

Certificate of Analysis

Product name	AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)
Catalogue Number	MBTC014
Lot Number	24MBTC014003-C
Expiry date	2027-06-10

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MTB RIF RESISTANT (531) CONTROL (SPUTUM)	24MBTC014106-C	2027-06-10

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	39000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides IS6110f TCAAGGAGCACATCAGCC IS6110r TCACGGTTCAGGGTTAGC Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353		

VIRCELL TOTAL MTB RIF RESISTANT (526) CONTROL (SPUTUM)	24MBTC014206-C	2027-06-10
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	22000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides IS6110f TCAAGGAGCACATCAGCC IS6110r TCACGGTTCAGGGTTAGC Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353		

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	Conde Ortega, Ana María	20/12/2024	