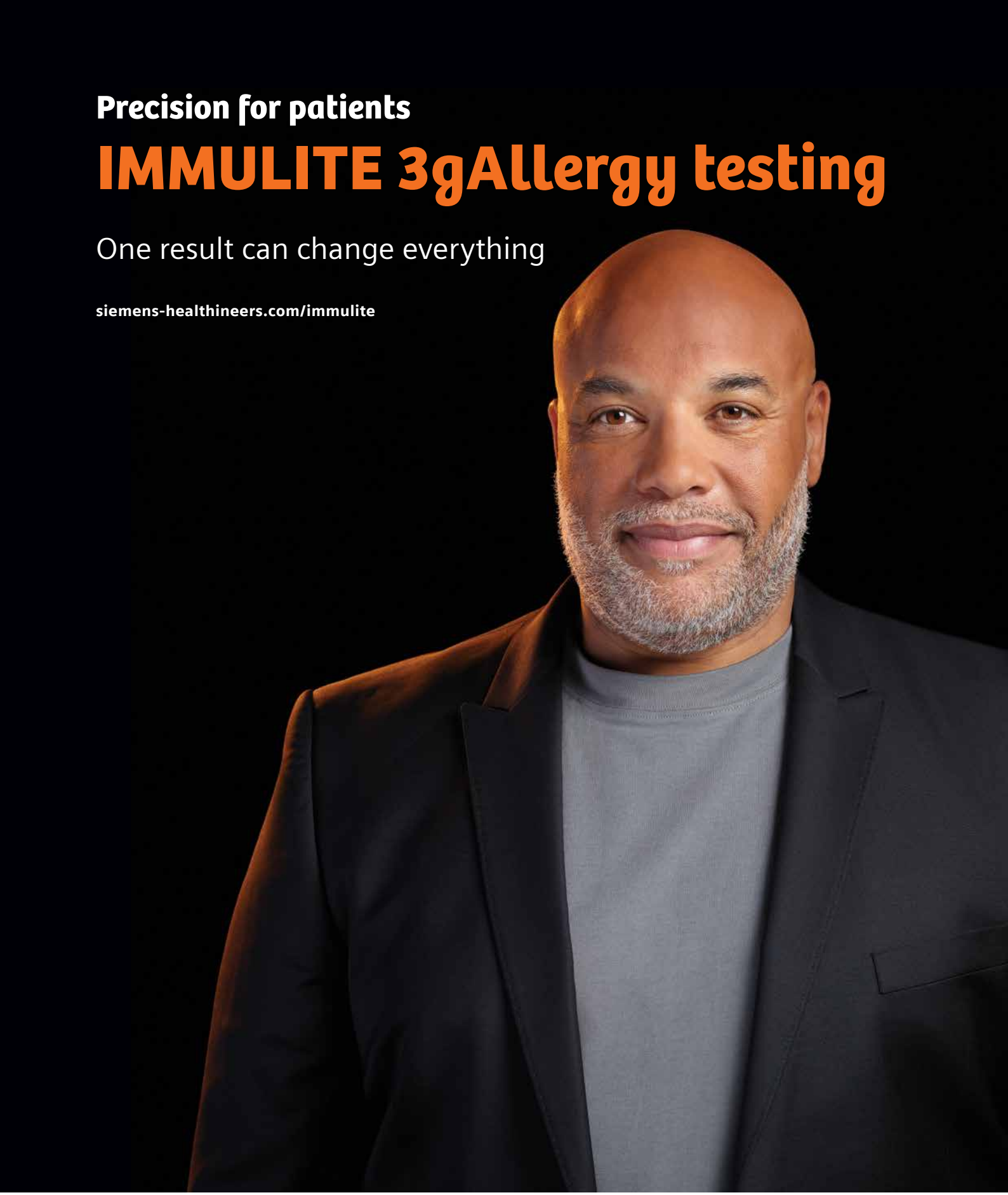
Precision for patients

IMMULITE 3gAllergy testing

One result can change everything

siemens-healthineers.com/immulite



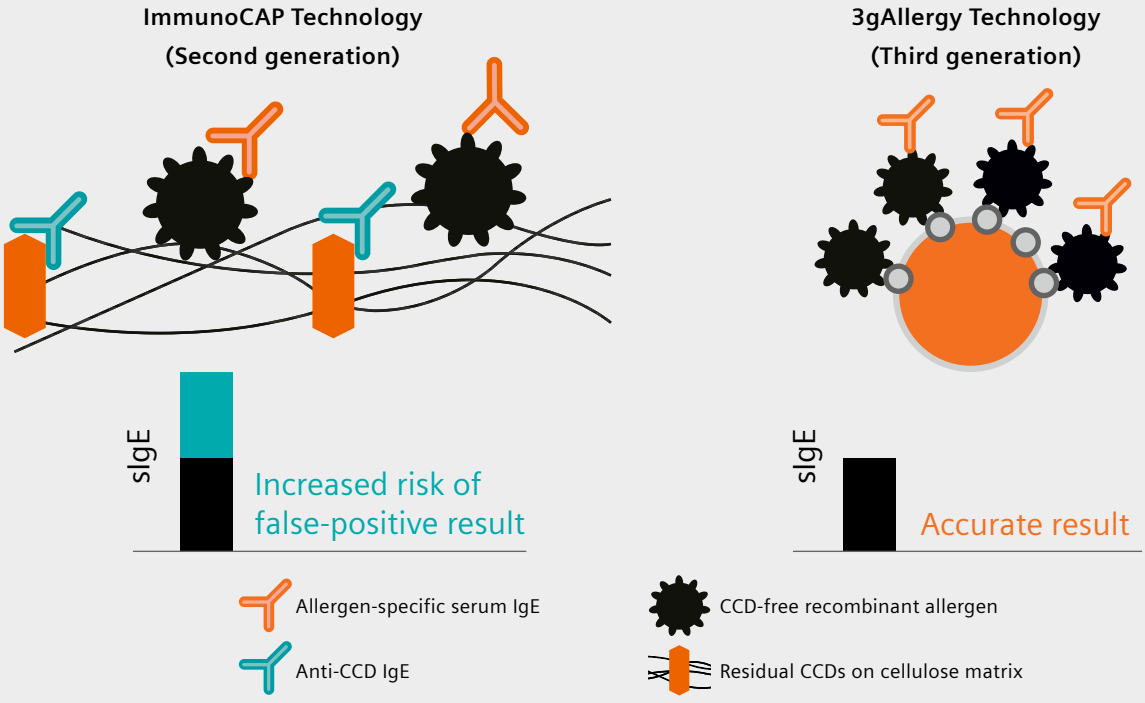
SIEMENS Healthineers

Accuracy is the new standard

IMMULITE 3gAllergy testing offers you more confidence in diagnosing high-risk allergies.

In up to 31% of allergy patients,*[1,2] cross-reactive carbohydrate determinants (CCDs) or high levels of total IgE can lead to false-positive specific IgE results.[3-7]

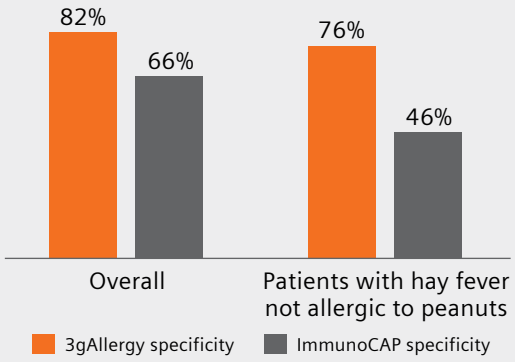
- Second-generation specific IgE assays – such as ImmunoCAP, which use cellulose-based solid phase technology – can exhibit interference due to CCDs. This may lead to false-positive specific IgE signals, even when CCD-free recombinant allergens are included.[3]
- Third-generation technologies, such as 3gAllergy technology, utilize bead-based solid-phase technology that may reduce CCD interference.[7,8]



IMMULITE 3gAllergy liquid allergen technology reduces interference from CCDs.

