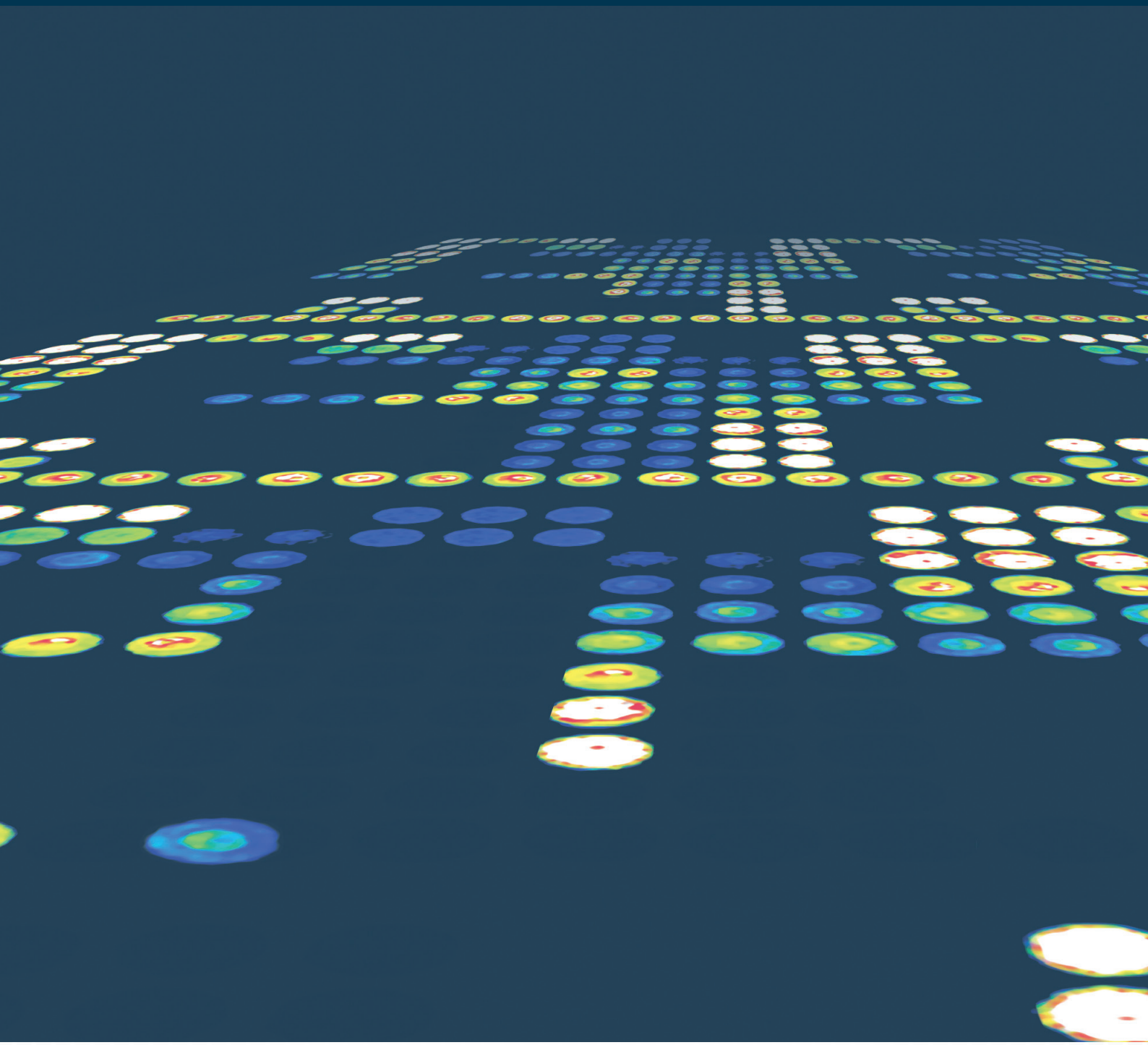
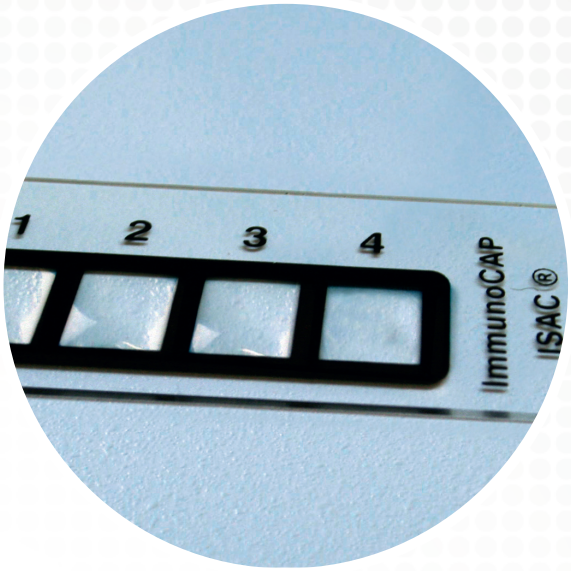
IMMUNOCAP® ISAC sIgE 112



