

Title **Cellbind reagent red cells release**

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

**Cellbind** vl

**A<sub>1</sub> reagent red cells** 10 ml

0.5 ± 0.1 %

IVD  2-8°C REF K7240 CE

LOT 8000460472 2024-05-12 0344

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

**Cellbind** vl

**A<sub>2</sub> reagent red cells** 10 ml

0.5 ± 0.1 %

IVD  2-8°C REF K7241 CE

LOT 8000460473 2024-05-12

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

**Cellbind** vl

**B reagent red cells** 10 ml

0.5 ± 0.1 %

IVD  2-8°C REF K7242 CE

LOT 8000460474 2024-05-12 0344

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

**Cellbind** vl

**O positive reagent red cells** 10 ml

0.5 ± 0.1 %

IVD  2-8°C REF K7243 CE

LOT 8000460475 2024-05-12

Analysis	Requirement					Result
		anti-A	anti-B	anti-D	DAT	
Antigen control	A <sub>1</sub> *	≥ 3+	0	n.t.**	0	Conform requirements
	A <sub>2</sub> *	≥ 2+	0	n.t.**	0	Conform requirements
	B	0	≥ 3+	n.t.**	0	Conform requirements
	O <sup>positive</sup>	0	0	≥ 2+	0	Conform requirements
Hematocrit	0.5 ± 0.1%					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.

\* Blood group 'A subtype' has been established in another technique and the results are conform specification.

\*\* n.t.: not tested.

Approved by

Date: 20 March 2024

QA/QC: 