



IMMULITE® 2000 Allergy Results In a Dutch Quality Control Survey

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In the spring of 2002, a Dutch Quality Control Survey revealed a large variation in IMMULITE® 2000 Allergy results. This surprising discovery prompted an investigative study among IMMULITE 2000 Allergy users in The Netherlands. The study demonstrated a very good interlaboratory coefficient of variation (%CV) for IMMULITE 2000 Allergy results on a serum pool, with the exception of four laboratories that reported discrepant results. The discrepancies were easily accounted for and traced to two main causes: clerical errors, from filling in survey data sheets by hand; and inadequate system maintenance. The findings of this study suggest that the variations indicated in the Dutch Quality Control Survey of last spring were due to similar causes, unassociated with the actual performance of IMMULITE 2000 Allergy.

The Dutch Quality Control Survey is performed in several rounds each year. During the time the discrepancies occurred, results of two consecutive rounds (which included cow's milk, allergen F2) were all positive, but varied over a wide range of units and differed by four classes.

Prior to 2003, samples used in these Dutch surveys were obtained from the British Quality Control Survey. We (the coordinators of the IMMULITE 2000 Allergy investigative study) were unable to determine the matrix of the British samples; however, it was obviously not serum. Consequently, samples for this investigative study were collected from Dutch laboratories instead. Sera collected by several laboratories were positive for F2, and the entire pool contained specific IgE for most of the routinely tested inhalant and food allergens run in Dutch laboratories. Twenty-two laboratories measured specific IgE for allergens in this pool on the IMMULITE 2000 Allergy system.

Individual allergen results were reported in kU/L, while AlaTOP® was reported as a ratio of the sample to the mean adjustor. All results were sent directly from the laboratories to an independent investigator for tabulation.

Laboratory participation was as follows:

- Nineteen laboratories ran all requested allergens.
- Three laboratories ran some, but not all, allergens, as they did not routinely run every requested allergen on the IMMULITE 2000 Allergy system. (Some were still using the original IMMULITE for part of their allergy testing.)
- One laboratory had evaluated the IMMULITE 2000, but the instrument was not in routine use.

The initial report indicated some discrepant results, which were accounted for and corrected (Figure 1). The discrepant results originated in four laboratories. After requesting the raw data from these facilities, we discovered that two of the laboratories had overlooked clerical errors. One laboratory made several mistakes when filling in the data sheets, while another applied an incorrect ratio when calculating the AlaTOP result.

The other two laboratories had not observed proper instrument maintenance recommendations. In the case of one facility, the origin of the discrepant results was attributable to reagents that had been exposed to excessively high temperatures. The remaining laboratory, which reported discrepant results for GP1 and E1, was in the process of evaluating IMMULITE 2000 Allergy. The system, however, was not in routine use and had not been run for several weeks prior to the testing for the study. After the instrument was checked and serviced, samples were retested. This time, the results were in range.

After these corrections were made, an organized report was achieved, with results from all laboratories congregating within a specific concentration range or class segment for each allergen, as well as for AlaTOP (Figure 2).

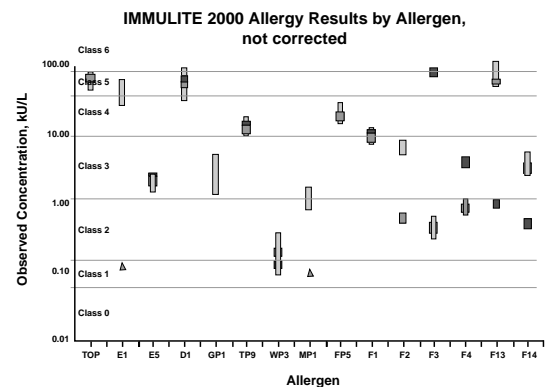


Figure 1.

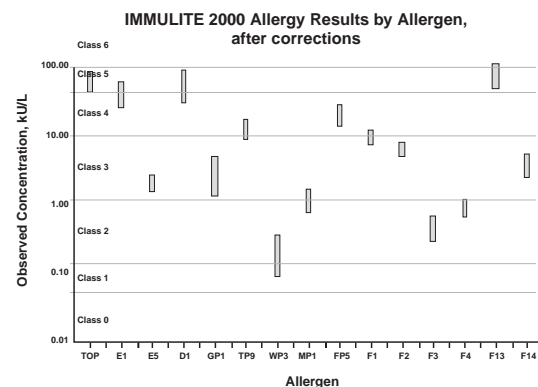


Figure 2.

Interlaboratory precision—IMMULITE 2000 Allergens

	TOP	E1	E5	D1	GP1	TP9	WP3	MP1
	ratio	kU/L	kU/L	kU/L	kU/L	kU/L	kU/L	kU/L
Mean:	58.33	36.28	2.02	48.53	2.53	11.67	0.17	1.15
SD:	7.45	5.41	0.15	10.76	0.74	1.39	0.06	0.13
%CV:	12.8	14.9	7.3	22.2	29.2	11.9	35.3	11.6
N:	21	20	20	20	21	18	20	21

	FP5	F1	F2	F2 corr.	F3	F4	F13	F14
	kU/L	kU/L	kU/L	kU/L	kU/L	kU/L	kU/L	kU/L
Mean:	17.99	9.14	5.89	6.16	0.44	0.86	69.83	3.41
SD:	2.30	0.55	1.31	0.50	0.60	0.08	10.41	0.41
%CV:	12.8	6.0	22.3	8.1	12.9	9.0	14.9	12.1
N:	21	21	21	21	21	21	21	21

Table 1.

Interlaboratory precision results demonstrated CVs below 20% in most cases (Table 1). The precision profile of the results for all 22 laboratories (Figure 3), also indicating CVs mostly below 20%, was very similar to the precision profile obtained during the NCCLS validation of IMMULITE 2000 Allergy.

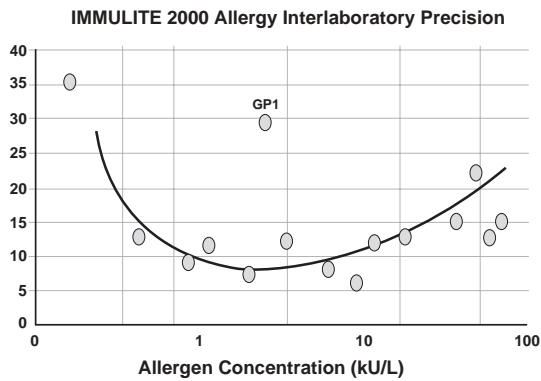


Figure 3.

Findings of this study confirm that the interlaboratory CVs for the most often used IMMULITE 2000 Allergy tests (in The Netherlands) on a serum pool are very good. It is apparent, however, that clerical errors still remain a problem in quality control surveys, especially when forms must be filled in by hand. In addition, it is important to note that after one week or more of non-use, the IMMULITE 2000 Allergy system requires proper maintenance by DPC service engineers to ensure the best possible performance. Bearing these issues in mind, users of IMMULITE 2000 Allergy can be assured of excellent precision in their results.