

Self-testing device for allergy detection in whole blood (IgE) (at-home allergy test)



FAST



EASY



ACCURATE



Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit www.adventlife.net.

ALLERGIES

A stuffy or runny nose, rashes on the skin, itchy nose, eyes or ears, coughing and sneezing are just some of the symptoms that occur in an allergic reaction. It is an immune system response caused by hypersensitivity to various substances that are harmless to the body, which causes some of the symptoms listed.

WHAT IS AN ALLERGIC REACTION?

Most commonly, an allergic reaction is defined as a hypersensitivity to substances known as allergens, which are usually harmless to most people. Immune cells incorrectly identify them as a threat. In response to this "attack," the immune system synthesizes immunoglobulin class E antibodies (IgE), resulting in an allergic reaction of the body.

WHAT ARE THE SYMPTOMS?

Depending on what provokes the allergic reaction, the symptoms can be very different. Some of the most common symptoms are:

- Skin problems (rash, itching, swelling, inflammation, pain, hives, eczema)
- Sneezing and coughing
- Nasal congestion
- Runny nose
- Difficulties when breathing
- Itching in the nose, eyes and ears
- Red or watery eyes
- Nausea, vomiting, diarrhoea

SELF-TESTING DEVICE FOR DETECTION OF ALLERGY MARKER IN WHOLE BLOOD

PURPOSE

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 that have a family history of allergies.

Through determining an IgE level higher than the average, the doctor can direct to a more specific search for substances causing allergic reactions, and can assign a therapy adapted to the patient.

With ALLERGY-Check® test, you can assess IgE levels in blood and detect any allergy sensitivity.

FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. **Do not freeze!**

1 test per box.

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 test uses a couple of antibodies detecting specifically IgE immunoglobulins by producing a coloured test line under the T mark of the cassette.

Easy to read results.

The ALLERGY-Check test is accurate and has been used for more than 10 years by professionals in the field (hospitals, laboratories, etc.). 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 occur.

CLINICAL EVALUATION RESULTS

Sensitivity: 98.52 %

Specificity: 93.90 %

Accuracy: 97.03 %

PROVIDED MATERIALS:

- 1 sealed aluminium pouch containing:
 - 1 test device
 - 1 plastic pipette
 - 1 desiccant bag

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

- 1 sterile lancet for blood sampling.
- 1 dropper bottle containing 1 mL of diluent.
- 1 instruction leaflet.

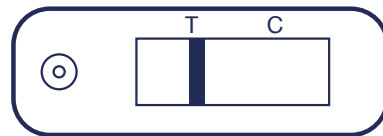
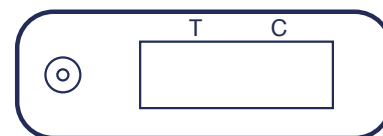
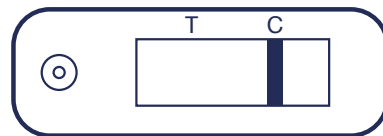
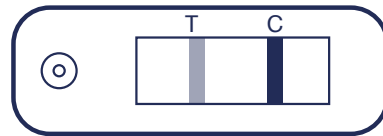
REQUIRED MATERIALS NOT PROVIDED:

Absorbent cotton and alcohol 70% vol. or alcohol pad.



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 hands with a clean towel.
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them within 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 $\frac{1}{4}$ of the way until you feel it separate from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished.
4. Clean the end of the middle finger or ring finger with cotton moistened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. Press the platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button.
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.
8. Without pressing the blood drop that has formed, put the plastic pipette in contact with the blood sample. The blood migrates into the pipette through capillarity to the line indicated on the pipette. You may rub your finger again to obtain more blood if the line is not reached. Avoid air bubbles as much as possible.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.
10. Wait 30-40 sec for the blood to be completely 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 device with an interval of 2-3 seconds between each drop.
11. Read the result after 10 minutes. Do not interpret after 15 minutes.



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

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

Invalid: 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 a new blood sample.

NOTE:

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

This test is exclusively intended for in vitro diagnostics use. External use only. **DO NOT SWALLOW.**

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.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not reuse the ALLERGY-Check® test.

Keep out of reach of children.

After use, all the components can be discarded in a dustbin.

Not suitable for children under 6 years old.