



# APHL Position Statement

## Quality Systems for Point of Care Testing

### A. Statement of Position

A Quality Management System (QMS) for point of care (POC) testing including rapid diagnostic tests (RDT) is needed to ensure that testing performed in all settings is of high quality globally.

### B. Implementation

The Association of Public Health Laboratories (APHL) will:

1. Collaborate with the Centers for Disease Control and Prevention (CDC), the US Department of State, other US federal agencies, and international partners engaged in the development, implementation and management of activities that ensure quality testing in all settings.
2. Develop and disseminate tools, standards, and resources necessary to assure the quality and effectiveness of POC testing.
3. Advocate for the adoption and implementation of this position with stakeholders.
4. Support defining the roles and responsibilities that local/regional/national laboratories may have in the training, oversight and management of POC testing.

### C. Background/Data Supporting Position

Although POC tests can be quite simple, they can also be performed incorrectly, resulting in diagnostic errors. POC diagnostic tests are used in settings where there is a need for immediate patient management decisions (e.g., emergency rooms, delivery rooms, primary care clinics, HIV testing and counseling facilities), where patients often do not

return for test results, or where traditional laboratory services are unavailable or too time-consuming to meet clinical needs. POC tests can provide diagnostic results conveniently and in real-time, resulting in less loss-to-follow-up, better treatment uptake, and improved health outcomes.

POC tests are a rapidly growing component of healthcare as diagnostic tests, particularly in low- and middle-income countries (LMIC). For the two most commonly used RDTs (HIV and malaria) the estimated global volume in 2014 was approximately 400 million tests.<sup>1,2</sup>

These tests are generally described as simple to perform, requiring little to no laboratory equipment or laboratory science education. Therefore, they are often performed by nurses, lay counselors, or community health workers.<sup>3</sup>

In many areas where POCs are widely used, structured training, and often periodic retraining is provided. However, personnel turnover, loss of skills over time, or inadequate understanding of test technology may lead to misuse of POCs and erroneous results.<sup>4</sup> In the US, such tests are often defined as “CLIA-waived” and are thus subject to minimal Quality Assurance (QA) requirements. However, guidelines still highly recommend robust QA for RDTs.<sup>5</sup> Because electronically reported POC test results may be used to influence disease surveillance and programmatic decisions,<sup>6,7</sup> it is important that these tests be quality assured.

APHL has extensive experience supporting the development and implementation of tools,

standards and resources to support both quality systems<sup>8</sup> and information systems in laboratories.<sup>9</sup> Applying this expertise to screening and diagnostic testing in all settings will lead to improvements in disease surveillance and public health.

## D. References

1. 314 million Malaria RDTs in 2014: [http://www.who.int/malaria/areas/diagnosis/rapid\\_diagnostic\\_tests/en/](http://www.who.int/malaria/areas/diagnosis/rapid_diagnostic_tests/en/)
2. World Health Organization. (2015) . Consolidated guidelines on HIV testing services: 5Cs: consent, confidentiality, counselling, correct results and connection 2015. World Health Organization. <http://www.who.int/iris/handle/10665/179870>
3. Community Health Workers Use Malaria Rapid Diagnostic Tests (RDTs) Safely and Accurately: Results of a Longitudinal Study in Zambia <https://www.ncbi.nlm.nih.gov/pubmed/22764292>
4. Technical guidance update on quality assurance for HIV rapid diagnostic tests (2015) <https://www.ncbi.nlm.nih.gov/books/NBK316036/>
5. Existing guidelines for CLIA-waived tests: [https://www.cdc.gov/hiv/pdf/testing\\_qa\\_guidelines.pdf](https://www.cdc.gov/hiv/pdf/testing_qa_guidelines.pdf)
6. Using electronic readers to monitor progress toward elimination of mother-to-child transmission of HIV and syphilis: An opinion piece. <https://www.ncbi.nlm.nih.gov/pubmed/25983212>
7. Comparison of a mobile phone-based malaria reporting system with source participant register data for capturing spatial and temporal trends in epidemiological indicators of malaria transmission collected by community health workers in rural Zambia <https://www.ncbi.nlm.nih.gov/pubmed/25495698>
8. APHL supports work in quality systems: [https://www.aphl.org/programs/quality\\_systems/Pages/default.aspx](https://www.aphl.org/programs/quality_systems/Pages/default.aspx)
9. APHL supports LIMS development: <https://www.aphl.org/programs/informatics/pages/global-lims-initiative.aspx>

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