

Title **Reagent red cells release**

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
MASPAT Indicator Red Cells
0.3 ± 0.1%
10 mL
IVD 2-8 °C
LOT 8000461258
REF K1139
2025-02-16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
A₁ reagent red cells
3 ± 1%
10 mL
IVD 2-8 °C
LOT 8000461257
REF K1140
2025 02 16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
A₂ reagent red cells
3 ± 1%
10 mL
IVD 2-8 °C
LOT 8000461259
REF K1141
2025 02-16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
B reagent red cells
3 ± 1%
10 mL
IVD 2-8 °C
LOT 8000461260
REF K1142
2025 02-16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
O positive reagent red cells
3 ± 1%
10 mL
IVD 2-8 °C
LOT 8000461261
REF K1143
2025 02 16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
O negative reagent red cells
3 ± 1%
10 mL
IVD 2-8 °C
LOT 8000461262
REF K1144
2025 02 16
UDI

Sanquin Plezmanlaan 125 1066 CX Amsterdam NL
CCC coombs control cells
3 ± 1%
10 ml
IVD 2-8 °C
LOT 8000461263
REF K1145
2025-02-16
UDI

Analysis	Requirement								Result
			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
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: 02 January 2025

QA/QC: 