



Doc. Nr. REA-S-0114

Datum 04 Jul 2025

Revisie 03

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Document Eigenaar PROD-QC

Titel MASPAT kit release

K1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit

Monoclonal Antibody Solid Phase

Platelet Antibody Test

IVD 96

LOT 8000461767

REF K1360



2-8 °C

2027-01-27

(01)1872068203
0025(10)800046
1767(17)270127

Component	Requirement	Result
Positive control Lot: <u>8000461401</u>	Positive reaction with: platelets Titration with: platelets $\geq 1:4$	Conform requirements Conform requirements
Negative control Lot: <u>8000461402</u>	Negative reaction with: platelets	Conform requirements
Anti-IgG Lot: <u>8000461340</u>	Titration with: platelets $\geq 1:4$	Conform requirements
Microplates Lot: <u>8000461706</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>8000461730</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 : 24 July 2025 Approved by QA/QC :

VERTROUWELIJK

Use copy according to REA-SOP-0002.

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