

# Certificate of Analysis



**Product Code:** EC-048S  
**Product:** Solus *E. coli* O157 ELISA (1 plate)  
**LOT / Batch:** EE040  
**Date of Manufacture:** 13 JUN 2022  
**Expiry Date:** 12 DEC 2023

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 <sup>4</sup> cfu/ml	0.526	>0.300
F2 <i>E. coli</i> O157 ~10 <sup>5</sup> cfu/ml	1.702	>0.500
F2 <i>E. coli</i> O157 ~10 <sup>6</sup> cfu/ml	2.395	>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 0.003	<i>E5 Serratia liquifaciens</i> 0.042
B	Positive control 1.916	<i>B7 Salmonella</i> Typhimurium 0.010
C	Substrate blank 0.044	<i>A8 E. coli</i> 0.003
D	<i>F2 E. coli</i> O157 NCTC 12900 >2.500	<i>E2 E. coli</i> (Wild Type) 0.019
E	<i>A9 Proteus mirabilis</i> 0.004	Absorbances read at 450nm
F	<i>I3 Citrobacter freundii</i> 0.025	
G	<i>A10 Klebsiella pneumoniae</i> 0.015	
H	<i>E4 Shigella sonnei</i> 0.019	

# Certificate of Analysis



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

Signed: Technical director/~~Operations~~ Manager/~~Quality~~ Manager *DSZ*.

Date: *20/6/22*.