

Title **Certificate of Analysis MAT Cell Set**

Product	MAT Cell Set
Product number	M2016

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MAT Cell Set

▽ 288

≤ 80°C

2025-01-01

LOT 8000460748

REF M2016

LOT|ORG 68 7107

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 <ul style="list-style-type: none"> < 0 1 Limit of Detection (based on mean blank+3x SD) <ul style="list-style-type: none"> ≤ 0 02 EU/mL³ Assurance of criteria for the endotoxin standard curve <ul style="list-style-type: none"> Regression statistically significant p < 0.01 Regression must not deviate significantly from linearity 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)

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

Approved QA/QC	Date	05 July 2024	Signature	
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