Quality Control Program

Purpose:
The purpose of the QC program is to monitor the quality of testing performed by Rapid HIV Testing sites and to ensure that problems related to the test systems, reagents or testing procedures are identified and addressed. Quality Control testing is an intrinsic part of any laboratory testing and must be done in order to provide proper patient care and to be in compliance with the standards of the NJ Department of Health and Senior Services and CLIA 88.

Elements of the Quality Control Program:
Quality control is an ongoing process designed to insure that an analytic system is functioning correctly. The basic premise of most quality control systems is that known samples are tested (simultaneously with patient unknowns) and the results compared with expected results. Failure to obtain the expected values is an indication that a problem may exist, and results in a series of actions designed to protect the patient and personnel from treatment based on aberrant and incorrect data.

Responsibilities:

1. It is the responsibility of the each rapid HIV site testing staff to complete quality control as specified in the policy. Patient testing may only be performed if Quality Control results are within the limits specified.

2. Periodically, the Rapid HIV Testing Support staff will inspect sites to ensure that proper procedures are being followed and documented for patient identification, patient preparation, specimen collection, specimen ID, specimen preservation and processing, and result reporting.

3. Quality Control (QC) specimens will be analyzed at a frequency determined by the laboratory director.

4. QC specimens will be analyzed on a rotating basis by all testing personnel within a rapid HIV testing site so that in each calendar quarter, each counselor has run at least one set of QC specimens.

5. It is the responsibility of the rapid HIV testing on-site coordinator to review all rapid HIV quality control on a weekly basis, to assure that testing and troubleshooting is done and documented.

6. The rapid HIV testing on-site coordinator will submit QC data to the Rapid HIV Testing Support Program on a monthly basis for review and central maintenance of records.

7. At his/her discretion, the Bioanalytical Laboratory Director may assign additional duties for the monitoring of performance and the correction of problems identified by the monitoring system to designated staff.

Quality Control Failures:
In the event of a quality control failure, the site should follow the HIV testing protocol and cease client testing until the problem is rectified.

Corrective Actions:
If a QC failure occurs it is essential to determine the cause of the failure.

- The initial step in examining a QC failure is to suspect the quality of the reagents or controls. It is often helpful to utilize a different set of reagent controls as a first step and repeat the procedure. If this fails, the next step would be to use a different lot of reagent test kits, or a box from a different shipment. If a different lot of reagent controls or kits are not available at the site, please contact the Rapid HIV Testing Support program.

- **In the face of a QC failure, cease patient testing until the issue is resolved. Document all corrective action on the back of the testing log sheet.** For example, if you repeat the QC and have obtained the appropriate results, record the new result and indicate whether you repeated the same QC sample from the same reagent control or whether you employed a different reagent control.

Frequency of Quality Control Samples:

- As specified in the specific procedure, i.e. weekly.
- When reagent kit storage has been out-of range.
- Each time a new reagent lot number or new test kit lot number is introduced. Central validation of all reagent lots prior to release will be performed for all inventory provided by the Rapid HIV Testing Support Program, so this does not need to be repeated at each site.
- Each time a new delivery or shipment of reagents is received by the Rapid HIV testing site.

QC Review:
All QC results must be reviewed on a regular basis.

Each person performing patient testing must first verify that QC was properly performed and documented at the appropriate interval. If QC has not yet been completed, patient testing may not be done. All testing personnel must initiate corrective action if QC results do not fall within the expected ranges.

The HIV rapid testing on-site coordinator will review documentation of QC on a weekly basis. The on-site coordinator is responsible for instituting corrective action for 'out of compliance' procedures. Additional help is available by calling staff at the Rapid HIV Testing Support program.

Action to Improve Services and to Resolve Problems:
All problems identified by the monitoring system will be corrected, documented and brought to the attention of the appropriate Rapid HIV Testing Support Program staff.

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