

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 <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">Y/N</span>

Date: 16 November 2022

Approved by QA/QC: \_\_\_\_\_

VERTROUWELIJK

Use copy according to REA-SOP-0002.

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