

IMMULITE 2000/XPi 3gAllergy Specific IgE

Cherry Component Allergen, rPru av 3 (*Prunus avium*, A599L2)*

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Background

Plant lipid transfer proteins (LTP) are highly conserved proteins of approximately 10 kD.¹ They are typically associated with more severe and systemic reactions such as urticaria and anaphylaxis in some populations, but less severe reactions in the form of oral allergy syndrome (OAS) in others.^{2,3} Because these proteins are so highly conserved, sensitization to LTP from one plant can result in allergic responses to other taxonomically related or unrelated fruits and vegetables.¹⁻³ Pru av 3 is an LTP isolated from cherry,^{4,5} and may be used to evaluate specific IgE reactivity in patients with suspected cherry allergy.¹⁻⁵ Monosensitization to Pru av 3 is rare; studies suggest that peach LTP (Pru p 3) is the likely primary allergic sensitizer, triggering allergic response to other Rosaceae via LTP cross-reactivity.^{2,3}



Biochemical Characteristics

Recombinant Pru av 3 (rPru av 3) protein was produced by heterologous expression in insect cells with a recombinant baculovirus.

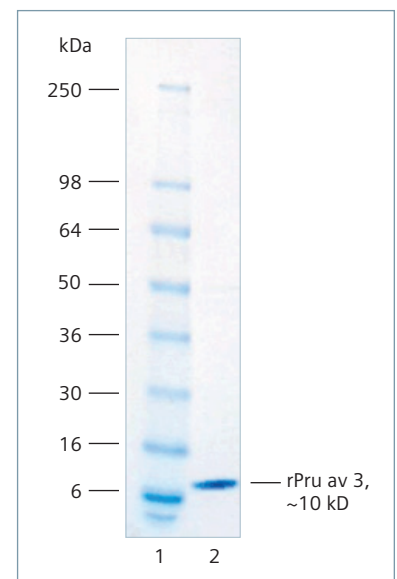
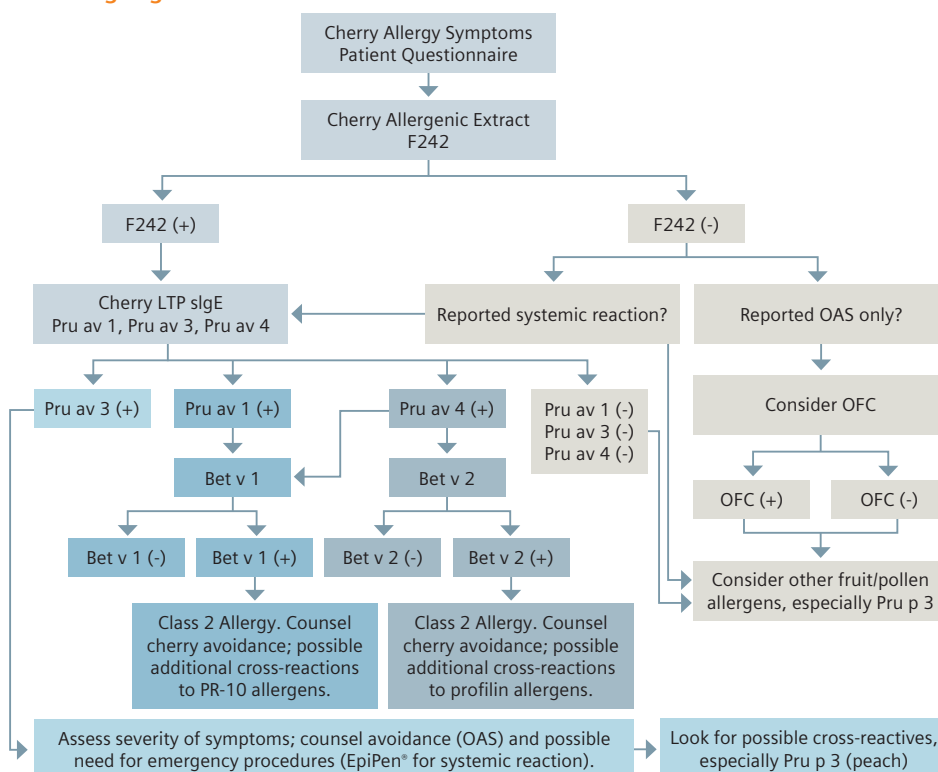


Figure 1. Coomassie Blue stained gel for rPru av 3 (lane 2).

Testing Algorithm¹⁻⁵



Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 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: rPru av 3

IMMULITE 2000			
	Clinical	Normal	Total
Positive (≥ 0.10 kU/L)	21	2	23
Negative	24	98	122
Total	45	100	145

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
47% (32 to 61%)	98% (95 to 101%)	82%

Additional clinical performance of the rPru av 3 specific allergen was demonstrated in comparison to the whole cherry extract allergen (F242). The same 145 clinical samples were tested with A599 and F242. The results are presented below.

Allergen: rPru av 3

IMMULITE 2000			
	F242 (Reference Method)		
A599 (Test Method)	21	2	Positive
	27	95	Negative
	Positive	Negative	

N=145

Overall percent agreement = 80% (116/145)
 Positive percent agreement = 44% (21/48)
 Negative percent agreement = 98% (95/97)

Analytical Performance

Precision: The average within-run and total precision using three samples and two lots of rPru av 3 allergen were 3.52% and 5.78%, 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	$Y = 1.000 + 0.0727$	0.9819 to 1.017	1.000
2	$Y = 0.9936 + 0.0636$	0.9797 to 1.008	1.000

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Global Siemens Headquarters
 Siemens AG
 Wittelsbacherplatz 2
 80333 Muenchen
 Germany

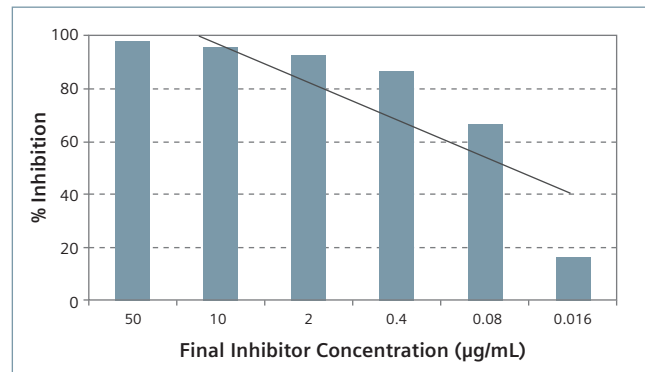
Global Siemens Healthcare Headquarters
 Siemens AG
 Healthcare Sector
 Henkestrasse 127
 91052 Erlangen, Germany
 Phone: +49 9131 84 - 0
www.siemens.com/healthcare

Global Division
 Siemens Healthcare Diagnostics Inc.
 511 Benedict Avenue
 Tarrytown, NY 10591-5005
 USA
www.siemens.com/diagnostics

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Identity Testing

Identity of rPru av 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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