

## Product Information

Product Name:	<b>ResistancePlus<sup>®</sup> MG</b>
Catalogue Number:	<b>20001L-01</b>
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:	24040072
Manufacture Date:	2024-10-28
Expiry Date:	2026-01-13
Storage Conditions:	<b>-15°C to -25°C</b>

## Test method:

**ResistancePlus<sup>®</sup> 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<sup>®</sup> 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	<i>M. genitalium</i> detected, 23S rRNA mutation not detected.	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2059G - 20 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058G - 24 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058C - 20 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058T - 20 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	<b>PASS</b>
Internal Control	<i>M. genitalium</i> not detected. IC valid	<b>PASS</b>
<i>No Template Control</i>	Negative Control valid.	<b>PASS</b>

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 (Nov 7, 2024 17:26 GMT+11)
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