

## Certificate of Analysis

<b>Product Code:</b>	<b>EC-0485</b>
<b>Product:</b>	Solus <i>E. coli</i> O157 ELISA (1 plate)
<b>LOT/Batch:</b>	<b>EE019</b>
<b>Date of Manufacture/Test:</b>	<b>02.01.2018</b>
<b>Expiry Date:</b>	<b>01.01.2019</b>

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</i> sp.	<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 <sup>4</sup> cfu/ml	0.261	<0.300
F2 <i>E. coli</i> O157 ~10 <sup>5</sup> cfu/ml	0.885	>0.500
F2 <i>E. coli</i> O157 ~10 <sup>6</sup> cfu/ml	1.551	>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 0.000	<i>E5 Serratia liquifaciens</i> 0.001
B	Positive control >2.50	<i>B7 Salmonella Typhimurium</i> 0.001
C	Substrate blank 0.055	<i>A8 E. coli</i> 0.001
D	<i>F2 E. coli</i> O157 NCTC 12900 >2.500	<i>E2 E. coli</i> (Wild Type) 0.005
E	<i>A9 Proteus mirabilis</i> 0.000	Absorbances read at 450nm
F	<i>A6 Citrobacter freundii</i> 0.000	
G	<i>A10 Klebsiella pneumoniae</i> 0.000	
H	<i>E4 Shigella sonnei</i> 0.001	

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

Signed: Operations director/Technical director/CEO



Date:

9/1/18

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