

## IMMULITE 2000/XPi 3gAllergy Specific IgE Birch Pollen Major Allergen, nBet v 1 (Betula verrucosa, Code A89L2)

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### Background

IMM Birch (*Betula verrucosa*) pollen is a major cause of allergy IMM in the northern parts of Europe and America that attributed IMM to about 22% of allergic individuals suffering from pollinosis.<sup>1</sup> IMM Six birch pollen allergens have already been identified IMM (Bet v 1, Bet v 2, Bet v 3, Bet v 4, Bet v 6, Bet v 7). Bet v 1, IMM a major allergenic protein of birch pollen, is a 17-kD protein IMM consisting of several isoallergens<sup>2</sup> and recognized by IgE IMM antibodies from almost all birch pollen-allergic patients.<sup>3</sup> IMM Oral allergy syndrome (OAS) as a result of primary IMM sensitization to Bet v 1 has been previously reported.



### Biochemical Characteristics

Native Pru p 3 (nPru p 3) protein was purified by conventional methods from *Prunus persica*.

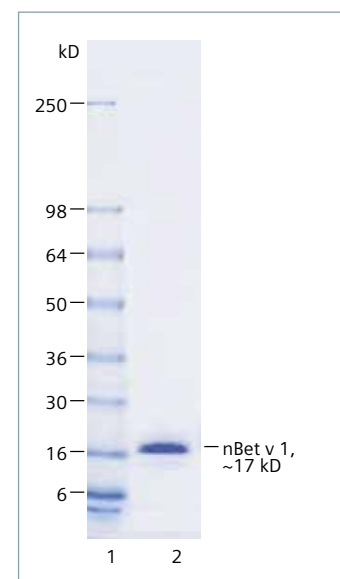
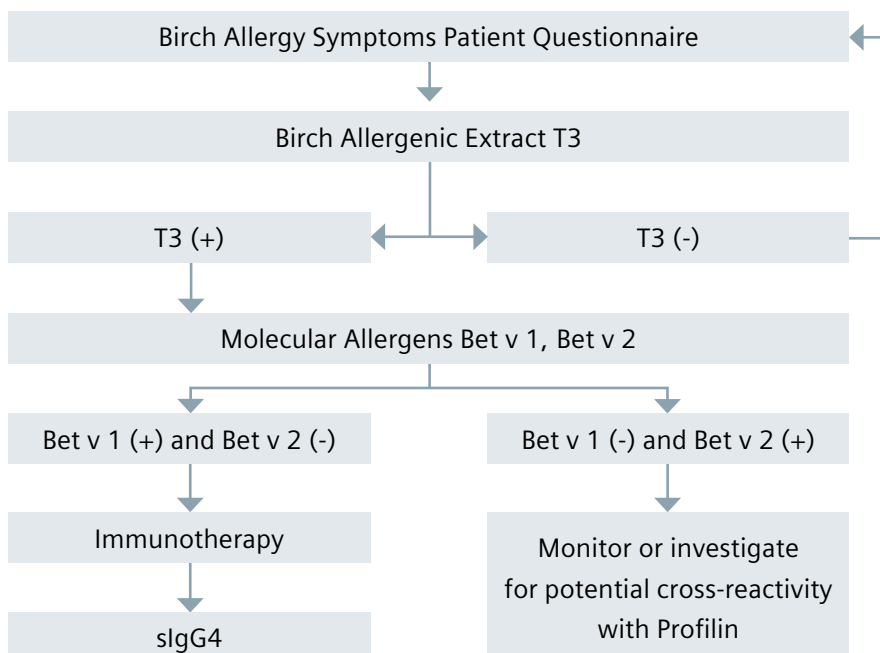


Figure 1. Coomassie Blue stained gel.

### Testing Algorithm<sup>4,6</sup>



### Clinical Performance

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

## Allergen: nBet v 1

IMMULITE 2000			
	Clinical	Normal	Total
Positive ( $\geq 0.10$ kU/L)	37	5	42
Negative	6	95	101
<b>Total</b>	<b>43</b>	<b>100</b>	<b>143</b>

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
86% (76% to 96%)	95% (91% to 99%)	92%

Additional clinical performance of the nBet v 1 specific allergen was demonstrated in comparison to the whole extract allergen T3 (Birch). A total of 143 samples were tested with A89 and T3. The results are presented below.

## Allergen: nBet v 1

IMMULITE 2000				
		T3 (Ref. Method)		
<b>A89 (Test Method)</b>		42	0	Positive
		11	90	Negative
		Positive	Negative	

**N=143**

Overall percent agreement = 92%  
 Positive percent agreement = 79%  
 Negative percent agreement = 100%

## Analytical Performance

**Precision:** The average within-run and total precision using three samples and three lots of nBet v 1 allergen was 3.58% and 4.13%, respectively.

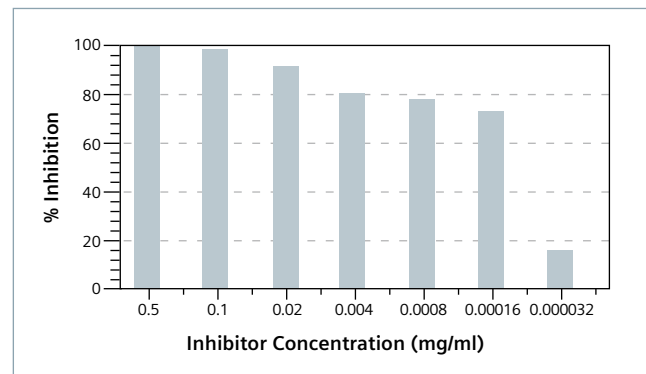
**Linearity:** Two samples were diluted in 2-fold serial dilutions. The undiluted (neat) and the diluted samples were assayed in two replicates and the observed value was reported based on the average of the two replicates. Comparisons of the observed to expected values were used to demonstrate linearity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

**Observed = 0.994 (Expected) + 0.1429**

Slope (95% Confidence Interval) = 0.994 (0.972 to 1.016)

## Identity Testing

Identity of nBet v 1 allergen was verified through competitive inhibition testing using a single serum sample. 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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