

Certificate of Analysis

Product name	AMPLIRUN® TOTAL CT/NG CONTROL (URINE)
Catalogue Number	MBTC003
Lot Number	23MBTC003002-C
Expiry date	2025-10-25

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL CT/NG CONTROL (URINE)	23MBTC003102-C	2025-10-25

Analysis	Specifications	Results
1. CHLAMYDIA TRACHOMATIS		
QUANTIFICATION TEST (copies/vial)	20000-50000	30000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2. NEISSERIA GONORRHOEAE		
QUANTIFICATION TEST (copies/vial)	20000 - 50000	40000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides 1. CHLAMYDIA TRACHOMATIS Ctr_F CATGAAACTCGTTCCGAAATAGAA Ctr_R TCAGAGCTTTACCTAACACGCATA Jaton K., et al. (2006) J Med Microbiol. 55(12):1667-74 2. NEISSERIA GONORRHOEAE NGO-16S.F TATCGGAACGTACCGGGTAGC NGO-16S.R GTATTACCGCGGCTGCTGGCA Chui L., et al. (2008). Clin Microbiol Infect. 14(5):473-9.		

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	Reca John, Isabel María	12/12/2023	