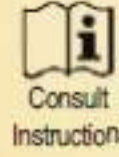


Coeliac Test

Instructions for use



Please read the instruction leaflet carefully before carrying out the test.

General information:

Coeliac disease is a lifelong genetically inherited gastrointestinal disorder that can cause a wide spectrum of clinical symptoms ranging from mild weakness, bone pain, constipation, chronic diarrhoea, abdominal bloating, and progressive weight loss. Also skin disorders and disorders of the central nervous system can exist and damage to the inner surface of the small intestine is caused by a permanent intolerance to gluten (1). Gluten is the most common name for specific proteins found in all forms of wheat, rye and barley that are harmful to persons with coeliac disease.

This Coeliac screening test is a home test intended to aid the detection of IgA antibodies to transglutaminase associated with Coeliac disease but the final diagnosis must be confirmed by a doctor.

Adopting a gluten free diet, will result in a slow reduction in antibodies (IgA antibodies to transglutaminase) associated with Coeliac disease, therefore if a gluten free diet has been followed for a long period of time prior to carrying out this test the antibodies may be undetectable and may produce a negative test result

Studies show that continuous consumption of gluten by diagnosed coeliacs can result in the increased chances of stomach or colon cancer.

Coeliac Disease can be diagnosed by relatively simple diagnostic tests. The testing can be done by screening the patient's blood for antitissue transglutaminase (tTGA), antigliadin (AGA) and endomysium antibodies (EmA) and a small biopsy procedure on the injured areas of the intestines.

The test requires a simple finger prick blood sample (10ul) and a visual result is available within 10 minutes indicating the presence/absence of IgA autoantibodies against Transglutaminase enzyme associated with Coeliac disease (4). The test has been patented (5).

Contents of Package

- Alcohol-soaked swab
- Lancet
- Tube with glass capillary
- Foil pouch containing the test strip
- Sample buffer solution
- Instruction leaflet

If the result is positive:

The test indicates that there is Coeliac disease associated IgA antibodies in the tested blood. Detection of these antibodies indicates a high probability of an existing Coeliac disease. For the final diagnosis and possible treatment, contact your doctor for advice. Do not start a gluten-free diet without consulting your doctor first.

If the test result is negative:

The test indicates that there is no coeliac disease associated IgA antibodies in the tested blood. An existing coeliac disease can virtually be ruled out. If gastrointestinal complaints are present, further medical investigation is necessary. Also, if you have been following a gluten-free diet, the level of IgA autoantibodies will decrease and may become undetectable a few weeks after the change in diet, or at least in the six months thereafter. Therefore you can have a negative result if you are following the gluten-free diet. This is also a way to monitor the effects of the gluten-free diet. In addition, in the case of a few rare medical cases, such as IgA deficiency, the test may render a false negative result. If the test is contrary to your expectations, consult your doctor.

References:

1. Fasano A. et al.: Arch Intern Med. 2003;163:286-292
2. Halsted C.H: New England Journal of Medicine, May 2, 1996, Vol.334,(18).
3. Goggins et al.: The American Journal of Gastroenterology. 1994, Vol.89,(8), 2-13.
4. Korponay-Szabo et al.: J Pediatr Gastroenterol Nutr., 2001, vol. 32,(3), 361, column 66.
5. Mäki,M., Korponay-Szabo,J., Patent Application PCT/FI02/00340, international publication number WO02/086509 A19.

Read instructions carefully before use!
 Keep out of reach of children.
 Do not use the test after expiry date.
 (See box flap)
 Do not use the test if the foil pouch is damaged.
 Store at 4° - 30°C (39° - 86°F).
 Avoid freezing.
 Use test only once.
 Do not use if accessories are broken.
 Do not take the test strip apart.
 Do not ingest buffer solution.
 The sample buffer solution contains 0.09% of sodium azide. Avoid contact with skin.
 For external use only.
 Copy prepared by 1st Health Products Ltd. April 2014



Lancet: **STERILE**



Approved Distributor: 1st Health Products Ltd,
 Unit 2 Lynx Business Park, Colliers Green,
 Goudhurst, Kent TN17 2LR, UK
 Tel: +44 (0) 1580 212758
 Customer CareLine: +44 (0) 1580 211358
 enquiries@1sthealthproducts.co.uk
 www.1sthealthproducts.co.uk
 SC8224A v.1



