



Analysis	Requirement					Result
Antigen control		anti-A	anti-B	anti-D	DAT	
	A_1*	≥ 3+	0	n.t.**	0	Conform requirements
	B	0	≥ 3+	n.t.**	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: 29 October 2026 QA: _____