Diagnosis of allergy in day to day practice

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dr ahujas” pathology and imaging centre
Diagnosis of allergy in day to day practice

- Basic concepts of ALLERGY
- Principles and Method of Allergy testing
- Application in Daily Practice
Allergy is a hypersensitivity disorder of the immune system and allergic reactions occur to normally harmless environmental substances known as allergens; these reactions are acquired, predictable, and rapid.

It is a type 1 hypersensitivity reaction.
In Allergic individuals (Allergic inflammation)
The discovery of IgE was made in Uppsala in 1967 by researchers Johansson, Bennich & Wide.

And it was from this discovery Phadia (formerly Pharmacia Diagnostics) was established.
Why test?

- Is it IgE-mediated allergy or not?
  - Identify/exclude allergy as a cause of the symptoms
  - Guide optimal treatment
  - Guide optimal referral (GPs/PCP)

- Be specific – identify the offending allergen(s)!
  - The medical history alone is not enough
  - SPT alone is not enough (over-diagnosing)
Allergy Diagnosis
– what difference does it make?

Identifying what the patient is allergic to can:

- Reduce exposure
- Reduce inflammation
- Reduce symptoms
- Reduce the need for medication
- Increase patient quality-of-life
IgE testing improves accuracy of allergy diagnoses

Case history in primary care
Efficiency 30-65%

Case history by Specialists
Efficiency 60-66%

Case history + IgE testing in primary care
Efficiency 85-97%

Williams PB et al. Ann Allergy Asthma Immunol 2003;91:26-33
Most allergic children have non-allergic parents

German asthmatic children with:
- Non-atopic parents 56%
- One atopic parent 38%
- Two atopic parents 6%

The majority of prospectively affected children will **not** be identified at birth by family history

Reference: Wahn U. Allergy 2000
**Individual allergens add up to symptoms**

– but which are they?

- Up to 80% of allergic patients are polysensitized, i.e. allergic to more than one allergen, average in primary care is three and often more.

- Triggers of allergic eczema & asthma symptoms can be both food and inhalant allergens.

![Symptom Threshold Diagram]

**Symptom Threshold**

- **Situation A**: Sensitized (IgE antibodies) but no symptoms
- **Situation B**: Third allergen exposure creates symptoms
- **Situation C**: Avoidance of allergen 1 third allergen does not produce symptoms
Individual allergens add up to symptoms

Patients with polysensitization may not display symptoms until their combined exposure to several individual allergens pushes them over the symptom threshold.

Elimination of one allergen may be enough to get the patient symptom free!
Food allergy increases the risk of severe asthma

High potential patient benefits in identifying and reducing exposure to relevant allergens.

Independent risk factors for life-threatening asthma, from a case-controlled analysis of children ventilated for asthma exacerbation.

Food allergy estimated to **4.5%** in asthma and/or rhinitis patients in Delhi

Table 3. Results of food challenge tests, namely open food challenge (OFC) and double-blind, placebo-controlled food challenge (DBPCFC) carried out on asthma and rhinitis patients

<table>
<thead>
<tr>
<th>Allergens</th>
<th>OFC Results</th>
<th></th>
<th>DBPCFC Results</th>
<th></th>
<th>SPT Wheat Size Range (mm)</th>
<th>Specific IgE Range (IU/mL)</th>
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<tbody>
<tr>
<td></td>
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<td>Patients Positive</td>
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<td>Wheat</td>
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<td>1</td>
<td>nd</td>
<td>nd</td>
<td>6</td>
<td>3.3</td>
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</tbody>
</table>

SPT=Skin prick test; IgE=Immunoglobulin E; nd=Not done

**29% SPT+ to any food tested**

Symptoms changes over time – “Allergy march”

Test regularly to get the true & actual picture
Who to test?

- All patients with recurrent or persistent “allergy-like” respiratory, skin and gastro symptoms
- Patients with uncontrolled allergy disease
Which ones?

- Eczema – 1 out of 3 children is allergic
- Rhinitis – 7 out of 10 children are allergic
- Wheezing – 2 out of 3 children are allergic
Blood tests will help you increase the number of correct diagnoses

*ImmuNoCAP blood test* increases certainty in allergy diagnosis and helps rule out allergy

References:
Basic concepts of ALLERGY

Principles and Method of Allergy testing

Application in Daily Practice
Allergy Diagnosis: Physical Examination and review of History of patient’s symptoms.

