

### AIM of the study

To evaluate in a prospective study the diagnostic performance of the Immulite 2000 System for the detection of total IgE, AlaTOP inhalant allergy screen and specific IgE in comparison with the UniCAP 100 routinely utilized in our laboratory

### MATERIALS AND METHODS

During a 3 months period, all serum samples from patients who were referred to the allergist for a suspected allergic disease were prospectively analyzed in parallel with both systems, according to the physician's request.

The two major immunoassay systems widely accepted and used in the clinical laboratories were tested.

The fully automated random-access analyzer **Immunité 2000** (DPC Los Angeles, CA; commercialized in Switzerland by Bühlmann Laboratories AG, Basel) based on the two-steps chemiluminescent immunoassay technique employs liquid allergen techniques. The allergens, in liquid phase, are covalently bound to a soluble biotinylated matrix. In the first step, patient serum, allergen and streptavidine coated beads are incubated together for 30' on constant agitation. After washing, alkaline phosphatase-labeled monoclonal antibody specific for human IgE is added is for 30'.(fig.1). The beads are washed again and the enzyme label is measured with a chemi-luminescent substrate.



Figure 1 Principle of the specific IgE assay on the Immulite 2000

In the semi-automated **UniCAP 100** analyzer (Phadia, Sweden) based on fluoroenzymometric assays, the allergens are covalently coupled into a high capacity flexible hydrophilic carrier polymer matrix (ImmunoCAP technology).

All assays were performed according to the instructions in their respective package inserts.

### RESULTS :

#### 1 Total IgE (n = 199)

Comparison of total IgE – correlation of Immulite 2000 vs UniCAP 100

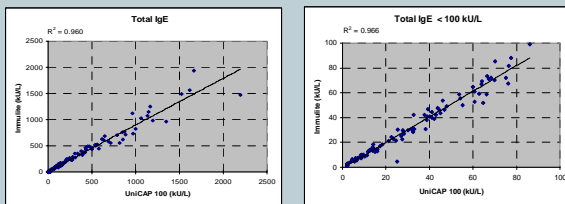


Figure 2 Total IgE correlation between Immulite 2000 and UniCAP 100. From the 199 samples tested, 98 had values under 100 kU/L. Measurement of total IgE in 199 individual patient sera yielded virtually similar results on both immunoassays.

#### 2 Allergy screen (AlaTOP) (n = 122)

Immunité 2000 AlaTOP		UniCAP 100 Phadiatop		83
		Negative	Positive	
No Reactive	76	7*	83	
Reactive	1***	26	27	
Undetermined	2	6**	8	
	79	39	118	

\* These results correspond to 5 serum samples (1 tested in triplicate), 3 of 5 have a clinical allergy history  
 \*\* These results correspond to 3 serum samples, each with a clinical allergy history  
 \*\*\* This serum sample belongs to a patient without respiratory symptoms  
 Comparing the in vitro results of both methods with available clinical data of the patient's history reflects a lower sensitivity and specificity of the AlaTOP.

#### 3 Specific IgE (n=751)

Allergens frequency : the 21 most frequent allergens requested

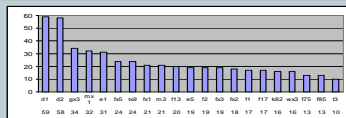


Figure 3 114 different allergens have been tested during the 3 months period of the study, 21 of them have been asked more than 10 times

#### 3 Specific IgE (continued)

Results dispatched according to the classes of positivity

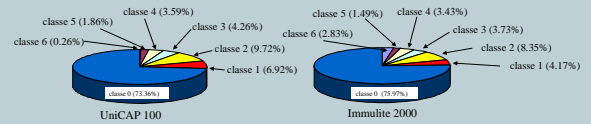


Figure 4 Percentage of results in class 6 is higher with Immulite 2000 than with UniCAP 100 (2.83 % versus 0.26%) whereas more results are detected in class 1 with UniCAP 100 (6.92% versus 4.17%)

