

Certificate of Analysis

Product name	AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)
Catalogue Number	MBTC020
Lot Number	23MBTC020002-C
Expiry date	2026-06-27

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)	23MBTC020102-C	2026-06-27

Analysis	Specifications	Results
1.ADENOVIRUS 4		
QUANTIFICATION TEST (copies/vial)	4000-10000	9400
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2.CORONAVIRUS		
QUANTIFICATION TEST (copies/vial)	4000-10000	9600
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3.INFLUENZA A H3N2		
QUANTIFICATION TEST (copies/vial)	4000-10000	5600
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
4.INFLUENZA B		
QUANTIFICATION TEST (copies/vial)	4000-10000	5200
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
5.NOVEL INFLUENZA A H1N1		
QUANTIFICATION TEST (copies/vial)	4000-10000	10000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
6.PARAINFLUENZA 1		
QUANTIFICATION TEST (copies/vial)	4000-10000	4200
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
7.PARAINFLUENZA 2		
QUANTIFICATION TEST (copies/vial)	4000-10000	4200
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
8.PARAINFLUENZA 3		
QUANTIFICATION TEST (copies/vial)	4000-10000	7400
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
9.RESPIRATORY SYNCYTIAL VIRUS (subtype A)		
QUANTIFICATION TEST (copies/vial)	4000-10000	5000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
10.RESPIRATORY SYNCYTIAL VIRUS (subtype B)		
QUANTIFICATION TEST (copies/vial)	4000-10000	9200
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION

Identity test oligonucleotides

Identity test oligonucleotides

1.ADENOVIRUS 4

ADENORESHEXONAQ1 GCCACSGTGGGGTTYCTAACTT
 ADENORESHEXONAQ2 GCCCAGTGGKCDTACATGCACATC
 Pauly, M., et al. (2017). Appl Environ Microbiol. 83(18)

2.CORONAVIRUS

CORON-229E-MG-F CATACTATCAACCCATTCAACAAG
 CORON-229E-MG-R CACGGCAACTGTCATGTATT
 Gaunt, E.R., et al. (2010). J Clin Microbiol. 48(8):2940-7.

3.INFLUENZA A H3N2

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

4. INFLUENZA B

Inf B-F CCCTGCTTGCTCGWAGYATGG

Inf B-R TGCTTATGGGAAGMACYACTTTG

Bonzel, L. and Hengel, H. (2009) NACHWEIS VIRALER RESPIRATORISCHER INFEKTIONEN MITTELS POLYMERASEKETTENREAKTION. Institut für Virologie der Heinrich-Heine-Universität Düsseldorf.

5. NOVEL INFLUENZA A H1N1

Flu A Fw GACCRATCCTGTACCTCTGAC

Flu A Rv GGGCATTYTGACAAKCGTCTACG

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

6. PARAINFLUENZA 1

PIS1 + CCGGTAATTCTCATACCTATG

PIS1 - CTTTGGAGCGGAGTTGTTAAG

Echevarria, J.E., et al. (1998). J Clin Microbiol, 36(5):1388-1391

7. PARAINFLUENZA 2

PIV2PR3 AACTATGTCCAGAGGAGGCTGCTGG

PIV2PR5 CCATGCCTGCATAAGCACACTGTAGC

Osiowy, C. (1998). J Clin Microbiol, 36(11):3149-3154

8. PARAINFLUENZA 3

PIV3s GGAGCATTGTGCATCTGTC

PIV3as TAGTGTGTAATGCAGCTCGT

Templeton, K. E., et al. (2004). J Clin Microbiol, 42(4):1564-1569

9. RESPIRATORY SYNCYTIAL VIRUS (subtype A)

RSVs GCCAAAAARTTRTTCCACAATA

RSVas TCTTCATCWCCATACTTTCTGTGA

Syrmis MW, et al. (2004). J Mol Diagn. 6(2):125-31.

10. RESPIRATORY SYNCYTIAL VIRUS (subtype B)

RSVs GCCAAAAARTTRTTCCACAATA

RSVas TCTTCATCWCCATACTTTCTGTGA

Syrmis MW, et al. (2004). J Mol Diagn. 6(2):125-31.

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	Conde Ortega, Ana María	11/01/2024	



Vircell, S.L.

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