

BIOCARD™ Celiac Test

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Biocard™ Celiac Test is a rapid, simple and reliable home test for the detection of celiac disease associated IgA autoantibodies from a fingertip blood sample

REF 3-028-401

Carefully read the instructions for use before testing. To perform a **Biocard™ Celiac Test** you will also need a timer. Perform the test in a well illuminated place.

PRINCIPLE OF THE TEST

Celiac disease is a serious, lifelong, gastrointestinal disorder that can cause a wide spectrum of clinical symptoms of diarrhea, abdominal distension, weight loss, malnutrition and skin disorders due to permanent intolerance to gluten, a complex mixture of storage proteins found in wheat, barley and rye. By following a gluten free diet, these symptoms can be avoided.

Biocard™ Celiac Test is a home test for the detection of celiac disease associated IgA antibodies to transglutaminase from a fingertip blood sample. **Biocard™ Celiac Test** can be used as an aid in the diagnosis of celiac disease, but the final diagnosis must be confirmed by a medical doctor. During the gluten free diet, celiac disease associated IgA autoantibody levels will decrease. Amount of antibodies will often become undetectable a few weeks after a change in the diet or latest in 6 months thereafter. Therefore you can have a negative test result if you are following the gluten free diet. Thus **Biocard™ Celiac Test** is good tool for monitoring the effect of gluten free diet. Gluten free diet should be started only according to the instructions of a medical doctor. The test requires only 1 drop (10 µl) of blood from the fingertip, and it can be carried out and evaluated in about 5 minutes. The sampling is practically painless.

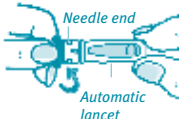
CONTENTS

- 1 aluminium pouch containing a test stick and a desiccant pouch
- 1 sterile automatic lancet
- 1 plastic vessel with a 10 microlitre glass capillary
- 1 alcohol-soaked swab
- 1 Plaster
- 1 tube containing 0,5 ml sample dilution buffer
- 1 package leaflet with instructions for use.

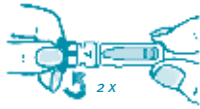
TEST PROCEDURE

Please read these instructions for use carefully before carrying out the test. All components required for the test should be at room temperature. Before taking the blood sample, **prepare all the test components:** the automatic lancet, the alcohol-soaked swab and the glass capillary. **Open the tube** containing the buffer by unscrewing the screw cap. Open the buffer tube and place it standing in the hole at the back of the box. Place the test card horizontally on a level dry surface (with application fields up).

- ① Twist the grey cap until it bounces up.

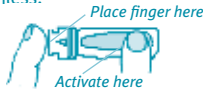


- ② Continue to rotate the cap for at least 2 full rounds and then pull it out.



- ③ Gently massage the fingertip then clean it with the alcohol-soaked swab. Leave until the finger is dry. Warming up your finger will make sample collection easier.

- ④ Press the automatic lancet with the round opening firmly against the cleaned fingertip, and activate it with the button. The puncture is practically painless.



- ⑤ Press a drop of blood out of the fingertip. Open the plastic vessel and remove with caution the glass capillary. Hold the glass capillary horizontally in the drop of blood until it has completely filled.

- ⑥ Place the filled glass capillary in the tube containing buffer and close the tube firmly with the screw cap. Shake the tube several times until the blood from the capillary is mixed completely with the buffer.



- ⑦ Take the test stick out of the aluminium sachet.

- ⑧ Remove the cap of the buffer tube again and place the test stick in the buffer tube. The level of the buffer should not exceed the max-level indicated on the test stick. Avoid any reagent drops or foam on the sides of the tube. The test result can be read after 5 minutes. Remove the test stick from the buffer tube for reading.



Note that a positive result can be read as soon as the test and control lines are clearly visible, which takes place in the majority of cases in less than 2 minutes. If the test result is unsettled or difficult to read after the 5 minutes testing time, wait for another 5 minutes and read the result once again. Do not read the test after more than 10 minutes

INTERPRETATION OF RESULTS

The test result is **positive** if a red control line appears in the control field (C) and a light to dark red line forms in the test field (T).



The test result is **negative** if a red control line appears in the control field (C) and no red line forms in the test field (T).



If no control line is formed, you have likely not followed the instruction for use or test unit is damaged. In such a case repeat the testing with new test unit.

Positive:

The test indicates that there are celiac disease associated IgA antibodies in the tested blood. Detection of these antibodies indicates with a high probability an existing celiac disease. For the final diagnosis and possible treatment go to your doctor.

Negative:

The test indicates that there are no celiac disease associated IgA antibodies in the tested blood. An existing celiac disease can virtually be ruled out. If gastrointestinal complaints are present, further medical investigation is necessary.

STORAGE

Store the test devices and accessories in room temperature (+10°C...+27°C). Avoid freezing. The shelf life of the tests is 24 months provided that the storage conditions are followed. The date of expiry is indicated on the aluminium pouch of the test device and on the outer carton box.

WARNINGS AND LIMITATIONS

- If the instructions for use are not followed in detail, outcome of the test may be false.
- A final diagnosis should only be made by a medical doctor, in conjunction with the clinical symptoms and further laboratory data.
- Do not start the gluten-free diet without consulting your medical doctor.
- Dispose all components in the original test package, as normal household waste.
- Do not use the test after the expiry date.
- Do not use the test if the aluminium pouch is damaged. Do not use broken accessories.
- When the aluminium sachet has been opened you should carry out the test within 20 minutes.
- The sample buffer contains 0.09 % sodium azide. Avoid contact with the skin. Do not swallow!
- **Biocard™ Celiac Test** is very reliable. Alcohol or painkillers do not affect the test result. The test may render a false negative result only in few medical cases, such as IgA deficiency. If the test result is contrary to your expectations, consult your doctor.
- All test components are intended for this test only. Do not reuse tests or accessories.
- Please keep **Biocard™ Celiac Test** out of the reach of children.

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