

## Product Information

Product Name:	<b>ResistancePlus<sup>®</sup> MG<sub>(550)</sub></b>
Catalogue Number:	<b>2000201</b>
Product Description:	Detection of <i>Mycoplasma genitalium</i> and 4 mutations in 23S rRNA on the ABI 7500 Fast. This product is approved for <i>in vitro</i> diagnostic use.
Lot Number:	25010001
Manufacture Date:	2025-01-10
Expiry Date:	2026-10-19
Storage Conditions:	<b>-15°C to -25°C</b>

## Test method:

**ResistancePlus<sup>®</sup> MG<sub>(550)</sub>** was tested with reference materials containing *M. genitalium* gene and 23S rRNA mutation sequences using the ABI 7500 Fast instrument with thermal cycling conditions stated in the IFU. The amplifications data was analysed using the **ResistancePlus<sup>®</sup> MG (7500)** 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	M. genitalium detected, 23S rRNA mutation not detected.	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2059G - 20 copies	M. genitalium, 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058G - 24 copies	M. genitalium, 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058C - 20 copies	M. genitalium, 23S rRNA mutation detected	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058T - 20 copies	M. genitalium, 23S rRNA mutation detected	<b>PASS</b>
Internal Control	M. genitalium not detected. IC valid	<b>PASS</b>
No Template Control	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	<u>Lexin Zhang</u> <small>Lexin Zhang [Jan 17, 2025 10:16 GMT+11]</small>
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