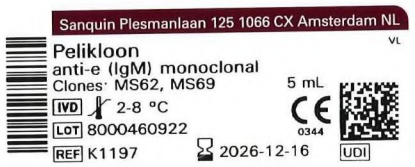
Titel **Pelikloon anti-e (IgM) monoclonal release**

K 1197

Clone numbers MS62/MS69



Analysis	Requirement		Result	
Specificity	Negative with cells negative for the e antigen		Conform requirements	
Avidity		Ee		
	Tube method	≥ 3+	Conform requirements	
	Microplate method	≥ 3+	Conform requirements	
	Cellbind Screen method	≥ 3+	Conform requirements	
	Cellbind Direct Type method	≥ 3+	Conform requirements	
Titer		Ee		
	Tube method	≥ 1:16	Conform requirements	
	Microplate method	≥ 1:16	Conform requirements	
Growthtest	no growth		Conform	
External release	released by Notified Body		Released	Y / N

Date: 24 January 2025 Approved by QA/QC: _____