

Analytical Performance Evaluation of Cor a 8, Cor a 9, and Cor a 14 Hazelnut Components on IMMULITE 2000 XPi

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Background

Tree nut allergy may affect up to 1.5% of people in Europe.¹ In hazelnut allergy, Cor a 9 (11S globulin) and Cor a 14 (2S albumin) are strongly associated with severe reactions and primary hazelnut allergy in children.² Cor a 8, a non-specific lipid transfer protein, is more prevalent in Mediterranean regions and linked to cross-reactivity with peach (Pru p 3).³ While Cor a 1 dominates sensitization rates, specific IgE (sIgE) to Cor a 9 and Cor a 14 are considered to provide the highest diagnostic accuracy for hazelnut allergy in children.² In this study, we report the analytical performance of the newly developed 3gAllergy hazelnut components rCor a 8, nCor a 9, and rCor a 14 on the IMMULITE 2000 XPi system.

Methods

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were determined per CLSI EP17-A2 for each allergen. Detection capability was determined using 2 reagent lots and a single analyzer per study. Linearity was assessed following CLSI ILA20 guidelines using serum pools diluted across the analytical range; data were analyzed by regression analysis. Method comparison followed CLSI EP09-A3, evaluating IMMULITE 2000 XPi results against a predicate device using two reagent lots. Per allergy guidance for EP09-03, a reduced n was used, and 50 negative and 30 positive samples were evaluated. Agreement was determined by concordance analysis of both reagent lots.

Results

Table 1. The highest observed LoB, LoD and LoQ for the three tested allergens and two reagent lots.

	Allergen	LoB	LoD	LoQ
Dose value (kU/L)	rCor a 8	0.068	0.094	0.132
	nCor a 9	0.022	0.041	0.086
	rCor a 14	0.041	0.063	0.068

These products are under development and not commercially available. Their future availability cannot be ensured.

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Linearity was demonstrated across clinically relevant ranges:

- rCor a 8 = 0.080 to 91.1 kU/L (Figure 1)
- nCor a 9 = 0.035 to 87.7 kU/L (Figure 2)
- rCor a 14 = 0.051 to 89.2 kU/L (Figure 3).

