

## Certificate of Analysis

<b>Product Code:</b>	<b>LIS-0480S</b>
<b>Product:</b>	Solus <i>Listeria</i> ELISA (5 plate)
<b>LOT/Batch:</b>	<b>EL128</b>
<b>Date of Manufacture/Test:</b>	<b>23.09.2019</b>
<b>Expiry Date:</b>	<b>22.09.2020</b>

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

Batch homogeneity: CV%	< 10%.
A panel of 9 non- <i>Listeria</i> sp.	<u>Satisfactory</u>
A panel of 10 <i>Listeria</i> sp.	<u>Satisfactory</u>

### 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>	2.358	>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>	0.354	>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>	1.130	>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>	0.510	>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>D5 L. ivanovii</i> >2.500	<i>E9 Bacillus cereus</i> 0.037
B	Positive control >2.500	<i>D9 L. monocytogenes</i> >2.500	<i>A8 E. coli</i> 0.031
C	Substrate blank 0.052	<i>D8 L. monocytogenes</i> >2.500	<i>C1 Staphylococcus aureus</i> 0.036
D	<i>C10 L. monocytogenes</i> >2.500	<i>D7 L. monocytogenes</i> >2.500	<i>E2 E. coli (WT)</i> 0.032
E	<i>G10 L. innocua</i> >2.500	<i>D10 L. seeligeri</i> 1.711	<i>E8 Brochothrix thermosphacta</i> 0.031
F	<i>D2 L. grayii (BHIB)</i> >2.500	<i>E7 Kurthia zopfii</i> 0.027	<i>E6 Enterococcus faecalis</i> 0.035
G	<i>D1 L. monocytogenes</i> >2.500	<i>F1 Streptococcus bovis</i> 0.032	Absorbances read at 450nm
H	<i>D6 L. welshimeri</i> >2.500	<i>F10 Enterococcus faecalis</i> (WT) 0.036	

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

Signed: Operations director/Technical director/CEO



Date:

1/10/19

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