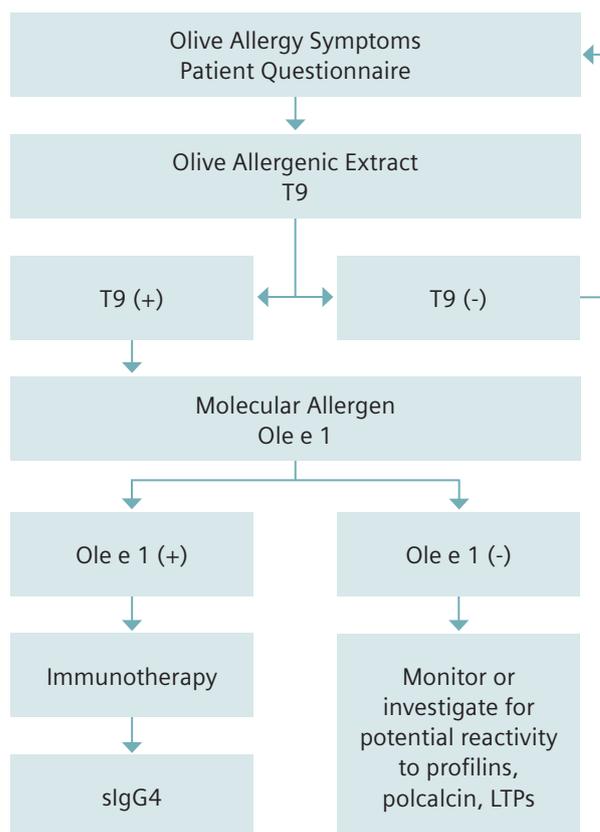


nOle e 1 Information Sheet

Background

Olive tree (*Olea europaea*) pollen is a major cause of type 1 seasonal allergy in the Mediterranean and can also be found in areas with a Mediterranean-type climate, including parts of Australia, South Africa, and North America.^{1,2} Ten olive tree pollen allergens have been identified (Ole e 1, Ole e 2, Ole e 3, Ole e 4, Ole e 5, Ole e 6, Ole e 7, Ole e 8, Ole e 9, Ole e 10).³ Ole e 1 is a major allergenic protein of olive tree pollen that exists in two main forms, glycosylated (~20kD) and non-glycosylated (~18.5kD).⁴ Homologous proteins are found in other members of the Oleaceae family such as Ash (Fra e 1), Privet (Lig v 1), and Lilac (Syr v 1).⁵ More than 80% of patients sensitized to olive pollen have IgE reactivity to the Ole e 1 allergenic molecule and common symptoms of exposure include asthma, rhinitis, and conjunctivitis.⁶⁻⁸

Testing Algorithm^{8,9}



Biochemical Characteristics

Native Ole e 1 (nOle e 1) protein was purified to homogeneity from olive (*Olea europaea*) pollen.

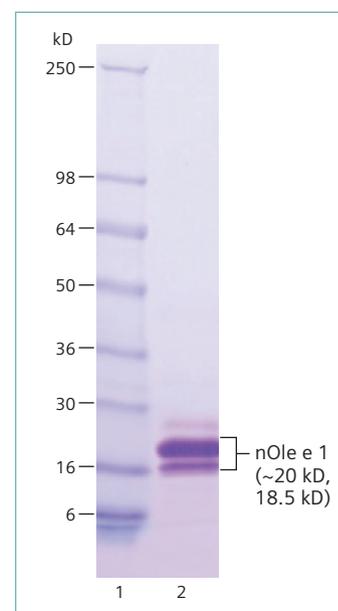


Figure 1. Coomassie Blue stained gel.

IMMULITE 2000/XPi 3gAllergy Specific IgE

Olive Pollen Major Allergen, nOle e 1 (*Olea europaea*, Code A482L2)

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Clinical Performance

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic and apparently healthy individuals against the nOle e 1 specific allergen. The results were obtained using the IMMULITE® 2000 3gAllergy™ Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the cross table below.

Allergen: nOle e 1

IMMULITE 2000			
	Clinical	Normal	Total
Positive (≥ 0.10 kU/L)	37	3	40
Negative	2	97	99
Total	39	100	139

Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	Overall Agreement
95% (88% to 102%)	97% (94% to 100%)	96%

Additional clinical performance of the nOle e 1 specific allergen was demonstrated in comparison to the whole extract allergen T9 (Olive). A total of 139 samples were tested with A482 and T9. The results are presented below.

Allergen: nOle e 1

IMMULITE 2000			
	T9 (Ref. Method)		
A482 (Test Method)	39	3	Positive
	1	96	Negative
	Positive	Negative	

N=139

Overall percent agreement = 97%
Positive percent agreement = 98%
Negative percent agreement = 97%

Analytical Performance

Precision: The average within-run and total precision using three samples and three lots of nOle e 1 allergen was 5.08% and 6.39%, respectively.

Linearity: Two samples were diluted in 2-fold serial dilutions. The undiluted (neat) and the diluted samples were assayed in two replicates and the observed value was reported based on the average of the two replicates. Comparisons of the observed to expected values were used to demonstrate linearity at concentrations within the assay limits.

Observed = 0.997 (Expected) + 0.0993

Slope (95% Confidence Interval) = 0.997 (0.974 to 1.020)

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