Celiac Test
Celiac Self-Test

Code MTR7027/H - Rev. 02 - 28/11/2022

INTENDED USE

Celiac disease (CD) also known as gluten-intolerance, is a disorder that involves a chronic immunologic reaction to the gluten contained in some cereal grains. This reaction causes destruction of villi, the tiny, fingerlike protrusions lining the small intestine, resulting in malabsorption of nutrients.
Disease symptoms include diarrhoea, abdominal bloating, weight loss, malnutrition and skin reactions. Diagnosis based on the detection of antibodies is rather accurate. It is worth mentioning that current guidelines like from the "American College of Gastroenterology" indicate that IgA anti-tTG detection remains the first choice marker for diagnosing coeliac disease in patients aged over 2 years old.
Celiac Test is an immunochromatographic test designed for the detection of antibodies against transgluta-minase and against gliadines in whole blood.

PRINCIPLE OF THE TEST

Celiac Test is an immunochromatographic test designed to detect, in human blood, IgA-type antibodies against human tissue transglutaminase (tTG), the main autoantigen recognized by the anti-endomysial antibodies, and antibodies against gliadins. The test uses a combination of:
1) red latex bead-conjugated human anti-IgA antibodies that will bond to the IgAs present in the sample and that will be taken up by the recombinant human tTG located in the membrane (position T1) if the sample contains IgA anti-tTGs, and/or deamidated gliadin peptides (DGP, position T2) if the sample presents anti-gliadin IgAs.
2) blue latex particles conjugated to an antigen recognized by an antibody specific for this antigen bound to the membrane forming the so called test control band.
On testing the sample, IgA-type antibodies present in coeliac patient blood or serum, which can include IgA anti-tTGs and/or anti-gliadin, will bond to the coloured latex beads coated with human anti-IgA antibodies. These conjugates of latex beads/anti-IgA antibodies/IgAs migrate by a chromatographic process towards the membrane where the test reading zone is located. In this zone, recombinant tTG protein and deamidated gliadin peptides are located in different positions (T1 and T2 respectively). They take up the latex conjugates that form based on the IgA anti-tTG and/or anti-gliadin IgA content in the sample, giving rise to the corresponding red lines that appear. These lines are used to interpret the test result after 15 minutes incubation at room temperature.

WHO DOES USE THE CELIAC TEST?

Celiac Test is useful in particular for: people with symptoms as abdominal bloating and pain, chronic diarrhea, vomiting, constipation); patients with a first degree family member with CD; patients with Type Idiabetes. The test is uself even for people suffering celiac disease in order to monitor if their nutritional planis correct (their results should be negative).

WHAT SHOULD I DO IF THE RESULT IS NEGATIVE ?

A negative result means that the levels of Iga Anti-transglutaminase and anti-deamidated gliading peptides are below the test's detection limit. Anyway isolated IgA deficiency in population with celiac disease is respectively common and affects 2–3% of patients with CD and in case of this patients results will be probably false negative, therefore patients will not be aware of their conditions. If symptoms persist, seek medical advice.

WHAT SHOULD I DO IF THE RESULT IS POSITIVE ?

A positive result means a probable celiac disease. Contact your medical doctor in to continue with diagnostic procedure. The final and definitive diagnosis is established by the clinician.

HOW ACCURATE IS THE TEST?

Accuracy (tTG) = 98,00 % | Accuracy (DGP) = 98,00 %

CONTENTS

1 hermetically sealed protective aluminium package containing 1 device for the Celiac Test; 1 plastic pipette; 1 buffer vial; 1 pain-free, sterile lancing devices for obtaining a blood sample (Owen Mumford Ltd.).

PRECAUTIONS

1) Read these instructions for use carefully before performing the test. The Test is reliable only if all the instructions are followed correctly.
2) Keep the Test out of the reach of children.
3) Do not use the Test after the expiry date or if the package has been damaged.
4) Follow the procedure exactly for the specified quantities of blood and diluent.
5) Store the Test components at a temperature between +2 °C and +30 °C. Do not free freeze it.
6) Use the test and lancing device once only.
7) Test for external use only. DO NOT SWALLOW.
8) In vitro diagnostic device for individual use.
9) Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
10) After using, please dispose of all components according to your local waste.
11) Do not take any decision of medical revelance without first consulting your medical doctor.

INTERPRETATION OF RESULTS

T1 = tTG | IgA Anti-transglutaminase
T2 = DGP | Anti-deamidated gliadin peptides

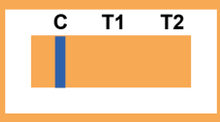
READ THE RESULTS AFTER EXACTLY 15 MINUTES.
DO NOT READ AFTER 20 MINUTES.

15 minutes

The intensity of the line colours is not relevant for the purposes of interpretation of the Test's results.
Do not take any decision of medical relevance without first consulting your medical doctor.

NEGATIVE RESULT

A coloured line appears only under the C (control) sign.

