

# Certificate of Analysis

<b>Product name</b>	AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL
<b>Catalogue Number</b>	MBTC027
<b>Lot Number</b>	24MBTC027002-C
<b>Expiry date</b>	2025-09-14

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MTB CONTROL (SPUTUM)	24MBTC013102-C	2025-09-14

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	26000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <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)	24MBTC014102-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	24000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <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)	24MBTC014202-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	21000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <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)	24MBTC015102-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	34000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <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)	24MBTC015202-C	2025-09-14
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	38000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> <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	26/03/2024	



Vircell, S.L.  
Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain T. +34 958 441 264  
info@vircell.com www.vircell.com