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Versie 2.0

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Titel **MASPAT kit release**

K 1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit
Monoclonal Antibody Solid Phase
Platelet Antibody Test



IVD ∇ 96
LOT 8000461039
REF K1360

www.sanquin.org/reagents
CE UDI
2-8 °C
2026-01-10
(01)1872068203
0025(10)800046
1039(17)260110

Component	Requirement	Result
Positive control Lot: 8000460874	Positive reaction with: platelets Titration with: platelets \geq 1:4	Conform requirements Conform requirements
Negative control Lot: 8000460726	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: 8000460992	Titration with: platelets \geq 1:4	Conform requirements
Microplates Lot: 8000460880	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: 8000460602	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 : 08 October 2024 Approved by QA/QC : 

VERTROUWELIJK