



Doc. nr. REA-S004-01-30-0542

Versie 2.0

Datum 06 May 2021 08:48:35 (GMT+01:00)

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Document eigenaar BBR

Titel Pelikloon anti-A,B (IgM) monoclonal release

K 1190

Clone numbers: ES4/ES15

Sanquin Plasmanlaan 125 1066 CX Amsterdam NL

Pelikloon VL140/c
anti-A,B (IgM) monoclonal
 Clones: ES4, ES15 **10mL**

IVD 2-8°C REF K1190 0344

LOT 8000460032 2027-03-04

Analysis	Requirement	Result																				
Specificity	Negative with O cells	Conform requirements																				
Avidity	<table border="1"> <thead> <tr> <th></th> <th>A₁</th> <th>A₂</th> <th>B</th> </tr> </thead> <tbody> <tr> <td>Tube method</td> <td>≥ 3+</td> <td>≥ 3+</td> <td>≥ 3+</td> </tr> <tr> <td>Microplate method</td> <td>≥ 3+</td> <td>≥ 3+</td> <td>≥ 3+</td> </tr> <tr> <td>Cellbind Screen method</td> <td>≥ 3+</td> <td>≥ 3+</td> <td>≥ 3+</td> </tr> <tr> <td>Cellbind Direct Type method</td> <td>≥ 3+</td> <td>≥ 3+</td> <td>≥ 3+</td> </tr> </tbody> </table>		A ₁	A ₂	B	Tube method	≥ 3+	≥ 3+	≥ 3+	Microplate method	≥ 3+	≥ 3+	≥ 3+	Cellbind Screen method	≥ 3+	≥ 3+	≥ 3+	Cellbind Direct Type method	≥ 3+	≥ 3+	≥ 3+	Conform requirements
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Growthtest	no growth	Conform																				
External release	released by Notified Body	Released <input checked="" type="checkbox"/> Y / <input type="checkbox"/> N																				

Date : 30 May 2024 Approved by QA/QC :

VERTROUWELIJK