

PROFICIENCY TESTING PROGRAM

Purpose:

The purpose of Proficiency Testing is to monitor the quality of technical services provided by physicians, nursing staff; medical assistants and any other individual trained and competent for rapid HIV testing and to ensure that problems related to these are identified and addressed. The monitoring system is designed to be compatible with the standards of the NJ Department of Health and Senior Services, and CLIA 88. Federal regulations, state regulations and deeming authorities such as the College of American Pathologists mandate that all testing facilities must successfully participate in an approved proficiency program for all regulated testing being performed in each specialty.

Proficiency testing is an ongoing part of a process intended to ensure that the analytic system of the testing site is functioning correctly. The basic premise of proficiency testing is that proficiency test specimens are tested simultaneously with patient unknowns and the results compared with results generated in many other institutions. Failure to obtain the expected values results in a series of corrective actions designed to protect UMDNJ-RWJMS and its clients from the generation of aberrant and incorrect data.

Responsibility:

The responsibility of the Rapid HIV Testing Support Program is to:

- Oversee and evaluate the quality of testing provided by sites licensed to perform rapid HIV testing under the auspices of RWJMS.
- Ensure laboratory compliance with existing federal and state regulations.
- Assist the staff at these sites in meeting the clinical laboratory testing needs of their patients.

Rapid HIV Testing Support sites staff must participate in the proficiency testing periodically as a requirement for inclusion in the Rapid HIV Testing Support Program, in accordance with state and federal regulations.

Procedure:

In order to provide central coordination of these activities and to alert the license holder of significant failures in proficiency performance, all proficiency testing is processed through the Department of Pathology. Annually, the Department elects to participate in a number of Proficiency Test programs from organizations including the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), the NJ Department of Health and Senior Services and the Center for Disease Control.

In order to insure compliance with state and federal regulations, all proficiency test (PT) specimens are shipped directly to each primary site licensed under RWJMS. As closely as possible, these specimens must be analyzed in the same manner, using the same testing methods as patient samples, by the same personnel who routinely test patient samples. Results are then forwarded to the Rapid HIV Testing Support Program on appropriate result sheets including reagent and control lot numbers and expiration dates and indicating the testing individual. These results will be submitted to the appropriate proficiency testing organization by the Rapid HIV Testing Support Program.

Proficiency testing will be rotated among all staff at the site certified to perform rapid HIV testing to ensure that all personnel performing patient testing are evaluated periodically. It is the responsibility of the Point of Care Testing staff to perform proficiency testing as specimens are received. There will be no interlaboratory communication about PT samples until after the submission of data deadline. PT samples may not be transferred to or discussed with another testing site or lab during testing period.

Action to Improve Services and Resolve Problems

Any failure of proficiency testing must be investigated by the Rapid HIV Testing Support Program staff in conjunction with the site staff that performed the proficiency testing and the on-site coordinator. These individuals will analyze the PT failure in an effort to identify the source of the failure and to develop a plan of corrective action. The results of the investigation and any corrective action taken must be documented appropriately, and be submitted to the Bioanalytical Laboratory Director. Additional technical assistance will be provided to the site by the HIV Rapid Testing Support Program to insure successful test performance by site staff and adequate analysis of proficiency test failures.

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