Manufactured by:
 Ani Biotech Oy, Tiilittie 3, FI-01720 Vantaa, Finland

SELFCheck

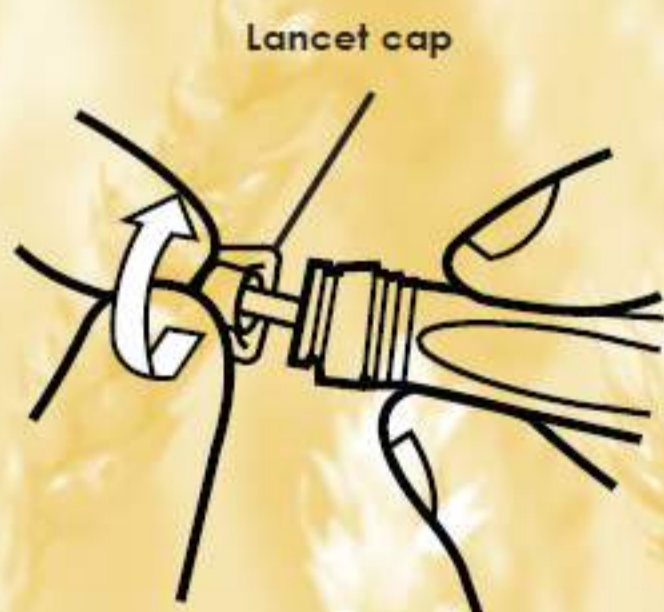
Instructions for use

1 Preparation

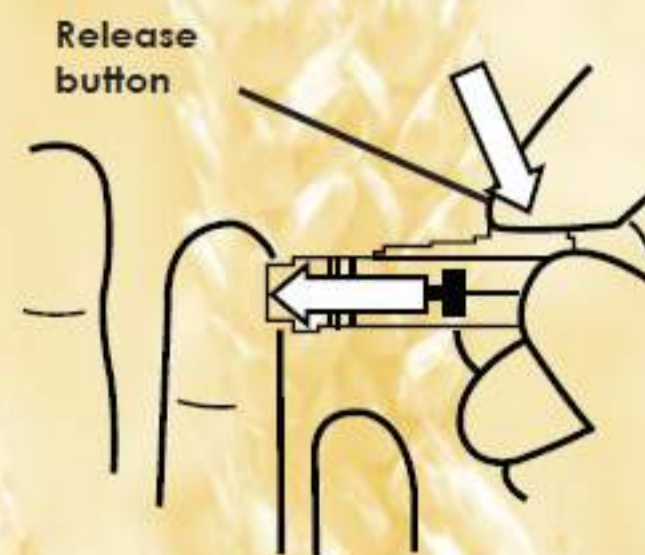
Do not open the sealed pouch until you are ready to carry out the test. Let the test pouch and buffer solution warm up to the room temperature before performing the test. Have a watch ready. Open the sealed pouch carefully avoiding damage to the test strip. Once the foil pouch has been opened, you should carry out the test within 10 minutes. Lay the test strip on a flat surface.

2 Using the lancet

Gently massage the fingertip and then clean it with the alcohol-soaked swab. Leave until finger is dry and then follow the instructions on the images below.



Twist the cap to "unlock" the lancet and continue to twist until the cap separates easily from the lancet body. **DO NOT PULL**



Place the lancet firmly against the side of your chosen finger and depress the release button. Wait until a drop of blood collects on your finger. After use, dispose of the lancet with household waste."

3 Collecting blood sample

Open the plastic vessel and remove, **with caution**, the glass capillary. Squeeze a drop of blood from the fingertip. Hold one end of the glass capillary horizontally (see picture) and touch the drop of blood with one end of the capillary until it has completely filled with blood. Transfer the filled capillary directly into the sample dilution buffer. The vial should be closed firmly with the screw cap and **inverted** repeatedly until the blood is well mixed with the buffer solution. **DO NOT SHAKE.**

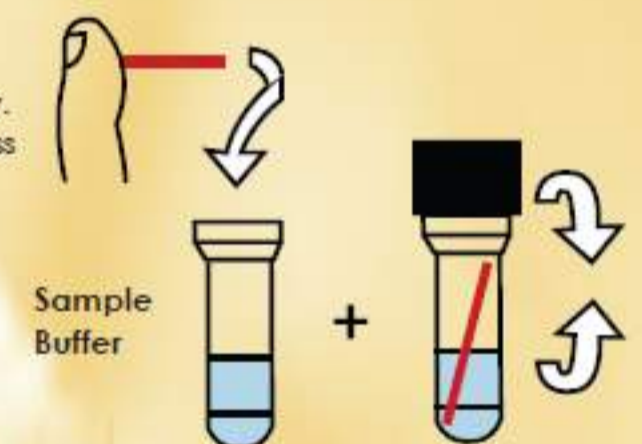


Fig 1. Blood Sample

4 Testing

Open the vial and, holding the test strip by the blue tape end, place the strip into the vial. The level of the buffer should not exceed the max level indicated on the test strip. Avoid any reagent drops or foam on the sides of the tube. Wait 5 minutes for the test to develop. Remove the test strip and read the result as shown below. If the test result is unsettled or difficult to read after 5 minutes testing time, wait for another 5 minutes and read the result once again. Do not interpret the results **after** 10 minutes.

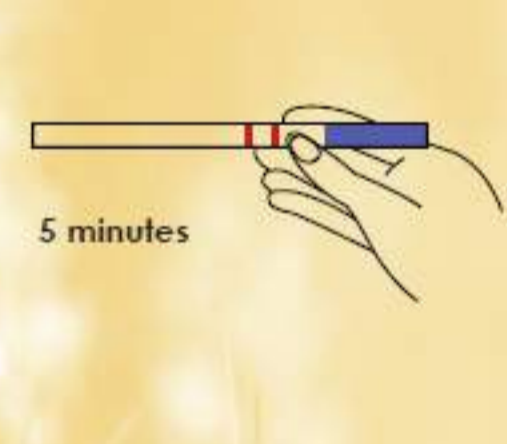


Fig 2. Testing

Interpreting the test results:

Positive result: The test is positive when two lines, test and control line appear on the test strip. Test line, nearest to the control line can vary from light to dark colour.

Negative result: the test is negative when one line appears on the test strip.

Invalid test: control line also serves as an internal control for proper function of the test. If no lines appear on the test strip, you have most likely not followed the instructions for use correctly or the test unit is damaged. The test should be repeated with a new test unit.