PRODUCT CHARACTERISTICS

Molecular Allergology

ImmunoCAP® ISAC



CONTENTS

INTENDED USE

ImmunoCAP® ISAC sIgE 112 is an in vitro semi-quantitative assay for the measurement of allergen specific IgE antibodies in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

PRINCIPLE OF TEST PROCEDURE

ImmunoCAP® ISAC sIgE 112 is a solid-phase immunoassay. Allergen components are immobilized on a solid substrate in a microarray format and react with the specific IgE in the patient sample. After washing away non-specific IgE, fluorescence-labeled anti-human IgE antibody is added to form a complex. After incubation unbound fluorescence-labeled anti-human IgE antibodies are removed by washing. The procedure is followed by fluorescence measurement using an appropriate microarray scanner. The higher the response value the higher concentration of IgE in the specimen. The test results are analyzed with Phadia Microarray Image Analysis (MIA) Software and ISAC Standardized Units for specific IgE (ISU-E) are estimated.

CLINICAL UTILITY

Most allergic patients are multi-sensitized with positive test results to numerous allergens and the true cause of symptoms can be difficult to identify due to an inconclusive medical history regarding the role of different allergens and reactions.

ImmunoCAP® ISAC can help to:

- Shed light on the real sensitization profile of multi-sensitized patients.
- Reveal potential risk for severe food-related reactions.
- Identify the IgE antibody profile in patients with unsatisfactory response to treatment.
- Assess patients with idiopathic anaphylaxis.

ImmunoCAP® ISAC can also reveal unexpected sensitizations or help to rule out allergy by delivering IgE results for a broad spectrum of allergens.

SAMPLE INFORMATION

30 µl of serum and heparin plasma. Venous or capillary blood can be used.

MEASURING RANGE

0.3 – 100 ISU-E.

PRECISION

The mean coefficient of variation per component within and between assays on ImmunoCAP® sIgE 112 is <25 % covering the measuring range.

Sample level	Mean Coefficient of Variation (CV %)	
	Within	Between
0.3 – 1 ISU-E	14	8
1 – 15 ISU-E	10	6
> 15 ISU-E	9	6

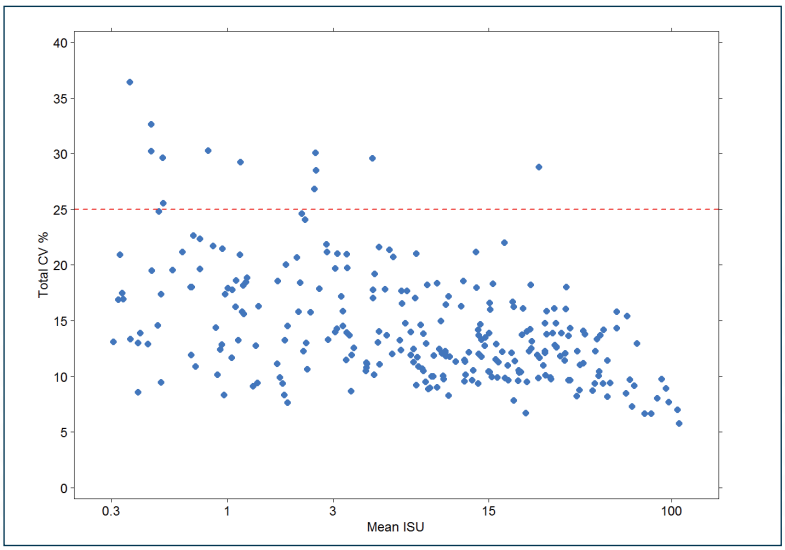


Figure 1. Total CV for four samples (covering 105 components) assayed in 3 replicates in 17 runs over a 4-week period on one chip lot.

