

## New Resources: Key Considerations for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems, and the HIV Point-of-Care Diagnostics Toolkit

Reaching the UNAIDS 90-90-90 treatment targets will require a massive expansion of HIV diagnostic services to ascertain HIV status and monitor the viral load of those initiated on and continuing ART.

The current scenario for HIV diagnostics does not meet the immense needs of the world's 36.7 million people living with HIV.<sup>1</sup> Exclusive reliance on conventional diagnostic technologies means that many clients do not have access to same-day test results, and instead wait days, weeks or sometimes months while their specimens and results are transported to and from centralized laboratories. These long turn-around times often result in high rates of client loss to follow up and delayed care and treatment decisions for both children and adults.

A key strategy to meet the testing and diagnostic needs of people living with HIV is the scale up of innovative testing, while strengthening existing laboratory systems. One such approach is strategic deployment of point-of-care (POC) testing, which will expand access to diagnostics and enable clients to receive test results during the same visit.

### WHAT IS POINT-OF-CARE TESTING?

POC testing refers to testing that takes place during a client visit, with results provided during the same visit. 'Near Point-of-Care' also refers to testing on-site and rapid results, but requires a higher-level facility where electricity is consistently accessible. POC and near POC devices are easy-to-use products that do not require complex specimen preparation, constant electricity, refrigeration, sophisticated laboratory infrastructure, or highly skilled human resources (see Table below for additional benefits and challenges).

Optimizing the balance between conventional laboratory network and POC testing in a country can strategically increase access to testing and diagnostics, and ultimately improve health outcomes.

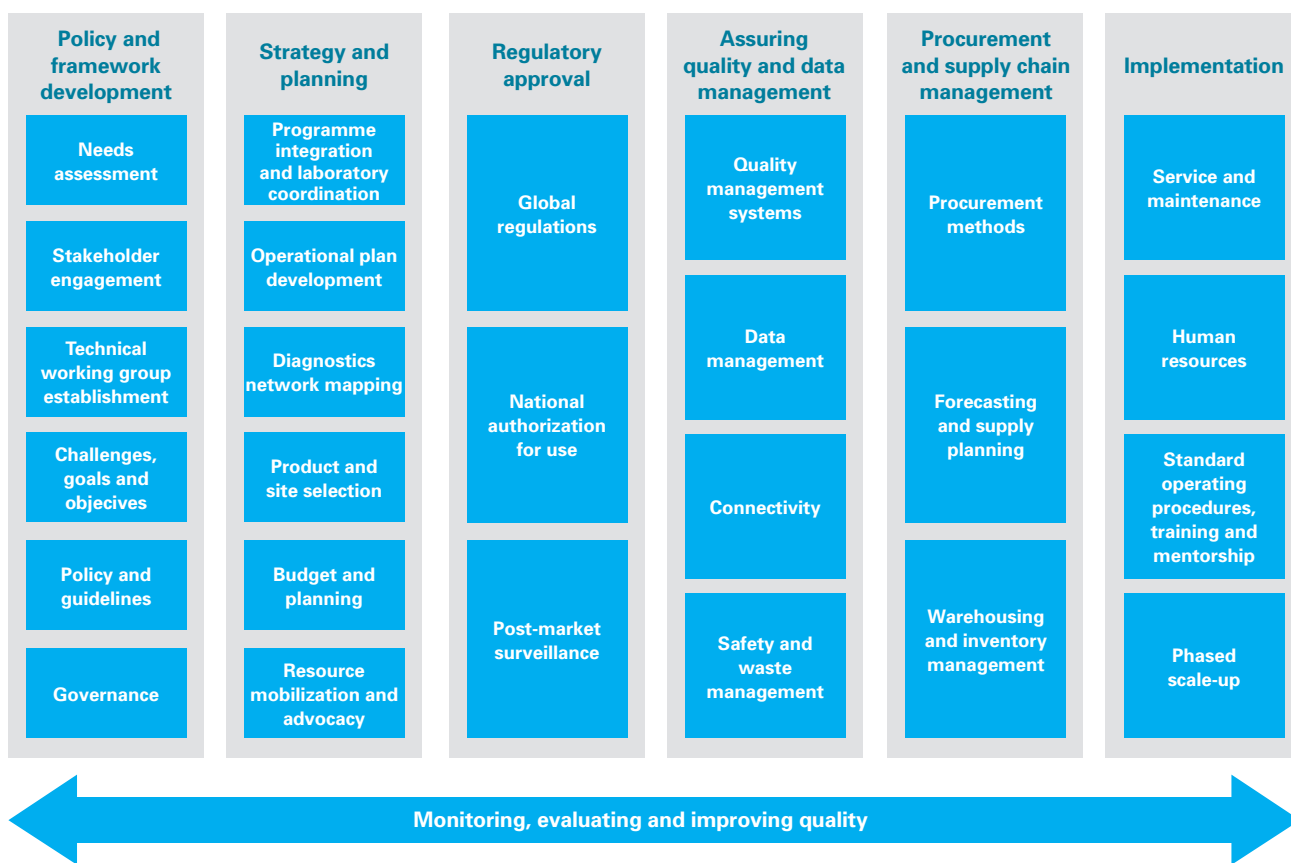
- **POC early infant diagnosis (EID):** Offering infant virologic testing at the point-of-care will help ensure that HIV-exposed infants are tested, diagnosed and quickly linked to life-saving care and treatment.
- **POC viral load (VL):** Same-day VL results may enable better monitoring of treatment, adherence counseling interventions, and faster enrollment on second- or third-line treatment regimens when needed.
- **POC CD4:** In settings where CD4 is still indicated, POC CD4 tests at HIV diagnosis can help improve patient management by accelerating linkage to care and initiation of treatment. This is particularly important during late presentation for HIV care – i.e., people with symptoms of advanced HIV disease and who are at high risk of opportunistic infections.

