

PathTROL™ Calprotectin A Control – Level 3

REF	PW820305	PathTROL™ Calprotectin A Control – Level 3	5x0.5ml
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Key to Symbols

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

Product Description

Intended use

PathTROL™ Calprotectin A Controls are a range of calprotectin positive controls designed for the continuous long-term quality control of faecal calprotectin tests, such as the Phadia® EliA™ Calprotectin 2 assay and other comparable assays, in clinical and research laboratories.

Composition

PathTROL™ Calprotectin A Controls consist of native human calprotectin in a lyophilised, bovine serum-based matrix, comparable to patient test samples.

The PathTROL™ Calprotectin A Level 3 control is supplied lyophilised in a clear micro-centrifuge tube with a **red** screw cap, for reconstitution in 0.5ml volumes.

PathQAS™ Calprotectin iQC Scheme

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

PathTROL™ controls also include 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 lyophilised PathTROL™ Calprotectin A Control Level 3 to come up to room temperature and reconstitute in 0.5ml of deionised water.
- Leave to stand for 5 minutes and then mix well inverting the tube several times or gentle vortexing. Ensure that all solid material is completely dissolved prior to use.
- Use the PathTROL™ Calprotectin A Control Level 3 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.
- Ensure that the control has come to room temperature before use and then test in the same way as an extracted patient sample, using the instructions provided by the manufacturer of the calprotectin test.

Stability and Storage

The PathTROL™ Calprotectin A Control Level 3 is stable until the expiry date printed on the outer packaging and tube label, when stored lyophilised and sealed in the original tube at 2-8°C.

Once reconstituted, the control sera can be stored at 2-8°C in their original tube, for a maximum of 3 days. Alternatively, the control sera can be aliquoted into plastic micro-tubes and stored at -20°C for 3 months.

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

Warnings and Precautions

- The PathTROL™ Calprotectin A Control Level 3 is for in vitro diagnostic use only and should not be used to calibrate a test.
- Contains human material: The control sera have 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 A controls should not be used beyond the expiry date printed on the tube label and packaging.
- PathTROL™ Calprotectin A controls should only be used when the tubes are intact. If the tubes are damaged the control serum should be discarded.