

# Certificate of Analysis

|                  |   |
|------------------|---|
| Product name     | AMPLIRUN® CLOSTRIDIUM DIFFICILE DNA CONTROL |
| Catalogue Number | MBC043-R                                    |
| Lot Number       | 24MBC043001-R                               |
| Expiry date      | 2027-01-01                                  |

| Kit contents            | Lot Number      | Expiry date |
|-------------------------|-----------------|-------------|
| VIRCELL CDI DNA CONTROL | 24MBC043101-R01 | 2027-01-01  |

| Analysis                                  | Specifications                            | Results                                   |
|---|---|---|
| QUANTIFICATION TEST (copies/μL)           | 10000 - 20000                             | 14133 ± 208                               |
| SPECIFIC AMPLIFICATION OF 1:1000 DILUTION | SPECIFIC AMPLIFICATION OF 1:1000 DILUTION | SPECIFIC AMPLIFICATION OF 1:1000 DILUTION |

## Identity test oligonucleotides

tcdB F ATAATGGTAGATTTATGATGGAACTAGGAA

tcdB R TCTTGATAAGCTGCCGCATATG

Hoegh, A.M., et al. (2013). J Clin Microbiol Infect Dis, 31(6):1073-1079

|   |              |            |
|---|--------------|------------|
| VIRCELL CONTROL RECONSTITUTION SOLUTION | 24MBCRS001-R | 2029-06-03 |
|---|--------------|------------|

This is to certify that the above kit performs in accordance with the Quality Control specifications of Vircell, S.L.  
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 | 04/07/2024 |  |