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

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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 Lyphochek® 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

Lyphochek 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.
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:

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\left( \frac{\text{Response of pos. control (pos. sample - neg. sample)}}{\text{Response of pos. control (pos. sample - neg. sample)}} \times 100 \right)
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Conclusions

In this study, using the Siemens IMMULITE 2000 and IMMULITE 2500 3g Allergy 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 Lyphochek 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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