

# Certificate of Analysis

Product name	AMPLIRUN® TOTAL CT/NG CONTROL (URINE)
Catalogue Number	MBTC003
Lot Number	24MBTC003001-C
Expiry date	2026-08-05

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL CT/NG CONTROL (URINE)	24MBTC003101-C	2026-08-05

Analysis	Specifications	Results
<b>1. CHLAMYDIA TRACHOMATIS</b>		
QUANTIFICATION TEST (copies/vial)	20000-50000	20000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>2. NEISSERIA GONORRHOEAE</b>		
QUANTIFICATION TEST (copies/vial)	20000 - 50000	22000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <b>1. CHLAMYDIA TRACHOMATIS</b> Ctr_F CATGAAACTCGTTCCGAAATAGAA Ctr_R TCAGAGCTTTACCTAACACGCATA <i>Jaton K., et al. (2006) J Med Microbiol. 55(12):1667-74</i>  <b>2. NEISSERIA GONORRHOEAE</b> NGO-16S.F TATCGGAACGTACCGGGTAGC NGO-16S.R GTATTACCGCGGCTGCTGGCA <i>Chui L., et al. (2008). Clin Microbiol Infect. 14(5):473-9.</i>		

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	12/02/2024	