

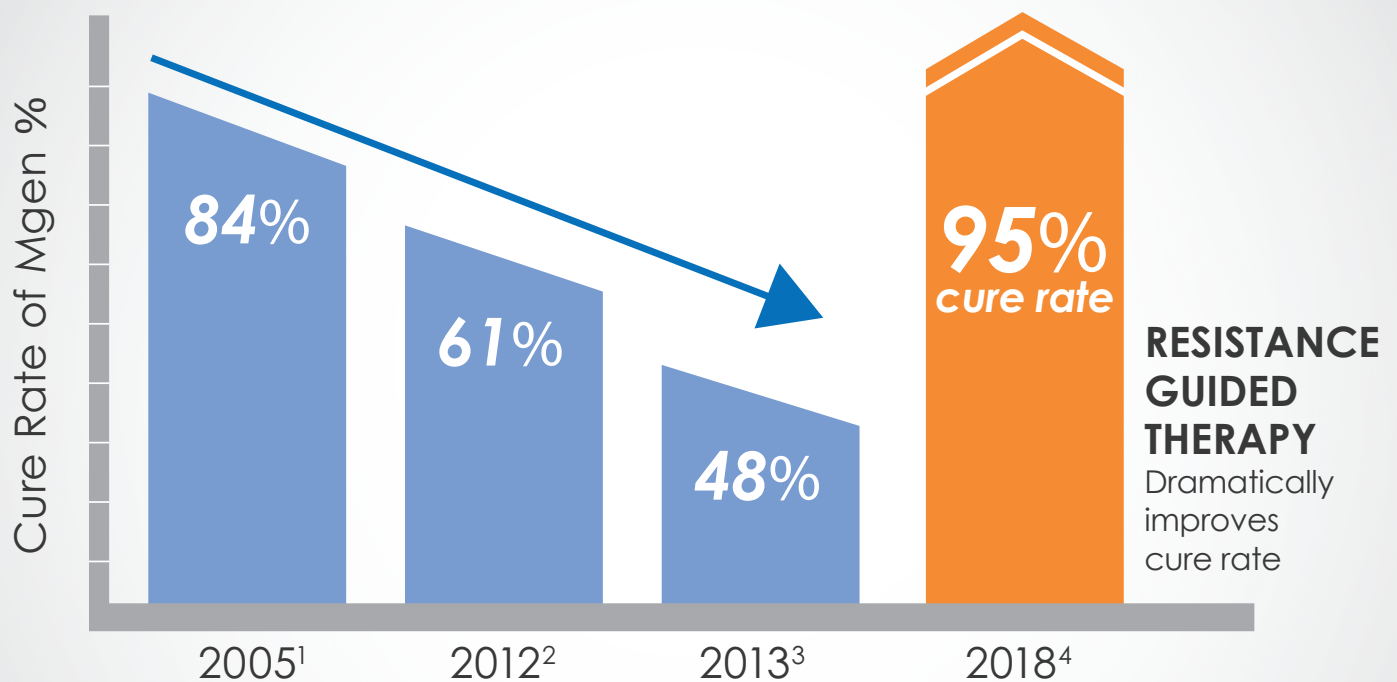
# ResistancePlus<sup>®</sup> MG

*M. genitalium* (Mgen) + macrolide resistance

## Enabling Resistance Guided Therapy

### Empirical Treatment

Rapid fall in cure rates of Mgen due to resistance



## Resistance Guided Therapy Increases Cure Rate<sup>4</sup>

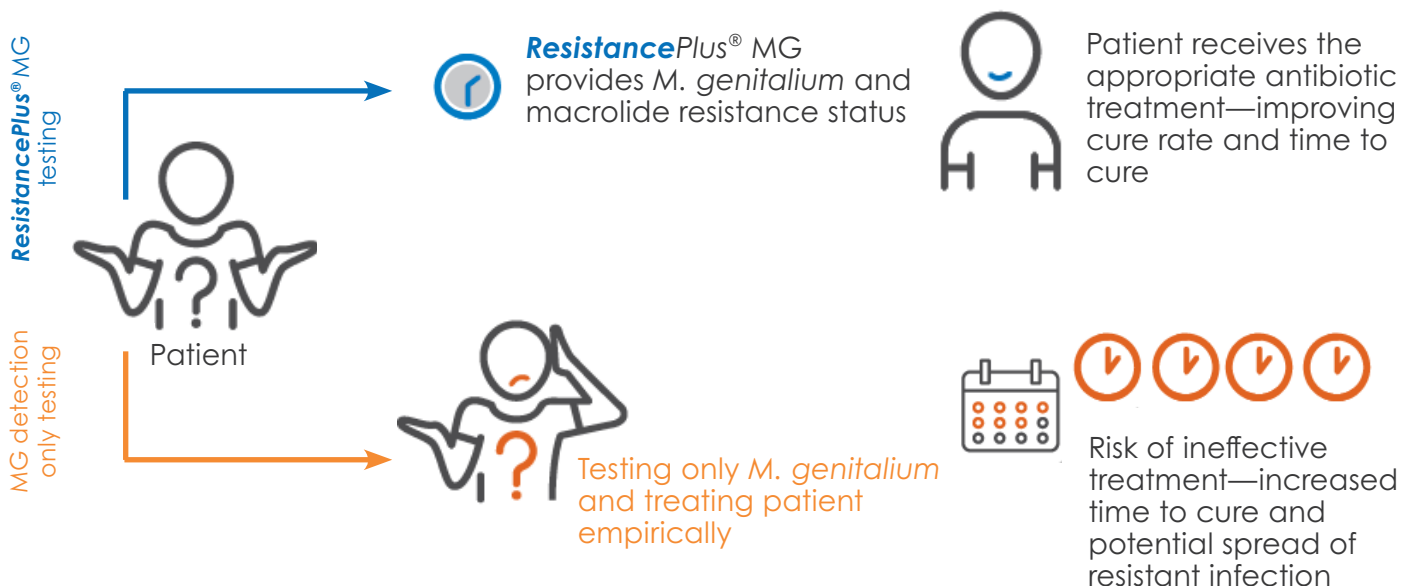
- ▶ **ResistancePlus<sup>®</sup> MG** is an IVDR Certified product.
- ▶ Resistance Guided Therapy is clinically demonstrated to improve patient cure rate and overall patient management.<sup>4</sup>
- ▶ Detection of macrolide resistance can reduce time to cure, preventing ongoing transmission.<sup>4</sup>
- ▶ Macrolide resistance testing is **recommended by International, British, French, US, and Australian guidelines** on Mgen infection.<sup>5-10</sup>

## Resistance & *Mycoplasma genitalium*

- ▶ *Mycoplasma genitalium* (Mgen) is a sexually transmitted infection causing nongonococcal urethritis (NGU) and cervicitis, and is associated with pelvic inflammatory disease (PID)<sup>4</sup>
- ▶ Prevalence of Mgen infections in the general population ranges from 1-3%, with an increased incidence in men with NGU (15-25%)<sup>8,11</sup>
- ▶ Mgen is more prevalent than gonorrhoea and presents clinically similar symptoms to chlamydia – leading to potential mistreatment and increased resistance<sup>12,13</sup>
