



A Customer's Experience in Routine Allergy Testing with IMMULITE® 2000 Allergy

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IMMULITE® 2000 Allergy had already caught the interest of City Laboratory in Hamburg, Germany before the system was even launched. Caught in the throes of an increasingly competitive business environment, the laboratory was actively seeking ways to reduce costs and increase laboratory efficiency, particularly for allergy testing. Upon learning that DPC was planning to release IMMULITE 2000 Allergy, City Laboratory looked forward to the possibility of consolidating its three allergy analyzers, which utilized two platforms. A system was immediately obtained for evaluation after the September 2001 launch, and test results indicated that the existing instruments and IMMULITE 2000 Allergy provided equivalent analytical quality. Since the installation, IMMULITE 2000 Allergy has enabled City Laboratory to consolidate its workstations and significantly decrease hands-on time for personnel. It reports tremendous improvements in productivity, high clinician acceptance and great DPC service and support.

Founded in 1949, City Laboratory is a privately owned facility. Since the late 1990s, the laboratory has been implementing cost-cutting measures and making operational improvements to cope with the increasingly difficult business climate affecting laboratory medicine in Germany.

Prior to installing the IMMULITE 2000 Allergy system, the laboratory was using two different platforms: a Centaur® (Bayer) for total IgE testing and two CAP systems (Pharmacia) for specific IgE testing. This system configuration required a great deal of manual labor for both the preanalytical and analytical phases, including such tasks as dividing samples, pipetting and organizing jobs into batches. In addition, this configuration also required large amounts of refrigerated storage and work space.

Management arranged for an in-house evaluation of IMMULITE 2000 Allergy, with the expectation that the system would enable the laboratory to achieve the following goals:

- Fully automate at least 85 percent of all requests for total and specific IgE
- Implement real workstation consolidation by reducing the number of instruments
- Test total and specific IgE on the same system
- Reduce hands-on time for personnel
- Increase overall productivity
- Validate the analytical/diagnostic quality.

List of all allergens switched to DPC IMMULITE 2000

Group	Allergens
Specials	C204, K82
Mites	D1, D2, D3, D70
Animals	EP1, E1, E2, E3, E5, E6, E70, E78, E82, E86
Food	FP1, FP2, FP3, FP5, F1, F2, F3, F4, F5, F13, F14, F17, F20, F25, F31, F33, F35, F44, F45, F49, F75, F77, F78, F79, F84, F92, F96, F208, F256
Grasses/Cereals	GP1, GP2, GP3, GP4, G3, G4, G8, G12, G13, G14, G15, G16
Dust	HP1, H1, H2
Insects	I1, I3, I71
Molds	MP1, M1, M2, M3, M4, M5, M6
Tree pollens	TP1, TP5, TP6, T2, T3, T4, T5, T7
Weed pollens	WP5, W6, W9

Table 1.

Mixtures/panels switched to DPC IMMULITE 2000

Panel	Allergens
EP1	E1, E3, E4, E5
FP1	F13, F17, F18, F20, F36
FP2	F3, F24, F37, F40, F41
FP3	F4, F7, F8, F10, F11
FP5	F1, F2, F3, F4, F13, F14
GP1	G3, G4, G5, G6, G8
GP2	G2, G5, G6, G8, G10, G17
GP3	G1, G5, G6, G12, G13
GP4	G1, G5, G7, G12, G13
HP1	H1, D1, D2, I6
MP1	M1, M2, M3, M5, M6
TP1	T1, T3, T7, T8, T10
TP5	T2, T4, T8, T12, T14
TP6	T1, T3, T5, T7, T10
WP5	W1, W6, W7, W8, W12

Table 2.

A master plan for validation was developed according to ISO/IEC 17025 and GLP/GMP standards, and an easy problem-free IMMULITE 2000 Allergy installation followed. Full training was not necessary in this case, as the laboratory was already using an IMMULITE 2000 for tumor marker, thyroid antibody and some infectious disease testing.

Validation of samples for total and specific IgE occurred in two phases and compared IMMULITE 2000 Allergy performance to that of the laboratory's existing methods. A total of 242 paired results for allergen mixtures/panels demonstrated nearly 90% agreement between IMMULITE 2000 Allergy and UniCAP®.

		Pharmacia		
		(242)	-	+
DPC	-	87	11	
	+	15	129	
		Mixtures/panels		
		89.3% agreement		

Table 3.

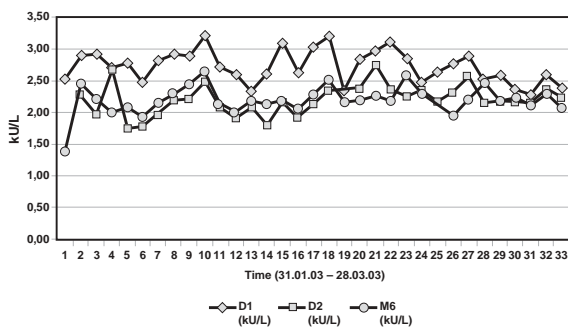
Most of the discrepancies occurred at lower IgE concentrations: between 1 and 3 kU/L on IMMULITE 2000 Allergy, and < 0.35 kU/L on UniCAP.

