



Complex solution in diagnostic and treatment of food intolerance

## Coeliac Screen™

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

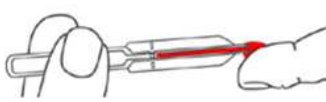

### INTENDED USE

Coeliac Screen™ is an immunochromatographic test designed to detect IgA/IgG/IgM antibodies in human blood against tissue transglutaminase, the main autoantigen associated with Coeliac disease. Detection of IgG antibodies is an important component to prevent false negative results being obtained with IgA-deficient patients (approximately 2-3% of the Coeliac population). Coeliac Screen™ can be used as a screening test to aid the diagnosis of Coeliac disease.

### SAMPLES

Coeliac Screen™ 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 (20ul).
  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

Negative



Positive



### STORAGE

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

### SENSITIVITY AND SPECIFICITY

Evaluation	Sensitivity	Specificity
1	89%	92%
2	99%	99%
3	94%	100%
<b>Overall</b>	<b>94%</b>	<b>97%</b>

### ORDERING INFORMATION

Code	Description	Pack Size	Shelf-Life
CNSCS	Coeliac Screen	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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