Molecular Laboratory Management and Reporting: A Short Course for Laboratory Professionals

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CERTIFICATE PROGRAM OUTLINE

Title	Speaker(s)	Description	Learning Objectives	Time to Complete
Welcome Remarks from Content Director	Erin Graf, PhD			
Pre-Course Questionnaire				1 min
FINANCIAL CONCEPTS FOR DIRECTING A LABORATORY				
Pre-Test for Financial Concepts for Directing a Laboratory Section				15 min
Balancing the Laboratory Budget	Jacquelyn Roth, PhD & Joseph Milano, MBA, PA (ASCP), HTL	This presentation reviews the basic elements of a clinical laboratory budget including laboratory expenses, capital and operating budgets, fixed and variable costs, and analysis of variance between calculated and actual budgets. An example return on investment is also calculated for both introduction of a new laboratory assay and replacement of an existing laboratory assay. Additional Material: ROI Calculator	• Review the various components of a typical laboratory budget • Describe how to construct a basic Return on Investment (ROI) • Discuss the purpose and necessary investigations conducted to explain variances in laboratory budgets	60 min
The ABCs of CPT® Coding	Anthony N. Sireci, MD; Aaron D. Bossler, MD, PhD; & Victoria M. Pratt, PhD	Knowledge of the coding structure of molecular medicine is crucial as these codes are incorporated and used by insurers to identify the services you provide to patients and understanding the basics of CPT® coding will benefit your laboratory practice and management. The American Medical Association (AMA) Current Procedural Terminology (CPT®) coding system is used throughout the United States as a main system of coding for health care services, including laboratory and pathology procedures. The AMP Economic Affairs Committee (EAC) is intimately involved in this process, both by submitting code change applications regularly but also by occupying a rotating seat on the Pathology Coding Caucus, which reviews and provides recommendations to the AMA CPT® Editorial Panel on applications for new or revised pathology and laboratory services. During this presentation, AMP members will be provided with a better understanding of the intricacies of the CPT® coding structure and process for laboratory and pathology codes. This presentation will also educate members by providing resources and tips for submitting your own code change application.	• Present a brief overview of coding for molecular pathology procedures and a history the evolution of molecular pathology coding. • Explain the AMA CPT® code change application processes and timelines. • Identify ways you can assist the EAC to ensure patient access to appropriate procedures.	60 min

Reimbursement: It's Never too Late to Start Getting Paid	Anthony Sireci, MD; Aaron Bossler, MD, PhD; & Gabriel Bien-Willner, MD, PhD	Understanding the processes for coding, pricing and coverage determination is at the heart of getting reimbursed for the clinical molecular procedures we perform. These presentations will review those processes and hear insights from a Medical Director for the Palmetto Medicare Administrative Contractor to help members understand the intent and breadth of the molecular procedure codes, understand how coverage policies and procedures affect determination of payment or nonpayment including the National Coverage Determination for NGS testing, and discuss the pricing process and the impact of PAMA on laboratory pricing.	• Understand current test coding and define tier 1 molecular pathology CPT codes. • Understand how coverage polices determine payment or nonpayment. • Understand and describe the impact of PAMA on laboratory pricing.	75 min
REGULATORY ASPECTS OF MOLECULAR LABORATORY DIRECTORSHIP				
Pre-Test for Regulatory Aspects of Molecular Laboratory Directorship Section				10 min
Lab Accreditation and Oversight (FDA, CLIA and CAP)	Cecilia Yeung, MD	In this lab management presentation we will review current agencies responsible for accreditation of laboratories touching briefly upon international standards but focusing on the US accreditation process and agencies. We will discuss management of personnel in an accredited lab including duties of the lab director. We will review the components of a quality management program and the components of an assay validation.	• Identify key agencies that are involved in the regulation of a clinical laboratory • Compile required personnel of Moderate versus High complexity testing laboratories • Compare the differences between validation of an FDA approved and non-approved assay	30 min
International EQA	Zandra Deans, PhD	This presentation will provide a summary of the mechanism by which laboratories can demonstrate the quality of genomic/genetic testing through external quality assessment (EQA)/proficiency testing. International EQA Providers are organizations accredited to International Standard ISO17043 and operate independently from accreditation bodies. This presentation will outline the benefits of these quality assurance schemes and how end to end assessment can be delivered. The effectiveness of these schemes and EQA Provider networks will be discussed to demonstrate how EQA can ensure patient safety and optimal patient care in the field of molecular pathology.	• Describe the importance of quality assurance programmes. • Ascertain the difference between EQA approaches and identify the benefits of independent assessment to International Standards. • Describe the value of demonstrating high quality service which incorporates the processes involved in end to end service delivery.	30min
Feel Like QC and IQCP are affecting your IQ?	Ana Maria Cardenas, PhD, D(ABMM)	This presentation sets the stage by reviewing the essentials of a quality management system. It then focuses on quality control, with special emphasis on the individualized quality control plan (IQCP). It covers the main components of an IQCP and gives the audience tools to develop and implement their own IQCP. Worksheet: Exercises in IQCP	• Describe a quality management system • Identify tests that are eligible for an IQCP • Develop and implement an effective IQCP	30 min

