

Certificate of Analysis

Product Code:	EC-048S
Product:	Solus <i>E. coli</i> O157 ELISA (1 plate)
LOT/Batch:	EE027
Date of Manufacture/Test:	19.08.2019
Expiry Date:	18.08.2020

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 spp.</i> :	<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	0.336	>0.300
F2 <i>E. coli</i> O157 ~10 ⁵ cfu/ml	1.341	>0.500
F2 <i>E. coli</i> O157 ~10 ⁶ cfu/ml	1.425	>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 0.005	<i>E5 Serratia liquifaciens</i> 0.017
B	Positive control 2.093	<i>B7 Salmonella Typhimurium</i> 0.012
C	Substrate blank 0.042	<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) 0.022
E	<i>A9 Proteus mirabilis</i> 0.007	Absorbances read at 450nm
F	<i>A6 Citrobacter freundii</i> 0.003	
G	<i>A10 Klebsiella pneumoniae</i> 0.007	
H	<i>E4 Shigella sonnei</i> 0.005	

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

Signed: Operations director/Technical director/CEO

Date:


 23/8/19

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