Comparison of specific IgE for results < 3.5 kU/L

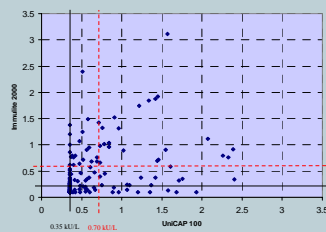
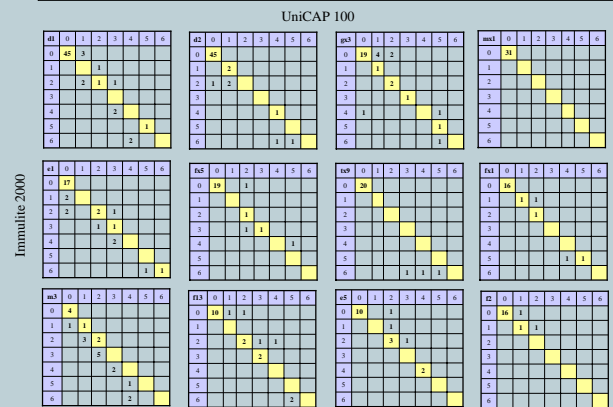


Figure 5 Repartition of the negative (<0.35 kU/L), doubtful (class 1: between 0.35 and 0.70 kU/L) and positive results (class 2: between 0.70 and 3.5 kU/L)

allergen	UniCAP + / Immulite -		allergen	UniCAP - / Immulite +	
	n =	class		n =	class
fx1	1	2/1	gx3	1	0/1
fx2	1	3/0	at1	2	1/2
fx5	1	2/0	at2	3	1/2 (2x)
gx3	2	2/0	e1	2	0/2
wx3	2	2/0	e2	1	0/2
d1	1	2/1	f1	1	0/2
e2	1	2/1	f17	3	1/2
e5	2	2/0	f75	2	0/2
f13	1	2/0	it5	2	1/2
f14	1	2/0	it5	2	1/2
f17	1	2/0	w9	1	1/2
it	2	2/0			
it5	1	2/0			
w6	1	2/1			
f31	3	2/0			
v7	1	2/0			
it3	1	2/1			

Table 1 Repartition of the UniCAP positive vs Immulite negative and UniCAP negative vs Immulite positive results with differences in class scores between the two immunoassays. A total of 47 discrepancy results were found (8% of the serum samples analyzed)

Agreement on class scores per individual allergens for the 12 most frequently requested allergens



UniCAP	False negative		False positive	
	n =	allergen	n =	allergen
2	gx3; e1	2	f14; wx3	
7	fx2; f17; gx3 (2x); fx5; f13; it5	3	e2; d2; e1	

Table 2 Repartition of the proven false negative and false positive results. Compared with the skin prick tests and the patient's clinical history data, we observed slightly more false negative and false positive results with the Immulite than with UniCAP system

Measuring the specific IgE levels to 33 allergens, which corresponds to 577 tests (tested more than 5 times) we observed a high agreement of both systems, with more than 79% of identical results, 94% within 1 class and 99.3% within 2 classes

### CONCLUSIONS :

We found a good overall agreement of both systems. Our data support that Immulite 2000 is a useful in vitro diagnostic tool

**Total IgE :** A very good agreement of both systems for total IgE was observed.

**Inhalant allergic screening:** The Phadiatop performs with a better specificity and sensitivity than the AlaTOP.

**Specific IgE :** We observed 100 % concordance with 4 allergens (mx1 n=31, f37 n=6 and t4 n=5). A significant discordance (more than 2 class scores) was observed for 4 sera (allergens gx3, tx9, fx2 and f75). In 29 sera we observed a 2 class scores discordance between the 2 systems (main allergens involved: f1 n=3; d1 n=2; d2 n=2; gx3 n=2; e1 n=2; m3 n=2; f13 n=2; wx3 n=2).

Even if the overall agreement is good, with more than 79% of identical results, 47/577 results (24 UniCAP positive and 23 UniCAP negative (8%)) could not be confirmed with the Immulite 2000. Our data demonstrated that during the 3 months period of the study, the DPC allergens panel did not cover the full range of the physician's requested allergens (12 not available allergens have been asked corresponding to 23 requests)