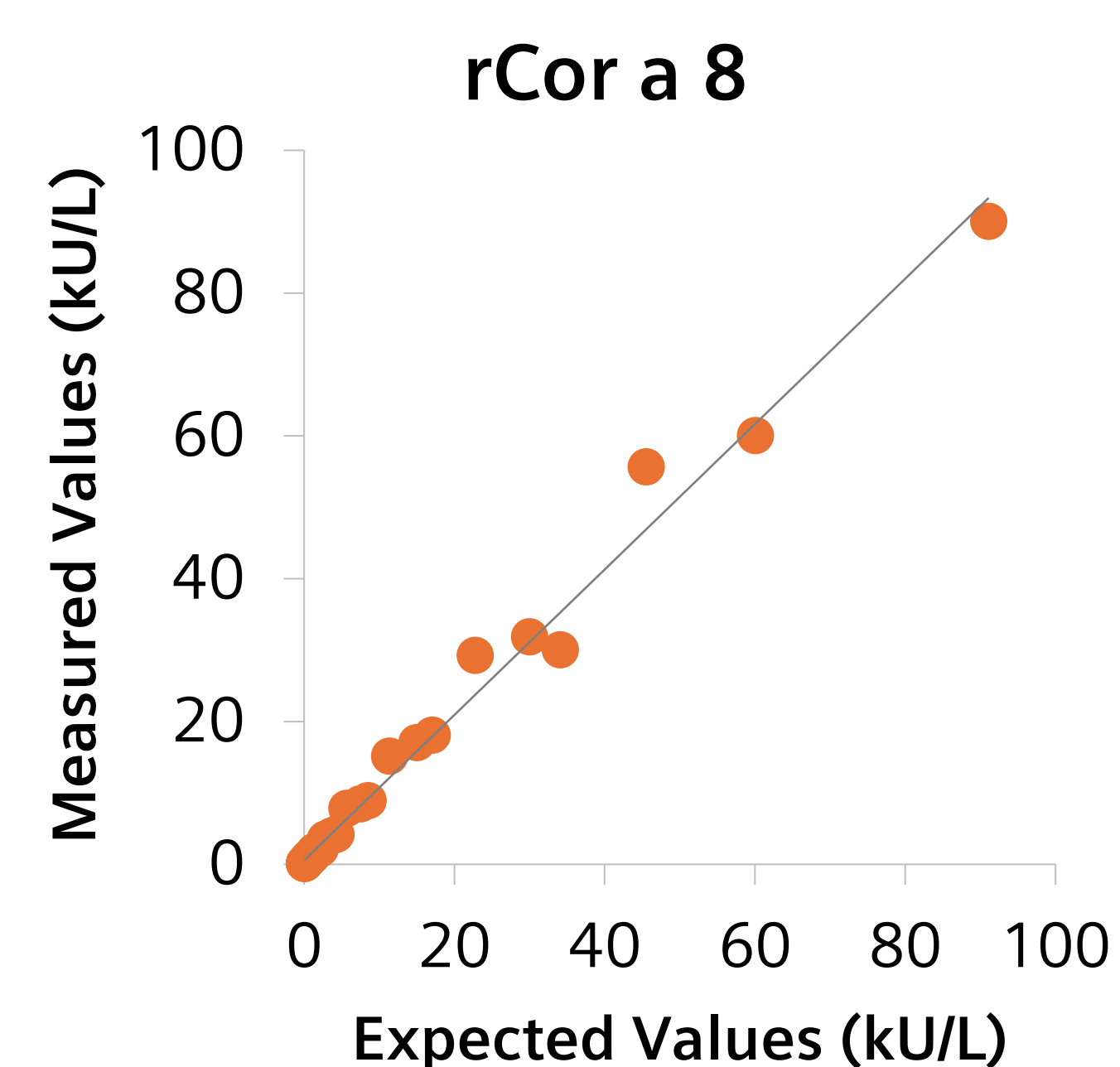


Figure 1. OLS regression of measured mean vs. expected value for one example rCor a 8 lot.

