

# IMMULITE 2000/XPi 3gAllergy Specific IgE

## Apple Component Allergen, rMal d 1 (*Malus domestica*, A464L2)\*

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### Background

Mal d 1 is a PR-10 protein associated with oral allergy syndrome (OAS) to apple.<sup>1</sup> It is a homologous protein to Bet v 1, which has been identified as a primary pollen sensitizer eliciting specific IgE antibodies.<sup>2</sup> Although Mal d 1 shares only 57% sequence homology with Bet v 1, 75% of the Mal d 1 tertiary structure binds anti-Bet v 1 antibodies.<sup>3</sup> Approximately 50 to 93% of birch pollen-allergic patients develop concomitant OAS reactions to fruits, nuts, and vegetables. Mal d 1-allergic individuals do not experience systemic reactions as PR-10 proteins are susceptible to degradation by heat and gastric digestion.<sup>4,5</sup>



### Biochemical Characteristics

Recombinant Mal d 1 protein (rMal d 1) was produced by heterologous expression in insect cells with a recombinant baculovirus.

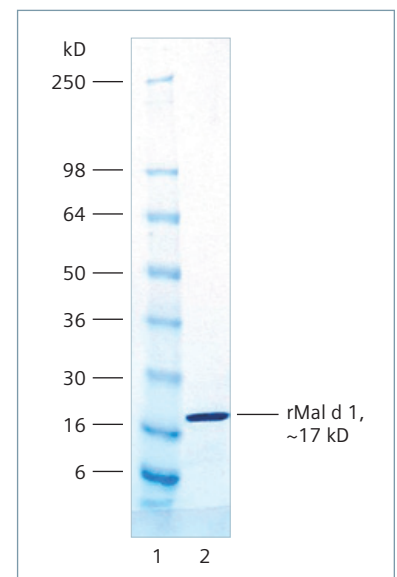
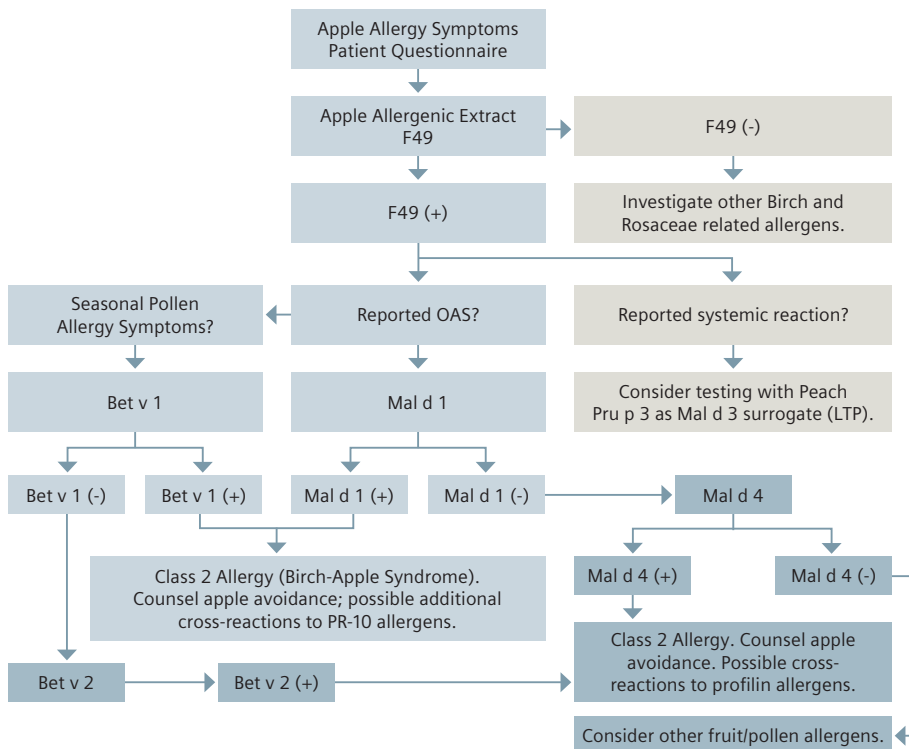


Figure 1. Coomassie Blue stained gel for rMal d 1 (lane 2).

### Testing Algorithm<sup>1,2,4,6</sup>



### Clinical Performance

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

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

## Allergen: rMal d 1

IMMULITE 2000			
	Clinical	Normal	Total
Positive ( $\geq 0.10$ kU/L)	37	0	37
Negative	8	100	108
<b>Total</b>	<b>45</b>	<b>100</b>	<b>145</b>

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
82% (71 to 93%)	100% (100 to 100%)	95%

Additional clinical performance of the rMal d 1 specific allergen was demonstrated in comparison to the whole apple extract allergen (F49). The same 145 clinical samples were tested with A464 and F49. The results are presented below.

## Allergen: rMal d 1

IMMULITE 2000			
	F49 (Reference Method)		
<b>A464 (Test Method)</b>	36	1	Positive
	11	97	Negative
	Positive	Negative	

**N=145**

Overall percent agreement = 92% (133/145)  
 Positive percent agreement = 77% (36/47)  
 Negative percent agreement = 99% (97/98)

## Analytical Performance

**Precision:** The average within-run and total precision using three samples and two lots of rMal d 1 allergen were 4.31% and 6.71%, 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	$Y = 1.005 + 0.1628$	0.9834 to 1.026	0.999
2	$Y = 1.032 - 0.0160$	0.9901 to 1.074	0.998

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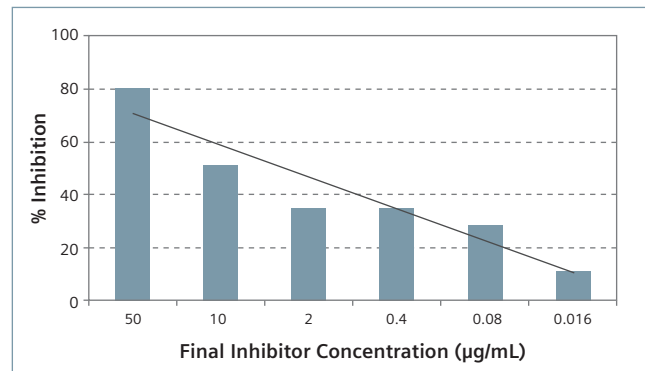
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## Identity Testing

Identity of rMal d 1 was verified through competitive inhibition testing using a single serum sample or pool of sera. 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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