


Titel **MASPAT kit release**

K 1360



Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit  
 Monoclonal Antibody Solid Phase  
 Platelet Antibody Test

CL

IVD  96  
 REF K1360  
 LOT 8000460065



 2-8 °C  
 2025-04-11  
 (01)1872068203  
 0025(10)800046  
 0065(17)250411

Component	Requirement	Result
Positive control Lot: 8000459781	Positive reaction with: platelets Titration with: platelets $\geq$ 1:4	Conform requirements Conform requirements
Negative control Lot: 8000459782	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: 8000459461	Titration with: platelets $\geq$ 1:4	Conform requirements
Microplates Lot: 8000459974	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: 8000459462	Conductivity 3.4 – 4.8 mScm <sup>-1</sup> 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 : 10 November 2023 Approved by QA/QC : 