



With Thermo Fisher Scientific ImmunoDiagnostics

**The experience you need.  
The results you can trust.**

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# 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**

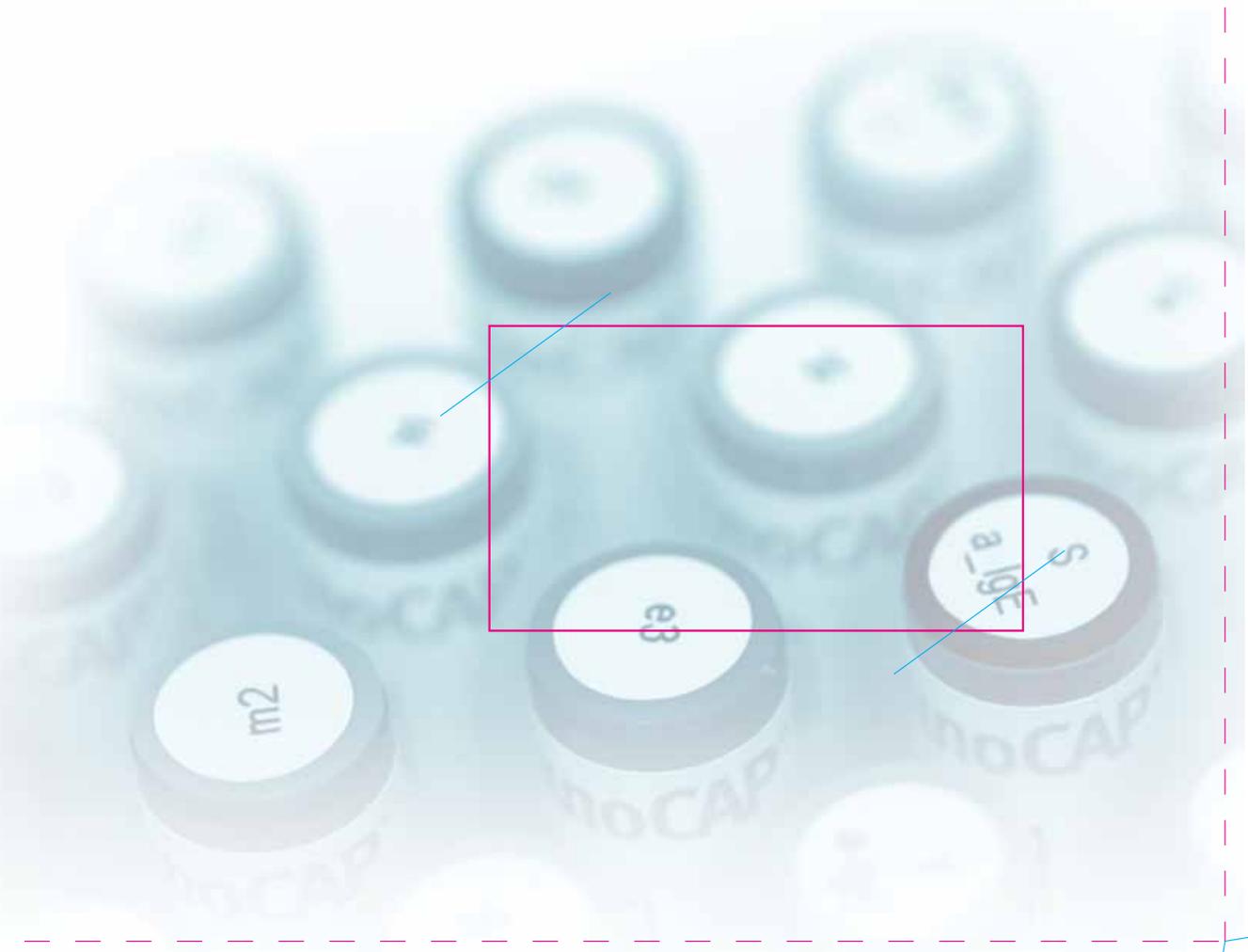
**Execute well-coordinated  
guideline-based education efforts**

**Improve appropriate utilization  
of diagnostic testing**

**Enhance patient care and more  
efficient healthcare utilization**

# Dedicated to advancing allergy and autoimmune diagnostics

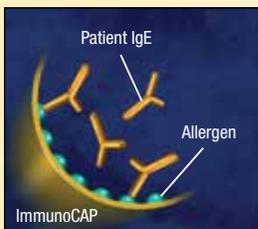
- Over 4 decades of continuous innovation.
- Market leader of allergy blood tests with approximately 80% market share worldwide.
- Number 1 in Europe in autoimmune diagnostics and expanding globally.
- The innovator of molecular diagnostics.



