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Analytical Performance Evaluation of Bet v 4 and Cor a 1 on IMMULITE 2000 XPi

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Background

Panallergens such as profilins and polcalcins are highly conserved proteins found across the plant kingdom and are key drivers of cross-reactivity among pollen species. Bet v 4, a polcalcin from birch pollen, is a calcium-binding protein that represents a minor allergen but serves as a marker for broad pollen sensitization.[1] Sensitization to Bet v 4 is generally associated with polysensitization to multiple pollen sources and may correlate with more severe respiratory disease and reduced efficacy of allergen immunotherapy.[1] Prevalence varies geographically, ranging from 5–11% in Northern and Central Europe to up to 27% in Southern European regions.[2,3] Cor a 1, a PR-10 protein and Bet v 1 homologue, is the major hazelnut allergen in birch-endemic areas, accounting for up to 90% of hazelnut sensitization.[4] IgE cross-reactivity between Bet v 1 and Cor a 1 often results in mild or clinically irrelevant food reactions, unlike seed storage proteins driving severe allergy.[4] Together, Bet v 4 and Cor a 1 are important molecular markers for identifying cross-reactivity patterns and guiding component-resolved diagnostics in pollen and food allergy.[1-3]

Methods

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were determined per CLSI EP17-A2. Linearity was assessed following CLSI ILA20 guidelines using serum pools diluted across the analytical range; data were analyzed by regression. 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 using both reagent lots.[5]

Results

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

	Allergen	LoB	LoD	LoQ
Dose value (kU/L)	rCor a 1	0.062	0.083	0.121
	rBet v 4	0.063	0.093	0.114

Linearity was confirmed across clinically relevant ranges (rCor a 1 : 0.046 – 94.0 kU/L, : rBet v 4 10.056 – 93.1 kU/L)

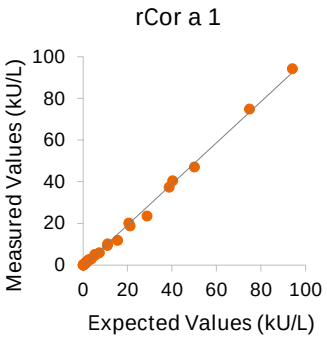

Figure 1. OLS regression of measured mean vs. expected value for one exemplary Cor a 1 lot.
y = 0.50 + 1.01x
R^2 = 0.998

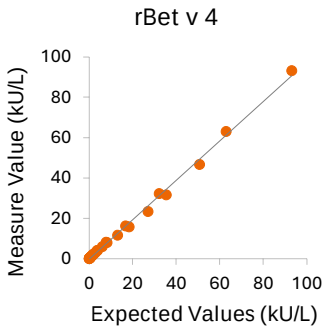

Figure 2. OLS regression of measured mean vs. expected value for one exemplary Bet v 4 lot.
y = 0.22 + 1.02x
R^2 = 0.996

The Method comparison demonstrated good agreement with predicate devices for both allergens, achieving 100% positive, negative, and overall agreement.

Table 2. Concordance table analysis between IMMULITE 2000 XPi System and a reference method showing the greatest observed discrepancy (across the two reagent lots used) for rCor a 1 and rBet v 4 using a 0.1 kU/L cutoff.

rCor a 1		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	30	0	30
	Negative	0	50	50
	Total	30	50	80
		% Agreement	100	

rBet v 4		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	30	0	30
	Negative	0	50	50
	Total	30	50	80
		% Agreement	100	

Conclusion

The allergens showed expected detection limits, appropriate linearity, and strong agreement with a 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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4. Valcour A, et al. Sensitization profiles to hazelnut allergens across the United States. Annals of Allergy, Asthma & Immunology, 2019;122(1):111-6.e1. https://doi.org/10.1016/j.anai.2018.09.466
5. All CLSI Guidelines can be found on the CLSI website: https://clsi.org

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