

Following Manufacturer's Instructions Correspondence Course

Course Description

Failure to follow manufacturer's instructions is one of the most frequently cited CLIA-88 deficiencies. Product manufacturers are required to provide certain information under FDA test approval guidelines. This course describes the required sections of a package insert including:

- Definitions of commonly used laboratory terminology.
- Format used for manufacturer's package inserts.
- Location of specific information within a package insert pertaining to: *Quality Control, Test Methodology Principles, Test Interpretation, Step by Step Procedural Instructions, Specimen Collection and Handling, Reagent Storage and Handling, and Test Variables and Interfaces.*
- Location of the test procedure or reagents revision date and its importance.
- How to determine the sensitivity and specificity of a test method and its importance.

Who Should Enroll?

Anyone involved with waived or moderate complexity testing (testing personnel, consultants, directors) particularly those working in physician office settings and laboratories. Medical Technologist and Medical Laboratory Technicians will also benefit from reviewing the information in this course.

Course Registration

Complete registration online using a credit card **or** by mailing a check with this paper application. Participants will be emailed the correspondence course materials and exam, unless a paper copy or CD copy is requested. (Additional \$6.00 charge for paper or CD).

Course Credits

Course exams must be completed and mailed to the Office of Laboratory Services for grading. A score of 70% or greater on the exams must be achieved to receive the continuing education credits.

Course Fee: \$15.00

Continuing Education Credit: 10 Contact Hours

FOLLOWING MANUFACTURER'S INSTRUCTIONS COURSE REQUEST	
Course will be <u>E-mailed</u> unless otherwise requested and additional fee paid.	
Name:	
Home Mailing Address:	
E-mail:	Home Phone:
Facility:	
Facility Address:	
Facility Phone:	Fax:
Paper Copy or CD Requested: CD <input type="checkbox"/> Paper <input type="checkbox"/> Additional \$6.00 charge.	
Mail Request Form and Check (made payable to WVDHHR State Lab) to:	
WV Office of Laboratory Services ATTN: Training & Evaluation 167 11 th Avenue South Charleston, WV 25303	