


CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) ISSUES FOR PFGE LABORATORIES

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Clinical Laboratory Improvement Amendments (CLIA)

- Act of Congress through which the Centers for Medicare and Medicaid Services (CMS)



Centers for Medicare and Medicaid Services (CMS)

- Regulate all lab testing performed on humans in the U.S through the Clinical Laboratory Improvement Amendments (CLIA)
- CLIA regulations (42FR495): in effect since 1992
- Promote good lab practices
- Assure reliable lab results and documentation



Key Features of the Law

- Standard based on complexity of testing, not laboratory site
- Law applies to virtually all clinical labs (approx. 180,000)
- Sanctions include remedial actions
- User fees



Technical Standards: Guiding Principles

- Ensure quality laboratory testing
- Encourage development of new technology
- Good laboratory practice
- Cost effective



Lab Testing Not Covered by CLIA

- Forensic testing
- Drug testing performed by labs certified by Substance Abuse and Mental Health Service Administration
- Research lab testing when no patient specific results are reported



CLIA Technical Standards:

- 1992 regulations implementing CLIA included requirements for:
- Patient test management (PTM)
- Quality control (QC)
- Proficiency testing (PT)
- Personnel qualification
- Quality assurance (QA)



CLIA Survey

- General laboratory safety
- Specimen collection & handling
- Testing
- Proficiency testing
- Equipment management
- Personnel qualification: competency assessment
- Quality assurance program
- Quality control program
- Quality improvement program

Exit Conference

- Inform the lab of the surveyor's findings and solicit additional information
- Provide instructions necessary for submitting a plan of correction for the deficiency cited



Plan of Corrections

- Your written plan of corrections
- Address each deficiency and each account of “evidence” as provided by the surveyor, in a specific manner
- Attach documentation of corrective action





CLIA Issues for PulseNet Laboratories

- Proficiency testing
- QC and Quality Management
 - Supervision, SOPs, assay validation
 - Test system, specimen handling, results and reporting
 - Records
 - Reagents
 - Controls



CLIA Issues for PulseNet Laboratories (continued)

- Instruments and equipment
 - Instrument maintenance log
 - Signal Detection Instruments
 - Film processing photographic equipment
 - Electrophoresis equipment and power supplies
 - pH meters, Centrifuge, Balances and weights



Quality Control and Quality Management

- Verification of PT Enrollment and Review of PT
 - Enrolled in an approved PT program for each regulated analyte (at least semi-annually)
 - PT samples must be handled in the same manner





Quality Control and Quality Management

- A written QC/QM program
- Review QC data at least monthly
- Ongoing evaluation of instrument maintenance and function, temperature, etc
- Document failed hybridization reaction
- Monitor sample turnaround times



Quality control and Quality Management (continued)

- Documentation of all relevant data for DNA probes, PCR primers, and other nucleic acid reagents
- Documentation of validation studies (sample size, sensitivity, specificity, accuracy, precision)
- Specimen handling and rejection criteria



Quality control and Quality Management (continued)

- Sample ID
 - Nucleic acid extraction
 - Specimen receipt
 - Nucleic acid quantification
 - Endonuclease digestion
 - Electrophoresis, Transfer, Hybridization
 - Detection, Enzymatic implication, Photography, Storage



Quality control and Quality Management (continued)

- Assay
 - Standard amounts of NA loaded on analytical gels
 - Positive, negative and sensitivity controls run for each assay
 - Interpretation of electrophoretic gels using objective criteria
 - NA amplification procedures for internal controls to detect a false negative reaction

Quality control and Quality Management (continued)

- Reporting of Test
 - Summary of methods, probes, & endonucleases used
 - Review of final report
 - Established critical values



Quality control and Quality Management (continued)

- Electrophoresis Equipment and Power Supplies
 - Suitable controls must be run and reviewed with each batch of patient samples
 - Acceptable electrophoretic separation
 - Periodic checking of displayed voltage with a voltmeter



Quality control and Quality Management (continued)

- Controls
 - Tolerance and acceptability limits defined
 - Verify the results of controls for acceptability before reporting
 - Test control specimens in the same manner as pt samples



Quality control and Quality Management (continued)

- Verification of Personnel Qualification
 - Personnel records, individual's education, experience and training for the position filled







ANY QUESTIONS?