure optimal care for people we serve, cost reduction and reduced environmental impact

- **Continue to stimulate innovation** through agreed supplier-driven projects

- Leverage procurement process to **support a robust pipeline of new products** intended to improve efficacy, reduce cost, & better meet the needs of end users in line with disease guidelines, latest WHO recommendations

- **Align with partners** regarding new innovative tests needed in the market and harness their support to facilitate new product introduction at scale

- Leverage innovations to **improve packaging, shipping costs, and product design and reduce plastic waste.**
Request for Proposals (RFP)

Approach & Timeline

Fabrice Abalain
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Global Fund

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Legal Counsel (Institutional Matters)
Global Fund
RFP process and timelines (indicative)

Phase I: Supplier and Partner Engagement (Q3 - Dec 2023)
- Consultations with suppliers and partners
- RDT Procurement Strategy Presentation Partners & Suppliers 11 Dec 2023
- Invite feedback from suppliers and partners

Phase II: RFP launch and bid submissions (Dec 2023 - Feb 2024)
- RFP documents are uploaded on Sourcing Platform, including both technical and commercial sections
- Q & A on the RFP documents and process
- Bid submissions

Phase III: Evaluations (Feb – Mar 2024)
- Evaluations
- Internal Approvals
- Award

Phase IV: Contracting (Q2 2024)
- Contract finalization & signature
RDT RFP

Commercial criteria (55%)
1. Unit Price & Total Landed Cost
2. Volume Discounted Price* & Total Landed Cost

Technical criteria (45%)
1. Product & Country Registration Coverage
2. Innovation & Sustainability
3. OTIF delivery performance (incl. capacity & lead time)
4. Regional manufacturing in sub-Saharan Africa

Compliance requirements:
• Financial Due Diligence
• Integrity Due Diligence

- The full scope of evaluation criteria will be reapplied at annual performance reviews for subsequent allocation periods
- There will be a process to consider new entrants and/or new products that become eligible for procurement after tender closure (subject to review)

* Volume Discounted Price to apply depending on product category
Legal Matters: Certificate of Conformance

RFP Bidders will be required to submit a signed certificate by an authorized officer, to acknowledge and agree (among other things):

- Bidder will comply with Global Fund’s Code of Conduct for Suppliers.
- Bidder’s RFP submission implies Bidder’s unconditional acceptance of the terms and conditions of the Strategic Partnership Agreement.
- Any reservations on the Partnership Agreement must be notified to the Global Fund as part of the RFP submission.
- Only limited, non-material amendments to the draft Strategic Partnership Agreement submitted as part of the Bidder’s proposal may be considered by the Global Fund.
- The reservations or amendment requests will be considered in the overall evaluation of the Organization’s proposal.
- Modifications to the following provisions of the Partnership Agreement will not be accepted:
  1. Record-Keeping and Audits,
  2. Governing Law and Dispute Resolution,
  3. No Waiver of Privileges and Immunities,
  4. Compliance with the Global Fund’s Quality Assurance Policy, Code of Conducts and Sanctions Panel Procedures,
  5. Principles set forth in Most Favored Nation clause.
Integrity Due Diligence
The Global Funds Ethics policies in relation to suppliers

RFP Schedules
• All suppliers must complete the IDD questionnaire to its full extent
• Information on ownership and control is required for sanctions checks
• Conflict of interest disclosures required to develop mitigations
• Policies and case histories required to assess the ability to fulfill obligations under the Code of Conduct and other policies
• Limited fulfilment of expectations will inform risk management decisions

Code of Conduct
• Prohibits both direct and indirect:
  • Corruption
  • Fraud
  • Coercion
  • Collusion
  • Anti-competitive practices
• Full and open disclosures of CoI, including potential and perceived
• Safeguarding (with obligatory reporting):
  • Protection from Sexual Exploitation, Abuse and Sexual Harassment
  • Child protection

Other documents
• Policy to Combat Fraud and Corruption
• Policy on Conflict of Interest
• Contractual terms with respect to ethical issues
• Sanctions Panel Procedures
Sourcing Platform used for all RFP communications

Welcome page & notifications

Good afternoon,

Things to Finish

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You Are Invited to Request for Proposal TGF-D-00011(RFP Test)

Actions

Accept Invitation

Decline Invitation
Communications & Support on Platform Access

• All communications with regards to this RFP, including clarification questions, shall be in writing and sent through the TGF Sourcing Platform using the online discussion (see below).

• Any communication from an RFP Participant to the Global Fund related to this RFP which is not through the designated channel (https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/), is not permitted and will not be answered.

• Should the Global Fund deem it necessary to revise the RFP as a result of a clarification, it shall do so as an amendment to the RFP available on the Global Fund’s website.
Sourcing Platform: Other Matters

Oracle Guided Learning (OGL)

- Feature which provides step-by-step and personalized guides in the negotiation module.

- Please open the following link in your browser to see the step guide (Supplier Creates Response to Negotiation Invitation):
  [https://guidedlearning.oracle.com/player/latest/api/scenario/export/v1/WpUIM+OJRoSJYo3jQu37UA/k7hjkr1/lang/--/?draft=undefined](https://guidedlearning.oracle.com/player/latest/api/scenario/export/v1/WpUIM+OJRoSJYo3jQu37UA/k7hjkr1/lang/--/?draft=undefined)

- Access to the OGL: Click on the “I” icon and select the appropriate Guide
Thank you