

Allergy identification

Rapid test for the detection of cat – hair –, grass pollen – and dust mite allergy

30 min



Accuracy
> 94 %



Allergy - a sensitive issue: Who or what is the trigger?

Many people suffer from allergy symptoms such as sneezing, blocked nose or stinging eyes, without knowing what they are allergic to.

Knowing where you stand: Allergy identification rapid test

The Allergy identification rapid test enables you to find out in minutes whether you have any allergies and what your body is allergic to: cat hair, grass pollen, dust mites. With this knowledge it is easier to avoid the allergens and discuss further measures with your doctor.

How reliable is the Veroyal® test?

The Allergy identification rapid test was developed for the purpose of making the accuracy and dependability of modern diagnostics also available for private use at home. The test can measure elevated levels in the blood of allergy antibodies of the Immunoglobulin E (IgE) type against cat hair, dust mites and grass pollen. **Accuracy, as evidenced by performance evaluation studies, is greater than 94 %.**

Is the test complicated to perform?

No: All you need are clean washed hands, a clock and a flat table surface. The exact test procedure is described overleaf. For children under 16 years of age, the test should be performed by a parent.

What should I pay attention to?

Warnings and important notes:

- If the details of the instruction leaflet are not correctly followed, false results may be produced.
- The accuracy of the self-test is dependent on the test being performed correctly.
- Using too little or too much blood can distort the result.
- The components supplied within a test-set are only intended for one-time use in combination with each other.
- In principle, a final diagnosis should only be made by the doctor in association with evaluating clinical symptoms and additional laboratory data.
- All test components can be discarded in the original packaging in the normal domestic waste.
- Do not use the test after the expiry date.
- Do not use the test if the foil bag has been opened or components are damaged.
- Do not use the test if the desiccant is green (and not yellow or pale yellowish-green).
- Perform the test directly after opening the foil bag.
- Please store the self-test out of the reach of children! Do not swallow any of the contents.
- Only for use outside of the body.

Important information:

Do not make any medical decisions without previously having obtained the advice of a doctor. If you performed the test to monitor an existing illness, you should only alter your current treatment if you are professionally qualified to do so.

www.veroyal.en

Materials

- 1 test cassette with desiccant in foil bag
- 1 container with reagent solution

NanoRepro AG
Untergasse 8
D-35037 Marburg
STERILE R 0483

- 1 automatic lancing device with sterile lancet for taking the blood sample

BD Vacutainer Systems
Plymouth, PL678P,
UK
STERILE R 0050

- 1 pipette

Safe-Tec Clinical Products
Cepartner: 4U bv3951
DB Maam, NL

- 1 alcohol swab

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany

- 1 plaster

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim,
Germany

- 1 instruction leaflet

Explanation of symbols

| | | |
|--|--|---|
| Consult instruction leaflet | In vitro diagnostic product (For use outside the body) | Expiry date (see imprint on packaging) |
| Store in a dry place at 4–25°C. Do not freeze. | Contents sufficient for 1 test | Do not re-use |
| Manufacturer | Sterilised by irradiation | Batch number (see imprint on packaging) |
| Reaction time in the test cassette | Rapid test for self-testing | |

NanoRepro AG
Untergasse 8
D-35037 Marburg
 0483
Distributed by:
EN – PAUL HARTMANN Ltd.
Heywood OL10 2TT
office@en.hartmann.info

Allergy identification

Rapid test for self-testing

This is how it's done:

1 • Lay out the test components on the table in front of you

- (1) Container with reagent solution
- (2) Alcohol swab
- (3) Automatic lancing device
- (4) Pipette
- (5) Test cassette
- (6) Plaster

Preparation

- Leave the test-set at room temperature for at least 2 hours. Use test-set at room temperature within 30 minutes after opening. Open the bag with the lancing device and the pipette. Do not pull the blue slider, move this only as instructed (15 min. after addition of the reagent solution). It is important that your hands are warm and dry, as this improves blood circulation and makes it easier to take the blood sample. Lay the test cassette and the container with the reagent solution on a clean, flat base.

