

CoeliacScreen™

ABOUT THIS TEST

CoeliacScreen™ is a simple, rapid and reliable diagnostic self test to detect the presence of coeliac disease associated IgA and IgG anti-transglutaminase antibodies in a finger tip sample of human blood.

Coeliac disease is a serious gastrointestinal autoimmune disorder that occurs in predisposed people of all ages from middle infancy onwards. It is a common condition affecting up to 1% of the UK and EIRE population and causes a wide range of symptoms such as diarrhoea, abdominal bloating, weight loss, skin ailments and signs of malnutrition. Coeliac disease is caused by a permanent intolerance to gluten, a group of proteins found in wheat, barley, rye and many other cereals, which results in an immune response and specific antibodies (IgA and IgG) to tissue transglutaminase being produced.

CoeliacScreen™ is used to support the diagnosis of coeliac disease, which must then be confirmed by your doctor. The clinical advice is normally to adopt a gluten-free diet to avoid the symptoms of the disease. A gluten-free diet will decrease disease symptoms and also the levels of the coeliac disease-associated IgA and IgG antibodies. These will often become undetectable a few weeks after adoption of the diet, and certainly within 6 weeks so if you are on a gluten-free diet, it is likely that your test result will be negative. A gluten free diet should only be followed in accordance with a physician's instruction.

KIT CONTENTS

1x sealed foil pouch containing:

- 1x test cassette with desiccant

1x plastic minigrip containing:

- 2x micropipettes
- 1x dropper bottle containing 1ml of test diluent (single use)
- 2x sterile single use lancets for blood sampling (Dir. 93/42/EEC CE0459 - Class IIa - Vitrex Medical A/S, Vasekaer 6-8, 2730 Herlev DENMARK)
- 1x Alcohol Swab (Dir 93/42/EEC Class 1 Vitrex Medical AS, Vasekaer 6-8, 2730 Herlev DENMARK)

1x Instruction for use

Please note you will also need a watch with a second hand, a clean paper tissue and a plaster (optional).

Test Diluent



Lancet



Swab



Cassette



Micropipette



PRECAUTIONS

Important - Read these test instructions carefully before use

1. Always read the instructions carefully before performing the test as it is only possible to interpret the results if the procedure is carried out exactly as instructed.
2. **Keep out of the reach of children.**
3. **FOR EXTERNAL USE ONLY. Test Diluent contains Proclin 300. May produce an allergic reaction. Do not swallow. Use only as an in vitro diagnostic device for self-testing purposes.**
4. **Do not use this test if you suffer from a blood clotting disease.**
5. Alcohol and local anaesthetics do not affect the test.
6. If blood comes in contact with any surfaces, wipe clean with disinfectant.
7. **DO NOT REUSE.** This is a single use test.
8. Do not use after the expiry date printed on the box label and on the foil pouch, or if the pouch is damaged.
9. Store between +8°C and +25°C. Do not freeze.
10. **DISPOSAL.** After use place the test cassette, used lancet, micropipette, buffer bottle and swab inside the foil pouch, replace in box and dispose of with your normal household waste.
11. Second lancet and second micropipette are to be used only if/when the first fail.
12. A final diagnosis has to be done by a physician on the basis of clinical symptoms and in support of further laboratory analysis.
13. Consult a doctor before starting a gluten-free diet.
14. CoeliacScreen has a 96.5% sensitivity and a 97.3% specificity
15. The test may result negative only in limited cases, for instance with low antibody titre
16. Contains desiccant. Do not ingest.

PREPARATION

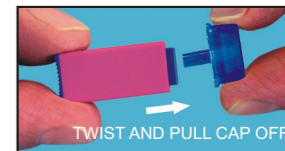
- Open the foil pouches and remove the test cassette and the other components.
- Familiarise yourself with the components of the test.
- Ensure you have plenty of light and a hard flat surface available on which to lay the cassette when you perform the test.
- Ensure all components have reached **room temperature** before starting.
- **Read the instructions thoroughly before taking the test**
- You will also need to have a **watch** with a second hand ready and a **clean paper tissue**.
- When ready to start the test wash your hands with soap in warm water to soften the skin and encourage blood flow in your fingers. Rinse thoroughly and dry.

TEST PROCEDURE

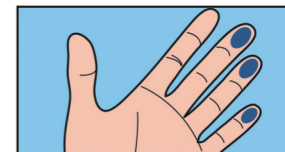
❶ Collect the blood sample

- Hold the lancet by its sides at one end and twist and pull the blue plastic cap from the other end.

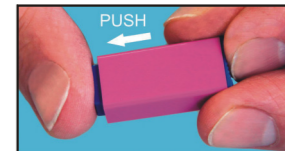
Warning: Do not use the Lancet if the cap has been removed or is missing.



- Shake your hands downwards to let blood flow.
- **Choose a site on the finger** as indicated by the shaded areas of the picture. Avoid areas of hard skin



- Press the end of lancet firmly against the cleaned site on your finger until the lancet is triggered.

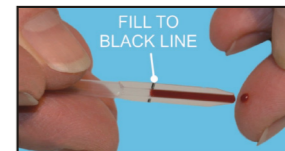


- A small drop of blood will appear. Massage the finger towards the tip to encourage the blood to flow and a drop to form.



- Touch the end of the micropipette against the blood drop. **Do not squeeze the bulb of the pipette** as the blood will be drawn into the pipette automatically (filling up by capillarity).

