



**GOLD
STANDARD
DIAGNOSTICS**



Certificate of Analysis (CoA)

Product: **Leptospira IgM**
 Prod.No.: **RE58941**
 Lot: **LEPM-093**
 Expiry: **2027-07-31**
 IFU: **Rev. 01**

Component	Number	Lot	Prod. Date	Expiry Date
MTP	1	MM0660-093	2026-01	2027-07-31
CONJ	1	KM0660-093	2026-01	2027-07-31
CONTROL -	1	NM0660-093	2026-01	2027-07-31
CUT OFF	1	CM0660-093	2026-01	2027-07-31
CONTROL +	1	PM0660-093	2026-01	2027-07-31
WASH BUF 20x	1	W-1130	2026-01	2028-01-31
SOLN STOP	1	S-1065	2025-12	2027-12-31
SUB TMB	1	T-079	2025-12	2028-12-10
DIL M	1	DM-350	2025-12	2027-12-31

Component	OD Value	OD Validation Criteria
CONTROL -	0.045	< 0.200 < Cut-off
CUT OFF	0.531	0.150-1.300
CONTROL +	1.018	> Cut-off


Component	Target Value [NTU]	Target Range [NTU]
CONTROL +	20.72	11.40 - 30.04


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: 2026-01-22

Approved by: 
 Quality Control

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