

Title **Certificate of Analysis MAT Cell Set**


Product	MAT Cell Set	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; font-size: small;">Sanquin Pleismanlaan 125 1066 CX Amsterdam NL</p> <h2 style="text-align: center;">MAT Cell Set</h2> <p style="text-align: center;">▽ 288</p> <p> 🌡️ ≤ 80°C LOT 8000461066 📅 2025 04 14 REF M2016 LOT/ORG 68 7193 </p> </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 x 10⁶ 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 EE/mL)³ > cut-off value • Assurance of criteria for the endotoxin standard curve. <ul style="list-style-type: none"> ○ 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) <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

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

Approved QA/QC	Date	08 October 2024	Signature	
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