

Product Information

Product Name:	ResistancePlus[®] MG
Catalogue Number:	20001L-01
Product Description:	Detection of <i>Mycoplasma genitalium</i> and 4 mutations in 23S rRNA on the LightCycler 480II thermocycler. This product is approved for <i>in vitro</i> diagnostic use.
Lot Number:	25020040
Manufacture Date:	2025-06-12
Expiry Date:	2026-10-19
Storage Conditions:	-25°C to -15°C

Test method:

ResistancePlus[®] MG kit was tested with reference materials containing *M. genitalium* gene and 23S rRNA mutation sequences using the LC480 II with thermal cycling conditions stated in the IFU. The amplifications were analysed using the **ResistancePlus[®] MG (LC480)** software for the interpretation of *M. genitalium* presence and 23S rRNA mutation status.

Results:

Test Samples	Specification	Result
	Software Interpretation	
<i>M. genitalium</i> , 23S rRNA wild type - 20 copies	Detected: <i>M. genitalium</i>	PASS
<i>M. genitalium</i> , 23S rRNA A2059G - 20 copies	Detected: <i>M. genitalium</i> , 23S rRNA mutation	PASS
<i>M. genitalium</i> , 23S rRNA A2058G - 24 copies	Detected: <i>M. genitalium</i> , 23S rRNA mutation	PASS
<i>M. genitalium</i> , 23S rRNA A2058C - 20 copies	Detected: <i>M. genitalium</i> , 23S rRNA mutation	PASS
<i>M. genitalium</i> , 23S rRNA A2058T - 20 copies	Detected: <i>M. genitalium</i> , 23S rRNA mutation	PASS
Internal Control	Control Valid	PASS
No Template Control	Control Valid	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	 <small>Lexin Zhang (Jun 19, 2025 09:31 GMT+10)</small>
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