

Certificate of Analysis

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|----------------------------------|---|
| Product Code: | EC-0485 |
| Product: | Solus <i>E. coli</i> O157 ELISA (1 plate) |
| LOT/Batch: | EE021 |
| Date of Manufacture/Test: | 06.08.2018 |
| Expiry Date: | 05.08.2019 |

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> sp. | <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 ⁴ cfu/ml | 0.172 | <0.300 |
| F2 <i>E. coli</i> O157 ~10 ⁵ cfu/ml | 0.692 | >0.500 |
| F2 <i>E. coli</i> O157 ~10 ⁶ cfu/ml | 1.721 | >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 0.001 | <i>E5 Serratia liquifaciens</i> 0.014 |
| B | Positive control >2.50 | <i>B7 Salmonella Typhimurium</i> 0.010 |
| C | Substrate blank 0.052 | <i>A8 E. coli</i> 0.016 |
| D | <i>F2 E. coli</i> O157 NCTC 12900 >2.500 | <i>E2 E. coli</i> (Wild Type) 0.007 |
| E | <i>A9 Proteus mirabilis</i> 0.042 | Absorbances read at 450nm |
| F | <i>A6 Citrobacter freundii</i> 0.043 | |
| G | <i>A10 Klebsiella pneumoniae</i> 0.026 | |
| H | <i>E4 Shigella sonnei</i> 0.020 | |

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

Signed: Operations director/Technical director/CEO

Date:



14/9/18

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