



9 January 2018

To: Recipients of EP09-A3

From: Jennifer K. Adams, MT(ASCP), MSHA
Vice President, Standards and Quality

Subject: Withdrawal of CLSI Document EP09-A3

CLSI was recently informed of errors and inconsistencies in CLSI document EP09-A3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. The issues cited include:

- Inability to replicate some examples provided in the guideline
- Inaccuracy of the bias definition generated when averaging bias over the assay range when the regression slope was poor
- Incomplete formula for computing the confidence intervals of bias estimates at medical decision points
- Inadequate coverage of Deming regression principles, especially with regard to the use of precision profiles
- Insufficient detail on performing bootstrapping for Passing-Bablok parameter confidence interval estimates

Because of these errors and inconsistencies, EP09-A3 has been withdrawn from the CLSI document library until appropriate corrections are made.

Please note the errors in EP09-A3 present negligible risk of harm to patients, because laboratories often use a software package or obtain assistance from a test system manufacturer when computing measurement procedure comparison statistics.

We appreciate your patience as corrections and enhancements are made to EP09-A3. A detailed description of the corrections will accompany the forthcoming corrected guideline. If you require any additional clarification regarding these corrections, please contact CLSI Customer Service (customerservice@clsi.org).