

# IMMULITE 2000/XPi 3gAllergy Specific IgE

## Peach Component Allergen, nPru p 3 (*Prunus persica*, A603L2)\*

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### Background

Plant lipid transfer proteins (LTP) are highly conserved proteins of approximately 10 kD.<sup>1</sup> They are found in the seeds, stems, flowers, leaves, and pollen of plants, and are considered panallergens.<sup>1</sup> LTPs are typically associated with more severe and systemic reactions such as urticaria and anaphylaxis.<sup>1,2</sup> Because these proteins are so highly conserved, sensitization to LTP from one plant can result in unexpected allergic responses to other taxonomically unrelated fruits or vegetables.<sup>1-3</sup> Pru p 3 is an LTP isolated from peach skin and pulp,<sup>1</sup> and may be used to evaluate specific IgE reactivity in patients with suspected peach allergy.<sup>1-4</sup> While peach LTP is typically the primary allergic sensitizer, cross-reactivity to LTP of other taxonomically related or unrelated plants may be responsible for peach allergy in some patients.<sup>4</sup>



### Biochemical Characteristics

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

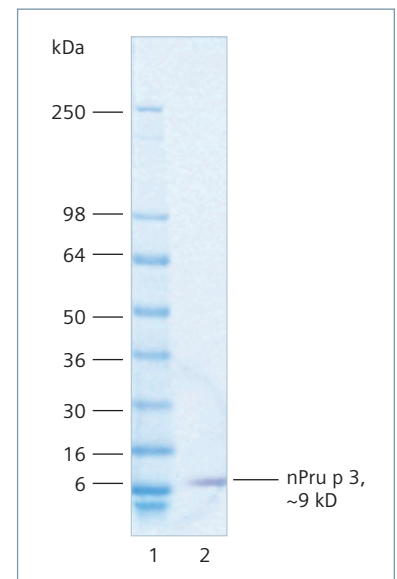
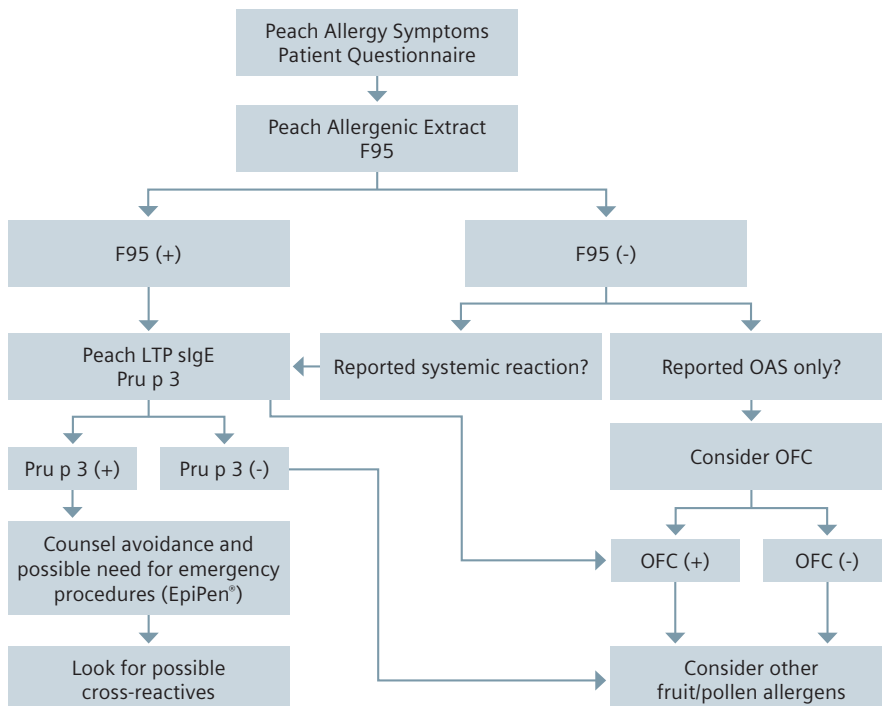


Figure 1. Coomassie Blue stained gel for nPru p 3 (lane 2).

### Testing Algorithm<sup>2-6</sup>



### Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic and apparently healthy individuals against the nPru p 3 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.

\*Not available for sale in the U.S.

## Allergen: nPru p 3

IMMULITE 2000			
	Clinical	Normal	Total
Positive ( $\geq 0.10$ kU/L)	22	0	22
Negative	23	100	123
<b>Total</b>	<b>45</b>	<b>100</b>	<b>145</b>

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
49% (34 to 63%)	100% (100 to 100%)	84%

Additional clinical performance of the nPru p 3 specific allergen was demonstrated in comparison to the whole peach extract allergen (F95); 146 clinical samples were tested with A603 and F95. The results are presented below.

## Allergen: nPru p 3

IMMULITE 2000			
	F95 (Reference Method)		
<b>A603 (Test Method)</b>	23	0	Positive
	24	99	Negative
	Positive	Negative	

**N=146**

Overall percent agreement = 84% (122/146)  
 Positive percent agreement = 49% (23/47)  
 Negative percent agreement = 100% (99/99)

## Analytical Performance

**Precision:** The average within-run and total precision using three samples and two lots of nPru p 3 allergen were 3.36% and 5.93%, 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 <sup>2</sup>
1	$Y = 1.002 + 0.0272$	0.9841 to 1.020	1.000
2	$Y = 1.004 + 0.0169$	0.9696 to 1.0392	0.998

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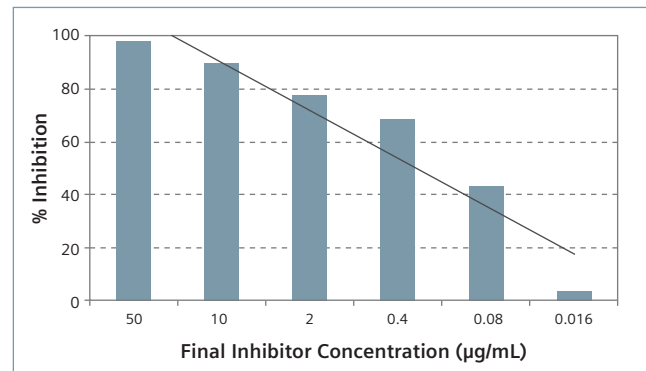
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## Identity Testing

Identity of nPru p 3 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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3. Asero R. Lipid transfer protein cross-reactivity assessed in vivo and in vitro in the office: pros and cons. *J Investig Allergol Clin Immunol.* 2011;21(2):129-36.
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6. Gamboa PM, Sanz ML, Lombardero M, Barber D, Sánchez-Monje R, Goikoetxea MJ, Antépara I, Ferrer M, Salcedo G. Component-resolved in vitro diagnosis in peach-allergic patients. *J Investig Allergol Clin Immunol.* 2009;19(1):13-20.