

EVALUATION OF THE NEW IMMUNOCAP™ 250 SYSTEM FOR ALLERGEN SPECIFIC IGE ANTIBODIES

L. Søgård and M. Mondrup

Department of Clinical Biochemistry University Hospital, Roskilde, Denmark

Introduction:

The aim of our study was to evaluate the performance of a new fully automated random access specific IgE system ImmunoCAP™ 250 developed by Pharmacia Diagnostics AB (Uppsala Sweden). We have compared the reported results and performance with those performed on UniCAP® 100 from Pharmacia Diagnostics and IMMULITE 2000 from DPC (Los Angeles USA), as all 3 systems claim calibration against same International Reference Preparation IRP 75/502.

We used the UniCAP®100 as reference method.

Conclusion:

ImmunoCAP™ 250 is an easy, reliable and time-saving system for detection of specific IgE.

In our study it looks like that the systems from Pharmacia Diagnostics and the system from DPC not are measuring the same epitops in the allergens (**fig. 2 + 4 + 5**).

An international recommendation for what should be in the allergens would be desirable from a laboratory point of view.

Results:

Variations of double determinations: 52 serum tests (B) with variable levels of specific IgE to 26 different allergens are analysed in double determination on the same standard calibration curve. (**table 1**).

Interserial spreading: 66 serum tests (A) with variable levels of specific IgE to 13 different allergens are analysed in single determination on two different calibration curves (**table 2**).

Intraseriel spreading: Serum tests with variable levels of specific IgE analysed 10 times in the same serial (**fig. 1 + table 3**).

Table 1.

Variation: duplicats	ImmunoCAP	UniCAP	IMMULITE
n	49	48	24
Pool CV%	3.88	4.02	5.06
Excluded: Result = 0 kU/L	3	2	3
Excluded: Lack of sample	0	2	25
Excluded: Result = 100 kU/L	0	0	0

Table 2.

Interserial variation	ImmunoCAP	UniCAP	IMMULITE
Pool cv%	7.90	9.98	11.11
n	23	33	17
Excluded: Result = 0 kU/L	32	32	35
Excluded: Lack of sample	1	11	10
Excluded: Result = 100 kU/L	0	0	4

Table 3.

Intraseriel variation	mean	cv%
IMMULITE t3a	19.5	9.85
IMMULITE t3b	4.05	7.28
UniCAP d1a	19.64	3.67
UniCAP d1b	4.59	3.31
UniCAP g6a	29.56	4.03
UniCAP g6b	6.72	2.78
UniCAP g6c	3.46	2.3
ImmunoCAP d1c	65.69	5.65
ImmunoCAP d1d	35.98	3.44
ImmunoCAP d1e	8.6	4.44
ImmunoCAP d1f	1.99	4.41
ImmunoCAP g6d	55.07	3.77
ImmunoCAP g6e	15.47	3.09
ImmunoCAP g6c	3.68	2.63

Table 4.

Control from Pharmacia						
allergen	ImmunoCAP	UniCAP	IMMULITE	mean	sd	cv%
d1	18.58	19.96	27.10	21.88	3.74	17.08
d2	12.94	14.05	18.88	15.29	2.58	16.85
f1	7.28	7.67	31.38	15.44	11.27	72.97
w6	8.95	9.27	17.05	11.76	3.74	31.84
n	12	16	4			
Control from DPC						
allergen	ImmunoCAP	UniCAP	IMMULITE	mean	sd	cv%
m6	3.73	4.65	4.88	4.42	0.50	11.30
d1	1.27	1.52	2.31	1.70	0.44	25.99
d2	1.17	1.42	2.61	1.73	0.63	36.45
n	2	2	5.00			
Calibration control from DPC						
a-IgE	ImmunoCAP	UniCAP	IMMULITE	mean	sd	cv%
level 1	1.78	1.98	2.03	1.93	0.11	5.60
level2	8.16	8.85	9.41	8.81	0.51	5.82
n	2	2	7			

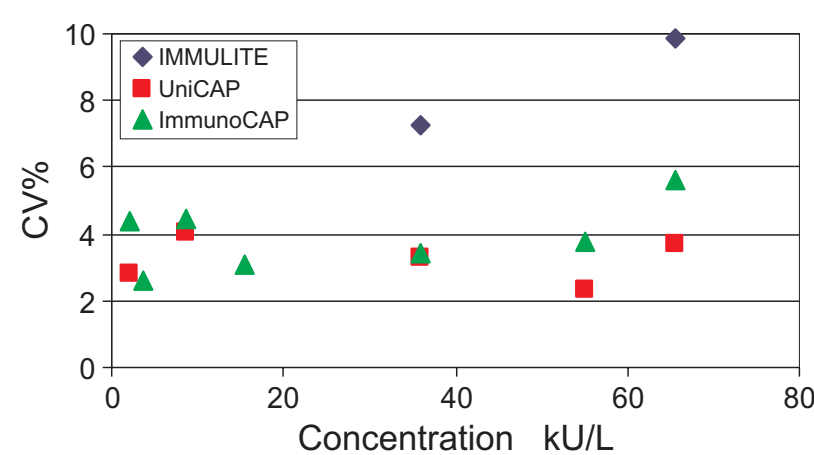


Figure 1. Intraseriel variation.