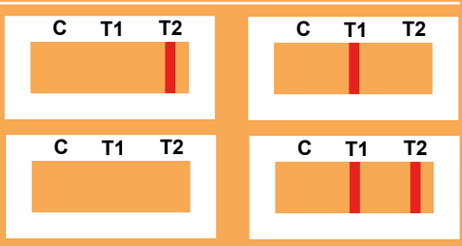


POSITIVE RESULT

Two or Three distinct colored lines appear. One is in the control region (C) ,one line in T1 or T2 or in both of them. **In this cases there is a probable celiac disease.**

RESULT NOT VALID

Control line (C) fails to appear (BLUE line does not appear). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new card.



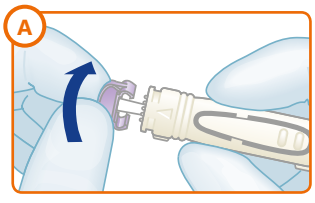
LANCET | PROCEDURE FOR USE

Lancet

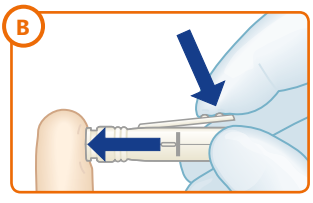
STERILE R

Owen Mumford Ltd.
Brook Hill, Woodstock
Oxford OX20 1TU
United Kingdom

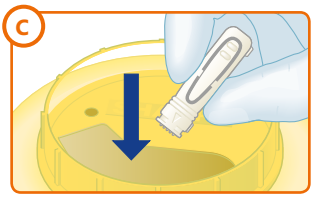
CE 0120



Twist off protective cap and discard lancet cap.

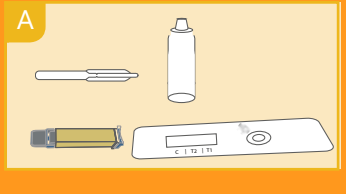


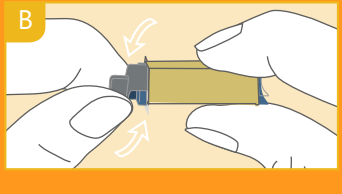
Press the Unistik® against the finger and PRESS the release button.

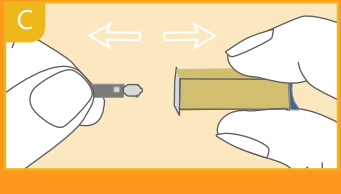


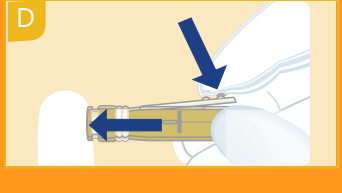
DISPOSE of the used Unistik® in a suitable sharps container.

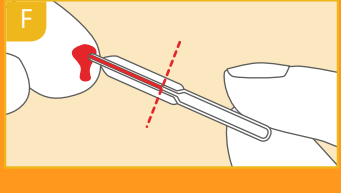
TEST | PROCEDURE FOR USE

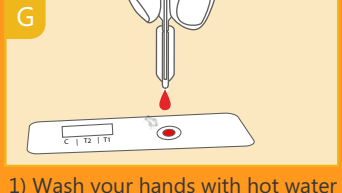


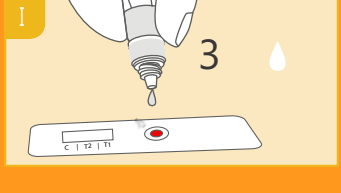












1) Wash your hands with hot water and soap, rinse with clean water and dry.
2) Lay out the material needed as follows: open the aluminium bag and take only the test strip case and the pipette. Discard the desiccant bag. Open the vial by unscrewing the white cap, making sure it does not fall to the ground. - fig. A
3) With care and without pulling, perform a 360°rotation of the lancing device's cap. - fig. B
4) Extract and discard the released cap. - fig. C
5) Press the lancet, on the side the cap was extracted from, against your fingertip (the tip of the ring-finger is recommended). - fig. D. The tip of the lancing device retracts automatically and safely after use. If the lancing device does not work correctly, use the second one supplied. If the second lancet is not used, it can be disposed of without any special precautions.
6) Keeping your hand pointing downwards, massage the tip of the finger until a large drop of blood forms. Do not use the first drop of blood, collect the next drop of blood. - fig. E
7) Take the pipette without pressing the bulb and place it in contact with the drop of blood. The blood will enter into the pipette by capillary action. Continue massaging your finger until the blood has reached the black line on the pipette. Avoid moving it away from the finger as much as you can, in order to prevent the formation of air bubbles. - f g. F
8) Press the pipette bulb 2 or 3 times to ensure that all the blood has moved into the sample well. fig. G
9) Open the cap of the diluent vial (- fig. H) and deposit 3-4 drops in the sameple well. fig. I
10) Disinfect the finger with the supplied disinfecting tissue and apply the medical patch.
11) Wait 15 minutes.

+2 °C +30°C IVD

	Consult instructions for use	IVD	In vitro diagnostics
	Use by date	REF	Catalog number
	Temperature limit		Manufacturer
CE	CE mark		Corrugated board
CE	Certifying body number		Do not re-use
LOT	Batch code		

CE 1434

Manufactured by:
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