

ALEX²® – Allergy Explorer

THE SMART WAY TO EXPLORE ALLERGY



MADX
MACRO ARRAY DIAGNOSTICS

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ALEX²
ALLERGY EXPLORER



Macro Array Diagnostics is a Vienna-based MedTech company. We develop, produce and distribute tests, instruments and software for allergy diagnostics and research applications. Our products allow flexible, reliable and affordable sensitization profiling of each patient. Our multidisciplinary team ensures that customers receive the most advanced tools to fulfill their diagnostic needs.

For more information visit:
www.macroarraydx.com

MULTIPLEX
Simultaneous
determination of
multiple analytes
(e.g. allergens)

Allergy Explorer is the first in vitro multiplex allergy test allowing simultaneous measurement of total IgE (tIgE) and specific IgE (sIgE) against a plethora of allergen extracts and molecular allergens.

Based on our test panel composition of allergen extracts and molecular allergens, a near complete picture of each patient's sensitization status is obtained. ALEX² is based on our proprietary nano-bead technology. Every allergen (extract) can be individually optimized for production. The flexible analysis software, allows our customers to analyze tailor-made allergen panels as they see fit for their clinical needs – **Multiplex on demand**.

The ALEX² assay protocol integrates a powerful Cross-reactive Carbohydrate Determinants (CCDs) inhibitor during serum incubation, which will clear up your specific IgE results. This reduces the interpretative burden for physicians of CCD positive patients and increases the specificity of our test results.

- Simultaneous measurement of total and specific IgE
- Near-complete allergen panel, individually optimized
- Multiplex test with on-demand panel composition
- Integrated CCD inhibition

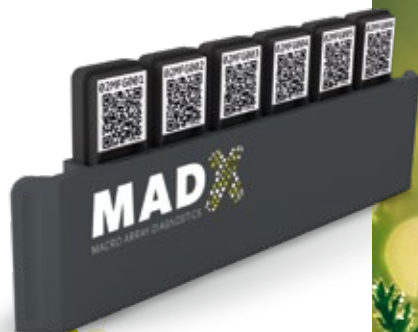




SIMULTANEOUS DETECTION OF tIgE, sIgE EXTRACTS & sIgE MOLECULAR ALLERGENS

Conventional single-plex test systems can be laborious in obtaining comprehensive sensitization profiles. Often, several testing cycles are required to come to a clear diagnosis, and total IgE has to be tested separately. To streamline this fragmented approach, ALEX² gives you a near complete picture of your patient's situation including total IgE. Close to 120 allergen extracts and up to 180 molecular allergens are at your disposal. Exclusively available molecular allergens include risk markers from storage protein families and other new markers (e.g. house dust mite, *malassezia sympodialis*).

For a full allergen list please visit our website
www.macroarraydx.com



ALLERGY EXPLORER KEY FEATURES

SINGLEPLEX

Determination
of one analyte
per assay
(e.g. one allergen)

ANIMAL DANDER

HYMENOPTERA VENOMS

LEGUMES

LATEX

POLLEN

SEA FOOD

MILK

FRUITS

SEEDS

EGG

SPICES

CCDs

TREE NUTS

CEREALS

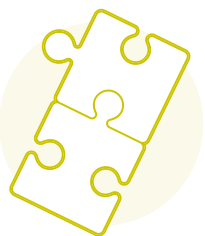
TOTAL IgE

SPORES

MITES

MEAT

VEGETABLES



DISCOVER THE POWER OF MULTIPLEX ON DEMAND

Specifically designed for ALEX², the Raptor analysis software offers maximum flexibility. Choose between up to 15 predefined symptomatic or allergen source based panels (like pollen, anaphylaxis, nuts, insects, etc.)

Lab measurement results will only be displayed and reported for the selected allergens. Alternatively, define your own custom allergen panels to match your personal and your patients needs. This allows you to account for regional differences in allergen exposure and avoids unnecessary testing.

- Full flexibility for physicians
- Adjust the ALEX² allergen panel to individual needs
- Avoid paralysis by analysis

