



20 June 2018

**To:** Recipients of EP09-A3

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

**Subject:** CLSI Document EP09 Correction

On 9 January 2018, CLSI document EP09, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition* was withdrawn because of errors and inconsistencies in the document. The issues cited are described below.

### Issues

- 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

### Corrections

In response to these concerns, the corrections and/or enhancements described below were made to the guideline.

- The content was reorganized to emphasize the process for performing a measurement procedure comparison.
- The document clearly specifies that manufacturers should use regression analysis to characterize bias (see Subchapter 2.2 and Chapter 6).
- Information on using precision profile information when performing Deming regressions was added.
- Additional information on determining confidence intervals for bias estimates at specified concentrations using regression fits is included (see Appendix F).
- Corrections were made to the description of the Passing-Bablok regression technique (see Appendix I).

- A detailed description of the bootstrap iterative technique for bias estimation was added (see Appendix K).
- Errors in the following equations and tables were corrected:
  - Appendix C, Table C1, row 1: The percent difference (“%Diff” column) was corrected to read -100.0%.
  - Appendix D, Table D2: The candidate measurement procedure dataset was corrected.
  - Appendix H, Equation H7: A missing minus (-) sign was inserted in the denominator.
  - Appendix I, Equation I6: “ $(2n - 5)$ ” was changed to “ $(2n + 5)$ .”

The corrections and enhancements presented in the corrected edition of EP09 will assist document users in obtaining accurate information when conducting measurement procedure comparison experiments.

If you previously purchased EP09, an electronic version of the corrected guideline will be e-mailed to you. If you do not receive the e-mail or experience any issues with the corrected file, or if you require any additional clarification regarding these corrections, please contact CLSI Customer Service at [customerservice@clsi.org](mailto:customerservice@clsi.org) or +1.610.688.0100.

We appreciate your commitment to CLSI and regret any inconvenience.