

Title **Certificate of Analysis MAT Cell Set**

Product	MAT Cell Set	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; margin: 0;">Sanquin Plesmanlaan 125 1066 CX Amsterdam NL</p> <p style="text-align: center; margin: 0;">MAT Cell Set</p> <p style="margin: 0;">▽ 288</p> <p style="margin: 0;"> ≤ -80°C LOT 8000460750 REF M2016 LOT/ORG 68 7179 </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: <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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