

# Certificate of Analysis



**Product Code:** LIS-0480S  
**Product:** Solus *Listeria* ELISA (5 plate)  
**LOT / Batch:** EL154  
**Date of Manufacture:** 29.03.2021  
**Expiry Date:** 28.06.2022

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> | 0.987         | >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>       | 0.566         | >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>     | 1.789         | >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>  | 0.887         | >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>       | 0.743         | >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<br>0.032            | <i>D7 L. monocytogenes</i><br>>2.500   | <i>E8 Brochothrix thermosphacta</i><br>0.025          |
| B | Positive control<br>>2.500           | <i>D8 L. monocytogenes</i><br>>2.500   | <i>E9 Bacillus cereus</i><br>0.024                    |
| C | Substrate blank<br>0.046             | <i>D9 L. monocytogenes</i><br>>2.500   | <i>E6 Enterococcus faecalis</i><br>0.040              |
| D | <i>G10 L. innocua</i><br>>2.500      | <i>C10 L. monocytogenes</i><br>>2.500  | <i>A8 Escherichia coli</i><br>0.024                   |
| E | <i>D5 L. ivanovii</i><br>>2.500      | <i>D10 L. seeligeri</i><br>0.549       | <i>C1 Staphylococcus aureus</i><br>0.030              |
| F | <i>D6 L. welshimeri</i><br>>2.500    | <i>G3 L. innocua</i><br>>2.500         | <i>E2 Escherichia coli (Wild Type)</i><br>0.030       |
| G | <i>D2 L. grayii</i><br>>2.500        | <i>F1 Streptococcus bovis</i><br>0.026 | <i>F10 Enterococcus faecalis (Wild type)</i><br>0.037 |
| H | <i>D1 L. monocytogenes</i><br>>2.500 | <i>E7 Kurthia zopfii</i><br>0.024      | Absorbances read at<br>450nm                          |

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

Signed: Technical director/Finance Leader/Quality Manager

Date: 1/6/21.