

Product Information

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| Product Name: | ResistancePlus® MG Positive Control |
| Catalogue Number: | 95001 |
| Product Description: | Amplification Control for ResistancePlus® MG assay (10 tests). |
| Lot Number: | 23020019 |
| Manufacture Date: | 2023/03/16 |
| Expiry Date: | 2024/10/06 |
| Storage Conditions: | -15°C to -25°C |

Test method:


ResistancePlus® MG Positive Control was tested with **ResistancePlus®** MG assay using the LightCycler 480II instrument with thermocycling conditions stated in the IFU. The amplification data was analysed using the **ResistancePlus®** MG (LC480) software for the interpretation of *M. genitalium* presence and 23S rRNA mutation status.

Results:

| Test Samples | Specification | Result |
|------------------------|--|---------------|
| | FastFinder Software Interpretation | |
| MG, 23S rRNA wild type | M. genitalium detected, 23S rRNA mutation not detected | PASSED |
| MG, 23S rRNA A2059G | M. genitalium detected, 23S rRNA mutation detected | PASSED |
| MG, 23S rRNA A2059C | M. genitalium detected, 23S rRNA mutation detected | PASSED |
| MG, 23S rRNA A2058G | M. genitalium detected, 23S rRNA mutation detected | PASSED |
| MG, 23S rRNA A2058C | M. genitalium detected, 23S rRNA mutation detected | PASSED |
| MG, 23S rRNA A2058T | M. genitalium detected, 23S rRNA mutation detected | PASSED |

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:

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| QA Approval |  <small>Ivy Chau (Mar 21, 2023 11:51 GMT+11)</small> |
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