

# Certificate of Analysis



**Product Code:** LIS-0480S  
**Product:** Solus *Listeria* ELISA (5 plate)  
**LOT / Batch:** EL145  
**Date of Manufacture:** 18.08.2020  
**Expiry Date:** 17.08.2021

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>	0.988	>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>	0.294	>0.250
D5 <i>L. ivanovii</i> ATCC 19119 10 <sup>7</sup>	2.092	>2.000
D6 <i>L. welshimeri</i> ATCC 35897 10 <sup>6</sup>	1.607	>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>	0.989	>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>	0.671	>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 0.034	D7 <i>L. monocytogenes</i> >2.500	E8 <i>Brochothrix thermosphacta</i> 0.052
B	Positive control >2.500	D8 <i>L. monocytogenes</i> >2.500	E9 <i>Bacillus cereus</i> 0.069
C	Substrate blank 0.050	D9 <i>L. monocytogenes</i> >2.500	E6 <i>Enterococcus faecalis</i> 0.048
D	G10 <i>L. innocua</i> >2.500	C10 <i>L. monocytogenes</i> >2.500	A8 <i>Escherichia coli</i> 0.038
E	D5 <i>L. ivanovii</i> >2.500	D10 <i>L. seeligeri</i> 1.511	C1 <i>Staphylococcus aureus</i> 0.054
F	D6 <i>L. welshimeri</i> >2.500	G3 <i>L. innocua</i> >2.500	E2 <i>Escherichia coli</i> (Wild Type) 0.042
G	D2 <i>L. grayii</i> >2.500	F1 <i>Streptococcus bovis</i> 0.046	F10 <i>Enterococcus faecalis</i> (Wild type) 0.048
H	D1 <i>L. monocytogenes</i> >2.500	E7 <i>Kurthia zopfii</i> 0.052	Absorbances read at 450nm

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

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

Date: 24/8/20