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

Maria Bello

Phadia User Group Meeting 2017

ThermoFisher SCIENTIFIC

IgE™ ImmunoCAP® Is it allergy?

Contents

IgE turns 50

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1967

- Gunnar Johansson & Hans Bennich, Uppsala University Hospital
- Japanese team, Kimishige & Teruko Ishizaka Denver, Colorado
- Leif Wide, RIST (RadioImmunoSorbentTest)

1972

- Phadebas® total IgE becomes the first commercially available total IgE test

1974

- Phadebas® RAST (RadioAllergoSorbentTest) is launched- for the first time measuring IgE antibodies is a reality

IgE turns 50

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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.

IgE turns 50

IgE turns 50

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, tymothy grass.

1999

- The first IgE test for specific protein components in natural sources becomes available in clinical practice

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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.

IgE turns 50

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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.

IgE turns 50

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NEW ImmunoCAP®
Der p 23

House dust mite component

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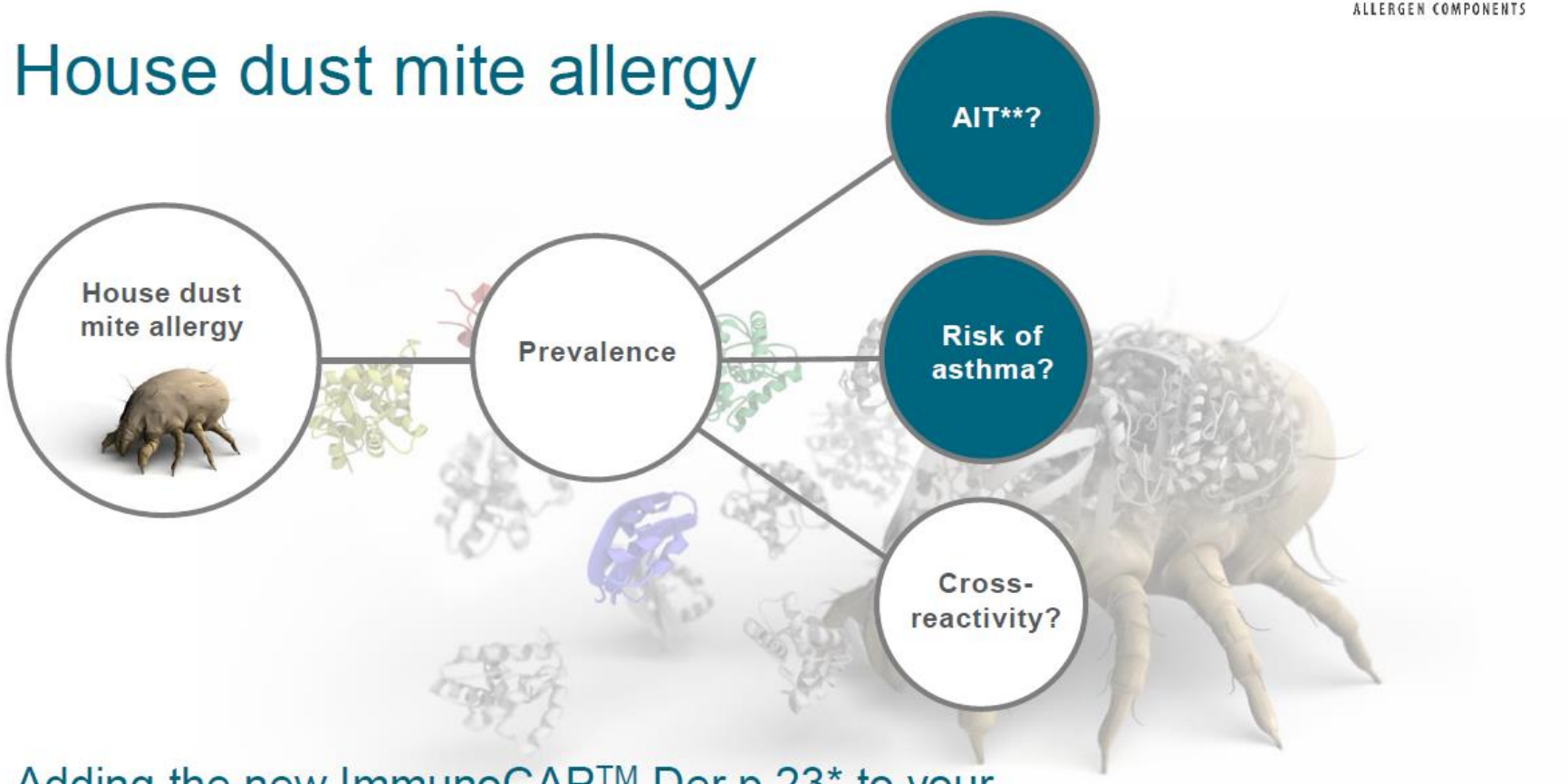
ImmunoCAP
ALLERGEN COMPONENTS

