PathTROL™ Tryptase Positive Control

REF

PW85101 PathTROL™ Tryptase Positive Control 1x0.5 ml
PW85105 PathTROL™ Tryptase Positive Control 5x0.5 ml

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™ Tryptase Positive Controls is lyophilised control plasma, containing Human Tryptase, which is designed for the continuous long-term quality control of Tryptase tests in clinical and research laboratories.

Composition

PathTROL™ Tryptase Positive Controls is lyophilised Human plasma containing native Human α-Tryptase and β-Tryptase comparable with patient plasma. The plasma does not contain any preservatives or stabilisers.

PathQAS™ Tryptase iQC Scheme

The PathTROL™ Tryptase Positive Control has a concentration range, of 20-25 ng/ml. A Certificate of Analysis of externally assigned target values for the ImmunoCAP® Tryptase test run on Phadia® Laboratory Systems is supplied with each control.

In addition, an optional enrolment in the PathQAS™ Allergy/Tryptase internal Quality Control scheme is included with the controls. Our peer-to-peer monthly QC scheme provides the comparison with user-group consensus values, local inter-laboratory comparison and independent third-party controls recommended for ISO 15189 compliance.

Preparation and performance of the test

- The PathTROL™ Tryptase Positive Control should be reconstituted with distilled water before use.
- Pipette 0.5ml of distilled water into the bottle and allow to stand at room temperature for 15 minutes. Before use, mix the reconstituted plasma by gently swirling the bottle.
- The PathTROL™ Tryptase Positive Control can be either transferred to a suitable polypropylene tube for testing and storage, or aliquoted into polypropylene tubes for testing and storing any remaining control plasma in the **original glass bottle** in the refrigerator.
- Ensure the aliquot has reached room temperature before use and then test in the same way as a patient sample using the instructions of the Tryptase test manufacturer.

Stability and Storage

The lyophilised PathTROL™ Tryptase Control is stable until the expiry date printed on the bottle label when stored at 2-8°C.

After reconstitution, the control plasma can be stored at 2-8°C in the original glass bottle or polypropylene tubes for up to 5 days.

The PathTROL™ Tryptase Positive Control can also be stored frozen after reconstitution at -20ºC for 1 month if required. The PathTROL™ Tryptase Positive Control should be aliquoted to 125µl and stored frozen in **glass bottles.** Frozen aliquots should be warmed to room temperature, mixed well, and transferred to polypropylene tubes for analysis.

Any remaining control from the testing aliquot that has been warmed to room temperature and is not required, should be discarded.

Warnings and Precautions

- The PathTROL™ Tryptase Positive Control is for in vitro diagnostic use only and must not be used to calibrate a test.
- Contains human material. The control sera have been tested and found negative for HIV ½ Ab and HCV Ab, and non-reactive for HBSAg, HBV-DNA, HCV-RNA, HIV-RNA and STS. **However, as a human source product it should be treated as a potentially infectious and handled appropriately.**
- Refer to ”Materials Safety Data Sheet” for more detailed safety information.
- PathTROL™ Tryptase Control should not be used past the printed expiration date. If signs of microbial contamination or excessive turbidity are observed, the plasma should be discarded.
- PathTROL™ Tryptase Controls should only be used when the bottles are intact. If the bottles are damaged in anyway, the control plasma should be discarded.

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
CE

Eurobio Scientific UK
Eclipse House, Curtis Road,
Dorking, RH4 1EJ, UK
Tel: 0044 1306 888777
www.eurobio-scientific.co.uk