

Titel **Pelikloon anti-D enhanced (IgM) monoclonal release**

K 1151

Clone numbers LDM1, ESD1M



Analysis	Requirement	Result																									
Specificity	Negative with Rh(D)negative, r'r and r''r cells	Conform requirements																									
Avidity	<table border="0"> <tr> <td></td> <td>Dd</td> <td>D_{weak}</td> <td>Dkl.VI</td> <td></td> </tr> <tr> <td>Tube method</td> <td>≥ 2+</td> <td>≥ W+</td> <td>≥ 1+</td> <td>Conform requirements</td> </tr> <tr> <td>Microplate method</td> <td>≥ 2+</td> <td>≥ W+</td> <td>≥ 1+</td> <td>Conform requirements</td> </tr> <tr> <td>Cellbind Screen method</td> <td>≥ 2+</td> <td>≥ 1+</td> <td>≥ 2+</td> <td>Conform requirements</td> </tr> <tr> <td>Cellbind Direct Type method</td> <td>≥ 2+</td> <td>≥ 1+</td> <td>≥ 2+</td> <td>Conform requirements</td> </tr> </table>		Dd	D _{weak}	Dkl.VI		Tube method	≥ 2+	≥ W+	≥ 1+	Conform requirements	Microplate method	≥ 2+	≥ W+	≥ 1+	Conform requirements	Cellbind Screen method	≥ 2+	≥ 1+	≥ 2+	Conform requirements	Cellbind Direct Type method	≥ 2+	≥ 1+	≥ 2+	Conform requirements	
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Tube method	≥ 1:32	Conform requirements																									
Microplate method	≥ 1:32	Conform requirements																									
Growth test	no growth	Conform																									
External release	released by Notified Body	Released <u>Y/N</u>																									

Date:

29 July 2022

Approved by QA/QC:



VERTROUWELIJK

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