With Thermo Fisher Scientific ImmunoDiagnostics

The experience you need.
The results you can trust.
Innovative science leads to compelling results

As the developers of world-class technology, we deliver innovative clinical concepts to advance allergy and autoimmune diagnostics. Our expertise and resources help enhance physician education to ultimately improve patient outcomes.

Our strategic solution

Define unmet clinical needs in the market

Execute well-coordinated guideline-based education efforts

Improve appropriate utilization of diagnostic testing

Enhance patient care and more efficient healthcare utilization
Dedicated to advancing allergy and autoimmune diagnostics

- Over 4 decades of continuous innovation.
- Market leader of allergy blood tests with approximately 80% market share worldwide.
- Number 1 in Europe in autoimmune diagnostics and expanding globally.
- The innovator of molecular diagnostics.
ImmunoCAP® Specific IgE Blood Testing

Design that makes a difference

As the most advanced specific IgE (sIgE) blood test available, ImmunoCAP® is the de facto reference standard. With an unmatched allergy portfolio detecting sensitization to more than 600 allergens and 80 allergen components, ImmunoCAP is the gold standard in quantitative specific IgE testing.

Unique solid phase supports an ideal sandwich immunoassay

1. The allergen of interest, covalently coupled to the solid phase, reacts with the specific IgE in the patient sample.

2. After washing away non-specific IgE, enzyme-labelled antibodies against IgE are added to form an antibody-allergen complex.

3. After incubation, unbound enzyme-labelled anti-IgE antibody is washed away and the bound complex is then incubated with a developing agent.

4. After stopping the reaction, the fluorescence of the eluate is measured. The higher the fluorescence, the more specific IgE in the sample.

Superior binding capacity provides exceptional test performance

The large amount of antigen bound to the solid phase (sponge) provides exceptional sensitivity and freedom from interference from other antibody isotypes. The ImmunoCAP sponge allows for thorough and vigorous washing of non-bound proteins and other reagents leading to:

- Low interference from non-bound proteins and other substances.
- Reliable reporting of sIgE down to 0.1 kU/L (LoQ).
- 150 times more binding than with coated beads.
- 3 times more binding than a two-dimensional paper disc.
Technology that you can count on

Accurate and precise test results based on proven assay technology\textsuperscript{3,4}

![Recombinant IgE to dust mite](image1)

![Weighted regression for dust mite](image2)

Adapted from Wood RA, et al.\textsuperscript{3}

Adapted from Wang J, et al.\textsuperscript{4}

Serum samples of known quantities of specific IgE served as the standard for comparison.\textsuperscript{3}

Specific IgE levels from a prospective cohort of 50 children were measured.\textsuperscript{4}

*These products are the trademarks of their respective manufacturers or companies.

\textit{“...the ImmunoCAP® system gave accurate results...the Immulite® system overestimated and the Turbo [MP] RAST** system underestimated their measurement of sIgE.”}\textsuperscript{3}

\textit{“Allergen-specific IgE levels obtained by different assays are not equivalent, which can potentially affect the treatment of patients with allergy.”}\textsuperscript{4}

Wood RA, et al

Wang J, et al

Trusted as the world’s leading allergy assay

- The assay technology of choice referenced in more than 4000 scientific publications.\textsuperscript{1,2}
- Flexibility to create customized profiles.
- Largest FDA-cleared allergen test menu.\textsuperscript{2}
- Acknowledged in NIH and international guidelines.\textsuperscript{5}

References:


Contact us today at 800.346.4364 or go to www.thermoscientific.com/phadia.
EliA® autoimmune assays measure autoantibodies to aid in the diagnosis of autoimmune diseases such as rheumatoid arthritis, celiac disease, and systemic lupus erythematosus. With discrete single-well testing that eliminates the microtiter plate (MTP) challenge, EliA offers high efficiency for reduced labor costs and hands-on time.

### Eliminate MTP challenges with EliA

<table>
<thead>
<tr>
<th>Feature</th>
<th>EliA (Phadia® 250)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discrete single-well format</td>
<td>✓</td>
</tr>
<tr>
<td>Continuous random access</td>
<td>✓</td>
</tr>
<tr>
<td>Master isotype 28-day stored calibration curve</td>
<td>✓</td>
</tr>
<tr>
<td>Does not require per-assay calibration</td>
<td>✓</td>
</tr>
<tr>
<td>Reflex capability</td>
<td>✓</td>
</tr>
<tr>
<td>Each antigen well processed under identical timing conditions</td>
<td>✓</td>
</tr>
<tr>
<td>CLIA moderate complexity</td>
<td>✓</td>
</tr>
</tbody>
</table>

**EliA well:** a single polystyrene-coated well that allows for proper 3-D structure presentation crucial for recognition by antibodies.