$$y = 0.51 + 1.04x$$

$$R^2 = 0.992$$

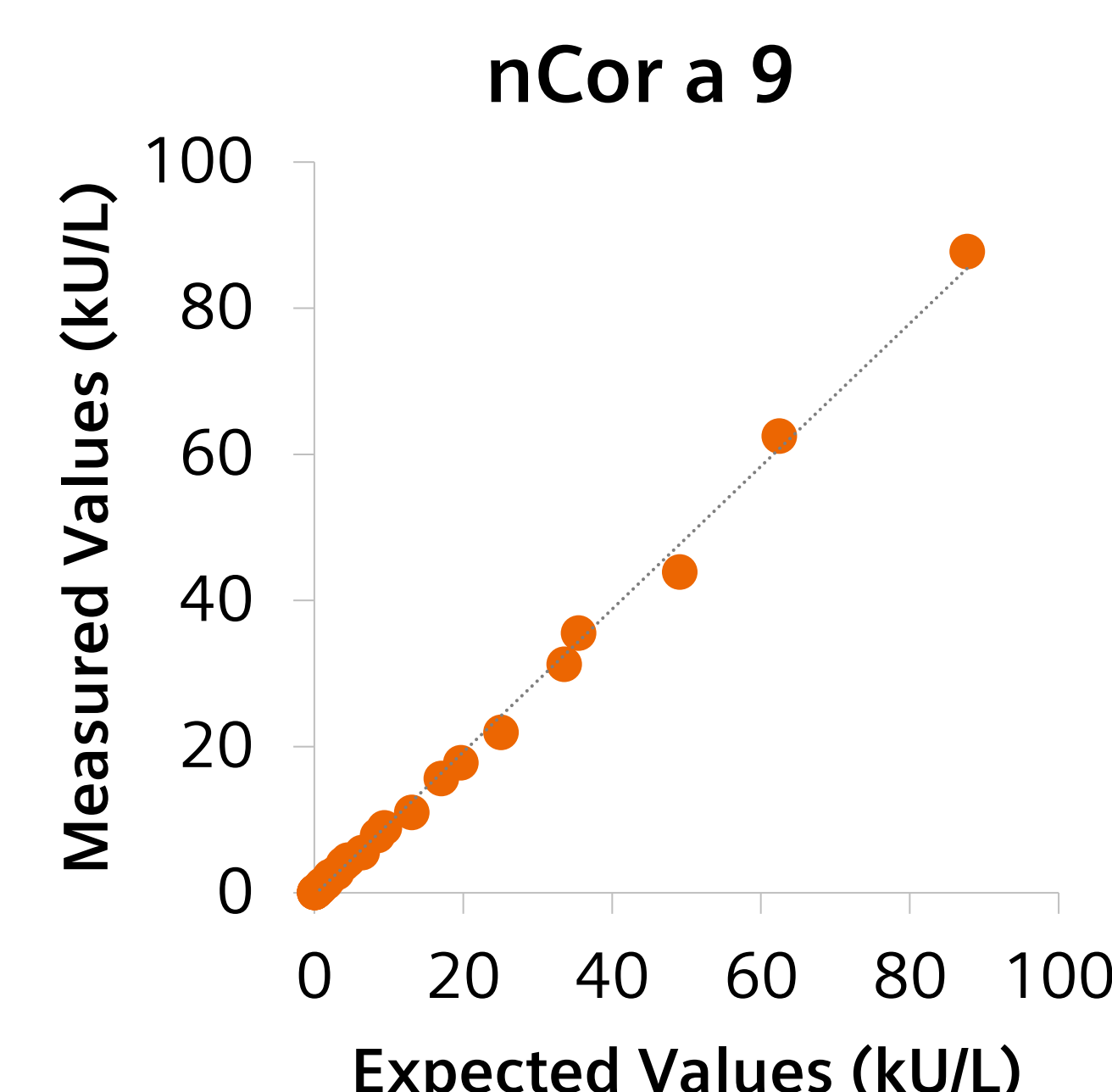


Figure 2. OLS regression of measured mean vs. expected value for one example nCor a 9 lot.

