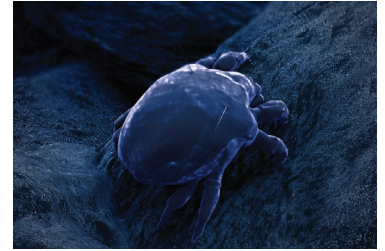


nDer p 1/nDer p 2 Information Sheet

Background

Development of allergic asthma in adults and children is commonly associated with sensitization to house dust mites (HDM).¹ IgE sensitivities are often directed toward major HDM allergens such as Der p 1 (24kD) and Der p 2 (15kD) from *Dermatophagoides pteronyssinus* (allergen code: D1).^{2,3} Der p 1 and Der p 2, individually, are recognized by more than 80% of D1-sensitized patient IgE and have a predictive value for D1 that is greater than 95%.⁴ Cross-reactivity has been observed between homologous proteins Der f 1 and Der f 2 from *Dermatophagoides farinae* to which *D. pteronyssinus* shares 80-90% sequence identity.⁵



Biochemical Characteristics

Native Der p 1 (nDer p 1) and native Der p 2 (nDer p 2) proteins were purified to homogeneity from *Dermatophagoides pteronyssinus*.

Testing Algorithm^{6,7}

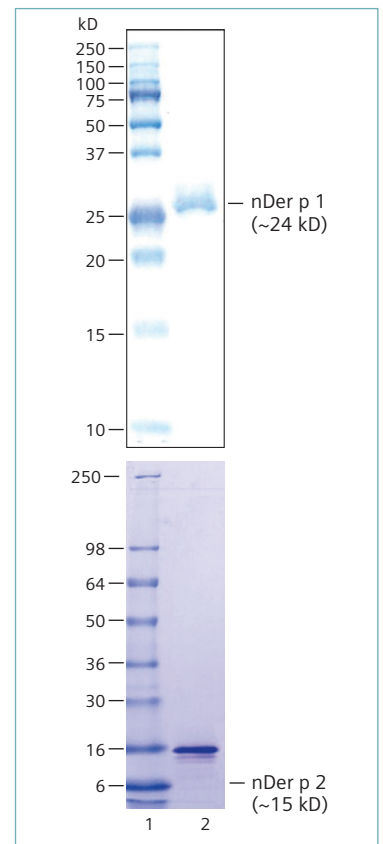
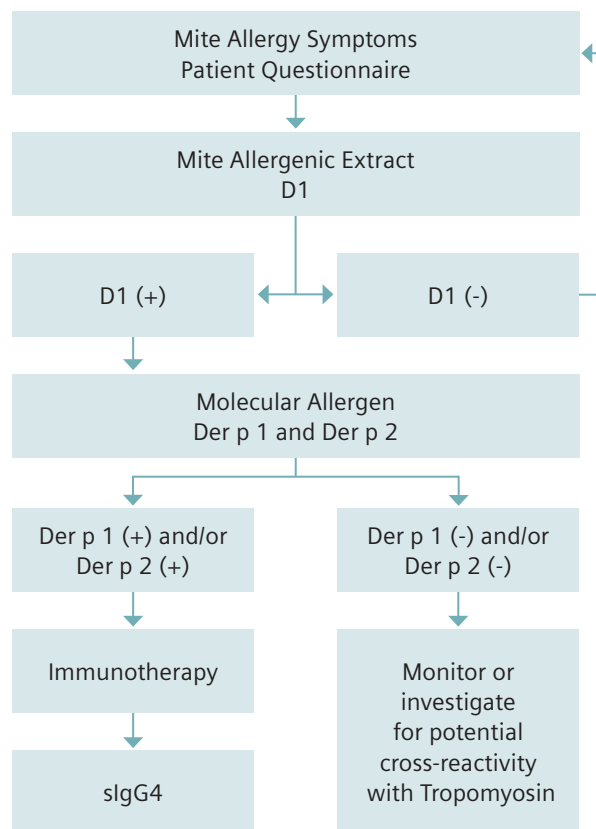


Figure 1. Coomassie Blue stained gel.

IMMULITE 2000/XPi 3gAllergy Specific IgE

Dermatophagoides pteronyssinus Major Allergens,
nDer p 1 (Code A310L2) and nDer p 2 (Code A316L2)

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Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic and apparently healthy individuals against nDer p 1 and nDer p 2 specific allergens. The results were obtained using the IMMULITE® 2000 3gAllergy™ Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the cross table below.

Allergens: nDer p 1 and nDer p 2

IMMULITE 2000				
		Clinical	Normal	Total
nDer p 1	Positive (≥0.10 kU/L)	49	3	52
	Negative	7	109	116
	Total	56	112	168
nDer p 2	Positive (≥0.10 kU/L)	51	2	53
	Negative	5	110	115
	Total	56	112	168
	Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)		Overall Agreement
nDer p 1	88% (79% to 96%)	97% (94% to 100%)		94%
nDer p 2	91% (84% to 99%)	98% (96% to 101%)		96%

Additional clinical performance of nDer p 1 and nDer p 2 specific allergens was demonstrated in comparison to the whole extract allergen D1 (*Dermatophagoides pteronyssinus*). A total of 107 samples were tested with A310/A316 and D1. The results are presented below.

Allergen: nDer p 1 and nDer p 2

IMMULITE 2000			
D1 (Ref. Method)			
A310 & A316 (Test Method)	50	0	Positive
	1	56	Negative
	Positive	Negative	

N=107

Overall percent agreement = 99%
Positive percent agreement = 98%
Negative percent agreement = 100%

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Analytical Performance

Precision: The average within-run and total precision using three samples and three lots of the nDer p 1 allergen was 4.24% and 5.08%, respectively. The average within-run and total precision using three samples and three lots of the nDer p 2 allergen was 6.18% and 7.50%, respectively.

Linearity: Two samples were diluted in 2-fold serial dilutions. The undiluted (neat) and the diluted samples were assayed in two replicates and the observed value was reported based on the average of the two replicates. Comparisons of the observed to expected values were used to demonstrate linearity at concentrations within the assay limits.

nDer p 1:

Observed = 0.996 (Expected) + 0.0213
Slope (95% Confidence Interval) = 0.996 (0.978 to 1.104)

nDer p 2:

Observed = 0.997 (Expected) + 0.0978
Slope (95% Confidence Interval) = 0.997 (0.987 to 1.007)

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