APHL Position Statement
Rapid HIV Testing

A. Statement of Position

APHL supports rapid HIV testing in settings where turnaround 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., some 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 but not limited to, appropriate training, quality control and competency evaluation.

B. Implementation

A function of public health, and specifically of public health laboratories, is to assure quality laboratory testing regardless of the testing site.[1] HIV testing is a critical public health issue. Because of their level of expertise, some public health laboratories may assist testing sites in compliance with regulatory requirements, establishing biohazard safety plans, and adhering to relevant state regulations (e.g. disease reporting). They also may provide supplemental testing on preliminary positive rapid results as well as assist in resolving discrepant results when multi-rapid test algorithms are utilized. Public health laboratories may also assist in meeting the need for a quality assurance program that is based on CDC guidelines[2] (which may include suggested enrollment in CDC's longstanding Model Performance Evaluation Program[3]). APHL recommends that the rapid HIV testing quality assurance program include supplemental testing referral of clients testing preliminary positive. Access to and routine use of supplemental testing should be a part of every rapid HIV test service. In addition, some public health laboratories may have the ability to assist registered waived sites, in agreement with CMS, with quality audit visits and to serve as an educational tool.

C. Background/Data Supporting Position

APHL is concerned about widespread, unmonitored[4] use of rapid HIV tests in community settings where adequate staff training, adherence to manufacturer's instructions, accurate test results, provision of or 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.

There are currently four CLIA-waived rapid tests for HIV. Sites that wish to administer these tests must follow the manufacturer's test instructions, which require having a quality assurance program in place. In order to facilitate implementation of the required quality assurance program, the CDC has developed quality assurance guidelines specifically for sites performing rapid HIV testing (posted at http://www.cdc.gov/hiv/pdf/testing_qa_guidlines.pdf).

D. References

1. Centers for Disease Control and Prevention. 2002. Core functions and capabilities of state public health laboratories: a report of the Association of Public Health Laboratories and National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect: defining the national agenda for fetal alcohol syndrome and other prenatal alcohol-related effects. MMWR; 51(RR-14):2. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm
2. See CDC Guidelines for a Quality Assurance Program at http://www.cdc.gov/hiv/pdf/testing_qa_guidlines.pdf
3. Information on CDC's MPEP program can be accessed at: www.cdc.gov/mpep/hiv-1rt.aspx
4. Wesolowski LG, Ethridge SF, Martin EG, Cadoff EM, MacKellar DA. (2009). Rapid human immunodeficiency virus test quality assurance practices and outcomes among testing sites affiliated with 17 public health departments. J Clin Microbiol 47(10):3333-5.

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