


Titel **MASPAT kit release**

K 1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit
 Monoclonal Antibody Solid Phase
 Platelet Antibody Test

 IVD  96
 REF K1360
 LOT 8000459211


2-8 °C

2024-08-21

 (01)1872068203
 0025(10)800045
 9211(17)240821

Component	Requirement	Result
Positive control Lot: 8000458519	Positive reaction with: platelets Titration with: platelets \geq 1:4	Conform requirements Conform requirements
Negative control Lot: 8000458520	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: 8000458517	Titration with: platelets \geq 1:4	Conform requirements
Microplates Lot: 8000458790	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: 8000458518	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 : 24 April 2023 Approved by QA/QC : 

VERTROUWELIJK

Use copy according to REA-SOP-0002.

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