



Doc. nr. REA-S004-01-31-0543

Versie 2.0

Datum 06 May 2021 08:48:38 (GMT+01:00)

Pagina 1 van 3

Document eigenaar BBR

Titel **Pelikloon anti-B monoclonal release**

K1189

Clone number: LB2

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL  
VL1396  
Pelikloon  
**anti-B (IgM) monoclonal**  
Clone: LB2  
10mL  
IVD 2-8°C REF K1189 CE 0344  
LOT 8000458115 2026-10-09

Analysis	Requirement	Result
Specificity	Negative with cells negative for the B antigen	Conform requirements
Avidity	Tube method	B $\geq 3+$ A <sub>1</sub> B $\geq 3+$ Conform requirements
	Microplate method	$\geq 3+$ $\geq 3+$ Conform requirements
	Cellbind Screen method	$\geq 3+$ $\geq 3+$ Conform requirements
	Cellbind Direct Type method	$\geq 3+$ $\geq 3+$ Conform requirements
Titer	Tube method	B $\geq 1:128$ A <sub>1</sub> B $\geq 1:32$ Conform requirements
	Microplate method	$\geq 1:128$ $\geq 1:32$ 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 : 19 January 2024 Approved by QA/QC

VERTROUWELIJK

Use copy according to REA-SOP-0002.  
Printed on: 08 Jan 2024 at: 03:51:43 pm ; Printed by W.HOLIERHOEK