

Certificate of Analysis

Product Information

Product Name:	ResistancePlus® MG S2A Positive Control	
Catalogue Number:	S2A-95004	
Product Description:	Amplification Control for ResistancePlus® MG FleXible assay (2 tests per positive control).	
Lot Number:	25030074	
Manufacture Date:	2025-10-09	
Expiry Date:	2027-01-01	
Storage Conditions:	-15°C to -25°C	

Test method:

ResistancePlus[®] MG S2A positive control was tested with **Resistance**Plus[®] MG FleXible assay using the GeneXpert[®] Instrument Systems with conditions from the **Resistance**Plus[®] MG FleXible ADF (Assay Definition File). The amplifications were analysed using the **GeneXpert[®] Dx** software for the interpretation of *M. genitalium* presence and 23S rRNA mutation status.

Results:

Test Samples	Specification	Result	
	Software Interpretation	Result	
MG, 23S rRNA wild type	M. genitalium detected 23S rRNA mutation not detected	PASS	
MG, 23S rRNA A2059G	M. genitalium, 23S rRNA mutation detected	PASS	
MG, 23S rRNA A2058G	M. genitalium, 23S rRNA mutation detected	PASS	
MG, 23S rRNA A2058C	M. genitalium, 23S rRNA mutation detected	PASS	
MG, 23S rRNA A2058T	M. genitalium, 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 13, 2025 10:13:43 GMT+11)
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