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Versie 2.0

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Document eigenaar BBR

Titel **Pelikloon anti-B monoclonal release**

K1189

Clone number: LB2

Sanquin Pleasmanlaan 125 1066 CX Amsterdam NL



Pelikloon anti-B (IgM) monoclonal
Clone: LB2

VL139/b

10 ml



IVD 2-8°C REF K1189 0344
LOT 8000459926 2025-07-31

| Analysis | Requirement | Result |
|------------------|--|--|
| Specificity | Negative with cells negative for the B antigen | Conform requirements |
| Avidity | Tube method | B $\geq 3+$ A ₁ 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 ₁ 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 |

Date : 29 September 2023 Approved by QA/QC :

VERTROUWELIJK

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