Procuring HIV Diagnostic Tools
Manufacturers, implementers and agencies

Market share of HIV RDT products
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Objective

- Provide a market analysis of procurement data for HIV Rapid Diagnostic tests (RDTs)
  - By country
  - By manufacturer
  - By product

- Scope and Method
  - Analysis of HIV RDT procurement 2009 - 2011
  - Data sources included:
    - Global Fund (GF) Price and Quality reporting Mechanism (PQR)
    - WHO Global Price Reporting Mechanism (GPRM)
      - Focus on Global Fund PQR in 2010-2011
## Total $US and volume of HIV RDTs

Procurement reported to Global Fund and WHO GPRM

<table>
<thead>
<tr>
<th>Year</th>
<th># of Tests</th>
<th>$US</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 GF</td>
<td>32'202'195</td>
<td>$20'831'400</td>
</tr>
<tr>
<td>2009 WHO</td>
<td>47'993'655</td>
<td>$39'709'185</td>
</tr>
<tr>
<td>Total 2009</td>
<td>80'195'850</td>
<td>$60'540'585</td>
</tr>
<tr>
<td>2010 GF</td>
<td>21'786'880</td>
<td>$23'613'992</td>
</tr>
<tr>
<td>2010 WHO</td>
<td>40'628'585</td>
<td>$32'985'603</td>
</tr>
<tr>
<td>Total 2010</td>
<td>62'415'465</td>
<td>$56'599'595</td>
</tr>
<tr>
<td>2011 GF</td>
<td>12'341'986</td>
<td>$13'210'694</td>
</tr>
<tr>
<td>Total 2011</td>
<td>12'341'986</td>
<td>$13'210'694</td>
</tr>
</tbody>
</table>

2009: India’s reported purchases accounted for 54% of all Global Fund reported purchases (21% of total tests procured)
Analysis of HIV RDT reported purchases to GF PQR and WHO GPRM

- Total number of HIV RDTs ranged from 80 million tests in 2009 dropping to 12 million tests in 2011
  - WHO GPRM data for 2011 shows $8.7 million revenue but no corresponding test numbers
    - Assuming an ASP of $0.95, # of tests for 2011 can be estimated at $8.2 million, bringing 2011 total # of tests to 20 million
  - Global Fund PQR data for 2009 shows 54% of tests reported procured were from India at a price of $0.31/Test
    - Subsequent years do not reflect the same procurement levels for India
- Focus of this analysis on 2010-2011, with implementation of Global Fund Quality Assurance Policy for Diagnostics
HIV RDTs 2010-2011
Top 7 countries in reported purchases to GF

- Tanzania: 23%
- Uganda: 19%
- Ethiopia: 16%
- Malawi: 16%
- Mozambique: 12%
- Zimbabwe: 8%
- Ghana: 6%
HIV RDTs 2010-2011
Top 7 Manufacturers in reported purchases to GF

- Orgenics: 28%
- Standard Diagnostics: 19%
- Inverness Medical: 28%
- Shanghai Kehua: 8%
- Trinity Biotech: 8%
- Chembio Diagnostic Systems: 5%
- Premier Medical: 4%
HIV RDTs 2010-2011
Top 7 Products in reported purchases to GF

- Determine HIV-1/2 w/b test: 36%
- Determine HIV-1/2: 20%
- SD Bioline HIV-1/2 Rapid: 4%
- Uni-Gold HIV-1/HIV-2: 8%
- SD Bioline HIV-1/2 3.0: 18%
- Diagnostic Kit for HIV(1+2) Antibody: 9%
- First Response HIV 1-2-0 Card: 5%
Analysis of HIV RDT reported purchases to Global Fund PQR

• Top 3 HIV procured RDTs in 2010-2011 were:
  – Determine HIV-1/2 and Determine HIV-1/2 WB test by Inverness (Alere) (also sold by Orgenics)
  – SD Bioline HIV-1/2 3.0 by Standard Diagnostics
  – Diagnostic Kit for HIV by Shanghai Kehua

• HIV RDT median price per test ranges from $1.08 in 2010 to $1.07 in 2011
Analysis of HIV RDT reported purchases to Global Fund PQR

• 45% of HIV RDTs procured in 2010 are now WHO prequalified
• 74% of HIV RDTs procured in 2010 have entered the WHO prequalification process or are prequalified
• 75% of HIV RDTs procured in 2011 are now WHO prequalified
• 78% of HIV RDTs procured in 2011 have entered the WHO prequalification process or are prequalified
Final remarks

• Improvements to the PQR have resulted in more accurate reporting of procurement by Grantees, helping to monitor compliance with the policy and market trends.

• Since the policy has been implemented, all reported HIV RDTs to the PQR have met the criteria of the Global Fund QA policy.

• An increasing number of HIV RDTs are WHO prequalified or under review for prequalification.