

ImmunoCAP[®]
System



ImmunoCAP[®] Systems
Optimized for allergy testing
- Precision
- Accuracy
- Consistency

Phadia

The ImmunoCAP® systems from Phadia offer an optimal allergy testing solution for every laboratory, regardless of testing volume requirements.

- ◆ From local clinics to the world's largest commercial laboratories
- ◆ From 1 to 30 000 tests per day
 - ↳ there is always an ImmunoCAP system designed for your needs.

ImmunoCAP systems all offer full automation and the same unrivalled ImmunoCAP technology, still the only technology giving true quantitative IgE measurements.

The ImmunoCAP® system is the number one choice worldwide for allergy testing both for research and general testing

A family to grow with

When your allergy testing grows you can simply add new ImmunoCAP instrumentation without having to abandon your previous system.

The unique ImmunoCAP Information Data Manager software allows you to integrate several ImmunoCAP systems into one network.

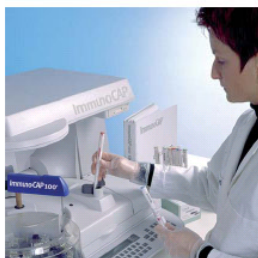
- ↳ without having to learn new software.



Technical features

Common system features

- ◆ World-leading ImmunoCAP technology providing accurate and reproducible test results
- ◆ True quantitative measurements
- ◆ Large panel of standardized high-quality allergens and autoimmunity tests



ImmunoCAP® 100[€]

Maximum flexibility in the small lab or clinic

- ◆ Fast and automated
- ◆ Single integrated unit
- ◆ Up to 48 different determinations in less than three hours
- ◆ Also for EIA* autoimmunity testing
- ◆ Run as stand-alone unit in a local clinic or in a cluster at a larger laboratory
- ◆ Connectable to mainframe
- ◆ Automatic dilution

ImmunoCAP® 250

Higher capacity and automation for increased productivity

- ◆ Ideal for medium-sized laboratories running 80-400 tests/day
- ◆ Fully automated, continuous random access and mainframe connection
- ◆ Throughput: 60 tests/hour
- ◆ Also for EIA* autoimmunity testing
- ◆ Positive identification and full traceability of all samples and reagents
- ◆ All reagents and up to 3 000 tests on-board
- ◆ Up to 6 different methods
- ◆ Automatic sample dilution
- ◆ Stand alone PC hosting the IDM system software
- ◆ Built-in touch screen



ImmunoCAP® 1000

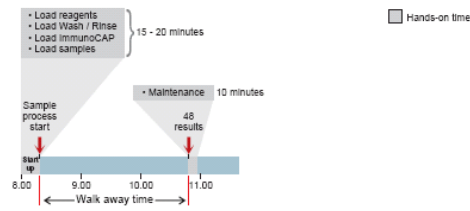
The optimal solution for the large cost-conscious laboratory to meet the growing need for allergy testing

- ◆ Fully automated, continuous random access and mainframe connection
- ◆ Throughput: 240 tests/hour
- ◆ Positive identification and full traceability of all samples and reagents
- ◆ All reagents and up to 10 000 tests on-board
- ◆ Stand alone PC hosting the IDM system software
- ◆ Built-in touch screen

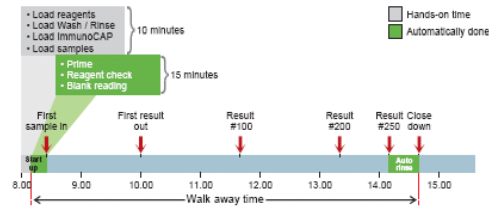
Automation for walk-away productivity

The ImmunoCAP® systems are all highly automated, requiring minimal hands-on time. Choosing the system with the capacity matching your needs for throughput ensures optimal productivity. Typical work-day schedules for each of the systems are shown below.

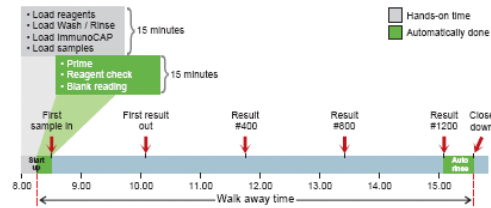
ImmunoCAP® 100€






ImmunoCAP® 250



ImmunoCAP® 1000



	 ImmunoCAP 100	 ImmunoCAP 250	 ImmunoCAP 1000
Test/assay	48	250-400	1,200-2,500
Methods/assay	4	6	3
Maximum test types on-board	N. A.	180+36	600+8
Test on-board	N. A.	~3,000	~10,000
Sample tube on-board	48	50	200
Sample loading during assay	No	Yes	Yes
ImmunoCAP technology	Yes	Yes	Yes
EliA technology	Yes	Yes	No
Barcode reading samples	Optional	Yes	Yes
Barcode reading reagents	Optional	Yes	Yes
Foot print	70 x 55cm	127 x 75cm	180 x 100cm
Weight	47kg	250kg	700kg
Power Supply	100-240V 50/60Hz	100-240V 50-/60Hz	230V 50/60Hz
Environmental temperature	18-32°C	18-32°C	18-32°C
ImmunoCAP Information Data Manager	Optional	Yes	Yes
LIS connection	Yes	Yes	Yes
Clustering	Yes	Yes	Yes

