

Certificate of Analysis

Product name	AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)
Catalogue Number	MBTC031
Lot Number	24MBTC031001-C
Expiry date	2026-10-11

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL SARS-CoV-2/ FluA/FluB/RSV CONTROL (SWAB)	24MBTC031101-C	2026-10-11

Analysis	Specifications	Results
1.SARS-COV-2		
QUANTIFICATION TEST (copies/vial)	10000-25000	10000
QUANTIFICATION TEST (IU/vial)	10000-25000	10000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2.INFLUENZA A H3N2		
QUANTIFICATION TEST (copies/vial)	10000-25000	14000
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	14500
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		
Syrmis 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 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	Martínez Ramírez, David	18/07/2024	