Greater specificity in peanut allergy

50% fewer false positives* in patients with suspected peanut allergy compared to ImmunoCAP testing*,[7]



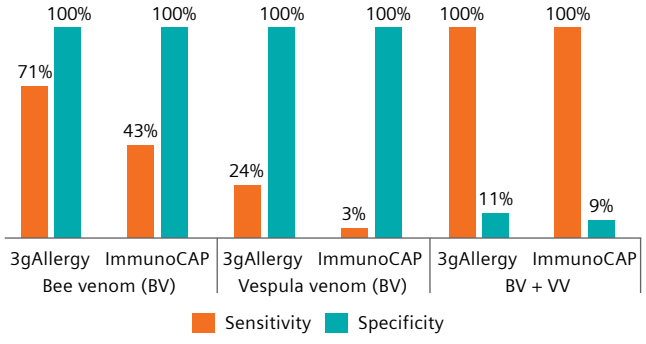
Adapted from Guillioux, 2009.[7]

Sensitivity of 3gAllergy and ImmunoCAP was 100%.[7]

Greater accuracy in venom allergy

3gAllergy testing showed ~23% fewer false-positive results than ImmunoCAP whole-extract testing in CCD-positive individuals with suspected venom allergy.†,[8]

3gAllergy component allergens show higher sensitivity than ImmunoCAP component allergens across venom-allergic populations (rApi m1 88% vs. 71% and rVes v5 93% vs. 82%), while maintaining high specificity.‡,[9]



Adapted from Neis, 2012.[8]

**A study of 125 patients grouped by peanut allergy and pollen sensitization: Ia (peanut allergy, no pollen), Ib (peanut allergy, grass pollen), IIa (no peanut allergy, no pollen), and IIb (hay fever with grass pollen sensitization, peanut tolerant). Peanut allergy was confirmed by history, SPT, and food challenge. Discordant lab values were tested for presence of anti-CCD IgE.[7]*

†Retrospective analysis of 39 CCD-positive Hymenoptera-allergic patients: true diagnoses were: 7 bee, 29 wasp, 3 double. ImmunoCAP whole-extract testing yielded 35 false double-positives; IMMULITE 3gAllergy yielded 27. Recombinant component testing improved accuracy but missed 9 cases.[8]

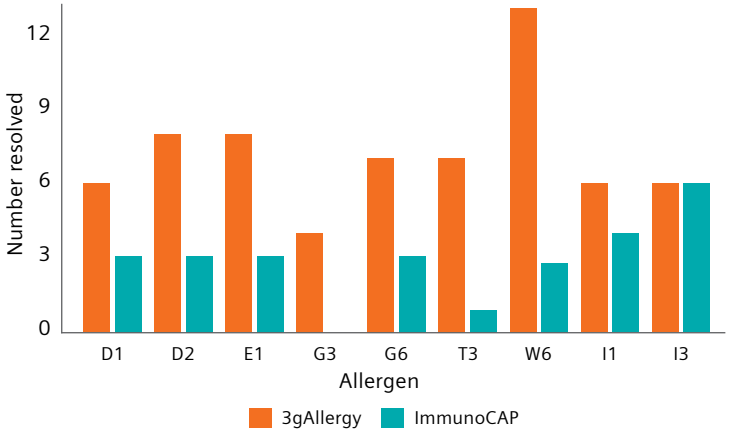
‡Cross-sectional comparison in general venom-allergic cohorts: bee (n=95), wasp (n=110), controls (n=49). Head-to-head recombinant components ImmunoCAP rApi m1 (i208) vs IMMULITE rApi m1 (a45) and ImmunoCAP rVes v5 (i209) vs. IMMULITE rVes v5 (a670). Sensitivity rApi m1 71% vs. 88% and rVes v5 82% vs. 93%; specificity 94 to 98% for both systems.[11]

Reliability is the new standard

Clinically-reliable results align with skin prick testing and are resilient at high total IgE – supporting more confident decisions.

