2.		Doc. nr.	REA-S008-03-03-0586	Versie	2.0
	Sanquin	Datum	14 May 2021 10:23:38 (GMT+01:00)	Pagina	1 van 3
Reagents			Document eigenaar		BBR
Titel	MASPAT kit release				
			Sanquin Plesmanla MASPAT kit	an 125 1066 CX Amsterdam	
K 1360			Monoclonal Antibody Solid Platelet Antibody Test	Phase	
			IVD 1 5 96	. (€ 1	
			REF K1360 LOT 8000457289	2-8 °C (01)1872068 0025(10)800 2024-05-02 7289(17)240	0045

Component	Requirement	Result
Positive control Lot: 8000456733	Positive reaction with: platelets Titration with:	Conform requirements
	platelets \geq 1:4	Conform requirements
Negative control	Negative reaction with:	
Lot: 8000456734	platelets	Conform requirements
Anti-IgG	Titration with:	
Lot: 8000456731	platelets \geq 1:4	Conform requirements
Microplates	Specificity:	10
Lot: 2000 457038	Platelets x positive control positive	Conform requirements
	Platelets x negative control negative	Conform requirements
	Coating tested platelets for reactivity and	
	homogeneity	Conform requirements
LISS	Conductivity 3.4 – 4.8 mScm ⁻¹	Conform requirements
Lot: 8000456732	рН 6.3-6.9	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

:03 November 2022 Approved by QA/QC