

ALLERGY-CHECK®

Ref. 18084/ZA

Self Diagnostic Test for the detection of allergy marker in blood.

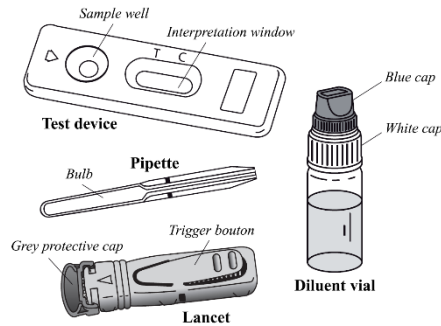
GENERAL POINTS

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 in different moments of life, but can affect children, teenagers, 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 doctor can direct to a more specific search for substances causing allergic manifestations, and can define a therapy adapted to the patient. With ALLERGY-CHECK® you can assess IgE levels in blood and detect any allergy sensitivity.

PRESENTATION

The box contains all the material necessary to perform a test:

- **1 sealed aluminium** pouch containing:
1 test device, 1 plastic pipette and 1 desiccant bag.
- Only open the protective pouch when you are ready to use the test. The desiccant pouch should not be used.
- **1 sterile lancet for blood sampling.**
- **1 dropper bottle containing 1 mL of diluent.**
- **1 instruction leaflet.**



Not provided necessary material: absorbent cotton and alcohol 70 % vol. or alcohol pad.

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic use. External use only. **DO NOT SWALLOW.**
2. **Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected. Follow strictly the indicated time, blood and diluent quantities.**
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if this pouch is damaged.
5. Do not reuse the ALLERGY-CHECK®.
6. **Keep out of reach of children.**
7. After use, all the components can be discarded in a dustbin.
8. Not suitable for children under 6 years' old.

PROCEDURE

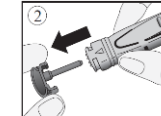
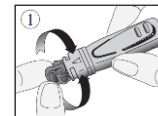
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. **Wash your hands thoroughly.** Use soap and warm water. Dry your hand with clean towel.



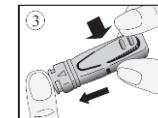
2. **Prepare the test device and the pipette.** Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.

3. **Prepare the lancet.** Hold the lancet **without touching the trigger button**. Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.



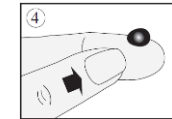
4. Clean the end of the middle finger or ring finger with cotton damped with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.

5. **Press platform firmly against the lateral side of the previously cleaned finger and press the release trigger button**③.



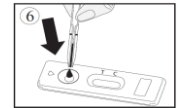
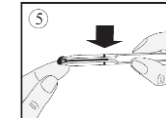
6. The tip will automatically retract into the body of the device.

7. Rub the finger's end to obtain enough whole blood sample ④.



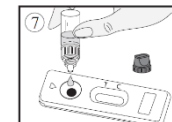
8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.

9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



10. Wait 30-40 sec for the blood being totally absorbed into the sample well. **Unscrew the blue cap** of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows:

Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device⑦ with an interval of 2-3 seconds between each drop.



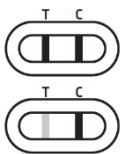
11. Read the result after 10 minutes. Do not interpret after 15 minutes.

RESULTS INTERPRETATION

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

1. 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.



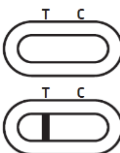
2. Negative result

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.



3. Invalid 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 invalid. It is recommended to repeat the test with a new ALLERGY-CHECK® device and new blood sample.



QUESTIONS AND ANSWERS

How does ALLERGY-CHECK® work?

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-CHECK® uses a couple of antibodies detecting specifically IgE immunoglobulins by producing a coloured test line under the T mark of the cassette. A control line capturing the reagent excess appears as a coloured line under the C mark of the cassette. In case both lines appear, the test indicates that the level of IgE antibodies is higher than normal (> 150 IU/mL determined against W.H.O.* reference).

*World Health Organisation

When should the test be performed?

ALLERGY-CHECK® 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.

Can the results be incorrect?

The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if ALLERGY-CHECK® gets wet before test performing or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure the collected blood volume is correct.

How to interpret the test if the colour and the intensity of the lines are different?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as positive regardless of the colour intensity of the test line is (T), even weak.

What is the line that appears under the mark C (Control) for?

When this line appears, it only means that the test has been performed well.

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.

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. Then, the doctor will decide whether additional analysis should be performed or will recommend you to consult an allergist.

What do I have to do if the result is negative?

If the result is negative, it means that the IgE (Immunoglobulin E) 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.

What is the accuracy of ALLERGY-CHECK®?

The ALLERGY-CHECK® is accurate and is used for more than 10 years by professionals in the field (hospitals, laboratories...). Evaluation reports show an overall agreement higher than 97.03% [91.15 – 99.61**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.

** CI 95%: 95% Confidence Interval.

Information on allergy and related diseases

1. Indications du dosage des IgE spécifiques. Haute Autorité de Santé. Mai 2005.

2. Web information : www.worldallergy.org

Sterile lancet: **STERILE R** **CE** 1639

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EC REP GERMANY

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	Read the instructions before use	IVD	For in vitro diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiration date
	Manufacturer	EC REP	Authorized EU representative		

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CHANGES DESCRIPTION

Changes type :

- N/A	Not Applicable (creation)
- Technical change	Addition, revision and/or removal of information related to the product.
- Administrative	Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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