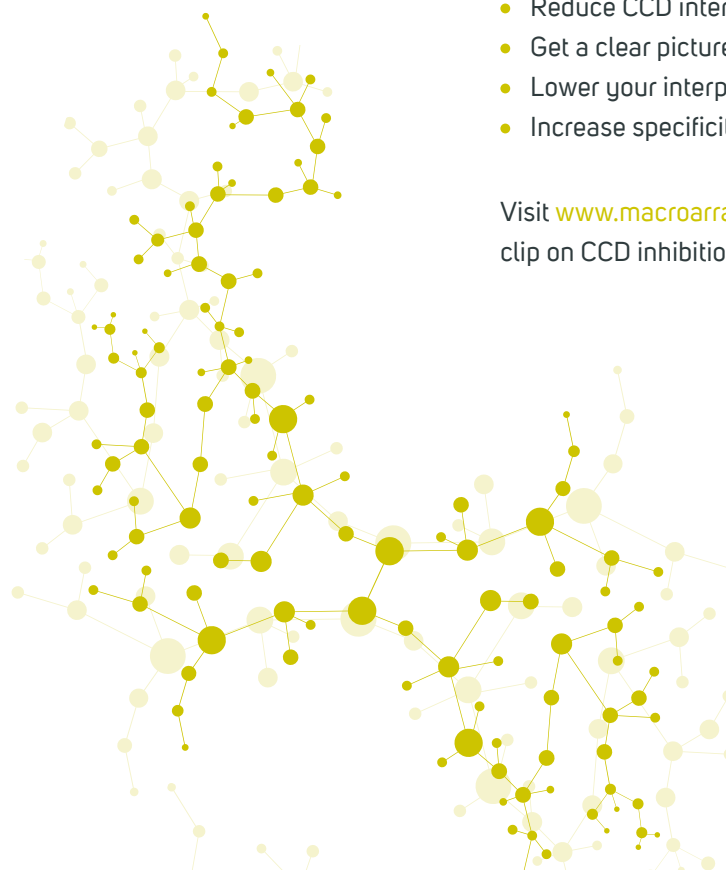


NEAR* CROSS-REACTIVE-DETERMINANTS (CCDs) FREE ALLERGY DIAGNOSIS

Most allergen preparations originating from plants or insects contain cross-reactive carbohydrate determinants (CCDs). IgE Antibodies directed against CCDs cross-react with all proteins containing these CCD epitopes. Approximately 25% of patients have anti-CCD IgEs, resulting in a significant number of positive sIgE results, especially when testing allergen extracts. Anti-CCD antibodies have been reported to be clinically insignificant (Malandain H et al. 2007; Eur Ann Allergy Clin Immunol).

- Reduce CCD interferences
- Get a clear picture of your patient's sensitizations
- Lower your interpretative burden and save time
- Increase specificity

Visit www.macroarraydx.com for an educational clip on CCD inhibition.



*see instructions for use

PRODUCT CHARACTERISTICS

ALEX² is a state-of-the-art multiplex ELISA test based on proven immunoassay chemistry and detection methods. The analytical performance parameters are aligned with the commercial assay systems currently available. A high correlation to reference methods is expected.

For further details please refer to our Instructions for Use or visit www.macroarraydx.com

OVERVIEW

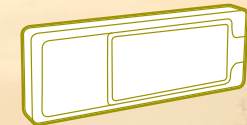
Detection method	Colourimetric enzyme assay
Assay time	3.5 hours
Tests per run	Up to 50 per operator, manual processing
Measuring range sIgE	0.3–50 kU _A /L, quantitative
Measuring range tIgE	≤ 20–2500 kU/L, semi-quantitative
Precision/CV % total	12%
Sample requirements	100 microliter serum or plasma (except EDTA)
Interference	No significant interference from high total IgE, hemoglobin, bilirubin or triglycerides. See instructions for use for details.
Calibration method	Integrated, batch and allergen correction factors encoded by integrated 2D barcode

REQUIRED EQUIPMENT

All necessary lab equipment for processing & analysis of ALEX² will be provided by Macro Array Diagnostics:

ALEX² KIT

1



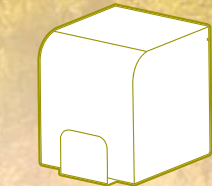
ARRAY HOLDER

2



IMAGEEXPLORER

3



LAB ROCKER & INCUBATION CHAMBER

4



RAPTOR ANALYSIS SOFTWARE

5



WINDOWS PC/LAPTOP
(ONLY PROVIDED ON REQUEST)

6





IMAGER

While some imaging or scanning devices are expensive, delicate and bulky, MADx's ImageXplorer is an easy-to-use and affordable device requiring only 15x18x18 cm of your precious lab space. Both connection and power supply are managed through your personal computers USB port. The acquisition and analysis of a single test takes only seconds.

KEY FEATURES IMAGEXPLORER

- Plug and play setup, easy to use
- Affordable for every lab
- Compact footprint
- Maintenance free



CUSTOMIZED ARRAYS FOR RESEARCH

To support your research efforts, we custom manufacture arrays with panels of selected ALEX² allergens combined with your own allergen preparations. Collaborations with scientists are always welcome at MADx!