Alignment with skin prick testing (SPT)

3gAllergy tests demonstrate greater reliability than ImmunoCAP tests, aligning with clinical SPT in 72% of discordant cases across nine allergens.[10,*]



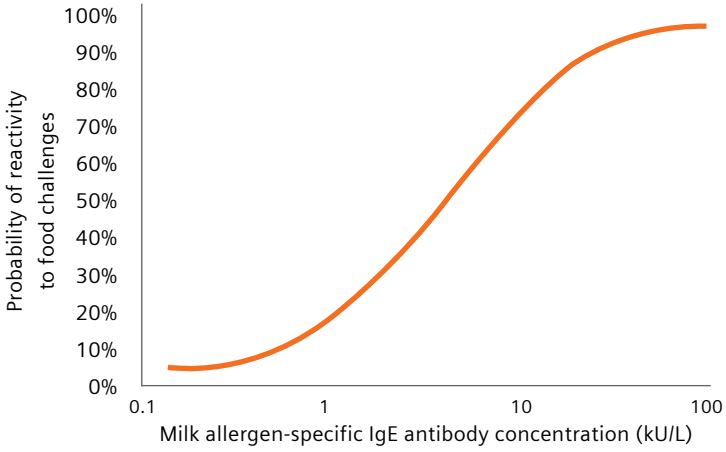
Adapted from Ollert et al, 2005.[10]

Reliable at high total IgE

Studies suggest IMMULITE 3gAllergy tests are less likely to produce false-positive results than ImmunoCAP tests, even when total IgE >1,000 IU/mL – supporting more confident clinical decisions.[7,10,11]

Predictive of oral food challenges (OFC)

The higher the IgE value, the higher the probability of reactivity to an oral food challenge. At higher specific IgE values, 3gAllergy tests have been shown to be predictive of oral food challenge (OFC) outcomes for milk, wheat, and egg.[12,13]

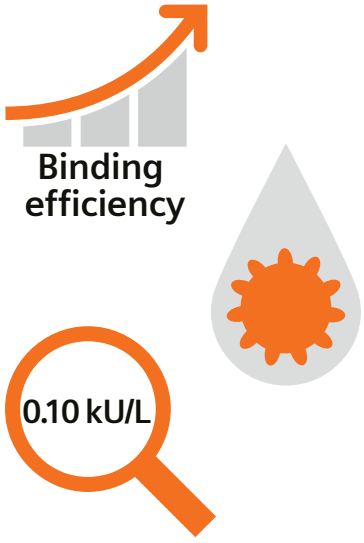


Adapted from Al Hawi et al, 2021.[13]

**Prospective cross-sectional comparison in suspected allergy patients using SPT as the clinical reference. Allergens tested were D1 Dermatophagoides pteronyssinus, D2 Dermatophagoides farinae, E1 cat, G3 orchard grass, G6 timothy grass, T3 birch, W6 mugwort, I1 honey bee venom, and I3 yellow jacket venom. An interassay comparison of ImmunoCAP vs. IMMULITE 3gAllergy across 766 paired results showed 88% overall agreement. Among 90 discordant results, 72% aligned with SPT for IMMULITE 3gAllergy vs. 28% for ImmunoCAP. ROC AUC and maximum achievable sensitivity were at least as high for IMMULITE 3gAllergy across all nine allergens, with the largest advantages observed for yellow jacket venom and a clear advantage for honey bee venom.[10]*

Accurate at low levels of IgE

- Supports superior antigen–antibody interactions due to a reduction of epitope blocking with liquid-phase assay technology.[9,10,12]
- Improves binding efficiency through optimized kinetics across a broad allergen assay menu.[9,10,12]
- Detects low-level sensitization with a working range starting at 0.10 kU/L.



