

Certificate of Analysis

Product Code: EC-048S
Product: Solus *E. coli* O157 ELISA (1 plate)
LOT/Batch: EE028
Date of Manufacture/Test: 16.12.2019
Expiry Date: 15.12.2020

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

Batch homogeneity CV%: < 10%.
 A panel of 8 non- *E. coli* O157 *Enterobacteriaceae* spp: 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	0.694	>0.300
F2 <i>E. coli</i> O157 ~10 ⁵ cfu/ml	1.466	>0.500
F2 <i>E. coli</i> O157 ~10 ⁶ cfu/ml	1.488	>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 0.002	<i>E5 Serratia liquifaciens</i> 0.014
B	Positive control >2.500	<i>B7 Salmonella</i> Typhimurium 0.018
C	Substrate blank 0.046	<i>A8 E. coli</i> 0.034
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> 0.016	Absorbances read at 450nm
F	<i>A6 Citrobacter freundii</i> 0.039	
G	<i>A10 Klebsiella pneumoniae</i> 0.013	
H	<i>E4 Shigella sonnei</i> 0.048	

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

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



Date: 20/12/19.

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