Quickly continue to massage the finger to give the next drop of blood and draw the blood into the pipette in quick succession until it reaches the **black line** on the pipette.



- **Note: If the blood flow stops during collection** let your arm hang loosely at your side for a short time and then massage your finger again. This usually restarts the blood flow.

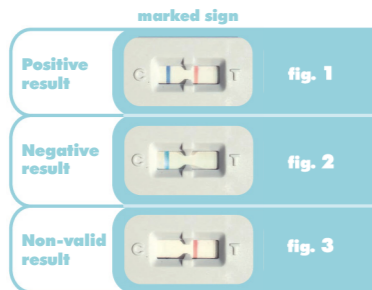
2 Testing the sample

- **Quickly drop the blood from the pipette** into the round well on the cassette labelled with an **arrow** by squeezing the bulb at the end of the pipette.
- Ensure all of the blood in the pipette is removed and if necessary also squeeze the tube of the pipette and cover the ventilation hole on the nozzle with a finger.
- **Wait 60 seconds.**
- Open the test diluent bottle (DIL) as indicated by the arrows and dispense two drops of test diluent into the round sample well.
Warning: Do not dispense more than 2 drops of diluent, otherwise the interpretation of the test may be difficult.
- Make a note of the time and wait **from 3 to 5 minutes.**
- You will start to see the blood sample/diluent mix migrate up the test cassette. **Do not move the cassette until the test time has completed.**
- After 5 minutes check for the presence of a **blue line** in the cassette window near to the **'C'** control mark and a possible **red line** near to the **'T'** test mark. The result must appear within 10 minutes.
- **Do not read the result after 10 minutes, the test won't be reliable.**



3 Reading the results

- **Positive Fig. 1:** A blue coloured line in the window near to the 'C' control mark **and** a red coloured line of variable intensity near the 'T' test mark means that the test is positive. This indicates the presence of antibodies associated with the coeliac disease. You should contact your local doctor and proceed with further laboratory diagnosis.
- **Negative Fig. 2:** A blue coloured line appears near to the 'C' control mark on the cassette. This is the control line and must always appear. In this case the presence of antibodies associated to the coeliac disease can be excluded. In the presence of gastrointestinal symptoms, perform further medical investigations.
- **Non Valid result Fig. 3:** A blue coloured line should always appear near the 'C' control mark. If there is no blue coloured line the test is invalid, even if a red line appears near the 'T' test mark. The non valid result could be due to a non correct procedure, a deterioration of the reagents or to a non correct amount of blood analysed. The test must be repeated.



Please note: In addition to the blue line by the 'C' control mark, **ANY red line seen near the 'T' test mark of the cassette** after the 5 minute test time is considered **POSITIVE**. The intensity of the coloured lines do not matter.

QUESTIONS AND ANSWERS

• How does CoeliacScreen™ work?

CoeliacScreen™ gives a positive result if you have antibodies (IgA or IgG) to Tissue Transglutaminase (tTG) that are associated with coeliac disease. If you have an IgA deficiency, which is more common in coeliac patients than normal, the test is positive if you have only IgG antibodies to tTG. The presence of at least one type of these antibodies indicates that there is a high probability that you have coeliac disease. If the test is negative and neither type of antibody has been detected then coeliac disease can be virtually ruled out.

• When should the test be used?

If you have one or more of the symptoms of coeliac disease including diarrhoea, abdominal bloating, weight loss, skin ailments or signs of malnutrition, taking the CoeliacScreen™ test for the condition is recommended.

• Is the test result correct?

CoeliacScreen™ has been validated against laboratory tests and has been shown to be very reliable, (96,5% sensitivity, 97,3% specificity), provided the instructions are followed carefully. The test can only give a false negative result in rare cases, such as when the levels of tTG antibodies are very low. Please note however that the test result can be adversely affected if insufficient blood is used or it is dispensed incorrectly.

• How to interpret the test if the colour and intensity of the lines are different?

The intensity of the coloured test lines are of no importance in the interpretation of the result. The coloured lines only need to be uniform and clearly visible and a red line of any intensity by the 'T' test mark should be regarded as positive.

• If I read the result after 10 minutes, will the result be reliable?

No, the result should be read within 10 minutes of adding the test diluent and is reliable only up to this time.

• What should I do if the test result is positive?

CoeliacScreen™ is a screening test for coeliac disease and a positive test result indicates that you have coeliac associated IgA or IgG antibodies. We would recommend that you seek medical advice from your doctor who will conduct further supporting laboratory tests and take into account any symptoms of the condition that you may have before making a definitive diagnosis. Only start a gluten-free diet on the advice of your doctor.

• What should I do if the test result is negative?

A negative test result indicates that it is very unlikely that you have coeliac disease. However, as no test is 100% effective and it is known that very low antibody levels the test may give a false negative result, we recommend that you consult your doctor if you have worrying gastrointestinal symptoms or the test result is contrary to your expectations.

Warning: A final diagnosis must be performed by a physician, based on clinical symptoms and further supporting laboratory tests.

	9125 catalogue number		Contains 1 test
	0123		Storage temperature +8° to +25°C
	Consult instructions for use		Do not reuse
	Caution		Sterile (Lancet)
	In Vitro Diagnostic Medical Device		Batch code
	Manufacturer		Use by:

Distributed by

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CoeliacScreen™ is also known by the name Xeliac® Test Pro. Xeliac® is a registered trade mark of Eurospital S.p.A, Italy