

# Certificate of Analysis



**Product Code:** LISM-0096  
**Product:** Solus *Listeria monocytogenes* ELISA (1 plate)  
**LOT / Batch:** LM011  
**Date of Manufacture:** 13.09.2021  
**Expiry Date:** 12.09.2022

This batch has been quality control tested to the following criteria:

Batch homogeneity: CV% < 10%.  
A panel of 18 non-*Listeria monocytogenes* Satisfactory  
A panel of 17 *Listeria monocytogenes* spp. Satisfactory

## Performance of In house Reference Standards

Sample (cfu/ml)	Net Signal OD	OD Specification
D7 <i>L. monocytogenes</i> LMG 21263 10 <sup>6</sup>	0.785	>0.500
D7 <i>L. monocytogenes</i> LMG 21263 10 <sup>7</sup>	>2.500	>1.500
D8 <i>L. monocytogenes</i> LMG 16783 10 <sup>6</sup>	0.346	>0.200
D8 <i>L. monocytogenes</i> LMG 16783 10 <sup>7</sup>	1.548	>1.500
D9 <i>L. monocytogenes</i> LMG 16780 10 <sup>6</sup>	0.248	>0.200
D9 <i>L. monocytogenes</i> LMG 16780 10 <sup>7</sup>	1.565	>1.500

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Net Optical Densities of samples grown in Supplemented Palcam broth at 37.0°C for 22 hours and boiled at 85-100°C for 20 minutes.

	1	2	3	4	5
A	Negative control 0.026	D9 <i>L. monocytogenes</i> ser. 1/2b >2.500	AM2 <i>L. monocytogenes</i> ser. 4d >2.500	F9 <i>L. welshimeri</i> 0.012	AJ2 <i>L. weihenstephanensis</i> 0.014
B	Positive control >2.500	AL10 <i>L. monocytogenes</i> ser. 1/2c >2.500	AN1 <i>L. monocytogenes</i> ser. 7 >2.500	A18 <i>L. fleischmanii</i> 0.015	A10 <i>L. newyorkensis</i> 0.017
C	Substrate blank 0.043	AM1 <i>L. monocytogenes</i> ser. 3a >2.500	AN9 <i>L. monocytogenes</i> (wild type) 1.578	A19 <i>L. marthii</i> 0.021	A17 <i>L. booriae</i> 0.011
D	D7 <i>L. monocytogenes</i> ser. 1 >2.500	AO1 <i>L. monocytogenes</i> ser. 4 >2.500	AN10 <i>L. monocytogenes</i> (wild type) 1.596	AJ1 <i>L. rocourtiae</i> 0.018	AM7 <i>B. cereus</i> 0.010
E	AL9 <i>L. monocytogenes</i> ser. 1a >2.500	D8 <i>L. monocytogenes</i> ser. 4a >2.500	D2 <i>L. grayii</i> 0.010	R2 <i>L. riparia</i> 0.013	AM8 <i>E. faecalis</i> 0.008
F	AM10 <i>L. monocytogenes</i> ser. 1/2 >2.500	AN8 <i>L. monocytogenes</i> ser. 4b >2.500	AM4 <i>L. innocua</i> 0.015	Q8 <i>L. aquatica</i> 0.027	A2 <i>S. aureus</i> 0.013
G	D1 <i>L. monocytogenes</i> ser. 1/2a >2.500	AM3 <i>L. monocytogenes</i> ser. 4b >2.500	D5 <i>L. ivanovii</i> 0.020	Q10 <i>L. floridiensis</i> 0.060	Absorbances read at 450nm
H	AP2 <i>L. monocytogenes</i> ser. 1/2a >2.500	AP3 <i>L. monocytogenes</i> ser. 4b >2.500	AM5 <i>L. seeligeri</i> 0.017	Q9 <i>L. cornellensis</i> 0.009	

Production Batch is approved for release as it gives satisfactory QC performance.

Signed: Technical Director/~~Operations Manager~~/Quality Manager

Date:

*D. Schmitt*  
21/9/21