2

- Twist the blue tip of the automatic lancing device (3) until it detaches. (Do not use if blue tip is missing).
- Massage the tip of your index finger and clean with the alcohol swab (2). Allow your finger to dry.
- Press the automatic lancing device (3) with the white spring-loaded mounting very hard against your clean fingertip, until it clicks and a puncture has been made.

3

- Massage your finger several times with the thumb of your other hand in the direction of the fingertip, with the fingernail facing upwards, until a large drop of blood appears.
- Squeeze the large drop of blood out of the fingertip.
- Hold the pipette (4) horizontally into the drop of blood until the indicated marking is reached.
- The pipette (4) fills automatically (capillary effect), do not squeeze it.
- Using too little or too much blood can distort the result.
- Use the enclosed plaster (6) if required.

4

- Hold the pipette (4) vertically and squeeze the blood gently into the smaller depression in the test cassette (5).
- If the blood does not come out, squeeze the black markings of the pipette (4).

5

- Screw open the container with the reagent solution (1) and pour the entire contents into the large well.
- Wait exactly 15 minutes and do not move the test cassette (5).

6

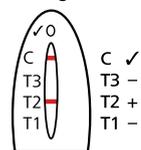
- Hold the test cassette (5) horizontally and pull the blue slider until it locks in place.
- Test progress indicator (✓) changes colour from blue to white.
- Lay the test cassette down onto a flat base again and do not move it for 15 minutes. In the event of a high IgE level, a positive result may now already be visible. You should wait a further 15 minutes to confirm a negative result. After a total of 30 minutes, the result can no longer be read accurately.

Positive result

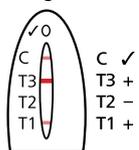
Allergy to 1 to 3 triggers (allergens)

Examples:

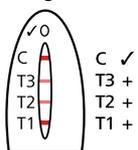
1 allergen



2 allergens



3 allergens



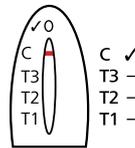
C = Control line
T1 = Cat hair
T2 = Dust mites
T3 = Grass pollen

In each case, the test result shows a red line in the control field (C) and one to three light or intense red lines in the test fields (T 1–3). Depending on how many pink-coloured or red lines appear in the test fields, this means that you possibly have an allergic reaction to one, two or all three allergens, as an increased amount of IgE antibodies was measured. That is, the test is positive in each of these cases. A positive result is only significant if you actually have or have had allergy symptoms in the past. Discuss how to proceed with your doctor.

False positive and false negative results:

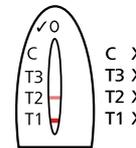
Elevated IgE values may be a useful indication of an allergy risk. A high IgE value alone is as yet not a definite sign that your allergy risk is increased. A positive result is only significant if you have actually had allergy symptoms. Conversely, however, even in the case of normal IgE values, it cannot be ruled out that you will have a risk of allergy in the future. Many people indeed have unusually high IgE values, but do not show any obvious symptoms. The protection afforded by the antibodies (IgE) may inhibit the occurrence of symptoms, or they are only rarely associated with the allergy trigger. Nevertheless, symptoms may occur at a later point in time. If you have a rheumatic illness (arthritis), it must be kept in mind that a very weak positive result can be observed even if you do not have any specific allergy.

Negative result



The test result shows a red line in the control field (C) and no line in the test fields (T 1–3). An increased amount of IgE allergy antibodies in the blood could not be detected. To clearly confirm a negative result, please wait a maximum of 30 min after pulling the blue slider.

Invalid result



If no line forms in the control field (C), the test has been performed incorrectly or incompletely. The test then provides no answer as to whether or not an allergy is present. Repeat the test with a new test cassette.