

# Certificate of Analysis

Product name	AMPLIRUN® TREPONEMA PALLIDUM DNA CONTROL
Catalogue Number	MBC109
Lot Number	25MBC109001-C
Expiry date	2027-06-26

Kit contents	Lot Number	Expiry date
VIRCELL TPA DNA CONTROL	25MBC109101-C01	2027-06-26

Analysis	Specifications	Results
QUANTIFICATION TEST (copies/μL)	700 - 2000	1427 ± 25
IDENTITY TEST	SPECIFIC AMPLIFICATION OF 1:100 DILUTION	SPECIFIC AMPLIFICATION OF 1:100 DILUTION

<b>Identity test oligonucleotides</b> TPA-ID-F1 TGC GCGTGTGCGAATGGTGTGGTC TPA-ID-R1 CACAGTGCTCAAAAACGCCTGCACG  Liu, H., et al. (2001). J Clin Microbiol, 39(5):1941-1946		
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VIRCELL CONTROL RECONSTITUTION SOLUTION	23MBCRS001-C	2028-10-13
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This is to certify that the above kit performs in accordance with the Quality Control specifications of Vircell, S.L. and fulfils the applicable general safety and performance requirements as established in 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	16/01/2025	