



## Recommended Curriculum Guidelines for Family Medicine Residents

# Office Laboratory Medicine

*This document was endorsed by the American Academy of Family Physicians (AAFP), the Association of Departments of Family Medicine (ADFM), the Association of Family Medicine Residency Directors (AFMRD) and the Society of Teachers of Family Medicine (STFM), and was developed in cooperation with the Carle Family Medicine Residency Program.*

### Introduction

This Curriculum Guideline defines a recommended training strategy for family medicine residents. Attitudes, knowledge and skills that are critical to family medicine should be attained through longitudinal experience that promotes educational competencies defined by the Accreditation Council for Graduate Medical Education (ACGME) <http://www.acgme.org>. The curriculum must include structured experience in several specified areas. Most of the resident's knowledge will be gained by caring for ambulatory patients who visit the family medicine center. Structured didactic lectures, conferences, journal clubs and workshops must be included in the curriculum with an emphasis on outcomes-oriented, evidence-based studies that delineate common and chronic diseases affecting patients of all ages. Targeted techniques of health promotion and disease prevention are hallmarks of family medicine. Appropriate referral patterns and provision of cost-effective care should also be part of the curriculum.

Program requirements specific to family medicine residencies may be found on the ACGME Web site. Current AAFP Curriculum Guidelines may be found online at <http://www.aafp.org/cg>. These guidelines are periodically updated and endorsed by the AAFP and, in many instances, other specialty societies as indicated on each guideline.

Each residency program is responsible for its own curriculum. ***This guideline provides a useful strategy to help residency programs form their curricula for educating family physicians.***

## **Preamble**

Accurate laboratory testing is imperative to good patient care. At the same time, patients are expecting results of tests to be available on increasingly short timelines. One solution to this problem is point-of-care testing commonly available on-site at many family medicine offices. Although many of these tests are waived from most federal oversight requirements, residents must become familiar with how to maintain a high-quality laboratory, including the essentials of quality assurance and quality control.

Residents learning to run a laboratory must become familiar with basic knowledge and skills that will allow the maintenance of a high-quality laboratory in compliance with federal and state regulations, including the regulations described in the Clinical Laboratory Improvement Amendment (CLIA-88). The resident will need to build a foundation in management responsibilities, regulatory requirements, safety considerations, test costs, benefits, staffing considerations and documentation requirements for office laboratory testing.

Residents will also need to be introduced to National and State Regulators, including the Commission on Office Laboratory Accreditation (COLA), the Joint Commission and Occupational Safety and Health Administration (OSHA). In addition, new regulations within the Health Insurance Portability and Accountability Act (HIPPA) are important in standardizing office laboratory testing.

Finally, residents should learn skills in performing multiple point-of-care tests. Even though they may not personally be performing all of these tests in their own medical practices, some residents may become the director of an office lab and therefore will be responsible for overseeing the staff that are conducting these tests. Hands-on experience in each of these skills is important during education in a Family Medicine Residency Program.

## **Competencies**

At the completion of residency training, a family medicine resident should:

- Be able to perform and interpret common tests done in the laboratory setting and be able to teach these skills to other individuals. (Patient Care, Practice-based Learning)
- Know the significance of quality control in the office lab, including the importance of documentation. (Patient Care, Systems-based Practice)
- Understand the basic principles of laboratory tests, including method selection, method verification, sensitivity, specificity, precision, accuracy and bias. (Medical Knowledge, Practice-based Learning)
- Be knowledgeable in the cost considerations of office laboratory testing. (Medical Knowledge, Systems-based Practice)

Additional competencies if resident wishes to meet CLIA certification requirements:

- Demonstrate knowledge of CLIA-88 regulations with both an understanding of the requirements for waived testing and an ability to follow the manufacturer's instructions in order to obtain reliable test outcomes. (Medical Knowledge, Systems-based Practice)
- Recognize other national and state regulations which factor into running an office laboratory. (Medical Knowledge, Systems-based Practice)
- Understand one's role as a potential laboratory director, including qualifications, responsibilities and the role in the relationship with others working in the lab. (Medical Knowledge, Systems-based Practice)

## **Attitudes**

The resident should demonstrate attitudes that encompass:

- Compassion in discussing unexpected, unwanted test results.
- Commitment to lifelong learning of available office-based diagnostic tests and their appropriate use in patient care.

## **Knowledge**

In the appropriate setting, the resident should demonstrate the ability to apply knowledge of:

1. The physician's role in the office lab, both as one who uses the lab and as a potential director of a lab
2. Ways in which point-of-care testing can improve the quality of patient care over traditional testing (e.g., INR testing, transcutaneous bilirubin levels)
3. The limits of a positive or negative test result in the diagnosis of a disease
4. The risks and benefits of performing lab tests, including negative outcomes and costs associated with ordering unnecessary lab tests
5. The resources which should be available when considering a new test
6. The importance of documentation, especially as it relates to quality control in the laboratory setting
7. Financial considerations in lab testing, including coding, billing and insurance reimbursement

Additional knowledge may be needed if the resident wishes to meet CLIA certification requirements and can be found at: <http://www.cdc.gov/clia/chronol.aspx>

## **Skills:**

In the appropriate setting, the resident should demonstrate the ability to independently perform or appropriately refer:

1. Use and care of the microscope
2. Skin scrapings
3. Vaginal smears
4. Blood draws
5. Urinalysis
6. Gram stain testing
7. Immunochemical assays
8. Fecal occult testing
9. Other point-of-care tests, including:
  - a. HbA1C
  - b. INR
  - c. Troponin
  - d. Glucose
  - e. Transcutaneous bilirubin
10. Discussion of test and test results

Additional skills may be needed if the resident wishes to meet CLIA certification requirements and can be found at <http://www.cdc.gov/clia/chronol.aspx>:

## **Implementation**

Implementation of this curriculum should include both focused and longitudinal experience throughout residency. Physicians who have demonstrated skill in use of an office laboratory should be available to act as role models to the residents, to give support and to offer advice.

If the resident wishes to meet CLIA certification requirements, additional implementation will be necessary. 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 medicine and laboratory educators.

## Resources

Stepp CA, Woods MA. Laboratory Procedures for Medical Office Personnel. Philadelphia, Pa.: Saunders, 1998.

Davis BG, Mass D, Bishop ML. Principles of Clinical Laboratory Utilization and Consultation. Philadelphia, Pa.: Saunders, 1999.

Jacobs DS, Oxley DK, DeMott WR, Wayne R. Jacobs & Demott Laboratory Test Handbook. 5<sup>th</sup> ed. Hudson, Oh.: Lexi-Comp, 2001.

Centers for Disease Control and Prevention. Regulations for implementing clinical laboratory improvement amendments of 1988: a summary. JAMA 1992;267:1725-7,1731-4.

Centers for Disease Control and Prevention. Good laboratory practices for waived testing sites: survey findings from testing sites holding a certificate waiver under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing. MMWR 2005;54(No. RR-13).

## Web Sites

Center of Laboratory Accreditation (COLA)  
<http://www.cola.org>

American Academy of Family Physicians- Proficiency Testing Program  
<http://www.aafp.org/pt>

Centers for Disease Control and Prevention  
<http://www.cdc.gov/clia/chronol.aspx>

Occupational Safety and Health Administration  
<http://www.osha.gov/SLTC/bloodbornepathogens/>

U.S. Department of Health and Human Services- Centers for Medicare and Medicaid Services

<http://www.cms.hhs.gov/cia>

The Joint Commission

<http://www.jointcommission.org/>

Published 05/1994

Revised 02/2000

Revised 02/2008