

Prevention at home.

REF 18084R

HEALTHY EUROPE S.R.L.  
20124 Milano - ITALY  
VEDA.LAB.  
61006 Alençon Cedex - FRANCE  
www.primahometest.com

Registered trademarks in European Union.

18084R - Itr - 1.1/02

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

## ALLERGY TEST

INSTRUCTIONS FOR USE

PRIMA<sup>®</sup> HOME TEST

## ALLERGY AND IgE

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 child, 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 doctor 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.

## CONTENT

THE BOX CONTAINS ALL THE NECESSARY TO PERFORM 1 ALLERGY TEST:

- 1 sealed aluminium pouch containing:
    - 1 plastic pipette
    - 1 desiccant bag
  - 1 sterile lancet for blood sampling
  - 1 dropper bottle containing 1 ml of diluent.
  - 1 instructions leaflet
- 

- \* Not provided necessary material: absorbent cotton and alcohol 70°
- \* Only open the protective pouch when you are ready to use the test.
- \* The desiccant bag should not be used.
- \* After use, all the components can be discarded in a dustbin.

## PRECAUTIONS

- 1) Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.
- 2) Keep out of the reach of children.
- 3) Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
- 4) Follow strictly the indicated time, blood and diluent quantities.
- 5) Store between +4°C and +30°C. Do not freeze.
- 6) Do not re-use the test device and lancet.
- 7) External use only. DO NOT SWALLOW.
- 8) This test is exclusively intended to in vitro diagnostic self-testing use.

## 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 orange small rod into the body of the lancet until hearing a **CLICK** indicating the device is activated. - **FIG. A**

Be careful not to push the trigger because the needle can come out too early.

- 4) Remove the orange rod by turning it on the left or on the right. - **FIG. B**

- 5) Clean the end of the forefinger or of the middle finger with a cotton pad damped with alcohol. Massage the end of the finger, from the base of the finger to the end, to enhance the blood flow.

- 6) **Strongly press** the extremity of the lancet on the part of the finger which is cleaned with alcohol in order to obtain a very good contact.

Press on the trigger button. - **FIG. C**

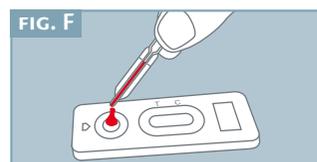
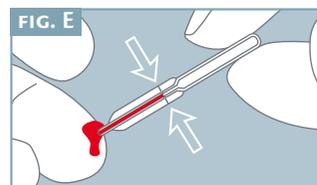
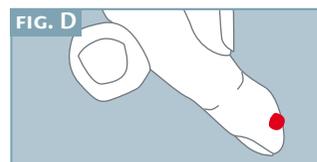
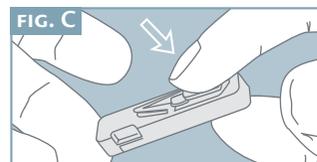
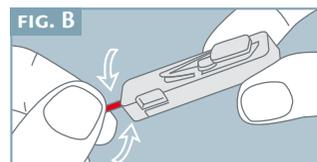
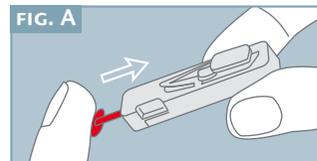
The tip retracts automatically and safely after use.

- 7) Keeping the hand down massage the end that was stung to obtain a blood drop. - **FIG. D**

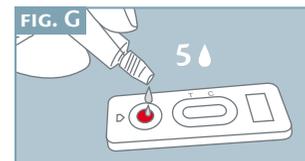
- 8) **Without pressing the pipette bulb**, put it in contact with the drop. - **FIG. E**

The blood migrates into the pipette through the capillarity to the line indicated on the pipette. You may massage again your finger to obtain more blood if the line is not reached. As far as possible, avoid of air bubbles.

- 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. Using the dropper bottle, add **5 drops** of diluent into the sample well of the device - **FIG. G**



- 11) Read the result after **10 minutes**.

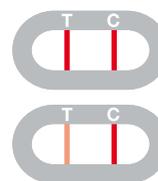
## RESULT INTERPRETATION

**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.



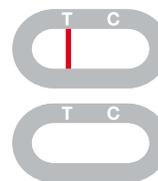
### NEGATIVE RESULT

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.

### 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 15 years, as the test sensitivity was adjusted on an adult population.

### 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.

### 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 clearly visible. The test should be considered as positive whatever the colour intensity of the test line is.

### WHAT IS THE LINE THAT APPEARS UNDER THE MARK C (CONTROL) FOR?

When this line appears, it only means that the test was performing 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 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 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 97% with reference methods.

### SYMBOLS

In vitro diagnostic device

Read the instructions before use

Store between +4°C and +30°C

Expiry date (last day of the months)

Do not reuse

List number

Lot number

Legal manufacturer

Lancet: **STERILE** **R**

