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Versie 2.0

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Document eigenaar BBR

Titel MASPAT kit release

K 1360

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

MASPAT kit

Monoclonal Antibody Solid Phase
Platelet Antibody Test

IVD Σ 96

LOT 8000460850

REF K1360



www.sanquin.org
/reagents



UDI



2-8 °C

2026-01-10

(01)1872068203
0025(10)800046
0850(17)260110

Component	Requirement	Result
Positive control Lot: 8000460718	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: 8000460673	Titration with: platelets \geq 1:4	Conform requirements
Microplates Lot: 8000460712	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 : 30 July 2024 Approved by QA/QC :

VERTROUWELIJK

Use copy according to REA-SOP-0002.

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