DOH STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

March 1, 2006

Re: Quality Control Requirements for Rapid HIV Testing

Dear Laboratory Director:

We are writing to inform you that, effective immediately, laboratories may adopt a performance based quality control program for rapid HIV testing in point-of-care settings within hospitals and other Article 28 licensed facilities. The Clinical Laboratory Evaluation Program (CLEP) is in the process of updating Laboratory Standards to reflect this change. Manufacturer's recommendations for quality control should be considered a baseline for any quality control program, and may be adopted provided the laboratory director has established and documented that the recommendations are appropriate for the testing environment and the many associated variables that affect test performance. Minimally, external quality control (positive and negative) must be run once each month and with change in test device lot number and receipt of new shipments.

In New York State, many people infected with HIV are as yet unaware of their infection and many do not receive their initial HIV diagnosis until late in the infection when they have already advanced to AIDS. A CDC initiative, *Advancing HIV Prevention: New Strategies for a Changing Epidemic,* is aimed at reducing barriers to early diagnosis of HIV infection. Among the strategies is to encourage use of the HIV rapid test at the point-of-care. In April 2005, Commissioner Novello issued a *Dear Colleague* letter that acknowledges the need to remove or reduce barriers to HIV testing. She urged that testing be more routinely offered in medical settings with consideration for the adoption of rapid HIV tests to allow the timely delivery of a test result.

The AIDS Institute and the Wadsworth Center's Clinical Laboratory Evaluation Program actively promote the use of rapid HIV testing and share the conviction that access to testing must be balanced by practices for safe and reliable test performance. Many laboratory directors have cited CLEP's quality control requirement for the use of matrix-matched (external) control materials each day that rapid HIV testing is performed as excessive and costly. While hospital and laboratory regulations require all testing within hospitals and other Article 28 facilities to be performed under the facility's clinical laboratory permit, this requirement for daily quality control is viewed as an obstacle to the deployment of rapid HIV testing resources to points-of-care within these settings.

Revised standards specific to the quality control of single-use devices with integrated procedural controls will be released soon. Questions and requests for additional information on technical testing issues and permit requirements may be directed to CLEP at (518) 485-5378 or by e-mail to CLEP@health.state.ny.us

Information on the clinical benefits of rapid HIV testing from the Center of Disease Control and Prevention can be found at http://www.cdc.gov/hiv/pubs/rt.htm. The New York State Department of Health website has additional rapid testing information that can be found at http://www.health.state.ny.us/aids/testing/rapid/index/htm.

Sincerely,

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Director, AIDS Institute

Richard W. Jenny, Ph.D.
Director, Clinical Laboratory Evaluation Program