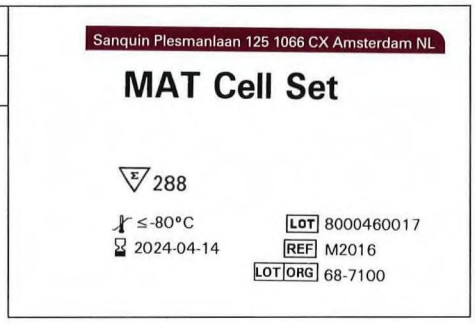
Title **Certificate of Analysis MAT Cell Set**

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
	• Limit of Detection (based on mean blank + 3x SD):
	  ○ ≤ 0.02 EU/mL[3]
	• Assurance of criteria for the endotoxin standard curve:
	  ○ Regression statistically significant: $p < 0.01$
	  ○ Regression must not deviate significantly from linearity: $p > 0.05$
		yes

	Detection of non-endotoxin pyrogens (NEPs):
	• Tested and found responsive towards NEPs:
	  • Peptidoglycan from *Staphylococcus aureus*
	  • Synthetic triacylated lipoprotein (Pam3CSK4)
	  • Flagellin from *Salmonella typhimurium* (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: ○ 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).
[3] Given as concentrations per sample (i.e. prior to addition of pMAT Cells to the samples).

Approved QA/QC	Date	12 October 2023	Signature	