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## 1. Description

<b>Components</b>	1 mL MACS® GMP HCMV pp65 – Recombinant Protein.
<b>Product format</b>	The recombinant pp65 is supplied in a solution containing 50 mM sodium dihydrogen phosphat, 300 mM sodium chloride, and 4 M urea.
<b>Identity</b>	Confirmed by chip electrophoresis.
<b>Source</b>	<i>E. coli</i> .
<b>Statement of origin</b>	No animal-, human-, or virus-derived materials were used for manufacture of this product.
<b>Purity</b>	≥80% as determined by chip electrophoresis.
<b>Endotoxin content</b>	<50 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
<b>Residual host cell DNA content</b>	<3 ng DNA/vial as determined by quantitative PCR specific for <i>E. coli</i> genomic DNA.
<b>Sterility</b>	Sterility of the bottled product is tested according to Ph. Eur.
<b>Transport</b>	At 2–8 °C.
<b>Storage</b>	Store MACS GMP HCMV pp65 – Recombinant Protein at 2–8 °C directly upon arrival. Do not freeze. The use-by date is indicated on the vial label.

## Quality statement

MACS GMP HCMV pp65 – Recombinant Protein is for research use and *ex vivo* cell culture processing only, and is not intended for human *in vivo* applications.

MACS GMP HCMV pp65 – Recombinant Protein is manufactured and tested under a certified ISO 9001 quality system and in compliance with relevant GMP guidelines. It is designed following the recommendations of USP <1043> on ancillary materials.

## 2. Applications

- MACS GMP HCMV pp65 – Recombinant Protein can be used for a variety of applications, for example, *in vitro* stimulation of pp65-specific CD4<sup>+</sup> and CD8<sup>+</sup> T cells for the enrichment of IFN-gamma-secreting T cells using the CliniMACS® Cytokine Capture System (IFN-gamma) (REF 279-01).

## 3. Warnings and precautions

- ▲ The instructions for use must be followed.
- ▲ For research use and *ex vivo* cell culture processing only.
- ▲ Not intended for human *in vivo* applications.
- ▲ Do not inject or infuse the product directly into a patient. Not for parenteral application.
- ▲ When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- ▲ For single use only. Do not reuse.
- ▲ Use undamaged and sealed vials only.
- ▲ Do not use after the use-by date indicated on the vial label.

## 4. Instructions for use

- ▲ One vial of MACS GMP HCMV pp65 – Recombinant Protein is sufficient to stimulate up to 10<sup>9</sup> cells.

### 4.1 Reagent and instrument requirements








- Sterile syringe and needle.
- CliniMACS® Cytokine Capture System (IFN-gamma) (REF 279-01).

### 4.2 Protocol

- ▲ Work under sterile conditions.
1. The restimulation is performed using RPMI 1640 Medium supplemented with 10% AB serum with an usual volume of the cell sample of 100 mL and a cell density of 0.5–1×10<sup>7</sup> cells/cm<sup>2</sup> and 1×10<sup>7</sup> cells/mL in a gas-permeable culture bag.

2. Use MACS GMP HCMV pp65 – Recombinant Protein in a dilution of 1:100, for example, use 1 mL of the antigen solution for a 100 mL cell sample.
3. Use an appropriate sterile syringe and sterile needle to inject the appropriate amount of the antigen solution to the culture bag.
4. Incubate the cell culture bag at 37 °C and 5–7% CO<sub>2</sub> between 4 and 6 hours.
5. The pp65-stimulated T cells can be enriched using the CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01).

## 5. Appendix: Glossary of symbols

	Order number
	Part number
	Batch code
	Manufacturer
	Use by
	Caution, consult accompanying documents
	Do not use if package is damaged

All protocols and data sheets are available at [www.miltenyibiotec.com](http://www.miltenyibiotec.com).

### Patents and legal statements

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