

Certificate of Analysis

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| Product name | AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) |
| Catalogue Number | MBTC031 |
| Lot Number | 23MBTC031003-C |
| Expiry date | 2026-01-27 |

| Kit contents | Lot Number | Expiry date |
|--|----------------|-------------|
| VIRCELL TOTAL SARS-CoV-2/ FluA/FluB/RSV CONTROL (SWAB) | 23MBTC031103-C | 2026-01-27 |

| 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 | Conde Ortega, Ana María | 09/11/2023 |  |