**Introduction**

Allergy and related diseases are an extensive and rapidly growing problem affecting up to 30%-40% of the world population and if untreated can lead to severe disease such as dermatitis, rhinitis, asthma and anaphylaxis. Very little information is available about the performance of diagnostics in tropical regions, a vast geographic zone, already home to over 40% of the world population. The two most commonly used methods for confirming allergen sensitization are skin prick testing and measurement of allergen-specific IgE. Both methods have similar diagnostic value in terms of sensitivity and specificity, which vary with the clinical conditions and allergens tested. This Australian study was an open intra-individual controlled performance evaluation to assess IgE specific antibodies to 20 allergen components of the FastCheckPOC® 20.

**Methodology Flowchart**

- Whole blood or serum samples were tested for atopy using the FastCheckPOC® 20 against 20 allergen sources. Total testing time was 30 minutes. See table 3.
- Specific IgE against the 20 allergen sources were quantified using the ImmunoCAP diagnostic system. See table 4.
- To confirm specific IgE to Hazelnut, 59 European subjects with CAP class 0 for hazelnut were tested using FCP. See figure 3.

The outcomes from the FastCheckPOC® 20 and ImmunoCAP sIgE quantification were compared for concordance. See figure 5.

**Table 1: Allergens in Australian Atope Panel.** The Australian Atope Panel #1 should include allergens found in the tropics such as Bermuda/Couch/Cynodon grass and Bahia/Paspalum grass, instead of Ragweed and Timothy grass.

**Table 2: Correlation of FCP Levels with ImmunoCAP Classes**

<table>
<thead>
<tr>
<th>FCP Level</th>
<th>Sensitization</th>
<th>CAP Class</th>
<th>IgE (kIU/L)</th>
<th>Reaction Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low</td>
<td>0-2</td>
<td>0-3.4</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>2-3</td>
<td>0.7-12.4</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>High</td>
<td>3-4</td>
<td>3-9.9</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Very high</td>
<td>4-5</td>
<td>12.4-100</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Very high</td>
<td>5-6</td>
<td>&gt;50</td>
<td></td>
</tr>
</tbody>
</table>

**Results**

**Table 3: FCP20 test data of 14 subjects.** FCP levels are stated in CAP classes. Light to dark shades indicate class 1 (low) to 6 (high) reactivity. See Table 2.

**Table 4: ImmunoCAP test data of 14 subjects.** sIgE quantities are stated in CAP classes. Light to dark shades indicate class 1 (low) to 6 (high) reactivity. See Table 2.

**Figure 1:** Reactions are shown as 3 vertical bars per allergen window, with a Lower Standard, the Test Reaction, and a Higher Standard. The intensity of the purple/black coloured bar of the Test Reaction is compared against the Lower Standard and the Higher Standard for each allergen. These results, Levels 1, 2, 3, 4, 5, correlate to the Classes and the kIU/L ranges of the ImmunoCAP system, considered to be the gold-standard sIgE assay system.

**Figure 2:** Australian intra-individual controlled multicenter performance evaluation study. 12 subjects were tested ImmunoCAP class 0 for hazelnut. From these 12 test data, 3 (25%) were tested FCP level 1 and 7 (58%) level 2.

**Figure 3:** European intra-individual controlled multicenter performance evaluation study. 59 subjects were tested ImmunoCAP class 0 for hazelnut. From these 59 test data, 41 (70%) were tested FCP level 2 and 13 (22%) level 2.

**Summary**

- The Hazelnut component of the FCP20 demonstrated higher values in both Australian and European studies, which might be due to non-specific binding to carbohydrate moieties, and needs further investigation.
- The correlation study between the FastCheckPOC® 20 and ImmunoCAP sIgE demonstrated overall 91.8% Sensitivity, 80.2% Specificity and 81.7% Accuracy for either whole finger-prick blood or for serum.

**Conclusions**

The FastCheckPOC® 20 is an exciting and innovative new diagnostic test system for the identification of allergens amongst Australian patients. With its inherent advantages of speed-of-result and easy availability, it should prove to be a valuable alternative to traditional skin prick testing and laboratory-based specific IgE tests. Current studies will guide the development of optimised allergen panels to enable the application in various geographic and population settings such as the tropics.