

CERTIFICATE OF ANALYSIS

Product: Anti-D (IgM/IgG)

Lot No. 65023

Source of Material: Monoclonal antibody

Mfg. Date 21 OCT 22

Volume 10 mL

Exp. Date 21 APR 24

Test Items	Specifications	Results
1. Appearance	Clear liquid No turbidity, precipitate, particle or gel formation	Complied
2. Label	Complete, Correct and Clear	Complied
3. pH	6.50 - 7.50	Complied
4. Titer (RT, 37 °C, IAT)	R ₁ r cell ≥ 1:64	Complied
5. Specificity test		Complied
- RT	R ₁ r cell ≥ 3+ R ₂ r cell ≥ 3+	
- RT, 37 °C, IAT	rr cell = Negative r'r cell = Negative r''r cell = Negative	
6. Avidity test	R ₁ r cell ≤ 60 sec Rh+ cell ≤ 60 sec	Complied
7. Microbial enumeration	NMT 1.0 CFU/mL	Complied

Narumon Worachun Date 23/02/2023

(Narumon Worachun)

Quality Assurance and Quality Control Manager

National Blood Centre, Thai Red Cross Society