SENSITIVITY

The Limit of Detection is < 0.3 ISU-E for all components.

SPECIFICITY

- The cross-reactivity with other human Immunoglobulins is non-detectable at physiological concentrations of IgA, IgD, IgG and IgM.
- No interferences of Total IgE concentratios up to at least 10 000 kU/l.
- No interferences from 5 % hemolysis or at very high concentrations of triglycerides up to 12 mg/ml.

LINEARITY

ImmunoCAP® ISAC sIgE 112 meets the requirements on linearity between dilutions of samples and the calibration curve. See Figure 2 for representative examples of dilution series.

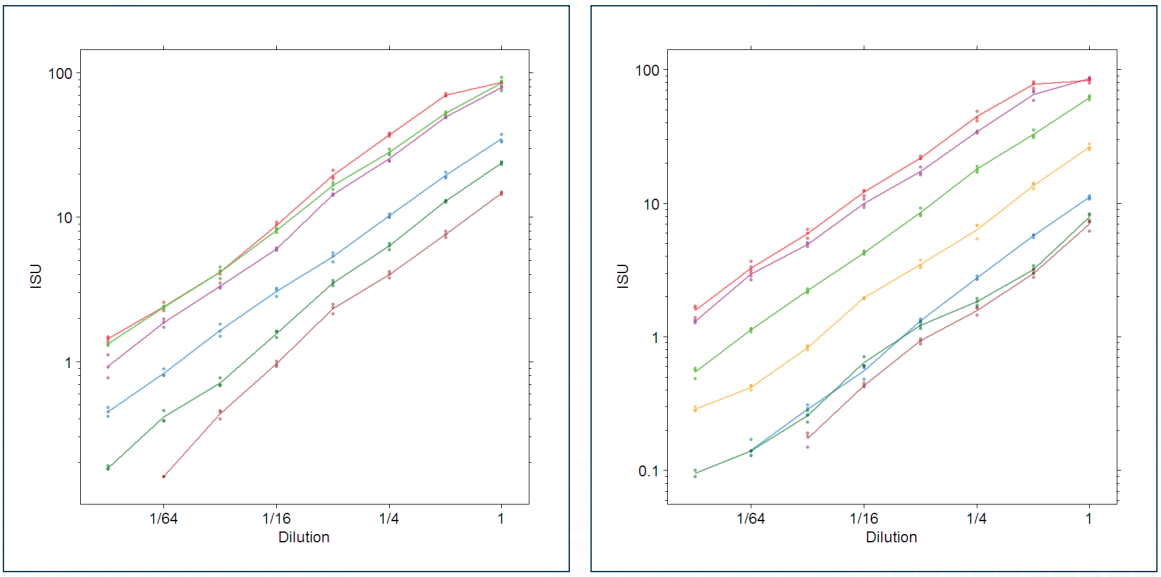


Figure 2. Examples of dilutions for Bet v 1 and Phl p 5.

HEALTHY CONTROLS

One hundred healthy non-atopic individuals were tested and in total 11 200 values have been analysed of which 99,991 % were undetectable. One single sample was identified with IgE abs to two components at 0.3 ISU-E and to one at 0.4 ISU-E.

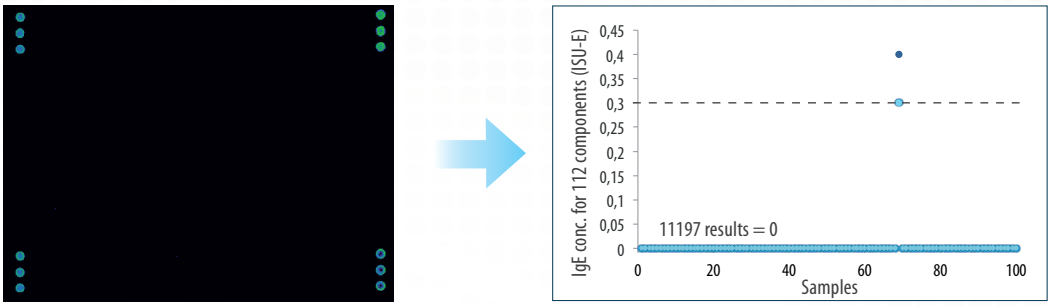


Figure 3. *Left)* Negative test result for one healthy control showing only guide dots. *Right)* Summary of test results for 100 healthy controls x 112 components.

