



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
Product number	M2016

Label

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MAT Cell Set

▽ 288

≤ -80°C

2026-06-17

LOT 8000462068

REF M2016

LOT/ORG 68 7193

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-HBcHepatitis C: Anti-HCV and HCV-NATHIV: Anti-HIV/1/2(O) and HIV-NATTreponema 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
	Detection of endotoxin: <ul style="list-style-type: none">Mean OD_{450nm – 550nm} of the blank: < 0.1Test sensitivity (0.02 EE/mL)³ > cut-off valueAssurance of criteria for the endotoxin standard curve:<ul style="list-style-type: none">Coefficient of determination: R² > 0.975Regression statistically significant: p < 0.01Lack of fit test: p > 0.05	yes
Monocyte Activation Test (MAT) ²	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	11 December 2025	Signature	
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