

Certificate of Analysis

Product name	AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL
Catalogue Number	MBTC027
Lot Number	24MBTC027001-C
Expiry date	2025-09-14

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MTB CONTROL (SPUTUM)	24MBTC013101-C	2025-09-14

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	26000
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)	24MBTC014101-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	32000
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)	24MBTC014201-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	28000
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)	24MBTC015101-C	2025-09-14
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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 INH RESISTANT (inhA) CONTROL (SPUTUM)	24MBTC015201-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	38000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides <i>IS6110f</i> TCAAGGAGCACATCAGCC <i>IS6110r</i> TCACGGTTCAGGGTTAGC		

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.

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	23/01/2024	



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