As of July 2017, there are two WHO Prequalified devices on the market for Infant Virologic Testing and EID (Alere™ q and Cepheid GeneXpert®), one device for viral load (Cepheid GeneXpert®), and two devices for CD4 (Alere™ Pima and BD FACSPresto™).<sup>2</sup>

### Summary of benefits and challenges related to point-of-care and near point-of-care technologies as compared with conventional laboratory network systems

	Benefits	Challenges/Limitations
Access	<ul style="list-style-type: none"> <li>• Results are produced at/near the site of patient care.</li> <li>• Faster turnaround time, even same-day results, allow for immediate clinical decisions, and same-day initiation of treatment, if indicated.</li> <li>• Shorter turnaround time for results reduces the likelihood of loss to follow-up.</li> </ul>	<ul style="list-style-type: none"> <li>• Patient wait times in the clinic, while the results are being generated, may be too long.</li> <li>• Clinic or patient flow may need to be adjusted or revised to provide same-day results.</li> <li>• It may not necessarily result in improved health outcomes, particularly for viral load and if a patient is not linked to care and treatment.</li> </ul>
Efficiency	<ul style="list-style-type: none"> <li>• Most infant virological and viral load POC IVDs can run approximately 8–20 tests per day, per instrument.</li> </ul>	<ul style="list-style-type: none"> <li>• The throughput of POC and some near POC devices is lower than throughput at the central level (at the central level one person can run 100 or more specimens per day).</li> <li>• If volume is high, more than one POC device may be needed to process the test volume, increasing the cost per test, if all devices are not used to capacity. If volume is low, cost per test may be higher due to lower utilization.</li> <li>• Near POC devices require constant electricity and both POC and near POC devices require some degree of temperature control for operation and storage of reagents (cartridges).</li> </ul>
Cost	<ul style="list-style-type: none"> <li>• An increased proportion of test results are returned to patients, with less wastage from repeated testing of patients who never receive their test results.</li> <li>• Prices of IVDs (instruments and test cartridges) are expected to decrease over time, except for current IVDs for infant virological testing.</li> </ul>	<ul style="list-style-type: none"> <li>• Making POC cost-effective in low volume areas is currently challenging.</li> <li>• Cost per test run is currently higher than conventional testing (the cost per result received could become comparable to and even lower than conventional laboratory-based testing, depending on the type of device used, the type of test run, and where the device is placed).</li> </ul>
Operability	<ul style="list-style-type: none"> <li>• POC devices can be operated by non-laboratory trained personnel.</li> <li>• POC devices require fewer procedural steps and commodities.</li> <li>• Some reagents and controls do not require refrigeration and have a shelf life of approximately 9 to 12 months, with efforts under way to extend shelf life.</li> <li>• Some devices use low specimen volumes, which are easier to collect.</li> <li>• Most POC devices have built-in quality controls.</li> <li>• Many devices use capillary whole blood; therefore, phlebotomy and specimen processing are not required (except for current near POC technologies for viral load).</li> </ul>	<ul style="list-style-type: none"> <li>• Turnover of operators at health-facility level may be high especially in remote or hard-to-reach areas, making quality testing by trained operators hard to sustain.</li> <li>• As may be already an issue within the conventional lab systems, POC devices will require reagent storage and inventory management, and some facilities (i.e., primary health-care clinics) may not have the requisite space, refrigeration or systems to support POC.</li> </ul>
Infrastructure	<ul style="list-style-type: none"> <li>• Tests can be performed in wider a range of sites with fewer infrastructure requirements.</li> <li>• Most POC devices are portable, and operable without constant electricity or need for air conditioning.</li> <li>• In remote and hard-to-reach sites where turnaround times for test results may be long, POC devices minimize reliance on specimen referral systems and/or centralized testing facilities.</li> </ul>	<ul style="list-style-type: none"> <li>• As with changes to conventional laboratory technologies, additional training is required.</li> <li>• Supervision and quality assurance may be more difficult due to a greater number of and more dispersed sites.</li> <li>• Near POC devices require constant electricity, computer interface and some degree of temperature control for operation and storage (cartridges).</li> </ul>

