Navigating Procurement of Automated Molecular Diagnostics for HIV Viral Load and Early Infant Diagnosis

The Partnership for Supply Chain Management

What are automated molecular diagnostics?

Molecular diagnostics identify a pathogen infection by detecting DNA or RNA from the pathogen. The detection of viral DNA or RNA is often referred to as a Viral Load (VL) test.

HIV VL tests are sometimes referred to simply as “Viral Load” because HIV VL tests were historically the first VL tests widely available in low- and middle-income countries. Early Infant Diagnosis (EID) of HIV can utilize the same platforms used for adult HIV VL.

Automated molecular diagnostics are often centralized, lab-based platforms with a high volume of tests per day (throughput). However near-point-of-care (POC), community-based automated platforms with a lower throughput are also used. These platforms are polyvalent, meaning that they can be used for a range of tests such as HIV, EID, SARS-CoV-2, tuberculosis (TB), hepatitis C (HCV), human papillomavirus (HPV), etc. depending on the supplier’s test portfolio.

OVERVIEW OF AUTOMATED MOLECULAR DIAGNOSTICS

INPUTS
- Samples
  - Sputum
  - Nasal swab
  - Plasma
  - Whole blood (WB)
  - Dried blood spot (DBS)
  - Plasma separation card (PSC)
- Reagents
- Controls
- Consumables

PROCESSING & DETECTION
- Diagnostic Platform
  - DNA/RNA extraction
  - PCR analysis

OUTPUT
- Results
  - Quantitative VL
  - Qualitative EID

Platforms commonly used for HIV VL and EID
(not exhaustive, not to scale)

Abbott m2000
Hologic Panther
Roche 48/58/68/8800
Cepheid GeneXpert
There are a range of procurement modes for HIV VL and EID tests.

### Example Modalities within the Range of Procurement Options

<table>
<thead>
<tr>
<th></th>
<th>Direct Purchase</th>
<th>Hybrid</th>
<th>“All-inclusive”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All components are purchased individually</td>
<td>More inclusive than direct purchase with certain cost components bundled</td>
<td>Test price includes all cost components and platform placement</td>
</tr>
<tr>
<td></td>
<td>Minimal responsibility of supplier</td>
<td>Equipment lease with no annual test volume commitment</td>
<td>Supplier agrees to meet certain Key Performance Indicators (KPIs)</td>
</tr>
<tr>
<td></td>
<td>Greater logistics risks for the recipient</td>
<td>Some cost components may be included</td>
<td>Volume commitments are required</td>
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<tr>
<td></td>
<td></td>
<td>Service and maintenance (S&amp;M) may be included</td>
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### Opportunities and Challenges of Procurement Modalities from Perspective of Principle Recipient

#### Direct Purchase

**Opportunities**
- Flexibility without volume commitments.
- May offer value when there is a significant existing platform install base.
- When “all-inclusive” eligibility requirements can not be met.

**Challenges**
- Requires the individual purchase of the platform, reagents and consumables.
- May be less cost effective than more inclusive modes of procurement.
- Limited cost component visibility due to hidden costs compared to more inclusive modes of procurement.

#### Hybrid

**Opportunities**
- Annual payments are made (often to the local distributor) for the use of a platform.

**Challenges**
- Minimum test volume thresholds or other commitments from the recipient may apply.

#### “All-inclusive” Procurement

**Opportunities**
- Combine multiple cost components such as: service and maintenance, loading from warehouse local agent fees, etc.
- Utilize more inclusive incoterms than direct purchase.
- May include the placement of a platform at no additional cost.
- KPIs that the supplier agrees to meet (e.g. time to respond to a service request).
- May help streamline procurement.

**Challenges**
- Minimum test volumes thresholds are required.
Detailed comparison of modes of procurement

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<tr>
<th></th>
<th>Direct Purchase</th>
<th>Hybrid Example</th>
<th>All-Inclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume commitment</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Instrument placed at no additional cost</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Reagents and propriety consumables purchased directly</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Service and maintenance (S&amp;M)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Invalid results due to instrument errors replaced</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>

THERE IS NO ONE-SIZE FITS ALL MODE OF PROCUREMENT WHICH IS BEST FOR ALL SCENARIOS

Some key considerations and questions for the recipient:

1. Inclusive agreements require test volume commitments.
2. Is there an existing footprint of a particular supplier’s platforms?
3. Is testing integrated across disease programs to maximize testing volumes and enable volume thresholds to be met?
4. Are diagnostic networks optimized for maximum utilization of platforms?
5. Has a procurement modality cost assessment been performed, which includes in-country cost components such distributor mark-ups?
6. Are there legacy direct purchase platforms which could be transitioned to inclusive agreements?