### Integrated assays with exceptional test performance

- Combines exceptional sensitivity with high specificity.
- Offers human recombinant/native antigens of high purity.
- Delivers semi-quantitative/quantitative results with clinically validated cutoffs.
Consolidation, standardization, and automation for autoimmune testing

EliA autoimmune tests

Detection of antibodies to TTG IgA for celiac disease testing

<table>
<thead>
<tr>
<th>Assay</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EliA</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Binding Site</td>
<td>98</td>
<td>91</td>
</tr>
<tr>
<td>Inova</td>
<td>98</td>
<td>100</td>
</tr>
</tbody>
</table>

Adapted from Wong RC, et al. Results from a comparative study designed to determine the performance of various commercial TTG IgA ELISA kits in the diagnosis of celiac disease in patients with biopsy-confirmed disease, compared to controls.

Detection of antibodies to CCP for rheumatoid arthritis testing

<table>
<thead>
<tr>
<th>Assay</th>
<th>Sensitivity at 98.5% Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>EliA</td>
<td>74</td>
</tr>
<tr>
<td>Axis-Shield</td>
<td>70</td>
</tr>
<tr>
<td>Inova</td>
<td>67</td>
</tr>
</tbody>
</table>

Adapted from Bizzaro N, et al. Results from a comparative study designed to determine analytical characteristics and diagnostic accuracy of several methods using various citrullinated antigen substrates.

References:
Traditional allergy testing measures specific IgE to the proteins within the whole allergen extract. Not all of these proteins are clinically relevant. ImmunoCAP® Allergen Component Testing offers a new level of detail, compared to the current standard, to better assess a patient’s risk of reaction. With the addition of ImmunoCAP Allergen Components to your test menu, your laboratory will be able to provide the test results necessary for your customers to better manage their patients with allergies.

**Characteristics of allergen protein components in sensitized patients**

ImmunoCAP technology allows quantification of allergen specific IgE down to 0.1 kU/l.

Patients with specific IgE directed towards one or both (phenotypes) of these peanut protein components may experience serious systemic reactions upon exposure; those caused by sensitization to storage proteins and to lipid transfer proteins (LTP), respectively. These are both stable proteins and abundant in peanuts. Patients with either the profilin and/or PR-10 phenotypes may be asymptomatic or may experience mainly local reactions upon exposure, as these proteins are readily degraded, heat sensitive and of low abundance in peanuts.¹
Offer ImmunoCAP® Allergen Components through your laboratory

Determine detailed specific IgE sensitization patterns to key allergens

**Egg Allergen Component Package**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Code</th>
<th>Suggested Test Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovalbumin</td>
<td>f232</td>
<td></td>
</tr>
<tr>
<td>Ovomucoid</td>
<td>f233</td>
<td></td>
</tr>
<tr>
<td>Egg White Complete Allergen Extract</td>
<td>f1</td>
<td>If Egg White Complete Allergen Extract (f1) is positive, reflex to f232 and f233</td>
</tr>
</tbody>
</table>

- Ovalbumin is susceptible to heat denaturation
- Ovomucoid is resistant to heat denaturation
- 70% of children with egg allergy can tolerate cooked egg

**Milk Allergen Component Package**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Code</th>
<th>Suggested Test Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>α-lactalbumin</td>
<td>f76</td>
<td>If Milk Complete Allergen Extract (f2) is positive, reflex to f76, f77, and f78</td>
</tr>
<tr>
<td>β-lactoglobulin</td>
<td>f77</td>
<td></td>
</tr>
<tr>
<td>Casein</td>
<td>f78</td>
<td></td>
</tr>
<tr>
<td>Milk Complete Allergen Extract</td>
<td>f2</td>
<td></td>
</tr>
</tbody>
</table>

- α-lactalbumin and β-lactoglobulin are susceptible to heat denaturation
- Casein is resistant to heat denaturation
- 75% of children with cow's milk allergy can tolerate baked milk

**Peanut Allergen Component Package**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Code</th>
<th>Suggested Test Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>rAra h 1 peanut</td>
<td>f422</td>
<td>If Peanut Complete Allergen Extract (f13) is positive, reflex to f422, f423, f424, f352, and f427</td>
</tr>
<tr>
<td>rAra h 2 peanut</td>
<td>f423</td>
<td></td>
</tr>
<tr>
<td>rAra h 3 peanut</td>
<td>f424</td>
<td></td>
</tr>
<tr>
<td>rAra h 8 peanut</td>
<td>f352</td>
<td></td>
</tr>
<tr>
<td>rAra h 9 peanut</td>
<td>f427</td>
<td></td>
</tr>
<tr>
<td>Peanut Complete Allergen Extract</td>
<td>f13</td>
<td></td>
</tr>
</tbody>
</table>

- Ara h 1, h 2, h 3 are storage proteins and are peanut specific markers
- Ara h 8 is a PR-10 protein and is a marker of tree pollen cross-reactivity
- Ara h 9 is a LPT protein and is a marker of peach cross-reactivity
- More than 77% of patients sensitized to peanut may not be at risk for a systemic reaction

Better risk assessment with peanut allergen components

**References:**
One platform for allergy and autoimmune diagnostics*

From community hospitals to high-volume laboratories—there is a Phadia Laboratory System designed for your needs.

