

# AllergoCHECK®

Cat, Dust Mite, Grass Pollen Allergy? Test yourself at home now!

Rapid test for the qualitative detection of elevated IgE antibody levels against cat hair, house dust mites and grass pollen in blood samples

## INSTRUCTIONS FOR USE

### INTRODUCTION

Typical signs of allergy are sneezing, a stuffy nose or burning eyes. In an allergy, the body's immune system reacts to essentially harmless substances from the environment (allergens) through a hypersensitivity reaction.

In the most common type of allergy (type I allergy), the immune system responds to allergen contact through the formation of immunoglobulin E (IgE) antibodies.

AllergoCHECK® can be used to detect antibodies to various airborne allergens to confirm an existing allergy. As a rapid immunochromatographic test for self-testing, AllergoCHECK® detects elevated IgE antibody levels specific to cat hair, house dust mites and grass pollen from a whole blood sample. If specific IgE antibodies (spec. IgE) are present against the said allergens, they bind to the membrane-fixed allergens and are visualised by colloidal gold-labeled anti-IgE antibodies. They produce a visible red line at the respective allergen line.

The test also includes an internal control system consisting of a control line (C-line). It confirms sufficient sample volume and a correct test procedure.

AllergoCHECK® achieves comparable results with laboratory tests. The test can be performed at any time of the year and does not require discontinuation of medication or the acute presence of allergic symptoms.

It serves to detect a sensitisation to the corresponding allergen. The specific IgE determination is part of the stepwise allergology diagnostic, so the test should only be evaluated together with other clinical information. The final diagnosis must be confirmed by a physician.

How the result is determined and interpreted requires a thorough reading of the instructions for use. All details should be understood before the test is performed.

### TEST CONTENTS

- 1 test cassette in a sealed pouch (spec. IgE e1, d1, g6)
- 1 transfer pipette  
Sarstedt AG & Co  
Sarstedtstraße 1  
D-51588 Nümbrecht
- 1 disposable ampule with sample dilution buffer  
IVD
- 1 automatic sterile lancet for comfortable blood sampling  
Owen Mumford Ltd.  
Brook Hill, Woodstock  
Oxfordshire, OX20 1TU, UK
- 1 alcohol pad  
Paul Hartmann AG  
89522 Heidenheim, Germany
- 1 plaster  
Paul Hartmann AG  
89522 Heidenheim, Germany

- 1 instructions for use
- 1 timer

### TEST PREPARATION

Let test cassette and solution bottle stand at room temperature (15°C to 25°C) before performing the test. The test should be performed immediately after opening the pouch. It is important that your hands are warm and dry, as it improves blood circulation and facilitates blood collection.

### TEST PERFORMANCE

Read the instructions for use completely before performing the test.

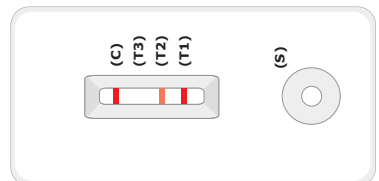
A step-by-step instruction is given on the next page and describes the test procedure.

### EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak the control line (C) is.

### POSITIVE RESULT

If a faint red to dark red control line (C) is visible in the result window and one or more faint red to dark red lines are visible in the test field (T), the test result is positive.



- T1 – Cat hair
- T2 – House dust mites
- T3 – Grass pollen

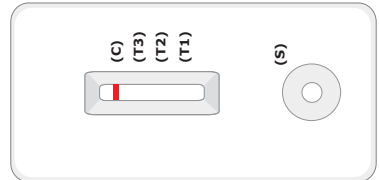
A faint or dark red line next to each test field indicates that an elevated level of IgE allergy antibodies has been measured and indicates that sensitisation to the allergen is present and you may be allergic to it.

A final diagnosis should be made by a physician in connection with the evaluation of clinical symptoms and other laboratory data. The physician can then discuss treatment options with you.

### NEGATIVE RESULT

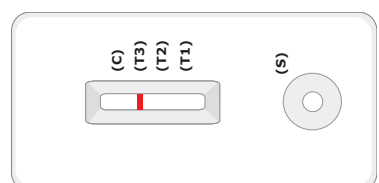
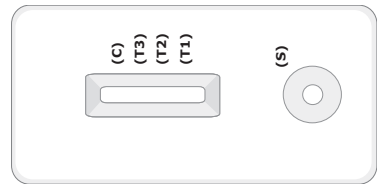
The test result is negative if a faint to dark red line appears in the control panel (C) and no faint to dark red line can be recognised in the test field (T). The test shows that no IgE antibodies that indicate an allergy are detectable in the blood sample. An allergy to cat hair, house dust mites and grass pollen can be almost ruled out. If allergic symptoms or other symptoms persist, further diagnostic evaluation by your physician is required.

