

**Product Information**

|                      |   |
|----------------------|---|
| Product Name:        | <b>ResistancePlus<sup>®</sup> MG</b>  |
| Catalogue Number:    | <b>20001L-01</b>  |
| Product Description: | Detection of <i>Mycoplasma genitalium</i> and 4 mutations in 23S rRNA on the LightCycler 480II thermocycler. This product is approved for <i>in vitro</i> diagnostic use. |
| Lot Number:          | 25030066  |
| Manufacture Date:    | 2025-09-04  |
| Expiry Date:         | 2026-10-19  |
| Storage Conditions:  | <b>-25°C to -15°C</b>   |

**Test method:**

**ResistancePlus<sup>®</sup> MG** kit was tested with reference materials containing *M. genitalium* gene and 23S rRNA mutation sequences using the LC480 II with thermal cycling conditions stated in the IFU. The amplifications were analysed using the **ResistancePlus<sup>®</sup> MG (LC480)** 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 | <b>Detected:</b> <i>M. genitalium</i>                     | <b>PASS</b> |
| <i>M. genitalium</i> , 23S rRNA A2059G - 20 copies    | <b>Detected:</b> <i>M. genitalium</i> , 23S rRNA mutation | <b>PASS</b> |
| <i>M. genitalium</i> , 23S rRNA A2058G - 24 copies    | <b>Detected:</b> <i>M. genitalium</i> , 23S rRNA mutation | <b>PASS</b> |
| <i>M. genitalium</i> , 23S rRNA A2058C - 20 copies    | <b>Detected:</b> <i>M. genitalium</i> , 23S rRNA mutation | <b>PASS</b> |
| <i>M. genitalium</i> , 23S rRNA A2058T - 20 copies    | <b>Detected:</b> <i>M. genitalium</i> , 23S rRNA mutation | <b>PASS</b> |
| Internal Control                                      | <b>Control Valid</b>                                      | <b>PASS</b> |
| No Template Control                                   | <b>Control Valid</b>                                      | <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:**

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| QA Approval | <br><small>Lexin Zhang (Sep 9, 2025 10:54:39 GMT+10)</small> |
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