SIEMENS

IMMULITE 2000/XPi 3gAllergy Specific IgE

Cherry Component Allergen, rPru av 1 (*Prunus avium*, A597L2)*

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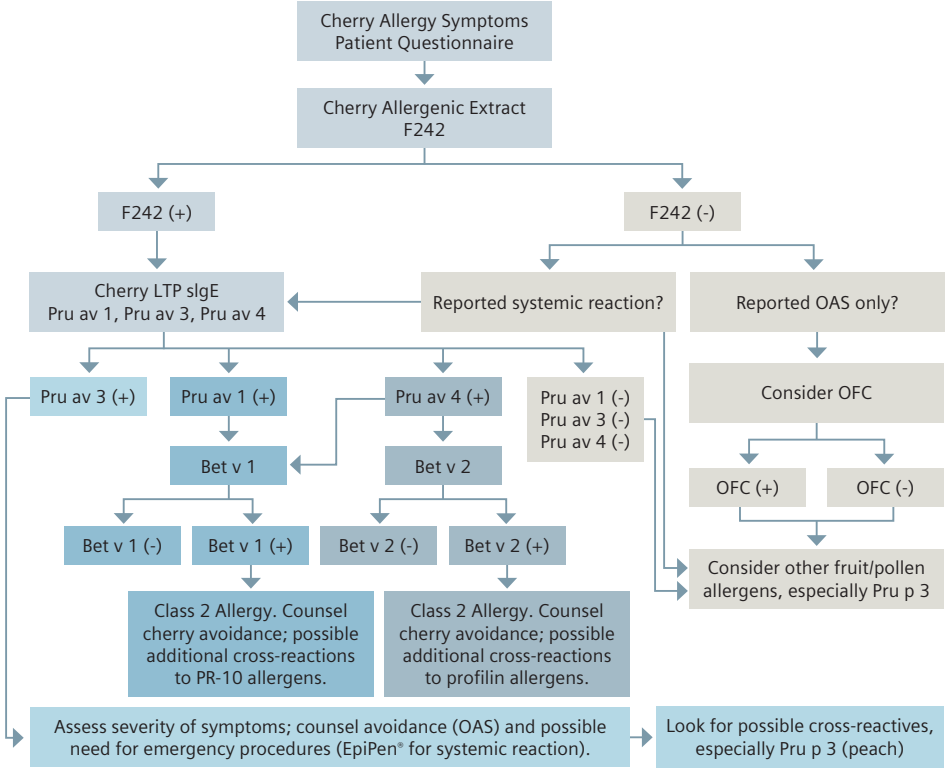
Background

Pru av 1 is a 17.7 kD PR-10 protein associated with oral allergy syndrome (OAS) to cherry.[1,2] It is a homologous protein to Bet v 1, which has been identified as a primary pollen sensitizer eliciting specific IgE antibodies and is considered a major allergen.[1-3] Although Pru av 1 shares only 59–64% sequence homology with Bet v 1, 75% of the tertiary structures of the two proteins are virtually identical and preincubation of cherry-allergic patient sera with Bet v 1 inhibits binding by Pru av 1.[4] Up to 90% percent of cherry-allergic patients manifest a concomitant allergy to birch pollen as primary sensitization arises via pollinosis.[5,6] Pru av 1-allergic individuals typically do not experience systemic reactions as PR-10 proteins are rapidly degraded by heat and gastric digestion.[5,6]

Testing Algorithm[1-6]



Biochemical Characteristics

Recombinant Pru av 1 (rPru av 1) protein was produced by heterologous expression in insect cells with a recombinant baculovirus.

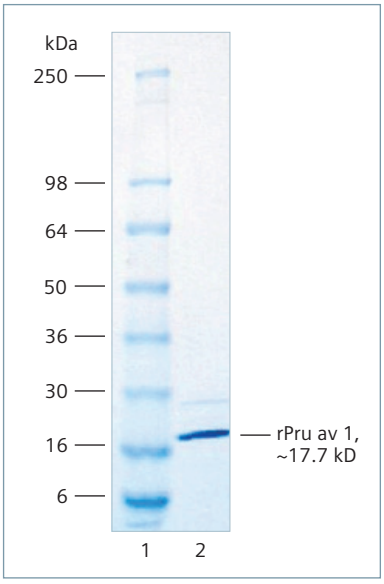


Figure 1. Coomassie Blue stained gel for rPru av 1 (lane 2).

Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 1 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.

Answers for life.

*Not available for sale in the U.S.

Allergen: rPru av 1

IMMULITE 2000			
	Clinical	Normal	**Total**
Positive (≥0.10 kU/L)	49	0	**49**
Negative	11	100	**111**
Total	**60**	**100**	**160**

Sensitivity (95% Confidence Interval)	**Specificity** (95% Confidence Interval)	**Overall Agreement**
82% (72 to 91%)	100% (100 to 100%)	93%

Additional clinical performance of the rPru av 1 specific allergen was demonstrated in comparison to the whole cherry extract allergen (F242); 159 clinical samples were tested with A597 and F242. The results are presented below.

Allergen: rPru av 1

IMMULITE 2000			
	F242 (Reference Method)		
A597 (Test Method)	46	2	Positive
	15	96	Negative
	Positive	Negative	

N=159

Overall percent agreement = 89% (142/159)
Positive percent agreement = 75% (46/61)
Negative percent agreement = 98% (96/98)

Analytical Performance

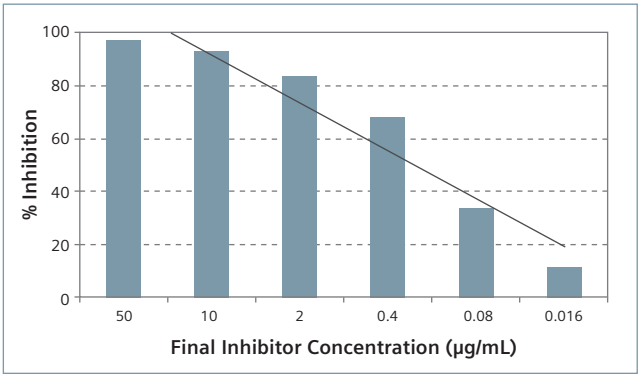
Precision: The average within-run and total precision using three samples and two lots of rPru av 1 allergen were 3.70% and 6.74%, respectively.

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 = 1.034 + 0.0206	0.9943 to 1.073	0.998
2	Y = 1.023 + 0.1099	0.9903 to 1.056	0.998

Identity Testing

Identity of rPru av 1 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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2. Breiteneder H, Radauer C. A classification of plant food allergens. J Allergy Clin Immunol. 2004;113(5):821-30.
3. Scheurer S, Pastorello EA, Wangorsch A, Kästner M, Haustein D, Vieths S. Recombinant allergens Pru av 1 and Pru av 4 and a newly identified lipid transfer protein in the in vitro diagnosis of cherry allergy. J Allergy Clin Immunol. 2001;107(4):724-31.
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6. Ballmer-Weber BK, Scheurer S, Fritsche P, Enrique E, Cistero-Bahima A, Haase T, et al. Component-resolved diagnosis with recombinant allergens in patients with cherry allergy. J Allergy Clin Immunol. 2002;110(1):167-73.

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