T sa	Doc. nr. REA-S008-03-03-0586		Versie	2.0
Sang	uin Datum 14 May 2021 10:23:38	(GMT+01:00)	Pagina	1 van 3
Reagen	Document eigenaar		nent eigenaar	BBI
Titel MASPAT	kit release			
K 1200	Sanquin Plesmanlaan 125 1066 CX Amsterdam NL MASPAT kit ^{c.} Monoclonal Antibody Solid Phase			
K 1360				
	Platelet Antibody		210 R	
		Ce	163368	
			145.00 %	
	REF K1360	2-8 °C	(01)1872068203 0025(10)800045	
	LOT 800045814	0 2024-08	5-02 8140(17)240502	
Component	Requirement	Result		7
omponent	nequiement	Nesuit		
Positive control	Positive reaction with:	Conform requirements		
.ot: 8000456733	platelets			
	Titration with:			
	platelets \geq 1:4	Conform requirements		
legative control	Negative reaction with:			
ot: 8000 456 734	platelets	Conform requirements		
nti-IgG	Titration with:			
ot: 8000456731	platelets ≥ 1:4	Conform requirements		
licroplates	Specificity:			
ot: 8000457067	Platelets x positive control positive	Conform requirements		
	Platelets x negative control negative	Conform requirements		
	Coating tested platelets for reactivity and			
	homogeneity Conform requirements			
				_
SS	Conductivity $3.4 - 4.8 \text{ mScm}^{-1}$	Conform requirements		
ot: 8000 457170	pH 6.3-6.9	Conform requiren	nents	_
rowth 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

:01 December 2022 Approved by QA/QC