

PathTROL™ Calprotectin EX Control Set



PW825024 PathTROL™ Calprotectin EX Control Set 4x0.75ml

PW825022 PathTROL™ Calprotectin EX Trial Pack 2x0.75ml

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™ Calprotectin EX Controls are calprotectin positive extraction controls designed for the continuous long-term quality control of faecal calprotectin tests, such as the Phadia® EliA®, Buhlmann fCAL® turbo and ELISA tests, Diasorin LIAISON®, IDK® Calprotectin ELISA and other comparable assays, in clinical and research laboratories.

Composition

PathTROL™ Calprotectin EX controls consist of lyophilised human faecal material containing native calprotectin.

The calprotectin in the faecal material is present in a native form that is comparable to patient stool test samples.

The PathTROL™ Calprotectin EX controls are supplied as a set of High and Low-level positive controls, lyophilised in brown glass bottles with either a **red** (high positive) or **yellow** (low positive) screw caps, for reconstitution in 0.75ml volumes.

PathQAS™ Calprotectin iQC Scheme

A Certificate of Analysis of target values for relevant tests is provided for each level of PathTROL™ Calprotectin EX control.

PathTROL™ Calprotectin extracted and extraction controls are supported with an optional enrolment in our internal Quality Control scheme, PathQAS™ Calprotectin. This scheme provides the user with a peer-to-peer comparison and assists with ISO 15189 compliance by providing a regular local inter-laboratory comparison combined with the advantages of using independent, third-party assay controls.

Preparation and performance of the test

- Allow the PathTROL™ Calprotectin EX Controls to come to room temperature and reconstitute in **0.75ml** of deionised water.
- Leave to stand for **10 minutes** at room temperature and then vortex for a minimum of **30 seconds** to ensure the reconstituted faecal material is homogenous before testing.
- Test the controls in the same way as a patient sample, using the instructions provided by the manufacturer of the faecal extraction tubes and calprotectin test.

Stability and Storage

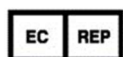
PathTROL™ Calprotectin EX controls are stable until the expiry date printed on the outer packaging and tube label, when stored lyophilised and sealed in the original bottles at 2-8°C.

Once reconstituted, the controls can be stored at 2-8°C in their original bottle, for a maximum of 12 hours. Do not use beyond this time, or freeze the control material.

Any remaining control that has been warmed to room temperature that is not required, should be discarded.

Warnings and Precautions

- PathTROL™ Calprotectin EX controls are for in vitro diagnostic use only and should not be used to calibrate a test.
- The native human faecal material used to produce PathTROL™ Calprotectin EX controls can vary in colour and turbidity. This is completely normal and will not affect the quality or homogeneity of the controls.
- Contains human material: The control has been tested and found negative for HIV 1&2 antibodies, HCV antibodies and HBs antigen. However, as a human source product it should be treated as potentially infectious and handled appropriately.**
- Refer to "Materials Safety Data Sheet" for more detailed safety information.
- PathTROL™ Calprotectin EX controls should not be used beyond the expiry date printed on the bottle labels and packaging.
- PathTROL™ Calprotectin EX controls should only be used when the bottles are intact. If the bottles are damaged, they should be discarded.



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