

Certificate of Analysis

Product name	AMPLIRUN® TOTAL FLU A/FLU B/RSV CONTROL (SWAB)
Catalogue Number	MBTC028
Lot Number	24MBTC028001-C
Expiry date	2025-11-15

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL FLU A/FLU B/RSV CONTROL (SWAB)	24MBTC028101-C	2025-11-15

Analysis	Specifications	Results
1.INFLUENZA A H3N2		
QUANTIFICATION TEST (copies/vial)	10000-25000	11000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2.INFLUENZA B		
QUANTIFICATION TEST (copies/vial)	10000-25000	17000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3.RESPIRATORY SYNCYTIAL VIRUS (subtype B)		
QUANTIFICATION TEST (copies/vial)	10000-25000	13000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION

Identity test oligonucleotides

1.INFLUENZA A H3N2

Flu A Fw: GACCRATCCTGTACCTCTGAC

Flu A Rv: GGGCATTYTGACAAACGCTCTACG

Chen Y., et al. (2011). J Clin Microbiol, 49 (4)1653-1656

2. INFLUENZA B

IFB-Fw: CGAGCGTYTTAATGAAGGACATTC

IFB-Rv: GACCAAATTGGGATAAGACTCCC

Ye F., et al. (2016). Virology journal, 15(1):175

3. RESPIRATORY SYNCYTIAL VIRUS (subtype B)

RSVs: GCCAAAAARTTRTTTCCACAATA

RSVs: TCTTCATCWCCTACTTTCTGTGA

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	Conde Ortega, Ana María	28/11/2024	