Production of External Quality Assessment Materials for Allergy Specific IgE Assay

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Introduction

Accurate identification of specific immunoglobulin E (sIgE) is crucial for diagnosing and managing various allergic diseases. In Korea, the use of sIgE immunoassays for allergic disease diagnosis has surged, highlighting the need for robust external quality assessment (EQA) to standardize these assays.

Aim

This study aimed to produce sIgE QC materials for an EQA program and assess their homogeneity and stability.

Methods

Subjects

840 residual serum samples were collected after the completion of allergy sIgE tests for patients referred to the SCL (Seoul Clinical Laboratories). This study was conducted after obtaining approval from the Institutional Review Board of the SCL (Approval No. SCL IRB 22-004).

Preparation of EQA materials

The samples were categorized into five groups based on various allergy sIgE concentration. The samples were frozen (-20° C) until the production of quality control materials.

The individually frozen serum samples were thawed and mixed within each of the five concentration groups, and filtered through sterile gauze to remove fibrous components.

Five different concentrations of pooled sera were screened by the AdvanSure MAST 108 assay (LG Life Science, Korea) and the ImmunoCAP® (Thermo-Fisher, Waltham, MA, USA) to select target allergy sIgE items.

The produced quality control materials were dispensed into sterile 2.0 mL Cryogenic vials (Corning Life Science, Corning, NY, USA) in 1.0 mL aliquots, sealed with caps, covered with paraffin film, and frozen again (-20°C) for storage.

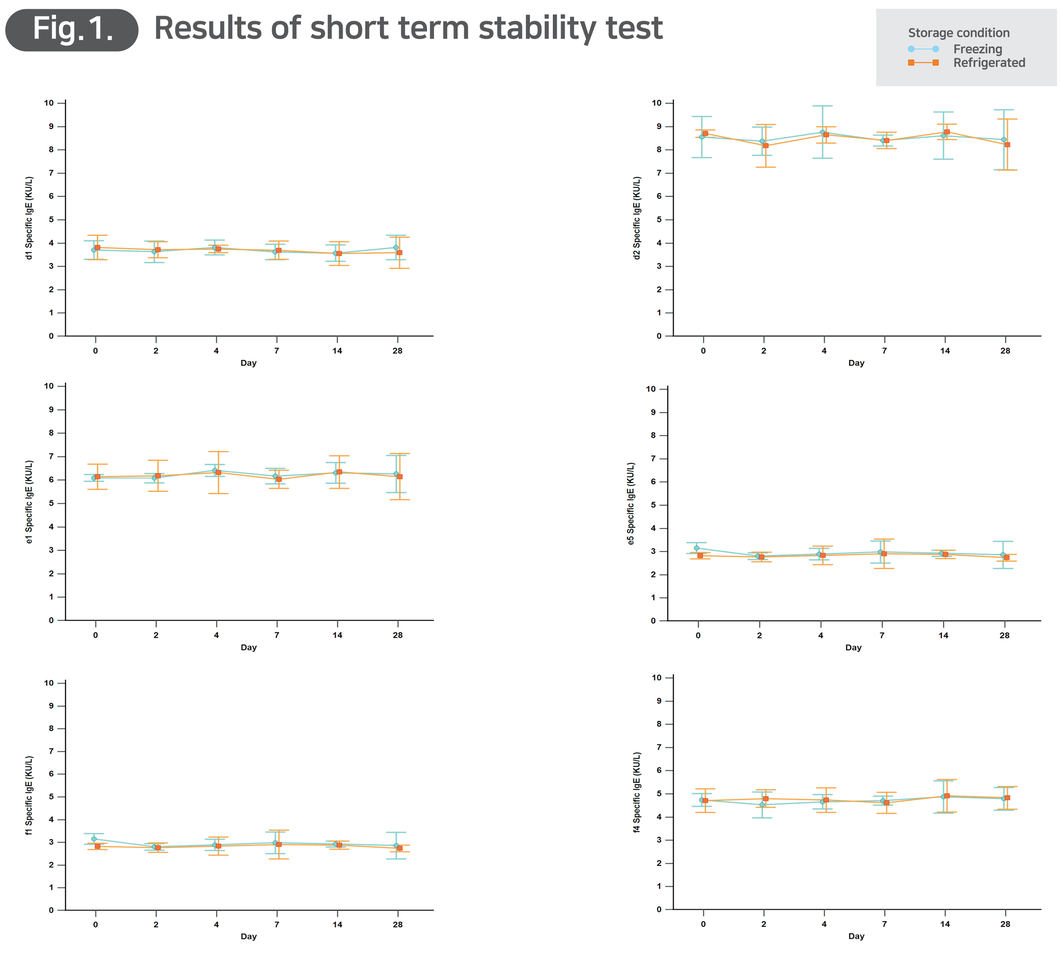
Validation of produced survey materials

These produced materials were evaluated for homogeneity between vials and stability (after two, four, seven, 14, and 28 days at 4℃ and -80℃) using the ImmunoCAP® assay.

