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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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To: Recipients of I/LA20, 3rd edition

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

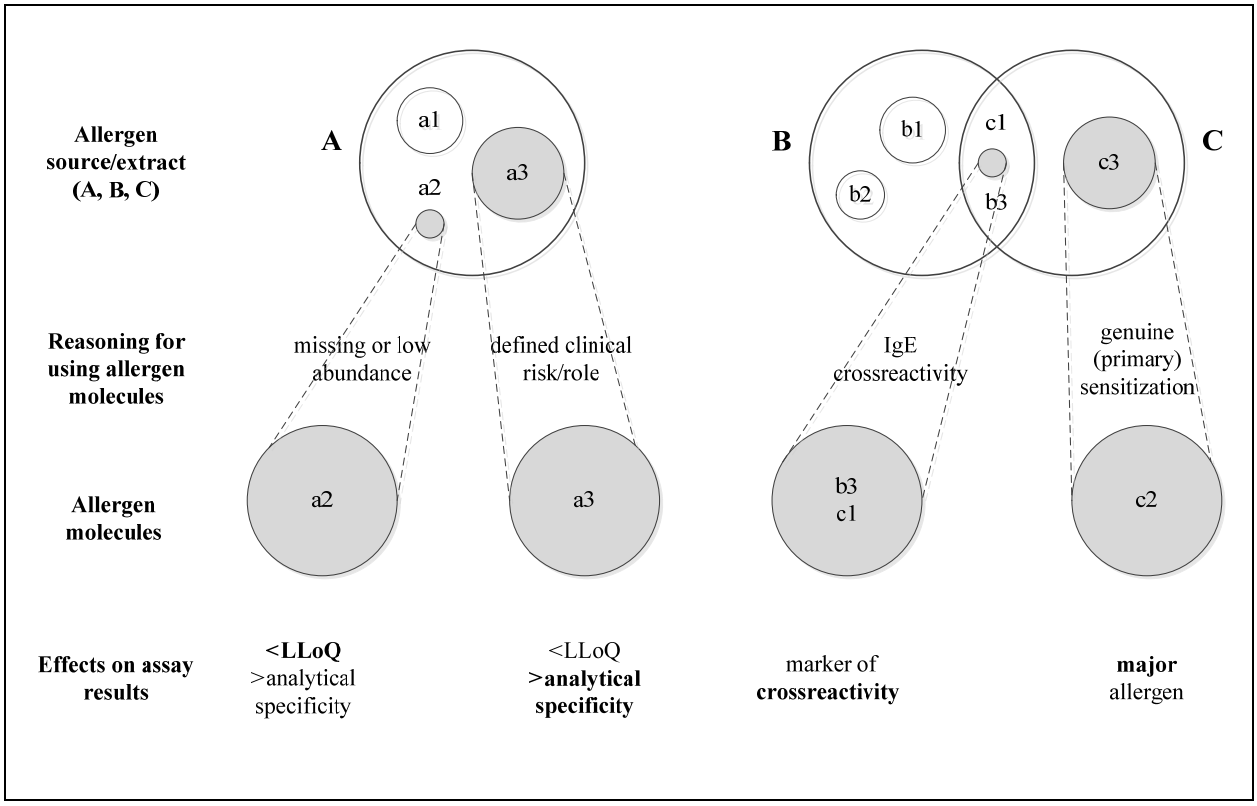
Subject: Editorial omission of Table From Figure 4

This notification is to inform you of editorial errors in in CLSI document I/LA20, *Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities*, 3rd ed.

The highlighted text shown below was revised on page 47 of the document.

Importantly, the principal and most essential reason for using allergen molecules in the diagnostic evaluation of a patient (see the table in Figure 4 for examples) is to enhance the assay-related issue of identifying "sensitization," which will aid but not directly improve the accuracy of the clinical interpretation or clinical diagnosis.

A table was inadvertently omitted from Figure 4 in Subchapter 6.2.1.4 on page 48 The corrected figure and figure legend are shown below.



