HIV Point-of-Care Diagnostics Toolkit

https://www.childrenaids.org/poc-toolkit-page
• What is the HIV Point-of-Care Diagnostics Toolkit?
• Why was the Toolkit developed?
• How is the Toolkit organized?
• How was the Toolkit developed?
• Are there other useful resources available for countries to learn from?
• How can you provide feedback on the Toolkit?
  • To provide feedback on this Toolkit or to share tools from your country context, contact Alex Costa at UNICEF (alecosta@unicef.org).
  • To share your thoughts about these resources and additional modules you would find useful, please take the survey.
This project is made possible thanks to Unitaid’s support.

Unitaid accelerates access to innovation so that critical health products can reach the people who most need them.
<table>
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<th>Category</th>
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| **Product and site selection**| • Global Fund’s Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool (GF)  
• EID and VL Product and Site Selection Tool (CHAI)  
• Guidance Note on Product Selection, Facility Upgrades, and Sample Transportation (EGPAF)  
• Side-by-Side Analysis of POC EID Products  
• Guidance for Site Enrollment (EGPAF)  
• USAID’s Laboratory Efficiency and Quality Improvement Planning tool (LabEQIP*) (USAID) |
| **Forecasting and supply planning** | • The primary tool in this module is ForLAB, a standardized, open-source quantification tool designed to help program managers forecast commodity needs for diagnostic services.  
• Forecasting and Supply Planning for the Scale-up of new POC EID/VL Technologies. |
| **Regulations**                | • Regulatory processes and frameworks for medical devices  
• Product evaluations  
• National approval for use and  
• Post-market surveillance |
| **Quality assurance**          | • The POC Quality Assurance Budgeting Tool (CHAI)  
• Stepwise Process for Improving the Quality of HIV-Related Point of Care Testing (SPI-POCT) Checklist  
• Site Monitoring Guidance (EGPAF)  
• Improving the Quality of HIV-Related Point of Care Testing: Insuring the Reliability and Accuracy of Test Results |
Product selection

The selection of POC products should be objective and transparent, deploying the most appropriate products to sites, complementing the existing laboratory network to maximize impact on patient access to testing. POC products should be selected in response to the specific needs, capacity, and limitations of selected sites and the laboratory-clinic network as a whole, as well as to ensure instruments are fit-for-purpose.

For countries receiving Global Fund grants, the Global Fund's Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool is designed to guide countries receiving Global Fund grants with the selection and procurement of viral load (VL) and early infant diagnosis (EID) technologies, including POC diagnostic technologies approved by the Global Fund. It is advised that countries using Global Fund funding to purchase POC diagnostic products discuss their needs with Global Fund procurement as part of the product selection process.

Clinton Health Access Initiative’s (CHAI) EID and VL Product and Site Selection Tool is an excel-based decision-making tool designed to help countries with:

- Selecting the most appropriate EID and VL products and sites for piloting and scaling up EID and VL point of care testing.
- Determining the optimal deployment of POC devices and conventional equipment to maximize patient impact while maintaining cost efficiency.

It is intended to help technical working groups (TWGS) and stakeholders better understand the current gaps in testing coverage in the country, identify the key country-specific criteria for selecting sites and POC products; and score those criteria to determine the balance between patient volume, access, and price when making decisions about site and product selection. It has been implemented in Cameroon, Malawi and Zimbabwe.

For guidance on how to use the CHAI EID and VL Product and Selection Tool, click here. For a version of the tool with sample data click here.

It is important to note that accurately completing the tool requires gathering site-level data, national programmatic indicators, and evaluating the relative importance of device performance characteristics. Assembling and cleaning the data can require significant time and sometimes, dedicated resources.

CHAI and the African Society of Laboratory Medicine are available to support use of the tool with technical assistance. For additional information, please contact Seth McGovern at CHAI (sethmcgovern@clintonhealthaccess.org).

