

Titel K1255 Pelikloon anti-D (IgM) monoclonal release

K1255
Clone number RUM1



Analysis	Requirement	Result
Specificity	Negative with Rh(D)negative, r'r and r''r cells	Conform requirements
Avidity	Dd D _{weak}	
	Tube method ≥ 3+ ≥ W+	Conform requirements
	Microplate method ≥ 3+ ≥ W+	Conform requirements
	Cellbind Screen method ≥ 3+ ≥ W+	Conform requirements
Cellbind Direct Type method ≥ 3+ ≥ W+	Conform requirements	
Titer	Dd	
	Tube method ≥ 1:64	Conform requirements
Microplate method ≥ 1:32	Conform requirements	
Growthtest	no growth	Conform
External release	released by Notified Body	Released Y/N

Date: 15 February 2024

Approved by 
QA/QC: _____