

Certificate of Analysis

Product name	AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)
Catalogue Number	MBTC029
Lot Number	23MBTC029002-C
Expiry date	2025-10-12

Kit contents	Lot Number	Expiry date
VIRCELL TOTAL MGE CONTROL (SWAB)	23MBTC029102-C	2025-10-12

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

VIRCELL TOTAL MGE RESISTANT (A2059G) CONTROL (SWAB)	23MBTC029202-C	2025-10-12
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	40000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides MGE-gap-605f GTGCTCGTGCTGCAGCTGT MGE-gap-794r GCTTGATTACTTGTCAACAGATGGAC Svenstrup H.F., et al. (2005). J Clin Microbiol. 43(7):3121-28.		

VIRCELL TOTAL MGE RESISTANT (A2058G) CONTROL (SWAB)	23MBTC029302-C	2025-10-12
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Analysis	Specifications	Results
QUANTIFICATION TEST (copies/vial)	20000-50000	41000
IDENTITY TEST	SPECIFIC AMPLIFICATION	SPECIFIC AMPLIFICATION
Identity test oligonucleotides MGE-gap-605f GTGCTCGTGCTGCAGCTGT MGE-gap-794r GCTTGATTACTTGTCAACAGATGGAC 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.

Vircell, S.L. manufactures under ISO 9001 and ISO 13485 certified quality systems.

Q.C. Testing by			
Position	Name	Date	Signature
Quality Control Department	Ramírez Galdeano, Jose Francisco	20/04/2023	



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