

Certificate of Analysis

Product Information

Product Name:	ResistancePlus® MG Positive Control	
Catalogue Number:	95001	
Product Description:	Amplification Control for Resistance Plus [®] MG assay (10 tests).	
Lot Number:	24020065	
Manufacture Date:	2024-09-27	
Expiry Date:	2026-04-23	
Storage Conditions:	-15°C to -25°C	

Test method:

ResistancePlus[®] MG Positive Control was tested with **Resistance**Plus[®] MG assay using the LightCycler 480II instrument with thermocycling conditions stated in the IFU. The amplification data was analysed using the **Resistance**Plus[®] MG (LC480) software for the interpretation of *M. genitalium* presence and 23S rRNA mutation status.

Results:

Test Samples	Specification FastFinder Software Interpretation	Result
MG, 23S rRNA wild type	M. genitalium detected, 23S rRNA mutation not detected	PASS
MG, 23S rRNA A2059G	M. genitalium detected, 23S rRNA mutation detected	PASS
MG, 23S rRNA A2058G	M. genitalium detected, 23S rRNA mutation detected	PASS
MG, 23S rRNA A2058C	M. genitalium detected, 23S rRNA mutation detected	PASS
MG, 23S rRNA A2058T	M. genitalium detected, 23S rRNA mutation detected	PASS

The Finished products were tested according to standard Quality Control methods. The results were verified against the design specifications, acceptance criteria and reviewed and approved by the Quality Department.

Quality Assurance Signature and Date:

QA Approval	Regine Citra Regine Citra (Oct 1, 2024 14:57 GMT+10)
-------------	--