FOODTEST .hu FOOD INTOLERANCE CENTER

Complex solution in diagnostic and treatment of food intolerance

Coeliac Screen™ Coeliac Monitor™

FREQUENTLY ASKED QUESTIONS

BLOOD SAMPLE COLLECTION

Q. What volume of whole blood is required to perform the test?

A. Coeliac Screen™ - 20µl, Coeliac Monitor™ - 15µl. The sample can be taken from a finger-prick sample or venous blood. The micropipette supplied in the kit will automatically fill with the required volume of blood.

Q. Can serum or plasma samples be used?

A. Yes. Serum or plasma samples should be pre-diluted using the Sample Diluent provided in the kit and 125µl of the diluted sample added to the test device.
Coeliac Screen™ - prepare a 1/10 dilution: 20µl serum/plasma + 180µl diluent.
Coeliac Monitor™ - prepare a 1/30 dilution: 5µl serum/plasma + 145µl diluent.

Q. Why does the first drop of blood need to be discarded?

A. The first drop of blood should be discarded to minimise excess tissue fluids contaminating the blood sample. A clean, dry tissue should be used. Do not squeeze the finger excessively as this may dilute the sample with tissue fluid.

Q. The blood sample is not being drawn into the micropipette. Why?

A. It is important to hold the micropipette in a HORIZONTAL position when collecting the sample and ensure that the ventilation hole is not covered. Touch the micropipette to the drop of blood, but do NOT squeeze the bulb.

Q. Can samples be stored prior to testing?

A. Finger-prick whole blood samples should be used immediately. Venous blood samples can be refrigerated at 2-8°C for 1 day prior to use.

Q. Can anticoagulants be used?

A. Yes. EDTA, citrate, heparin and ACD are all suitable for use.

KIT STORAGE/STABILITY

Q. Do the kits require any specific storage conditions?

A. Yes. Kits should be refrigerated at 2-8°C.

Q. Do the kits require refrigeration during delivery/shipment?

A. No. Refrigerated shipment is not required, provided that kits are stored at 2-8°C within 1 week of dispatch. Stability studies have shown that the test performance is not compromised during this time.

Q. What is the shelf-life of the kits?

A. 24 months.

Q. Once opened, how long is the bottle of Sample Diluent stable for?

A. Provided that the kit has been refrigerated at 2-8°C, the Sample Diluent will remain stable for the duration of the kit's shelf-life.

TEST PRINCIPLE

Q. Some competitor kits only test for IgA-tTG. Why is it important to test IgG also?

A. IgA-tTG is the key autoantibody associated with Coeliac disease. However, approximately 3% of the Coeliac population is IgA-deficient and false negative results would be obtained with IgA-only tests. NICE guidelines recommend that patients who are strongly suspected of having Coeliac disease, but are IgA-tTG negative, should be tested for IgG-tTG also.

TEST PROCEDURE

Q. I can't expel the blood sample from the micropipette. What should I do?

A. Place your fingers over the ventilation holes on the micropipette (in-between the black lines) and then squeeze the bulb. The blood sample should now be expelled from the micropipette.

RESULT INTERPRETATION

Q. Can I read the test result after 10 minutes?

A. No. The test result should be read within 10 minutes of adding the Sample Diluent. Lines that appear after 10 minutes have no diagnostic value and should be disregarded.

Q. Is the colour intensity of the test line relevant to the result?

A. No. The tests are designed to be qualitative and no quantitative interpretation should be made with respect to the colour intensity of the test line when reporting the result. Any pink test line that appears within 10 minutes, regardless of how weak or strong, represents a positive result.

Q. A control line did not appear within 10 minutes. What could be the cause?

A. This could indicate that the test procedure was not followed correctly, an incorrect volume of sample was added, the reagents had deteriorated or the kit had expired. The test result is invalid and should be repeated.

Q. What should I recommend if the Coeliac Screen™ test result is positive?

A. A positive test result indicates that tTG antibodies associated with Coeliac disease have been detected and there is a high probability of an existing disease. We would recommend that the patient be referred to a medical professional for a final diagnosis and to discuss treatment options.

Q. What should I recommend if the Coeliac Screen™ test result is negative?

A. A negative test result indicates that tTG antibodies associated with Coeliac disease have not been detected and there is a low probability of an existing disease. However, no diagnostic test is 100% accurate (please refer to TEST PERFORMANCE), so the patient should always be referred to a medical professional for further investigation if they are experiencing gastrointestinal discomfort/symptoms.

TEST PERFORMANCE

Q. How accurate are the tests?

A. The tests have undergone numerous evaluations using human sera taken from diagnosed and undiagnosed Coeliac patients. The test performance was established by comparing test results against existing laboratory methodologies:

Coeliac Screen™

EVALUATION	SENSITIVITY	SPECIFICITY
1	89%	92%
2	99%	99%
3	94%	100%
Overall	**94%**	**97%**

Coeliac Monitor™

EVALUATION	SENSITIVITY		SPECIFICITY	
	tTG	Gliadin	tTG	Gliadin
1	90%	58%	92%	80%
2	75%	100%	100%	99%
Overall	**83%**	**79%**	**96%**	**90%**

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