Focusing more specifically on EID, the Elizabeth Glaser Pediatric AIDS Foundation's (EGPAF) guidance notes (below) are collectively designed to help countries select the most appropriate products and sites to support the piloting and scale up of POC EID technologies, including within the context of a hub and spoke model.
Introduction

The Early Infant Diagnosis (EID) and Viral Load Product and Site Selection Tool is designed to assist countries in selecting the most appropriate EID and VL products and sites for piloting and scale-up of POC diagnostic technologies. Currently, site selection options include the Alere Q, Cepheid GeneXpert, Cepheid Omnia, and Diagnostics for the Real World's Samba II. The tool will be expanded as other products receive regulatory approval through WHO-PQ, FDA, or CE-marking for HBV 2-2 viral load and EID testing. Omnia is expected to be on the market in 2017, and Alere Q’s viral load assay cartridge is in development.

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Note: Use of tool requires Microsoft Excel 2007 or later.
### 3. Insert inputs and assumptions

#### Country Guidelines

- **% of patients for ART per year**
- **Percent of patients requiring second viral load test due to treatment failure or non-adherence**
- **Prevalence rate in HIV-infected infants**

#### Lab Infrastructure and Operations

- **Number of PCR instruments in country**
- **Number of centralized testing labs**
- **Maximum number of POC devices per site**
- **Frequency of 5T per week**
- **Variable costs per test (S)**
- **Variable costs per site (S)**

#### Sample transport costs

- **Fixed costs (5 per site)**
- **Number of sites accessing sample transport**
- **Frequency of 5T per week**
- **Variable costs per test (S)**
- **Variable costs per site (S)**

#### Cost per PCR machine (S)

- **Cost per PCR machine (S)**
- **Cost per centralized lab (Lyne)**
- **Cost per test (5 per site for all testing commodities)**
- **Labor technician salary per hour**
- **Number of lab technicians required for POC device**

#### Cost of running centralized lab

- **Annual cost for PCR machine for service and maintenance (S)**

#### Cost of running POC

- **Avg. cost per PCR machine (S)**
- **Lifespan of device (S)**
- **Avg. cost per test (S)**
- **Number of lab technicians required for POC device**
- **Overhead cost per site (S)**

#### Health impact

- **Low HIV prevalence with conventional EDL testing**
- **High HIV prevalence with conventional EDL testing**

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**Note:** The data and assumptions are based on typical values and are subject to variation based on specific site conditions.
### Site Profiles

**INSTRUCTIONS:** Enter site information and distances to other sites. In addition to inserting replication numbers, the formula will be included along with the distances. If you do not wish to include replication numbers, simply enter the distances. The model will automatically calculate the distances between sites. The model will consider the number of sites, not the number of replications. For example, if you have 3 sites and 3 replications, the model will calculate the distances between each site. If you do not want to use replication numbers, you can enter the distances directly. However, if you enter distances with replication numbers, you must enter distances for each replication. The model will then calculate the average distance between each site. If a distance is entered for one replication, the model will calculate the average distance between all replications. If you enter a distance for only one replication, the model will calculate the average distance between all other replications.

#### Site Name | District | # of ART PIs | # of PAT PIs | Avg TAT in D & E | Existing Access | Existing Access | ART Dil | Probable ART Dil
--- | --- | --- | --- | --- | --- | --- | --- | ---
Site A | District 1 | 5 | 3 | 120 | 0.0 | 0.0 | 0.1 | 0.2
Site B | District 2 | 4 | 2 | 110 | 0.0 | 0.0 | 0.1 | 0.2
Site C | District 3 | 6 | 4 | 130 | 0.0 | 0.0 | 0.1 | 0.2
Site D | District 4 | 7 | 5 | 140 | 0.0 | 0.0 | 0.1 | 0.2
Site E | District 5 | 8 | 6 | 150 | 0.0 | 0.0 | 0.1 | 0.2
Site F | District 6 | 9 | 7 | 160 | 0.0 | 0.0 | 0.1 | 0.2
Site G | District 7 | 10 | 8 | 170 | 0.0 | 0.0 | 0.1 | 0.2
Site H | District 8 | 11 | 9 | 180 | 0.0 | 0.0 | 0.1 | 0.2
Site I | District 9 | 12 | 10 | 190 | 0.0 | 0.0 | 0.1 | 0.2
Site J | District 10 | 13 | 11 | 200 | 0.0 | 0.0 | 0.1 | 0.2