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

The Partnership for Supply Chain Management

November 2023

The purpose of this document

This document provides a non-technical overview of the diagnostics commonly utilized for HIV viral load tests and early infant diagnosis. It also presents, at a high level, the various modes of procurement for these tests.

Glossary

Molecular diagnostic - Test that identifies a pathogen based on the detection of DNA or RNA.

Platform - Diagnostic instrument also known by other general terms such as system, analyzer, instrument, or machine.

Supplier - Manufacturer of a diagnostic platform and the associated proprietary reagents.

Polyvalent (multi-disease testing) - Description of a platform which is able to perform a range of tests based on the supplier's test menu. For example, using the same test platform for HIV and hepatitis C (HCV) testing.

Consumable - Generic category of single use, ancillary items which are needed to perform a test (e.g. gloves, tubes, pipette tips, etc.).

Reagent - One of the chemicals required to run an assay (test)

Dried Blood Spot (DBS) - Dried whole blood sample from a finger stick or infant's heel stick.

cobas Plasma Separation Card (PSC) – Roche's proprietary product for preserving plasma for molecular diagnostics from a small volume of whole blood.

Sputum – A sample of saliva and mucus coughed up from the respiratory tract often used for tuberculosis testing.

Polymerase Chain Reaction (PCR) – Chemical process used to copy DNA in a sample to enable detection. A variation known as Reverse Transcription (RT-PCR) is used to detect RNA targets.

Extraction - Process of removing the DNA or RNA from a pathogen in a sample to enable subsequent PCR or RT-PCR.

Viral Load (VL) - The amount of virus in a sample. Commonly measured by PCR or RT-PCR.

Early Infant Diagnosis (EID) - Qualitative, PCR-based test to diagnose children between 6 weeks and 18 months of age.

Incoterm - Definition of shipping and trade terms published by the International Chamber of Commerce (ICC) to ensure clarity and consistency in international trade agreements.

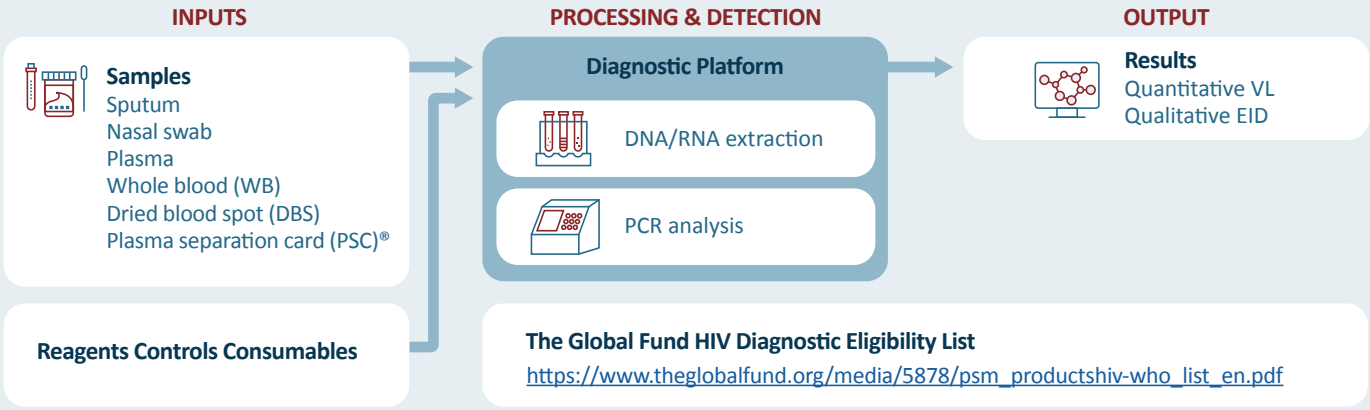
What are automated molecular diagnostics?

Molecular diagnostics identify a pathogen by detecting the pathogen's DNA or RNA. The detection of viral RNA (or DNA) is 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 (LMICs). Early Infant Diagnosis (EID) of HIV can utilize the same platforms used for adult HIV VL.

Automated molecular diagnostics are centralized, lab-based platforms with a high volume of tests per day (throughput). However near-point-of-care (nPOC), community-based automated platforms having a lower throughput are also used. These platforms are polyvalent, meaning that they can be used for multi-disease testing 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



There are a range of procurement modes for HIV VL and EID tests

EXAMPLE MODALITIES WITHIN THE RANGE OF PROCUREMENT OPTIONS

OPPORTUNITIES AND CHALLENGES OF PROCUREMENT MODALITIES FROM PERSPECTIVE OF PRINCIPLE RECIPIENT

	Opportunities	Challenges
Direct Purchase	• 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.	• 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	• Annual payments are made (often to the local distributor) for the use of a platform.	• Minimum test volume thresholds or other commitments from the recipient may apply.
"All-inclusive" Procurement	• 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.	• Minimum test volumes thresholds are required.

Detailed comparison of modes of procurement

	Direct Purchase	Hybrid Example	All-Inclusive
Volume commitment			✔
Instrument placed at no additional cost		✔	✔
Reagents and propriety consumables purchased directly	✔	✔	✔
Service and maintenance (S&M)		✔	✔
Invalid results due to instrument errors replaced			✔

**Inclusion of components in these examples may vary for each mode of procurement*

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?

pfscm@pfscm.org | www.pfscm.org | +1-571-227-8600

2733 Crystal Drive, 4th Floor
Arlington, VA 22202