

# Certificate of Analysis



**Product Code:** LIS-0480S  
**Product:** Solus *Listeria* ELISA (5 plate)  
**LOT / Batch:** EL159  
**Date of Manufacture:** 5<sup>th</sup> July 2021  
**Expiry Date:** 4<sup>th</sup> October 2022

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

Batch homogeneity: CV% < 10%.  
A panel of 9 non-*Listeria* spp: Satisfactory  
A panel of 11 *Listeria* spp: Satisfactory

## Performance of In house Reference Standards

Sample (cfu/ml)	Net Signal OD	OD Specification
C10 <i>L. monocytogenes</i> ATCC 13932 10 <sup>6</sup>	1.419	>0.400
C10 <i>L. monocytogenes</i> ATCC 13932 10 <sup>7</sup>	>2.500	>2.000
D5 <i>L. ivanovii</i> ATCC 19119 10 <sup>6</sup>	0.635	>0.250
D5 <i>L. ivanovii</i> ATCC 19119 10 <sup>7</sup>	>2.500	>2.000
D6 <i>L. welshimeri</i> ATCC 35897 10 <sup>6</sup>	>2.500	>1.500
D6 <i>L. welshimeri</i> ATCC 35897 10 <sup>7</sup>	>2.500	>2.000
D7 <i>L. monocytogenes</i> ATCC 19111 10 <sup>6</sup>	1.212	>0.400
D7 <i>L. monocytogenes</i> ATCC 19111 10 <sup>7</sup>	>2.500	>2.000
G3 <i>L. innocua</i> (wild type) 10 <sup>6</sup>	1.052	>0.250
G3 <i>L. innocua</i> (wild type) 10 <sup>7</sup>	>2.500	>2.000

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Net Optical Densities of samples grown in RELM at 30.0°C for 24 hours and boiled at 85-100°C for 20 minutes.

	1	2	3
A	Negative control 0.027	D7 <i>L. monocytogenes</i> >2.500	E8 <i>Brochothrix thermosphacta</i> 0.025
B	Positive control >2.500	D8 <i>L. monocytogenes</i> >2.500	E9 <i>Bacillus cereus</i> 0.038
C	Substrate blank 0.045	D9 <i>L. monocytogenes</i> >2.500	E6 <i>Enterococcus faecalis</i> 0.028
D	G10 <i>L. innocua</i> >2.500	C10 <i>L. monocytogenes</i> >2.500	AT5 <i>Bacillus brevis</i> (Wild type) 0.029
E	D5 <i>L. ivanovii</i> >2.500	D10 <i>L. seeligeri</i> 0.661	C1 <i>Staphylococcus aureus</i> 0.031
F	D6 <i>L. welshimeri</i> >2.500	G3 <i>L. innocua</i> >2.500	AT6 <i>Bacillus cereus</i> (Wild type) 0.034
G	D2 <i>L. grayii</i> >2.500	F1 <i>Streptococcus bovis</i> 0.029	F10 <i>Enterococcus faecalis</i> (Wild type) 0.045
H	D1 <i>L. monocytogenes</i> >2.500	E7 <i>Kurthia zopfii</i> 0.028	Absorbances read at 450nm

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

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

Date:

13.07.2021