




Title **Certificate of Analysis MAT Cell Set**

<b>Product</b>	<b>MAT Cell Set</b>	<div style="border: 1px solid black; padding: 5px;"> <div style="background-color: #d3d3d3; text-align: center; font-weight: bold; font-size: small;">Sanquin Plesmanlaan 125 1066 CX Amsterdam NL</div> <div style="text-align: center; font-weight: bold; font-size: large;">MAT Cell Set</div> <div style="text-align: center; margin-top: 10px;">  </div> <div style="display: flex; justify-content: space-between; font-size: x-small;"> <div>  ≤ -80°C   2024-12-10         </div> <div style="text-align: right;"> <div style="border: 1px solid black; padding: 2px; display: inline-block; font-size: x-small;">LOT</div> 8000460719  <div style="border: 1px solid black; padding: 2px; display: inline-block; font-size: x-small;">REF</div> M2016  <div style="border: 1px solid black; padding: 2px; display: inline-block; font-size: x-small;">LOT ORG</div> 68-7107         </div> </div> </div>
<b>Product number</b>	<b>M2016</b>	
<b>Label</b>		


**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:               <ul style="list-style-type: none"> <li>○ &lt; 0.1</li> </ul> </li> <li>• Limit of Detection (based on mean blank+3x SD):               <ul style="list-style-type: none"> <li>○ ≤ 0.02 EU/mL<sup>3</sup></li> </ul> </li> <li>• Assurance of criteria for the endotoxin standard curve:               <ul style="list-style-type: none"> <li>○ Regression statistically significant: p &lt; 0.01</li> <li>○ Regression must not deviate significantly from linearity: 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).

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

Approved QA/QC	Date	17 June 2024	Signature	
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