

Title **Certificate of Analysis MAT Cell Set**

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| Product | MAT Cell Set | <div style="border: 1px solid black; padding: 5px;"> <p style="font-size: small; color: red; margin: 0;">Sanquin Plesmanlaan 125 1066 CX Amsterdam NL</p> <p style="text-align: center; font-size: large; font-weight: bold; margin: 5px 0;">MAT Cell Set</p> <p style="margin: 5px 0;">  288  ≤ -80°C  2026-09-02 </p> <p style="font-size: x-small; margin: 5px 0;"> LOT 8000462252 REF M2016 LOT ORG 68-7186 </p> </div> |
| Product number | M2016 | |
| Label | | |

Test results

| Description | Specification | Meets specification |
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| 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: < 0.1 Test sensitivity (0.02 EE/mL)³ > cut-off value Assurance of criteria for the endotoxin standard curve: <ul style="list-style-type: none"> Coefficient of determination. R² > 0.975 Regression statistically significant: p < 0.01 Lack of fit test: 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) or PeliKine Human IL-6 ELISA Rapid Set (REFs M2018 and M2019)"

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

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| Approved QA/QC | Date | 05 March 2026 | Signature |  |
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