- ▶ Increasing rates of antibiotic resistance coupled with lower prevalence in general population mean current guidelines do not recommend screening for Mgen in asymptomatic populations<sup>5,7,8,9</sup>

## Resistance & *Mycoplasma genitalium*

**ResistancePlus**<sup>®</sup> MG provides therapeutic guidance recommendations, enabling clinicians to make informed treatment decisions. Resistance guided therapy is clinically demonstrated to increase overall patient cure rate.<sup>4</sup>



*“Although the subclinical nature of Mgen in the rectum questions its significance, the high prevalence seen at this site could be a potential source of onward urethral transmission. Future work should assess the need for appropriate screening and treatment of MG infection in MSM, particularly those with HIV infection and high-risk sexual behaviour.”<sup>14</sup>*

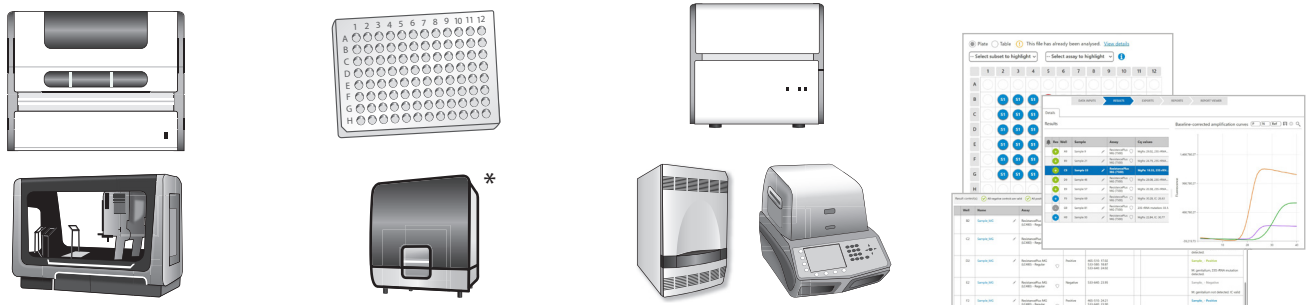
# ResistancePlus<sup>®</sup> MG

## A flexible and cost effective solution for your laboratory

- ▶ A single well test, combining Mgen detection and macrolide resistance – a clear advantage compared with detection-only tests
- ▶ Easily implemented into your existing workflow, reduce time to resistance data
- ▶ Pack sizes to suit your laboratory throughput, minimising reagent wastage

## Easy set up, Simple Analysis, Fast Results

Implement the complete SpeedX solution and get from sample to answer faster.



