27 October 2025

To: Recipients of CLSI EP30-Ed2

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Vice President, Standards and Quality

Subject: Correction

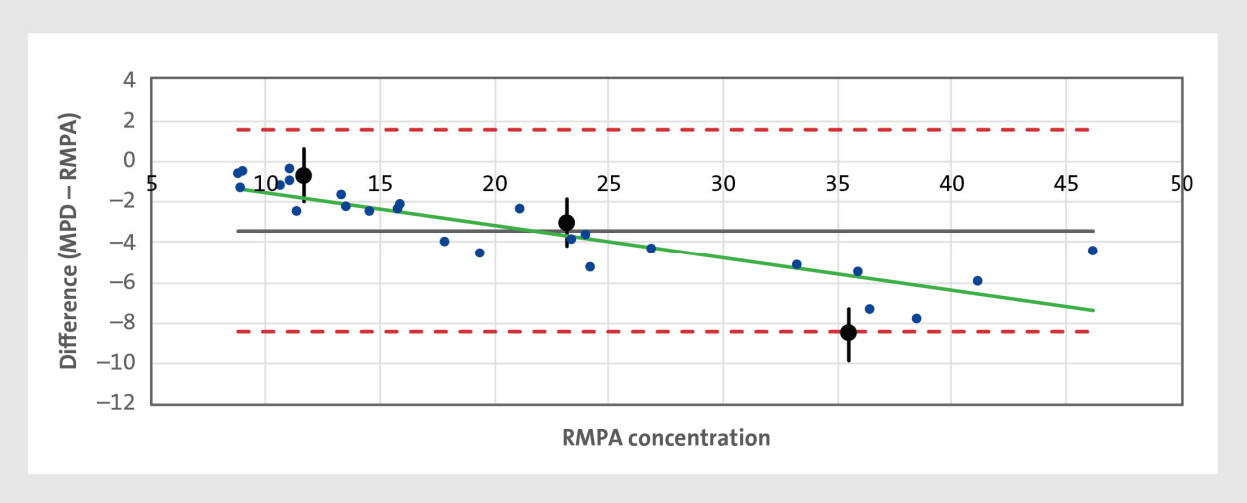
This notice is intended to inform users of a correction made to CLSI EP30, *Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine*, 2nd ed. The correction is described below and shown as highlighted and/or stricken text in the excerpts, as applicable.

The coverage factor in CLSI EP30-Ed2-DS was applied twice while the reference material confidence intervals were computed. After the calculation was corrected in the datasheet tabs "Part 2 – Initial" and "Part 2 – Adjust," the plots and summary tables of commutability changed. As a result, CLSI EP30 was corrected as described below.

Subchapter 7.5.1.3. Difference in Bias Approach:

Figure 4. Example Data With No Adjustment for Nonconstant Difference in Bias:

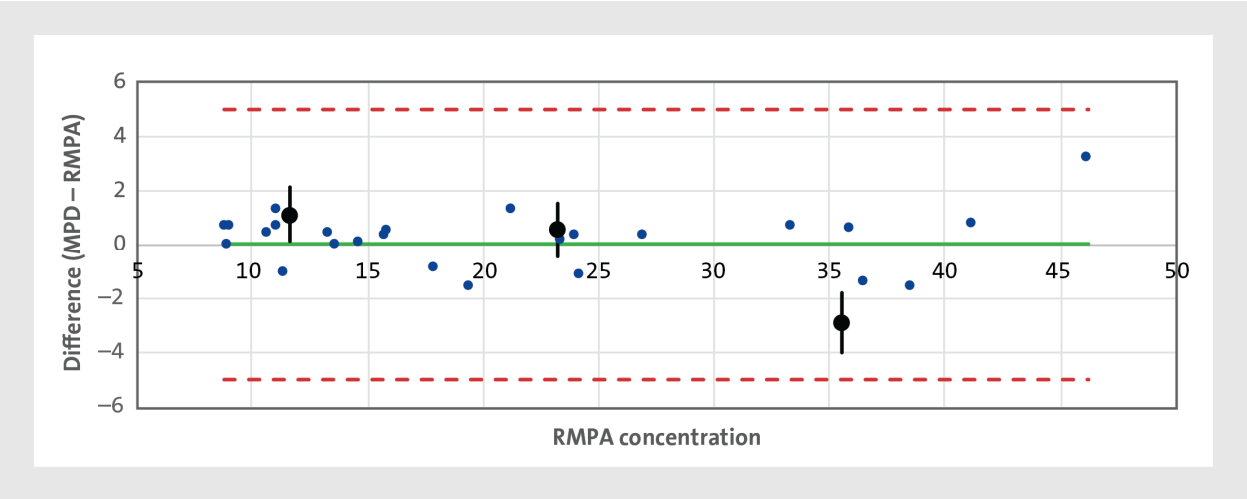
Figure 4 is displayed incorrectly as having a wide reference material confidence interval. Figure 4 has been corrected to show a narrower reference material confidence interval:



The corrections in Figure 4 resulted in changes to the paragraph below Figure 4. The second sentence has been corrected to read, "The ~~CI of the RM is close to exceeding the difference criterion at the low concentration and the~~RM mean ~~does exceed~~is below the difference criterion at the high concentration."

