



Background and Aim

Many allergies are mediated by immunoglobulins of the IgE class. In sensitized individuals suffering from this immediate (atopic or anaphylactic) type of allergy, IgE molecules act as points of contact between the allergen and specialized cells that release histamine and other agents upon exposure to the allergen. This initiates the events which we recognize as allergic reactions. When evaluated in the light of other clinical and laboratory findings, *in vitro* allergen-specific IgE tests can help the physician identify the allergen(s) to which an individual is sensitized.

The aim of this study was to determine levels of allergen-specific IgE in commercially available immunoassay controls. To this end, the Bio-Rad Lyphocheck® Immunoassay Plus Control, Trilevel MiniPak #370, levels 1, 2, and 3, lot 40220, were analyzed in the Siemens 3gAllergy™ Specific IgE assay using six inhalant specific allergens: Dermatophagoides pteronyssinus (D1L4), Dermatophagoides farinae (D2L4), Cat Dander-Epithelium (E1L4), Orchard Grass (G3L4), Timothy Grass (G6L4), and Birch (T3L4). This white paper summarizes the means and ranges determined by testing this commercially available control with the Siemens 3gAllergy Specific IgE assay on both the IMMULITE® 2000 and IMMULITE® 2500 systems.

Materials and Methods

Lyphocheck Immunoassay Plus Control, MiniPak #370 were obtained from Bio-Rad Laboratories, Inc. Level 1 (40221), level 2 (40222), and level 3 (40223) were reconstituted per the manufacturer's package insert instructions using 5.0 mL distilled water per vial. The controls were equilibrated by standing at 15°C–25°C for 15 minutes before analysis. Controls were reconstituted immediately prior to testing for value assignment and assayed as patient specimens. Testing was performed as specified in the Siemens 3gAllergy Specific IgE package insert. Controls, like patient samples, should be stored at –20°C for long-term storage.

The mean values and ranges reported here were derived from replicate analysis (N = 110 per control level) and are specific for this lot of controls. Values and ranges were determined for the following six inhalant allergens: Dermatophagoides pteronyssinus (D1L4), Dermatophagoides farinae (D2L4), Cat Dander-Epithelium (E1L4), Orchard Grass (G3L4), Timothy Grass (G6L4), and Birch (T3L4). It is recommended that each laboratory establish its own means and acceptable ranges and use those provided as guidelines only.

Allergen specificity toward each control level was verified through competitive inhibition

Use of Bio-Rad Lyphocheck Immunoassay Plus Control, Trilevel MiniPak #370X in the Siemens 3gAllergy Specific IgE Assays

Debra Hovanec-Burns, Tom Chuang, and Susan Maldonado

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studies. These studies were performed by incubating 250 µL of each control with 70 µL of inhibitor extract at a concentration of 5 mg/mL. The mixture was incubated at 15°C–25°C with shaking for 1 hour, allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and appropriate control was assayed. The percent inhibition was calculated according to the following formula:

$$\left(\frac{\text{Response of pos. control (pos. sample - neg. sample)} - \text{sample response with inhibitor extract}}{\text{Response of pos. control (pos. sample - neg. sample)}} \right) \times 100$$

Conclusions

In this study, using the Siemens IMMULITE 2000 and IMMULITE 2500 3gAllergy Specific IgE assays, the presence of specific IgE for 6 specific allergens (D1, D2, E1, G3, G6, and T3) was demonstrated in the commercially available Bio-Rad Lyphocheck Immunoassay Plus Control, Trilevel MiniPak #370, levels 1, 2, and 3, lot 40220. The specificity of the reactivity to the specific allergens was confirmed by competitive inhibition studies; greater than 93% inhibition was obtained for each of the allergens evaluated.

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Results

Table 1. Established targets

Allergen	Units	Level 1 – 40221		Level 2 – 40222		Level 3 – 40223	
		Mean	Range	Mean	Range	Mean	Range
D1L4	kU/L	2.83	1.23 – 4.42	2.81	1.19 – 4.43	3.49	1.34 – 5.63
D2L4	kU/L	2.58	1.07 – 4.09	2.61	1.05 – 4.17	3.07	1.34 – 4.80
E1L4	kU/L	2.93	1.13 – 4.73	2.81	1.10 – 4.53	2.82	1.06 – 4.59
G3L4	kU/L	2.72	1.40 – 4.04	2.32	1.29 – 3.34	1.88	1.08 – 2.67
G6L4	kU/L	2.36	1.21 – 3.52	2.03	1.04 – 3.01	1.65	0.83 – 2.48
T3L4	kU/L	1.62	0.78 – 2.47	1.34	0.69 – 1.99	1.42	0.70 – 2.14

Table 2. Assessment of specificity

Allergen	Control Level	Percent Inhibition
D1L4 Dermatophagoides pteronyssinus	1 – 40221	100
	2 – 40222	100
	3 – 40223	100
D2L4 Dermatophagoides farinae	1 – 40221	100
	2 – 40222	100
	3 – 40223	100
E1L4 Cat Dander-Epithelium	1 – 40221	94
	2 – 40222	94
	3 – 40223	93
G3L4 Orchard Grass	1 – 40221	100
	2 – 40222	100
	3 – 40223	100
G6L4 Timothy Grass	1 – 40221	100
	2 – 40222	100
	3 – 40223	100
T3L4 Birch	1 – 40221	100
	2 – 40222	100
	3 – 40223	100

Siemens Global Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Germany
Telephone: +49 9131 84 - 0
www.siemens.com/healthcare

Global Division

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
www.siemens.com/diagnostics

www.siemens.com/diagnostics