COMPARISON WITH IMMUNOCAP® ALLERGEN COMPONENT

Representative examples of comparison between recombinant ImmunoCAP® allergen components and the corresponding component on ISAC.

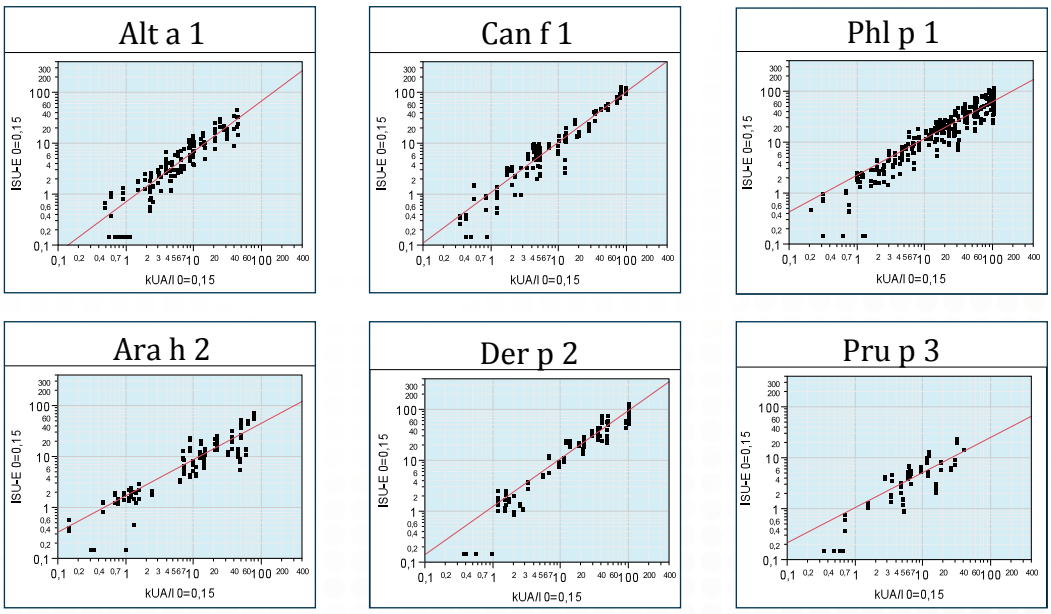


Figure 4. Comparisons of ImmunoCAP® allergen component versus ISAC components.(Negative values set to 0.15).