Examples of the Utility of Allergen Molecules as Reagents

Examples (allergen source, allergen carrier)	Lowered LLoQ	Increased Analytical Specificity/Selectivity	Crossreactive Allergens	Species-/Family-Specific Major Allergens
Cat		**Fel d 2**	**Fel d 2**	**Fel d 1**
Hazelnut	**Cor a 1** (Bet v 1-homolog)	**Cor a 14** (2S albumin) **Cor a 9** (11S globulin) **Cor a 8** (LTP, Mediterranean)		
Kiwi	**Act d 8** (Bet v 1-homolog)		**Act d 8** (Bet v 1-homolog)	
Peach	**Pru p 1** (Bet v 1-homolog)	**Pru p 3** (LTP, marker, Mediterranean)	**Pru p 1** (Bet v 1-homolog), **Pru p 4** (Profilin)	
Peanut	Ara h 10, Ara h 11 (oleosins)	**Ara h 1** (7S globulin) **Ara h 2** (2S albumin) **Ara h 3** (11S globulin) Ara h 6/7 (2S albumin) **Ara h 9** (LTP, Mediterranean)	Ara h 8 (Bet v 1-homolog), Ara h 5*	
Soy	**Gly m 4** (Bet v 1- homolog)	**Gly m 5** **Gly m 6**		
Wheat	**Tri a 19** (omega-5-gliadin)			
Meat	**alpha-GAL**	**alpha-GAL**		
Bee venom	**Api m 3**, Api m 4, **Api m 10**	**Api m 1, Api m 3**, Api m 4, **Api m 10**		**Api m 1, Api m 3,** Api m 4, **Api m 10**
Wasp venom	**Ves v 5**	**Ves v 1, Ves v 5**		**Ves v 1, Ves v 5**
Birch (hazel, alder, birch pollen) and beech trees (beech, oak pollen)		**Bet v 1**	**Bet v 2,*** **Bet v 4**†	**Bet v 1**
Oleaceae (ash, olive pollen)		**Ole e 1**	Ole e 2,* Ole e 3†	**Ole e 1**

Examples (allergen source, allergen carrier)	Lowered LLoQ	Increased Analytical Specificity/Selectivity	Crossreactive Allergens	Species-/Family-Specific Major Allergens
Poaceae (pollen from moderate climate grasses)		**Phl p 1, Phl p 5**	**Phl p 12,[*] Phl p 7[†]**	**Phl p 1, Phl p 5**
Mugwort pollen		**Art v 1**	Art v 4,[*] Art v 5[†]	**Art v 1**
Ragweed pollen		**Amb a 1**	Amb a 8,[*] Amb a 10[†]	**Amb a 1**

[*] Profilin (panallergen in pollen and plant foods).
[†] Polcalcin (panallergen in pollen, see Table 6 for definitions).
Abbreviations: IgE, immunoglobulin E; LLoQ, lower limit of quantitation; LTP, lipid transfer protein.

Figure 4. Reagent Patterns. Reagent patterns based on allergen sources/extracts (upper row), with typical reasons for using allergen molecules as reagents in allergen-specific singleplex IgE assays (middle row) and how IgE anti-allergenic molecule results can lower the assay's final LLoQ and enhance the analytical specificity of the generated assay results. The table provides specific examples that correspond with the conditions depicted in Figure 4. Allergen molecules as reagents from various allergen sources/extracts are represented in the left column. Reasons for using specific allergen molecules and improved assay performance (depicted in the upper row) vary due to the individual diagnostic question and the specific allergen applied. Bolded letters indicate availability as reagents mainly outside the United States (eg, Europe, Japan). Reagents depicted in unbolded letters are not yet available as reagents.

As a result of this correction, table designations—and their corresponding crossreferences—require correction throughout the remainder of the document. The table designation corrections are outlined below.

- Table 8 in Subchapter 6.2.2 becomes Table 7
- Table 9 in Subchapter 6.2.2 becomes Table 8
- Tables 10A and 10B in Subchapter 6.2.2 become Table 9A and 9B, respectively
- Table 11 in Chapter 7 becomes Table 10
- Table 12 in Subchapter 8.1.1.13 becomes Table 11
- Table 13 in Subchapter 9.3 becomes Table 12
- Table 14 in Chapter 11 becomes Table 13
- Table 15 in Subchapter 11.1 becomes Table 14
- Table 16 in Subchapter 11.1.3 becomes Table 15

Finally, a typographical error was corrected in Table 6 on page 45. In the first column, fourth row of the table, the spelling of the term "polcalcin" was corrected.

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

We appreciate your commitment to CLSI, and regret any inconvenience.