Figure 5. CS and RM Differences Corrected for b(μ):

Figure 5 is displayed incorrectly as having a wide reference material confidence interval. Figure 5 has been corrected to show a narrower reference material confidence interval:



Subchapter 7.5.2.2.2. Mathematical Recalibration Example Using Three Levels of Reference Materials:

Additional text has been added to Subchapter 7.5.2.2.2 to explain that the three RM-level calibration is a two-step process. First, the dependent, measured measurement procedure (MP) clinical sample (CS) values (y-axis) are fit via a regression to the independent target values (x-axis) for each MP. This regression must subsequently be inverted so that the expected MP values (ie, target) can be derived from the measured MP values. This process was used in CLSI EP30-Ed2-DS, but it was not adequately explained in the text. To accomplish this, the text was corrected to read:

"~~Using the MP-specific slope and intercept from the regression analyses above, the recalibrated CS values are calculated for each MP. The example for MPA is:~~

~~Recalibrated CS value for MPA = MPA slope • current calibrator MPA CS value + MPA intercept~~

The recalibration process starts with the MP-specific slope and intercept from the regression analyses above:

Measured CS value = Target value • slope + intercept

The recalibrated CS values are calculated for each MP by inverting the regression to achieve expected target values from the measured values. The example for MPA is:

Recalibrated CS value for MPA = (current calibrator MPA CS value − MPA intercept) / MPA slope"

Appendix D. Commutability Assessment Using Difference in Bias:

Correcting the calculation in CLSI EP30-Ed2-DS resulted in changes to the fourth and fifth paragraphs of Appendix D.

Two sentences in the fourth paragraph were corrected to read:

- "In CLSI EP30-Ed2-DS, the tab labeled "Part 2 – Adjust" includes ~~a simulation using six replicates for the RM samples, with the underlying variability remaining the same~~the same CS and RM data but with the bias function subtracted."

- "In Figure D1, ~~RMA and RMB are commutable (C) and RMC is indeterminate (I)~~RMA, RMB, and RMC are commutable (C)."

Two sentences in the fifth paragraph were corrected to read:

- "~~The two lowest RM levels (RMA and RMB) are seen as commutable, while the highest RM level (RMC) is I1. The results for all six RM comparisons are provided in Table D1 below~~All RM levels (RMA, RMB, and RMC) are seen as commutable. The results for all nine MP to RMP comparisons are provided in Table D1 below."

Figure D1. Commutability Assessment for Three RM Samples Using the Difference in Bias Approach:

Figure D1 is displayed incorrectly as having a wide reference material confidence interval. Figure D1 has been corrected to show a narrower reference material confidence interval:

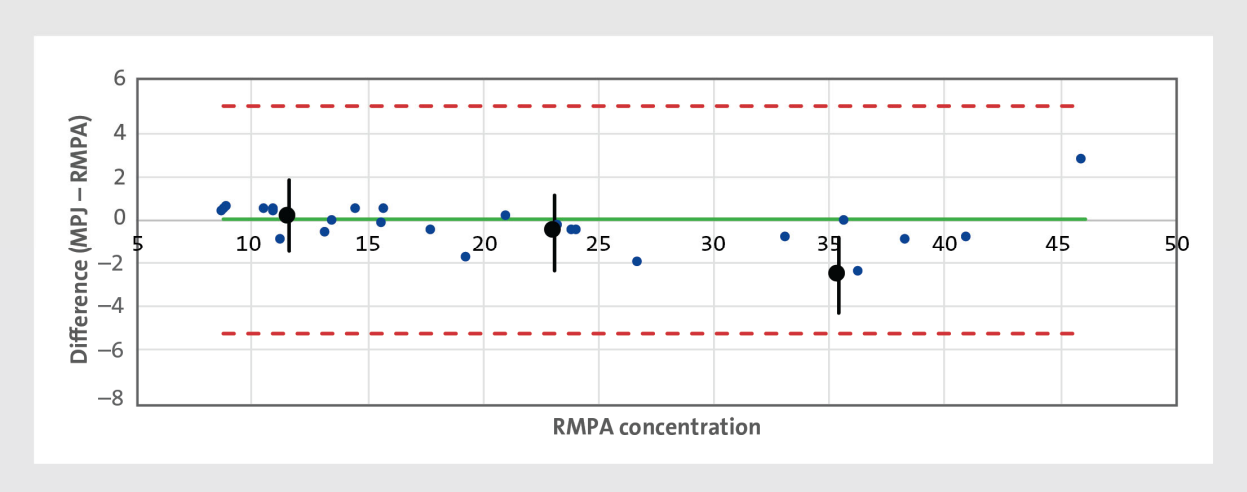


Table D1. Results for Nine MP Comparisons Using the Difference in Bias Approach:

The correction to Figure D1 resulted in changes to Table D1. The Table D1 was title was also corrected to read "Nine MP" rather than "Six RM":

Table D1. Results for ~~Six RM~~Nine MP Comparisons Using the Difference in Bias Approach

	Sample	MPB	MPC	MPD	MPE	MPF	MPG	MPH	MPI	MPJ
Regression Adjusted	RMA	C	C	C	C	C	C	I1	C	C
	RMB	C	C	C	C	C	C	I1	~~I1~~C	C
	RMC	C	I1	C	~~I1~~C	~~I1~~C	~~I1~~C	I1	C	~~I1~~C

The text beneath Table D1 was corrected to align with the corrected data in Table D1:

"Because there was a bias in results over the measured interval, the commutability assessment after bias correction is appropriate. For the bias-adjusted analysis, there were ~~18~~23 commutable and ~~nine~~four indeterminate results, all categorized as I1.

RMA and RMB are commutable with CS for use with most MPs and indeterminate for use with ~~a few~~one of the MPs (MPH). RMC had ~~the most~~two indeterminate results, also shown in ~~Figure~~Table D1."

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