

Title **Cellbind reagent red cells release**



Analysis	Requirement					Result
		anti-A	anti-B	anti-D	DAT	
Antigen control	A ₁ *	≥ 3+	0	n.t.**	0	Conform requirements
	A ₂ *	≥ 2+	0	n.t.**	0	Conform requirements
	B	0	≥ 3+	n.t.**	0	Conform requirements
	O ^{positive}	0	0	≥ 2+	0	Conform requirements
	Hematocrit	0.5 ± 0.1%				

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: 02 January 2025

QA/QC: 