

Certificate of Analysis

Product name	AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL
Catalogue Number	MBTC027
Lot Number	24MBTC027003-C
Expiry date	2026-07-19

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MTB CONTROL (SPUTUM)	24MBTC013104-C	2026-07-19

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	37000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</i>		

VIRCELL TOTAL MTB RIF RESISTANT (531) CONTROL (SPUTUM)	24MBTC014105-C	2026-07-19
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	34000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</i>		

VIRCELL TOTAL MTB RIF RESISTANT (526) CONTROL (SPUTUM)	24MBTC014205-C	2026-07-19
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	21000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</i>		


VIRCELL TOTAL MTB INH RESISTANT (katG) CONTROL (SPUTUM)	24MBTC015103-C	2026-07-19
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	50000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC <i>Sanjuan-Jimenez R., et al. (2013). PLoS One, 8(3): e58353</i>		

VIRCELL TOTAL MTB INH RESISTANT (inhA) CONTROL (SPUTUM)	24MBTC015203-C	2026-07-19
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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</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC <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	Conde Ortega, Ana María	01/10/2024	



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