

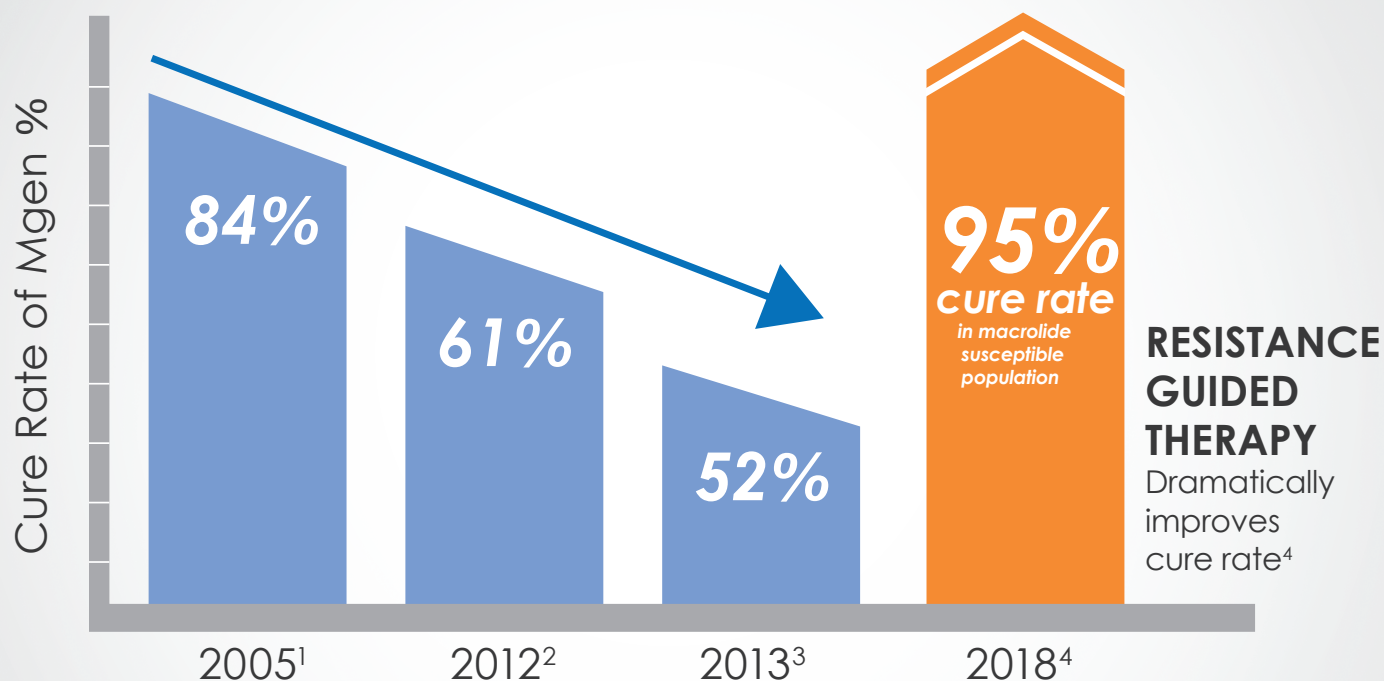
# ResistancePlus<sup>®</sup> MG

*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>1</sup>

- ▶ 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>5</sup>
- ▶ Macrolide resistance testing is **recommended by International, British, and Australian guidelines** on Mgen infection.<sup>6-9</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 (10-20%).<sup>9,10</sup>
- ▶ Mgen is more prevalent than gonorrhoea and presents clinically similar symptoms to chlamydia – leading to potential mistreatment and increased resistance.<sup>11,12</sup>
- ▶ Mgen is commonly detected in rectal samples, is often asymptomatic, and exhibits high rates of macrolide resistance.<sup>5,9,13</sup>

**7.6x**

Rates of Mgen **significantly higher** in HIV-positive MSM compared to HIV-negative<sup>13</sup>

**Rectal Mgen**

**8.9%**

Anorectum is the **most common** infection site for Mgen<sup>5</sup>

**Rectal resistance**

**75.6%**

High percentage of anorectal infections harbour **macrolide resistance**<sup>5</sup>

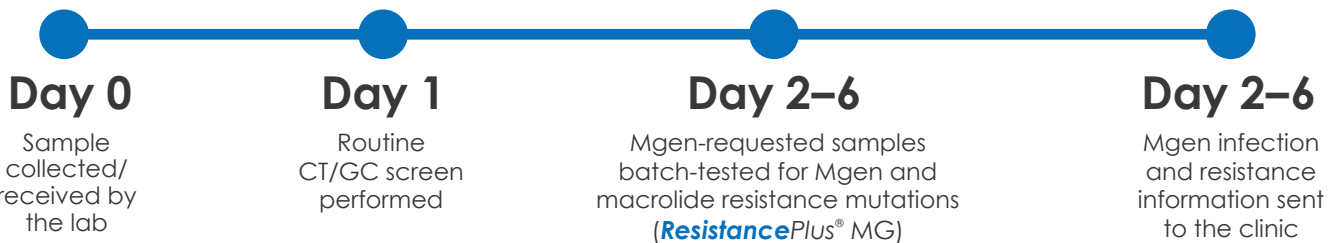
*“Although the subclinical nature of Mgen in the rectum questions its significance, the high prevalence seen at this site could be a potential source of onward urethral transmission. Future work should assess the need for appropriate screening and treatment of MG infection in MSM, particularly those with HIV infection and high-risk sexual behaviour.”<sup>13</sup>*

