



FAST



EASY



ACCURATE



Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit www.adventlife.net.

CELIAC DISEASE

Celiac disease is a long-term autoimmune disorder affecting the small intestine that can occur in genetically predisposed people. It is caused by intolerance to the ingestion of gluten which are various proteins found in wheat, barley and rye. It is estimated to affect 1% of people worldwide.

HOW IS CELIAC DISEASE TREATED?

Currently, the only treatment for Celiac disease, after being diagnosed, is a strict lifelong gluten-free diet.

WHAT ARE THE SYMPTOMS?

Typical symptoms of celiac disease include:

- Chronic diarrhoea
- Abdominal pain
- Gas
- Weight loss
- Anaemia
- Osteoporosis
- Severe fatigue
- Stunted growth, in case children are affected

SELF-TESTING DEVICE FOR DETECTION OF ANTI-TISSUE TRANSGLUTAMINASE IgA ANTIBODIES ASSOCIATED WITH GLUTEN INTOLERANCE AND, THEREFORE, CELIAC DISEASE IN WHOLE BLOOD

PURPOSE

When gluten intolerance is present, there is a production of IgA type specific antibodies directed against t-TG. The GLUTEN'ALARM® allows the detection of these specific antibodies and therefore showing evidences of gluten intolerance when they are concentrated enough (>10U/mL determined against samples reference panels).

Currently, highly effective whole blood tests are the first line screening method to detect Celiac disease. They are mainly based on the detection of anti tissue-transglutaminase (t-TG) IgA type antibodies.

GLUTEN'ALARM® is a highly specific immunological rapid test for the detection of anti t-TG IgA type antibodies in whole blood finger-prick samples.

FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. Do not freeze!

1 test per box.

GLUTEN'ALARM® is a highly specific immunological rapid test for the detection of anti t-TG IgA type antibodies in whole blood finger-prick samples.

Easy to read.

The GLUTEN'ALARM® test is accurate. Evaluation reports show an overall agreement higher than 97% [90.79 – 99.60] with reference methods. Although this test is reliable, false positive or false negative results could be obtained

CLINICAL EVALUATION RESULTS

Sensitivity: 97.00 %

Specificity: 96.00 %

Accuracy: 97.00 %

PROVIDED MATERIALS:

- 1 sealed aluminium pouch containing:
 - 1 test device
 - 1 plastic pipette
 - 1 desiccant bag

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

- 1 sterile lancet for blood sampling.
- 1 dropper bottle containing 1 mL of diluent.
- 1 instruction leaflet.

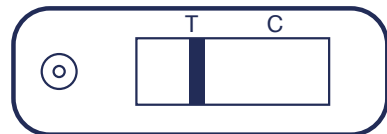
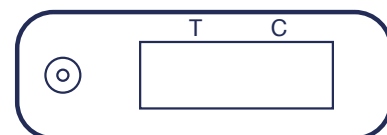
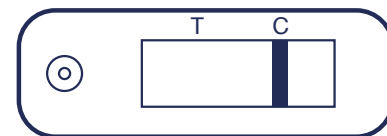
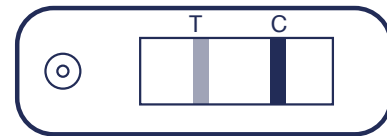
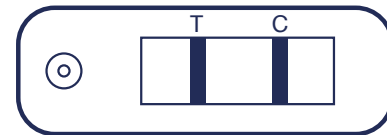
REQUIRED MATERIALS NOT PROVIDED:

Absorbent cotton and alcohol 70% vol. or alcohol pad.



Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. Wash your hands thoroughly. Use soap and warm water. Dry your hands with a clean towel.
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them within reach of your hands (you will need them later). Discard the desiccant bag.
3. Prepare the lancet. Hold the lancet without touching the trigger button. Unlock the lancet cap twisting it $\frac{1}{4}$ of the way until you feel it separate from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished.
4. Clean the end of the middle finger or ring finger with cotton moistened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. Press the platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button.
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.
8. Without pressing the blood drop that has formed, put the plastic pipette in contact with the blood sample. The blood migrates into the pipette through capillarity to the line indicated on the pipette. You may rub your finger again to obtain more blood if the line is not reached. Avoid air bubbles as much as possible.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.
10. Wait 30-40 sec for the blood to be completely absorbed into the sample well. Unscrew the blue cap of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows: Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device with an interval of 2-3 seconds between each drop.
11. Read the result after 10 minutes. Do not interpret after 15 minutes.



Positive: Two coloured lines appear in the window under the marks T (Test) and C (Control). The colour intensity of the T line may be clearer than the intensity of the C line. This result means that the blood sample contains anti-t-TG IgA type antibodies and that you should consult a doctor.

Negative: Only one coloured line appears under the mark C (Control). This result means that no anti-t-TG IgA type antibodies are detected in the blood sample.

Invalid: 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 invalid. It is recommended to repeat the test with another GLUTEN'ALARM® test with a new blood sample.

NOTE:

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

This test is exclusively intended for in vitro diagnostics use. External use only. DO NOT SWALLOW.

Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.

Follow strictly the indicated time, blood and diluent quantities.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not reuse the GLUTEN'ALARM® test.

Keep out of reach of children.

After use, all the components can be discarded in a dustbin.

Not suitable for children under 2 years of age.