

BIOCARD™ Celiac Test

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Biocard™ Celiac Test is a rapid, simple and reliable immunochromatographic test for the qualitative detection of anti-tTG IgA antibodies from a fingertip blood sample.

REF 3-028-000

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 (CD) 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 (Dermatitis herpetiformis) due to permanent intolerance to gluten, a complex mixture of storage proteins found in wheat, barley and rye. It was first described by Samuel Gee in 1888.

Studies have found the prevalence of CD to be highly variable from population to population and the true prevalence has been difficult to ascertain. The disparate criteria in diagnosing of CD are often the cause. If only the clinical criteria are used the incidence of CD is much lower compared with incidence established by serological methods. Using serological methods of diagnosis, the incidence of CD in the general population is app. 1 in 100.

The enzyme tissue transglutaminase (tTG) has been identified as the endomysial antigen in CD. A strong indication of CD is the presence of antibodies specific for the tTG.

Biocard™ Celiac Test is a rapid immunochromatographic test that detects the anti-tTG IgA antibodies from a blood sample. If the sample contains anti-tTG IgA antibodies these will bind with the gold labelled antibodies, with tTG derived from red blood cells and with the stationary reagents in the test membrane forming a visible, red test line. The test also contains total IgA measuring system. Red line in the control window shows that there are IgA antibodies in the sample. This will make it impossible to get false negative results in the case of IgA deficiency.

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.

CONTENTS

- 10 aluminium sachets containing a test card and a pipette
- 10 automatic lancets for obtaining a blood sample
- 10 plastic vessels with a 10 microlitre glass capillary
- 10 alcohol-soaked swabs
- 10 tubes containing 0,5 ml sample buffer
- 1 package leaflet with instructions for use.

SAMPLES

Biocard™ Celiac Test is intended for use with capillary whole blood samples, but also IV whole blood samples may be used. If using IV samples start the test procedure from phase 6 by adding 10 microlitres of whole blood sample into the tube containing the buffer. The sample dilution is 1/50.

IV samples should be analyzed within one working day or frozen for later studies. Blood may be collected in EDTA or citrate tubes. Diluted samples (capillary or IV) should be used within one working day.

TEST PROCEDURE

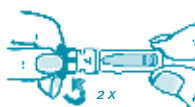
All components required for the test should be at room temperature.

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 removing the cap.

- ① Twist off the grey cap until it bounces up.

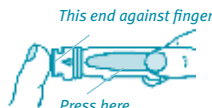


- ② After that rotate it for at least 2 full turns and then pull it out.



- ③ Gently massage the fingertip and then clean it with the alcohol-soaked swab. Wait until the finger is dry.

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



- ⑤ Press a drop of blood out of your 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 cap. Shake the tube several times until blood from the capillary is mixed completely with the buffer.



- ⑦ Take the test card and the pipette out of the aluminium sachet. Place the test card horizontally on a level dry surface (with application fields up). Remove the cap of the buffer tube again and remove a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and drop 3 drops onto it. After applying the drops, do not touch and move the test card for 2 minutes.



The test result can be read after 5 minutes. If the result is not clear wait another 5 minutes and read it again. 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. Do not read the test after more than 10 minutes.

INTERPRETATION OF RESULTS

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

Positive



The test result is **negative** if a light to dark red line appears in the control field (C) and no red line forms in the test field (T). In the case of a faint control line, IgA titer is low and negative result should be confirmed with some other way.

Negative



If there is no line either in the test field or in the control field or the line intensity in the control field is faint, there are either no IgA antibodies or the titer of IgA antibodies is low in the sample. The incidence of IgA deficiency is about 0,5 % in the normal population and among CD patients about 2-3 %. There is no possibility to detect celiac disease in this case with **Biocard™ Celiac Test**.

IgA deficiency



Positive:

The test indicates that there are anti-tTG IgA antibodies in the blood sample. The detection of these antibodies indicates with a high probability an existing celiac disease.

Negative:

The test indicates that there are no anti-tTG 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.

IgA deficiency:

The test indicates that either IgA antibody titer is low or there are no IgA antibodies in the sample. Since the test line measures IgA antibodies against tTG there is no possibility to detect celiac disease with the **Biocard™ Celiac Test** in that case separate IgG testing should be done. Anti-tTG IgA antibody titers diminish with the institution of a gluten free diet, often within weeks and by 6 months may be undetectable. Therefore **Biocard™ Celiac Test** may be used for monitoring the effects of gluten free diet.

STORAGE

Store the test devices, buffer and accessories in room temperature at +10°C...+27°C. Avoid freezing.

The self 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.

SENSITIVITY AND SPECIFICITY

Sensitivity of **Biocard™ Celiac Test** was studied with 390 clinical samples and the results were compared to the biopsy proven clinical diagnosis.

Biocard™ Celiac Disease	Clinical diagnosis	
	+	-
	+221	6
	-5	158

Biocard™ Celiac Test showed 97,8 % sensitivity and 96,3 % specificity with the cut-off of 5 U/ml.

WARNINGS AND LIMITATIONS

- ❖ If the instructions for use are not followed in detail, outcome of the test may be false. Do not reuse tests or accessories.
- ❖ A final diagnosis should in principle only be made in conjunction with the clinical symptoms and further laboratory data.
- ❖ Use only whole blood samples, tTG derived from red blood cells is needed for the proper functioning of the test.
- ❖ General laboratory procedures and precautions shall be followed in the handling and disposal of samples and used materials.
- ❖ Do not use the test after the expiry date.
- ❖ Do not use the test if the aluminium sachet is damaged or broken accessories.
- ❖ After the aluminium sachet has been opened, the test should be carried out within the next 15 minutes.
- ❖ Do not mix reagents or tests from different lots.
- ❖ The sample buffer contains 0.09 % sodium azide. Avoid contact with the skin. Do not swallow!
- ❖ The incidence of IgA deficiency in CD patients is 2 – 3 %. Patients with IgA deficiency can not be diagnosed as coeliacs with **Biocard™ Celiac Test**.

REFERENCES

1. T.Raivio, K. Kaukinen, E.Nemes, K. Laurila, P. Collin, J.P. Kovacs, M. Mäki, I.R. Korponay-Szabo Self Transglutaminase-based rapid celiac disease antibody detection by lateral flow method *Aliment Pharmacol Ther* 24, 147-154, 2006:
2. I.R. Korponay-Szabo, T. Raivio, K. Laurila, J. Opre, R. Kiraly, J.P. Kovacs, K. Kaukinen, L. Fesus, M. Mäki Coeliac disease case finding and diet monitoring by point of care testing *Aliment Pharmacol Ther*, 22, 729-737, 2005
3. G. Nemes, A. Ventura, M. Stefano, G. Di Leo, V. Baldas, A. Tommasini, F. Ferrara, A. Taddio, A. Citta, D. Sblattero, R. Marzari, T. Not Looking for celiac disease: Diagnostic accuracy of two rapid commercial assays *Am. J of Gastroenterol*, 101, 1-4, 2006 et al
4. Vijay Kumar, *Immunoglobulin deficiency and celiac disease, CLI*, 2004, Vol 28, no. 3, p. 10-11
5. Markku Mäki et al, *Prevalence of Celiac Disease among Children in Finland, N Eng J Med* 2003; 348: 2517-24

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MANUFACTURER:

Ani Biotech Oy
Tiilitie 3, 01720 Vantaa,
FINLAND
<http://www.anibiotech.fi>
e-mail: info@anibiotech.fi
tel. +358-20 155 7510
fax. +358-20 155 7511

