

Certificate of Analysis

| | |
|----------------------------------|---------------------------------------|
| Product Code: | LIS-0096S |
| Product: | Solus <i>Listeria</i> ELISA (1 plate) |
| LOT/Batch: | EL131 |
| Date of Manufacture/Test: | 04.11.2019 |
| Expiry Date: | 03.11.2020 |

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 ⁶ | 1.352 | >0.400 |
| C10 <i>L. monocytogenes</i> ATCC 13932 10 ⁷ | >2.500 | >2.000 |
| D5 <i>L. ivanovii</i> ATCC 19119 10 ⁶ | 0.370 | >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 | 1.348 | >0.400 |
| D7 <i>L. monocytogenes</i> ATCC 19111 10 ⁷ | >2.500 | >2.000 |
| G3 <i>L. innocua</i> (wild type) 10 ⁶ | 0.498 | >0.250 |
| G3 <i>L. innocua</i> (wild type) 10 ⁷ | >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 0.017 | <i>D5 L. ivanovii</i> >2.500 | <i>E9 Bacillus cereus</i> 0.017 |
| B | Positive control >2.500 | <i>D9 L. monocytogenes</i> >2.500 | <i>A8 E. coli</i> 0.010 |
| C | Substrate blank 0.062 | <i>D8 L. monocytogenes</i> >2.500 | <i>C1 Staphylococcus aureus</i> 0.020 |
| D | <i>C10 L. monocytogenes</i> >2.500 | <i>D7 L. monocytogenes</i> >2.500 | <i>E2 E. coli (WT)</i> 0.012 |
| E | <i>G10 L. innocua</i> >2.500 | <i>D10 L. seeligeri</i> 1.523 | <i>E8 Brochothrix thermosphacta</i> 0.009 |
| F | <i>D2 L. grayii (BHIB)</i> >2.500 | <i>E7 Kurthia zopfii</i> 0.016 | <i>E6 Enterococcus faecalis</i> 0.011 |
| G | <i>D1 L. monocytogenes</i> >2.500 | <i>F1 Streptococcus bovis</i> 0.009 | Absorbances read at 450nm |
| H | <i>D6 L. welshimeri</i> >2.500 | <i>F10 Enterococcus faecalis (WT)</i> 0.022 | |

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

Signed: ~~Operations director/Technical director/CEO~~



Date:

28/11/19.

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