- SPT

Immunocap:
Blood sIgE versus SPT

Why ImmunoCAP...
- Totally safe
- Standardized and reproducible
- No patient/procedure variation
- No drug interactions
- Not dependant on skin condition
- Quantitative - Decision points possible
- Better patient’s acceptance
Value of ImmunoCAP® results

- Show patients’ baseline/profile of IgE antibodies
- Evaluate which allergens are the most probable for causing symptoms
- Evaluate if specific immunotherapy (SIT) is an option
- Follow changes over time to:
  - reflect the effect of and compliance with allergen avoidance/reduction
  - optimize medical strategies
  - evaluate tolerance development (food allergy, SIT)
  - avoid unnecessary food challenges
ImmunoCAP® allergy blood testing

“ImmunoCAP is in worldwide use, and is a de facto standard to which other methods are compared.”

Ref: Dolen WK, Allergy 2003;58:717-23.
ImmunoCAP® blood testing

- Can be performed irrespective of:
  - Age
  - Symptom
  - Disease activity/or severity (e.g. active eczema)
  - Antihistamine/steroid medication
  - Pregnancy (hormone influence)

- Is calibrated to WHO ref. preparation for IgE
- Gives true quantitative levels (kU_A/l)
- Shows consistency of results between laboratories
- Offers Molecular Allergology (CRD)
IMMUNOCAP-GOLD STANDARD TECHNOLOGY

- It is the only specific IgE assay to receive USFDA approval to quantitatively report its detection limit 0.1kU/l. This is based on CLSI/NCCLS-17A limits of detection and quantification guidelines of October 2004.

- WHO recommends cut off limit 0.35 kU/l and it is the only device which follows WHO calibration norms.
More than 40 years of market leadership - important milestones:

1st generation

1974 – Phadebas RAST
The first laboratory test for specific IgE-antibodies. The paper disc technology combining quality with a large panel of allergens became the “gold standard” of allergy testing.

2nd generation

1989 – Pharmacia CAP System®
The ImmunoCAP technology brought new standards of quality and capacity to the market, also introducing semi-automation to increase laboratory efficiency.

3rd generation

1996 – UniCAP® 100
Introducing full automation and quick assay procedure. Further improvements in precision and reproducibility through improved chemistry, standardized handling and environmental control laid the foundation for truly quantitative measurements. Already 4000 instruments on the market.

4th generation

2001/2004 – ImmunoCAP® 1000 and 250
The unsurpassed quality of ImmunoCAP® 100 combined with even higher automation, speed, capacity and continuous random access ability.
Facts:
Extremely low serum concentration of specific IgE

**Physicochemical properties of human immunoglobulin classes**

<table>
<thead>
<tr>
<th>Property</th>
<th>IgG1</th>
<th>IgG2</th>
<th>IgG3</th>
<th>IgG4</th>
<th>IgM</th>
<th>IgA1</th>
<th>IgA2</th>
<th>slgA</th>
<th>IgD</th>
<th>IgE</th>
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<tr>
<td>heavy chain</td>
<td>g₁</td>
<td>g₂</td>
<td>g₃</td>
<td>g₄</td>
<td>m</td>
<td>a₁</td>
<td>a₂</td>
<td>a₁/a₂</td>
<td>d</td>
<td>e</td>
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<td>mean serum conc. (mg/ml)</td>
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<td>7s</td>
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<td>11s</td>
<td>7s</td>
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<td>146</td>
<td>170</td>
<td>146</td>
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<td>160</td>
<td>160</td>
<td>335</td>
<td>184</td>
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<td>20</td>
<td>7</td>
<td>21</td>
<td>10</td>
<td>6</td>
<td>6</td>
<td>?</td>
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<td>2</td>
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<td>% intravascular distribution</td>
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<td>45</td>
<td>45</td>
<td>45</td>
<td>80</td>
<td>42</td>
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<td>carbohydrate (%)</td>
<td>2-3</td>
<td>2-3</td>
<td>2-3</td>
<td>2-3</td>
<td>12</td>
<td>7-11</td>
<td>7-11</td>
<td>7-11</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>
**Design: Solid Phase ImmunoCAP®**

Extremely high binding capacity

- Tube passive coating: 1
- Paper disc activated: 50
- Cellulose foam activated: 150

3-dimensional cellulose polymer.

Covalent coupling through CNBr-activation
ImmunoCAP Used in over 4000 publications addressing clinical questions in allergy:

- “…not all serum IgE assays are the same. Most of the studies cited use the Pharmacia CAP or ImmunoCAP assay….” Lieberman J. et al. 2011.

- “…the majority of research performed to date on the predictive power of quantitative food-specific IgE antibody levels has been performed using the ImmunoCAP system.” Eckman J. et al. 2009.

