

**Titel Pelikloon anti-D mix (IgG-IgM) monoclonal release**

K 1157

Clone numbers TH28/MS26



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<sub>weak</sub></td> </tr> <tr> <td>Tube method</td> <td>≥ 2+</td> <td>≥ W+</td> </tr> <tr> <td>Microplate method</td> <td>≥ 2+</td> <td>≥ W+</td> </tr> <tr> <td>Cellbind Screen method</td> <td>≥ 2+</td> <td>≥ 1+</td> </tr> </table>		Dd	D <sub>weak</sub>	Tube method	≥ 2+	≥ W+	Microplate method	≥ 2+	≥ W+	Cellbind Screen method	≥ 2+	≥ 1+	Conform requirements
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Tube method	≥ 1:32	≥ 1:4 (IAT)												
Microplate method	≥ 1:32	n.a.												
Growthtest	no growth	Conform												
External release	released by Notified Body	Released <span style="border: 1px solid blue; border-radius: 50%; padding: 2px;">Y/N</span>												

Date: 15 March 2022

Approved by

QA/QC: 

VERTROUWELIJK