

MilkCHECK®

Milk Allergy? Test yourself at home now!
Rapid test for the detection of allergy antibodies to milk

to be aware...

For self-testing

INSTRUCTIONS FOR USE

INTRODUCTION

MilkCHECK® IgE Allergy Test is a simple, safe and accurate way to detect high levels of allergy antibodies called Immunoglobulin E (IgE) to milk protein in the blood. High levels of IgE are associated with increased susceptibility to allergy.

The test requires only a small amount of blood obtained hygienically and with minimal discomfort.

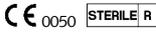
MilkCHECK® results have been proven to compare well to laboratory tests, but no single method to diagnose allergy is completely accurate. A parent should perform the test on children under 16 years old.

The test can be used at any time of the year. You do not need to be having an allergic reaction at the time of testing. It is not necessary to stop any medication before using this product.

TEST CONTENTS

- 1 test cassette in a sealed pouch and 1 desiccant sachet
- 1 pipette
- 1 developer solution bottle
- 1 automatic sterile lancet for comfortable blood sampling

BD Vacutainer Systems
Plymouth, PL67BP, UK



- 1 alcohol pad
- Paul Hartmann AG
89522 Heidenheim, Germany



- 1 plaster
- Paul Hartmann AG
89522 Heidenheim, Germany



- 1 instruction pamphlet

Sachet must be yellow or pale greenish yellow to be effective. If it's green, contact your local distributor/retailer.

Additionally required:

- 1 timer
- 1 clean tissue

TEST PREPARATION

The test kit should be stored and used at normal room temperature. If it has been stored at a much lower temperature then leave the test kit unopened at room temperature for a minimum of 2 hours. The test cassette should be used within 30 minutes of opening the foil pouch. Wash your hands with soap and warm water; rinse well with warm water; dry with a clean towel - it is important that your hands are warm and dry as this improves the blood flow and makes it easier to collect the blood sample. Find a quiet place to perform the test, preferably sitting down in front of a table.

Then open the:

- Pack containing the sterile lancet, pipette and the developer solution bottle.
- Foil pouched test cassette.

Do not pull or move the blue slider until instructed (15 minutes after adding developer solution).

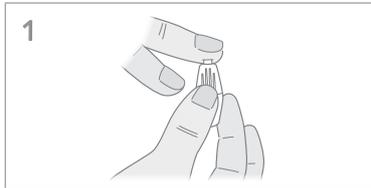
- Place all parts on a clean, level surface.

OBTAINING THE BLOOD DROP

This is simple and causes little discomfort. Only a small drop of blood is required.

Do not use the lancet if its blue tab (marked <=>) is missing.

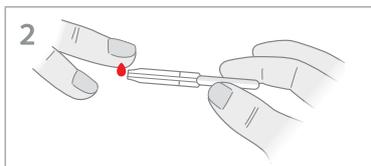
- Using gentle pressure, massage the finger from which the sample is to be taken (the middle or ring finger is the best) by gently working the thumb of your hand up to the tip of the finger several times.
- Twist and pull off the blue tab from the lancet to reveal the spring-loaded white contact piece beneath.
- Holding the indented side grips of the lancet between the thumb and forefinger of your free hand press the white contact piece firmly against the soft pad of your finger tip until a click is heard.
- The needle immediately retracts into the lancet for safe disposal and cannot be reused. Using a dry tissue, wipe away the first sign of blood from the fingertip.
- Contact your local distributor/retailer if you have difficulty using the lancet or in obtaining a satisfactory amount of blood. It is important to press the lancet very firmly against the fingertip otherwise the skin will not be punctured.



COLLECTING THE BLOOD DROP

1. With the finger nail pointing upwards, continue to **gently** massage the thumb of your **free hand** to the tip of the finger several times until a **large drop** of blood appears.
2. With the finger nail still pointing upwards, hold the pipette **horizontally**, and touch the tip of the pipette to the drop of blood. Continue adding blood to the pipette until the blood fills the tip to the lines.
3. Capillary action will automatically draw blood to the fill lines then stop.

CAUTION: Filling is automatic: Never squeeze the pipette when filling with blood. Using too much or too little blood may give an incorrect result.



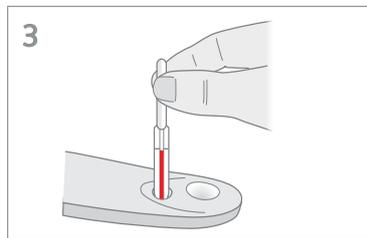
ADDING THE BLOOD TO THE TEST CASSETTE

To expel the blood, align the tip of the pipette into the **smaller** well on the test cassette marked:



Squeeze the bulb gently to expel the blood into the bottom of the well.

If the blood won't expel, hold the pipette vertically over the well by gripping on either side of the black level markers and squeeze the bulb. Wait approximately 1 minute for the blood to absorb then discard the pipette.



ADDING THE DEVELOPER SOLUTION

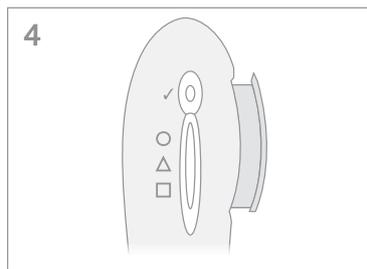
Carefully unscrew the cap from the developer solution bottle and pour all the contents of the bottle into the large well just below the blood well.

