Individuals with allergic sensitivity to various substances such as pollens, animal hairs or feathers or some foods, have abnormally high levels of IgE (Immunoglobulin E) antibodies. That sensitivity can be developed at different moments of life, but can affect children, adolescents, and adults.

The main allergy symptoms are redness on the skin, rash, lacrimation, repetitive sneezing, and oedema. Those symptoms can be mixed up with usual signs of viral and bacterial infections such as flu, cold, and bacterial sore throat. That is why it is important to check if the IgE level is abnormally high in those cases or in subjects having family history of allergy.

Through determining an immunoglobulin E level higher than the average, the physician can direct to a more specific search for substances causing allergic manifestations, and can define a therapy adapted to the patient.

With ALLERGY TEST, you can assess IgE levels in blood and detect any allergy sensitivity. It can be used also for children from 6 years old.

### CONTENT

- 1 test device
- 1 plastic pipette
- 2 sterile lancets for blood sampling
- 1 disinfectant pad
- 1 instructions leaflet
- 1 dropper bottle containing 1 mL of diluent.

### PRECAUTIONS

1. Carefully read the instructions before performing the test. The test is easy to use if the instructions are carefully respected.
2. Follow strictly the indicated time, blood and diluent quantities.
3. Do not use after the expiry date printed on the label or on the protective pouch.
4. Keep out of reach of children. Carefully follow all the instructions for the test. The test is easy to use if the instructions are carefully respected.
5. Only open the protective pouch when you are ready to use the test.
6. Store between +4°C and +30°C. Do not freeze.
7. Do not store the test device where there is high humidity.
8. Do not re-use the Allergy test device and lancet.
9. DO NOT SWALLOW.
10. Do not use after the expiry date printed on the label or on the protective pouch.
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**ALLERGY TEST - IGE**

Easy to use rapid Self-Test for the detection of allergy sensitivity - IgE.
PROCEDURE

1) Wash your hands with soap and rinse with clear warm water.
2) Tear the protective pouch (from the notch) and only get out the device and the pipette. Dispose of the small desiccant bag.
3) Push the small orange rod into the body of the lancet until hearing a CLICK indicating the device is activated.  - FIG. A
4) Be careful not to push the trigger because the needle can come out too early.
5) Remove the orange rod by turning it on the left or on the right.  - FIG. B
6) Clean the end of the forefinger or of the middle finger with the disinfectant pad.
7) Keep the hand down massage the end that was pricked to obtain a blood drop.  - FIG. C
8) Without pressing the pipette bulb, put it in contact with the drop.  - FIG. D
9) Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.  - FIG. F
10) Wait for the blood totally being dispensed in the well. Unscrew the blue cap of the plastic dropper (leave the white cap tightly screwed) and add 5 drops of diluent into the sample well of the device.  - FIG. G
11) Read the result after 10 minutes.

RESULT INTERPRETATION

READ THE RESULT AFTER 10 MINUTES. DO NOT READ THE RESULT AFTER 15 MINUTES.

The intensity of the line colour does not have any importance for the interpretation of the test result.

POSITIVE RESULT
Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C. This result means that the IgE antibodies level in blood is higher than the norm. You should consult a doctor as you may suffer from an allergy or from an allergic predisposition.

NEGATIVE RESULT
Only one coloured line appears under the mark C (Control). This result means that the IgE antibodies level in blood is normal and that there is no allergy sensitivity.

NON VALID RESULT
No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. In this case, it is not possible to interpret the test, which must be considered as non valid. It is recommended to repeat the test with a new Allergy Test and a sample of fresh blood.

F.A.Q. - QUESTIONS AND ANSWERS

HOW DOES THE ALLERGY TEST WORKS?
IgE antibodies are produced by the body in reaction to the presence of one or several allergens likely to cause more or less serious complications in subjects exposed to allergenic substances. ALLERGY TEST specifically identifies IgE antibodies and indicates if the level is higher than the average.

WHAT DO I HAVE TO DO IF THE RESULT IS NEGATIVE?
If the result is negative, it means that the test was performing well. In principle, there is no risk of allergy sensitivity. However if the symptoms persist, it is recommended to consult your doctor.

WHAT DO I HAVE TO DO IF THE RESULT IS POSITIVE?
If the result is positive, it means that the IgE (Immunoglobulin E) antibodies level in blood is higher than the norm and that you should consult a doctor showing him the test result.

WHAT DO I HAVE TO DO IF THE RESULT IS INCOMPLETE?
If the result is incomplete, it means that the test was not performed well. The test should be considered as positive whatever the colour intensity of the test line is.

WHAT DO I HAVE TO DO IF THE RESULT IS INCORRECT?
If I read the result after 15 minutes, will the result be reliable?
No. The result should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

CAN THE RESULT BE INCORRECT?
The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if ALLERGY TEST gets wet before test performing or if the quantity of blood dispensed in the sample well is not sufficient, or if the number of diluent drops are less than 4 or more than 5. The plastic pipette provided in the box allows making sure the collected blood volume is correct.

WHAT IS THE LINE THAT APPEARS UNDER THE MARK C (CONTROL) FOR?
When the disinfectant pad is cleaned with the disinfectant pad.

WHAT IF I READ THE RESULT AFTER 15 MINUTES, WILL THE RESULT BE RELIABLE?
No. The result should be read within 10 minutes after adding the diluent.

CAN THE RESULT BE INCORRECT?
The test result is incomplete if:

- The device is not activated.
- The blue cap is not tightly screwed and the plastic dropper do not have the required quantity of diluent.
- The pipette bulb is not pressed until hearing a CLICK.
- The quantity of blood dispensed into the sample well is not sufficient.
- The tests are not performed in the case of symptoms that can be associated with the allergy, such as rashes and redness on the skin, lacrimation or repetitive sneezing in presence of dust or in contact with animals (dog, cat, etc.), or appearance of oedema after ingesting particular food.

The test can be performed at any time, but not in subjects younger than 6 years.

WHAT DO I HAVE TO DO IF THE RESULT IS NEGATIVE?
- Soak between +4°C and +30°C
- Read the instructions before use
- Do not reuse
- 5 drops
- Expired date (last day of the months)
- Legal manufacturer
- 4.83

WHEN SHOULD THE TEST BE USED?
ALLERGY TEST should be performed in the case of symptoms that can be associated with the allergy, such as rashes and redness on the skin, lacrimation or repetitive sneezing in presence of dust or in contact with animals (dog, cat, etc.), or appearance of oedema after ingesting particular food. The test can be performed at any time, but not in subjects younger than 6 years.

WHAT IS THE ACCURACY OF ALLERGY TEST?
The Allergy TEST is very accurate and is used for more than 10 years by professionals in the field (hospitals, laboratories...). Evaluation reports show that an overall agreement of at least 96% with reference methods.

WHAT DO I HAVE TO DO IF THE RESULT IS NEGATIVE?
The test is negative if one or several allergens are present in the body, which means that the IgE antibodies level in blood is normal. In principle, there is no risk of allergy sensitivity. However if the symptoms persist, it is recommended to consult your doctor.