



3 October 2014

To: Recipients of EP14-A3

From: Jennifer K. Adams, MT(ASCP), MSHA

Subject: Error in Section 2.4.3 and Appendix C in CLSI Document EP14-A3

This notification is to inform you of errors in CLSI document EP14-A3, *Evaluation of Commutability of Processed Samples; Approved Guideline—Third Edition*, Section 2.4.3 (pages 14 and 15) and Appendix C, Example C2 (page 37).

A graph of a Deming regression of two measurement procedures is shown in Figure 5 in Section 2.4.3 and also in Appendix C, Example C2. The calculations that precede the conclusion and the graph in Appendix C, Example C2 are correct. However, the conclusion that the processed samples are commutable is not. The error is due to an incorrect value for  $t$  used for the processed samples.

The table below provides more detail.

**Error in CLSI Document EP14-A3.** The source of error in the processed samples evaluation in Appendix C, Example C2 was the previous value for  $t$ , 2.6901, which was incorrect. The correct value is 2.0211.

	X	Y	Y pred	Min	Max	SE	$t$
a	2.894	2.840	2.894	2.851	2.936	0.0209	2.0211
b	2.601	2.552	2.600	2.558	2.641	0.0206	2.0211
c	3.196	3.219	3.196	3.152	3.239	0.0216	2.0211
d	2.017	1.966	2.013	1.970	2.057	0.0216	2.0211
e	3.477	3.472	3.478	3.432	3.524	0.0228	2.0211
f	2.310	2.257	2.308	2.266	2.350	0.0208	2.0211
g	1.704	1.647	1.700	1.654	1.746	0.0228	2.0211

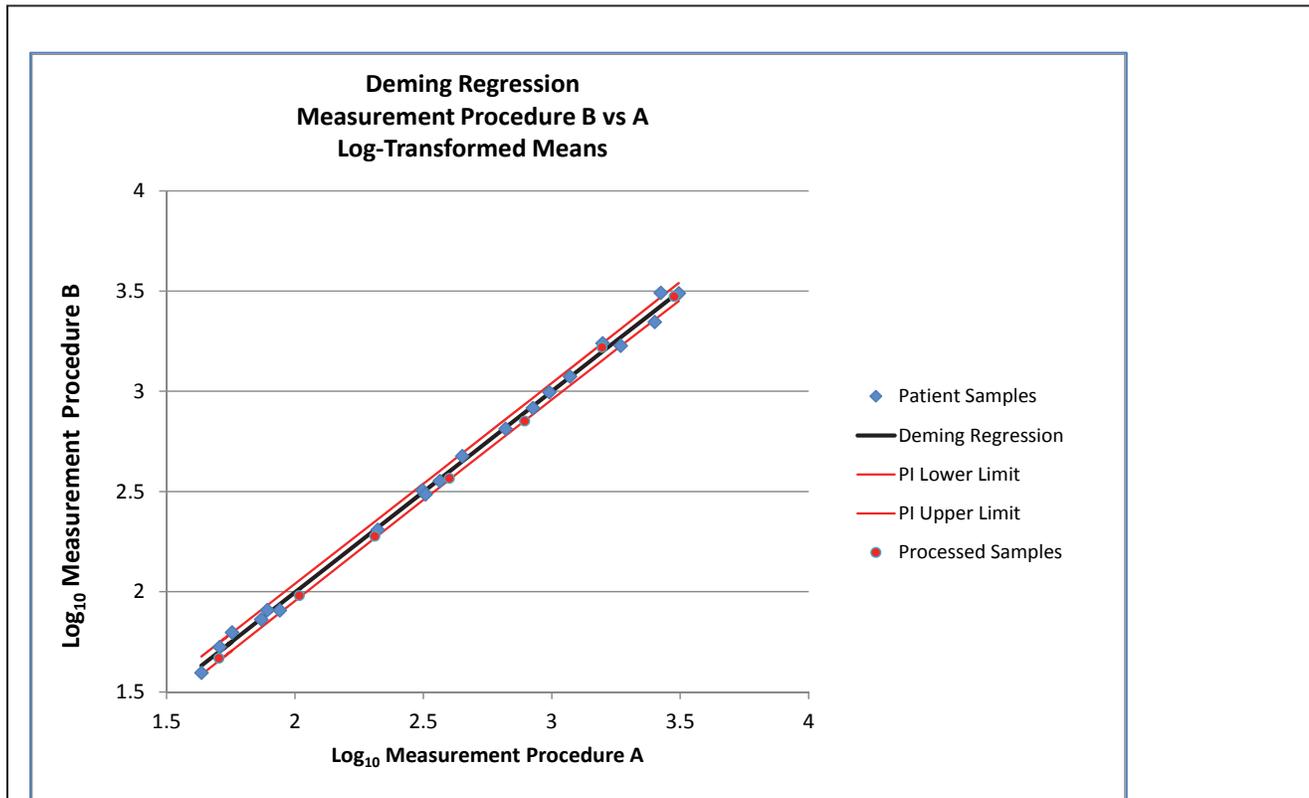
Abbreviations: PI, prediction interval; SE, standard error; Y pred, Y predicted value.

The graphs in Example C2 are correct because the  $t$  value for the patient sample prediction interval was correct.

Because the same graph is used in Section 2.4.3 to illustrate an example of commutable samples, it may cause some confusion, because the plotted processed sample results appear to be borderline to noncommutable.



As a result of these findings, Figure 5 was replaced, and a reference to Example C1 in Appendix C was removed from the accompanying note, as shown below.



Abbreviation: PI, prediction interval.

### Figure 5. Deming Regression of Log-Transformed Means

**NOTE:** Even when the processed samples (or some defined interval of them) are considered to be commutable, there still may be an apparent but statistically insignificant systematic bias (noncommutability) across the interval of the processed samples ~~(see Appendix C, Example C1)~~. The methodology and statistical analysis are not designed to provide estimates for this noted systematic bias. Any remedial actions based upon this finding would require further testing and analysis to better characterize this bias.

In addition, text was revised in Appendix C, Example C2, as shown below.

The regression of the transformed means of the patient samples with the processed sample points plotted on the same graph are shown in Figure C6. ~~Five of the processed samples are not within the PI limits demonstrating that they are noncommutable. All processed samples are within the PI limits demonstrating that they are commutable.~~ Figure C7 shows that if the untransformed means are plotted using Deming regression, the error about the regression line changes in proportion to the concentration, which is undesirable.

If you require any additional clarification regarding this correction, please contact CLSI Customer Service ([customerservice@clsi.org](mailto:customerservice@clsi.org)). We appreciate your commitment to CLSI, and regret any inconvenience.