

# In-vitro atopy testing in Australia using a novel modified ELISA system - The FastCheckPOC® 20

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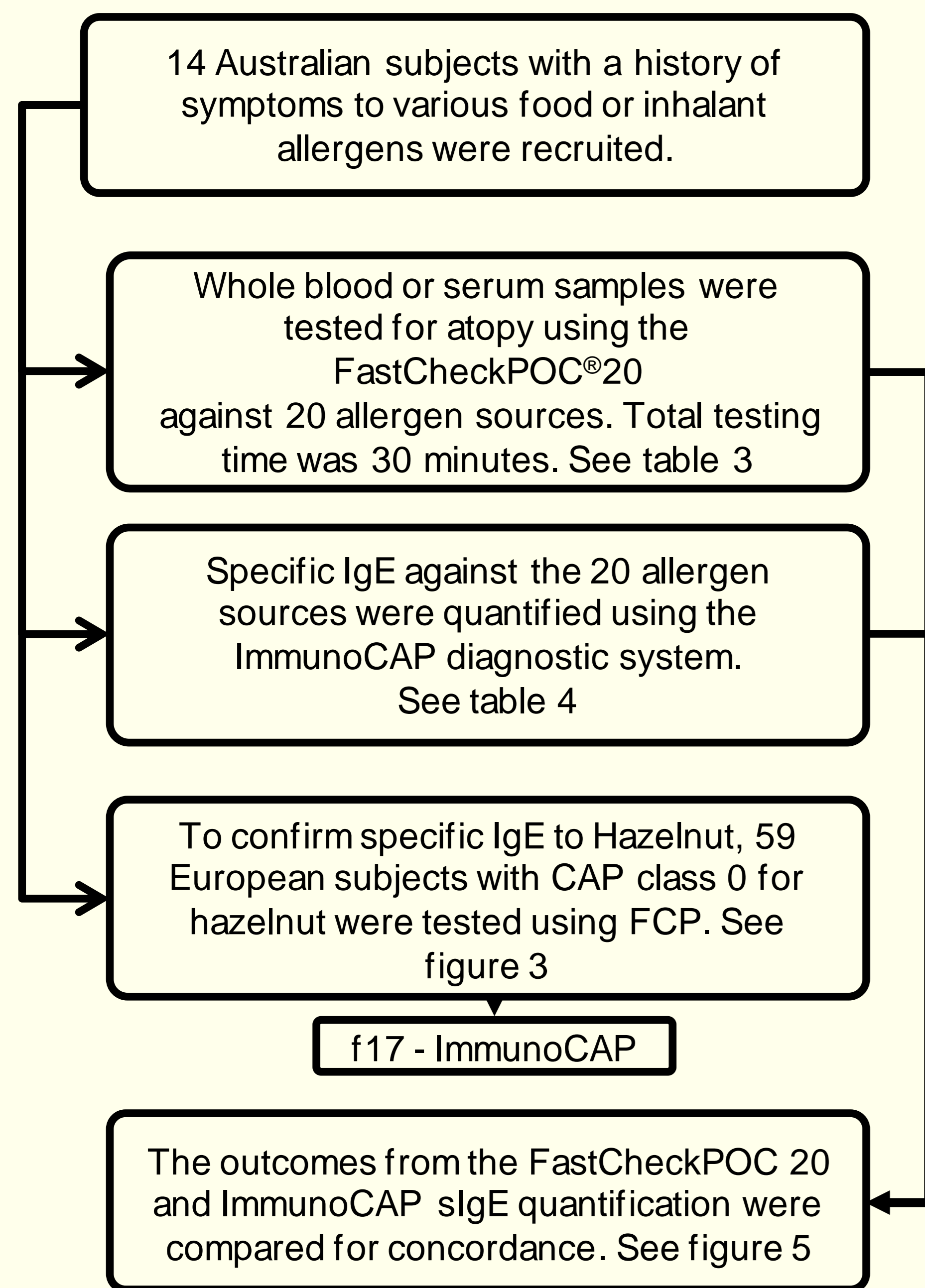
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## Introduction

