

Certificate of Analysis

Product name	AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)
Catalogue Number	MBTC022-R
Lot Number	25MBTC022001-R
Expiry date	2027-11-21

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)	25MBTC022101-R	2027-11-21

Analysis	Specifications	Results
1. BORDETELLA PERTUSSIS		
QUANTIFICATION TEST (copies/vial)	10000-25000	16000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
2. CHLAMYDOPHILA PNEUMONIAE		
QUANTIFICATION TEST (copies/vial)	10000-25000	16500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
3. CHLAMYDOPHILA PSITTACI		
QUANTIFICATION TEST (copies/vial)	10000-25000	20500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
4. COXIELLA BURNETII		
QUANTIFICATION TEST (copies/vial)	10000-25000	18500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
5. LEGIONELLA PNEUMOPHILA		
QUANTIFICATION TEST (copies/vial)	10000-25000	24500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
6. MYCOPLASMA PNEUMONIAE		
QUANTIFICATION TEST (copies/vial)	10000-25000	21500
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION

Identity test oligonucleotides

1. BORDETELLA PERTUSSIS

Pertussis toxin prom Fwd TTCGTCGTACAAAACCTCGA
 Pertussis toxin prom Rev GTTCATGCCGTGTTGGATTG
 Grogan, J.A., et al. (2011). J Med Microbiol, 60:722-729

2. CHLAMYDOPHILA PNEUMONIAE

CPN90 GGTCTCAACCCATCCGTGTCGG
 CPN91 TGCGGAAAGCTGATTCTACAGTT
 Hardick, J., et al. (2004). J Mol Diagn, 6(2):132-136

3. CHLAMYDOPHILA PSITTACI

F1-incA-Cpsi GCCATCATGCTTGTTCGTTT
 R1-incA-Cpsi CGGCGTGCCACTTGAGA
 Menard, A., et al. (2006). J Med Microbiol. 55(4):471-473

4. COXIELLA BURNETII

COBU-icdpr1_f GACCGACCCATTATCCCT
 COBU-icdpr1_r CGGCGTAGATCTCCATCCA
 De Bruin, A., et al. (2011). Appl Environ Microbiol, 77(18):6516-6523


5. LEGIONELLA PNEUMOPHILA

Leg-F-23S55 GTACTAATTGGCTGATTGTCTTGACC
 Leg-R-23S55 CCTGGCGATGACCTACTT TCG
 Kodani, M., et al. (2011). J Clin Microbiol, 49(6):2175-2182

6. MYCOPLASMA PNEUMONIAE

Mpn-3-identi.F TCTTCAGGCTCAGGTCAA
 Mpn-4-identi.R TTCCCGTATTAGTATTAGGC
 Pitcher, D., et al. (2006). J Med Microbiol, 55(Pt 2):149-55

*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	Tejera García, Hugo	05/06/2025	



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