

9 September 2021

To: Recipients of EP35, 1st ed.  
 From: Jennifer K. Adams, MT(ASCP), MSHA  
 Vice President, Standards and Quality  
 Subject: Combined Corrections

This notice is intended to inform users of corrections made to CLSI document EP35, *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures*, 1st ed. The corrections are described below and shown as highlighted, stricken, and/or red text in the excerpts.

**Correction: 9 September 2021**

**Appendix A. Worked Example of a Quantitative Measurement Procedure, Plasma vs Serum:**

In section A5, Comparison of Repeatability of Heparinized Plasma and Serum:

- The lower limit of % CV for subinterval < 200 pg/mL is listed incorrectly as “(0.77, 2.66).” The lower limit of % CV for subinterval < 200 pg/mL has been corrected to read “(0.76, 2.66).” This value has also been corrected in Table A6 (see table excerpt below).
- The upper limit of % CV for subinterval 200-500 pg/mL is listed incorrectly as “(0.68, 2.13).” The upper limit of % CV for subinterval 200-500 pg/mL has been corrected to read “(0.68, 2.12).”
- The upper limit of % CV for the subinterval > 500 pg/mL is listed incorrectly as “(0.67, 2.34).” The upper limit of % CV for the subinterval > 500 pg/mL has been corrected to read “(0.67, 2.33).” This value has also been corrected in Table A6 (see table excerpt below).

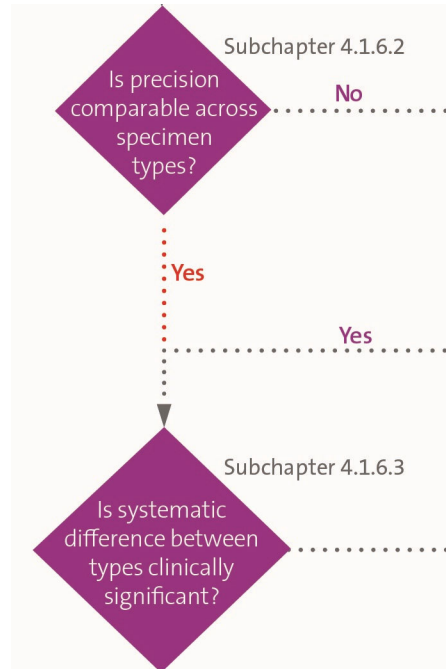
**Table A6. Repeatability Analysis Summary**

Subinterval		Serum	Heparinized Plasma	Ratios (95% CI)
< 200 pg/mL 11 subjects	% CV	4.36%	6.19%	% CV <sub>plasma</sub> / % CV <sub>serum</sub> = 1.42 95% CI: ( <del>0.77</del> 0.76, 2.66)
> 500 pg/mL 11 subjects	% CV	2.66%	3.33%	% CV <sub>plasma</sub> / % CV <sub>serum</sub> = 1.25 95% CI: (0.67, <del>2.34</del> 2.33)

Correction: 17 June 2020

**Subchapter 2.2. Establishing Specimen Equivalence or Suitability Process Flow Charts:**

On the left side of Figure 2, Establishing Equivalence for Similar-Matrix Specimen Types Flow Chart, a “Yes” arrow is missing from the bottom of the diamond that reads, “Is precision comparable across specimen types?”, which should connect to the diamond that reads, “Is systematic difference between types clinically significant?”. Figure 2 has been corrected to include the “Yes” arrow.



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

We appreciate your commitment to CLSI and regret any inconvenience.