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

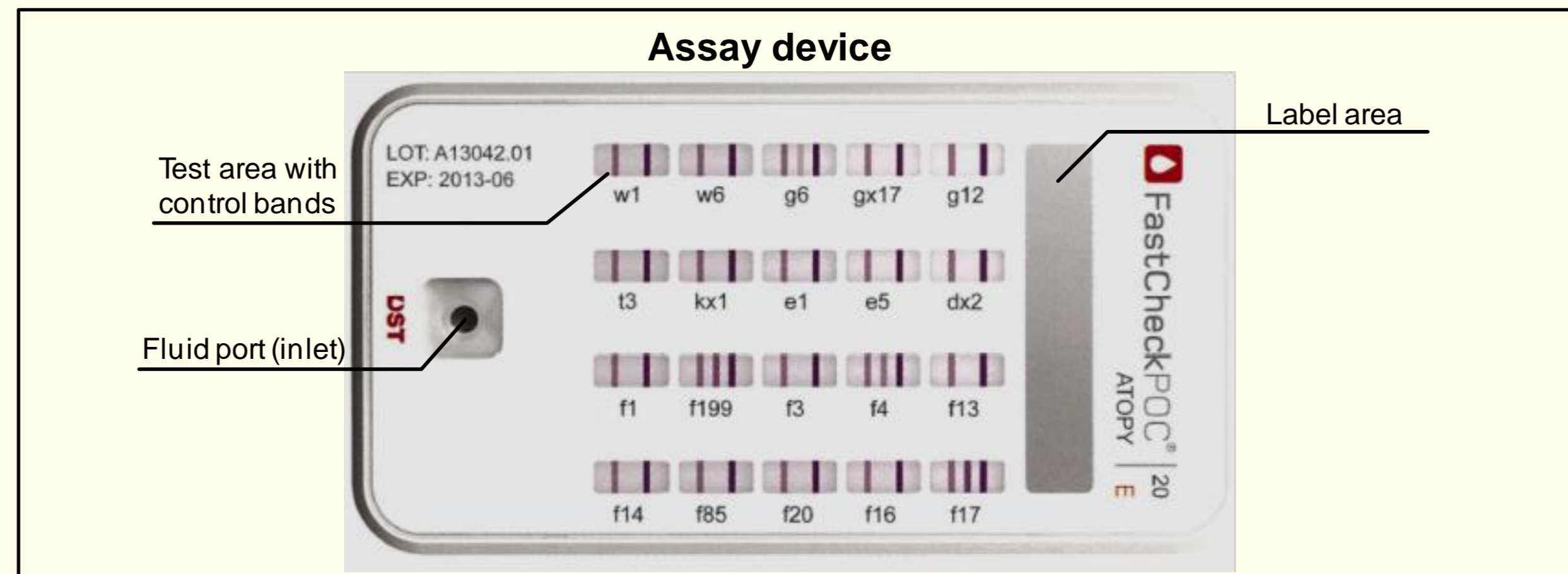


**Table 1:** Allergens in European Atopy Panel. The Australian Atopy Panel #1 should include allergens found in the tropics such as Bermuda/Couch/Cynodon grass and Bahia/Paspalum grass, instead of Ragweed and Timothy grass

| Code | Allergen source    | Scientific Name                 |
|------|--------------------|---------------------------------|
| w1   | Common ragweed (P) | <i>Ambrosia artemisiifolia</i>  |
| w6   | Mugwort (P)        | <i>Artemisia vulgaris</i>       |
| g6   | Timothy grass (P)  | <i>Phleum pratense</i>          |
| gx17 | Grass Mix (P)      | 1)                              |
| g12  | Rye (P)            | <i>Secale cereale</i>           |
| t3   | Silver Birch (P)   | <i>Betula verrucosa</i>         |
| kx1  | Ficus/Latex mix    | 2)                              |
| e1   | Cat dander         | <i>Felis domesticus</i>         |
| e5   | Dog dander         | <i>Canis familiaris</i>         |
| dx2  | Dust mite mix      | 3)                              |
| f1   | Egg white          | <i>Ovum gallinae</i>            |
| f199 | Milk               | <i>Bos primigenius f.taurus</i> |
| f3   | Cod                | <i>Gadus morhua</i>             |
| f4   | Wheat              | <i>Triticum aestivum</i>        |
| f13  | Peanut             | <i>Arachis hypogaea</i>         |
| f14  | Soy bean           | <i>Glycine max</i>              |
| f85  | Celery             | <i>Apium graveolens</i>         |
| f20  | Almond             | <i>Prunus amygdalus</i>         |
| f16  | Walnut             | <i>Juglans regia</i>            |
| f17  | Hazelnut           | <i>Corylus avellana</i>         |