N. A. = Not Applicable

The way to precise and correct IgE measurements

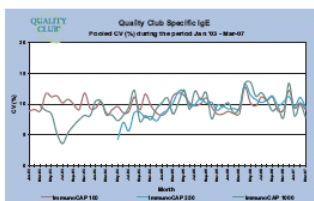
The ImmunoCAP® systems are developed specifically for allergy testing. The instruments, reagents and test procedures are optimized for the special requirements involved in the task of making precise measurements of IgE antibodies.

- ✦ ImmunoCAP consistently shows better performance than any other allergy test system in independent quality assessment programs like the EuroEQAS allergy program.
- ✦ The precision achieved with ImmunoCAP is in fact comparable to standard clinical chemistry immunoassays, whereas other allergy test methods show considerably higher coefficient of variation (CV).
- ✦ In other words, with other methods the same sample will give varying results at different laboratories and at different points in time and the clinical usefulness of the results will therefore be limited.

ImmunoCAP gives precise and reproducible results, regardless of laboratory, operator time, time occasion, lot number, instrument and country.

Quality Club™ is the largest external quality assessment program for allergy testing, with approximately 900 members in 37 countries.

This gives the member laboratories the possibility to compare their results with other laboratories world-wide. Quality Club data verify the very low variation in test results, covering all the possible sources of variation, including different laboratories, users, instruments, reagents, and dozens of ImmunoCAP lots.



"UniCAP 100 fulfils the requirements for the quality assurance of quantitative immunological determinations in medical laboratories and can thus be recommended for quantitative *in vitro* allergy diagnosis."

"UniCAP 100 is ergonomic, easy to handle, quick, robust and precise and can be recommended for quantitative *in vitro* allergy diagnosis."

Reference: *Investigation of Pharmacia UniCAP 100 for in vitro allergy diagnosis, Clin Lab 1999;45:229-35, Author: Liappis, Lantto, et al.*

"UniCAP is an efficient laboratory system for routine diagnostic testing allergy and a valuable tool for basic studies on allergens and antibodies."

"In conclusion, the studies verify the diagnostic efficiency of the new generation of ImmunoCAP technology and the automated UniCAP immunoassay system."

Reference: *Specific IgE antibodies in the diagnosis of atopic disease, Allergy 1998; 53: 763-8, Author: Paganelli, Sastre, Lindholm, et al.*

"The imprecision levels appear satisfactory for UniCAP 100, being within a CV 10%"

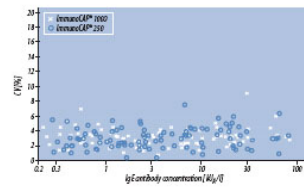
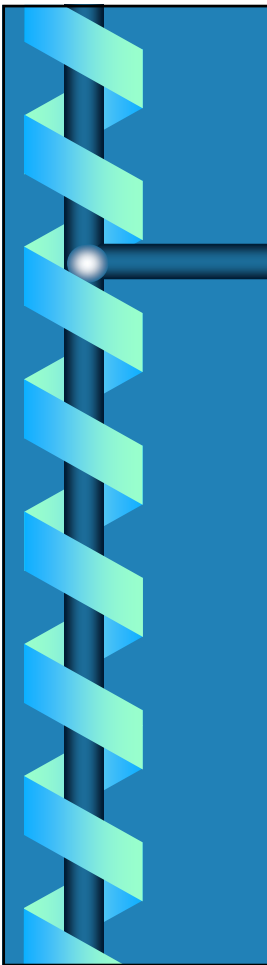
"The imprecision found in Immulite 2000 for the positive control serum was markedly higher, the CV being in the region of 25%, a level which appears excessive for this type of determination, and which, for unknown reasons, is much higher than the average found with the same instrument in our laboratory for routine immunochemical determinations (where the CV ranges from 4% for β SA to 11% for intact PTH)."

