

Certificate of Analysis

Product Code: EC-048S
Product: Solus E. coli O157 ELISA (1 plate)
LOT/Batch: EE018
Date of Manufacture/Test: 29.08.2017
Expiry Date: 28.08.2018

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

Batch homogeneity CV%: < 10%.
 A panel of 8 non- *E. coli* O157 *Enterobacteriaceae* sp. Satisfactory
 Non toxigenic *E. coli* O157 NCTC 12900: Satisfactory

Performance of In house Reference Standards

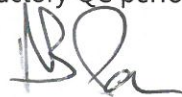
| Sample | Net Signal OD | Specification OD |
|--|---------------|------------------|
| F2 <i>E. coli</i> O157 ~10 ⁴ cfu/ml | 0.228 | <0.300 |
| F2 <i>E. coli</i> O157 ~10 ⁵ cfu/ml | 0.911 | >0.500 |
| F2 <i>E. coli</i> O157 ~10 ⁶ cfu/ml | 1.678 | >1.000 |

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 0.006 | <i>E5 Serratia liquifaciens</i> 0.018 |
| B | Positive control 1.883 | <i>B7 Salmonella</i> Typhimurium 0.005 |
| C | Substrate blank 0.045 | <i>A8 E. coli</i> 0.005 |
| D | <i>F2 E. coli</i> O157 NCTC 12900 >2.500 | <i>E2 E. coli</i> (Wild Type) 0.030 |
| E | <i>A9 Proteus mirabilis</i> 0.008 | Absorbances read at 450nm |
| F | <i>A6 Citrobacter freundii</i> 0.006 | |
| G | <i>A10 Klebsiella pneumoniae</i> 0.004 | |
| H | <i>E4 Shigella sonnei</i> 0.034 | |

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

Signed: Operations director/Technical director/CEO



Date:

5/9/17

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