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

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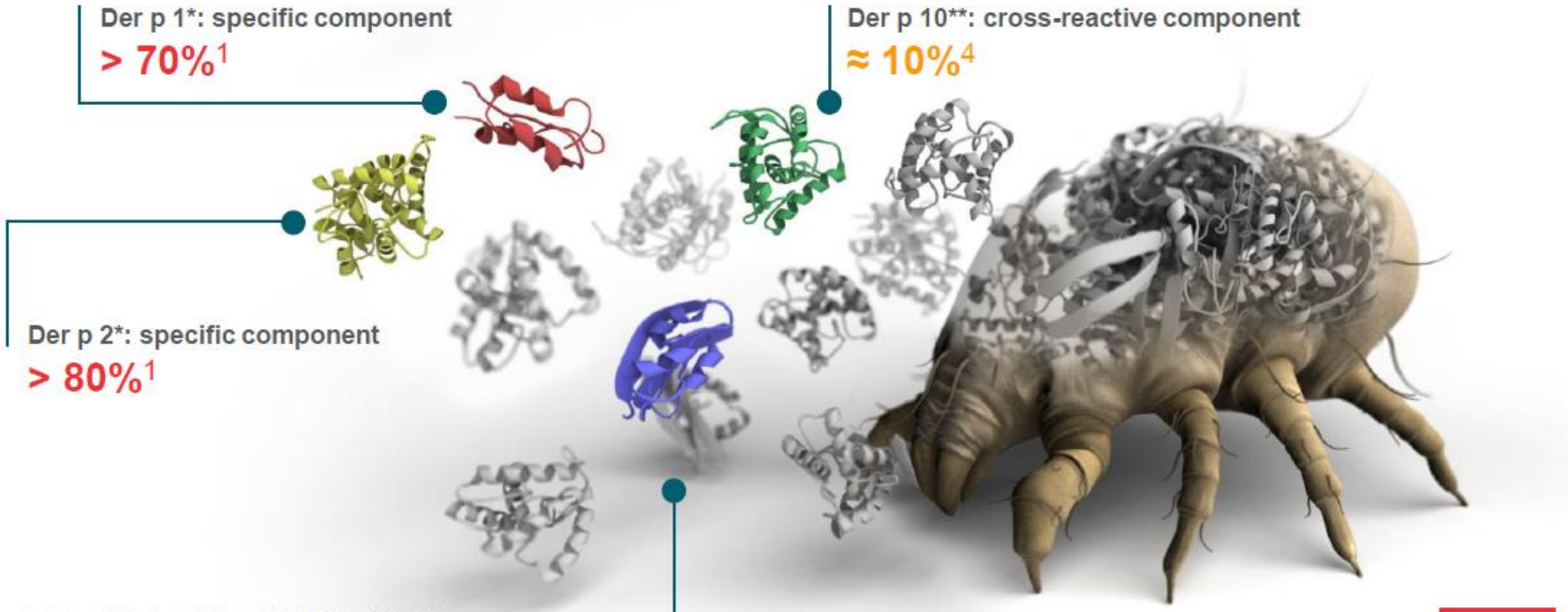
Key to accurate management is knowing the sensitization profile

ImmunoCAP ALLERGEN COMPONENTS

Frequency of sensitization among HDM allergic children and adults



NEW!

1. Batard T. et al. Allergy 2016; 71: 220–229.
2. Weghofer M. et al. J Immunol 2013; 190:3059-3067.
3. Mueller GA. Et al. Clin Exp Allergy. 2016;46(2):365-76.
4. Resch Y. et al. Clin Exp Allergy. 2011 October ; 41(10): 1468–1477.

