PHARMA *SOUTHERN AFRICA*

GLUTEN' ALARM®

Ref. 150084/ZA

Self Diagnostic Test for the detection of anti-tissue transglutaminase IgA antibodies associated with celiac disease in the blood.

GENERAL POINTS

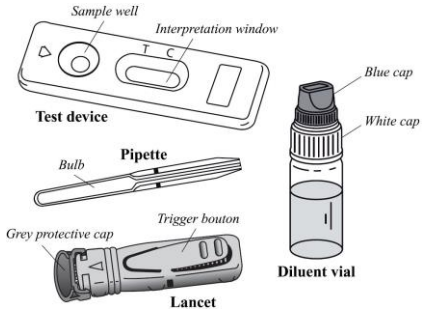
Celiac disease is a long-term autoimmune disorder affecting the small intestine that can occur in genetically predisposed people. It is caused by intolerance to the ingestion of gluten which are various proteins found in wheat, barley and rye. It is estimated to affect 1% people worldwide. Typical symptoms include chronic diarrhea, abdominal pain, gas, weight loss but also anaemia, osteoporosis, extreme fatigue and even delayed growth in case children are affected.
Currently, the only treatment for Celiac disease, after being diagnosed, is a strict life long gluten-free diet.
Currently, highly effective whole blood tests are the first line screening method to detect the 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 finger prick whole blood samples.

PRESENTATION

The box contains all the material necessary to perform a test:
- **1 sealed aluminium pouch** containing:
  1 test device, 1 plastic pipette and 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.**



Not provided necessary material: absorbent cotton and alcohol 70 % vol. or alcohol pad.

PRECAUTIONS

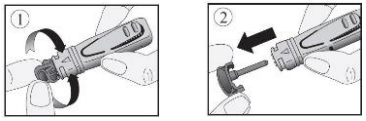
1. This test is exclusively intended for *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected. Follow strictly the indicated time, blood and diluent quantities.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
5. Do not re-use GLUTEN' ALARM®.
6. **Keep out of the reach of children.**
7. After use, all components can be discarded in a dustbin.
8. Not suitable for children under 2 years' old.

PROCEDURE

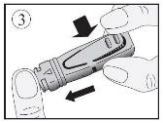
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.

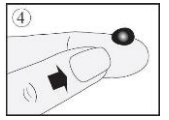
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.
3. **Prepare the lancet.** Hold the lancet **without touching the trigger button.** Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.



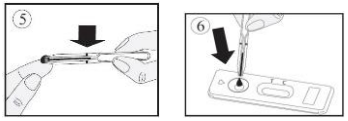
4. Clean the end of the middle finger or ring finger with cotton damped with alcohol.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button**③.



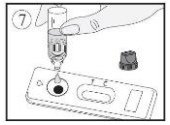
The tip will automatically retract into the body of the device.
6. Rub the finger's end to obtain enough whole blood sample.④.



7. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
8. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



9. Wait 30-40 sec for the blood being totally 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 device⑦ with an interval of 2-3 seconds between each drop.



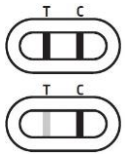
10. Read the result after 15 minutes. Do not interpret after 20 minutes.

RESULTS INTERPRETATION

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

1. Positive result

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 blood sample contains anti-t-TG IgA type antibodies and **that you should consult a doctor.**

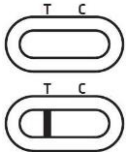


2. Negative result

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.

3. Invalid result

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 ® with a new blood sample.



QUESTIONS AND ANSWERS

How does GLUTEN' ALARM ® work?
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).

When should the test be performed?
GLUTEN' ALARM® should be performed in case of gluten intolerance symptoms or in the case members of the family are already showing this problem. This disease is indeed occurring in genetically predisposed individuals. The test should be performed while being on regular diet (not gluten free diet) to make the result valid.

Can the results be incorrect?
The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if GLUTEN' ALARM® gets wet before test performing or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure the collected whole blood volume is correct.

How to interpret the test if the colour and the intensity of the lines are different?
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as positive regardless of the colour intensity of the test line (T), even weak.

What is the line that appears under the mark C (Control) for?
When this line appears, it only means that the test has been performed well.

If I read the result after 20 minutes, will the result be reliable?
No. The result should be read within 15 minutes after adding the diluent. The result is reliable up to 20 minutes.

What do I have to do if the result is positive?
If the result is positive, it means that anti-t-TG IgA type antibodies are present in blood and that you should consult a doctor to show the test results. Then, the doctor will decide whether additional investigation should be performed.

What do I have to do if the result is negative?
If the result is negative, it means that the test could not detect anti-t-TG IgA type antibodies in blood sample. In limited cases, IgA deficiency may also lead to false negative results. Meanwhile it is recommended to consult a doctor if symptoms persist.

What is the accuracy of GLUTEN' ALARM ®?
The **GLUTEN' ALARM®** 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.
***** CI 95%: 95% Confidence Interval***

Information on Celiac disease
1. Fasano A (Apr 2005). « Clinical presentation of celiac disease in the pediatric population ». *Gastroenterology* (Review). 128 (4 Suppl 1): S68-73.
2. « Symptoms & Causes of Celiac Disease | NIDDK". *National institute of Diabetes and Digestive and Kidney Diseases*. June 2016. Archives from the original on 24 April 2017. Retrieved 24 April 2017.

Sterile lancet: STERILE R

CE 1639

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EC REP GERMANY
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	Read the instructions before use	IVD	For *in vitro* diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiration date
	Manufacturer	EC REP	Authorized EU representative		

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CE 0483

CHANGES DESCRIPTION
Changes type:

- N/A	Not Applicable (creation)
- Technical change	Addition, revision and/or removal of information related to the product.
- Administrative	Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	**Creation**

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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