SIEMENS

IMMULITE 2000/XPi 3gAllergy Specific IgE

Birch Pollen Component Allergen, rBet v 2 (*Betula verrucosa*, A127L2)*

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Background

Profilin allergens are responsible for multiple pollen and food sensitization with extensive cross-reactivity.[1,2] The IgE conformational epitopes in profilin are highly conserved, which is key to maintaining its cross-reactive nature in plant allergens. The Bet v 2 profilin from birch pollen may be used to evaluate IgE reactivity in patients with suspected birch allergy or other cross-reactivities between mugwort, grass pollen, celery, carrots, and hazelnut.[3-5]

Biochemical Characteristics

Recombinant Bet v 2 (rBet v 2) protein was produced by heterologous expression in *E. coli*.

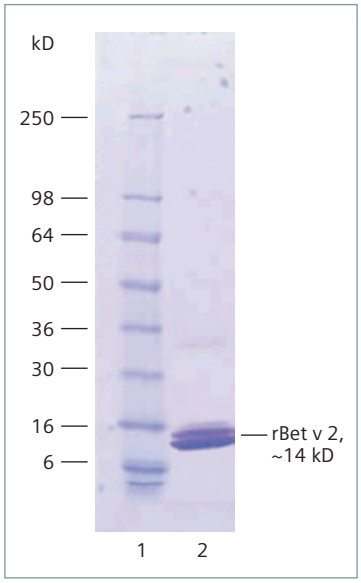
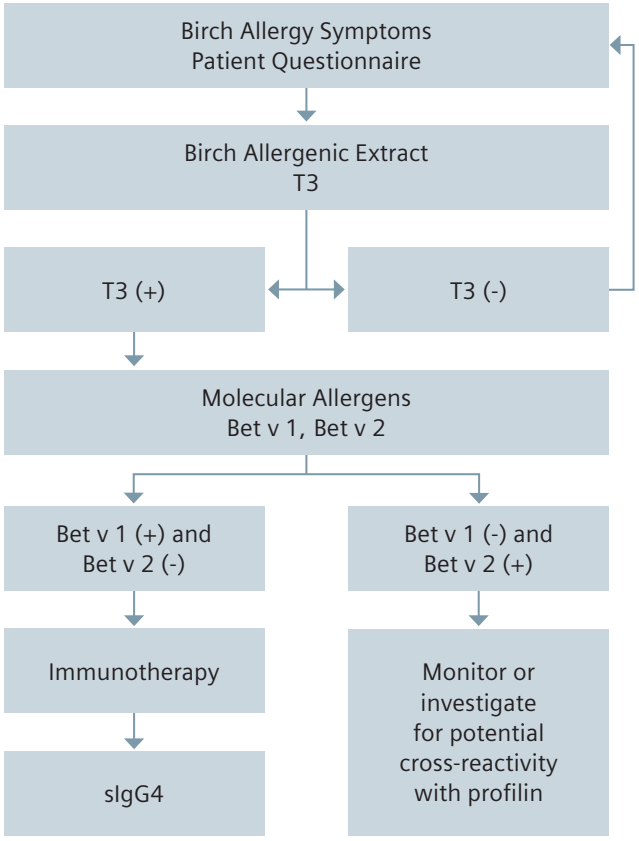


Figure 1. Coomassie Blue stained gel for rBet v 2 (lane 2).

Testing Algorithm[6-8]



Clinical Performance

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

Answers for life.

*Not available for sale in the U.S.

Allergen: rBet v 2

IMMULITE 2000			
	Clinical	Normal	**Total**
Positive (≥0.10 kU/L)	28	4	**32**
Negative	28	96	**124**
Total	**56**	**100**	**156**

Sensitivity (95% Confidence Interval)	**Specificity** (95% Confidence Interval)	**Overall Agreement**
50% (37 to 63%)	96% (92 to 100%)	80%

Additional clinical performance of the rBet v 2 specific allergen was demonstrated in comparison to the whole birch pollen extract allergen (T3). The same 156 clinical samples were tested with A127 and T3. The results are presented below:

Allergen: rBet v 2

IMMULITE 2000			
	T3 (Ref. Method)		
A127 (Test Method)	30	2	Positive
	29	95	Negative
	Positive	Negative	

N=156

Overall percent agreement = 80% (125/156)
Positive percent agreement = 51% (30/59)
Negative percent agreement = 98% (95/97)

Analytical Performance

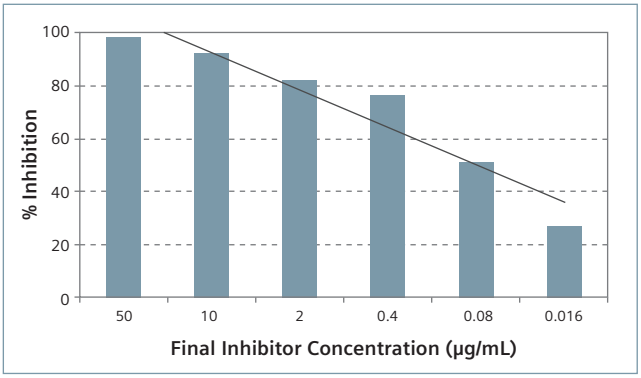
Precision: The average within-run and total precision using three samples and three lots of rBet v 2 allergen were 3.66% and 6.20%, respectively.

Linearity: Two samples were diluted in serial dilutions to 5 levels using two allergen lots. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate linearity at concentrations within the assay limits. Regression statistics for each allergen comparing the observed results to expected results are presented below:

Lot	Regression Equation	Slope 95% CI	R^2
1	Y = 1.024x – 0.0256	0.9951 to 1.053	0.999
2	Y = 1.061x + 0.0999	0.9747 to 1.148	0.990

Identity Testing

Identity of rBet v 2 was verified through competitive inhibition testing using a single serum sample or pool of sera. A negative sample was used to measure the background response. The percentage inhibitions are represented in the graph below showing correlation to increasing inhibitor concentrations.



References:

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