16 December 2025

To: Recipients of CLSI EP06-Ed2-IG and CLSI EP06-Ed2-WB

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

Subject: Correction

This notice is intended to inform users of corrections made to CLSI EP06-Ed2-WB, *User Verification of Linearity Workbook*, 1st ed., which is used with CLSI EP06-Ed2-IG, *User Verification of Linearity Implementation Guide*, 1st ed. The corrections are described below and shown in the red boxes in the excerpts.

EP06-Ed2-WB, Data Entry tab:

The workbook incorrectly did not include a model to handle a fixed intercept of 0. The workbook has been corrected with the addition of the "no intercept" regression fit, which has been made the default precision profile fit. The "intercept" fit results are listed to allow the user to see the difference from the "no intercept" fit. The plot now uses the "no intercept" regression as default.

Change from:

Study results:

Sample number (low to high):	1	2	3	4	5	6
First measured replicate:	36.0	338.0	777.0	1650.0	2500.0	3350.0
Second measured replicate:	35.0	341.0	791.0	1653.0	2377.0	3293.0
Mean:	35.50	339.50	784.00	1651.50	2438.50	3321.50
Measured SD:	0.71	2.12	9.90	2.12	86.97	40.31
Precision profile sigma:	0.71	3.10	11.50	27.91	42.79	59.48

Number of samples:	6	SD = standard deviation
Precision profile slope:	0.0189	sigma = precision profile fitted SD
Precision profile intercept:	-3.3203	

To:

Study results:

Sample number (low to high):	1	2	3	4	5	6
First measured replicate:	36.00	338.00	777.00	1650.00	2500.00	3350.00
Second measured replicate:	35.00	341.00	791.00	1653.00	2377.00	3293.00
Mean:	35.50	339.50	784.00	1651.50	2438.50	3321.50
Measured SD:	0.71	2.12	9.90	2.12	86.97	40.31
Precision profile sigma:	0.71	5.95	13.73	28.93	42.71	58.18

	Slope	Intercept	
Number of samples:	6		SD = standard deviation
Profile with no intercept:	0.0175	0	sigma = precision profile fitted SD
Profile with intercept:	0.0189	-3.3203	

EP06-Ed2-WB, Linearity tab:

The formulas used in the workbook incorrectly did not include the number of replicates in the calculation of the lower limit and upper limit of the confidence interval (CI). In the corrected workbook, the 90% adjusted quantile is calculated (unrounded) for both 5-point and 6-point studies. Both the "intercept" and "no intercept" regressions are performed. The regression with the lowest summed (weighted) residual difference between given and predicted values is used in the linearity calculations. The lower and upper limits of the difference in CI use the correct formula with the sigma value being divided by the square root of the number of replicates (SQRT[2]). The CI results may be slightly different than what is in the guideline for this data set because (1) the computed 90% adjusted quartile is used rather than the rounded estimate from the guideline and (2) the "intercept" regression may be used if its summed, weighted residual difference is lower than the "no intercept" regression.

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