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IMMULITE 2000/XPi 3gAllergy Specific IgE

Honeybee *(Apis mellifera)* venom component: hyaluronidase, rApi m 2 (A46L2)

Allergen Background

Hyaluronidase (Api m 2) is a major glycoprotein allergen in honeybee venom *(Apis mellifera)*. Recombinant Api m 2 (rApi m 2) has similar enzymatic activity, carbohydrate compositions, and IgE binding with the native Api m 2 (nApi m 2).[1]Due to the high degree of cross-reactivity with vespid and bumblebee hyaluronidases, rApi m 2 may be used as a diagnostic tool for a broad spectrum of hypersensitivity reactions to Hymenoptera venoms.[2-5] It is estimated that 15-25% of the general population is sensitized to Hymenoptera venoms, one of the most important among them being venom from honeybee stings. The reactions to honeybee venom may include large local reactions and systemic anaphylactic reactions such as urticaria, angioedema, gastrointestinal symptoms, and severe pulmonary and cardiovascular events that may have a fatal outcome.[4] Systemic anaphylactic reactions are in most cases IgE-mediated.

Biochemical Characteristics

Amino acid sequence of honeybee venom, Api m 2 was cloned and expressed using Sf9 insect cells infected by a recombinant baculovirus.

Clinical Performance

Clinical performance of the rApi m 2-specific allergen was demonstrated in comparison to the native honeybee venom extract (I1). A total of 58 samples were tested with A46 and I1. The results were obtained using the IMMULITE® 2000 3gAllergy™ Specific IgE assay. Overall positive and negative agreements are presented in the table on the right.

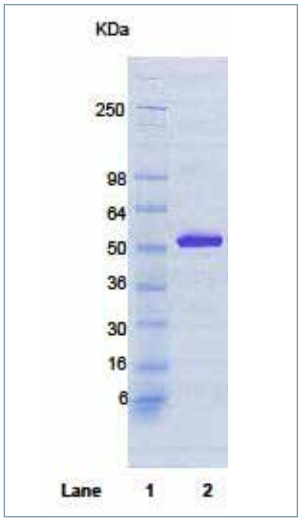

Figure 1.
Coomassie Blue stained gel of rApi m 2, ~52KDa.

Allergen: rApi m 2
IMMULITE 2000
I1 (Reference Method)

A46 (Test Method)	Positive	Negative	
	27	2	Positive
	4	25	Negative
	Positive	Negative	

N=58
Overall percent agreement: 90% (52/58)
Positive percent agreement: 87% (27/31)
Negative percent agreement: 93% (25/27)

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Analytical Performance

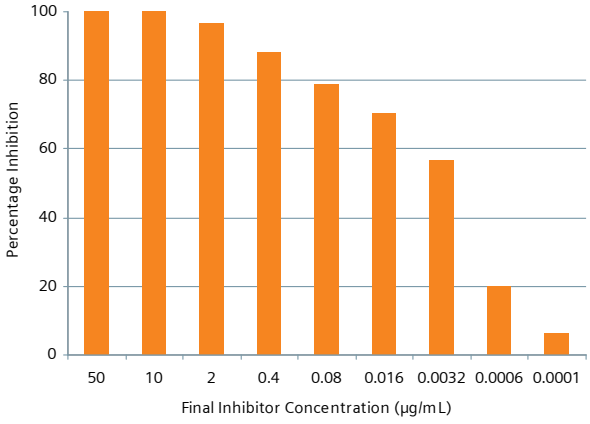
Precision: The average repeatability and within-lab precision using three samples and three lots of rApi m 2 allergen was 4.54% and 5.56%, respectively.

Linearity: Two positive samples were diluted with a low sample in increments of 12.5% and tested using three allergen lots. The undiluted (neat) and the diluted samples were assayed in three replicates, and the observed value was reported based on the average of the three replicates. Comparisons of the observed to the expected values were used to demonstrate linearity at concentrations within the assay limits.

Regression Equation	Slope 95% CI	R^2
y = 1.03x - 0.04	0.98–1.07	0.996

Identity Testing

Identity of rApi m 2 allergen 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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