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Revision 03

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Document Owner BBR

Title Pelikloon anti-D mix (IgG-IgM) monoclonal release

K1157

Clone numbers TH28/MS26



Analysis	Requirement			Result
Specificity	Negative with Rh(D)negative, r'r and r'r cells cells			Conform requirements
Avidity		Dd	Dweak	
	Tube method	≥ 2+	≥ W+	Conform requirements
	Microplate method	≥ 2+	≥ W+	Conform requirements
	Cellbind Screen method	≥ 2+	≥ 1+	Conform requirements
Titer		Dd	Dkl.VI	
	Tube method	≥ 1:32	≥ 1:4 (IAT)	Conform requirements
	Microplate method	≥ 1:32	n.a.	Conform requirements
Growthtest	no growth			Conform
External release	released by Notified Body			Released ☒ Y/N

Date: 01 May 2024

Approved by

QA/QC:

CONFIDENTIAL

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