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Revisie 03
Pagina 1 van 1
Document Eigenaar PROD-QC

Titel MASPAT kit release

K1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASSPAT kit
Monoclonal Antibody Solid Phase
Platelet Antibody Test

www.sanquin.org/reagents

IVD Σ 96
LOT 8000461677
REF K1360

CE UDI

2-8 °C
2026-08-07

(01)1872068203
0025(10)800046
1677(17)260807



Component	Requirement	Result
Positive control Lot: 8000461401	Positive reaction with: platelets Titration with: platelets $\geq 1:4$	Conform requirements Conform requirements
Negative control Lot: 8000461147	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: 8000461340	Titration with: platelets $\geq 1:4$	Conform requirements
Microplates Lot: 8000461617	Specificity: Platelets x positive control positive Platelets x negative control negative Coating tested platelets for reactivity and homogeneity	Conform requirements Conform requirements Conform requirements
LISS Lot: 8000461145	Conductivity 3.4 – 4.8 mScm ⁻¹ pH 6.3 – 6.9	Conform requirements Conform requirements
Growth test	no growth	Conform

All the sera used in the production of this reagent have been tested for the markers of specific disease transmitting agents in accordance with the current EU guidelines to GMP and found to be non reactive

Date

: 17 June 2025

Approved by QA/QC

: 

VERTROUWELIJK

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