

newfoundland

Coeliac Test



Watch the instruction video
→ 

REF 180077-1

What is the Newfoundland Coeliac Test?

The Newfoundland Coeliac Test is a self-test to check for specific antibodies for coeliac disease screening. Coeliac disease is an autoimmune disease caused by an adverse reaction to gluten consumption. For more information, please visit our website: <https://www.newfoundland.io/tests/coeliac>

What is coeliac disease?

Coeliac disease is when the immune system attacks its own tissues when you eat gluten, damaging the gut (small intestine) and preventing the body from absorbing nutrients effectively. Coeliac disease is not an allergy or food intolerance. It is an immune reaction to gluten, which is a dietary protein found in a number of grains such as wheat, barley, rye and spelt. Common foods that contain gluten include pasta, cakes, breakfast cereals, most types of bread and most beers.

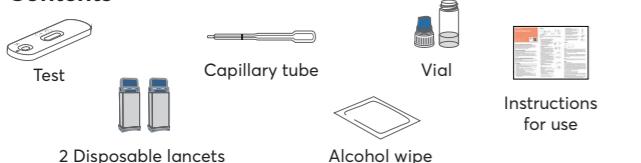
Who is the Newfoundland Coeliac Test for?

Individuals showing symptoms of coeliac disease or those with a family history of coeliac disease. Symptoms include bloating, diarrhoea, nausea, wind, constipation, tiredness, mouth ulcers, sudden or unexpected weight loss and anaemia.

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. Store the test kit between 4°C and 30°C. Do not freeze.
3. For self-testing in vitro diagnostic use only. Cannot be reused.
4. Keep out of the reach of children. Not recommended for children under 16.
5. The test is for external use only. Do not swallow.
6. Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
7. Do not eat, drink or smoke in the area where the specimens or kits are handled.
8. 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



Instructions

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

1. Wash your hands with warm water and soap, carefully drying your hands afterwards. **Warning:** Use of lotions and hand creams should be avoided before testing.
2. Remove the contents from the kit including the test cassette, capillary tube and open the vial by unscrewing the white cap. Do not dispose of the cap.

Obtaining a blood sample

3. Hold the lancet and twist the cap to remove it.
4. Use the alcohol wipe provided to clean the finger that will be pricked with the lancet. Massage your hand from the palm to the fingertip to increase blood flow (the side of the ring finger is recommended).
5. Place the lancet against the fingertip and press down firmly to draw blood. The tip of the lancet automatically retracts after use. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions.
6. Holding the hand downwards, massage the finger until a large drop of blood forms. Wipe away the first drop and collect the second drop of blood using the capillary tube.

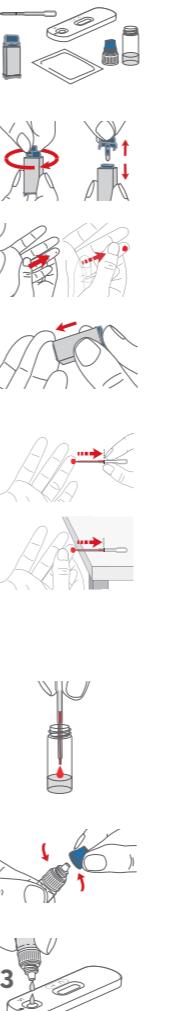
Note: Please see below how to use the capillary tube before using it.

Tips

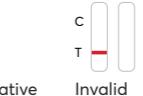
Hold the capillary tube horizontally and slightly downward. Without squeezing, touch the tip of the pipette to the blood. Capillary action will automatically draw the blood sample. You may need to massage your finger again if more blood is required. Collect to the fill line and stop.

Performing the test

7. Gently squeeze the dropper to apply the blood sample into the previously opened vial. Screw the cap back onto the vial and mix well for at least 10 seconds.
8. Squeeze the bulb until all the blood in the capillary tube is applied. If you don't apply sufficient blood to the test hole, the result may be inaccurate.
9. Unscrew the blue cap from the vial (leave the white cap tightly screwed on). Deposit 3 drops into the sample well on the cassette (S).
10. Wait 10 minutes and then read the results as indicated. Do not interpret the test after 15 minutes.



Results

		
Positive	Negative	Invalid

Positive

Two coloured lines appear: one in the control region (C) and one in the test region (T). The test should be interpreted as positive even if there is only a faint line in the test region. This means anti-DGP antibodies have been detected in the blood and therefore coeliac disease is probable. You should contact your GP to discuss the result further.

Negative

One coloured line appears in the control region (C). No line appears in the test region (T). This means there are no anti-DGP antibodies in the blood or that their concentration is below the test's detection limit and coeliac disease is unlikely.

Invalid

The control line (C) fails to appear. Review the instructions and repeat with a new test kit. If the problem persists, contact support@newfoundland.io

FAQs

How does the test work?

Gliadin is a protein component in gluten responsible for the immune reaction that causes intestinal inflammation in patients suffering from coeliac disease. Recent studies of the diagnosis of coeliac disease have shown that deamidated gliadin peptides in particular can trigger strong immune reactions. Antibodies directed against these peptides allow for very accurate diagnosis of coeliac disease. The Newfoundland Coeliac Test reveals the presence of IgA and IgG antibodies in the blood against deamidated gliadin peptides (anti-DGP). A positive result means that the concentration of these antibodies is approximately 20 U/ml (units/ml), which indicates coeliac disease.

How accurate is the test?

The Newfoundland Coeliac Test is 90% accurate. Although this test is reliable, it is still possible false positive and false negative results may be produced.

Can I take the test if I'm on a gluten-free diet?

No. The symptoms and the level of coeliac disease-associated antibodies decrease in people on a gluten-free diet until they are no longer detectable.

What should I do if the result is positive?

A positive result means that the levels of class IgA and class IgG anti-DGP antibodies are approximately 20 U/ml, which indicates coeliac disease. In this case you should consult your GP, who will decide how to proceed.

What should I do if the result is negative?

A negative result means that the levels of class IgA and class IgG anti-DGP antibodies are below the test's control detection limit and would indicate no sign of coeliac disease. If symptoms persist, contact your GP.

How do I interpret the result if the colour and intensity of the test (T) and control (C) bands are different?

The test should be interpreted as positive regardless of how dark the red/pink colour is on the test and Control lines. The lines should both be even and full. For the result to be considered positive, the line in the test region must be red/pink in colour (provided the control line is also visible); any line of a different colour in the test region should be interpreted as negative.

Can the result be incorrect?

If the instructions have been followed accurately then the result should be considered correct. However, the result may be incorrect if the device has come into contact with other liquids before being used; part of the diluent is accidentally spilled; the required volume of blood sample has not been met or the number of drops of solution dispensed into the well is fewer than 3 or more than 4. The plastic pipette with a marked fill line included in the kit allows users to be sure they have collected the right amount of blood.

What are the common symptoms of coeliac disease?

- Diarrhoea • Abdominal pain (stomach ache) • Bloating and wind • Indigestion • Constipation • Vomiting • Tiredness • Mouth ulcers • Sudden or unexpected weight loss • Anaemia

Medical devices inside the kit**STERILE****Lancet** **CE** See manufacturer's details printed on the flowpack.**Alcohol cleansing wipe** **CE** See the label of the gauze included in the kit. Sufficient for <n> test Temperature Limit Do not reuse **IVD** For in vitro diagnostic use Lot Number Do not use if package is damaged Use by Catalogue number Sterilised using irradiation **EC REP** Authorised Representative in the European Community **CE** CE Marking Read the instructions before use PRIMA Lab SA
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