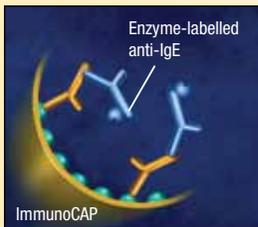
## Design that makes a difference

As the most advanced specific IgE (sIgE) blood test available, ImmunoCAP® is the *de facto* reference standard.<sup>1</sup> 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.

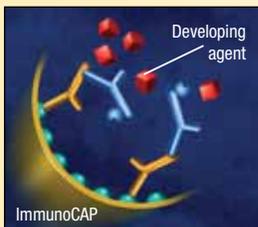
### Unique solid phase supports an ideal sandwich immunoassay<sup>1,2</sup>



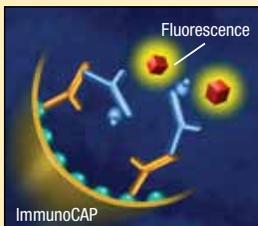
- 1 The allergen of interest, covalently coupled to the solid phase, reacts with the specific IgE in the patient sample.



- 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.

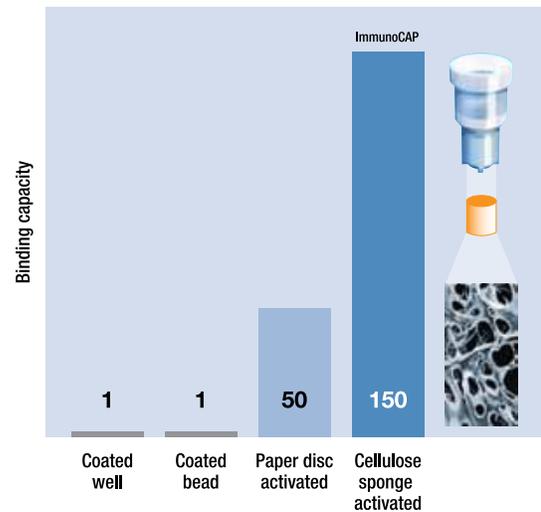


- 4 After stopping the reaction, the fluorescence of the eluate is measured. The higher the fluorescence, the more specific IgE in the sample.

### Superior binding capacity provides exceptional test performance<sup>2</sup>

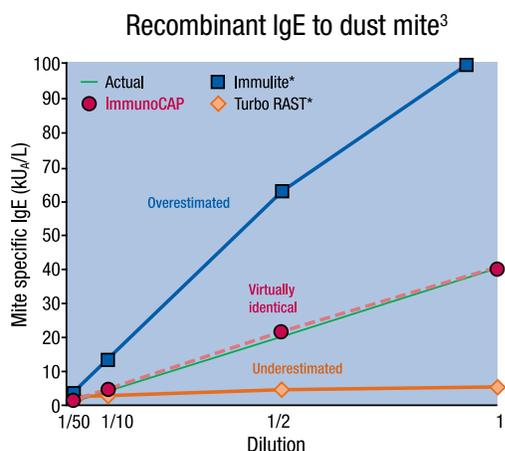
The large amount of antigen bound to the solid phase (sponge) provides exceptional sensitivity and freedom from interference from other antibody isotypes. The ImmunoCAP sponge allows for thorough and vigorous washing of non-bound proteins and other reagents leading to:

- Low interference from non-bound proteins and other substances.
- Reliable reporting of sIgE down to 0.1 kU<sub>A</sub>/L (LoQ).
- 150 times more binding than with coated beads.
- 3 times more binding than a two-dimensional paper disc.