The Australian Atopy Panel #1 can be modified in future, and can be an all-Inhalant Panel or an all-Ingestant Panel

- Grass mix (P)  
Sweet vernal grass *Anthoxanthum odoratum*  
Orchard grass *Dactylis glomerata*  
Rye grass *Lolium perenne*  
Kentucky blue grass *Poa pratensis*
- Ficus/Latex mix *Ficus benjamini*  
*Hevea brasiliensis*
- Dust mite mix *Dermatophagoides pteronyssinus*  
*Dermatophagoides farinae*



**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 s-IgE assay system.

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

| FCP20-Level | Sensitization | CAP Class | sIgE (kUA/L) | Reaction Signal |
|-------------|---------------|-----------|--------------|-----------------|
| 1           | Low           | 0-2       | 0-3.4        |                 |
| 2           | Moderate      | 2-3       | 0.7-17.4     |                 |
| 3           | High          | 3-4       | 3.5-49.9     |                 |
| 4           | Very high     | 4-5       | 17.5-100     |                 |
| 5           | Very high     | 5-6       | >50          |                 |

## 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.

| Subjects | DST Diagnostic FastCheck POC 20 |     |     |     |     |     |     |     |     |     |     |     |     |     |
|----------|---------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|          | A                               | B   | C   | D   | E   | F   | G   | H   | I   | J   | K   | L   | M   | N   |
| w1       | 0-2                             | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 3-4 | 2-3 | 0-2 | 0-2 |
| w6       | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| g6       | 0-2                             | 0-2 | 2-3 | 0-2 | 3-4 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 4-5 | 0-2 | 0-2 |
| gx17     | 0-2                             | 0-2 | 2-3 | 2-3 | 4-5 | 0-2 | 0-2 | 3-4 | 0-2 | 2-3 | 0-2 | 5-6 | 0-2 | 2-3 |
| g12      | 0-2                             | 3-4 | 2-3 | 0-2 | 3-4 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 4-5 | 0-2 | 0-2 |
| t3       | 0-2                             | 0-2 | 0-2 | 2-3 | 2-3 | 2-3 | 0-2 | 0-2 | 2-3 | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 |
| kx1      | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| e1       | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 2-3 | 0-2 | 2-3 | 0-2 |
| e5       | 0-2                             | 2-3 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 2-3 | 0-2 | 3-4 | 0-2 | 2-3 | 0-2 |
| dx2      | 4-5                             | 3-4 | 0-2 | 3-4 | 2-3 | 0-2 | 0-2 | 2-3 | 2-3 | 3-4 | 2-3 | 0-2 | 0-2 | 5-6 |
| f1       | 0-2                             | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 |
| f199     | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 3-4 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 2-3 |
| f3       | 2-3                             | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f4       | 0-2                             | 0-2 | 3-4 | 0-2 | 3-4 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 3-4 | 0-2 | 0-2 |
| f13      | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 2-3 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f14      | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f85      | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f20      | 0-2                             | 3-4 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f16      | 0-2                             | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 | 0-2 |
| f17      | 2-3                             | 0-2 | 0-2 | 2-3 | 2-3 | 2-3 | 2-3 | 3-4 | 4-5 | 0-2 | 2-3 | 2-3 | 2-3 | 2-3 |

