

Certificate of Analysis (CoA)



**GOLD
STANDARD
DIAGNOSTICS**



Product: **Rubella Virus IgM μ -capture**
 Prod.No.: **RE57091**
 Lot: **RUBM-169N**
 Expiry: **2026-10-31**
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MM0400-169	2025-04	2026-10-31
CONJS	1	KM0400-169	2025-04	2026-10-31
CONTROL -	1	NM0400-169	2025-04	2026-10-31
CUT OFF	1	CM0400-169	2025-04	2026-10-31
CONTROL +	1	PM0400-169	2025-04	2026-10-31
WASH BUF 20x	1	W-1108	2025-02	2027-02-28
SOLN STOP	1	S-1039	2025-01	2027-01-31
SUB TMB	1	T-077	2022-09	2027-03-31
DIL	1	D-490	2024-12	2026-12-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.054	< Cut-off
CUT OFF	0.312	0.150-1.300
CONTROL +	0.780	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	26.15	14.38 - 37.91

The target value and target range of **CONTROL +** may be used optionally.
 The positive control is valid if the absorbance value of **CONTROL +** > **CUT OFF**.

Final Report issued: 2025-04-24

Approved by: 
 Quality Control

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