CLSI updated standards and software

January 2015—The Clinical and Laboratory Standards Institute has published two updated standards and released a new version of its StatisPro software.

User Verification of Precision and Estimation of Bias; Approved Guideline—Third Edition (EP15-A3) describes the estimation of imprecision and of bias for clinical laboratory quantitative measurement procedures using a protocol that can be completed in five days. Included in this edition are guidelines for duration, experimental designs, materials, data analysis summarization, and interpretation—techniques that are adaptable for a range of analytes and device complexity.

The document development committee had two principal goals for EP15: to develop a testing protocol suitable for use in a large clinical laboratory yet simple enough to be applicable in a point-of-care setting or physician's office laboratory and to develop a protocol sufficiently rigorous to provide statistically valid conclusions for verification studies. The bias is assessed by a recovery experiment. Instead of using manual worksheets, calculations may be performed with method evaluation software or generic spreadsheet software.

Another new standard, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition (EP05-A3), is intended for use by manufacturers of quantitative measurement procedures and for laboratories that develop or modify such procedures. It provides guidance for studies intended to establish the within-site precision performance characteristics of quantitative measurement procedures used in clinical laboratories and also for studies addressing site-to-site variability.

Multiple experimental protocols are described, along with considerations on how to select and optimize the protocols best suited for a specific measurement procedure, or assay, and its intended use. Included are guidelines for duration, experimental designs, materials, data analysis, summarization, and interpretation—techniques adaptable for a spectrum of measurands and system complexities.

Version 3.0 of StatisPro software guides users through protocols to establish and verify test-method performance characteristics. The protocols follow CLSI standards, so users can be confident that their analyses meet regulatory and accreditation requirements.

StatisPro 3.0 includes an implementation of CLSI document EP09-A3—Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition and of EP17-A2—Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.

[CLSI](), 610-688-0100