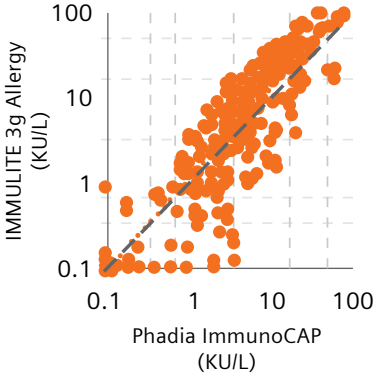
Proven results

- IMMULITE technology is used in >6000 publications with diagnostic focus.*
- 3gAllergy technology is backed by >200 publications and referenced in guidelines.‡,14,15

Strong analytical correlation with second-generation testing

Third-generation 3gAllergy technology has consistent linearity and high agreement for major allergens vs. second-generation assays (ImmunoCAP).[12,13,16]

Correlation of third-generation IMMULITE 3gAllergy technology with second-generation ImmunoCAP technology†,‡



Embase search for „('immulite'/exp OR immulite) AND 'diagnosis'/lnk AND 'article'/it"
†Based on 440 observations across 15 allergens. UK IMMQAS Specific IgE scheme; distributions 161 to 251 (March 2016 – March 2025)
‡Data on file at Siemens Healthineers

IMMULITE 2000 XPi System is the new standard in patient-centric precision care.

IMMULITE 2000 XPi System supports accurate, reliable, and versatile testing for precise patient care.



Reliable results minimize false positives and CCD interference.

Liquid-phase technology offers superior specificity in high-risk patients.*

Comprehensive menu of 500+† allergens, molecular components, and immune markers.

**Patients suspected of peanut or hymenoptera venom allergy*
†~300 allergens in the U.S.

A comprehensive menu – including allergy, autoimmunity, and inflammation – for the modern immunology laboratory.

Comprehensive and versatile testing menu

- 500+* allergens: extracts, components, and mixes for precise sensitization profiling
- 40+ clinically relevant components for advanced molecular diagnostics
- Enables differentiation of true sensitization vs. cross-reactivity and supports individual risk assessment

Broad immune insights

- Assays for total IgE, allergen-specific IgE, ECP†, allergen-specific IgG†, and IgG4†
- Critical for helping manage allergy, asthma, allergic bronchopulmonary aspergillosis, and chronic pulmonary aspergillosis, where sIgE and sIgG profiles may contribute to therapy decisions

Supports testing in inflammation and immune-mediated disorders

- Biomarkers: IL-1β‡, sIL-2R‡, IL-6‡, IL-8‡, IL-10‡, TNF-α‡
- May support assessment of pathophysiology in:
  - Sarcoidosis[17]
  - Hemophagocytic Lymphohistiocytosis[18]
  - Invasive Pulmonary Aspergillosis[19]
  - Rheumatoid Arthritis[20-21]
  - Inflammatory Bowel Disease[22]

Scan to review the full assay menu.

Actionable insights for allergy and beyond.

**~300 allergens in the U.S.*
†Not for sale in the U.S.
‡Research Use Only in U.S.
Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

In allergy, one result can change everything.

Patient-centric care starts with accuracy and has a profound impact on more than just treatment decisions

The impact of allergy testing results – both positive and negative – can be life changing to a patient, making precise results paramount. And while we understand the potential complications of a false-negative result, we shouldn't underestimate the impact of a false-positive result, which may contribute to:

- Unnecessary dietary restrictions
- Costly and time-consuming oral food challenges
- Unnecessary immunotherapy or environmental remediation
- Limitations to life experiences

All trademarks are the property of their respective owners. Product availability may vary from country to country and is subject to varying regulatory equirements. Please contact your local representative for availability.