*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]

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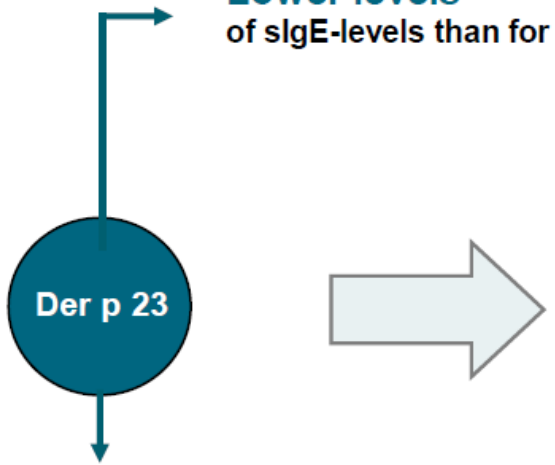
ImmunoCAP
ALLERGEN COMPONENTS

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 sIgE-levels than for Der p 1 & 2[3]



..but more potent
in activating mast cells[3]

Der p 23 added to your test profile help you:

Choose AIT**

- Der p 23 amount in fecal particles/bodies is low and may therefore be underrepresented# in AIT [2,5]

Assess risk for asthma

- Early sensitization to Der p 1, 2 & 23 is associated with asthma development[6]

1. Becker S et al. Int Arch Allergy Immunol. 2016;170(2):132-7.
2. Weghofer M. et al. J Immunol. 2013;190(7):3059-67.
3. Mueller GA. Et al. Clin Exp Allergy. 2016;46(2):365-76.
4. Resch Y. et al. J Allergy Clin Immunol 2015;136:1083-91.
5. Thomas WR. Allergology International 64 (2015) 304-11.
6. Posa D. et al. J Allergy Clin Immunol 2017;139:541-9

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

ImmunoCAP ALLERGEN COMPONENTS

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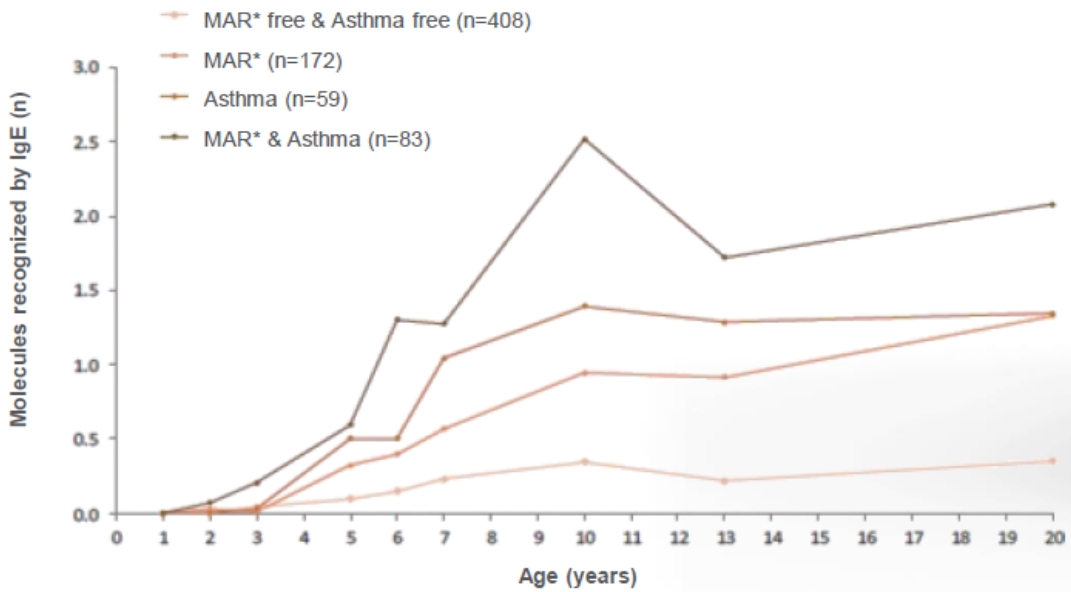
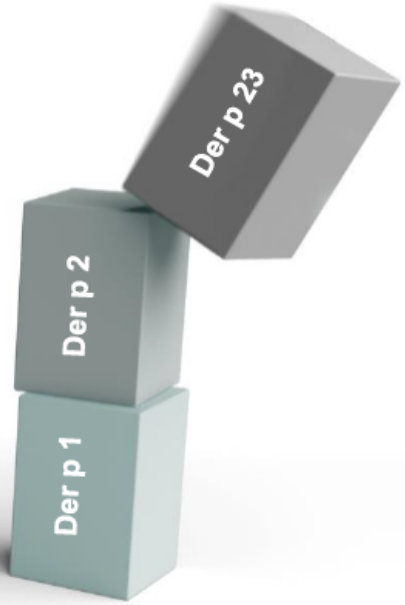
Sensitization starts in early ages[1]





