



Doc. nr. REA-S004-01-41-0552

Versie 2.0

Datum 14 Feb 2020 10:17:23 (GMT+02:00)

Pagina 1 van 3

Document eigenaar BBR

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	Dd D _{weak}	
	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: 16 July 2021

Approved by

QA/QC:

VERTROUWELIJK