

# Certificate of Analysis (CoA)



**GOLD  
STANDARD  
DIAGNOSTICS**



Product: **Parvovirus B19 IgM**  
 Prod.No.: **RE57291**  
 Lot: **PARM-201N**  
 Expiry: **2026-07-31**  
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
<b>MTP</b>	1	MM0370-201	2025-01	2026-07-31
<b>CONJ</b>	1	KM0370-201	2025-01	2026-07-31
<b>CONTROL -</b>	1	NM0370-201	2025-01	2026-07-31
<b>CUT OFF</b>	1	CM0370-201	2025-01	2026-07-31
<b>CONTROL +</b>	1	PM0370-201	2025-01	2026-07-31
<b>WASH BUF 20x</b>	1	W-1104	2024-12	2026-12-31
<b>SOLN STOP</b>	1	S-1035	2024-10	2026-10-31
<b>SUB TMB</b>	1	T-077	2022-09	2027-03-31
<b>DIL M</b>	1	DM-341	2024-10	2026-10-31

Component	OD Value	OD Validation Criteria
<b>CONTROL -</b>	0.020	< 0.200 < Cut-off
<b>CUT OFF</b>	0.651	0.150-1.300
<b>CONTROL +</b>	1.178	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
<b>CONTROL +</b>	20.18	11.10 - 29.27

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**.

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Approved by:   
 Quality Control

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