

Certificate of Analysis



Product Code: LIS-0480S
Product: Solus *Listeria* ELISA (5 plate)
LOT / Batch: EL143
Date of Manufacture: 07.07.2020
Expiry Date: 06.07.2021

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 ⁶	1.402	>0.400
C10 <i>L. monocytogenes</i> ATCC 13932 10 ⁷	>2.500	>2.000
D5 <i>L. ivanovii</i> ATCC 19119 10 ⁶	0.428	>0.250
D5 <i>L. ivanovii</i> ATCC 19119 10 ⁷	>2.500	>2.000
D6 <i>L. welshimeri</i> ATCC 35897 10 ⁶	>2.500	>1.500
D6 <i>L. welshimeri</i> ATCC 35897 10 ⁷	>2.500	>2.000
D7 <i>L. monocytogenes</i> ATCC 19111 10 ⁶	1.383	>0.400
D7 <i>L. monocytogenes</i> ATCC 19111 10 ⁷	>2.500	>2.000
G3 <i>L. innocua</i> (wild type) 10 ⁶	0.859	>0.250
G3 <i>L. innocua</i> (wild type) 10 ⁷	>2.500	>2.000

Certificate of Analysis



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 0.029	D7 <i>L. monocytogenes</i> >2.500	E8 <i>Brochothrix thermosphacta</i> 0.030
B	Positive control >2.500	D8 <i>L. monocytogenes</i> >2.500	E9 <i>Bacillus cereus</i> 0.027
C	Substrate blank 0.050	D9 <i>L. monocytogenes</i> >2.500	E6 <i>Enterococcus faecalis</i> 0.043
D	G10 <i>L. innocua</i> >2.500	C10 <i>L. monocytogenes</i> >2.500	A8 <i>Escherichia coli</i> 0.030
E	D5 <i>L. ivanovii</i> >2.500	D10 <i>L. seeligeri</i> 1.556	C1 <i>Staphylococcus aureus</i> 0.037
F	D6 <i>L. welshimeri</i> >2.500	G3 <i>L. innocua</i> >2.500	E2 <i>Escherichia coli</i> (Wild Type) 0.034
G	D2 <i>L. grayii</i> >2.500	F1 <i>Streptococcus bovis</i> 0.030	F10 <i>Enterococcus faecalis</i> (Wild type) 0.048
H	D1 <i>L. monocytogenes</i> >2.500	E7 <i>Kurthia zopfii</i> 0.031	Absorbances read at 450nm

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

Signed: Technical director/Finance Leader/Quality Manager

Date:

15/7/20