

Allergoset[®]-IgE Outdoor I

Instructions for use

1. Introduction

Allergic diseases are triggered by environmental factors (allergens) in genetically predisposed individuals. Following allergen exposure the immune system becomes activated. Immunoglobulin E (IgE) starts to be produced by B-lymphocyte cells of the immune system. After repeated encounter with the same allergen, mast cells of the immune system become sensitised by allergen-IgE complexes and bioactive substances, such as histamine, are released. These substances cause allergic symptoms.

The presence of allergen-specific IgE antibodies in serum indicates that the allergen is involved in the allergic disease, or in the sensitisation stage of the immune system preceding allergy.

Allergoset[®]-IgE Outdoor I detects IgE antibodies specific for 10 different allergens. On the test stick each allergen-mix is represented by a separate dot.

Allergoset[®]-IgE Outdoor I shows not only the presence of antigen specific IgE antibodies but also their quantity (titre) classified into five INTEX categories from 0 (not detectable) to 4 (very high).

2. Test principle of Allergoset[®]-IgE Outdoor I

Allergoset[®]-IgE Outdoor I is an immunoblot assay based on the sandwich-ELISA principle, and carried out as a two step immunological reaction.

First allergen-specific IgE antibodies of the sample (serum or heparinised plasma) react with different allergens bound to the solid phase (dipstick). Each allergen is represented by a dot on the dipstick. Second the unbound antibodies are removed by washing. Third the dipstick is reacted with peroxidase-labelled monoclonal (mouse) anti-IgE antibodies (conjugate). Fourth excess reagent is removed by washing, and the dipstick is placed into an enzyme-substrate solution. A chromogen helps to make the peroxidase reaction visible. Finally the test result can be seen as a coloured dot. The colour intensity is proportional to the concentration of allergen-specific IgE antibody level of the sample.

The evaluation of the test dipstick is assisted by a colour card which is included in the test kit. The results are expressed in INTEX categories (IgE titres) from 0 to 4.

Each dipstick has two control dots, a negative control and an IgE-positive control, the latter indicating that the test operates properly.

3. Materials provided

- 12 dipsticks in blister cards
 each dipstick contains:

	Negative Control
	Positive Control
	Bee venom (i1)
	Wasp venom (i3)
	Pollen of orchard grass (g3)
	Pollen of english rye grass (g5)
	Pollen of blue grass (g8)
	Pollen of dandelion (w8)
	Pollen of plantain (w9)
	Pollen of alder (t2)
	Pollen of hazel (t4)
	Pollen of sallow (t12)

- 2 bottles: Conjugate IgE sp. 6 ml monoclonal (mouse) anti-human IgE peroxidase, stabilised
- 1 bottle: Substrate Buffer 10 ml substrate buffer, stabilised
- 1 bottle: Chromogen 5 ml chromogen, 4-chloro-1-naphthol/H₂O₂ in methanol / glycerol
- 12 patient cards
- 1 colour card 2
- 1 detailed instruction sheet including short instructions

4. Additional materials needed

- Glass beaker or equivalent
- De-ionised or distilled water
- Paper towel
- Watch
- Marking pen

5. Storage and Stability

Between 2-8 °C Allergoset[®]-IgE Outdoor I remains stable until the expiry date printed on the kit. Reagents in each package of Allergoset[®]-IgE Outdoor I test kit are matched for best performance, and therefore should not be interchanged with reagents from another package.

6. Sample collection and preparation

Allergoset[®]-IgE Outdoor I is undertaken by serum or heparinised plasma samples collected according to standard medicinal procedures. Samples can be stored refrigerated at 2-8 °C for a period up to 5 days. For longer term storage samples must be kept frozen at -20 °C. Repeated freezing and thawing should be avoided.

All samples should be brought to room temperature (18-30 °C) before undertaking the test.

7. General comments to the assay procedure

- Dipsticks, reagents and samples must be brought to room temperature.
- The indicated incubation times must be strictly followed in order to obtain uniform and comparable results.
- Samples can be processed individually or in a series.