References:

1. Altmann F. Coping with cross-reactive carbohydrate determinants in allergy diagnosis. Allergo J Int [Internet]. 2016;25(4):98–105. Available from: http://dx.doi.org/10.1007/s40629-016-0115-3.
2. Nemet S, Elbirt D, Cohen R, Mahlab-Guri K, Bezalel-Rosenberg S, Asher I, et al. Clinical significance of very high IgE levels (≥1000 IU/mL): Population-based study of 118,211 adults. J Allergy Clin Immunol Glob [Internet]. 2025;4(2):100403. Available from: http://dx.doi.org/10.1016/j.jacig.2025.100403.
3. Hemmer W, Altmann F, Holzweber F, Gruber C, Wantke F, Wöhrl S. ImmunoCAP cellulose displays cross-reactive carbohydrate determinant (CCD) epitopes and can cause false-positive test results in patients with high anti-CCD IgE antibody levels. J Allergy Clin Immunol [Internet]. 2018;141(1):372-381.e3. Available from: http://dx.doi.org/10.1016/j.jaci.2017.04.028.
4. Sinson E, Ocampo C, Liao C, Nguyen S, Dinh L, Rodems K, et al. Cross-reactive carbohydrate determinant interference in cellulose-based IgE allergy tests utilizing recombinant allergen components. PLoS One [Internet]. 2020;15(4):e0231344. Available from: http://dx.doi.org/10.1371/journal.pone.0231344.
5. ImmunoCAP™ Specific IgE Directions for Use 52-5291-EN/11.
6. ImmunoCAP™ Specific IgE Conjugate 100 and 400 Directions for Use 52-5256-US/31.
7. Guilloux L, Morisset M, Codreanu F, Parisot L, Moneret-Vautrin DA. Peanut allergy diagnosis in the context of grass pollen sensitization for 125 patients: roles of peanut and cross-reactive carbohydrate determinants specific IgE. Int Arch Allergy Immunol [Internet]. 2009;149(2):91–7. Available from: http://dx.doi. org/10.1159/000189190.
8. Neis MM, Merk HF. Value of component based diagnostics in IgE-mediated hymenoptera sting reactions. Cutan Ocul Toxicol [Internet]. 2012;31(2):117–23. Available from: http://dx.doi.org/10.3109/15569527.2011.621080.
9. Šelb J, Kogovšek R, Šilar M, Košnik M, Korošec P. Improved recombinant Api m 1- and Ves v 5-based IgE testing to dissect bee and yellow jacket allergy and their correlation with the severity of the sting reaction. Clin Exp Allergy [Internet]. 2016;46(4):621–30. Available from: http://dx.doi.org/10.1111/cea.12639
10. Ollert M, Weissenbacher S, Rakoski J, Ring J. Allergen-specific IgE measured by a continuous random-access immunoanalyzer: interassay comparison and agreement with skin testing. Clin Chem [Internet]. 2005;51(7):1241–9. Available from: http://dx.doi.org/10.1373/clinchem.2004.046565.
11. Li TM, Chuang T, Tse S, Hovanec-Burns D, El Shami AS. Development and validation of a third generation allergen-specific IgE assay on the continuous random access IMMULITE 2000 analyzer. Ann Clin Lab Sci. 2004 Winter;34(1):67–74.
12. Furuya K, Nagao M, Sato Y, Ito S, Fujisawa T, IPAD3g investigators. Predictive values of egg-specific IgE by two commonly used assay systems for the diagnosis of egg allergy in young children: a prospective multicenter study. Allergy [Internet]. 2016;71(10):1435–43. Available from: http://dx.doi.org/10.1111/all.12912.
