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Revision

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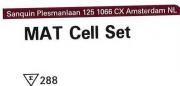
**Document Owner** 

**UVR** 

Title Certificate of Analysis MAT Cell Set

Product	MAT Cell Set	
Product number	M2016	

Label



¥ ≤ 80°C 2026-05-25

LOT 8000462058 **REF** M2016 LOT ORG 68-7193

## **Test results**

Description		
Qualification of donors and cells	Qualified according to European Pharmacopoeia chapter 2.6.30, section 5	yes
Donor infectious disease testing	All donors are screened and found negative for.  Hepatitis B: HBsAg, HBV-NAT and anti-HBc Hepatitis C: Anti-HCV and HCV-NAT HIV' Anti-HIV/1/2/(O) and HIV-NAT Treponema pallidum' anti-TP	yes
Characteristics of cell pool	Consists of a pool of cryopreserved Peripheral Blood Mononuclear Cells (PBMC) isolated from four single donors	yes
	Cell concentration per vial after thawing from liquid nitrogen:  • 4 – 6 x 10 <sup>6</sup> cells/mL <sup>1</sup>	yes
Monocyte Activation Test	Detection of endotoxin:  Mean OD <sub>450nm - 550nm</sub> of the blank: < 0.1  Test sensitivity (0.02 EE/mL) <sup>3</sup> > cut-off value  Assurance of criteria for the endotoxin standard curve:  Coefficient of determination: R <sup>2</sup> > 0.975  Regression statistically significant: p < 0.01  Lack of fit test: p > 0.05	yes
(MAT) <sup>2</sup>	Detection of non-endotoxin pyrogens (NEPs):  Tested and found responsive towards NEPs: Peptidoglycan from Staphylococcus aureus Synthetic triacylated lipoprotein (Pam3CSK4) Flagellin from Salmonella typhimurium (FLA-ST) Heat-Killed Staphylococcus aureus (HKSA)	yes
	Consideration of the averaging effect of pooling cells:  • EC <sub>50</sub> of endotoxin standard curve of each single donor:  • 50-200% of EC <sub>50</sub> of standard curve of the pool	yes

Determined by using an automated cell counter <sup>2</sup> Results obtained using PeliKine compact human IL-6 kit (REF M1916) and PeliKine tool set 1 (REF M1980) or PeliKine Human IL-6 ELISA Rapid Set (REFs M2018 and M2019)".

<sup>3</sup> Given as concentrations per sample (i.e. prior to addition of pMAT Cells to the samples)

Approved QA/QC	Date	21 November 2025	Signature	
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