Reference: *In Vitro allergy diagnosis: comparison of a new method of fully automated determination of Specific IgE, using Immulite 2000 compared with UniCAP 100, European Annals of Allergy and Clinical Immunology 2003; 56: 351-8, Author: G Vignati, E Pastor, S Portakapi, R Termpoit.*

The truly quantitative allergy test

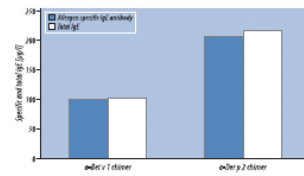
ImmunoCAP is the test system giving results with enough precision to be called truly quantitative. An inferior test system, where the values obtained from the same sample may vary from one test occasion to another, is of course not a reliable tool for following the fine-scale development of IgE sensitization in a patient over time.

The ImmunoCAP systems consistently give precise, quantitative results reported in kU_A/L. The calibrator is directly traceable and parallel to the WHO reference preparation 75/502 for IgE. Dilution curves shows accurate results for the whole measuring range.



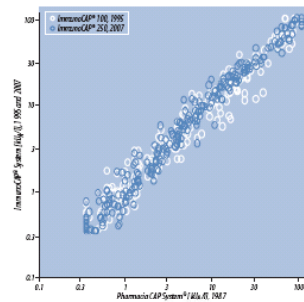
Precision

The intra-assay precision (CV%) of ImmunoCAP is as good as standard clinical chemistry immunoassays, which is quite remarkable considering the extremely low concentrations of IgE antibodies found in the serum of even severely allergic patients and the possible interference from immunoglobulins of other classes.



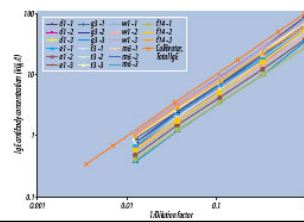
Accuracy

ImmunoCAP IgE antibody results are truly quantitative and comparable to IgE protein mass units, where 1 U_x IgE antibody = 1 IU IgE = 2.42 ng of IgE.



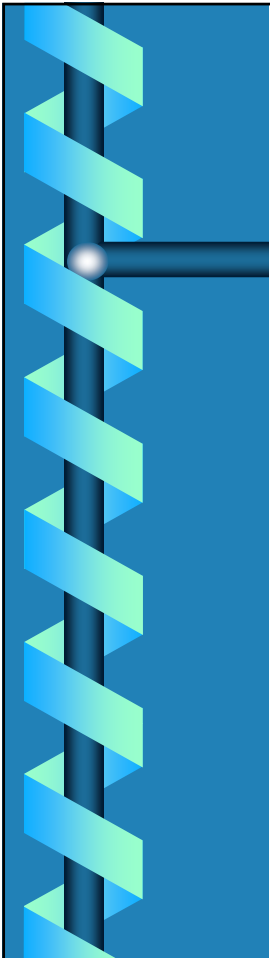
Consistency

Seventy samples from a clinical trial were first assayed for specific IgE antibodies to eleven allergens in 1987, using Pharmacia CAP System[®]. The samples were stored at -20°C and eight years later reassayed with ImmunoCAP 100. After 20 years storage the samples were again reassayed, this time using ImmunoCAP 250. The results showed very good agreement; r=0.97 1995/1987 and r=0.99 2007/1987.



Parallelism

Parallelism between calibrators and dilutions of sample has been repeatedly verified on the different instruments based on the ImmunoCAP technology.



Thirty years of market leadership

Phadia developed *in vitro* allergy testing in the early 1970s. We were the pioneers in allergy test development and also developed the allergen code standard. Today's ImmunoCAP® systems are the result of thirty years of technology, chemistry and instrument development. ImmunoCAP systems are the most frequently used in routine testing and in clinical studies – the reference systems in allergy testing.

The development history includes several important milestones:

1st generation

1974 – Phadebas RAST

The first laboratory test for specific IgE-antibodies. The paper disc technology combining quality with a large panel of allergens became the 'gold standard' of allergy testing.

2nd generation

1989 – Pharmacia CAP System®

The ImmunoCAP technology brought new standards of quality and capacity to the market, also introducing semi-automation to increase laboratory efficiency.

3rd generation

1996 – UniCAP® 100

Introducing full automation and quick assay procedure. Further improvements in precision and reproducibility through improved chemistry, standardized handling and environmental control laid the foundation for truly quantitative measurements. Already 4000 instruments on the market.

4th generation

2001/2004 – ImmunoCAP® 1000 and 250

The unsurpassed quality of ImmunoCAP® 100® combined with even higher automation, speed, capacity and continuous random access ability availability.

All systems are CE-marked according to 98/79/EC. *In vitro* diagnostic medical device directive for all EU countries and including Norway and Switzerland.

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