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Versie 2.0

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Document eigenaar BBR

Titel **Pelikloon anti-D (IgM) monoclonal release**

K1255

Clone number RUM1

Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

Pelikloon anti-D (IgM) monoclonal 10 ml
Clone: RUM-1

IVD 2-8°C REF K1255 CE
LOT 8000458678 2026-01-29 0344

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 <u>Y/N</u>

Approved by

Date: 27 February 2023

QA/QC:

VERTROUWELIJK