**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.

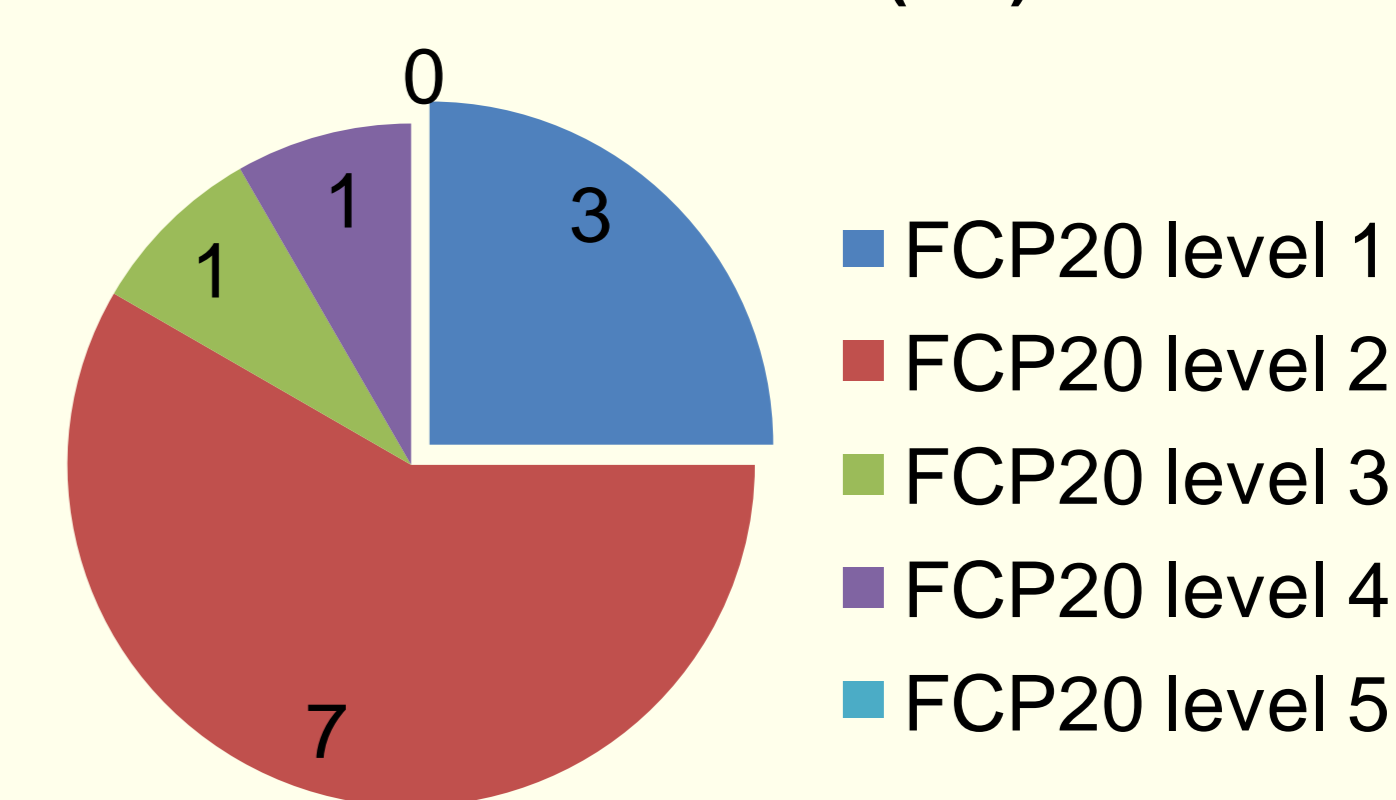
| Subjects | Thermo-Fisher ImmunoCAP s-IgE |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|
|          | A                             | B | C | D | E | F | G | H | I | J | K | L | M | N |
| w1       | 0                             | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| w6       | 1                             | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| g6       | 0                             | 2 | 0 | 0 | 3 | 0 | 2 | 0 | 0 | 0 | 0 | 4 | 0 | 0 |
| gx17     | 1                             | 2 | 0 | 0 | 3 | 0 | 3 | 0 | 0 | 1 | 0 | 5 | 0 | 0 |
| g12      | 0                             | 2 | 0 | 0 | 2 | 0 | 2 | 0 | 0 | 0 | 0 | 4 | 0 | 0 |
| t3       | 0                             | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| kx1      | 0                             | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| e1       | 0                             | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 0 |
| e5       | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 |
| dx2      | 3                             | 4 | 3 | 3 | 0 | 2 | 2 | 3 | 2 | 4 | 2 | 3 | 0 | 6 |
| f1       | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| f199     | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| f3       | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| f4       | 0                             | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 |
| f13      | 0                             | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| f14      | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| f85      | 0                             | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| f20      | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| f16      | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| f17      | 0                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |

**Table 5:** Schematic representation of concordance of result between FCP20 and ImmunoCAP values for the 14 subjects.

| Subjects | DST Diagnostic FastCheck POC 20 |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------|---------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|
|          | A                               | B | C | D | E | F | G | H | I | J | K | L | M | N |
| w1       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| w6       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| g6       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| gx17     |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| g12      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| t3       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| kx1      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| e1       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| e5       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| dx2      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f1       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f199     |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f3       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f4       |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f13      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f14      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f85      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f20      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f16      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| f17      |                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |

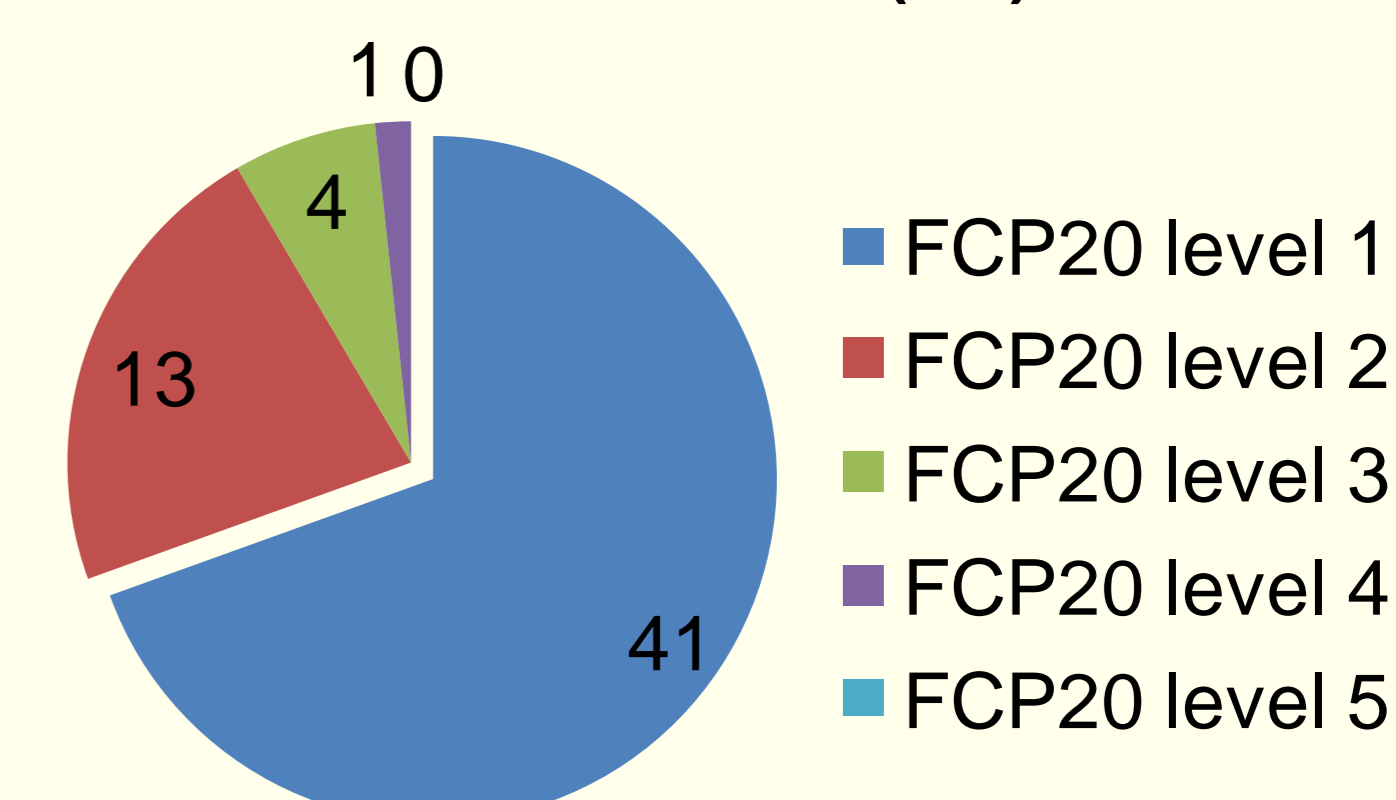
Concordance of Result: Value Differences  
 FCP levels match CAP levels (Green), FCP levels are higher than CAP levels (Yellow), FCP levels are lower than CAP levels (Red), FCP levels and CAP levels are negative (White)