- “Today, there are mainly 3 methods: Turbo RAST, Immulite and ImmunoCAP. ImmunoCAP is the assay that has been most extensively studied.” Cox L. et al. 2008.

- “Testing should be performed using a validated laboratory method, such as ImmunoCAP (Phadia AB, Uppsala, Sweden)….” Bacharier L.B. et al. 2008.
Established clinical decision points has been developed from trials with ImmunoCAP:

- “The published predictive values in the literature to date have been generated with the ImmunoCAP system…” Hamilton RG. et al. 2011.

- “To date, however, the reported IgE anti-food values leading to the generation of predictive cutpoints have been exclusively measured by using 1 of 3 clinically available IgE antibody assays, namely, the ImmunoCAP.” Hamilton RG. 2010.

- “To date, the ImmunoCAP (Phadia, Uppsala, Sweden) has been the only clinically used IgE antibody immunoassay that has been systematically evaluated for its predictive value in food allergy studies.” Eckman J. et al. 2009.

- “Clinicians rely on these decision points, which were originally established using the ImmunoCAP assay, to determine when oral food challenges are appropriate.” Wang J. et al. 2008.
Anti-Histamine has no effect on Immunocap testing

Adverse skin conditions, again- do not effect our testing (but does effect in Skin Prick Test)

And testing can be done during pregnancy as well (but is contraindicated during Skin Prick)

We do have Lab Community & Quality Club

So, true accuracy, high precision and outstanding quality; makes IMMUNOCAP league apart.
Basic concepts of ALLERGY

Principles and Method of Allergy testing

Application in Daily Practice
Is it allergy or not?

A revised Nomenclature for Allergy

**Hypersensitivity**

- Allergic hypersensitivity (immunological mechanism defined or strongly suspected)
  - IgE-mediated
    - Non-atopic
      - Insect sting
      - Helminthes
      - Drugs
      - Other
    - Atopic
  - Not IgE-mediated
    - T cell: e.g., contact dermatitis, celiac
    - Eosinophil: e.g., gastroenteropathy
    - IgG mediated: e.g., allergic alveolitis
    - Other
- Non-allergic hypersensitivity (immunological mechanism excluded)

Created with nitroPDF professional
Suggested test procedure

I. Suspicion of allergy:
   Case history

II. Confirmation/Exclusion of atopy:
   Phadiatop® Infant/Phadiatop®
   - Positive
   - Negative

III. Identification of allergens:
   - Phadisym™ Eczema
   - Phadisym™ Wheeze/Rhinitis Child
   - Phadisym™ Asthma/Rhinitis Adult
Total IgE – clinical performance

- **Sensitivity only ~50% in adults**, better in children
  - Only 60% of allergic asthmatics have increased IgE
  - Only 40% of allergic rhinitis patients have increased IgE

- **Specificity ~80%**
  - Increased total IgE due to other reasons than allergy e.g.:
    - Atopic dermatitis
    - Parasites (e.g. *Ascaris, Schistosoma*)
    - Virus & bacterial infections (e.g. RSV, Staph.)
    - Graft Versus Host Disease (GVHD)
    - Hyper-IgE Syndrome

- **Performance not good enough for screening!**

Two age-depending versions

1. Phadiatop (≥ 5 years of age)
   – Measures IgE abs to common inhalant allergen for the age

2. Phadiatop Infant (0-4 years)
   – Measures IgE abs to common food & inhalant allergens for the age
Phadiatop®/Phadiatop® Infant - atopy grading

- A blood test designed to differentiate between atopic and non-atopic patients
- Demonstrates the presence of IgE antibodies to common inhalant allergens
- Acts as an objective and reliable first step when screening for allergy
- Sensitivity & specificity >90%
- A positive test has to be followed-up with suspected allergen-specific tests or panels
# Interpretation of IgE ab results

<table>
<thead>
<tr>
<th>Quantitative result</th>
<th>IgE ab level</th>
<th>Symptom relation</th>
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<tr>
<td>&lt;0.1</td>
<td>Undetectable</td>
<td>Unlikely</td>
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<td>0.1 – 0.5</td>
<td>Very low</td>
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<tr>
<td>0.5 – 2</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>2 – 15</td>
<td>Moderate</td>
<td>Common</td>
</tr>
<tr>
<td>15 – 50</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>&gt;50</td>
<td>Very high</td>
<td>Very high</td>
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Value of low IgE antibody levels?

