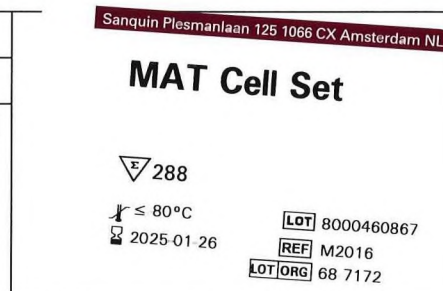


Title **Certificate of Analysis MAT Cell Set**

Product	MAT Cell Set
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"> <li>Hepatitis B HBsAg, HBV-NAT and anti-HBc</li> <li>Hepatitis C: Anti-HCV and HCV-NAT</li> <li>HIV: Anti-HIV/1/2/(O) and HIV-NAT</li> <li>Treponema pallidum: anti-TP</li> </ul>	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"> <li>4 – 6 x 10<sup>6</sup> cells/mL<sup>1</sup></li> </ul>	yes
Monocyte Activation Test (MAT) <sup>2</sup>	Detection of endotoxin: <ul style="list-style-type: none"> <li>Mean OD<sub>450nm</sub> – 550nm of the blank: &lt; 0.1</li> <li>Test sensitivity (0.02 EE/mL)<sup>3</sup> &gt; cut-off value</li> <li>Assurance of criteria for the endotoxin standard curve: <ul style="list-style-type: none"> <li>Coefficient of determination R<sup>2</sup> &gt; 0.975</li> <li>Regression statistically significant: p &lt; 0.01</li> <li>Lack of fit test p &gt; 0.05</li> </ul> </li> </ul>	yes
	Detection of non-endotoxin pyrogens (NEPs): <ul style="list-style-type: none"> <li>Tested and found responsive towards NEPs: <ul style="list-style-type: none"> <li>Peptidoglycan from <i>Staphylococcus aureus</i></li> <li>Synthetic triacylated lipoprotein (Pam3CSK4)</li> <li>Flagellin from <i>Salmonella typhimurium</i> (FLA-ST)</li> <li>Heat-Killed <i>Staphylococcus aureus</i> (HKSA)</li> </ul> </li> </ul>	yes
	Consideration of the averaging effect of pooling cells <ul style="list-style-type: none"> <li>EC<sub>50</sub> of endotoxin standard curve of each single donor <ul style="list-style-type: none"> <li>50-200% of EC<sub>50</sub> of standard curve of the pool</li> </ul> </li> </ul>	yes

<sup>1</sup> Determined by using an automated cell counter <sup>2</sup> 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)<sup>3</sup>.

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

Approved QA/QC	Date	26 July 2024	Signature	
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