

Title MASPAT kit release

K1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit
Monoclonal Antibody Solid Phase
Platelet Antibody Test

IVD Σ 96
LOT 8100000006
REF K1360

www.sanquin.org/reagents

CE UDI

2-8 °C
2027-11-11

(01)1872068203
0025(10)810000
0006(17)271111



Component	Requirement	Result
Positive control Lot: <u>8000462417</u>	Positive reaction with: platelets Titration with: platelets $\geq 1:4$	Conform requirements Conform requirements
Negative control Lot: <u>8000461979</u>	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: <u>8000462276</u>	Titration with: platelets $\geq 1:4$	Conform requirements
Microplates Lot: <u>8000462192</u>	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: <u>8000462238</u>	Conductivity $3.4 - 4.8 \text{ mScm}^{-1}$ 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 : 15 July 2026 Approved by QA/QC : 

CONFIDENTIAL