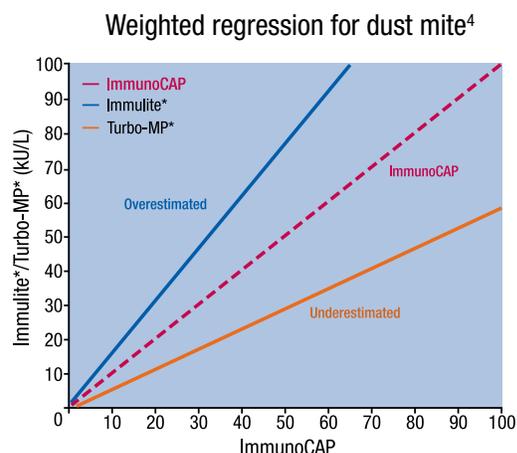


# Technology that you can count on

Accurate and precise test results based on proven assay technology<sup>3,4</sup>



Adapted from Wood RA, et al.<sup>3</sup>  
 Serum samples of known quantities of specific IgE served as the standard for comparison.<sup>3</sup>  
 \*These products are the trademarks of their respective manufacturers or companies.



Adapted from Wang J, et al.<sup>4</sup>  
 Specific IgE levels from a prospective cohort of 50 children were measured.<sup>4</sup>  
 \*These products are the trademarks of their respective manufacturers or companies.

*"...the ImmunoCAP<sup>®</sup> system gave accurate results...the Immulite<sup>®</sup> system overestimated and the Turbo [MP] RAST<sup>®</sup> system underestimated their measurement of sIgE."<sup>3</sup>*

Wood RA, et al

*"Allergen-specific IgE levels obtained by different assays are not equivalent, which can potentially affect the treatment of patients with allergy."<sup>4</sup>*

Wang J, et al

## Trusted as the world's leading allergy assay

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

### References:

1. Johansson SGO. *Expert Rev Mol Diagn.* 2004;4(3):273-279.
2. Data on file. Thermo Fisher Scientific, Inc.
3. Wood RA, et al. *Ann Allergy Asthma Immunol.* 2007;99(1):34-41.
4. Wang J, et al. *J Allergy Clin Immunol.* 2008;121(5):1219-1224.
5. Boyce JA, et al. *J Allergy Clin Immunol.* 2010;126(6):S1-S58.

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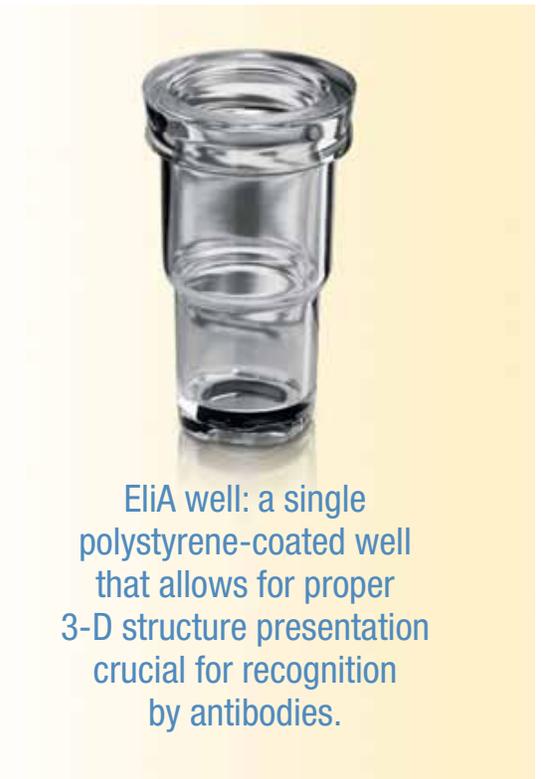
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## Optimization of routine autoimmune testing

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<sup>1</sup>

	EliA (Phadia® 250)
Discrete single-well format	✓
Continuous random access	✓
Master isotype 28-day stored calibration curve	✓
Does not require per-assay calibration	✓
Reflex capability	✓
Each antigen well processed under identical timing conditions	✓
CLIA moderate complexity	✓



