

Certificate of Analysis

Product name	AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)
Catalogue Number	MBTC021
Lot Number	24MBTC021002-C
Expiry date	2027-03-23

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)	24MBTC021102-C	2027-03-23

Analysis	Specifications	Results
1.CAMPYLOBACTER JEJUNI		
QUANTIFICATION TEST (copies/vial)	10000-25000	18000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2.CLOSTRIDIUM DIFFICILE		
QUANTIFICATION TEST (copies/vial)	10000-25000	11000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3.ESCHERICHIA COLI		
QUANTIFICATION TEST (copies/vial)	10000-25000	23000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
4.SALMONELLA ENTERITIDIS		
QUANTIFICATION TEST (copies/vial)	10000-25000	10000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
5.SHIGELLA FLEXNERI		
QUANTIFICATION TEST (copies/vial)	10000-25000	11500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
6.YERSINIA ENTEROCOLITICA		
QUANTIFICATION TEST (copies/vial)	10000-25000	12500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION

Identity test oligonucleotides

1.CAMPYLOBACTER JEJUNI

CJEJU F3 CTGGTGGTTTTGAAGCAAAGATT

CJEJU R3 CAATACCAGTGTCTAAAGTGCGTTTAT

Best, E.L., et al. (2003). FEMS Microbiol Lett, 229(2): 237-241

2.CLOSTRIDIUM DIFFICILE

tcdB F ATAATGGTAGATTATGATGGAAGTAGGAA

tcdB R TCTTGATAAGCTGCCGCATATG

Hoegh, A.M., et al. (2013) Eur J Clin Microbiol Infect Dis. 31(6):1073-1079.

3.ESCHERICHIA COLI (EHEC/VTEC)

VTEC-VT1-Fw CATTGTCTGGTGACAGTAGCT

VTEC-VT2-Rv CCCGTAATTGCGCACTGAG

Bischoff, C., et al. (2005) J Microbiol Methods. 61:335-41.

4.SALMONELLA ENTERITIDIS

S.entericaF GGTAAGGGGCTTCGGTATC

S.entericaR TATTGGCTCCTGAATACGC

Lee, S. H., et al (2009). J Vet Sci. 10(1):43-51

5.SHIGELLA FLEXNERI

Shig-ipaH-F TGGAAAACTCAGTGCCTCT

Shig-ipaH-R CCAGTCGGTAAATTCATTCT

Luscher, D. & Athwegg, M. (1994) Mol Cell Probes. 8:285-290


6.YERSINIA ENTEROCOLITICA

Yent.foxA.FWang ACGGCGGTGATGTGAACAA

Yent.foxA.RWang GGGTCCACTGCAGCACATT

Wang, J.Z., et al. (2014). J Clin Microbiol. 52(12):4443-4444

This is to certify that the above kit performs in accordance with the Quality Control specifications of Vircell, S.L. and fulfils the essential requirements as established in Directive 98/79/CE and part of Regulation (EU) 2017/746. Vircell, S.L. manufactures under ISO 9001 and ISO 13485 certified quality systems.

Q.C. Testing by			
Position	Name	Date	Signature
Quality Control Department	Conde Ortega, Ana María	04/11/2024	



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