- Customized solutions for your research needs
- Minimum order requirement of only 300 tests
- Price on request



CLINICAL UTILITY

The ALEX² test is intended to support the diagnosis of allergic diseases in conjunction with other diagnostic findings such as anamnesis, clinical history or physical examination.

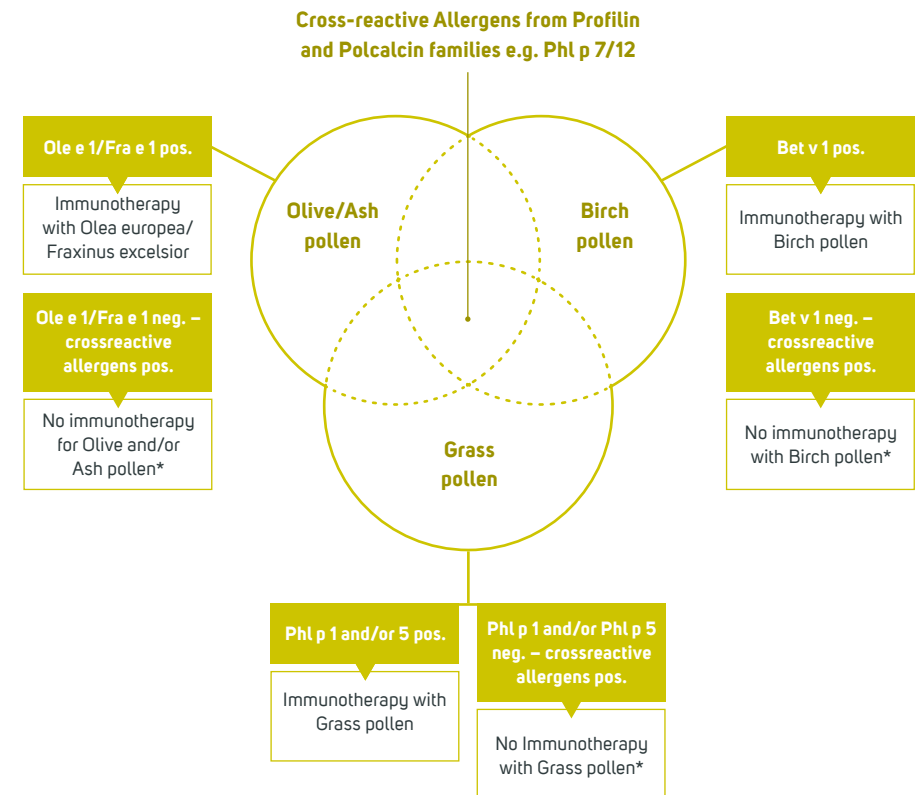
In addition to identifying the sensitizing allergen sources, ALEX² provides an almost complete and high resolution molecular IgE profile at no additional effort or cost. Compared to extract-based diagnostics alone, this can add relevant diagnostic information on:

- Indication for specific immunotherapy
- Risk-assessment for your patient to avoid severe allergic reactions to foods
- Molecular information about cross-reactivity



1 INDICATION FOR IMMUNOTHERAPY

Specific immunotherapy is a causal treatment for allergic diseases especially in inhalative- and venom allergies. With a diagnostic approach that only uses extracts, often multiple allergen sources show a positive test result. These results can either indicate a true co-sensitization or a cross-sensitization. To resolve this dilemma molecular allergens are used.



* look further for primary sensitizer

Source: based on SIT indication (Molekulare Allergiediagnostik, Kleine-Tebbe&Jakob 2015, p.189)

2 RISK ASSESSMENT

Extract-based allergy tests have proven useful for the identification of the culprit allergen source. However, only an additional molecular view can give all the relevant clues to complement the extract test results and to reach the optimal therapeutic decision.

For example, storage proteins such as Ara h 1,2,3 or 6 can cause allergic symptoms up to anaphylactic shock. In contrast, Ara h 8, the PR-10 protein is usually not able to cause serious harm, while still rendering the extract test result positive, thus generating potential uncertainty for both physician and patient. Similar constellations exist for various other food allergens such as soy, hazel-, or walnut.



Source: Risk assessment in peanut (Molekulare Allergiediagnostik, Kleine-Tebbe&Jakob 2015, p.207, Adaption)

ORDERING INFORMATION

ALEX² gives you the full picture, not just pieces of the puzzle.

Order address: orders@macroarraydx.com

Product	Art. No.
2 Array holders	14-0000-00
ImageXplorer	11-0000-01
Raptor analysis software	12-0000-01
Incubation chamber	15-0000-00
Lab rocker	13-0000-00
ALEX ² Kit (20 tests)	02-2001-01

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