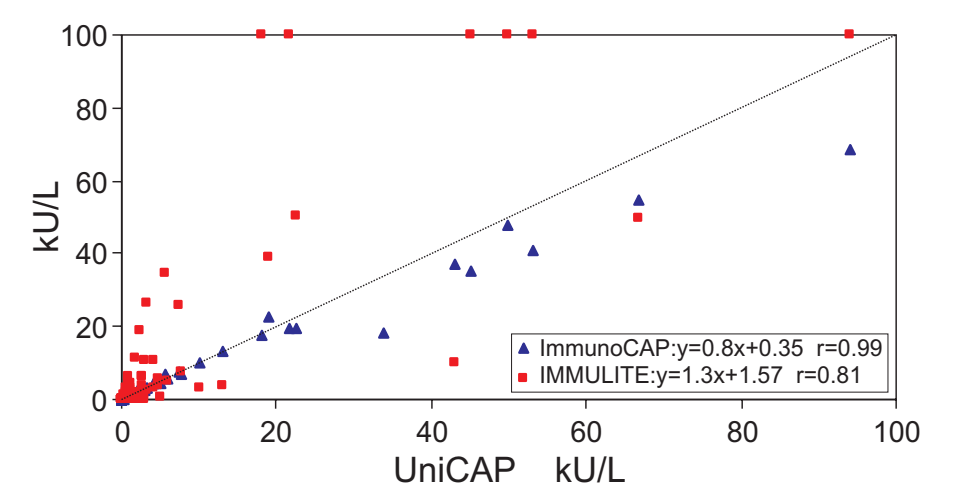


Figure 2. Correlation between Methods.

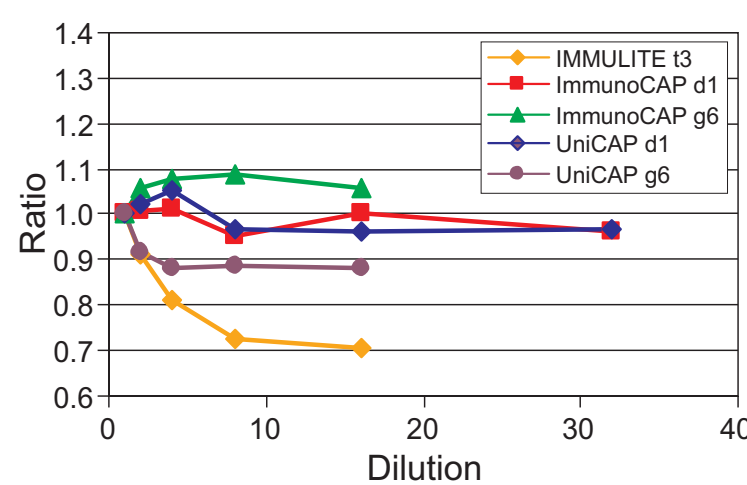


Figure 3. Linearity.

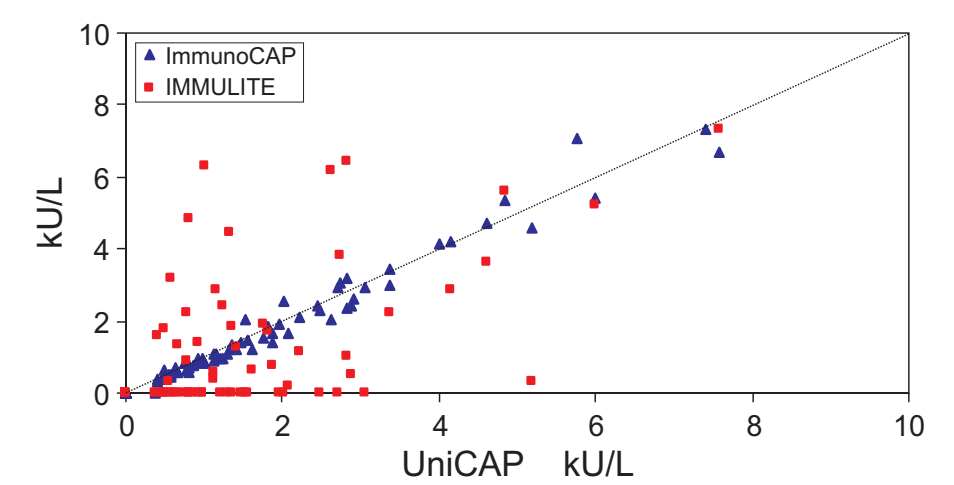


Figure 4. Correlation between Methods (0 til 10 kU/L).

