50 years of IgE and where we are today including a recap on the CLSI guidelines.

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Phadia User Group Meeting 2017
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# IgE turns 50

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| • Gunnar Johansson & Hans Bennich, Uppsala University Hospital  
• Japanese team, Kimishige & Teruko Ishizaka Denver, Colorado  
• Leif Wide, RIST (RadioImmunoSorbentTest) | • Phadebas® total IgE becomes the first commercially available total IgE test | • Phadebas® RAST (RadioAllergoSorbentTest) is launched - for the first time measuring IgE antibodies is a reality |
IgE turns 50

1982
• The first allergen component is introduced

1986
• ImmunoCAP® Phadiatop the first test to detect atopic disease, helps rule in or out allergies.

1987
• PhARF (Phadia Allergy Research Forum) is established, the most prestigious prize in allergy.
• In association with Uppsala University and WAO, AAAI and EAACI.
1989
• Pharmacia launches Pharmacia CAP System® by introducing a new solid-phase called ImmunoCAP®.

1995
• UniCAP® 100 is introduced, the world’s first automated laboratory system for allergy testing
• 2001 PH250, 2004 PH1000, 2010 PH2500 & PH5000
• First component test: birth, timothy grass.

1999
• The first IgE test for specific protein components in natural sources becomes available in clinical practice.
IgE turns 50

2005
- ImmunoCAP® rapid is announced, the first IgE allergy point of care test

2009
- ImmunoCAP® ISAC, the first multiplexing in vitro diagnostic test with allergen components, becomes available.

2014
- Over 650 complete allergens components can now be detected.
The world celebrates the 50 year anniversary of IgE, and all the current and future discoveries that continue to improve diagnosis, treatment, and the quality of life for everyone affected by allergies and asthma.
NEW ImmunoCAP®
Der p 23

House dust mite component
House dust mite allergy

Adding the new ImmunoCAP™ Der p 23* to your ImmunoCAP test profile help you decide on patient management

*ImmunocAP Allergen d209, Allergen component rDer p 23, House dust mite
**Allergen Immunotherapy
Key to accurate management is knowing the sensitization profile

Frequency of sensitization among HDM allergic children and adults


Der p 1*: specific component
> 70%¹

Der p 10**: cross-reactive component
≈ 10%⁴

Der p 2*: specific component
> 80%¹

Der p 23*: Specific component with high allergenicity
up to 74%²,³

*High cross-reactivity between Der p 1 and Der f 1 resp. Der p 2 and Der f 2 resp. Der p 23 and Der f 23 from D. Farinae.⁸
**Mite tropomyosins such as Der p 10 and Der f 10 are widely cross-reactive among invertebrates.⁸
Introducing **ImmunoCAP™ Der p 23**

Up to 74% of HDM allergic patients are Der p 23 sensitized\(^1,2\) and 4-6% are mono sensitized\(^3-4\)

**Lower levels** of IgE-levels than for Der p 1 & 2\(^5\)

**Der p 23 added to your test profile help you:**

Choose **A IT**\(^**\)

- Der p 23 amount in fecal particles/bodies is low and may therefore be underrepresented\(^6\) in AIT\(^2,5\)

Assess risk for asthma

- Early sensitization to Der p 1, 2 & 23 is associated with asthma development\(^6\)

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*ImmuNoCAP Allergen d209, Allergen component rDer p 23, House dust mite

**A IT** Allergen Immunotherapy

*Der p 23 content of extracts has not been studied.
Early sensitization to Der p 1, 2 & 23 is associated with asthma development

Sensitization starts in early ages\(^1\)

Asthmatic patients are sensitized to more components than those without asthma\(^2\)

\(^1\) Mite-related allergic rhinitis

Suggested test profile: HDM allergy

**ImmunoCAP TM**
Whole Allergens

- *Dermatophagoides pteronyssinus* (d1) and *Dermatophagoides farinae* (d2)

**ImmunoCAP TM**
Allergen Components

- Der p 1* (d202) / Der p 2* (d203) / Der p 23* (d209)
- Der p 10** (d205)

**Clinical implications**

**Choice of AIT**
- Differentiation between Der p 1, 2 & 23 sensitization helps choose appropriate AIT1-3
- Der p 2 sensitized patients may benefit from AIT* based on purified mite body cultures4,9 or carefully standardized pharmaceuticals10,11
- Der p 23 amount in fecal particles/bodies is low and may therefore be underrepresented6 in AIT12,13

**Assess risk for asthma**
- Early sensitization to Der p 1, 2 & 23 is associated with asthma development14
- Asthmatic patients are sensitized to more components than those without asthma15

**Further examination needed**
- Cross-reactivity between HDM, crustaceans, insects and molluscs
- If Der p 10 is dominant, food allergy can be suspected
CLSI guidelines

IgE antibody assays
Clinical and Laboratory Standards Institute

- A not-for-profit membership organization.
- Develops consensus-based clinical standards that enable laboratories to fulfil their responsibilities through high-quality testing practices.
- A global membership base with a common mission: to develop & promote standards that are respected worldwide to improve patient care.
- http://clsi.org/
Objective

• To summarize the current state of clinically used assay technologies for quantifying total IgE and IgE ab levels.
• Define performance criteria and methods for qualification of assay reagents for manufacturer & users.
• Discuss potential causes for quantitative result discordance among the different IgE ab assays.
• Outline manufacturer & user QC measures.
• Provide guideline to regulatory agencies for validations.
Thank you
For your attention