

Titel **MASPAT kit release**

K1360

**Sanquin Plesmanlaan 125 1066 CX Amsterdam NL**

**MASPAT kit**  
Monoclonal Antibody Solid Phase  
Platelet Antibody Test

www.sanquin.org/reagents

IVD 96  
LOT 8000461750  
REF K1360

CE UDI

2-8 °C  
2026-08-07

(01)1872068203  
0025(10)800046  
1750(17)260807



| Component                                  | Requirement                                                                                                                                               | Result                                                               |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Positive control<br>Lot: <u>8000461401</u> | Positive reaction with:<br>platelets<br>Titration with:<br>platelets $\geq 1:4$                                                                           | Conform requirements<br>Conform requirements                         |
| Negative control<br>Lot: <u>8000461402</u> | Negative reaction with:<br>platelets                                                                                                                      | Conform requirements                                                 |
| Anti-IgG<br>Lot: <u>8000461340</u>         | Titration with:<br>platelets $\geq 1:4$                                                                                                                   | Conform requirements                                                 |
| Microplates<br>Lot: <u>8000461706</u>      | Specificity:<br>Platelets x positive control positive<br>Platelets x negative control negative<br>Coating tested platelets for reactivity and homogeneity | Conform requirements<br>Conform requirements<br>Conform requirements |
| LISS<br>Lot: <u>8000461145</u>             | Conductivity $3.4 - 4.8 \text{ mScm}^{-1}$<br>pH $6.3 - 6.9$                                                                                              | Conform requirements<br>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

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