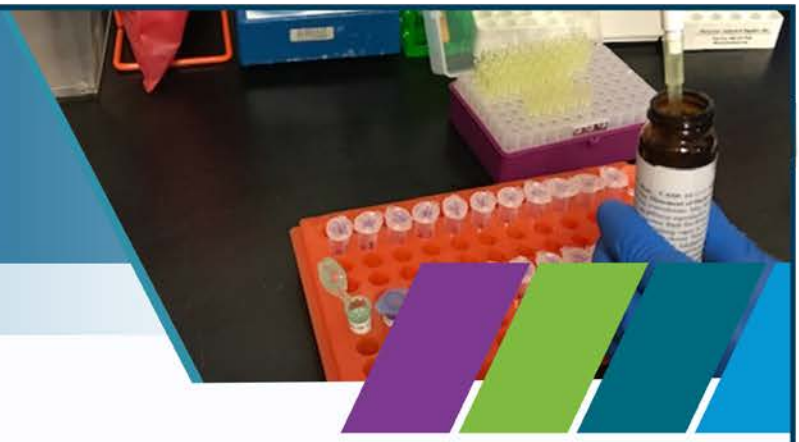
Establishment and Validation of a New Test Using LC-MS/MS in a Biochemical Genetics Laboratory



DESCRIPTION

The majority of biochemical genetic testing laboratories in the United States perform clinical diagnostic tests on various specimen types that may include urine, plasma or serum, cerebrospinal fluid, whole blood, dried blood spots and cell cultures from patients with suspected inherited metabolic disorders (IMDs). Since the advent of expanded newborn screening for IMDs there has been an increasing demand for biochemical genetic testing using tandem mass spectrometry and other technologies. This basic-to-intermediate-level eLearning course describes a step-by-step process of establishing and validating a new clinical assay using liquid chromatography - tandem mass spectrometry (LC-MS/MS) in a biochemical genetic laboratory. An example of plasma methylmalonic acid quantification is used to illustrate the development of a validation plan, assay validation process, and the contents of a validation report.

AUDIENCE

This online course is designed appropriate for laboratory professionals working or aspiring to work in a biochemical genetics laboratory.

SPECIAL NEEDS

Course content is closed-captioned, where applicable, and optimized for a screen reader.

FREE REGISTRATION

- Locate the course online at www.cdc.gov/labtraining.
- Follow the link to register for the course in TRAIN.
- If you have difficulty with the online registration process, please email labtraining@cdc.gov.

OBJECTIVES

At the conclusion of this course, the learner will be able to:

- Explain the regulatory environment of a biochemical genetics laboratory
- Define the steps required to establish and validate an assay based on LC-MS/MS
- Explain the principles of an LC-MS/MS assay using a specific example
- Explain in detail the steps required to validate the assay
- Describe in detail the contents of the validation report

CONTINUING EDUCATION

The Centers for Disease Control and Prevention Division of Laboratory Systems is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program.

This course is approved for 1.5 contact hour(s) of P.A.C.E.® credit. P.A.C.E.® number: 288-021-20.