Have the result confirmed by a physician especially in case of an autoimmune disease, as false-negative results may occur in rare cases.



### INVALID TEST RESULT

If there is no control line (C) or only a test line (T) in the result window, the test did not run correctly and the results are not valid. The test should be repeated with a new blood sample and a new test. It is important that you carefully follow the instructions for the test.



### PERFORMANCE EVALUATION

AllergoCHECK®	Reference Test		
	Positive	Negative	Total
Positive	88	3	91
Negative	6	168	174
Total	94	171	265

Sensitivity: 93.62 %  
Trueness: 96.60 %

Specificity: 98.25 %  
Accuracy: 96.70 %

### WARNINGS AND IMPORTANT INFORMATION

- The test may only be performed by adult users.
- The test is intended for use outside the body only.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Keep out of reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 2°C and 30°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test.

### Explanation of symbols:

Follow instructions	In vitro diagnostic medical device (for external use)	Best before (See imprint on package)
Store at 2-30°C DO NOT FREEZE	Content sufficient for 1 test	Do not reuse
Manufacturer	Sterilization by irradiation	Batchnumber (See imprint on package)
Reference number		

REF: 8600005

CE 0483

Instructions English  
Revision from 2019-01 (Rev. 03)

NanoRepro AG  
Untergasse 8  
D-35037 Marburg  
www.nano.ag

For the love of life.

... to breathe deeply

For self-testing

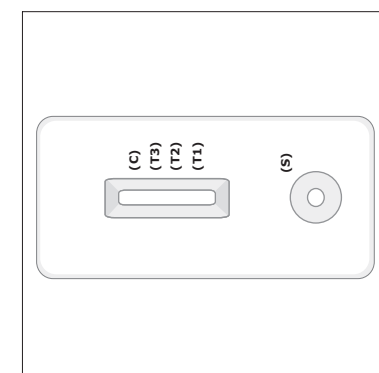
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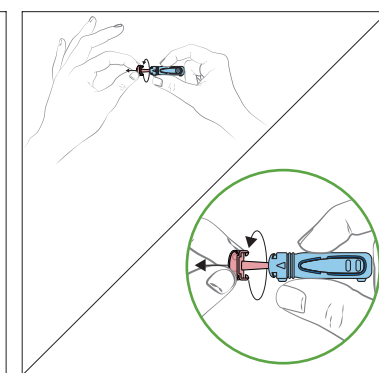
## STEP-BY-STEP INSTRUCTION

### STEP 1



Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

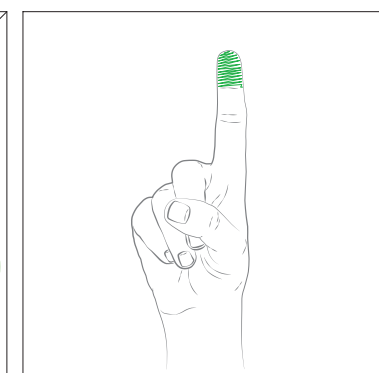
### STEP 2



Please note: The lancing device can only be triggered once.

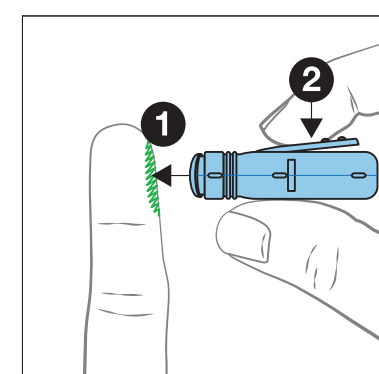
Twist the grey cap on the automatic lancet until the cap separates easily from the lancet body. Then twist it at least two more times before removing the cap, otherwise the proper function cannot be ensured.

### STEP 3



Slowly massage your fingertip and clean it using the alcohol pad. Now let the arm hang loosely on the body for a few minutes to improve the blood flow in the fingers.