### 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

## Demonstrated performance in autoimmune testing

### Detection of antibodies to tTG IgA for celiac disease testing<sup>2</sup>

Assay	Sensitivity (%)	Specificity (%)
EliA	100	100
Binding Site	98	91
Inova	98	100

Adapted from Wong RC, et al.<sup>2</sup>

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.<sup>2</sup>

### Detection of antibodies to CCP for rheumatoid arthritis testing<sup>3</sup>

Assay	Sensitivity at 98.5% Specificity
EliA	74
Axis-Shield	70
Inova	67

Adapted from Bizzaro N, et al.<sup>3</sup>

Results from a comparative study designed to determine analytical characteristics and diagnostic accuracy of several methods using various citrullinated antigen substrates.<sup>3</sup>

## EliA autoimmune tests

Product	Units	CPT Code
<b>Connective Tissue Diseases</b>		
EliA dsDNA Well	IU/ml	86225
EliA Symphony Well (U1RNP, RNP70, Sm, Ro (SS-A), La (SS-B), CENP, Scl-70, Jo-1)	Ratio	86038
EliA U1RNP Well	U/ml	86235
EliA RNP70 Well	U/ml	86235
EliA Sm Well	U/ml	86235
EliA Ro (SS-A) Well	U/ml	86235
EliA La (SS-B) Well	U/ml	86235
EliA CENP Well	U/ml	86235
EliA Scl-70 Well	U/ml	86235
EliA Jo-1 Well	U/ml	86235
<b>Rheumatoid Arthritis</b>		
EliA CCP Well	U/ml	86200
EliA RF IgA Well	IU/ml	86431
EliA RF IgM Well	IU/ml	86431

Product	Units	CPT Code
<b>Antiphospholipid Syndrome</b>		
EliA Cardiolipin IgA Well	APL-U/ml	86147
EliA Cardiolipin IgG Well	GPL-U/ml	86147
EliA Cardiolipin IgM Well	MPL-U/ml	86147
EliA B2-Glycoprotein I IgA Well	U/ml	86146
EliA B2-Glycoprotein I IgG Well	U/ml	86146
EliA B2-Glycoprotein I IgM Well	U/ml	86146
<b>Celiac Disease</b>		
EliA Celikey® (tTG) IgA Well	U/ml	83516
EliA Celikey® (tTG) IgG Well	U/ml	83516
EliA Gliadin DP IgA Well	U/ml	83516
EliA Gliadin DP IgG Well	U/ml	83516
EliA Gliadin IgA Well	U/ml	83516
EliA Gliadin IgG Well	U/ml	83516
<b>Autoimmune Thyroid Diseases</b>		
ImmunoCAP® Thyroglobulin	IU/ml	86800
ImmunoCAP® Thyroid Peroxidase	IU/ml	86376

**EliA®**

**Excellence in Autoimmunity**

#### References:

1. Data on file. Thermo Fisher Scientific.
2. Wong RC, et al. *J Clin Pathol.* 2002;55(7):488-494.
3. Bizzaro N, et al. *Clin Chem.* 2007;53(8):1527-1533.

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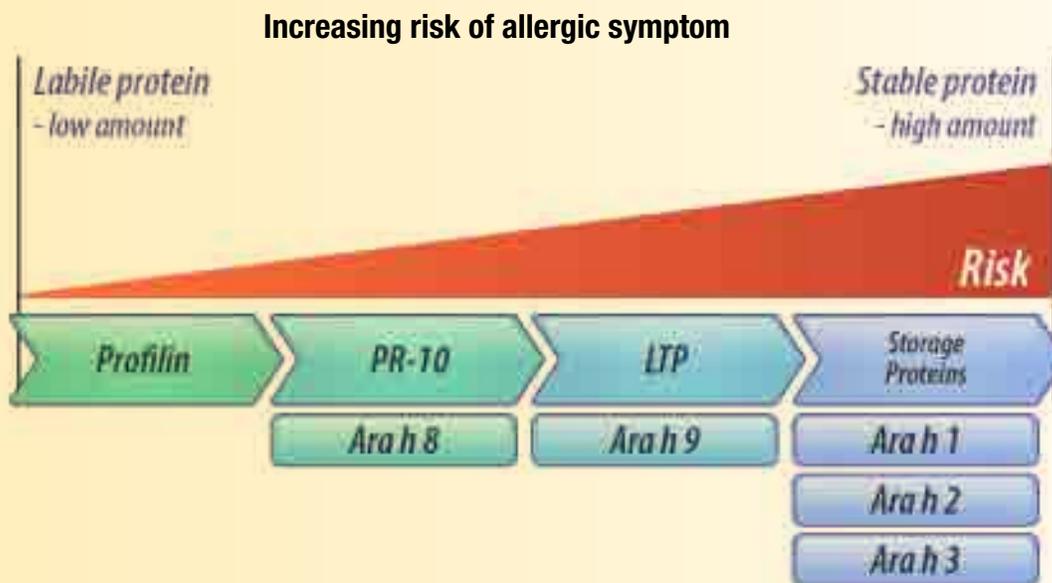
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# ImmunoCAP® Allergen Components

