

Certificate of Analysis

Product name	AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)
Catalogue Number	MBTC024-R
Lot Number	23MBTC024003-R
Expiry date	2026-04-26

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL CT/NG/TV/MGE CONTROL (SWAB)	23MBTC024103-R	2026-04-26

Analysis	Specifications	Results
1. CHLAMYDIA TRACHOMATIS		
QUANTIFICATION TEST (copies/vial)	20000 - 50000	48000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2. NEISSERIA GONORRHOEA		
QUANTIFICATION TEST (copies/vial)	20000 - 50000	34000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3. TRICHOMONAS VAGINALIS		
QUANTIFICATION TEST (copies/vial)	20000-50000	22000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
4. MYCOPLASMA GENITALIUM		
QUANTIFICATION TEST (copies/vial)	20000-50000	34000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides 1. CHLAMYDIA TRACHOMATIS CTR-MOMP 1F GACTTTGTTTCGACCGTGTT CTR-MOMP 2R ACARAATACATCAAACGATCCCA <i>Hopkins, M.J., et al. (2010). Sex Transm Infect., 86(3):207-211</i> 2. NEISSERIA GONORRHOEA NGO-16S.F TATCGGAACGTACCGGGTAGC NGO-16S.R GTATTACCGCGGCTGCTGGCA <i>Boel, C.H., et al. (2005). J Clin Microbiol., 43: 2231-2235</i> 3. TRICHOMONAS VAGINALIS TVA F CATTGATAACGAAGCTCTTACGAT TVA R GCATGTTGTGCCGACATAACCAT3 <i>Hardick, J., et al. (2003). J Clin Microbiol., 41(12):5619-5622</i> 4. MYCOPLASMA GENITALIUM MGE-Mg219-F2 GTTCATTATGCGCACCAG MGE-Mg219-R2 ATCAACATGCCGCTCGATCC <i>Chalker, V.J.(2009). J Med Microbiol., 58(7):895-899</i>		

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	07/11/2023	