



Doc. No. REA-S-0312

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Revision 03

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Document Owner UVR

Title Certificate of Analysis MAT Cell Set

Product	MAT Cell Set	Label	Sanquin Plesmanlaan 125 1066 CX Amsterdam NL MAT Cell set Safety data sheet available on request RUO LOT ORG 68-7235 288 LOT 8100100033 ≤ -80°C REF M2016 2027-01-21
Product number	M2016		

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 10⁶ cells/mL¹	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: - Coefficient of determination: R² > 0.975 - Regression statistically significant: p < 0.01 - Lack of fit test: p > 0.05	yes
	Detection of non-endotoxin pyrogens (NEPs): - Tested and found responsive towards NEPs: - Peptidoglycan from <i>Staphylococcus aureus</i> - Synthetic triacylated lipoprotein (Pam3CSK4) - Flagellin from <i>Salmonella typhimurium</i> (FLA-ST) - Heat-Killed <i>Staphylococcus aureus</i> (HKSA)	yes
	Consideration of the averaging effect of pooling cells: - EC₅₀ of endotoxin standard curve of each single donor: 50-200% of EC₅₀ 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	21 July 2026	Signature	
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