

Certificate of Analysis

Product name	AMPLIRUN® TOTAL CT/NG CONTROL (URINE)
Catalogue Number	MBTC003
Lot Number	23MBTC003001-C
Expiry date	2025-10-25

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL CT/NG CONTROL (URINE)	23MBTC003101-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	Ramírez Galdeano, Jose Francisco	09/05/2023	



Vircell, S.L.
 Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain T. +34 958 441 264
 info@vircell.com www.vircell.com