

Title **Certificate of Analysis MAT Cell Set**

<b>Product</b>	<b>MAT Cell Set</b>	<p style="text-align: right; font-size: small;">Sanquin Plesmanlaan 125 1066 CX Amsterdam NL</p> <h2 style="text-align: center;">MAT Cell Set</h2> <p style="text-align: center;">▽ 288</p> <p> <span style="font-size: x-small;">T ≤ 80°C</span>                <span style="font-size: x-small;">LOT 8000460980</span>  <span style="font-size: x-small;">2025-03-04</span>                <span style="font-size: x-small;">REF M2016</span>  <span style="font-size: x-small;">LOT/ORG 68 7186</span> </p>
<b>Product number</b>	<b>M2016</b>	

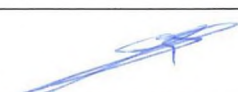
Label

**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 – 550nm</sub> 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	09 September 2024	Signature	
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