

## IMMULITE 2000 3gAllergy Specific IgE Assay

# House Dust Mite Component Allergens (*Dermatophagoides pteronyssinus*)

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### Background

House dust mite (HDM) sensitization is a major contributor to allergic diseases such as allergic rhinitis (AR) and allergic asthma (AA) in both children and adults.<sup>1</sup> Among the most clinically significant HDM species are *Dermatophagoides pteronyssinus*, *Dermatophagoides farinae*, and *Blomia tropicalis*. These mites thrive in indoor environments and are a common source of perennial allergen exposure.

Diagnosis of HDM allergy often involves in vitro blood testing using HDM extracts, which effectively identifies sensitization and helps guide allergen-specific immunotherapy. However, advances in molecular diagnostics have enhanced the precision of allergy profiling. For instance, Der p 1 and Der p 2, two major allergens from *D. pteronyssinus*, are detected in over 80% of sensitized individuals and offer a predictive value exceeding 95%.<sup>2-4</sup>

Der p 10, a tropomyosin, is a pan-allergen responsible for cross-reactivity not only among mites but also with cockroaches, shellfish, and helminths, which can complicate diagnosis and management.<sup>5</sup>

Der p 23 is associated with an increased risk of developing allergic asthma.<sup>5</sup>



### Biochemical Characteristics

Der p 1, Der p 2, and Der p 23 are commonly recognized allergens in house dust mite-sensitized individuals and are relevant in the context of allergic airway diseases. Der p 10 may contribute to cross-reactivity with other invertebrate allergens derived from, e.g. shellfish or cockroach, and can be considered in broader sensitization profiles.<sup>5</sup>

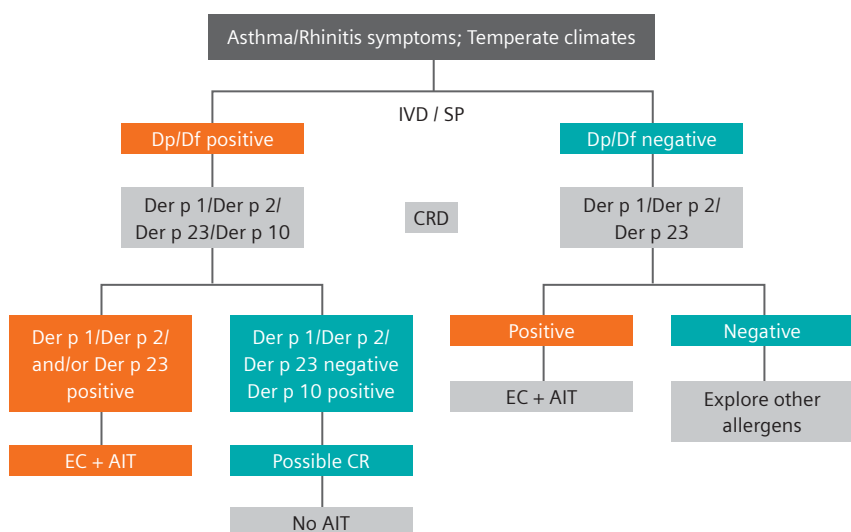
nDer p 1 and nDer p 2 allergens, available on the IMMULITE 2000 and IMMULITE 2000 XPi Systems, are native proteins, whereas rDer p 10\* and rDer p 23\* are provided as recombinant proteins.

**Table 1.** Biochemical Characteristics of nDer p 1, nDer p 2, rDer p 10, and rDer p 23 as used on the IMMULITE 2000/2000 XPi Systems.<sup>6-9</sup>

Allergen	Type	Allergen Family
nDer p 1	Native	Cysteine protease
nDer p 2	Native	Lipid-binding (MD-2-like)
rDer p 10	Recombinant	Tropomyosin
rDer p 23	Recombinant	Peritrophin-like protein

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

### Example Testing Algorithm According to Published Literature<sup>5</sup>



AIT: Allergen Immunotherapy. CR: Cross-reactivity. CRD: Component Resolved Diagnosis.

Df: Dermatophagoides farinae extract. Dp: Dermatophagoides pteronyssinus extract. EC: Environmental Control.

IVD: In Vitro Diagnostics. SP: Skin Prick.

