

Product Information

Product Name:	ResistancePlus[®] MG₍₆₇₅₎
Catalogue Number:	2000301
Product Description:	Detection of <i>Mycoplasma genitalium</i> and 5 mutations in 23S rRNA on the BioRad CFX96™. This product is approved for <i>in vitro</i> diagnostic use.
Lot Number:	23020063
Manufacture Date:	2023-10-13
Expiry Date:	2024-09-30
Storage Conditions:	-15°C to -25°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 amplifications 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 - 30 copies	<i>M. genitalium</i> detected, 23S rRNA mutation not detected.	PASS
<i>M. genitalium</i> , 23S rRNA A2059G - 30 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	PASS
<i>M. genitalium</i> , 23S rRNA A2059C - 45 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	PASS
<i>M. genitalium</i> , 23S rRNA A2058G - 36 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	PASS
<i>M. genitalium</i> , 23S rRNA A2058C - 30 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	PASS
<i>M. genitalium</i> , 23S rRNA A2058T - 30 copies	<i>M. genitalium</i> , 23S rRNA mutation detected	PASS
Internal Control	<i>M. genitalium</i> not detected. IC valid	PASS
No Template Control	Negative 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>Regine Citra</u> Regine Citra (Oct 19, 2023 11:18 GMT+11)
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