Biochemical Genetic Testing Series

Applying Quality Standards to Biochemical Genetic Testing
March 4, 2015 • 2:00–3:00 pm ET

Biochemical Genetic Test Establishment and Verification
April 8, 2015 • 2:00–3:00 pm ET

APHL Training Webinar Series

Applying Quality Standards to Biochemical Genetic Testing
March 4, 2015 • 2:00–3:00 pm ET

DESCRIPTION
Biochemical genetic testing encompasses specialized procedures for the screening, diagnosis and management of patients with inborn errors of metabolism. These laboratory procedures involve complex analytical methods and instruments to evaluate levels of metabolites, metabolic profiles, enzyme activities and protein function. The application of general regulatory requirements to biochemical genetics testing has been challenging, owing in part to the lack of commercially available reagents and controls, limited proficiency testing material, and lack of guidance on the applicability of regulatory standards originally crafted for other laboratory disciplines. This webinar addresses quality management issues specifically related to biochemical genetic testing using the recommendations from the “Good Laboratory Practices for Biochemical Genetics Testing and Newborn Screening for Inherited Metabolic Disorders” published by CDC in 2012.

OBJECTIVES
At the conclusion of the program, the participant will be able to:
• Discuss the unique challenges of biochemical genetics testing compared to other types of clinical laboratory testing with respect to the implementation of quality procedures.
• Describe the application of general laboratory quality guidelines to specific biochemical genetics tests including amino acid analysis and enzyme assays.

Biochemical Genetic Test Establishment and Verification
April 8, 2015 • 2:00–3:00 pm ET

DESCRIPTION
The majority of biochemical genetic tests are laboratory-developed tests (LDT) that are not FDA approved or cleared. As such, rigorous validation is required before new tests are introduced into clinical testing. For quantitative single or multiple metabolites assays, analytical performance characteristics including accuracy, precision, analytical sensitivity and specificity, reportable ranges, and reference intervals of the reported metabolites must be established or verified. In addition, the clinical validity and utility should be demonstrated if not previously established in literature. This webinar will focus on the analytical validation workflow using the recommendations from the “Good Laboratory Practices for Biochemical Genetics Testing and Newborn Screening for Inherited Metabolic Disorders” published by CDC in 2012 as a framework. Challenges involved in establishing and verifying new biochemical genetic tests will also be discussed.

OBJECTIVES
At the conclusion of the program, the participant will be able to:
• Describe the basic elements of analytical test validation and their application to biochemical genetics testing.
• Recognize the importance of addressing clinical validity in addition to analytical validity in the development of new biochemical genetics tests.

FACULTY
Tina M. Cowan, PhD, Associate Professor of Pathology and Director, Clinical Biochemical Genetics Laboratory, Stanford University, Palo Alto, CA
Chunli Yu, M.D., FACMG, Associate Professor, Director of Biochemical Genetics Division, Mount Sinai Genetic Testing Laboratory, Department of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai, New York, NY

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Series # 588-623-15 Course # 588-621,622-15
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AUDIENCE
This intermediate-level program is appropriate for laboratory professionals working in biochemical genetic testing or newborn screening for inherited metabolic disorders.

CONTINUING EDUCATION
Continuing education credit is available for the first six months after the live program date. After the six months, participants will receive a certificate of attendance.

The Association of Public Health Laboratories (APHL) is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. Participants who successfully complete each program will be awarded 1.0 contact hours. P.A.C.E.® is accepted by all licensure states except Florida. APHL is a Florida and CPH-recertification approved CE provider; each course has been approved for 1.0 contact hours.

REGISTRATION
Register for the series or an individual program

- This program is free. Please limit one registration per site.
- Biochemical Genetic Testing Series registration deadline: March 2, 2015
- Individual Program deadline: Two days before each program
- Registration per site (for one phone line):
  - Biochemical Genetic Testing Series (two webinars) - Series includes one connection to the live program with unlimited attendance for everyone AND unlimited access to the archived program.
  - Single webinar from the Biochemical Genetic Testing Series includes one connection to the live program with unlimited attendance for everyone AND unlimited access to the archived program.
- Select a site facilitator who can receive all communication via email
- Site facilitator must register online at www.aphl.org/courses/Pages/588-623-15.aspx. Having difficulty with the online registration process? Please email registrar@aphl.org or call 240.485.2727 from 8:00 am–4:30 pm ET.
- After your facility’s registration is confirmed, the site facilitator will receive all necessary instructions and paperwork via email.
- For program content information, please email webinar@aphl.org.

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