

PathTROL™ Allergy Control – Level 1










REF

PW80101

PathTROL™ Allergy Control – Level 1

5x1 ml

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™ Allergy Controls are liquid control sera, containing allergen-specific IgE at two levels that are designed for the continuous long-term quality control of allergy tests in clinical laboratories.

Composition

PathTROL™ Allergy Controls are liquid and consist of human serum containing human IgE with the following specificities:

- g06 Timothy Grass (*P. pratense*)
- g12 Cultivated Rye (*S. cereale*)
- w06 Mugwort (*A. vulgaris*)
- d01 House Dust Mite (*D. pteronyssinus*)
- d02 House Dust Mite (*D. farinae*)
- e01 Cat Epithelia
- f17 Hazelnut
- f13 Peanut
- f02 Milk
- Total IgE

The analytes are present in native form in a physiological serum matrix comparable to patient serum. To guarantee long-term stability, the sera contain a preservative (0.02% Sodium azide).

PathQAS™ Allergy iQC Scheme

The control sera are available in two clinically relevant concentration ranges; Level 1 (Low) and Level 2 (High). A Certificate of Analysis of target values for each type of IgE antibody is supplied with each control.

In addition, an optional enrolment in the PathQAS™ Allergy 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™ Allergy Controls are ready to use.
- Just before use, mix the sera by gently inverting the bottle several times.
- Take an aliquot from the bottle and place the original bottle back into the refrigerator.
- Allow the aliquot to stand at room temperature for 15 minutes before use and then test in the same way as a patient sample using the instructions of the reagent manufacturer.

Stability and Storage

PathTROL™ Allergy Controls are stable until the expiry date printed on the bottle label if they are kept sealed in the original bottle at 2-8°C. Once opened, the control sera in the original vial must be kept in the refrigerator 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 sera from the aliquot that has been warmed to room temperature and that is not required, should be discarded.

Warnings and Precautions

- The PathTROL™ Allergy Controls are 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 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™ Allergy Controls should not be used past the printed expiry date. If signs of microbial contamination or excessive turbidity are observed, the sera should be discarded.
- PathTROL™ Allergy Controls should only be used when the bottles are intact. If the bottles are damaged in any way the control serum should be discarded.



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