## Impact patient management now with ImmunoCAP allergen component testing

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<sub>A</sub>/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.<sup>1</sup>

# Offer ImmunoCAP® Allergen Components through your laboratory

Determine detailed specific IgE sensitization patterns to key allergens

## Egg Allergen Component Package

Test Name	Test Code	Suggested Test Strategy
Ovalbumin	f232	If Egg White Complete Allergen Extract (f1) is positive, reflex to f232 and f233
Ovomucoid	f233	
Egg White Complete Allergen Extract	f1	

- Ovalbumin is susceptible to heat denaturation<sup>2</sup>
- Ovomucoid is resistant to heat denaturation<sup>2</sup>
- 70% of children with egg allergy can tolerate cooked egg<sup>3</sup>

## Milk Allergen Component Package

Test Name	Test Code	Suggested Test Strategy
$\alpha$ -lactalbumin	f76	If Milk Complete Allergen Extract (f2) is positive, reflex to f76, f77, and f78
$\beta$ -lactoglobulin	f77	
Casein	f78	
Milk Complete Allergen Extract	f2	

- $\alpha$ -lactalbumin and  $\beta$ -lactoglobulin are susceptible to heat denaturation<sup>4</sup>
- Casein is resistant to heat denaturation<sup>5</sup>
- 75% of children with cow's milk allergy can tolerate baked milk<sup>5</sup>

## Better risk assessment with peanut allergen components

### Peanut Allergen Component Package

Test Name	Test Code	Suggested Test Strategy
rAra h 1 peanut	f422	If Peanut Complete Allergen Extract (f13) is positive, reflex to f422, f423, f424, f352, and f427
rAra h 2 peanut	f423	
rAra h 3 peanut	f424	
rAra h 8 peanut	f352	
rAra h 9 peanut	f427	
Peanut Complete Allergen Extract	f13	

- Ara h 1, h 2, h 3 are storage proteins and are peanut specific markers<sup>1</sup>
- Ara h 8 is a PR-10 protein and is a marker of tree pollen cross-reactivity<sup>1</sup>
- Ara h 9 is a LPT protein and is a marker of peach cross-reactivity<sup>1</sup>
- More than 77% of patients sensitized to peanut may not be at risk for a systemic reaction<sup>6</sup>



#### References:

1. ImmunoDiagnostics Journal No. 4, 2013. Clinical Utility of Peanuts. 2. Benhamou AH, et al. *Allergy*. 2010;65(3):283-289. 3. Lemon-Mulé H, et al. *J Allergy Clin Immunol*. 2008;122(5):977-983. 4. Wal JM, *Ann Allergy Asthma Immunol*. 2004;93(5 Suppl 3):S2-S11. 5. Nowak-Węgrzyn A, et al. *J Allergy Clin Immunol*. 2008; 122(2):342-347. 6. Nicolaou N, et al. *J Allergy Clin Immunol*. 2010;125(1):191-197.