90  
min

Sample extraction  
(Automated)

60  
min

PCR setup (Manual)  
\*Automated set-up  
protocols available

70  
min

Amplification with  
**ResistancePlus<sup>®</sup> MG**

10  
min

Data interpretation  
(Automated)

## SpeedX Analysis **ResistancePlus<sup>®</sup> MG**

The complete solution includes validated software for automated result calling and simple sample processing. Supporting rapid, routine diagnostics with quality control, searchable databases, audit-trail, and user traceability. High security and GDPR compliant with LIS compatibility.

**ResistancePlus®** MG is a multiplex qPCR test for detection of Mgen and four azithromycin resistance markers, validated for male and female urine and vaginal swabs.<sup>15</sup> Powered by proprietary **PlexPCR®** technologies demonstrating improved multiplex performance compared with other probe-based tests.<sup>16</sup>

#### Single-well **PlexPCR®** Test

Channel	Target
1	<i>M. genitalium</i> (MgPa)
2	23S rRNA (A2058T, A2058C, A2058G, A2059G)
3	Internal Control

#### Demonstrated clinical performance<sup>15</sup>

	MG Detection	Resistance Markers
Sensitivity	98.8%	96.3%
Specificity	100%	91.3%

Validated with male and female urine and vaginal swabs.<sup>15</sup>

**Validated sample types:** validated with male and female urine and vaginal swabs, from symptomatic and asymptomatic patients.<sup>15</sup>

**Validated collection devices:** neat urine, dry swab, multiCollect Specimen Collection Kit (Abbott), Aptima® Urine Specimen Collection Kit (Hologic), Aptima® Multitest swab specimen collection kit (Hologic), DeltaSwab ViCUM® 2 mL + Standard flocced swab (Deltalab), Vacumed® Urine without preservative (FL medical), Regular FLOQSwab™ in 1 mL of UTM™ (Copan), cobas® PCR media (Roche).<sup>15</sup>

#### **ResistancePlus®** MG Positive Control

One control covers all your needs – Mgen detection and 4 mutations conferring macrolide resistance.

Product	Compatible	Size	Cat#
<b>ResistancePlus®</b> MG*	LC480 II	100 reactions	20001L-01
<b>ResistancePlus®</b> MG* <sub>(675)</sub>	CFX96 Dx / Touch	100 reactions	2000301
<b>ResistancePlus®</b> MG* <sub>(550)</sub>	ABI 7500 Fast Dx	100 reactions	2000201
<b>ResistancePlus®</b> MG Positive Control	All platforms	10 reactions	95001

\*Not for sale in USA.

**References:** 1. Bradshaw CS et al. PLOS ONE 2008;3(11):e3618. 2. Bissessor M et al. Clin Infect Dis. 2015;60(8):1228-36. 3. Read TRH et al. Clin Infect Dis. 2017;64(3):250-256. 4. Read TRH et al. CID 2019; 68(4):554-560 5. Jensen J et al. 2021 European guideline on the management of Mycoplasma genitalium infections. J Eur Acad Dermatol Venereol. 2022 May;36(5):641-650. 6. Horner PJ et al. 2016 European guideline on the management of non-gonococcal urethritis. 7. Australian STI Management Guidelines – Mycoplasma genitalium 2018. 8. Soni S et al. British Association for Sexual Health and HIV national guideline for the management of infection with Mycoplasma genitalium (2018) 9. HAS (Haute Autorité de Santé) evaluation report available at [https://www.has-sante.fr/jcms/p\\_3356494/fr/diagnostic-biologique-des-mycoplasmes-urogenitaux-dans-les-infections-genitales-basses-rapport-d-evaluation](https://www.has-sante.fr/jcms/p_3356494/fr/diagnostic-biologique-des-mycoplasmes-urogenitaux-dans-les-infections-genitales-basses-rapport-d-evaluation) 10. Centers for Disease Control and Prevention STI Treatment Guidelines, 2021 Mycoplasma genitalium. Available online at: <https://www.cdc.gov/std/treatment-guidelines/mycoplasma-genitalium.htm> 11. Baumann L et al. Sex Transm Infect 2018;94:255-262. 12. Manhart LE et al. Am J Public Health. 2007;97(6):1118-25. 13. Bradshaw CS et al. J Infect Dis. 2017;216 (suppl\_2):S412-S419. 14. Soni S. Sex Transm Infect. 2010 Feb;86(1):21-4. 15. **ResistancePlus®** MG Instructions for use 16. Tan LY et al. PLOS ONE. 2017; 12(1): e0170087.

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