

Certificate of Analysis



Product Code: EC-048S
Product: Solus *E. coli* O157 ELISA (1 plate)
LOT / Batch: EE031
Date of Manufacture: 21.07.2020
Expiry Date: 20.07.2021

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-toxicogenic *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	0.777	>0.300
F2 <i>E. coli</i> O157 ~10 ⁵ cfu/ml	1.723	>0.500
F2 <i>E. coli</i> O157 ~10 ⁶ cfu/ml	1.821	>1.000

Net Optical Densities read at 450nm of samples grown in mTSB + Novobiocin (20mg/L) for 20 hours at 41.5°C

	1	2
A	Negative control 0.041	<i>E5 Serratia liquifaciens</i> 0.010
B	Positive control 1.807	<i>B7 Salmonella Typhimurium</i> 0.009
C	Substrate blank 0.036	<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) 0.004
E	<i>A9 Proteus mirabilis</i> 0.052	Absorbances read at 450nm
F	<i>I3 Citrobacter freundii</i> 0.024	
G	<i>A10 Klebsiella pneumoniae</i> 0.022	
H	<i>E4 Shigella sonnei</i> 0.014	

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

Signed: Technical director/Finance Leader/Quality Manager

Date: 27/7/20.