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# Phadia Laboratory Systems

## 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



Phadia® 250



Phadia® 1000



Phadia® 2500



Phadia® 5000

\*Phadia® 1000 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.<sup>1</sup>

## Accurate, consistent diagnostic test results

Correct diagnosis saves costs (for example, in rhinitis,<sup>2,3</sup> peanut allergy,<sup>4</sup> and GI diseases).<sup>5</sup>

## 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<sup>6,7</sup>

#### References:

1. Datta P. *MLO Med Lab Obs.* 2004;36(11):28-31. 2. Portnoy JM, et al. *Cur Allergy Asthma Rep.* 2004;4:439-446. 3. Zethraeus N, et al. *Ital J Pediatr.* 2010;36:61-67. 4. Hermansson LL, et al. *Value Health.* 2012;15:A68. Abstract PMD33. 5. Mindemark M. *The Use of Laboratory Analyses in Sweden: Quality and Cost-Effectiveness in Test Utilization* [dissertation]. Uppsala, Sweden: Uppsala University; 2010. 6. National Institutes of Health. *Guidelines for the Diagnosis and Management of Asthma, 2007.* <http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf>. Accessed June 6, 2012. 7. Bizzaro N, et al. *Clin Chem.* 2007;53(8):1527-1533.

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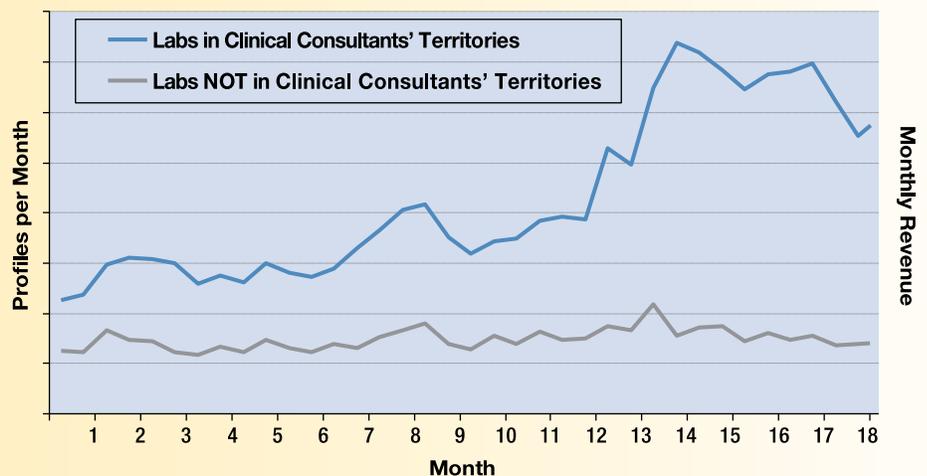
## Driving awareness of value-based testing

# Our dedication is your advantage

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.

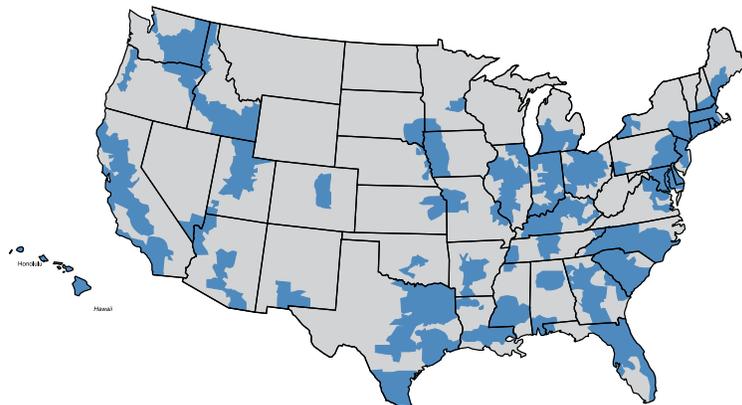
## Clinical expertise and resources fulfill unmet clinical needs

