

Certificate of Analysis

Product name	AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)
Catalogue Number	MBTC031
Lot Number	23MBTC031002-C
Expiry date	2026-01-25

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL SARS-CoV-2/ FluA/FluB/RSV CONTROL (SWAB)	23MBTC031102-C	2026-01-25

Analysis	Specifications	Results
1.SARS-COV-2		
QUANTIFICATION TEST (copies/vial)	10000-25000	11000
QUANTIFICATION TEST (IU/vial)	10000-25000	11000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2.INFLUENZA A H3N2		
QUANTIFICATION TEST (copies/vial)	10000-25000	16500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3.INFLUENZA B		
QUANTIFICATION TEST (copies/vial)	10000-25000	12500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
4.RESPIRATORY SYNCYTIAL VIRUS (subtype B)		
QUANTIFICATION TEST (copies/vial)	10000-25000	22000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION

Identity test oligonucleotides

1. SARS-CoV-2

CorVWuh_E_F1 ACAGGTACGTTAATAGTTAATAGCGT
 CorVWuh_E_R2 ATATTGCAGCAGTACGCACACA
 Corman, V.M., et al. (2020) Euro Surveill., 25(3):2000045

2.INFLUENZA A H3N2

Flu A Fw GACCRATCCTGTACCTCTGAC
 Flu A Rv GGGCATTYTGACAAKCGTCTACG
 Chen Y., et al. (2011). J Clin Microbiol, 49 (4)1653-1656

3.INFLUENZA B

IFB-Fw CGAGCGTYTTAATGAAGGACATTC
 IFB-Rv GACCAAATTGGGATAAGACTCCC
 Ye F., et al. (2016). Virology journal, 15(1):175

4.RESPIRATORY SYNCYTIAL VIRUS (subtype B)

RSVs GCCAAAAARTTRTTCCACAATA
 RSVs TCTTCATCWCCATACTTTCTGTGA
 Symmis M.W., et al. (2004). J Mol Diagn., 6(2) 125-131

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.

Vircell, S.L. manufactures under ISO 9001 and ISO 13485 certified quality systems.

Q.C. Testing by

Position	Name	Date	Signature
Quality Control Department	Reca John, Isabel María	03/08/2023	



Vircell, S.L.
 Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain T. +34 958 441 264
 info@vircell.com www.vircell.com