Analytical Verification of House Dust Mite Allergen Assays on the IMMULITE 2000 XPi System

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Background

House dust mite allergy is a prevalent health issue affecting approximately 1–2% of the global population, which translates to an estimated 65–130 million individuals.[1] These allergies are among the most common indoor triggers known to contribute to conditions such as allergic asthma, rhinitis, and dermatitis. In light of this, we conducted a verification study to assess the analytical performance of specialized assays designed to detect rDer p 10 and rDer p 23, which are key house dust mite allergens on the IMMULITE 2000 XPi Immunoassay System.

Methods

The evaluated house dust mite assays on the IMMULITE 2000 XPi system operate as solid-phase, two-step chemiluminescent immunoassays that utilize liquid-phase kinetics using a bead-based format. The first reaction involves binding the allergen protein to any allergen-specific IgE present in the patient sample via a solid-phase bead. In the second step, a murine anti-human IgE monoclonal antibody is introduced, and the measured emitted light signal is proportional to the analyte concentration in the sample.

Performance validation included method comparison studies using 50 positive and 100 negative patient samples, analyzed using concordance table assessments. Assay precision was evaluated through a 20-day study model, while potential interference was assessed using a panel of endogenous substances, pharmaceutical compounds, and cross-reactivity tests. Linearity was determined using regression analysis and both the limit of quantitation (LoQ) and competitive inhibition were assessed following CLSI I/LA20-A3 guidelines.[2]

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

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Results

The assays for both rDer p 10 and rDer p 23 demonstrated good correlation with commercially available diagnostic tests. Each assay exhibited acceptable precision, with LoD values ranging from 0.016-0.018 kU/L and LoQ values from 0.114–0.126 kU/L. The assays maintained linearity from the LoQ up to sample concentrations between 59.8 and 84.3 kU/L. Out of ten potential interferents tested, none had a significant impact (≤10%) apart from omalizumab, which showed interference of −10.7% for rDer p 23.

Table 1. Concordance table analysis showing the greatest observed discrepancy of rDer p 10 and rDer p 23 between IMMULITE 2000 XPi System and a reference method using 0.1 kU/L as cutoff.

Der p 10		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	50	0	50
	Negative	0	100	100
	Total	50	100	150
		% Agreement	100	

Der p 23		Predicate Device		
		Positive	Negative	Total
IMMULITE 2000 XPi System	Positive	50	6	56
	Negative	0	94	94
	Total	50	100	150
		% Agreement	96	

Table 2. The highest observed LoD and LoQ for both allergens and three reagent lots.

	Allergen	LoD	LoQ
Dose value (kU/L)	Der p 10	0.016	0.114
	Der p 23	0.018	0.126

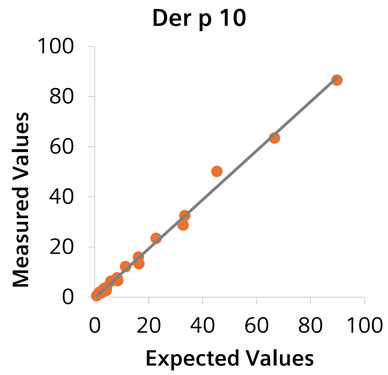

Figure 1. Weighted LS regression of measured mean vs. expected value for one exemplary Der p 10 lot.

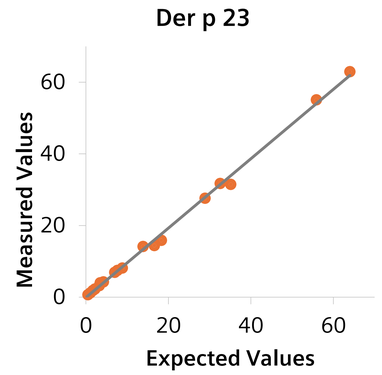

Figure 2. Weighted LS regression of measured mean vs. expected value for one exemplary Der p 23 lot.

Table 3. Interference data showing the maximum percentage bias observed for both allergens at sIgE levels of <3.5 and >3.5 kU/L.

Interferent	Test concentration	%Bias	
		Der p 10	Der p 23
Conjugated Bilirubin	40 mg/dL	-4.9	-9.4
Unconjugated Bilirubin	40 mg/dL	-4.9	6.9
Hemoglobin	1000 mg/dL	-3.9	4.3
Intralipid	3000 mg/dL	5.4	6.2
Diphenhydramine	19.5 µmol/L	1.3	-4.1
Methylprednisolone	1000 ng/mL	5.9	2.2
Ranitidine	19.2 µmol/L	-2.1	-5.3
Omalizumab	0.12 mg/mL	3.5	-10.7
Human serum albumin	120 g/L	4.4	9.2
Rheumatoid Factor	500 IU/L	-2.6	8.4

Conclusion

These findings indicate that the IMMULITE 2000 XPi system can be effectively utilized for the detection and quantification of sIgE against rDer p 10 and rDer p 23, providing a precise and reliable diagnostic approach for house dust mite allergy.

References

1. Huang HJ, Sarzsinszky E, Vrtala S. House dust mite allergy: The importance of house dust mite allergens for diagnosis and immunotherapy. *Mol Immunol.* 2023; 158;54-6
2. CLSI ILA20 3rd edition 2016. Available at ILA20 | Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities. Accessed May 15, 2025.