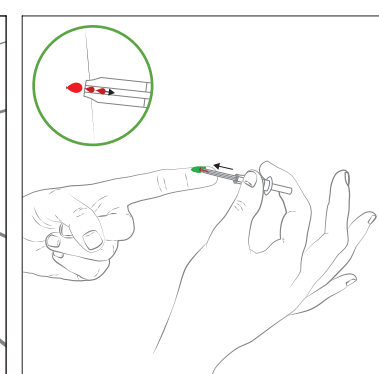
### STEP 4



Wait until the fingertip is dry, as residual alcohol can interfere with the test result.

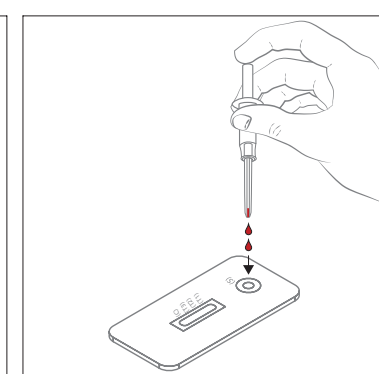
Press the automatic lancing device with the round opening firmly against the clean fingertip 1 and activate it by pushing the button 2. Massage the fingertip to form a blood drop without touching the puncture site.

### STEP 5



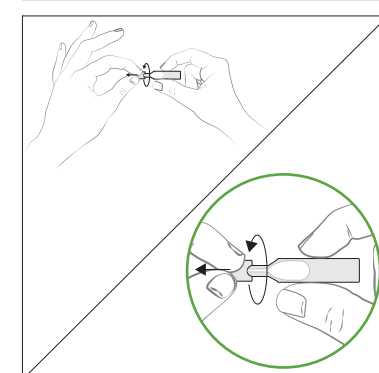
Pick up the transfer pipette and hold it horizontally to slightly inclined in the drop of blood until it has been filled to the white filter. Make sure that the opening at the end of the white plunger is not obstructed, since that would interrupt the capillary force and the sample cannot be obtained. If the drop of blood is insufficient, massage your finger towards the tip of the finger to obtain more blood.

### STEP 6



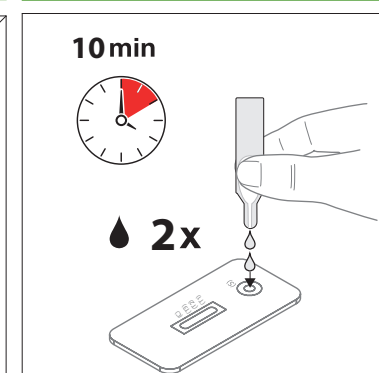
Hold the blood-filled transfer pipette vertically above the sample application field (S) and carefully pour all contents into it by pushing the white plunger slowly and completely downwards. Be careful not to create air bubbles. Let the blood seep in and proceed directly to step 7.

### STEP 7



Open the disposable ampoule by turning the breaking point.

### STEP 8

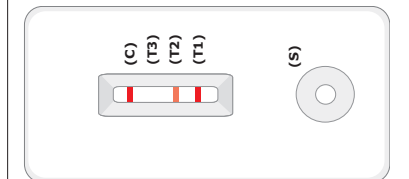


Add exactly 2 drops to the sample well (S). Please note that there should be no liquid applied to the result windows marked with the letters (T) and (C). Do not touch or move the test cassette after adding the drops to the sample well (S).

Read the result 10-15 minutes after adding the sample. Low IgE-values may be missed before the 10 minutes have elapsed, and false positive results may occur after more than 15 minutes.

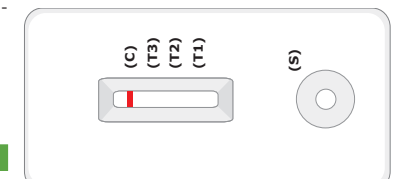
## ERGEBNIS

### POSITIVE

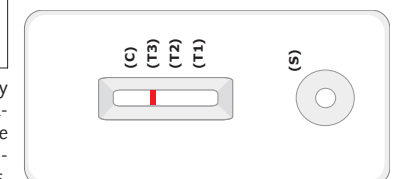
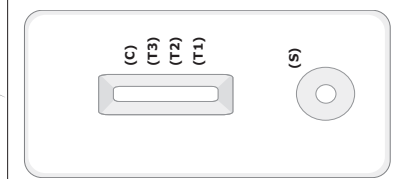


- T1 – Cat hair
- T2 – House dust mites
- T3 – Grass pollen

### NEGATIVE



### INVALID



If not all of the required blood volume is applied, the resulting test result is not valid.

You will find a demonstration video for handling the transfer pipette in the product description on our homepage.

www.zuhausestest.de

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... to breathe deeply

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