

LABORATORY SAVVY FOR THE PHYSICIAN OFFICE LABORATORY

Part 1 - The Importance of Following Manufacturer's Instructions

This is the first in a series of topics that provide basic practical laboratory knowledge. It is designed primarily for personnel working in nontraditional laboratories such as physician offices or point-of-care settings. It is appropriate for all complexity levels of laboratories--waived, moderate & high. The first topic is entitled "The Importance of Following Manufacturer's Instructions." Failure to follow manufacturer's instructions is one of the most frequently cited CLIA-88 deficiencies. The course describes in detail the sections of the product manufacturer's literature or package inserts that the manufacturers are required to provide in following FDA test approval guidelines. All package inserts follow the same general format.

Participants will receive by mail all educational materials and exams. There are two (2) exams to be completed for this course. The first exam will cover the chapter information. The second exam will make use of a package insert following the FDA specified format. An average score of 70% for both exams will be required to pass the course. A certificate of satisfactory completion with contact hours will be issued from the Department of Health and Human Resources, Bureau for Public Health, Office of Laboratory Services.

Who Should Enroll?

Anyone involved with waived or moderate complexity laboratory testing (testing personnel, consultants, directors) particularly those working in physician office laboratories or other physician office settings. Medical technologists (MT) and medical laboratory technicians (MLT) will also benefit from reviewing the information in this course and are eligible to enroll.

Course Objectives

At the conclusion of the course, the participant will be able to:

- Know the definitions of commonly used laboratory terminology.
- Outline the format of a manufacturer's package insert.
- Know where to locate specific information within a package insert pertaining to:
 - Quality Control
 - Specimen collection and handling
 - Test methodology principles
 - Reagent storage and handling
 - Step-by-step procedural instructions
 - Test interpretation
 - Test variables and interferences
- Locate the date in which the test procedure or test reagent has been revised and know its importance related to documentation.
- Know how to determine the sensitivity and specificity of a test method and its importance.

Continuing Education Credit: 10 contact hrs.

This course meets the continuing education requirements for the Clinical Laboratory Practitioner's License but is not a requirement for the Clinical Laboratory Practitioner's License. It is one option of a source for training.

It is also approved for continuing education credits with the WV Nurses Licensing Board.

FOR ADDITIONAL INFORMATION, CONTACT:

Sharon Cibrik
WV Office of Laboratory Services (OLS)
(304) 558-3530

NEW: Website

For information on other OLS sponsored courses and the WV Office of Laboratory Services, see our website at www.wvdhhr.org/labservices

Course Schedule

The course is available by request. Certificates of successful completion will be awarded approximately 3-4 weeks after the completion date.

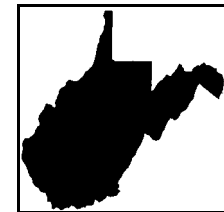
Course Fee:

Per Registrant \$10.00

(Make check payable to State of West Virginia DHHR Lab and submit with application. NO CASH, PLEASE.)

Registrants and participants may register as either the **primary registrant** or **additional registrant**. The **primary registrant** will serve as **site coordinator** if there is more than one registrant from a facility. One set of material and exams will be sent to the primary registrant of each site who is responsible for making additional copies for participating staff, seeing that exams are taken on an individual basis, and submitting them to the Office of Laboratory Services for grading. Each participant at a site will complete the registration form and designate themselves as either the primary registrant or additional registrant. Although it is recommended that this course be completed within 6 weeks, you may complete at your own pace.

*We would like to offer this course free of charge but expenses of printing and postage are beyond budgeting allowance.



REGISTRATION FORM - Manufacturer's Instructions
(Please duplicate this form as needed)

Name:		I am registering as the: (Check One)	Facility Coordinator ()
Home address:			Additional Registrant ()
City/State/Zip	Home Phone:	If additional, Indicate Primary Registrant's name:	
Facility:			
Facility Mailing Address:		Send my certificate to: (Check one)	Home address ()
			Facility Address ()
City/State/Zip:		Your e-mail address:	
Work Phone:	Fax:	Date of Registration:	

LSAVVY-2001

MAIL TO: TRAINING & EVALUATION SECTION, WV OFFICE OF LABORATORY SERVICES
 167 11TH AVENUE, SOUTH CHARLESTON, WV 25303
 Phone: 304-558-3530 FAX: 304-558-2006

WV OFFICE OF LABORATORY SERVICES
 167 11TH AVENUE
 SOUTH CHARLESTON, WV 25303
 (304) 558-3530
 Fax: 558-2006

Laboratory Savvy
 for
 The Physician Office Laboratory

First in a Series

**FOLLOWING
 MANUFACTURER'S
 INSTRUCTIONS**



**Course
 Announcement**

WEST VIRGINIA DEPARTMENT OF
 HEALTH & HUMAN RESOURCES
 OFFICE OF LABORATORY SERVICES (OLS)
 Training & Evaluation Section
 167 11th Avenue
 South Charleston, WV 25303