

# Certificate of Analysis

Product name	AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)
Catalogue Number	MBTC029
Lot Number	24MBTC029002-C
Expiry date	2025-10-12

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MGE CONTROL (SWAB)	24MBTC029102-C	2025-10-12

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	32000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> MGE-gap-605f GTGCTCGTGCTGCAGCTGT MGE-gap-794r GCTTGATTACTTGTTCACAGATGGAC Svenstrup H.F., et al. (2005). J Clin Microbiol. 43(7):3121-28.		

VIRCELL TOTAL MGE RESISTANT (A2059G) CONTROL (SWAB)	24MBTC029202-C	2025-10-12
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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> MGE-gap-605f GTGCTCGTGCTGCAGCTGT MGE-gap-794r GCTTGATTACTTGTTCACAGATGGAC Svenstrup H.F., et al. (2005). J Clin Microbiol. 43(7):3121-28.		

VIRCELL TOTAL MGE RESISTANT (A2058G) CONTROL (SWAB)	24MBTC029302-C	2025-10-12
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	42000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
<b>Identity test oligonucleotides</b> MGE-gap-605f GTGCTCGTGCTGCAGCTGT MGE-gap-794r GCTTGATTACTTGTTCACAGATGGAC Svenstrup H.F., et al. (2005). J Clin Microbiol. 43(7):3121-28.		

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	28/11/2024	