

3 November 2025

To: Recipients of CLSI EP35-Ed2

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

Subject: Correction

This notice is intended to inform users of corrections made to CLSI EP35, *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Procedures*, 2nd ed. The corrections are described below and shown as either circled or highlighted text in the excerpt.

Appendix B. Worked Example of a Qualitative Examination, Plasma vs Serum

Table B1. Example Specimen Type Equivalence Study Results With Two Replicates

Shading in the following cells in Table B1 was missing: subject 119, serum replicate 1; subject 201, plasma replicate 1; and subject 203, serum replicate 1.

119	NEG	Pos	Pos	Pos
120	Pos	Pos	Pos	Pos
201	NEG	NEG	Pos	NEG
202	NEG	NEG	NEG	NEG
203	Pos	NEG	NEG	NEG

Shading in Table B1 was corrected:

119	NEG	Pos	Pos	Pos
120	Pos	Pos	Pos	Pos
201	NEG	NEG	Pos	NEG
202	NEG	NEG	NEG	NEG
203	Pos	NEG	NEG	NEG

Table B4. Example Specimen Type Equivalence Study Results With Three Replicates

Shading in the following cell in Table B4 was missing: subject 203, serum replicate 1.

203	Pos	NEG	NEG	NEG	NEG	NEG
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Shading in Table B4 was corrected:

203	Pos	NEG	NEG	NEG	NEG	NEG
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Appendix C. Calculating Confidence Intervals for Standard Deviation Ratios

Equation (C5) is listed incorrectly as:

$$F\left(1 - \frac{\alpha}{2}, v_1, v_2\right) = \frac{1}{F\left(\frac{\alpha}{2}, v_1, v_2\right)}$$

Equation (C5) has been corrected to read:

$$F\left(1 - \frac{\alpha}{2}, v_1, v_2\right) = \frac{1}{F\left(\frac{\alpha}{2}, v_2, v_1\right)}$$

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