8. Assay procedure of Allergoset[®]-IgE Outdoor I

① Preparatory steps

- Bring Allergoset[®]-IgE Outdoor I blister and samples (serum or heparinised plasma) to room temperature (18-30 °C).
- Use one separate blister card for each sample.
- Open the blister at the upper left corner and take out the dipstick. Cut the blister as shown and mark the dipstick.
- **Do not touch the test fields of the dipstick.**
- For incubation put the blister card into vertical position (blister racks are available on request).

② First immunological reaction

- Using a pipette fill up blister no. 1 until the mark (1) with the **sample**.
- Immerse dipstick into the sample. Remove air bubbles from the blister by vertical movements of the dipstick.
- Incubate at room temperature **overnight** (16-24 hours).

③ First wash

- Bring all liquid reagents of Allergoset[®]-IgE Outdoor I to room temperature (18-30 °C).
- Place the dipstick into a glass beaker filled with distilled water and incubate (leave there) for 10 minutes. Discard the water after use. Because of slow diffusion the length of this wash should not be shortened.
- Remove dipstick from water and gently blot it on a folded soft paper towel to remove residual water.

④ Second immunological reaction

- Fill up blister no. 2 until mark (1) with (mouse) anti-human IgE-peroxidase (bottle: **Conjugate IgE sp.**). Hold the bottle slightly tilted, with its orifice touching the blister wall inside, and gently press the bottle.
- Immerse dipstick in the conjugate test solution. Remove air bubbles from the blister by vertical movements of the dipstick.
- Incubate dipstick at room temperature for **1 hour**.

⑤ Second wash

- Place the dipstick into a glass beaker filled with distilled water, and incubate at room temperature for 10 minutes. Discard the water after use.
- Repeat wash step with fresh distilled water.
- Remove dipstick from water and gently blot it on a folded soft paper towel to remove residual water.

⑥ Enzyme reaction

- Fill up blister no. 3 with chromogen solution (bottle: **Chromogen**) until the first mark (**1/6**), and subsequently with substrate buffer (bottle: **Substrate Buffer**) until the second mark (**1**). Hold the bottle slightly tilted, with its orifice touching the blister wall inside, and gently press the bottle.
- Place dipstick into blister no. 3. **Immediately after soaking the dipstick mix the two solutions thoroughly by moving up and down the dipstick 5 to 6 times.**
- Incubate dipstick at room temperature for **15 minutes**.

⑦ Third wash

- Place the dipstick into a glass beaker filled with distilled water, and incubate at room temperature for 5 minutes.
- Take dipstick out of the beaker and gently blot it on a folded soft paper towel to remove residual water.
- Dry dipstick in the dark (e.g. in a drawer or a box) at room temperature for 30 minutes.

9. Evaluation of Allergoset[®]-IgE Outdoor I

The test result for a given allergen is positive, when the corresponding dot is coloured in blue. The intensity of the colour should be assessed with the assistance of the colour card 2 included in each test kit. The colour intensity is proportional to the concentration of antigen-specific IgE in the sample. The INTEX-class therefore reflects the following blood level of allergen specific IgE:

INTEX-category	Allergen specific IgE-level
0	not measurable
1	low
2	intermediate
3	high
4	very high

IMPORTANT

- If exposed to light for a longer period of time, the colour on the dipstick may fade.
- If the test has been undertaken properly, the field of the negative control must be white (uncoloured) and the colour intensity of the positive control dot should appear coloured as INTEX category 2 or higher. If the positive control on the dipstick is not clearly visible, the test is invalid.









10. Diagnosis



For a diagnosis, in addition to the results of Allergoset[®]-IgE Outdoor I, the patient history, results of physical examination and if available, the results of other laboratory tests (e.g. skin test) should also be considered.

The Allergoset[®]-IgE Outdoor I contains mixtures of allergens at each test field. For more extended diagnosis of the specification of single allergens from a recognized mixture INTEX offers additional Allergoset[®]-test systems for the specific allergy diagnosis:

Allergoset[®]-IgE Basic Screen, Allergoset[®]-IgE Inhalant, Allergoset[®]-IgE Food

11. Symbols

	Article number		For single use only
	Lot number		Expiry date
	Storage		Content
	Only for in vitro diagnostics		Instructions for use

Allergoset [®] -IgE Outdoor I		
	12 Blisters	AO1212



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