**Hazelnut-ImmunoCAP (f17) Class 0**

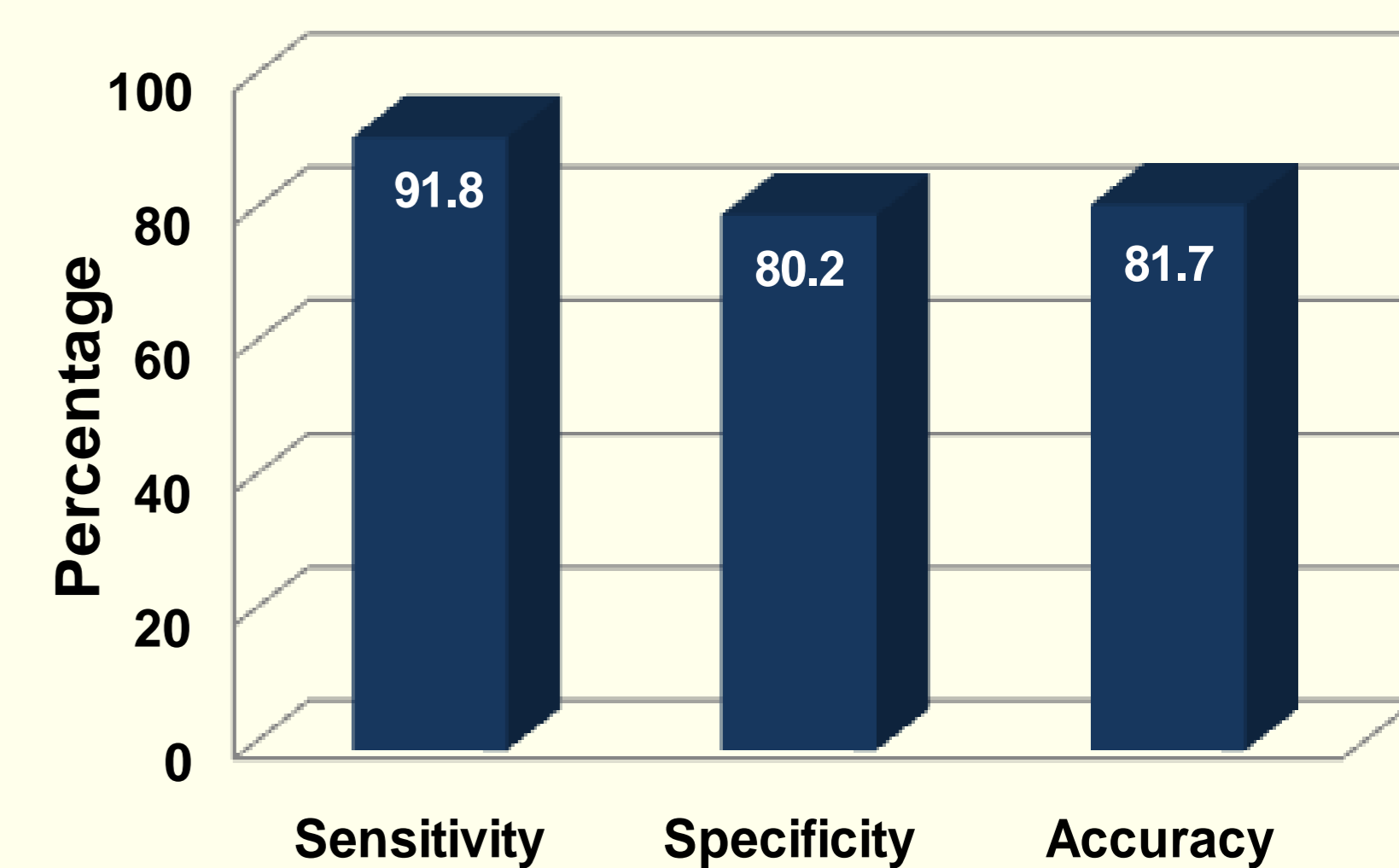


**Figure 2:** Australian intra-individual controlled multicenter performance evaluation study. 12 subjects were tested ImmunoCAP class 0 for f17 hazelnut. From these 12 test data, 3 (25%) were tested FCP20 level 1, and 7 (58%) level 2.

**Hazelnut-ImmunoCAP (f17) Class 0**



**Figure 3:** European intra-individual controlled multicenter performance evaluation study. 59 subjects were tested ImmunoCAP class 0 for f17 hazelnut. From these 59 test data, 41 (70%) were tested FCP20 level 1 and 13 (22%) level 2.



**Figure 4:** Assay sensitivity, specificity and accuracy of the FastCheckPOC®20 with 14 allergic patients using ImmunoCAP values as the gold standard.

## 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 s-IgE 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 populations and geographic settings such as the Tropics.

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## Contact

