26 April 2024

To: Recipients of CLSI EP25-Ed2

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Subject: Combined Corrections

This notice is intended to inform users of corrections made to CLSI EP25, *Evaluation of Stability of* In Vitro *Medical Laboratory Test Reagents,* 2nd ed. The corrections are described below and shown as highlighted text in the excerpts.

Correction: 26 April 2024

Subchapter 5.2. Data Analysis for Each Metric's Dataset:

Equation (6) is listed incorrectly as:

$$\%\text{Change} = b_1 T_{N+1}$$

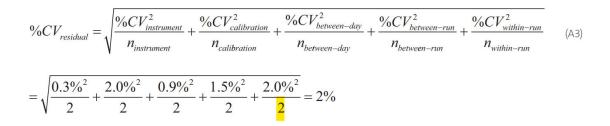Equation (6) has been corrected to read:

$$\text{Change} = b_1 T_{N+1}$$

Correction: 14 February 2024

Appendix A: Power Analysis for Stability Studies Based on Linear Regression: Example A2. Multiple Variance Components

In the example for equation (A3), the total number of factor levels sampled per time point for within-run component is listed incorrectly as "2." The 2 has been corrected to read "8."

$$\%CV_{residual} = \sqrt{\frac{\%CV^2_{instrument}}{n_{instrument}} + \frac{\%CV^2_{calibration}}{n_{calibration}} + \frac{\%CV^2_{between-day}}{n_{between-day}} + \frac{\%CV^2_{between-run}}{n_{between-run}} + \frac{\%CV^2_{within-run}}{n_{within-run}}} \quad (A3)$$

$$= \sqrt{\frac{0.3\%^2}{2} + \frac{2.0\%^2}{2} + \frac{0.9\%^2}{2} + \frac{1.5\%^2}{2} + \frac{2.0\%^2}{2}} = 2\%$$

Appendix C: Table C1. Example of Mean Results for Each Time Point

In Table C1, the slope of the high control and the change at T_N and the change at T_N, 95% CL at the low control are listed incorrectly. The value of the slope should be listed as "-9.103×10^{-3}." The value of the change at T_N should be listed as "-4.14%," and the change at T_N, 95% CL should be listed as "-5.13%."

Slope	-1.567×10^{-3}	-2.873×10^{-3}	9.103×10^{-3}
Change at T_N	-8.07%	4.14%	-3.32%
Change at T_N, 95% CL	-9.26%	5.13%	-4.17%

Appendix D: D5 Calculating Confidence Interval for %Change

In equation (D14), the mean of all time values is listed incorrectly as squared. The superscripted "2" has been removed.

$$Cov(b_0, b_1) = -\hat{\sigma}^2 \left(\frac{\bar{T}^2}{S_{TT}} \right) \quad (D14)$$

If you require any additional clarification regarding these corrections, please contact CLSI Customer Service (customerservice@clsi.org).