KEY COMPONENTS OF A HIGH QUALITY AND HIGH VALUE LABORATORY OPERATION				
Pre-Test on Key Components of a High Quality and High Value Laboratory Operation				15 min
Molecular Assay Validation in Clinical Laboratories	Margaret L. Gulley, MD	Assay validation is a vital component of medical practice in molecular laboratories, so that new assays can be introduced and improvements can be made to existing assays once the assay is shown to be analytically sound and clinically useful. This presentation reviews the 4 phases of an assay validation study, from initial design through evidence collection to implementation. Tips are provided to facilitate validation of complex genomic tests. Additional Material: Validation/Verification Outline Template	• Discuss the processes of assay design, evidence generation, and vetting before introducing new assays into clinical service • Discuss strategies to meet regulatory and medical standards for judging that an assay can be used in patient management	60 min
Process Improvement/QA	Laurel Glaser, MD, PhD	This lab management lecture will review models of human error and introduce the PDSA cycle framework for process improvement. Use of the model, and common pitfalls will be illustrated using examples from the molecular pathology laboratory. Worksheet: Plan, Do, Study, and Act (PDSA) Exercise	• Recognize common modes of human error and identify strategies to mitigate patient harm. • Describe the components of the PDSA cycle model for quality improvement. • Enumerate common mistakes and challenges faced when using this approach in the molecular pathology laboratory.	60 min
Ethical Issues in Molecular Pathology	Lauren B. Smith, MD	A discussion of ethical issues in molecular pathology will be presented. Ethical principles and a framework for analyzing ethical issues will be reviewed. Ethics as it relates to targetable mutations, germline testing, data sharing, genetic testing in children, newborn screening, preimplantation genetics, and laboratory stewardship will be the focus. Worksheet: Exercises in Ethical Issues in Molecular Pathology	• Review ethical issues that arise in molecular/genetic pathology • Review ethical principles • Suggest approaches for navigating ethical dilemmas	60 min
KEY COMPONENTS OF A ROBUST REPORTING STRUCTURE				
Pre-test for Key Components of a Robust Reporting Structure Section				15 min

Professionalism and Communications	Lorinda A. Soma, MD	The purpose of this discussion is to consider the importance of behavioral aspects of professionalism in medicine, and the relevance of communication as part of those non-cognitive attributes. We will consider how to be a better communicator through coaching and listening, and discuss two methods on how to approach a difficult conversation.
		
		Worksheet: Exercises in Difficult Conversations
			• Define professionalism and identify the components that most commonly to lead to success and compromise
			• Describe growth versus fixed mindset and how it relates to becoming better communicators
			• Determine key components for good communication
			  • Identify which components you are proficient in, and where you need to apply more effort
			  • Utilize two models to approach a difficult conversation
				15 min

Data Analytics and Informatics for Lab 2.0	Noah Hoffman MD, PhD & Patrick Mathias, MD, PhD	This presentation will provide an overview of the motivation, prerequisites, infrastructure, skills and tools for data management and analytics in the clinical laboratory. Topics include data science in the context of other subcategories within the discipline of informatics; a model for data science workflow; example applications of analytics in the lab; infrastructure for managing and analyzing data; basics of SQL; tools for literate programming; data management patterns and antipatterns.	• List at least 2 disciplines within the field of informatics that are most relevant to the practice of molecular pathology. • Explain the 5 steps in a general data science workflow for analyses in healthcare. • Describe how a key is used in structured query language. • Describe best practices for representing data and performing analyses reproducibly.	60 min
Reporting Results of Molecular Pathology Laboratory Tests	Margaret L. Gulley, MD	Recommended elements of a molecular pathology report include information about the patient, the specimen, analytic findings and their clinical significance. Clearly and concise reporting of analytic results, based on interpretation of raw data in the controls and in the patient specimen, is further interpreted for its medical significance to guide downstream clinical decisions. Required and optional elements of reports are discussed, as well as what NOT to report. Gene nomenclature is reviewed.	• Identify sections of a Molecular Lab Report • Discuss required versus optional elements on a report • Convey analytic & clinical Interpretations • Describe standard gene nomenclature	60 min
CAPSTONE SESSION WITH ANCILLARY MATERIALS				
Capstone Session	Erin Graf, PhD	This short presentation provides a holistic view of how the content in this certificate program can help to achieve the ultimate goal of improved patient care and better outcomes. Specifically, it focuses on the critical importance of laboratory result communications and reporting. To this end, additional materials are included to aid learners in the creation of high quality reports. Additional Materials: • Molecular in my Pocket Card: Key Elements for Effective Reporting of Molecular Diagnostic Tests • Sample Reports		5 min
Closing Remarks	Erin Graf, PhD			1-2 min
Course Evaluation				5-10 min
Post-Test				60 min
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