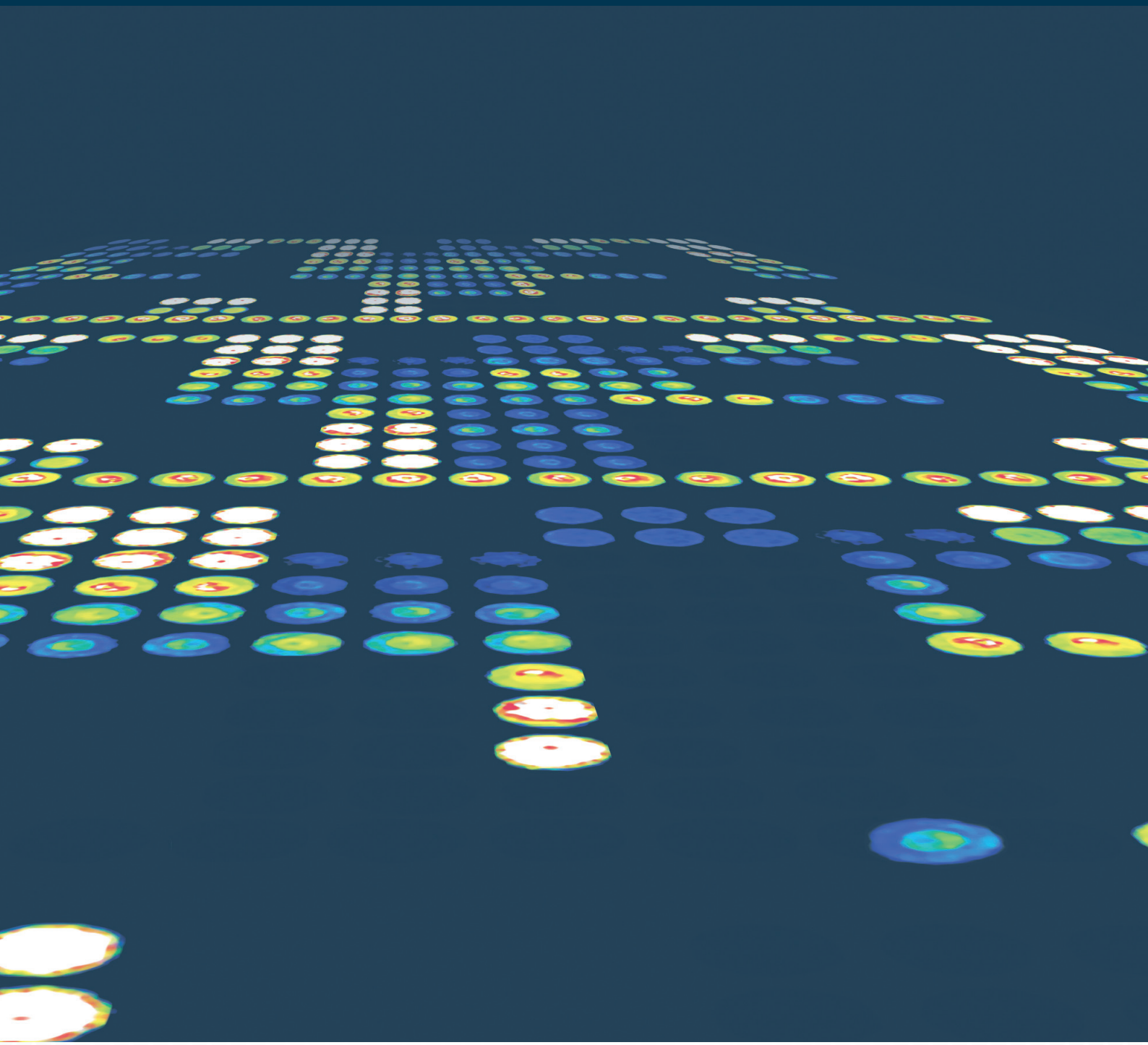
ORDERING INFORMATION

ImmunoCAP® ISAC 112

Product	Size	Art.No.
ImmunoCAP® ISAC sIgE 112	20 tests	81-1011-01
ImmunoCAP® ISAC sIgG4 112	20 tests	81-1012-01
ImmunoCAP® ISAC Starter Pack		81-1010-01
ImmunoCAP® Washing Solution	6 x 1 l	10-9422-01

EXAMPLES OF PUBLISHED IMMUNOCAP® ISAC 103 STUDIES

- The ImmunoCAP® ISAC molecular allergology approach in adult multi-sensitized Italian patients with respiratory symptoms. *Melioli G, Bonifazi F, Bonini S, Maggi E, Mussap M, Passalacqua G, Rossi ER, Vacca A, Canonica GW; on behalf of the Italian Board for ISAC (IBI)*. Clin Biochem. 2011 Aug; 44(12): 1005–1011
- Use of allergen components begins a new era in pediatric allergology. *Magnus P. Borres, Motohiro Ebisawa & Philippe A. Eigenmann*. Pediatric Allergy and Immunology 2011; 22; 454–461
- Microarray of allergenic component-based diagnosis in food allergy. *Maria L. Sanz, Ana B. Blázquez and Blanca E. Garcia*. Current Opinion in Allergy and Clinical Immunology 2011; 11(3): 204–209
- A new tool in the field of in-vitro diagnosis of allergy: preliminary results in the comparison of ImmunoCAP® 250 with the ImmunoCAP® ISAC. *Romy Gadisseur*, Jean-Paul Chapelle and Etienne Cavalier.* Clin Chem Lab Med 2011; 49(2): 277–280
- Comparison of conventional and component resolved diagnostics by two different methods (Advia-Centaur/Microarray-ISAC) in pollen allergy. *M.T. Lizaso, B.E. García, A.I. Tabar, E Lasa, S. Echechipía, M.J. Álvarez, M. Anda, B. Gómez.* Ann. Allergy Asthma Immunol. 2011 Jul; 107(1): 35–41
- Molecular diagnosis in allergy. *Sastre J.* Clin Exp Allergy. 2010; 40: 1442–1460



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