

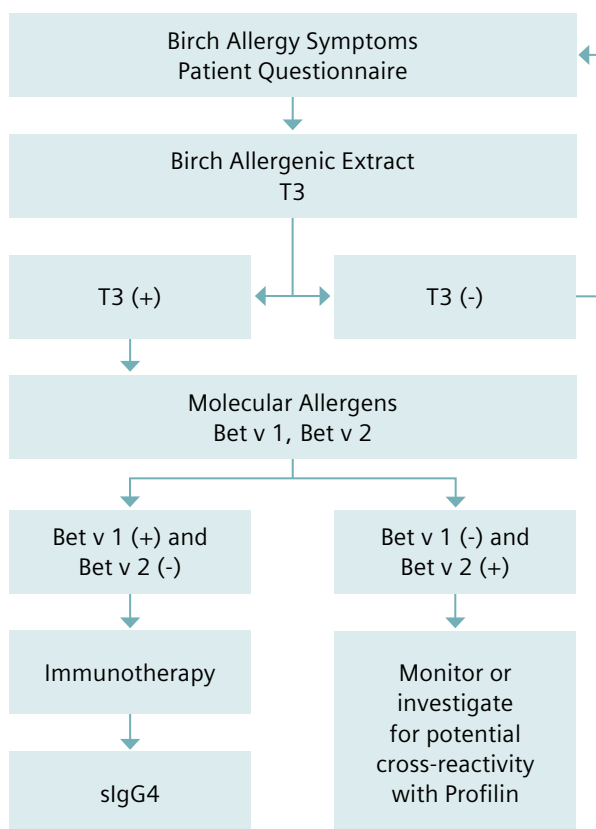
# nBet v 1 Information Sheet

## Background

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



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



## Biochemical Characteristics

Native Bet v 1 (nBet v 1) protein was purified to homogeneity from birch (*Betula verrucosa*) pollen.

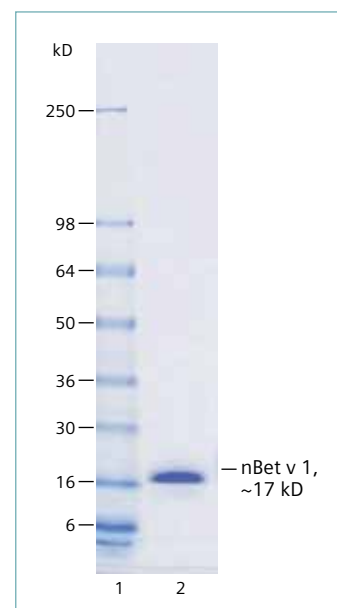


Figure 1. Coomassie Blue stained gel.

## IMMULITE 2000/XPi\* 3gAllergy Specific IgE

Birch Pollen Major Allergen, nBet v 1 (*Betula verrucosa*, Code A89L2)

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## 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 below.

### 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%

\*IMMULITE XPi not available for sale in the U.S.

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## 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.

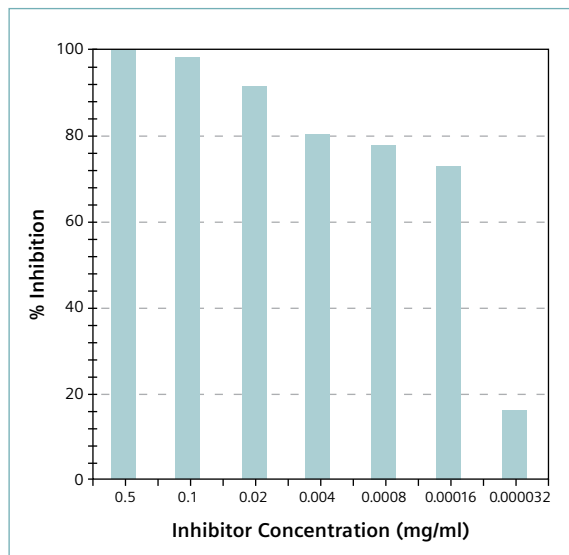
**Linearity:** Two samples were diluted in 2-fold serial dilutions. The undiluted (neat) and the diluted samples were assayed in two replicates and the observed value was reported based on the average of the two replicates. Comparisons of the observed to expected values were used to demonstrate linearity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