ImmunoCAP ISAC, an innovative tool in allergy diagnosis

Promotional article sponsored by Phadia SAS

Allergy *in vitro* diagnostic tools

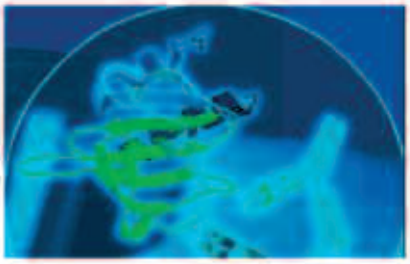
Diagnosis of type I allergy is based on anamnesis, provocation testing, and serological determination of total and specific IgE. Historically available standard products for *in vitro* or *in vivo* allergy testing have consisted in allergen extracts prepared from biological raw materials (e.g., pollen, mites, animal dander, moulds, foods, venoms, etc.). They consist of natural mixtures of allergenic and non-allergenic molecules which respective representativeness in the final product has ever been a challenge successfully took up by Phadia. However, the need for increased specificity resulting from a better knowledge of the composition of allergenic sources has been satisfied by the recent development of tests specific for allergen components obtained thanks to genetic engineering or extensive purification.

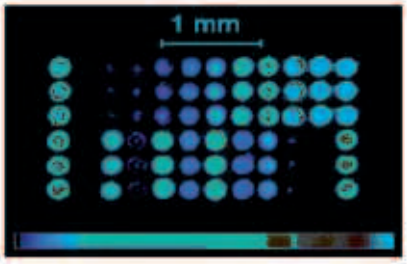
Component resolved Diagnosis

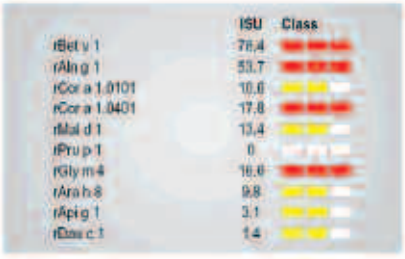
Highly cross-reactive allergen components are present in many biological sources, as an example profilin is found in a broad variety of plant pollens and plant derived foods. A sensitisation towards such a panallergen creates positive test results against numerous allergen extracts. Consequently, when using extract based specific IgE testing it may be difficult to identify the correct allergen source, more especially when cross-reactive allergen components are involved.
The application of recombinant DNA technology to the field of allergen characterization has allowed revealing the molecular nature of the most common allergens. The use of allergen components instead of crude, natural extracts for allergy diagnosis provides each patient with its individual IgE reactivity profile. The knowledge of which components are involved – specific marker or indicating crossreactivity – is the starting point for more informative and powerful diagnostics. Today, the increasing availability of allergen components, either recombinant or purified natural, leads to the way for a new era in allergy diagnosis and gradual transition towards Component Resolved Diagnostic (CRD).
Phadia already offers more than 60 individual allergen components for *in vitro* allergy testing with the ImmunoCAP technology. However, as some patients develop very complex allergen specific IgE sensitization patterns, a new type of serological test exploring a larger number of individual allergens is required for a comprehensive analysis of their IgE binding pattern.

ImmunoCAP® ISAC

In the recent years, the originally DNA focused biochip technology has been adapted for the monitoring of multiple binding events on a protein level. The benefits of this innovative approach are the minute sample volumes, the high sensitivity and the enormous number of measurements conceivable in a single drop of sample liquid, e.g. human blood.
VBC Genomics and Phadia have combined this innovative biochip technology with cutting-edge research in molecular allergology to develop a novel diagnostic test, ImmunoCAP® ISAC (Immuno Solid-phase Allergen Chip). This miniaturized immunoassay allows for multiplex measurement of specific IgE antibodies to many purified natural or recombinant allergen components using only 20 µl of serum or plasma.
ImmunoCAP® ISAC is the first multiplex *in vitro* diagnostic tool for the allergy specialist that is based exclu-







sively on allergen components. The test detects IgE antibodies related to grass- or tree-pollen, animal dander, food, insect venom and mould allergens, amongst others. To date, 103 allergens are included in ImmunoCAP® ISAC, covering a broad spectrum of different allergies. ImmunoCAP® ISAC allows a better understanding of the IgE-reactivity profile and leads to the improvement of the diagnosis and the treatment of patients with complex patterns of allergen specific IgE sensitizations.

Advantages of ImmunoCAP® ISAC technology

- Multiplex specific IgE measurement to allergen components from over 40 common allergen sources in a single test.
- Component resolved diagnosis (CRD) using only purified natural or recombinant allergen components.
- Marker allergen components – specific and indicating cross-reactivity.
- Semi-quantitative results based on fluorescence measurements.
- High reliability by intrinsic replicate testing and quality controls.
- 20 µl of patient serum/plasma give complete results.
- Capillary blood sampling enables less invasive procedure for testing young children.