

# Certificate of Analysis



**Product Code:** LIS-0480S  
**Product:** Solus *Listeria* ELISA (5 plate)  
**LOT / Batch:** EL150  
**Date of Manufacture:** 30.11.2020  
**Expiry Date:** 29.11.2021

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>	0.880	>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>	0.882	>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>	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>	0.486	>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 0.038	<i>D7 L. monocytogenes</i> >2.500	<i>E8 Brochothrix thermosphacta</i> 0.043
B	Positive control >2.500	<i>D8 L. monocytogenes</i> >2.500	<i>E9 Bacillus cereus</i> 0.040
C	Substrate blank 0.063	<i>D9 L. monocytogenes</i> >2.500	<i>E6 Enterococcus faecalis</i> 0.051
D	<i>G10 L. innocua</i> >2.500	<i>C10 L. monocytogenes</i> >2.500	<i>A8 Escherichia coli</i> 0.044
E	<i>D5 L. ivanovii</i> >2.500	<i>D10 L. seeligeri</i> 1.647	<i>C1 Staphylococcus aureus</i> 0.050
F	<i>D6 L. welshimeri</i> >2.500	<i>G3 L. innocua</i> >2.500	<i>E2 Escherichia coli (Wild Type)</i> 0.033
G	<i>D2 L. grayii</i> >2.500	<i>F1 Streptococcus bovis</i> 0.042	<i>F10 Enterococcus faecalis (Wild type)</i> 0.044
H	<i>D1 L. monocytogenes</i> >2.500	<i>E7 Kurthia zopfii</i> 0.035	Absorbances read at 450nm

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

Signed: Technical director/Finance Leader/Quality Manager

Date: 8/12/20