

Certificate of Analysis



Product Code: LISM-0096
Product: Solus *Listeria monocytogenes* ELISA (1 plate)
LOT / Batch: LM008
Date of Manufacture: 09.11.2020
Expiry Date: 08.11.2021

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 ⁶	0.593	>0.500
D7 <i>L. monocytogenes</i> LMG 21263 10 ⁷	>2.500	>1.500
D8 <i>L. monocytogenes</i> LMG 16783 10 ⁶	>2.500	>0.200
D8 <i>L. monocytogenes</i> LMG 16783 10 ⁷	>2.500	>1.500
D9 <i>L. monocytogenes</i> LMG 16780 10 ⁶	0.263	>0.200
D9 <i>L. monocytogenes</i> LMG 16780 10 ⁷	2.265	>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 0.021	D9 <i>L. monocytogenes</i> ser. 1/2b >2.500	AM2 <i>L. monocytogenes</i> ser. 4d >2.500	F9 <i>L. welshimeri</i> 0.033	AJ2 <i>L. weihenstephanensis</i> 0.023
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> 0.041	A110 <i>L. newyorkensis</i> 0.024
C	Substrate blank 0.039	AM1 <i>L. monocytogenes</i> ser. 3a >2.500	AN9 <i>L. monocytogenes</i> (wild type) 2.235	A19 <i>L. marthii</i> 0.036	A17 <i>L. booriae</i> 0.030
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) 1.799	AJ1 <i>L. rocourtiae</i> 0.033	AM7 <i>B. cereus</i> 0.014
E	AL9 <i>L. monocytogenes</i> ser. 1a >2.500	D8 <i>L. monocytogenes</i> ser. 4a >2.500	D2 <i>L. grayii</i> 0.025	R2 <i>L. riparia</i> 0.034	AM8 <i>E. faecalis</i> 0.017
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> 0.019	Q8 <i>L. aquatica</i> 0023	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> 0.023	Q10 <i>L. floridiensis</i> 0.029	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> 0.040	Q9 <i>L. cornellensis</i> 0.030	

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

Signed: Technical Director/~~Finance Leader~~/Quality Manager

Date: 17/11/20.