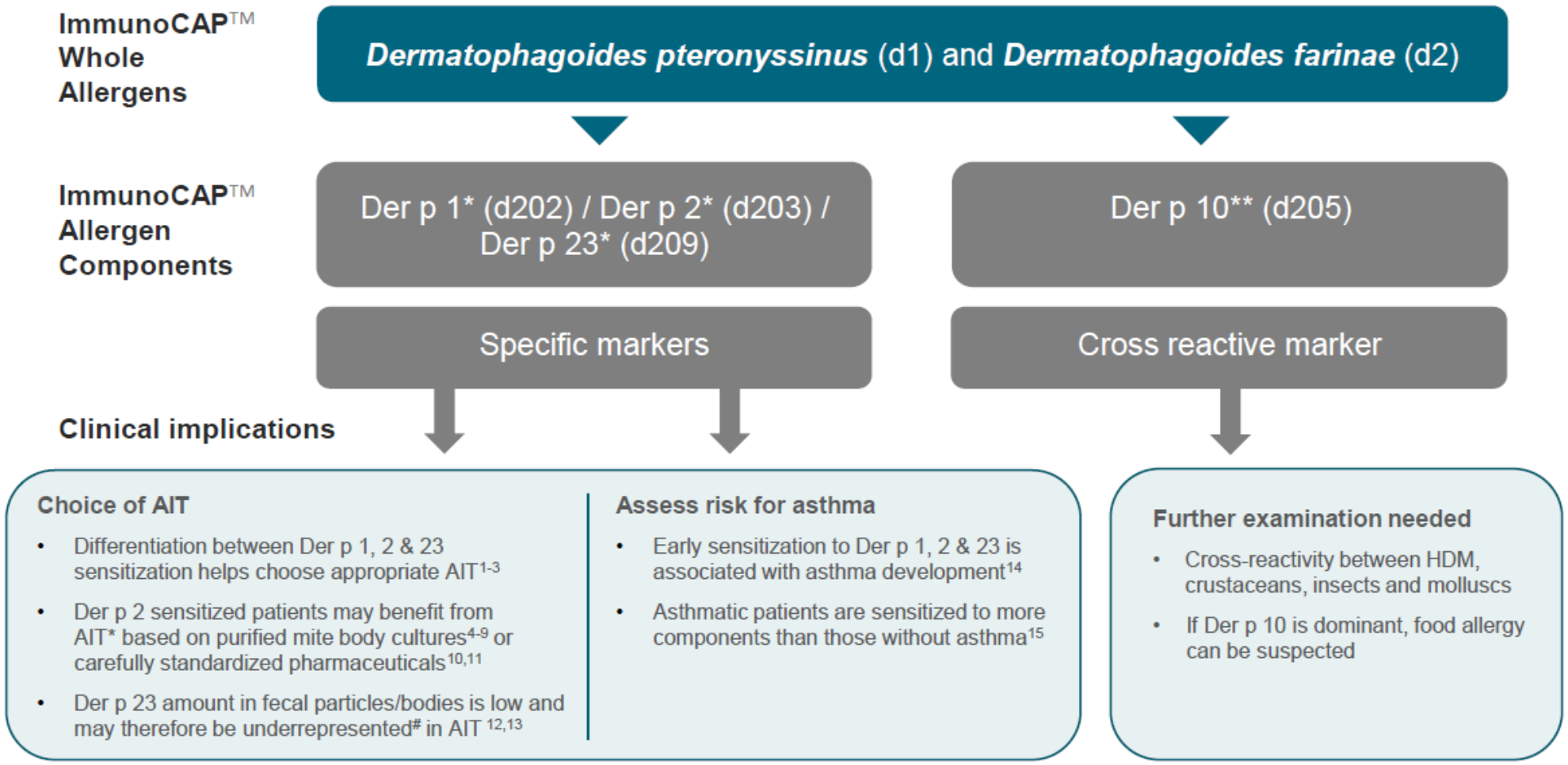
Asthmatic patients are sensitized to more components than those without asthma[2]

** Mite-related allergic rhinitis*

1. Posa D. et al. J Allergy Clin Immunol 2017;139:541-9

2. Resch Y. et al. J Allergy Clin Immunol 2015;136:1083-91

Suggested test profile: HDM allergy



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CLSI guidelines

IgE antibody assays

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Is it allergy?

Clinical and Laboratory Standards Institute

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- 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