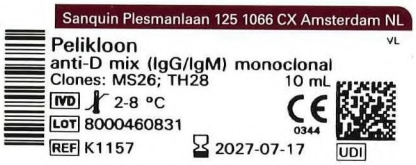
Title **Pelikloon anti-D mix (IgG-IgM) monoclonal release**

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_{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: 13 August 2024

Approved by

QA/QC: _____