0.1 - 0.5 kU$_A$/l

- The degree of sensitization is very low & relation to symptoms is uncommon, but low levels ...
  - identify sensitization earlier than before
  - are of interest in order to follow the development of sensitization
  - may appear even before symptoms have developed
  - may predict which allergens could cause problem in the future
  - more important for small children
  - more relevant in drug & venom allergy
## Efficiency of Phadiatop (21 external studies)

<table>
<thead>
<tr>
<th>Authors</th>
<th>Number</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Efficiency</th>
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<td>0.07</td>
<td>0.07</td>
<td>0.06</td>
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</table>

Reference: Eriksson NE. Allergy 1990;45:285-292
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   - Case history

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     - Negative

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   - Phadisym™ Eczema
   - Phadisym™ Wheeze/Rhinitis Child
   - Phadisym™ Asthma/Rhinitis Adult
A changeable march of symptoms & allergens over time

Michael, 3 months old

Early sensitization is predictive of future allergies

ImmunoCAP™ Specific IgE blood test

KU/L

16.0

Cow’s milk

May

August

Cow’s milk free diet

Allergen-specific IgE antibody profile over time.
Peter, 7 years old & his “allergy march”

Allergen-specific IgE antibody profile over time.
Few allergens responsible for majority of allergies

ImmunoCAP® Symptom profiles

<table>
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<tr>
<th>Eczema</th>
<th>Wheeze/Rhinitis Child</th>
<th>Asthma/Rhinitis Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>f1  Egg white</td>
<td>g6  Timothy</td>
<td>g6  Timothy</td>
</tr>
<tr>
<td>f2  Cow’s milk</td>
<td>t3  Birch</td>
<td>t3  Birch</td>
</tr>
<tr>
<td>f3  Fish</td>
<td>t9  Olive</td>
<td>t9  Olive</td>
</tr>
<tr>
<td>f4  Wheat</td>
<td>w21 Parietaria</td>
<td>w21 Parietaria</td>
</tr>
<tr>
<td>f13 Peanut</td>
<td>e1  Cat</td>
<td>e1  Cat</td>
</tr>
<tr>
<td>f14 Soy bean</td>
<td>e5  Dog</td>
<td>e5  Dog</td>
</tr>
<tr>
<td>f17 Hazel nut</td>
<td>d1  D. pteronyssinus</td>
<td>d1  D. pteronyssinus</td>
</tr>
<tr>
<td>d1  D. pteronyssinus</td>
<td>f1  Egg white</td>
<td>f1  Egg white</td>
</tr>
<tr>
<td>e1  Cat</td>
<td>f2  Cow’s milk</td>
<td>f2  Cow’s milk</td>
</tr>
<tr>
<td>e5  Dog</td>
<td>f13 Peanut</td>
<td>f13 Peanut</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10 allergens being responsible for 95% of allergies in children in the UK

Reference: Symptom Profile Meeting London 2004
(G Lack, H Cox, C Doyle, S Leech, M Levy, J Hourihane, G Roberts, M Borres)
Symptom panels/profiles

- Should help GPs (non-specialists) to select the right allergens
- Should identify the allergic patient or exclude the non-allergic
- A panel will not/should not cover “everything”; only common relevant allergens
- Should be reasonably priced for patients
- A positive panel could always be followed-up with extra tests according to patient history (and not included) alt. a comprehensive allergen panel
Which are the common Indian allergens?