## Key considerations for introducing HIV POC technologies



### Key Considerations Document

*Key Considerations for Introducing Point-of-Care Diagnostic Technologies in National Health Systems* provides background information on HIV POC testing and its contribution to meeting the 90-90-90 treatment targets. It outlines key steps for introducing HIV POC technologies into national health programs, covering an array of topics across the planning and implementation continuum of POC HIV diagnostics (see Figure above).

### HIV Point-of Care Diagnostics Toolkit

Developed through a joint inter-agency consensus-building process<sup>3</sup>, the *HIV Point-of Care Diagnostics Toolkit* contains various

practical tools and guidance to support countries with the planning and integration of POC HIV diagnostics into their national laboratory networks.

A complement to *Key Consideration for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems*, the Toolkit currently consists of four modules:

- Product and Site Selection
- Forecasting and Supply Planning
- Regulations
- Quality Assurance

Additional modules are under development.

Both *Key Considerations for Introducing New HIV Point-of-Care Diagnostic*

*Technologies in National Health Systems*, and the *HIV Point-of-Care Diagnostics Toolkit* were developed in the context of pioneering, catalytic investments made by Unitaid in new point-of-care HIV diagnostic technologies across 15 countries in Sub-Saharan Africa: Cameroon, Cote d'Ivoire, Democratic Republic of the Congo, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Senegal, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Robust implementation experience across more than 10 countries served as the foundation for the development of both resources.

To access these resources, please visit: <http://www.childrenandaids.org/poc-toolkit-page>

1. UNAIDS, 2016

2. [http://www.who.int/diagnostics\\_laboratory/evaluations/PQ\\_list/en/](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/)

3. The contributions of the following organizations are gratefully acknowledged: African Society for Laboratory Medicine, U.S. Centers for Disease Control and Prevention, Clinton Health Access Initiative, Foundation for Innovative New Diagnostics, Office of the U.S. Global AIDS Coordinator and Health Diplomacy, Elizabeth Glaser Pediatric AIDS Foundation, London School of Hygiene & Tropical Medicine/International Diagnostics Centre, International Center for AIDS Care and Treatment Programs, Médecins Sans Frontières, Solthis, Unitaid, UNICEF, the United States Agency for International Development, and the World Health Organization.

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