13. Al Hawi Y, Nagao M, Furuya K, Sato Y, Ito S, Hori H, et al. Agreement between predictive, allergen-specific IgE values assessed by ImmunoCAP and IMMULITE 2000 3gAllergy™ assay systems for milk and wheat allergies. Allergy Asthma Immunol Res [Internet]. 2021;13(1):141–53. Available from: http://dx.doi.org/10.4168/aair.2021.13.1.14.
14. Santos AF, Riggioni C, Agache I, Akdis CA, Akdis M, Alvarez-Perea A, et al. EAACI guidelines on the diagnosis of IgE-mediated food allergy. Allergy [Internet]. 2023;78(12):3057–76. Available from: http://dx.doi.org/10.1111/all.15902.
15. Bernstein IL, Li JT, Bernstein DI, Hamilton R, Spector SL, Tan R, et al. Allergy diagnostic testing: an updated practice parameter. Ann Allergy Asthma Immunol [Internet]. 2008;100(3 Suppl 3):S1-148. Available from: http://dx.doi.org/10.1016/s1081-1206(10)60305-5.
16. Hamilton RG, Mudd K, White MA, Wood RA. Extension of food allergen specific IgE ranges from the ImmunoCAP to the IMMULITE systems. Ann Allergy Asthma Immunol [Internet]. 2011;107(2):139–44. Available from: http://dx.doi.org/10.1016/j.anai.2011.04.012.
17. Gupta S, Miloni Parmar, Padappayil RP, Bansal A, Daouk S. Role of serum Soluble Interleukin-2 receptor level in the diagnosis of sarcoidosis: A systematic review and meta-analysis. Sarcoidosis Vasc Diffuse Lung Dis [Internet]. 2023;40(1):e2023005. Available from: http://dx.doi.org/10.36141/svdld.v40i1.13499.
18. Henter J-I, Horne A, Aricó M, Egeler RM, Filipovich AH, Imashuku S, et al. HLH-2004: Diagnostic and therapeutic guidelines for hemophagocytic lymphohistiocytosis. Pediatr Blood Cancer [Internet]. 2007;48(2):124–31. Available from: http://dx.doi.org/10.1002/pbc.21039.
19. Heldt S, Prattes J, Eigl S, Spiess B, Flick H, Rabensteiner J, et al. Diagnosis of invasive aspergillosis in hematological malignancy patients: Performance of cytokines, Asp LFD, and Aspergillus PCR in same day blood and bronchoalveolar lavage samples. J Infect [Internet]. 2018;77(3):235–41. Available from: http://dx.doi.org/10.1016/j.jinf.2018.05.001.
20. Wang Q, Liu Y, Wu J, Chen S, Hu T, Liu Y, et al. Potential significance of changes in serum levels of IL-17, TNF-α and DKK-1 in the progression of the rheumatoid arthritis. Autoimmunity [Internet]. 2023;56(1):2276068. Available from: http://dx.doi.org/10.1080/08916934.2023.2276068.
21. Scherger S, Henao-Martinez AF, Franco-Paredes C, Ngo BT, Grimshaw A, Sah R, et al. Circulating TNF-α levels in rheumatoid arthritis: a systematic review and meta-analysis and comparison to TNF-α levels in sepsis. Ther Adv Infect Dis [Internet]. 2025;12(20499361251368006):20499361251368006. Available from: http://dx.doi.org/10.1177/20499361251368006.
22. Liu D, Saikam V, Skrada KA, Merlin D, Iyer SS. Inflammatory bowel disease biomarkers. Med Res Rev [Internet]. 2022;42(5):1856–87. Available from: http://dx.doi.org/10.1002/med.21893.

Siemens Healthineers Headquarters
Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim, Germany
Phone: +49 9191 18-0
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Specialty Lab Solutions
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

Published by Siemens Healthcare Diagnostics Inc. · SLS-26-4526-76 · QR700036180 · 03-2026 · *©Siemens Healthcare Diagnostics Inc., 2026*