

newfoundland

Allergy Test



Finger-prick
blood



Results within
30 mins



Over 96%
accurate

Watch the
instruction
video



What is the Newfoundland Allergy Test?

The Newfoundland Allergy Test detects high levels of allergy antibodies called immunoglobulin E (IgE) in the blood. High levels of IgE indicate an allergic reaction. The Newfoundland Allergy Test screens for allergies to cats, house dust mites and grass pollen, commonly known as hay fever.

<https://www.newfoundland.io/tests/allergy>

Who is the Newfoundland Allergy Test for?

For people who want to check for an allergy to cats, dust and grass pollen/hay fever.

Symptoms of an allergic reaction can include:

- A runny nose or sneezing
- Pain or tenderness around your cheeks, eyes or forehead
- Coughing, wheezing or breathlessness
- Itchy skin or a raised rash

Precautions

1. Read the instructions carefully before use. Incorrect operation can cause unreliable results.
2. Do not use after the expiry date or if the pouch has been damaged. The test should remain in the sealed pouch until use.
3. Store the test kit between 4°C and 25°C. Do not freeze.
4. The test should be used within 30 minutes of opening the foil pouch.
5. Do not eat, drink or smoke in the area where the specimens or kits are handled.
6. For self-testing in vitro diagnostic use only. Cannot be reused.
7. The test is for external use only. Do not swallow.
8. Keep out of the reach of children.
9. An adult (18+) should perform the test on children under the age of 16.
10. Handle with care. To dispose of the test kit, the test and box contents should be placed safely in a bin and thrown away with your household waste.

Contents



Blood transfer tube



Lancet



Instructions for use

Test

Materials required but not provided:
• Timer • Clean, dry tissue

Instructions

To watch the instruction in video format, please scan the QR code above or follow <https://www.newfoundland.io/tests/allergy> to our how-to video.

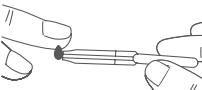
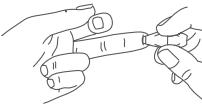
Preparation:

1. Wash your hands with soap and warm water, then dry.
2. Remove the test from the foil pouch and place on a clean, level surface. Then open the package containing the lancet, blood transfer tube and the tube of developer solution.



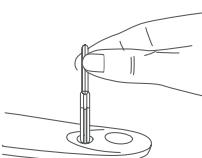
Obtaining a blood sample:

3. Hold the lancet and twist the blue cap to remove, revealing the white contact piece beneath. the tube of developer solution. **Warning:** Do not use the lancet if the blue tab marked ⇛ is missing.
4. Massage your hand from the wrist to the fingertip to increase blood flow.
5. 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 for safe disposal and cannot be reused.
6. Wipe away the first drop of blood with a clean tissue.
7. Collect the second drop of blood using the blood tube. **Note:** Please see below how to use the blood transfer tube first before using it:
 - a. Ensure the finger nail is facing upwards.
 - b. Hold the blood tube horizontally and, WITHOUT squeezing, touch the tip of the tube to the blood drop.
 - c. Capillary action will automatically draw the blood sample. You may need to massage your finger again if more blood is required. Collect to the fill line and stop.

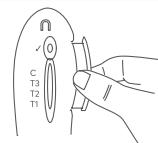


Performing the test:

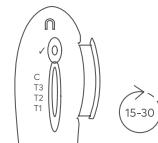
8. Gently squeeze the dropper to apply the blood sample into the smaller well on the test kit marked Δ. **Warning:** Squeeze the bulb until all the blood in the capillary tube is applied. If the blood does not expel, hold the tube vertically over the well by gripping either side of the black level markers and squeezing the bulb. If you don't apply sufficient blood to the test hole, the result may be inaccurate.
9. Wait approximately 1 minute for the blood to absorb then discard the blood transfer tube.
10. Unscrew the cap of the developer solution and carefully pour all of the solution into the larger well just below the blood sample well. Start a timer for 15 minutes. **Note:** Do not move or pick up the test once you have added the developer solution.



11. After waiting exactly 15 minutes, pick up the test, keeping it horizontal, and pull the blue slider out until you feel it click into place. The test working indicator (marked ✓) will change from blue to white.



12. Place the test back on a level surface and wait for 30 minutes before interpreting the results. **Note:** If you have very high levels of IgE antibodies a positive result may be generated within 15 minutes. However, it is necessary to wait 30 minutes after pulling the blue slider to confirm a completely negative result.



Results

C Control line
T3 Grass pollen (hay fever)
T2 Dust mite
T1 Cat

In order for the test to be valid, a red/pink line must appear next to the control band (C) in the result window. If the control line fails to appear, review the instructions and repeat with a new test kit. If the problem persists, contact support@newfoundland.io. A pink/red line (regardless of intensity) next to the T1, T2 or T3 symbols on the result window indicates that high levels of allergy antibodies have been detected and you may have an allergy to that allergen (cat, dust mite, hay fever). Even a faint line should be considered positive. If there is no line next to the T1, T2 or T3 symbols, then the result should be considered negative for that allergen and an allergy has not been detected.

FAQs

How does the test work?

High levels of IgE can be a useful indicator of the risk of allergy but a high level of IgE by itself will not conclusively diagnose an allergy. It is important that you have or have had allergy symptoms for a positive result to be significant.

How accurate is the test?

The Newfoundland Allergy Test is over 96% accurate. Although the test is reliable, it is still possible false positive and false negative results can be produced.

Can I take the test at any time?

Yes. The test can be used at any time of the year and 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.

What should I do if the result is positive?

A positive result means that the level of antibodies in the blood was greater than the cut off level (3.5kU/l) and indicates an allergy. You should contact your GP to discuss the result further and agree on the best course of treatment.

What should I do if the result is negative?

A negative result means that the level of antibodies in the blood was less than the cut-off value (0.35kU/l) and indicates an allergy is unlikely. However, this cannot completely rule out a risk of suffering from or developing allergies in the future.

What if the result is positive but I don't have any symptoms?

Some people can have abnormally high IgE levels but may not suffer from any obvious symptoms. They may be able to cope through the presence of protective antibodies (IgG) or 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.

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Medical devices inside the kit

STERILE | R

Lancet

CE 0350 Directive 93/42/EC

 Becton & Dickinson Company,
1 Becton Drive, NJ, 07417, USA

EC REP Becton Dickinson UK Ltd,
Oxford, UK

Blood Tube

CE IVD Directive 98/79/EC

 Safe-Tec Clinical Products,
142 Railroad Drive, Ivyland, PA 18974, USA

EC REP CEpartner4U BV,
3951 DB Maarn, NL

 Tests per kit

 Temperature Limit

IVD For in vitro diagnostic use

LOT Lot Number

 Use by

 Catalogue number

 Do not reuse

 Do not use if package is damaged

 Sterilised using irradiation

 Read the instructions before use

CE CE Marking

 Legal manufacturer

EC REP Authorised Representative
in the European Community

 Imutest Limited
Wilmslow, Cheshire, SK9 5DQ, UK

EC REP Advena Ltd. Tower Business Centre
2nd Flr. Tower Street, Swatar, BKR 4013, Malta

CE 0344