

Residency Program Solutions Office Laboratory Medicine

This document has been endorsed by the American Academy of Family Physicians and was developed in cooperation with the Association of Departments of Family Medicine, the Association of Family Practice Residency Directors and the Society of Teachers of Family Medicine.

Laboratory testing in the physician's office improves efficiency and quality of patient care because test results can be available at the time the patient is seen. Laboratory technology has produced systems that are reliable, simple to use and inexpensive.

Residents should obtain the knowledge and skills required to maintain a high-quality laboratory for their patients. In addition, residents should be able to qualify to direct a laboratory in compliance with federal and state regulations.

An understanding of federal regulations such as Clinical Laboratory Improvement Amendment (CLIA-88), the role of the laboratory director and the essentials of quality assurance and quality control is essential. In addition, residents should learn about the requirements of the physical plant, equipment, laboratory needs, written policies and procedures, including an understanding of the role of the Commission on Office Laboratory accreditation (COLA), Joint Commission on Accreditation of Healthcare Organizations. (JCAHO) and Occupational Safety and Health Administration (OSHA) safety requirements.

Residents should also be able to evaluate the feasibility of performing tests, considering laboratory space, office staff and financial implications. Test volumes, equipment and reagent costs, technician time, cost of quality control, testing liability and charge to the patient should also be considered.

Knowledge

1. CLIA-88
 1. Categories of testing complexity
 2. Certification requirements and application process
 1. Types of certification
 2. Application process
 3. Application and inspection fees
 4. Requested information
 1. Name of tests
 2. Methodology
 3. Volume of tests
 4. Qualification of personnel
 3. Laboratory agreements
 1. Inspection
 2. Record availability
 3. Proficiency testing requirement
 4. Notification of changes
 4. Federal and state inspections
 1. Fees

2. Entrance interview
3. Assessment of facilities
4. Selection of representative samples
 1. Criteria used
 2. An expanded sample
5. Legal implications for noncompliance with CLIA standards
5. Accreditation options
 1. COLA
 2. JCAHO
 3. College of American Pathologists
2. Testing systems and equipment
 1. Selecting a reference laboratory: service, quality, price
 2. Instrument maintenance/function: calibration
 1. Instrument documentation
 2. Log of equipment
 3. Instrument troubleshooting
 4. CLIA requirements for maintenance performance
 3. Selecting qualitative test kits
 1. Factors to consider in test-kit instrument selection
 1. Ease of performance/CLIA test complexity
 2. Cost per billable test
 3. Space for testing and storage
 4. Accuracy, sensitivity and specificity
 2. CLIA requirement for initiating a new test
 3. Precaution before using test kits
 4. Evaluation of sample kits: group A beta streptococcus kits, chlamydia, urine, chorionic gonadotropin
 4. Starting a new test
 1. Method selection
 2. Method verification
 5. Traditional laboratory terms
 1. Sensitivity
 2. Specificity
 3. Precision
 4. Accuracy
 5. Bias
 6. Specimen collection and integrity
 1. Specimen collection
 1. Blood
 2. Microbiology
 3. Urine
 2. Specimen processing
 3. Specimen storage
 4. Problems related to specimens
 1. Improper labeling
 2. Insufficient quantity
 3. Improper collection
 4. Deterioration
 5. Specimen tracking
 5. CLIA assessment of specimen integrity
 1. Collection

- 2. Assessment of skills of testing and surveying personnel
 - 6. Assessment of equipment and supplies
 - 3. Laboratory personnel
 - 1. Laboratory director
 - 1. Qualifications of laboratory director
 - 2. Responsibilities
 - 1. Overall operation and administration
 - 2. Job descriptions
 - 3. Choosing competent personnel
 - 4. Supervisor
 - 5. Testing supervision
 - 6. Evaluation of personnel performance
 - 1. Need for continuing education
 - 7. Maintaining personnel file
 - 2. Minimum personnel requirements
 - 3. Testing personnel and requirements for certification
 - 1. Medical technologists, bachelor of science degree, experience
 - 2. Medical laboratory technician, two years of college, experience
 - 3. Medical assistant, high school, experience and/or training
 - 4. Typical tasks of personnel
 - 5. Average salaries of medical technologists and medical laboratory technicians
 - 1. Regional salaries
 - 2. National salaries
 - 6. Consultants
4. Quality assurance and quality control program
 - 1. Components
 - 1. Procedure manual
 - 2. Policies and standards
 - 3. Specimen collection and handling
 - 4. Specimen tracking
 - 5. Calibration
 - 6. Quality control
 - 1. Qualitative testing (i.e., pregnancy test)
 - 2. Semiquantitative testing (i.e., urine dipstick)
 - 3. Quantitative testing (i.e., creatinine)
 - 7. Record keeping
 - 8. Proficiency testing and results
 - 9. Safety requirements
 - 1. OSHA
 - 2. Blood-borne pathogens
 - 3. Hazardous materials
 - 10. Inspections
 - 11. Problem log
 - 2. Proficiency testing
 - 1. Definition and terminology
 - 2. Enrollment
 - 3. Selecting a proficiency testing program
 - 4. Processing and handling patient samples
 - 5. Interpretation of results
 - 1. Acceptable performance
 - 2. Unacceptable performance

