

CERTIFICATE OF ANALYSIS

<b>Product:</b> Anti-D (IgM/IgG)	<b>Lot No.</b> 65013
<b>Source of Material:</b> Monoclonal antibody	<b>Mfg. Date</b> 15 MAR 22
<b>Volume</b> 10 mL	<b>Exp. Date</b> 15 SEP 23

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 <sub>1</sub> r cell ≥ 1:64	Complied
5. Specificity test		Complied
- RT	R <sub>1</sub> r cell ≥ 3+ R <sub>2</sub> r cell ≥ 3+	
- RT, 37 °C, IAT	rr cell = Negative r'r cell = Negative r''r cell = Negative	
6. Avidity test	R <sub>1</sub> r cell ≤ 60 sec Rh+ cell ≤ 60 sec	Complied
7. Microbial enumeration	NMT 1.0 CFU/mL	Complied

Narumon Worachun Date 06/09/2022

(Narumon Worachun)

(Acting) Quality Assurance and Quality Control Manager

National Blood Centre, Thai Red Cross Society