## Performance

**Table 2.** Concordance between one exemplary lot of nDer p 1, nDer p 2, rDer p 10, and rDer p 23 on the IMMULITE 2000/2000 XPI Systems and either a clinical diagnosis using 0.1 kU/L as the cutoff (nDer p 1 and nDer p 2) or a reference method (rDer p 10 and rDer p 23).<sup>10,\*</sup>

IMMULITE 2000/XPI 3gAllergy Assay		Clinical Diagnosis		
		Atopic	Non-atopic	Total
nDer p 1	Positive	49	3	52
	Negative	7	109	116
	<b>Total</b>	<b>56</b>	<b>112</b>	<b>168</b>
nDer p 2	Positive	51	2	53
	Negative	5	110	115
	<b>Total</b>	<b>56</b>	<b>112</b>	<b>168</b>
		Reference Method		
		Positive	Negative	Total
rDer p 10	Positive	50	0	50
	Negative	0	100	100
	<b>Total</b>	<b>50</b>	<b>100</b>	<b>150</b>
rDer p 23	Positive	50	6	56
	Negative	0	94	94
	<b>Total</b>	<b>50</b>	<b>100</b>	<b>150</b>

Clinical validation of the allergens nDer p 1, nDer p 2, rDer p 10, and rDer p 23 demonstrated good concordance with a clinical diagnosis or reference method using 0.1 kU/L as the cutoff (Table 2).

Sensitivity and specificity were calculated based on comparison to a clinical diagnosis or a reference method using characterized samples and a single, exemplary lot. The allergens showed good sensitivity and specificity (>85%) (Table 3). Sensitivity ranged from 88–100%, confirming sensitivity for detecting allergen-specific IgE. Specificity ranged from 94–100%, supporting the test's capability in helping to rule out sensitization.

These results confirm the assay's reliability and clinical utility in accurately identifying allergic sensitization, and support accurate, component-level diagnosis in allergy management.

**Table 3.** Sensitivity and Specificity of nDer p 1, nDer p 2, rDer p 10, and rDer p 23 based on a single, exemplary lot and comparison to either clinical diagnosis (nDer p 1 and nDer p 2) or a reference method (rDer p 10 and rDer p 23).\*

	Sensitivity	Specificity
nDer p 1	88%	97%
nDer p 2	91%	98%
rDer p 10	100%	100%
rDer p 23	100%	94%

\*Data on file.

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## References:

- Vallance G, et al. House dust mite control measures in the treatment of asthma. *Ther Clin Risk Manag.* 2006;2(4):347-54.
- Wong C, et al. House dust mite Der p 1 elevates the release of inflammatory cytokines and expression of adhesion molecules in co-culture of human eosinophils and bronchial epithelial cells. *Int Immunol.* 2006;8(8):1327-35.
- Brown A, et al. House dust mite Der p 1 down regulates defenses of the lung by inactivating elastase inhibitors. *Am J Respir Cell Mol Biol.* 2003;29:381-389.
- Trombone A, et al. Use of a chimeric ELISA to investigate immunoglobulin E antibody responses to Der p 1 and Der p 2 in mite-allergic patients with asthma, wheezing and/or rhinitis. *Clin Exp Allergy.* 2002 Sep;32(9):1323-8.
- Dramburg S, Hilger C, Santos AF, de las Vecillas L, Aalberse RC, Acevedo N, Aglas L, Altmann F, Arruda KL, Asero R, Ballmer-Weber B, Barber D, Beyer K, Biedermann T, Bilo MB, Blank S, Bosshard PP, Breiteneder H, Brough HA, Hoffmann-Sommergruber K. (2023). *Molecular Allergy User's Guide 2.0. Pediatric Allergy and Immunology*, 34(S28). <https://doi.org/10.1111/pai.13854>
- Der p 1. WHO/IUIS. 2025. [Accessed 7-22-2025]. Available from: <http://www.allergen.org/viewallergen.php?aid=289>
- Der p 2. WHO/IUIS. 2025. [Accessed 7-22-2025]. Available from: <http://www.allergen.org/viewallergen.php?aid=293>
- Der p 10. WHO/IUIS. 2025. [Accessed 7-22-2025]. Available from: <https://www.allergen.org/viewallergen.php?aid=290>
- Der p 23. WHO/IUIS. 2025. [Accessed 7-22-2025]. Available from: <https://www.allergen.org/viewallergen.php?aid=296>
- 510(k) Substantial Equivalence Determination Decision Summary Assay Only Template. [Accessed 7-22-2025]. Available from: [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/K093987.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/K093987.pdf)

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