
APHL Position/Policy Statement

APHL Position Statement/Policy Statement on Rapid HIV Testing

A. Statement of Position

APHL supports rapid HIV testing in settings where turn around time dictates immediate patient management decisions (e.g., emergency rooms, delivery rooms, occupational exposures), and where clients often do not return for testing results, e.g., publicly funded counseling and testing sites. This support is predicated upon the implementation and maintenance of a comprehensive quality assurance program at the testing site, to include appropriate training, quality control and competency evaluation.

B. Background/Data Supporting Position

APHL is concerned about widespread, unmonitored use of rapid HIV tests in community settings where adequate staff training, adherence to manufacturer's instructions, accurate test results, appropriate referral for confirmatory testing, and timely and complete disease reporting may not occur.

In 1992, the Health Care Finance Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), began a program allowing select rapid clinical tests to be administered and processed in settings that are exempted or *waived* from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Examples of waived testing sites include many nontraditional testing facilities, such as adult day care centers, ambulances, correctional institutions, health fairs, pharmacies, and schools. Since CLIA's inception, the number of waived testing sites has risen to about 56 percent of the total 174,500 laboratories enrolled in the CLIA program, or roughly 97,700 sites. To qualify as a waived site, a facility must register with the CMS CLIA program through designated state agencies to receive a certificate of waiver (or work under an organization that has a certificate of waiver), pay biennial certification fees, agree to follow the manufacturer's test instructions for waived tests, allow random CMS inspections, and comply with all applicable state and federal laws.

Waived testing sites are allowed to perform exempted or waived tests. The number of tests waived under CLIA has increased from 8 in 1992 to approximately 70 in 2004. Of these, the first waived HIV test — the OraQuick™ rapid HIV-1 antibody test produced by Orasure Technologies — was approved in 2003. Sites that wish to administer the OraQuick™ HIV test must meet some additional requirements, including having a quality assurance program in place (as stipulated in the manufacturer's test instructions), providing training to test personnel to ensure that the manufacturers' instructions are followed, and adhering to all HIV test requirements/guidelines issued by the local state health agency. In addition, arrangements must be in place to access confirmatory testing for clients who test preliminary positive on the rapid screening test. Regulation and oversight of non-traditional laboratories (i.e. community based organizations) performing HIV waived testing is limited. Manufacturers and distributors of HIV waived tests are not required to verify that a facility has a Certificate of Waiver (COW) prior to shipping products, and the vast numbers of COW laboratories in the United States hamper CMS's ability to inspect under CLIA. To facilitate implementation of the required quality assurance program, the CDC has developed quality assurance guidelines specifically for sites performing

the OraQuick™ HIV test (posted at www.cdc.gov/hiv/rapid_testing).

A core function of public health laboratories is to assure quality laboratory testing regardless of the testing site. HIV testing is a critical public health issue. Because of their level of expertise, public health laboratories can assist in compliance with regulatory requirements. Public health laboratories can also assist in meeting the need for a quality assurance program that is based on CDC guidelines¹ and may include enrollment in CDC's longstanding Model Performance Evaluation Program (MPEP).² They also promote implementing biohazard safety plans, performing confirmatory testing of positive results, and following any relevant state health agency regulations and/or state laws (e.g., disease reporting). In addition, some public health laboratories may conduct quality audit visits, in agreement with CMS, to registered waived sites within their states to monitor compliance and to serve as an educational tool.

C. References

1. See CDC Guidelines for a Quality Assurance Program at www.cdc.gov/hiv/rapid_testing
2. Information on CDC's MPEP program can be accessed at www.phppo.cdc.gov/mpep/enrollment.asp

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