


## Product Information

Product Name:	<b>ResistancePlus® MG Flexible</b>		
Catalogue Number:	<b>S2A-2000410</b>		
Product Description:	Detection of <i>Mycoplasma genitalium</i> and 4 mutations in 23S rRNA on the GeneXpert® Instrument Systems This product is approved for <i>in vitro</i> diagnostic use.		
Master Lot Number:	24030054		
Cart P/N:	2000410-CART		
Manufacture Date:	2024-08-23		
Expiry Date:	2025-11-09		
Storage Conditions:	<b>Reagent: -15°C to -25°C</b> <b>Cart: 2°C to 28°C</b>		
Reagent P/N:	<b>2000410-R</b>		

## Test method:

**ResistancePlus® MG Flexible** kit was tested with reference materials containing *M. genitalium* gene and 23S rRNA mutation sequences using the GeneXpert® Instrument Systems with conditions from the **ResistancePlus® MG Flexible** ADF (Assay Definition File). The amplifications were analysed using the **GeneXpert® Dx** 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 - 1000 copies	<i>M. genitalium</i> DETECTED, 23S rRNA mutation NOT DETECTED	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2059G - 1000 copies	<i>M. genitalium</i> DETECTED, 23S rRNA mutation DETECTED	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058G - 1000 copies	<i>M. genitalium</i> DETECTED, 23S rRNA mutation DETECTED	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058C - 1000 copies	<i>M. genitalium</i> DETECTED, 23S rRNA mutation DETECTED	<b>PASS</b>
<i>M. genitalium</i> , 23S rRNA A2058T - 1000 copies	<i>M. genitalium</i> DETECTED, 23S rRNA mutation DETECTED	<b>PASS</b>
Internal Control	<i>M. genitalium</i> NOT DETECTED, 23S rRNA mutation NOT DETECTED	<b>PASS</b>
No Template Control	INVALID	<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 (Sep 9, 2024 11:25 GMT+10)
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