Results

- The total coefficient of variation of allergy sIgE QC materials across the different concentrations ranged from 2.10% to 7.92%.
- Short-term stability analysis indicated that the three sIgE QC materials for six assays remained stable for up to 28 days under both refrigerated and frozen condition (Fig.1.).
- No significant inhomogeneity was noted between vials, confirming no significant inhomogeneity (Table 1).

Fig.1. Results of short term stability test



Analyzed by Dunnett against a control comparisons using MedCalc® Statistical Software ver. 22.016.
d1, *Dermatophagoides pteronyssinus* ; d2, *Dermatophagoides farinae* ; e1, Cat dander ; e5, Dog dander ; f1, Egg white ; f4, Wheat.

Table 1. Results of homogeneity test

No	Specific IgE		Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	Vial 9	Vial 10	Mean (KU/L)	SD (KU/L)	CV (%)
01	f1 N=3	Mean (KU/L)	6.65	6.80	6.45	6.57	7.00	6.48	6.85	6.78	6.72	6.89			
		SD (KU/L)	0.49	0.12	0.23	0.30	0.22	0.51	0.39	0.46	0.44	0.30	6.72	0.35	5.24
		CV (%)	7.43	1.80	3.58	4.60	3.19	7.81	5.75	6.78	6.51	4.36			
	f4 N=3	Mean (KU/L)	5.11	5.25	5.20	4.92	5.17	5.14	4.92	5.12	5.11	5.02			
		SD (KU/L)	0.27	0.13	0.03	0.21	0.16	0.22	0.28	0.13	0.24	0.29	5.10	0.21	4.05
		CV (%)	5.32	2.48	0.62	4.17	3.12	4.35	5.72	2.62	4.67	5.84			
02	d1 N=3	Mean (KU/L)	4.21	4.18	4.59	4.53	4.34	4.33	4.46	4.43	4.52	4.08			
		SD (KU/L)	0.29	0.38	0.35	0.33	0.42	0.37	0.19	0.36	0.31	0.37	4.37	0.33	7.48
		CV (%)	6.77	9.03	7.52	7.34	9.62	8.57	4.30	8.01	6.85	9.03			
	d2 N=3	Mean (KU/L)	9.24	9.49	9.49	9.56	9.91	9.28	9.55	9.55	9.92	9.63			
		SD (KU/L)	0.39	0.48	0.43	0.83	0.70	0.38	0.38	0.48	0.93	0.84	9.56	0.56	5.83
		CV (%)	4.19	5.09	4.54	8.63	7.05	4.09	3.98	5.07	9.33	8.77			
03	e1 N=3	Mean (KU/L)	6.41	6.24	6.33	6.30	6.38	6.32	6.30	6.38	6.25	6.29			
		SD (KU/L)	0.18	0.13	0.29	0.06	0.09	0.33	0.13	0.27	0.12	0.17	6.32	0.17	2.73
		CV (%)	2.81	2.07	4.54	0.92	1.35	5.29	2.09	4.22	1.92	2.71			
	e5 N=3	Mean (KU/L)	3.53	3.54	3.50	3.35	3.55	3.52	3.51	3.44	3.41	3.34			
		SD (KU/L)	0.07	0.09	0.19	0.12	0.03	0.09	0.03	0.10	0.10	0.16	3.47	0.12	3.39
		CV (%)	1.98	2.41	5.36	3.44	0.75	2.48	0.99	2.94	2.86	4.71			

Analyzed by ANOVA using MedCalc® Statistical Software ver. 22.016.
f1, Egg white ; f4, Wheat ; d1, *Dermatophagoides pteronyssinus* ; d2, *Dermatophagoides farinae* ; e1, Cat dander ; e5, Dog dander.

Conclusion

The sIgE QC materials, derived from remnant sera, demonstrated homogeneity between vials and stability for at least 28 days under refrigerated and frozen conditions. These findings have practical implications for the production of sIgE EQA materials.

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