

Product Information

Product Name:	ResistancePlus[®] MG₍₆₇₅₎
Catalogue Number:	2000301
Product Description:	Detection of <i>Mycoplasma genitalium</i> and 4 mutations in 23S rRNA on the BioRad CFX96™. This product is approved for <i>in vitro</i> diagnostic use.
Lot Number:	26020026
Manufacture Date:	2026-04-17
Expiry Date:	2028-03-11
Storage Conditions:	-25°C to -15°C

Test method:

ResistancePlus[®] MG₍₆₇₅₎ is tested with reference materials containing *M. genitalium* gene and 23S rRNA mutation sequences using the BioRad CFX96™ instrument with thermal cycling conditions stated in the IFU. The amplification data was analysed using the **ResistancePlus[®] MG (CFX)** 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
<i>No Template Control</i>	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	<u>Lexin Zhang</u> <small>Lexin Zhang (Apr 29, 2026 13:36:04 GMT+10)</small>
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