

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

LYPHOCHEK is a registered trademark of Bio-Rad Laboratories, Inc., Irvine, CA, 92618, USA.

3gAllergy, IMMULITE, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

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

Global Division

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

www.siemens.com/diagnostics

Use of Bio-Rad Controls with the Siemens 3gAllergy Specific IgE Assays

White Paper

Debra Hovanec-Burns, Tom Chuang, Rachel Morris, and Wendy Roberts

Answers for life.

SIEMENS

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 that we recognize as allergic reactions. When evaluated in 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, lots 40220, 40230, and 40240, 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 these commercially available controls with the Siemens 3gAllergy Specific IgE assay on the IMMULITE® 2000, IMMULITE® 2000 XPi®, and the IMMULITE® 2500 systems.



*Not for sale in the U.S.

Materials and Methods

LYPHOCHEK Immunoassay Plus Control, MiniPak #370 was obtained from Bio-Rad Laboratories, Inc. level 1 (40221, 40231, 40241), level 2 (40222, 40232, 40242), and level 3 (40223, 40233, 40243) 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 and are specific for these 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.

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 | 4.0 | 2.08–6.01 | 3.3 | 1.69–4.91 | 2.6 | 1.33–3.95 |
| T3L4 | kU/L | 1.62 | 0.78–2.47 | 1.34 | 0.69–1.99 | 1.42 | 0.70–2.14 |

| Allergen | Units | Level 1 – 40231 | | Level 2 – 40232 | | Level 3 – 40233 | |
|----------|-------|-----------------|-----------|-----------------|-----------|-----------------|-----------|
| | | Mean | Range | Mean | Range | Mean | Range |
| D1L4 | kU/L | 4.97 | 2.16–7.78 | 2.18 | 0.92–3.44 | 3.72 | 1.42–6.02 |
| D2L4 | kU/L | 4.16 | 1.71–6.61 | 1.95 | 0.78–3.12 | 3.14 | 1.36–4.92 |
| E1L4 | kU/L | 2.58 | 1.00–4.16 | 1.95 | 0.76–3.14 | 2.24 | 0.84–3.64 |
| G3L4 | kU/L | 4.1 | 1.57–6.63 | 2.53 | 1.40–3.66 | 1.71 | 0.98–2.44 |
| G6L4 | kU/L | 5.32 | 2.70–7.94 | 3.32 | 1.69–4.95 | 2.12 | 1.09–3.15 |
| T3L4 | kU/L | 1.9 | 0.92–2.88 | 1.53 | 0.78–2.28 | 1.84 | 0.91–2.77 |

| Allergen | Units | Level 1 – 40241 | | Level 2 – 40242 | | Level 3 – 40243 | |
|----------|-------|-----------------|-----------|-----------------|-----------|-----------------|-----------|
| | | Mean | Range | Mean | Range | Mean | Range |
| D1L4 | kU/L | 4.93 | 2.15–7.71 | 2.73 | 1.15–4.31 | 3.24 | 1.24–5.24 |
| D2L4 | kU/L | 4.87 | 2.01–7.73 | 2.56 | 1.02–4.10 | 2.93 | 1.27–4.59 |
| E1L4 | kU/L | 3.54 | 1.36–5.72 | 3.12 | 1.22–5.02 | 3.4 | 1.28–5.52 |
| G3L4 | kU/L | 3.45 | 1.31–5.59 | 2.86 | 1.58–4.14 | 3.87 | 2.23–5.51 |
| G6L4 | kU/L | 4.75 | 2.41–7.09 | 3.89 | 1.97–5.81 | 5.31 | 2.73–7.89 |
| T3L4 | kU/L | 3.07 | 1.47–4.67 | 2.35 | 1.19–3.51 | 2.49 | 1.23–3.75 |

Conclusions

In this study, using the Siemens IMMULITE 2000, IMMULITE 2000 XPi®, and IMMULITE 2500 3gAllergy Specific IgE assays, the presence of specific IgE for six 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, lots 40220, 40230, and 40240.