*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.<sup>1</sup>*



## Clinical Consultants' Territories

- 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.<sup>1</sup>

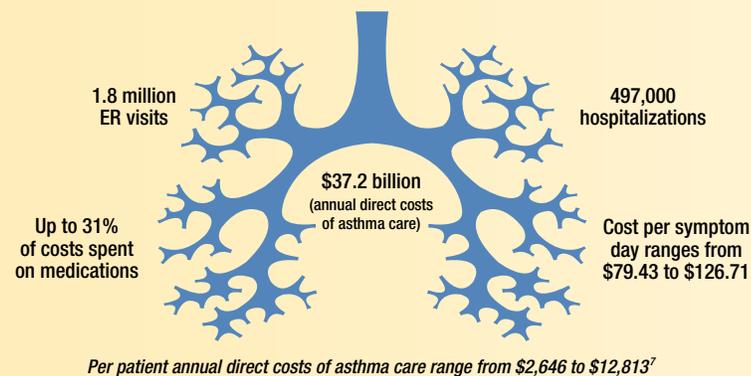


# Value-based testing supports guideline-based care

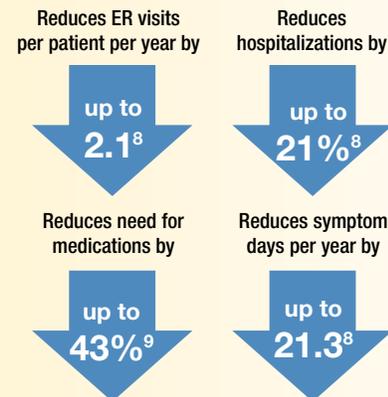
In proper asthma management, accurate trigger identification is essential

25 million people in the United States have asthma<sup>2</sup>

## Asthma exacts a major clinical and economic toll<sup>3-6</sup>



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



## Providing solutions for today's diagnostic challenges.

### References:

1. Data on file. Phadia Laboratory Systems.
2. Centers for Disease Control and Prevention Web site. <http://www.cdc.gov/nchs/fastats/asthma.htm>. Accessed February 22, 2012.
3. Kwong KYC, et al. *Am J Manag Care*. 2011;17(suppl 17):S447-S459.
4. Kamble S, et al. *J Asthma*. 2009;46:73-80.
5. National Center for Health Statistics. <http://www.cdc.gov/nchs/data/hestat/asthma03-05/asthma03-05.htm>. Accessed April 10, 2012.
6. Bollinger ME, et al. *Ann Allergy Asthma Immunol*. 2010;105:274-281.
7. Cisternas MG, et al. *J Allergy Clin Immunol*. 2003;111:1212-1218.
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9. Zethraeus N, et al. *Ital J Pediatr*. 2010;36:61-67.