Operational efficiency for any size lab

- **Flexible scalability** from Phadia® 100 to Phadia® 5000 to meet the demands of small to large facilities.
- **High efficiency** for reduced hands-on time.
- **Integrated assay technology** and automated instrument systems.
- **Best-in-class service and support** to enhance your productivity.
- **Same-run, same-day results** for allergy and autoimmune diagnostics on Phadia® 250, Phadia® 2500, and Phadia® 5000.
- **CLIA** moderate complexity.

*Phadia® 100 allergy only.*
Technology that makes a difference in patient care

The current healthcare environment in the United States puts pressure on clinicians and laboratory services to make accurate diagnoses in a cost-effective and time-efficient manner based on test results with high clinical value. With ImmunoCAP® and EliA®, clinicians can have the tools to meet today’s healthcare challenges.

Patient assessment
Approximately 70%-80% of medical decisions are based on laboratory results.

Accurate, consistent diagnostic test results
Correct diagnosis saves costs (for example, in rhinitis, peanut allergy, and GI diseases).

Confirmed diagnosis to support informed treatment decisions
Quality of life can be improved with a correct diagnosis.

Ongoing patient assessment
ImmunoCAP provides unmatched accuracy. EliA produces accurate, standardized, and reproducible results.

Enhance patient outcomes

References:

Thermo Fisher Scientific
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Working with the global leader in allergy and autoimmune testing has several advantages, including a dedicated sales force to educate clinicians in your area. With Thermo Fisher Scientific ImmunoDiagnostics as your partner, it is possible to differentiate your lab in a competitive market.

Clinical expertise and resources fulfill unmet clinical needs

With a dedicated group of more than 200 clinical consultants and a team of clinical educators, our support helps drive appropriate market demand for your lab.¹

- By educating clinicians on guideline-based approach to care, the impact of clinical consultants on accounts has been shown to increase profiles per month by 70% compared to accounts that are not covered by clinical consultants.¹
Value-based testing supports guideline-based care

In proper asthma management, accurate trigger identification is essential

25 million people in the United States have asthma.

Asthma exacts a major clinical and economic toll.

- 1.8 million ER visits
- 487,000 hospitalizations
- $37.2 billion (annual direct costs of asthma care)
- Up to 31% of costs spent on medications

The use of specific IgE testing helps improve symptoms and decrease costs

- Reduces ER visits per patient per year by up to 2.1%
- Reduces hospitalizations by up to 21.3%
- Reduces need for medications by up to 43%
- Reduces symptom days per year by up to 21.3%

Providing solutions for today’s diagnostic challenges.

References:

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A legacy of innovation

**ALLERGY DIAGNOSTICS**

1967
- First commercial IgE blood test: Pharmacia introduces the first blood test for Total IgE (PRIST).

1972
- RAST*: Pharmacia introduces the first commercial laboratory test for specific IgE antibodies.

1974
- ImmunoCAP®: Introduction of ImmunoCAP®: Specific IgE blood test, which revolutionizes IgE assay technology.

1989
- UniCAP® 100: First automated platform for allergy diagnostics.

1996
- Decision points established: ImmunoCAP technology chosen to establish food challenge decision points for four major allergens.

1997
- Established a clinical focus in the marketplace: Physician education channel introduced in the US.

2000
- A new level of sensitivity: ImmunoCAP accurately measures and reports specific IgE down to 0.1 kU/L.

2005
- PIRL*: Phadia Immunology Reference Laboratory established as an incubator of innovation.

2008
- Updated food allergy guidelines: NIH food guidelines state ImmunoCAP results are not interchangeable with other methods.

2010
- A new era in allergy diagnostics: Phadia introduces ImmunoCAP Molecular Allergy.

2011
- Innovation continues in allergy diagnostics: ImmunoDiagnostics expands offering of ImmunoCAP Molecular Allergy.

2012
- Phadia joins a global leader in laboratory equipment, supplies, and services.

**AUTOIMMUNE DIAGNOSTICS**

1983
- Elias is founded: Academic researchers develop new technologies for autoimmune assays.

1990
- Eukaryotic expression system: Elias uses unique Bacteriodes Expression System to achieve superior standardized results.

1992
- Varelisa is introduced: Novel ELSA assays are made available for a broad range of autoimmune diseases.

1994
- Pharmacology Diagnostics acquires Elias: The combination of cutting-edge technology and extensive experience in autoimmunity begins.

1997
- Elias® introduced on Phadia 100: Integration of the first automated platform for discrete single-well testing and onboard dilution for autoimmune disease.

2001
- EIA available on Phadia 250: Random-access testing on a fully automated platform is introduced for higher accuracy, efficiency, and simpler handling.

2005
- Acquisition of VBC Genomics: Phadia acquires biotech technology.

2007
- Elias comes to the US: Following widespread use and leadership in Europe, Elias assays are introduced in the US.

2008
- Expansion of EIA portfolio: Phadia introduces additional assays for key autoimmune disorders.

2009
- New autoimmune markers are FDA cleared: Phadia continues to introduce state-of-the-art specific protein assays for superior performance.

2010
- Phadia joins a global leader in laboratory equipment, supplies, and services.

2011
- Innovation continues in autoimmune diagnostics: ImmunoDiagnostics expands EIA test offerings.

2012

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