Evaluation of UniCAP® 100 for *in vitro* Allergy Diagnosis

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INTRODUCTION

Several studies indicate that the prevalence of allergic diseases has steadily increased in the Western industrialized countries and is at present estimated to be between 30% and 40%.[1,2] Every fifth child and every second to third adult are affected.

Responsible for this high incidence of allergic diseases is not only the patient's genetic predisposition, but also exposure to ecological pollutants (SO_2, NO_2), tobacco smoke, the nutrition received during the first year of life, damp or badly ventilated rooms, and the fur or feathers of domestic animals.[3]

Due to this high incidence, the importance of *in vivo* and *in vitro* allergy diagnosis increases. In the *in vitro* allergy diagnosis, we need not only precise and accurate results, but also methods and analytical systems that are easy and quick to perform.

The aim of the present study was to evaluate the recently introduced UniCAP 100 instrument.

MATERIAL AND METHODS

UniCAP 100 (Pharmacia & Upjohn Diagnostics AB, Uppsala, Sweden) is a fast, fully integrated, automated system based on ImmunoCAP™ technology and utilizes the same fluoroenzyme immunoassay (FEIA) technology used in Pharmacia CAP System™.[4] All functions that are required for a complete test procedure–such as patient information management, sample and reagent handling, processing, measurement, evaluation and printout of results–are included.

The system uses ImmunoCAP technology for the measurement of total IgE and specific IgE antibodies in which the solid phase consists of a flexible hydrophilic carrier polymer encased in a reaction vessel. The carrier consists of a CNBr-activated cellulose derivative, which can bind at least 3 times more protein than a corresponding paper disk and about 50 times more than can be absorbed by the inner surface of a traditionally coated tube. The system utilizes IgE specific combinations of monoclonal ß-galactosidase conjugated antibodies generating fluorescence by splitting the fluorogenic substrate 4-methylumbelliferyl-ß-D-galactoside to 4-methylumbelliferon.

The assay is calibrated against the World Health Organization reference preparation for IgE 75/502 and includes 2 sets of calibrators: 0.35/0.7/3.5/17.5/50/100 kU/L for specific IgE antibodies and 2/10/50/200/1000/2000/5000 for total IgE.

The evaluation of UniCAP 100 was performed during a time period greater than 1 year (60 assays), using Pharmacia Specific IgE Control, human serum lot no. 13693 for the determination of 12 specific IgE antibodies:

d1 = *Dermatophagoides pteronyssinus* (house dust mite)
d2 = *Dermatophagoides farinae* (house dust mite)
e1 = cat dander
e5 = dog dander
f1 = egg white
g3 = *Dactylis glomerata* (cocksfoot)
g6 = *Phleum pratense* (timothy)
m2 = *Cladosporium herbarum*
t3 = *Betula verrucosa* (common silver birch)
t7 = *Quercus alba* (oak)
w1 = *Ambrosia elatior* (common ragweed)
w6 = *Artemisia vulgaris* (mugwort)

and Pharmacia Total IgE LMH Control, human serum lot nos. 16513, 16514, and 16515 for the determination of total IgE

During the course of the study, we used 8 different lots of standard reagents, 7 different lots of antibody-enzyme conjugate and fluorescence reagents, and between 5 and 10 lots of ImmunoCAP for determination of each species of specific IgE antibodies.

For determination of total IgE, we used 5 different lots of standard reagents, 7 lots of antibody-enzyme conjugate and fluorescence reagents, and 4 lots of total IgE conjugate.

CONCLUSIONS

The results for intra-assay precision (coefficients of variation between 1.4% and 3.3%), inter-assay precision (coefficients of variation between 3.5% and 11.0%), and all results within the stated ranges in the control serum package insert fulfill the requirements for the quality assurance of quantitative determinations in medical laboratories.

UniCAP 100 is ergonomic, easy and quick to perform, robust, precise, and accurate and fits well into laboratory working practices.

It can be recommended for the quantitative measurement of total IgE and specific IgE for *in vitro* allergy diagnosis.

Fig 1. Result plots of specific IgE d1, d2, e1, and e5 (A), f1, g3, g6, and m2 (B), t3, t7, w1, and w6 (C), and total IgE L, M, and H (D) obtained during 1 year and 60 UniCAP 100 assay runs.