# ResistancePlus<sup>®</sup> MG

## A flexible and cost effective solution for your laboratory

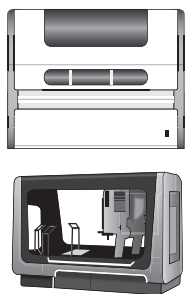
- ▶ A single well test, combining Mgen detection and macrolide resistance – a clear advantage compared with detection-only tests.
- ▶ Easily implemented into your existing workflow, with minimal disruption.
- ▶ Pack sizes to suit your laboratory throughput, minimising reagent wastage.
- ▶ Positive controls available as well as amplification control material to enable testing from pre-extracted samples.

### Simple workflow with minimal disruption or resource requirements



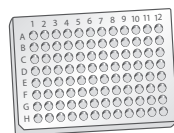
### Easy set up, Simple Analysis, Fast Results<sup>†</sup>

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



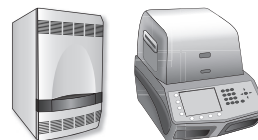
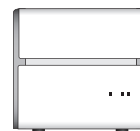
**90  
min**

Sample extraction  
(Automated)



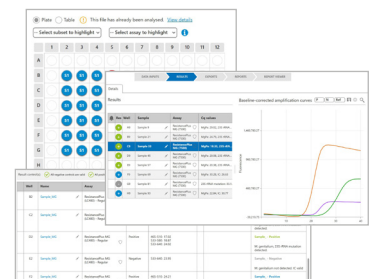
**60  
min**

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



**70  
min**

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



**10  
min**

Data interpretation  
(Automated)

Test	Resistance Detection	Time Of Sample To Answer
ResistancePlus <sup>®</sup> MG	Yes	3 hours 10 minutes
Competitor D	Yes	7 hours 10 minutes
Competitor F	No	3 hours 10 minutes
Competitor S	No	4 hours

† Total time calculated using over-lapping workflow of manual and automated steps.

**ResistancePlus®** MG is a multiplex qPCR test for detection of Mgen and five azithromycin resistance markers, validated for a range of specimen types including anorectal swabs.<sup>14</sup> Powered by proprietary **PlexPCR®** technologies demonstrating improved multiplex performance compared with other probe-based tests.<sup>15</sup>

#### Single-well **PlexPCR®** Test

Channel	Target
1	<i>M. genitalium</i> (MgPa)
2	23S rRNA (A2058T, A2058C, A2058G, A2059C, A2059G)
3	Internal Control

#### Demonstrated clinical performance<sup>3</sup>

	MG Detection	Resistance Markers
Sensitivity	98%	92.5%
Sensitivity	100%	100%

Validated with urine, multiple swabs (anal, rectal, cervical, endocervical, vaginal, urethral, pharyngeal) and extracts (using **PlexPCR®** Amplification Control).<sup>11</sup>

### SpeedX Analysis **ResistancePlus®** 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 Positive Control

One control covers all your needs – Mgen detection and 5 mutations conferring macrolide resistance.

Product	Compatible	Size	Cat#
<b>ResistancePlus®</b> MG*	LC480 II	100 reactions	20001L-01
		25 reactions	2000125
	ABI 7500/ 7500 Fast/Dx	100 reactions	2000201
		25 reactions	2000225
	CFX96 IVD/ CFX96 Touch	100 reactions	2000301
		25 reactions	2000325
<b>ResistancePlus®</b> MG Positive Control	All platforms	10 reactions	95001
<b>PlexPCR®</b> Amplification Control	All platforms	400 reactions	90002

**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. Couldwell DL et al. Sex Transm Infect. 2018 Mar 22. pii: sextrans-2017-053480. doi: 10.1136 6. Jensen J, Cusini, M, Gomberg, M. 2016 European guideline on Mycoplasma genitalium infections. 7. Horner PJ et al. 2016 European guideline on the management of non-gonococcal urethritis. 8. Australian STI Management Guidelines – Mycoplasma genitalium 2018. 9. Soni S et. al. British Association for Sexual Health and HIV national guideline for the management of infection with Mycoplasma genitalium (2018) 10. Baumann L et al. Sex Transm Infect 2018;94:255-262. 11. Manhart LE et al. Am J Public Health. 2007;97(6):1118-25. 12. Bradshaw CS et al. J Infect Dis. 2017;216 (suppl\_2):S412-S419. 13. Soni S. Sex Transm Infect. 2010 Feb;86(1):21-4. 14. **ResistancePlus®** MG Instructions for use 15. Tan LY et al. PLOS ONE. 2017; 12(1): e0170087

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