

Titel reagent red cells release

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
MASPAT Indicator Red Cells
 0.3 ± 0.1%
 10 mL
 IVD 2-8 °C
 LOT 8000460464
 REF K1139 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
A1 reagent red cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460462
 REF K1140 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
A2 reagent red cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460465
 REF K1141 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
B reagent red cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460466
 REF K1142 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
O positive reagent red cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460467
 REF K1143 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
O negative reagent red cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460468
 REF K1144 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
CCC coombs control cells
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460469
 REF K1145 2024-05-12 UDI

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL
CCC coombs control cells strong
 3 ± 1%
 10 mL
 IVD 2-8 °C
 LOT 8000460463
 REF K1138 2024-05-12 UDI

Analysis	Requirement							Result	
	MIRC	anti-A	anti-B	anti-A ₁	anti-D	DAT	IAT control		
Antigen control	MIRC	0.3%	0	0	n.t.*	n.t.*	≥ 2+	n.t.*	Conform requirements
	A ₁	3%	≥ 3+	0	≥ 3+	n.t.*	0	n.t.*	Conform requirements
	A ₂	3%	≥ 2+	0	0	n.t.*	0	n.t.*	Conform requirements
	B	3%	0	≥ 3+	n.t.*	n.t.*	0	n.t.*	Conform requirements
	O _{positive}	3%	0	0	n.t.*	≥ 2+	0	n.t.*	Conform requirements
	O _{negative}	3%	0	0	n.t.*	0	0	n.t.*	Conform requirements
	CCC	3%	0	0	n.t.*	n.t.*	≥ 2+	1+ ≥ ≤ 2+	Conform requirements
	CCCstrong	3%	0	0	n.t.*	n.t.*	≥ 3+	1+ ≥ ≤ 3+	Conform requirements
Hematocrit	MIRC	0.3 ± 0.1%							Conform requirements
	All other cells	3 ± 1%							Conform requirements

All the donor units used in the production of this reagent have been tested for the markers of specific disease transmitting agents in accordance with current EU guidelines to GMP and found to be non reactive.

*n.t.: not tested.

Approved by

Date: 28 march 2024

QA/QC: 

VERTROUWELIJK