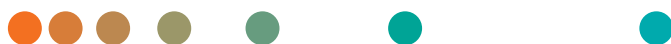


IMMULITE 2000 3gAllergy Specific IgE Assay

Peanut Allergens (*Arachis hypogaea*)

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Background

Peanut allergy is one of the most common and potentially severe food allergies worldwide. Reactions can vary widely, from mild itching to life-threatening anaphylaxis. At the core of these allergic responses are specific peanut proteins, known as allergen components, which are recognized by the immune system. Each component has distinct biochemical and clinical characteristics. Component-resolved diagnostics (CRD) enable the measurement of IgE antibodies against these individual peanut proteins. This more specific allergen testing helps clinicians assess the risk of severe reactions, tailor management plans, and identify candidates for immunotherapy.¹ Alongside skin prick testing and oral food challenges, laboratory-based IgE testing plays a vital role in the accurate diagnosis and personalized care of patients with peanut allergy.



Biochemical Characteristics

Peanut allergens differ in their molecular structure, biological function, and stability. These factors directly influence the severity and persistence of allergic reactions.

Storage proteins (Ara h 1, Ara h 2, Ara h 3, Ara h 6) are highly stable and resistant to heat and enzymatic digestion. Their structural robustness allows them to remain allergenic even after cooking or digestion, and they are closely associated with systemic, potentially severe allergic reactions.

Ara h 8 (PR-10 protein) is structurally related to pollen allergens and is typically heat- and digestion-labile. Sensitization to this protein is often linked to mild, localized symptoms such as itching in the mouth or throat (oral allergy syndrome). The lipid transfer protein Ara h 9 is another stable molecule that resists degradation and is often associated with more severe or systemic reactions.¹⁻⁸

Example of Testing Algorithm According to Published Literature¹

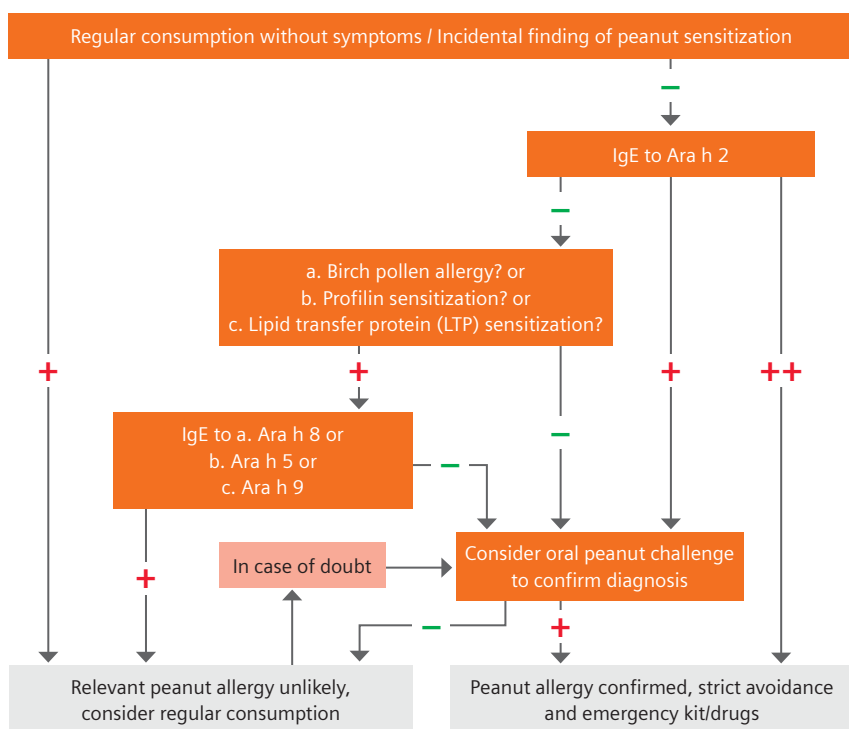


Table 1. Overview of peanut components available on IMMULITE 2000/2000 XPi Systems.²

Component	Protein group	Type
nAra h 1	Storage protein	Native
rAra h 2	Storage protein	Recombinant
nAra h 3	Storage protein	Native
nAra h 6	Storage protein	Native
rAra h 8	PR-10 protein	Recombinant
rAra h 9	Lipid transferprotein	Recombinant

Performance

The peanut components demonstrate analytical reliability, with strong repeatability and consistency within the laboratory setting. Coefficients of variation (%CV) for both repeatability and within-lab precision are typically between 3% and 7% across a wide range of concentrations. This level of precision enables dependable detection of allergen-specific IgE, supporting confident clinical decision-making even at low analyte levels. The robust performance across both native and recombinant components underlines the role of routine diagnostics in enabling confident clinical decision-making in peanut allergy.

Table 2. Repeatability and within-lab performance for each of the six peanut component allergens available on IMMULITE 2000/2000 XPi Systems.*

Allergen	Mean (kU/L)	Repeatability		Within-lab	
		SD	%CV	SD	%CV
nAra h 1	0.707	0.023	3.3	0.035	5.0
	4.62	0.201	4.3	0.242	5.2
	14.4	0.592	4.2	0.757	5.3
rAra h 2	0.510	0.019	3.7	0.035	6.9
	4.28	0.262	6.1	0.302	7.0
	75.9	2.926	3.9	4.094	5.4
nAra h 3	0.439	0.023	5.2	0.029	6.6
	3.95	0.165	4.2	0.252	6.4
	16.2	0.876	5.4	1.005	6.2
nAra h 6	0.402	0.019	4.8	0.022	5.4
	4.00	0.203	5.1	0.249	6.2
	16.5	0.718	4.4	0.882	5.3
rAra h 8	0.390	0.022	5.7	0.024	6.1
	4.10	0.194	4.7	0.222	5.4
	15.2	0.561	3.7	0.690	4.6
rAra h 9	0.756	0.045	6.0	0.049	6.5
	3.82	0.252	6.6	0.341	8.9
	14.3	0.851	6.0	0.963	6.7

The peanut components show strong agreement with a reference method (>90%), demonstrating high clinical reliability. Positive agreement reached 100% for key allergens such as nAra h 1, rAra h 2, nAra h 3, and nAra h 6, confirming sensitivity for detecting allergen-specific IgE. Negative agreement ranged from 90% to 100%, supporting the test's specificity in helping to rule out sensitization. These results highlight the clinical utility in identifying peanut sensitization and supporting accurate, component-level diagnosis in allergy management.

Table 3. Agreement of peanut components available on IMMULITE 2000/2000 XPi Systems with a reference method.*

Allergen	Number of samples (n)	Positive % agreement	Negative % agreement
nAra h 1	150	100	93
rAra h 2	130	100	100
nAra h 3	150	100	90
nAra h 6	150	100	96
rAra h 8	150	96	99
rAra h 9	150	94	93

*Data on file.

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