



Complex solution in diagnostic and treatment of food intolerance

Coeliac Monitor™

Rapid, point-of-care test for the detection of human anti-gliadin and anti-tissue transglutaminase (tTG) antibodies in whole blood

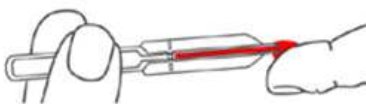

INTENDED USE

Coeliac Monitor™ is an immunochromatographic test designed to detect human IgA antibodies against tissue transglutaminase (tTG), the main autoantigen associated with Coeliac disease, and anti-IgA gliadin antibodies associated with the consumption of gluten. Coeliac Monitor™ can be used to monitor the effectiveness of a gluten-free diet, which is recommended to improve symptoms of Coeliac disease.

SAMPLES

Coeliac Monitor™ has been designed for use with fresh, non-haemolysed blood samples. The kit contains micropipettes to collect a sample from finger-prick whole blood. Plasma and serum samples can also be used.

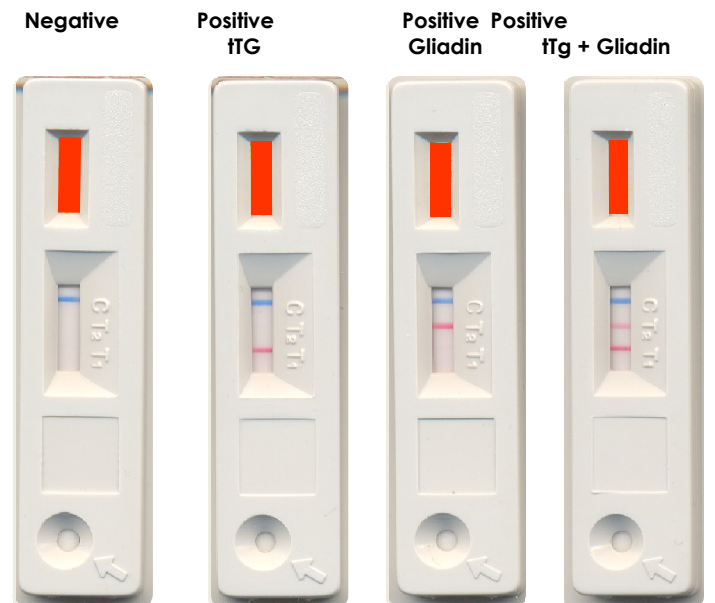
TEST PROCEDURE

1. Prick a finger using the safety lancet provided.
 2. Gently massage the finger in the direction of the puncture to obtain a drop of blood. Discard the first drop of blood and collect the next drop.
 3. Touch the drop of blood with the micropipette.
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4. Capillary action will fill the micropipette with the required volume of blood to the black line (15ul).
 5. Squeeze the bulb of the micropipette to dispense the blood sample into the round window.
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6. Wait for 60 seconds, until the blood is absorbed.
7. Add 2 drops of dilution buffer to round window.

8. Read the results at the end of 10 minutes.

RESULT INTERPRETATION



The Coeliac Monitor™ kit must be stored at 2 - 8°C. The expiry date is printed on the box.

SENSITIVITY AND SPECIFICITY

Evaluation	Sensitivity		Specificity	
	tTG	Gliadin	tTG	Gliadin
1	90%	58%	92%	80%
2	75%	100%	100%	99%
Overall	83%	79%	96%	90%

ORDERING INFORMATION

Code	Description	Pack Size	Shelf-Life
CNSCM	Coeliac Monitor	5 Tests	24 months

INTERFERENCE SUBSTANCES

Interference substances that are likely to be present in blood were added to a diluent and sensitivity curves performed. None of the substances were found to affect the test performance.

CE FOR PROFESSIONAL USE ONLY

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