

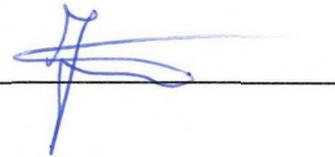
Title **Pelikloon anti-D mix (IgG-IgM) monoclonal release**

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 D <sub>weak</sub> 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 <u>Y/N</u>

Date: 03 September 2025

Approved by   
QA/QC: \_\_\_\_\_