

Certificate of Analysis

Product name	AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)
Catalogue Number	MBTC015
Lot Number	25MBTC015001-C
Expiry date	2026-11-21

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MTB INH RESISTANT (katG) CONTROL (SPUTUM)	25MBTC015101-C	2026-11-21

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	50000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f TCAAGGAGCACATCAGCC</i> <i>IS6110r TCACGGTTCAGGGTTAGC</i> <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</i>		

VIRCELL TOTAL MTB INH RESISTANT (inhA) CONTROL (SPUTUM)	25MBTC015201-C	2026-11-28
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	47000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f TCAAGGAGCACATCAGCC</i> <i>IS6110r TCACGGTTCAGGGTTAGC</i> <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</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 and part of Regulation (EU) 2017/746. 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	18/02/2025	