A total of 862 samples were tested with 68 single allergens. Results demonstrated a 76% exact concordance of classes, 92% total concordance within 1 class and 98% total concordance within 2 classes. Of the negative results (Class 0), 69% occurred in the same sample on both systems. Although this figure seems fairly high, a large number of positive results was not necessarily expected, as samples were drawn in late winter, early spring and early summer, when certain seasonal allergen counts tend to be low.

An analysis of the discrepancies showed that only 16 out of the 862 samples (2%) were discrepant (± 2 classes). Interpretation of discrepancies was not possible due to a lack of clinical information in most of the cases.

IMMULITE 2000 Allergy reagents D1, D2 and M6 underwent a 2-month testing period, during which stability for all three remained good (Figure 1). Internal quality control for this same period demonstrated CVs of 8.8% for D1 and 10.6% for both D2 and M6. These CVs were comparable to those of UniCAP, if not better in some cases (Table 4).

IMMULITE 2000 Allergy Internal QC (daily controls, supplied by DPC, second period)



Period	D1		D2		M6		n
	M ± SD	CV (%)	M ± SD	CV (%)	M ± SD	CV (%)	
31.01.–28.03.	2.7 ± 0.2	8.8	2.2 ± 0.2	10.6	2.2 ± 0.2	10.6	35

Figure 1.

Pharmacia CAP Internal QC (daily controls, supplied by Pharmacia)

Period	D1		D2		E6		n
	M ± SD	CV (%)	M ± SD	CV (%)	M ± SD	CV (%)	
18.03.–11.10.	8.8 ± 1.2	13.6	5.8 ± 0.6	10.1	5.4 ± 0.7	13.9	52

Table 4.

In addition, linearity studies of IMMULITE 2000 Allergy produced acceptable recovery results on two samples under six dilutions ranging from 1:1 to 1:32.

Linearity of IMMULITE 2000 Allergy (samples from daily routine, diluted with negative serum)

Allergen D2			
Dilution (1:x)	Value	Calculated	Recovery (%)
1	20.70	20.70	100.00%
2	9.46	18.92	91.40%
4	4.54	18.16	87.73%
8	2.13	17.04	82.32%
16	1.05	16.80	81.16%
32	0.44	14.08	68.02%

Allergen T3			
Dilution (1:x)	Value	Calculated	Recovery (%)
1	30.30	30.30	100.00%
2	13.30	26.60	87.79%
4	6.21	24.84	81.98%
8	3.01	24.08	79.47%
16	1.57	25.12	82.90%
32	0.87	27.84	91.88%

Table 5.

A regression analysis comparing total IgE results for IMMULITE 2000 Allergy and the Centaur demonstrated good agreement.

Comparison of total IgE between BAYER CENTAUR and DPC IMMULITE 2000 Allergy

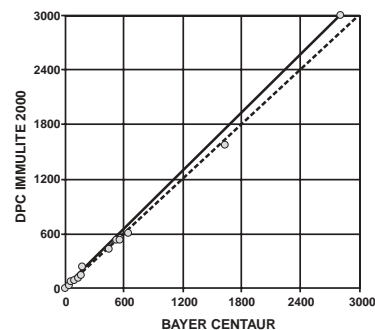


Figure 2.

At concentrations of 0 to 50 kU/L, IMMULITE 2000 Allergy measured slightly higher, while levels over 50 kU/L were in total agreement. These results, as well as the rest of the method evaluation findings, confirmed that IMMULITE 2000 Allergy provided equivalent analytical quality for total IgE and specific IgE testing, when compared to the existing systems.

At this point, all laboratory referring physicians and laboratories were informed of the intent to change methods. They were provided with evaluation results from the laboratory, as well as from beta sites, and given a timeline for the changeover period and training. IMMULITE 2000 Allergy was then officially incorporated into City Laboratory's instrumentation, and a reorganization of all workflow processes ensued. Some of the workflow changes included the following:

- Reduction in the number of aliquots drawn from the primary tube (only one now required)
- Consolidation of more than 95 percent of the laboratory's allergy testing (allergens with more than 20 requests per year) on IMMULITE 2000 Allergy (Tables 1 and 2)
- Considerable reduction in hands-on time, as the IMMULITE 2000 Allergy system is now conveniently located beside the other IMMULITE 2000 and clinical chemistry instruments
- Continuous sample analysis throughout the business day, providing physicians with mostly same-day or early next-day results.

Conclusion

Besides its impressive analytical results, IMMULITE 2000 Allergy has provided City Laboratory with real workstation consolidation and greatly improved productivity, without any complaints from customers. While the laboratory has suggestions for further product automation, it has found the instrument handling to be comparable to any other random access system.

