

# Certificate of Analysis (CoA)



**GOLD  
STANDARD  
DIAGNOSTICS**



Product: **Borrelia burgdorferi IgM**  
 Prod.No.: **30113478**  
 Lot: **BORM-156**  
 Expiry: **2026-10-31**  
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
<b>MTP</b>	1	MM0040-156	2025-04	2026-10-31
<b>CONJ</b>	1	KM0040-156	2025-04	2026-10-31
<b>CONTROL -</b>	1	NM0040-156	2025-04	2026-10-31
<b>CUT OFF</b>	1	CM0040-156	2025-04	2026-10-31
<b>CONTROL +</b>	1	PM0040-156	2025-04	2026-10-31
<b>WASH BUF 20x</b>	1	W-1109	2025-02	2027-02-28
<b>SOLN STOP</b>	1	S-1040	2025-02	2027-02-28
<b>SUB TMB</b>	1	T-077	2022-09	2027-03-31
<b>DIL M</b>	1	DM-344	2025-04	2027-04-30

Component	OD Value	OD Validation Criteria
<b>CONTROL -</b>	0.025	< 0.200 < Cut-off
<b>CUT OFF</b>	0.510	0.150-1.300
<b>CONTROL +</b>	1.093	> Cut-off

Component	Target Value [NTU]	Target Range [NTU]
<b>CONTROL +</b>	22.44	12.34 - 32.54

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: AC  
 Quality Control

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