

## Certificate of Analysis

|                                  |   |
|----------------------------------|---|
| <b>Product Code:</b>             | <b>EC-048S</b>                            |
| <b>Product:</b>                  | Solus <i>E. coli</i> O157 ELISA (1 plate) |
| <b>LOT/Batch:</b>                | <b>EE029</b>                              |
| <b>Date of Manufacture/Test:</b> | <b>02.03.2020</b>                         |
| <b>Expiry Date:</b>              | <b>01.03.2021</b>                         |

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

|  |                     |
|--|---------------------|
| Batch homogeneity CV%:   | < 10%.              |
| A panel of 8 non- <i>E. coli</i> O157 <i>Enterobacteriaceae</i> spp: | <u>Satisfactory</u> |
| Non toxigenic <i>E. coli</i> O157 NCTC 12900:                        | <u>Satisfactory</u> |

### Performance of In house Reference Standards


| Sample   | Net Signal OD | Specification OD |
|--|---------------|------------------|
| F2 <i>E. coli</i> O157 ~10 <sup>4</sup> cfu/ml | 0.956         | >0.300           |
| F2 <i>E. coli</i> O157 ~10 <sup>5</sup> cfu/ml | 1.469         | >0.500           |
| F2 <i>E. coli</i> O157 ~10 <sup>6</sup> cfu/ml | 1.850         | >1.000           |

Net Optical Densities read at 450nm of samples grown in mTSB + Novobiocin (20mg/L) for 20 hours at 37°C

|   | 1   | 2   |
|---|---|---|
| A | Negative control<br>0.000                   | <i>E5 Serratia liquifaciens</i><br>0.019  |
| B | Positive control<br>2.374                   | <i>B7 Salmonella</i> Typhimurium<br>0.022 |
| C | Substrate blank<br>0.062                    | <i>A8 E. coli</i><br>0.022                |
| D | <i>F2 E. coli</i> O157 NCTC 12900<br>>2.500 | <i>E2 E. coli</i> (Wild Type)<br>0.014    |
| E | <i>A9 Proteus mirabilis</i><br>0.019        | Absorbances read at 450nm                 |
| F | <i>A6 Citrobacter freundii</i><br>0.038     |   |
| G | <i>A10 Klebsiella pneumoniae</i><br>0.039   |   |
| H | <i>E4 Shigella sonnei</i><br>0.019          |   |

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

Signed: Operations director/Technical director/CEO



10/3/2020

Date:

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