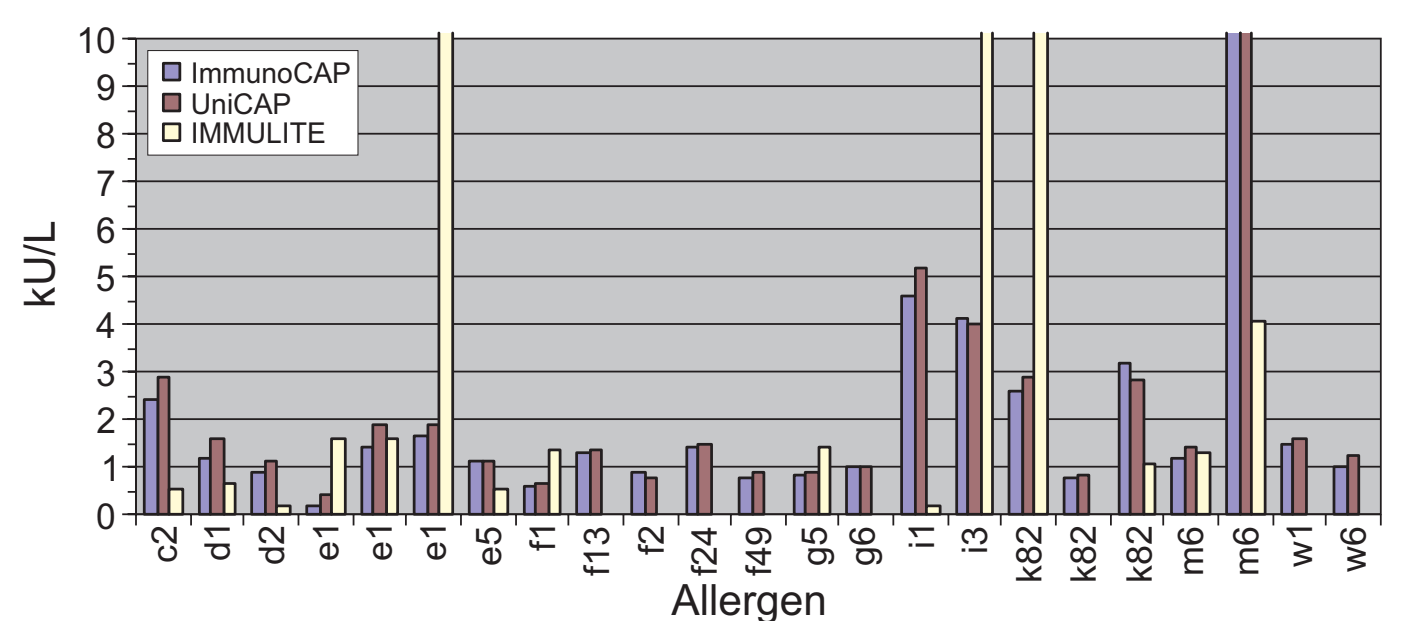


Figure 5. Correlation.

Methods:

The ImmunoCAP™ 250 is based on the well-known ImmunoCAP™ solid phase technology. Allergens are covalent coupled to a high capacity flexible hydrophilic cellulose-derivate encased in a capsule. The enzyme labelled tracer gives a fluorescence eluate, and the responses are measured with the in-build fluorometer.

The UniCAP® 100 is based on the same principle.

IMMULITE 2000 Third Generation Allergen-Specific IgE is a solid-phase, two-step chemiluminescence immunoassay that exploits liquid phase kinetics in a bead format.

Materials:

The test material we have chosen to analyse is serum from patients suspected from atopi(A) and patients, who are referred to specialists of lung diseases and allergy under suspicion of asthma(B), some of these patients(B) have had skin prick test too. The allergens involved appear in table1. By choosing test material from these groups of patients we got a more equal representation of positive and negative test than if we have chosen the normal population, and by it minimize the bias of preponderance of negative test. We have chosen to define results < 0.35 kU/L as 0 kU/L and results > 100 kU/L as 100 kU/L.