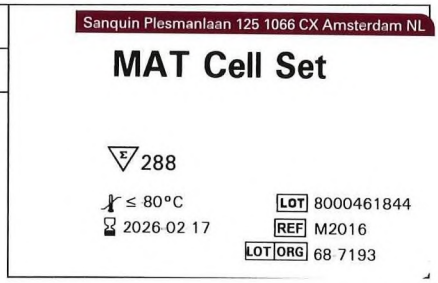
Title **Certificate of Analysis MAT Cell Set**

Product	**MAT Cell Set**
Product number	**M2016**

Label



Test results

Description	Specification	Meets specification
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 10^6 cells/mL[1]	yes
Monocyte Activation Test (MAT)[2]	Detection of endotoxin • Mean $OD_{450nm-550nm}$ of the blank < 0 1 • Test sensitivity (0 02 EE/mL)[3] > cut-off value • Assurance of criteria for the endotoxin standard curve o Coefficient of determination R^2 > 0 975 o Regression statistically significant p < 0 01 o Lack of fit test p > 0 05	yes
	Detection of non-endotoxin pyrogens (NEPs) • Tested and found responsive towards NEPs • Peptidoglycan from *Staphylococcus aureus* • Synthetic triacylated lipoprotein (Pam3CSK4) • Flagellin from *Salmonella typhimunum* (FLA-ST) • Heat-Killed *Staphylococcus aureus* (HKSA)	yes
	Consideration of the averaging effect of pooling cells • EC_{50} of endotoxin standard curve of each single donor o 50-200% of EC_{50} of standard curve of the pool	yes

[1] Determined by using an automated cell counter [2] 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)"
[3] Given as concentrations per sample (i e prior to addition of pMAT Cells to the samples)

Approved QA/QC	Date	20 August 2025	Signature	