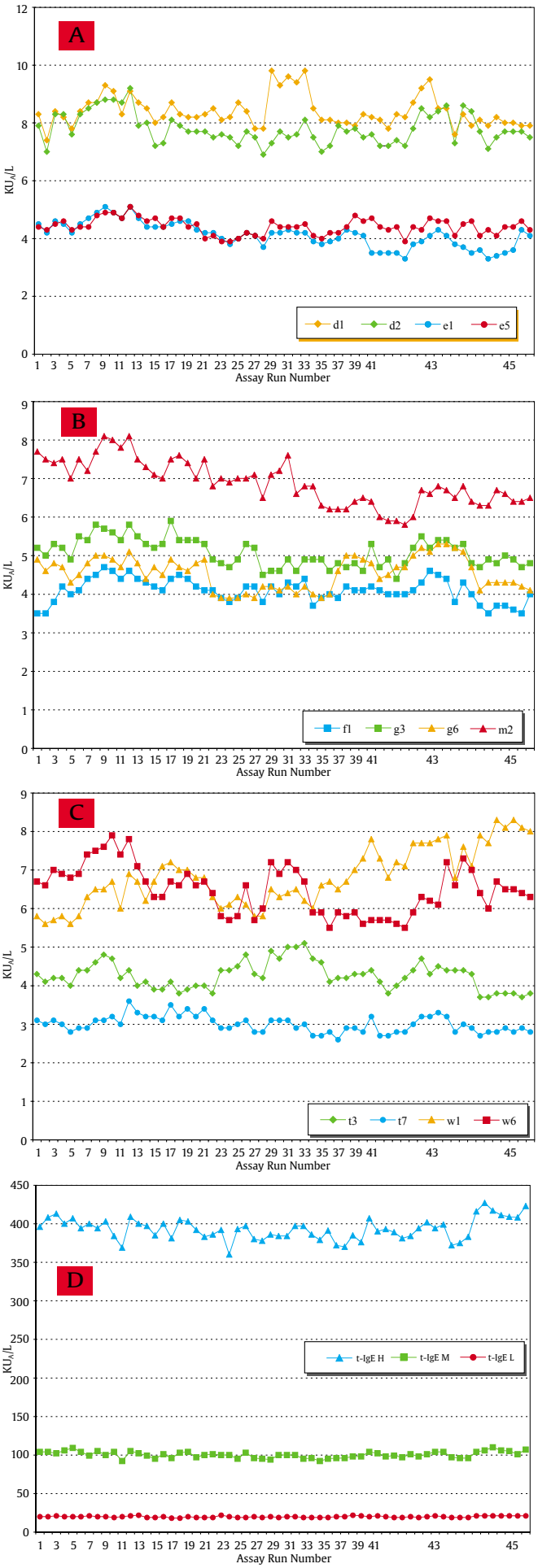

Table 1. Results of the intra-assay precision and accuracy (n=20) of specific IgE antibodies: d1, d2, e1, e5, f1, g3, g6, m2, t3, t7, w1, w6 (control serum lot 13693), and total IgE (control serum lot 16514) obtained by UniCAP 100. Units in kU$_A$/L (specific IgE) and kU/L (total IgE).

$\bar{x}$ = mean value, SD = standard deviation, CV = coefficient of variation, confidence range = valid range given in package insert

	$\bar{x}$	SD	%CV	confidence range
d1	7.49	0.19	2.5	6.2 - 13.0
d2	7.03	0.12	1.7	6.2 - 11.0
e1	3.42	0.11	3.2	3.3 - 6.1
e5	4.27	0.14	3.3	3.1 - 5.7
f1	4.25	0.07	1.7	3.0 - 5.6
g3	5.04	0.10	2.0	4.0 - 7.5
g6	4.22	0.13	3.1	3.7 - 6.8
m2	6.90	0.13	1.9	4.9 - 9.1
t3	4.38	0.14	3.2	3.4 - 6.4
t7	3.85	0.07	1.8	2.5 - 4.6
w1	7.28	0.19	2.6	5.3 - 9.9
w6	7.38	0.15	2.0	5.2 - 9.6
IgE	100.92	1.43	1.4	87.0 - 121.0

Table 2. Results of the inter-assay precision and accuracy (n=60) of specific IgE antibodies: d1, d2, e1, e5, f1, g3, g6, m2, t3, t7, w1, w6 (control serum lot 13693), and total IgE (control serum lots 16513, 16514, 16515) obtained by UniCAP 100 over 1 year. Units in kU$_A$/L (specific IgE) and kU/L (total IgE).

$\bar{x}$ = mean value, SD = standard deviation, CV = coefficient of variation, confidence range = valid range given in package insert

	$\bar{x}$	SD	%CV	confidence range
d1	8.39	0.53	6.3	6.2 - 13.0
d2	7.80	0.52	6.7	6.2 - 11.0
e1	4.12	0.44	10.7	3.3 - 6.1
e5	4.41	0.27	6.1	3.1 - 5.7
f1	4.09	0.30	7.3	3.0 - 5.6
g3	5.07	0.36	7.1	4.0 - 7.5
g6	4.54	0.41	9.0	3.7 - 6.8
m2	6.87	0.60	8.7	4.9 - 9.1
t3	4.25	0.36	8.5	3.4 - 6.4
t7	3.00	0.21	7.0	2.5 - 4.6
w1	6.81	0.75	11.0	5.3 - 9.9
w6	6.49	0.62	9.6	5.2 - 9.6
IgE	19.89	0.96	4.8	18.0 - 24.0
	100.23	4.16	4.2	87.0 - 121.0
	393.13	13.88	3.5	333.0 - 461.0

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