

# PathTROL™ Tryptase High Positive Control

**REF**

**PW85201 PathTROL™ Tryptase High Positive Control 1x0.5 ml**

**PW85205 PathTROL™ Tryptase High Positive Control 5x0.5 ml**

## Key to Symbols

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

## Product Description

### Intended use

PathTROL™ Tryptase High Positive Control are lyophilised control plasma, containing Human  $\alpha$ -Tryptase, which are designed for the continuous long-term quality control of Tryptase tests in clinical and research laboratories.

### Composition

PathTROL™ Tryptase Positive Control is lyophilised Human plasma controls containing native Human  $\alpha$ -Tryptase and  $\beta$ -Tryptase comparable with patient plasma. The plasmas do not contain any preservatives or stabilisers.

## PathQAS™ Tryptase iQC Scheme

The PathTROL High Positive Control Concentration range (~80-100 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 High 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 High 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 High Positive 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 High Positive Control can also be stored frozen after reconstitution at -20°C for 1 month if required. The plasma should be stored frozen in **glass bottles** in 125µl aliquots. 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 High Positive control is for in vitro diagnostic use only and must not be used to calibrate a test.
- Contains human material. The control plasmas 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™ Tryptase High Positive Controls should not be used past their printed expiration date. If signs of microbial contamination or excessive turbidity are observed, the plasma should be discarded.
- PathTROL™ Tryptase High Positive Controls should only be used when the bottles are intact. If the bottles are damaged in anyway, the control plasma should be discarded.