Then wait **exactly 15 minutes. Do not move or pick up the test cassette once you have added the developer solution.** If the developer solution bottle is not completely filled with pale blue liquid, contact your local distributor/retailer.

PULLING THE SLIDER

Only after waiting exactly 15 minutes pick up the test cassette, keeping it **horizontal**, and pull the blue slider until you feel it click into place. The test working indicator will change from blue to white.

Place the test cassette back on a level surface and leave undisturbed. If you have very high levels of IgE antibodies you may see a positive result within 15 minutes. However, it is necessary to wait 30 minutes after pulling the blue slider to confirm a completely negative result.



INTERPRETATION OF RESULTS

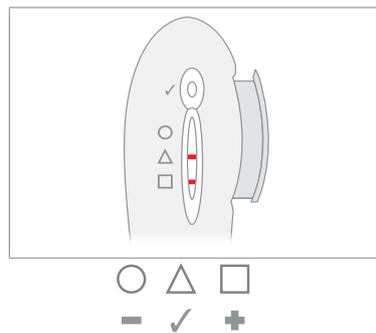
Control line:

A pink or red line opposite the Δ symbol indicates the test has worked correctly. No line should be visible opposite the \circ symbol.

Positive:

Read the result after waiting exactly 15 minutes. A pink or red line opposite the \square (irrespective of the intensity) indicates that high levels of IgE allergy antibodies have been detected and you may have sensitivity to that specific allergen.

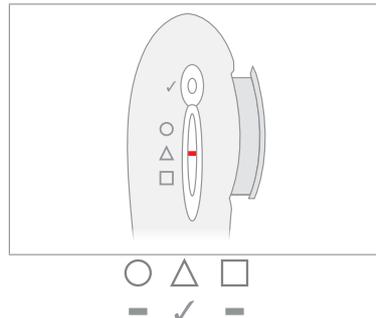
It is essential that you have, or have had at sometime in the past, symptoms for a positive result to be significant. Even a faint pink line opposite the \square symbol should be recorded as a positive result.



Negative

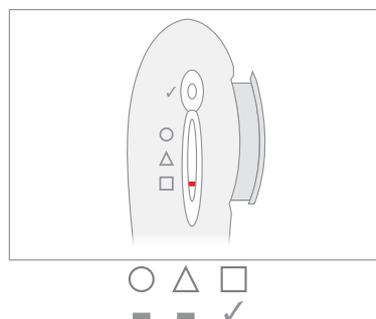
To confirm a completely negative result it is necessary to wait 30 minutes after pulling the blue slider.

No line opposite the \square symbol indicates negative result. There are no high levels of IgE allergy antibodies detected.



Invalid

- No line opposite Δ symbol indicates invalid result.
- A line is visible opposite the \circ symbol.



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to be aware...

CLEANING UP AFTER THE TEST

To prevent contamination, after use place the test cassette, pipette, developer solution bottle and used lancet into the original box and secure the lid. Dispose of the box in your dustbin. **Do not disassemble the test cassette.** For help, contact your local distributor/realer.

FALSE POSITIVE AND FALSE NEGATIVE RESULTS

High levels of IgE can be a useful indicator of the risk of allergy but a high level of IgE, by itself, will not definitely indicate that you are at a high risk of suffering or developing allergies. It is important that you have or have had allergy symptoms for a positive result to be significant. Neither can normal levels completely rule out a risk of suffering or developing allergies in the future.

Some people can have abnormally high IgE levels but may not suffer obvious symptoms. They may be able to cope through the presence of protective antibodies (IgG), or they rarely come into contact with the offending allergen that could trigger their symptoms. However, they may still develop symptoms in later life. If you have rheumatoid disease (arthritis) it should be noted that very weak positive results may be observed even if you do not have an allergy.

*** It is important that once you confirm you have a food allergy you seek medical advice ***

You should not attempt to check your sensitivity by eating a food you suspect may be causing the problem. Similarly, avoidance of common foods such as milk should only take place after consultation with a dietician or your doctor as unnecessary avoidance of these foods can lead to nutritional deficiencies.

WARNINGS AND IMPORTANT INFORMATION

Do not take any decision of medical relevance without first consulting your doctor. If this test has been used for monitoring an existing disease you should not change your treatment unless you have received appropriate training.

- The test is intended for use outside the body only.
- Not to be taken internally. Avoid developer solution contact with skin and eyes.
- Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 4°C und 25°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by the physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- All test components can be disposed in household waste.

Explanation of symbols:

 Follow instructions	 In vitro diagnostic medical device (for external use)	 Best before (See imprint on package)
 Store at 4°C - 25°C Do not freeze	 Content sufficient for 1 test	 Do not reuse
 Manufacturer	 Sterilization by irradiation	 Batchnumber (See imprint on package)

CE 0483



Manufacturer of MilkCHECK

Instructions English
Revision from 2016-02 (Rev.01)

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D-35037 Marburg
www.nano.ag



For the love of life.