# allergia

# **ELISA KITS**

for Allergy Diagnostics



The allergia kits are used for in vitro diagnostics in humans of allergen-specific IgE antibodies in serum or plasma. DST develops, manufactures and markets in vitro diagnostics for laboratory use – a variety of microtiter plate-based detection systems: ELISA (enzyme-linked immunosorbent assay) kits for diagnostics of specific IgE.

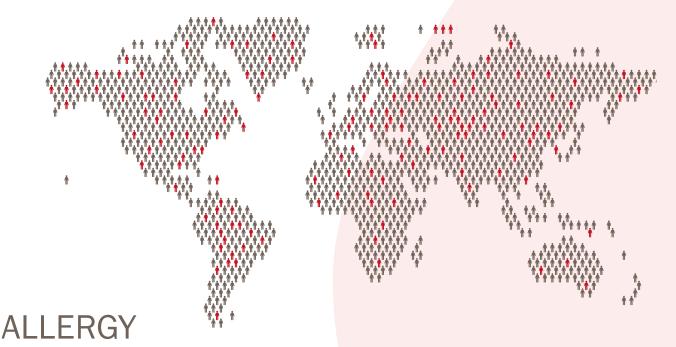


### INTENDED USE

The allergia kits are used for the quantitative determination of specific IgE antibodies against a selection of over 600 high quality, respiratory, food and environmental allergens, including purified major and recombinant ones.

allergia is an in vitro enzyme immunoassay for the simultaneous, quantitative measurement of allergen specific IgE antibodies in human plasma or serum. It's intention is to be used as a tool to support the diagnosis of patients presenting various clinical symptoms associated with allergy. The advantage of the test is a non-invasive, quantitative measurement of plasma or serum samples for several allergen extracts or -mixes at once.

For more information, please see Package leaflet.



Allergic reactions (Type 1 hypersensitivity) tend to be mediated by IgE and manifest clinically as anaphylaxis, allergic asthma, urticaria, angioedema, allergic rhinitis, some types of drug reactions, and atopic dermatitis.

An estimated 30-40 % of the world's population has allergies to one or more common environmental antigens (WOA 2012) and, although rarely life-threatening, these cause much distress and lost time from school and work.

## allergia

# ELISA KIT FOR DETECTION OF SPECIFIC IGE (HUMAN)

#### **Test principle**

allergia ELISA kits are enzyme immunoassay for in vitro detection of allergen-specific IgE in serum or plasma of humans. Allergens are bound on the surface of each well of the microtiter plate. For testing, a diluted sample (serum or plasma) is added to the wells. Specific IgE antibodies of the sample bind to the antigens in the wells during incubation, and non-bound components of serum or plasma are washed away after incubation. Subsequently, digoxigenin-labeled anti-human IgE antibodies and radish peroxidase-coupled anti-digoxigenin antibodies (conjugate) are added.

The digoxigenin-labeled anti-human IgE antibodies bind to IgE antibodies of the sample, standards and controls. The conjugate binds to the digoxigenin-labeled anti-human IgE antibodies. Subsequently, unbound detection anti-

Reference: Package leaflet

bodies are washed away. A color substrate TMB (3,3', 5,5'-tetramethylbenzidine) is added, which is converted by the horseradish peroxidase conjugate bound enzyme. The reaction is stopped by adding a stop solution. A yellow dye is formed and the respective intensity correlates with the proportional amount of locally-bound antibody. The dye formed is quantified photometrically by measuring the extinction. The quantification of the tests is carried out using a point-to-point regression of a 6-point standard curve. Standards are calibrated according to the WHO reference serum 75/5021.

The identified units/mL can be assigned to the respective CAP-classes and provide the level of specific IgE sensitization (Table 1).

## allergia FEATURES AND BENEFITS

- **♦** Kit comes with step-by-step Quick Guide.
- ♠ All necessary reagents for the ELISA are included in the kit
- Requires 50 microliters of serum or plasma per allergen
- **♦ Total assay time: 2.0 hours**
- ♦ Detection range of specific IgE starting from 0.35 kU/L

- ♦ he identified units/ml can be assigned to CAP classes and represent the degree of the specific lgE sensitization
  - ♦ Sensitivity 82.6 % & Specificity 87.8 %
  - **♦** Intra-assay precision/Inter-assay precision: mean coefficient of variation 4.47 %/4.61 %
  - allergia kits can be used with standard automated and semi-automated ELISA analyzers as well.

**Table 1:**Correlation between U/ml of allergen-specific IgE, the CAP-class and the level of IgE-mediated sensitization

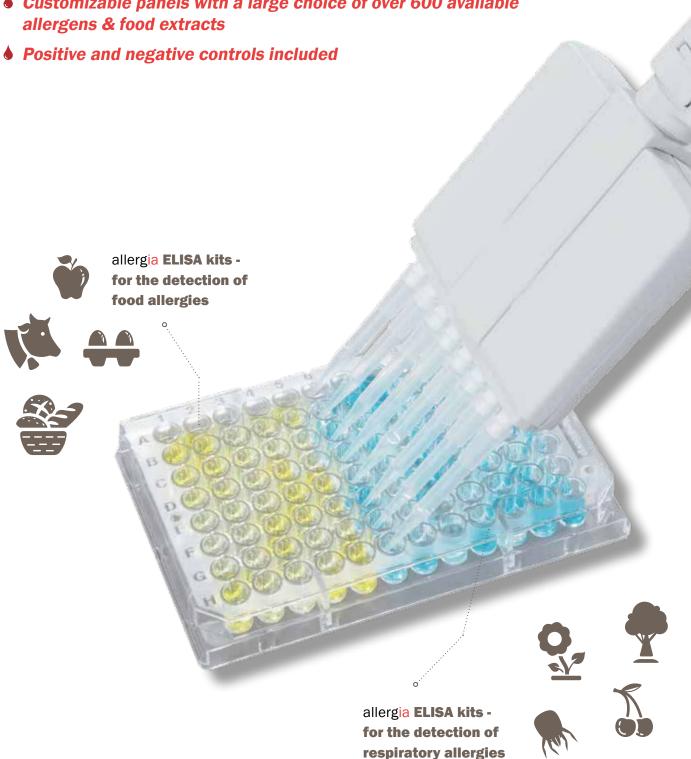
allergen-specific IgE		
CAP-class	U/mL	Sensitization
0	0.00 - 0.34	none
1	0.35 - 0.69	very low
2	0.70 - 3.49	low - moderate
3	3.50 - 17.49	moderate
4	17.50 - 49.99	high
5	50.00 - 99.99	very high
6	≥ 100	extremly high

# allergia ELISA KITS EASE OF USE, CUSTOMIZABLE PANELS.

allergia ELISA kits can be coated with allergens of your choice according to the geographical region, season and food culture. DST extracts more than 600 allergens and foods at its own manufacturing facility, and because of years of research and development our allergens possess excellent reactivity and certified quality and purity. This ensures accurate and clear diagnostic results from all our ELISA kits.









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DST specializes in diagnostic solutions for allergies, food intolerances and professional diet optimization. Our allergen extract production has one of the largest offers in the market: 600 high quality, respiratory, food and environmental allergens and food extracts, including purified major and recombinant

DST is certified by the TÜV Rheinland according to EN ISO 13485.