6. Documentation
 1. Maintenance of records
 2. Review by director
5. Written policies and procedures
 1. Procedure manual
 1. Standard format
 2. Name of test
 3. Specimen collecting, handling and rejection
 4. Materials
 5. Procedures (step by step)
 6. Interpretation
 7. Quality control
 8. Calibration procedure
 9. Limitations of procedure, interfering substances
 10. Reference range, panic values
 11. References
 12. Signed and dated by director, then reviewed annually
 2. Ways to resolve problems in testing process
 3. Documentation
 4. Record retention
6. Physical plant and laboratory safety management
 1. Laboratory design
 1. Space requirements
 2. Administrator
 3. Equipment fee
 4. Electric design
 5. Lighting
 6. Plumbing
 7. Fire safety
 8. Waste storage
 2. Bloodborne pathogen regulations
 1. Exposure
 1. Universal precautions
 2. Hepatitis B vaccination
 3. Postexposure evaluation and follow-up
 4. Communication of hazards to employees
 5. Warning signs
 3. Occupational exposure to hazardous chemicals in the laboratory
 1. Permissible exposure limits (PEL)
 2. Exposure and monitoring
 3. Hazard identification

Skills

1. Use and care of the microscope
2. Urinalysis
 1. Chemical reactions
 2. Microscopic
 1. Crystals
 2. Red blood cells
 3. White blood cells

4. Epithelial casts
3. Quality control
4. Specific gravity, pH
3. Complete blood count
 1. Manual white blood cell count/red blood cell count
 2. Hemoglobin
 3. Peripheral smear
 1. Manual differentiation
 2. Morphology
 3. Platelet estimate
 4. Automated procedures not requiring operator interaction
 5. Spun microhematocrit
4. Chlamydia testing
5. Gram stain test
 1. Staining procedure
 2. Gram-negative
 3. Gram-positive
 4. Morphology
 1. Cocci vs. rods vs. coccobacilli
 2. Diplococci, tetrads, etc.
6. Vaginal smears
 1. Potassium hydroxide and wet mount
 2. Clue cells
 3. Yeast
 4. Trichomonas vaginalis
 5. White blood cells and bacteria
7. Pinworm preparation
8. Skin scrapings
 1. Yeast
 2. Fungal elements
 3. Mites
9. Immunochemical assays
 1. Rapid streptococcus test
 1. Methodology
 2. Procedure
 3. Quality control
 2. Mononucleosis test
 3. Urine/serum pregnancy test
 4. Other
 1. Influenza tests
 2. Chlamydia
10. Sedimentation rate
11. Fecal occult blood
12. Cultures
 1. Gonorrhea screens
 1. Plating
 2. Incubator protocol
 3. Interpretation
 2. Throat
 3. Urine
 1. Colony counts

2. Susceptibility testing
13. Chemistry analyzer tests
 1. Methodology
 2. Procedure
 3. Quality control
 4. Calibration
 5. Maintenance

Implementation

The minimal educational experience required by CLIA is 20 hours of didactic and laboratory workshops. It is suggested that the experience be divided into approximately 15 hours of didactic training and at least five hours of laboratory skills. The 15 hours of didactic time could meet the CLIA certification for laboratory director if the following times are allocated:

Regulations: 1 hour
Physical plant: 1 hour
Testing systems and equipment: 3 hours
Quality assurance: 3 hours
Quality control: 3 hours
Laboratory personnel: 2 hours
Written policies, procedures and individual performance responsibilities: 2 hours

The guidelines can be accomplished on a longitudinal basis or through an in-depth, intense experience utilizing family-practice and laboratory educators.

Resources

1. Stepp CA, Woods MA. Laboratory procedures for medical office personnel. Philadelphia: Saunders, 1998.
2. Davis BG, Mass D, Bishop ML. Principles of clinical laboratory utilization and consultation. Philadelphia: Saunders, 1999.
3. Jacobs DS. Laboratory test handbook. Hudson: Lexi-Comp, 1996.
4. COLA. A voluntary education and accreditation program for physicians' office laboratories. 9881 Broken Land Parkway, Columbia, Md 21046. E-mail: info@COLA.org; Web site: <http://www.cola.org/>
5. Centers for Disease Control and Prevention. Regulations for implementing Clinical Laboratory Improvement Amendments of 1988: a summary. JAMA 1992;267:1725-7,1731-4.
6. AAFP-PT site for POLs: <http://www.aafp.org/pt>
7. CLIA-related publications from the Federal Register and Code of Federal Regulations: <http://www.phppo.cdc.gov/clia/chronol.aspx>
8. Bloodborne pathogens regulations: <http://www.osha-slc.gov/SLTC/bloodbornepathogens/index.html>
9. HCFA's page on the CLIA program: <http://cms.hhs.gov/clia/default.asp>

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