



Title Certificate of Analysis MAT Cell Set


Product	MAT Cell Set	<div>Sanquin Plesmanlaan 125 1066 CX Amsterdam NL</div> <div>MAT Cell Set</div> <div>  <div>  $\leq -80^{\circ}\text{C}$ <div> <div>LOT</div> <div>8000461732</div> </div> <div> <div>REF</div> <div>M2016</div> </div> <div> <div>LOT/ORG</div> <div>68-7221</div> </div> </div> </div>
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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> $4 - 6 \times 10^6$ cells/mL¹ 	yes
Monocyte Activation Test (MAT) ²	Detection of endotoxin: <ul style="list-style-type: none"> Mean OD_{450nm - 550nm} of the blank: < 0.1 Test sensitivity $(0.02 \text{ EE/mL})^3 > \text{cut-off value}$ Assurance of criteria for the endotoxin standard curve: <ul style="list-style-type: none"> Coefficient of determination: $R^2 > 0.975$ Regression statistically significant: $p < 0.01$ Lack of fit test: $p > 0.05$ 	yes
	Detection of non-endotoxin pyrogens (NEPs): <ul style="list-style-type: none"> Tested and found responsive towards NEPs: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> EC₅₀ of endotoxin standard curve of each single donor: <ul style="list-style-type: none"> 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	27 June 2025	Signature	
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CONFIDENTIAL

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