










PathTROL™ Coeliac Control

REF

PW880101 PathTROL™ Coeliac Control 1x1ml
PW880105 PathTROL™ Coeliac Control 5x1ml
PW880110 PathTROL™ Coeliac Control 10x1ml

Key to Symbols

	Manufactured by		Consult instructions for use		Lot number
	Expiry date		CE mark		Catalogue number
	Storage temperature		For in vitro diagnostic use		EU representative

Product Description

Intended use

PathTROL™ Coeliac Control is a liquid control serum containing autoimmune IgG, and/or IgA antibodies that is designed for the continuous long-term quality control of Coeliac autoimmune tests in clinical and research laboratories.

Composition

PathTROL™ Coeliac Control is liquid and consists of human serum containing human antibodies with the following specificities:

Tissue transglutaminase IgA
Tissue transglutaminase IgG
Deamidated Gliadin IgA
Deamidated Gliadin IgG

The analytes are present in native form in a physiological serum matrix comparable to patient serum. To guarantee long-term stability, the serum contains a preservative (0.09% Sodium azide).

PathTROL™ Coeliac Control is supplied in a clear microcentrifuge tube with a **yellow** screw cap, in 1ml volume.

PathQAS™ Autoimmune iQC Scheme

A Certificate of Analysis of target values is provided for each type of autoimmune antibody contained in the control.

In addition, an optional enrolment in our PathQAS™ Autoimmune internal Quality Control scheme is included with the controls. This peer- to-peer monthly QC scheme provides the comparison with user-group consensus values, local inter-laboratory comparison combined with the independent, third-party controls that are recommended for ISO 15189 compliance.

Preparation and performance of the test

- The PathTROL™ Coeliac Control is ready to use.
- Just before use, mix the serum by gently inverting the tube several times.
- Use the PathTROL™ Coeliac Control serum directly from the original tube if this can be loaded onto the test instrument. Alternatively take an aliquot from the original tube into a suitable container for testing. After testing, place the original tube back into the refrigerator for storage.
- Allow the PathTROL™ Coeliac Control to stand at room temperature for 15 minutes before use and then test in the same way as a patient sample, using the instructions provided by the manufacturer of the test.

Stability and Storage

PathTROL™ Coeliac Control is stable until the expiry date printed on the bottle label when kept sealed in the original tube and stored at 2-8°C.

Once opened, the control sera must be kept in the refrigerator in the original tube and should be used within 60 days.

After opening the control, it is possible to store it below -20 °C until expiry date, but do not use for more than 3 freeze-thaw cycles.

Any remaining control serum from test aliquots that has been warmed to room temperature and that is not required, should be discarded.

Warnings and Precautions

- The PathTROL™ Coeliac Control is for in vitro diagnostic use only. It should not be used to calibrate a test.
- Contains human material. The control sera have been tested and found negative for HIV1/2 Ab and HCV Ab, and non-reactive for HBsAg, HBV-DNA, HCV-RNA, HIV-RNA and STS. **However, as human source products they should be treated as potentially infectious and handled appropriately.**
- Refer to "Materials Safety Data Sheet" for more detailed safety information.
- PathTROL™ Coeliac Control should not be used beyond the expiry date printed on the tube label and packaging. If there are any signs of microbial contamination or excessive turbidity in the sera, they should be discarded.
- PathTROL™ Coeliac Control should only be used when the tube is intact. If the tube is damaged the control serum should be discarded.



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