Expert Review Panel for Diagnostics: update

3RD DECEMBER 2019, JOINT UNICEF, UNFPA AND WHO MEETING WITH MANUFACTURERS AND SUPPLIERS, COPENHAGEN

TheGlobalFund
Overview

- Product Quality and Strategy Implementation
- QA Policy and demand drivers for Expert Review Panels for Diagnostics (ERPD)
- ERPD Process, evaluation outcomes and examples
- Resources, Information and Documentation

WHO released new guidelines on HIV self-testing and partner notification ahead of World AIDS Day 2016 (29 November 2016)
Aim of MSS:
Leverage GF’s position to facilitate healthier global markets for health products – today and in the future

- Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies
- Support efforts to stimulate innovation and facilitate the rapid introduction and scale-up of cost-effective health technologies and implementation models


Maximize impact against HIV, TB and malaria
Build resilient & sustainable systems for health
Promote & protect human rights and gender equality
Mobilize increased resources

Having the right product for the right population at the right time at the right place in the right way
QA Policy for Diagnostic Products (May 2017)

**Products in the scope of the policy (not exhaustive):**
Rapid Diagnostic Tests for malaria, HIV, TB, Hepatitis B, Hepatitis C, Syphilis, Equipment/consumables, IVD reagents, calibrators, Software, Microscopes, Imaging equipment, ...

**Products not in the scope of the policy (not exhaustive):**
Products for general laboratory use, gloves, syringes, needles, test tubes, ...

**I Clinical Criteria (section 6)**
- Compliance with National guidelines
- Consistent with WHO Guidance

Funding request must give evidence and technical justification if needed.

**IIa GENERAL Quality Criteria for ALL Diagnostics Products (section 7)**
- Manufacturing site for all products:
  - Compliant with ISO 13485* for IVD and Imaging Equipment
  - Compliant with ISO 9001* (all others)

* or equivalent

**IIb Additional SPECIAL Quality Criteria for a selection of IVDs (section 8)**
- Prequalified by WHO PQ
- Recommended by WHO TB programme
- Authorized through stringent regulatory assessment (in high risk classification) by authorities being founding member of GHTF**
- Assessed by WHO Expert Review Panel

** not for HIV ST

*The Global Fund * Le Fonds mondial * El Fondo Mundial * Глобальный фонд * 全球基金 * الصندوق العالمي
# Global Fund QA Policy compliance options ("pathways")

<table>
<thead>
<tr>
<th>Quality Criteria according section 8 of GF QA Policy</th>
<th>HIV (RDT)</th>
<th>HIV-Syphilis (RDT)</th>
<th>Malaria (RDT)</th>
<th>Malaria critical</th>
<th>HIV critical (RDT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Prequalified by WHO PQ</td>
<td>++</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>ii. Recommended by WHO TB programme</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>iii. Stringent regulatory assessment (high risk)</td>
<td>++</td>
<td>0</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>iv. Assessed by GF/WHO Expert Review Panel</td>
<td>0</td>
<td>1+</td>
<td>2+</td>
<td>2+</td>
<td>1</td>
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- **Regulatory path exists**
- **Regulatory path does not exist**
- **Regulatory path not accepted**
Global Fund List of Eligible Products for HIV Self Testing (Ver 15 / 14 July 2017)

<table>
<thead>
<tr>
<th>HIV Self Tests</th>
<th>Rapid Diagnostic Tests (RDTs)</th>
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- **HIV Self Tests**:
  - On-Quick HIV Test
  - On-Quick HIV Test

- **Rapid Diagnostic Tests (RDTs)**:
  - Sample size: 300
  - Results: 20 minutes
  - Accuracy: 99%

Note: This list is subject to change and is updated regularly. For the most current information, please refer to the Global Fund's official website.
Main steps & Timeline – ERP process for Diagnostic Products (ERPD)

I. Design of the EoI
   - 4 weeks

II. Publication & Communication of the EoI
   - 8 weeks

III. Management of Submissions
   - 2 weeks

IV. ERP Review
   - 6 weeks

V. Management of Reports & Decision
   - 2 weeks

VI. Management of Additional Data
   - 4 weeks

VII. ERP Review
   - 6 weeks

VIII. Management of Reports & Decision
   - 2 weeks

### Key Deliverables
- Finalized scope of diagnostic product categories to accept EoI
- “Invitation for EoI” published on TGF website
- Manufacturer submit an EoI (questionnaire)
- Manufacturer are informed about the screening outcome of the Product Questionnaire
- ERP Review
- ERP Meeting
- TGF receives the outcome of the ERP Review
- Inform manufacturer on the outcome
- Update TGF List of diagnostic products
- Request Additional Data / NOT ALL
- Transfer of additional data from manufacturer for ERP
- ERP Review
- TGF receives ERP Reports
- Inform manufacturer on the outcome
- Update of TGF List of diagnostic products


Note: Timeline are given for indicative purpose only

Rev. Date 11-11-2019
Categorization of products reviewed by ERPD

Classification of products reviewed in four categories:

• Products classified in **Categories 1 and 2** may be considered for time-limited procurement.

• Products classified in **Category 3** may be considered for time-limited procurement only if there is no other option and the risk of not diagnosing and/or making treatment decisions is higher than the risk of using the product.

• Products classified in **Category 4** may not be considered for procurement under any circumstances.
Where to find documentation on The Global Fund website

- Overview
- Updates
- Market Shaping Strategy
- Procurement Tools
- Health Product Procurement
- Information for Suppliers
- Price & Quality Reporting
- Quality Assurance
- Medicines
- Diagnostic Products
- Other Products
- Expert Review Panel
- Information Notice
- View Related Resources

Diagnostic Products

- Overview
- Updates
- Information for Suppliers
- Policies & Principles
- Quality Assurance
- Diagnostics
- Products

- Quality Assurance Policy for Diagnostic Products
  - Download in English (Excel Format)

ELIGIBLE PRODUCT LISTS

- List of Rapid Diagnostic Test Kits for Malaria Classified According to the Quality Assurance Policy
  - Download in English
- List of HIV Diagnostic Test Kits and Equipments Classified According to the Quality Assurance Policy
  - Download in English

Related Resources

- Expert Review Panel for Diagnostics Terms of Reference
  - English
  - French
- Expert Review Panel for Pharmaceutical Products Terms of Reference
  - English
Look back to 2019
Thanks for the good collaboration in the past …

Winter Round call in February  
Sommer Round call in September

… all the best for 2020!
Thanks for your attention
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