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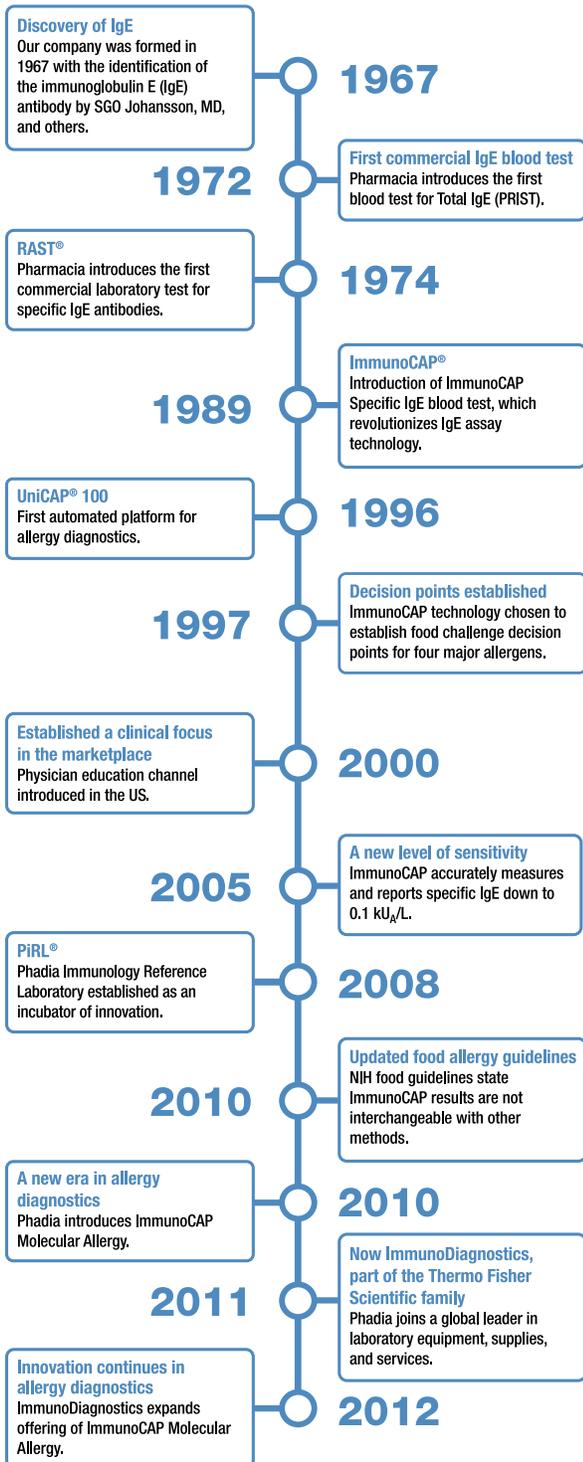
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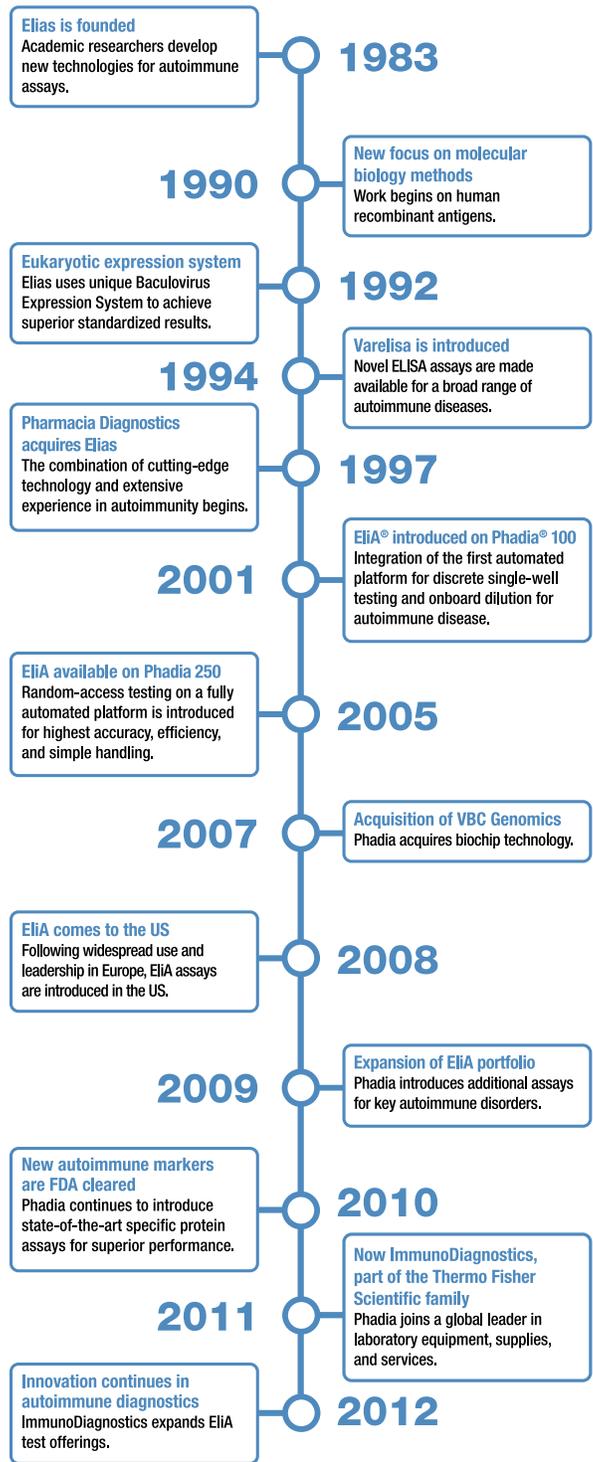
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# A legacy of innovation

## ALLERGY DIAGNOSTICS



## AUTOIMMUNE DIAGNOSTICS



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