$$y = 0.32 + 1.02x$$

$$R^2 = 0.999$$

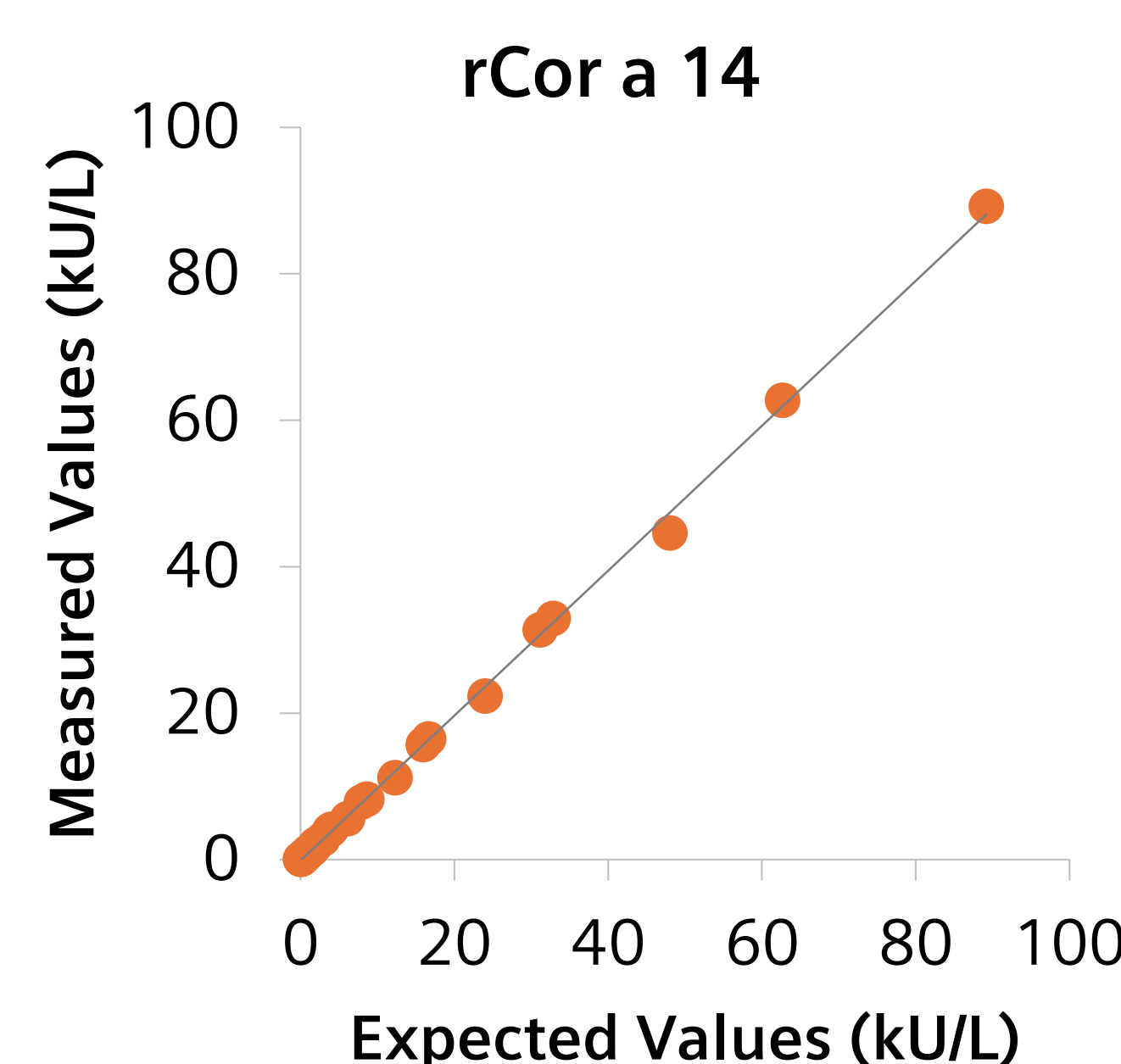


Figure 3. OLS regression of measured vs. expected value for one example rCor a 14 lot.

$$y = 0.14 + 1.01x$$

$$R^2 = 1.00$$

Method comparison showed strong agreement with predicate devices: rCor a 8 and rCor a 14 achieved 96.7% positive and 100% negative agreement (98.8% overall), while nCor a 9 achieved 100% for both.

Table 2. Concordance analysis showing the greatest observed discrepancy (between the two reagent lots) for rCor a 8, nCor a 9, and rCor a 14 between IMMULITE 2000 XPi System and a reference method using 0.1 kU/L as cutoff.

rCor a 8		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	29	0	29
	Negative	1	50	51
	Total	30	50	80
		% Agreement	98.8	

nCor a 9		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	30	0	30
	Negative	0	50	50
	Total	30	50	80
		% Agreement	100	

rCor a 14		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	29	0	29
	Negative	1	50	51
	Total	30	50	80
		% Agreement	98.8	

Conclusion

The allergens showed expected detection limits, appropriate linearity, and strong agreement with the reference method. These results confirm the assay's sensitivity, precision, and reliability, supporting its suitability for routine clinical use in allergy diagnostics.

References

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3. Schulten V et al. Pru p 3, the nonspecific lipid transfer protein from peach, dominates the immune response to its homolog in hazelnut. *Allergy*. 2001;66(8):1005-13. DOI: [10.1111/j.1398-9995.2011.02567.x](https://doi.org/10.1111/j.1398-9995.2011.02567.x)