

IMMULITE 2000/XPi 3gAllergy Specific IgE

Cherry Component Allergen, rPru av 4 (*Prunus avium*, A600L2)*

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Background

Pru av 4, a member of the profilin family of allergens, is an approximately 15 kD protein associated with oral allergy syndrome (OAS) to cherry.^{1,2} It is a homologous protein to Bet v 2, which has been identified as a minor pollen sensitizer in approximately 10–30% of pollen-allergic individuals.²⁻⁴ Pru av 4 shares over 70% amino acid homology and a very similar tertiary structure with other profilins.⁴ It is highly thermolabile and rapidly enzyme degradable, accounting for its inability to elicit systemic reaction, and its loss of allergenicity in cooked foods.³ Primary sensitization to Pru av 4 develops through pollinosis and cross-reactivity to Bet v 2, and is not presumed to arise directly from cherry ingestion without previous sensitization to birch or grass profilin.³



Biochemical Characteristics

Recombinant Pru av 4 (rPru av 4) protein was produced by heterologous expression in *E. coli*.

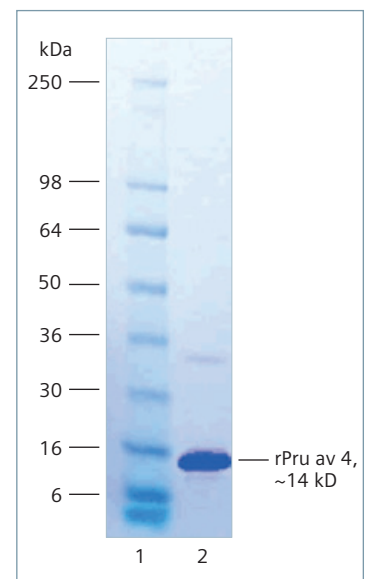
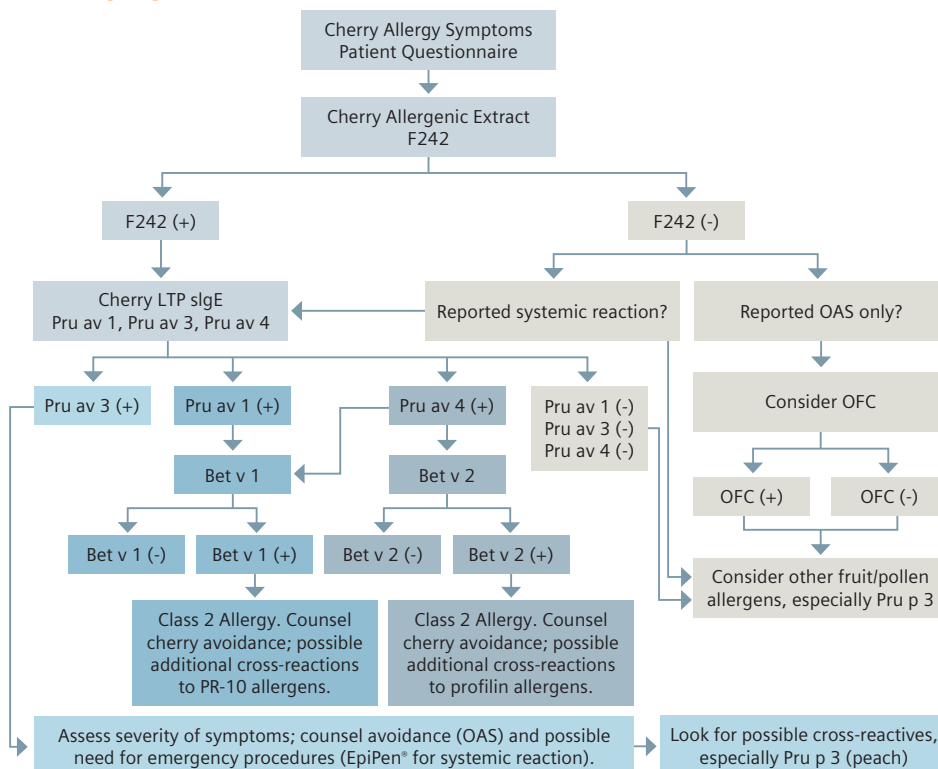


Figure 1. Coomassie Blue stained gel for rPru av 4 (lane 2).

Testing Algorithm^{2,4-6}



Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 4 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: rPru av 4

IMMULITE 2000			
	Clinical	Normal	Total
Positive (≥ 0.10 kU/L)	27	4	31
Negative	29	96	125
Total	56	100	156

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
48% (35 to 61%)	96% (92 to 100%)	79%

Additional clinical performance of the rPru av 4 specific allergen was demonstrated in comparison to the whole cherry extract allergen (F242). The same 156 clinical samples were tested with A600 and F242. The results are presented below.

Allergen: rPru av 4

IMMULITE 2000			
	F242 (Reference Method)		
A600 (Test Method)	26	5	Positive
	26	99	Negative
	Positive	Negative	

N=156

Overall percent agreement = 80% (125/156)
 Positive percent agreement = 50% (26/52)
 Negative percent agreement = 95% (99/104)

Analytical Performance

Precision: The average within-run and total precision using three samples and two lots of rPru av 4 allergen were 3.73% and 6.32%, 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	$Y = 0.9777 - 0.0478$	0.9507 to 1.005	0.999
2	$Y = 1.000 - 0.0079$	0.9895 to 1.012	1.000

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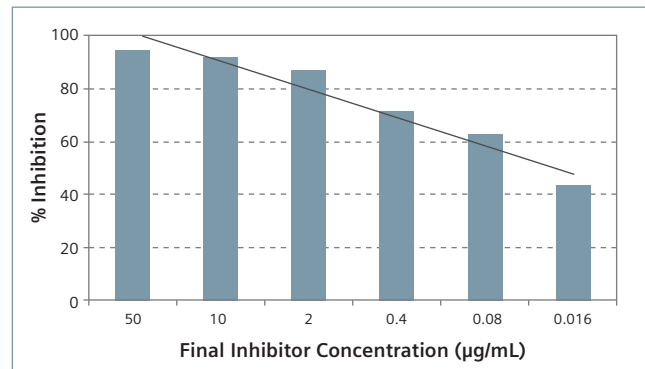
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Identity Testing

Identity of rPru av 4 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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