Common food allergens among the respiratory population in Calcutta

Reference: Mandal et al. WAO Journal January 2009
### Skin test positivity

**Mumbai**

3,389 patients tested 2003-2007

---

#### Table 6 — Skin Test Positivity Percentage for Some Individual Allergens

<table>
<thead>
<tr>
<th>Allergens</th>
<th>Per cent positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Children</td>
</tr>
<tr>
<td>Pollen</td>
<td></td>
</tr>
<tr>
<td><em>Parthenium hysterophorus</em></td>
<td>11.68%</td>
</tr>
<tr>
<td><em>Cynodon dactylon</em></td>
<td>14.02%</td>
</tr>
<tr>
<td><em>Cocos nucifera</em></td>
<td>10.34%</td>
</tr>
<tr>
<td>Fungi</td>
<td></td>
</tr>
<tr>
<td><em>Alternaria tenius</em></td>
<td>25.67%</td>
</tr>
<tr>
<td><em>Aspergillus fumigatus</em></td>
<td>24.96%</td>
</tr>
<tr>
<td>Insects</td>
<td></td>
</tr>
<tr>
<td>Mosquito</td>
<td>57.91%</td>
</tr>
<tr>
<td>House fly</td>
<td>52.26%</td>
</tr>
<tr>
<td>Cockroach</td>
<td>46.88%</td>
</tr>
<tr>
<td>Dust Mites</td>
<td></td>
</tr>
<tr>
<td><em>D Farinae</em></td>
<td>74.29%</td>
</tr>
<tr>
<td><em>D Fennesigninus</em></td>
<td>38.42%</td>
</tr>
<tr>
<td>Danders</td>
<td></td>
</tr>
<tr>
<td>Cat</td>
<td>35.38%</td>
</tr>
<tr>
<td>Dog</td>
<td>36.77%</td>
</tr>
<tr>
<td>Foods</td>
<td></td>
</tr>
<tr>
<td>Peanuts</td>
<td>26.55%</td>
</tr>
<tr>
<td>Chocolate</td>
<td>25.18%</td>
</tr>
<tr>
<td>Fish</td>
<td>23.48%</td>
</tr>
<tr>
<td>Coconut</td>
<td>19.86%</td>
</tr>
<tr>
<td>Cashew nut</td>
<td>21.39%</td>
</tr>
<tr>
<td>Legumes (dals)</td>
<td>22.63%</td>
</tr>
<tr>
<td>Soya bean</td>
<td>19.69%</td>
</tr>
<tr>
<td>Lemon</td>
<td>13.26%</td>
</tr>
<tr>
<td>Milk</td>
<td>13.04%</td>
</tr>
<tr>
<td>Wheat</td>
<td>11.92%</td>
</tr>
<tr>
<td>Chicken</td>
<td></td>
</tr>
<tr>
<td>Rice</td>
<td></td>
</tr>
<tr>
<td>Meat</td>
<td></td>
</tr>
<tr>
<td>Egg</td>
<td></td>
</tr>
</tbody>
</table>

Skin test positivity in Calcutta

Mandal et al. WAO Journal 2009;2:9-12
Which are the important local allergens?

(with focus on Dehradoon)
Allergic Rhinitis

Allergic Rhinitis is defined as symptomatic disorder of nose, induced after allergen exposure by an IgE mediated inflammation of the nasal membrane.

Major symptoms -
Rhinorrhea, Nasal obstruction, nasal itching, sneezing.
Case history and physical examination alone may lead to uncertain diagnoses

Misdiagnosed rhinitis has a significant impact on patient well-being

• Approx. 65% of patient diagnosed as having allergic rhinitis and prescribed antihistamine are not allergic

• Allergic rhinitis is often confused with recurrent infectious cold, leading to unnecessary use of antibiotics
Rhinitis

Allergic rhinitis

IgE-mediated rhinitis

Reference:
Johansson SGO et al.

Non-allergic rhinitis

Non-IgE-mediated allergic rhinitis
Food Allergy

Adverse food reactions

Non-toxic reaction

Immunologically mediated (food allergy)

Not IgE-mediated e.g., coeliac disease

IgE-mediated

Toxic reaction

Non-immunological (food intolerance)

Unknown

Pharmacological (e.g., histamine, tyramine)

Enzymatic (lactose intolerance)

Adapted from EAACI Position Paper, Allergy 1995, 50:623-635
Dermatitis

Eczema
  Non-atopic eczema
  Atopic eczema

Contact dermatitis
  Allergic CD
  Non-allergic CD

Other forms of dermatitis

Individual allergens add up to symptoms

Elimination of one allergen may be enough to get the patient symptom free!

Patients with polysensitization may not display symptoms until their combined exposure to several individual allergens pushes them over the symptom threshold.
Reasons to quantify allergen-specific IgE antibodies

Sensitization and common allergic disorders may develop into severe conditions later in life ("the allergy march")

**Diagnosis:** Identifying the offending allergens is essential for avoidance/elimination and quantification of IgE ab helps to pick out the most probable ones

**Prognosis:** Early sensitization can be predictive of future allergies, the higher the IgE ab level, the higher the risk.

**Follow-up:** Quantification helps monitoring patient’s allergic status over time such as avoidance/elimination effects and development of tolerance or disease deterioration
Conclusion

Detection of IgE antibodies
➢ Provides information that the sensitization process has been initiated.
➢ Along with symptoms and a positive case history, confirms the causative allergen.
➢ Without symptoms may predict later development of allergic disease.
➢ Allows careful avoidance strategies for treatment.

Treatment strategies with rapid and consistent positive result include: preventive actions
   close observation
   allergen avoidance
   guides SIT
Allergy is nothing to sneeze at!

Better patient management needs the best tools
Conclusion

ImmunoCAP is the first choice in allergy diagnosis and can be safely and reliably used in all patients and in all clinical settings.
Atopy grading with Phadiatop®/Phadiatop® Infant

• A blood test designed to differentiate between atopic and non-atopic patients.

• Demonstrates the presence of IgE antibodies to common inhalant allergens.

• Acts as an objective and reliable first step when testing for allergy.