

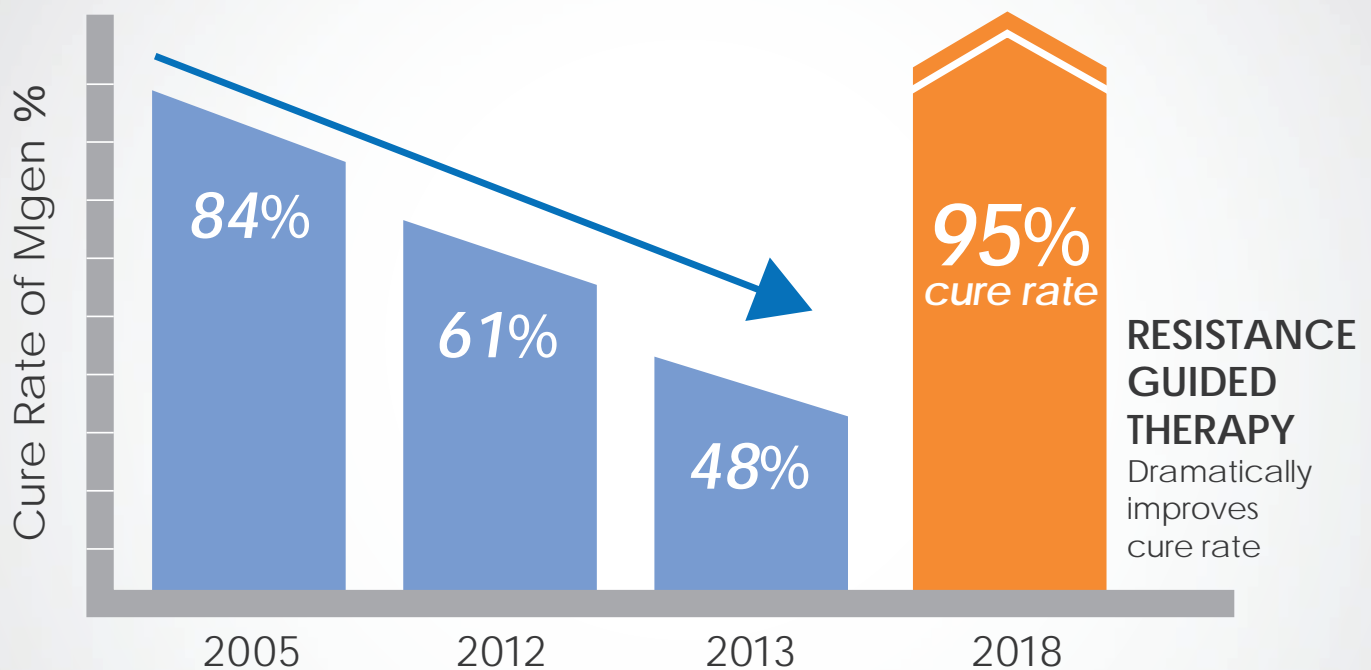
ResistancePlus[®] MG

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 Rate¹

- ▶ Resistance Guided Therapy is clinically demonstrated to improve patient cure rate and overall patient management.¹
- ▶ Detection of macrolide resistance can reduce time to cure, preventing ongoing transmission.²
- ▶ Macrolide resistance testing is **recommended by International, British, and Australian guidelines** on Mgen infection.³⁻⁶

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).¹
- ▶ Prevalence of Mgen infections in the general population ranges from 1-3%, with an increased incidence in men with NGU (10-20%).^{6,7}
- ▶ Mgen is more prevalent than gonorrhoea and presents clinically similar symptoms to chlamydia – leading to potential mistreatment and increased resistance.^{8,9}
- ▶ Mgen is commonly detected in rectal samples, is often asymptomatic, and exhibits high rates of macrolide resistance.^{2,6,10}

Rectal Mgen

8.9%

Anorectum is the **most common** infection site for Mgen²

Rectal resistance

76%

High percentage of anorectal infections harbour **macrolide resistance**

HIV+ MSM

88%

Rates of Mgen **significantly higher** in HIV-positive MSM compared to other STIs¹⁰

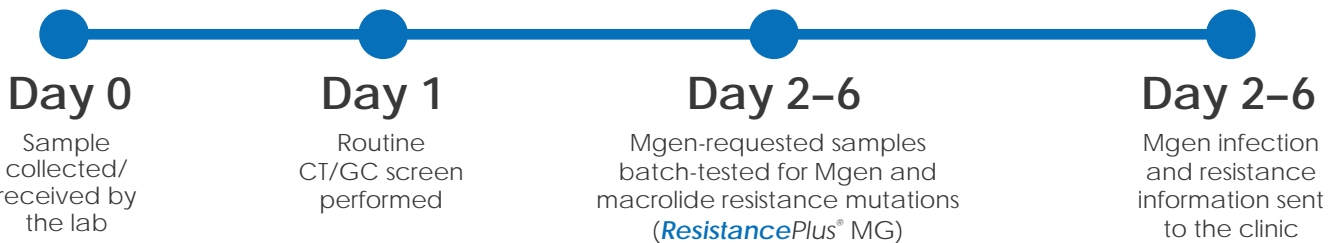
“Although the subclinical nature of Mgen in the rectum questions its significance, the high prevalence seen at this site could be a potential source of onward urethral transmission. Future work should assess the need for appropriate screening and treatment of MG infection in MSM, particularly those with HIV infection and high-risk sexual behaviour.”¹⁰

ResistancePlus® MG

A flexible and cost effective solution for your laboratory

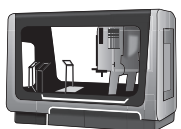
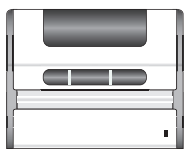
- ▶ A single well test, combining Mgen detection and macrolide resistance – a clear advantage compared with detection-only tests.
- ▶ Easily implemented into your existing workflow, with minimal disruption.
- ▶ Pack sizes to suit your laboratory throughput, minimising reagent wastage.
- ▶ Positive controls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

Simple workflow with minimal disruption or resource requirements



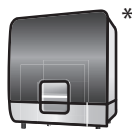
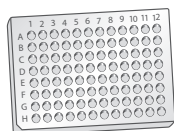
Easy set up, Simple Analysis, Fast Results†

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



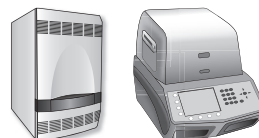
90
min

Sample extraction
(Automated)



60
min

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



70
min

Amplification with
ResistancePlus® MG



10
min

Data interpretation
(Automated)

Test	Resistance Detection	Time Of Sample To Answer
ResistancePlus® 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.¹¹ Powered by proprietary **PlexPCR**[®] technologies demonstrating improved multiplex performance compared with other probe-based tests.¹²

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 performance³

	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).¹¹

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#
ResistancePlus [®] 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
ResistancePlus [®] MG Positive Control	All platforms	10 reactions	95001
PlexPCR [®] Amplification Control	All platforms	400 reactions	90002

References: 1. Read TRH et al. CID 2019; 68(4):554-560 2. Couldwell DL et al. Sex Transm Infect. 2018 Mar 22. pii: sextrans-2017-053480. doi: 10.1136 3. Jensen J, Cusini, M, Gomberg, M. 2016 European guideline on Mycoplasma genitalium infections. 4. Homer PJ et al. 2016 European guideline on the management of non-gonococcal urethritis. 5. Australian STI Management Guidelines – Mycoplasma genitalium 2018. 6. Soni S et al. British Association for Sexual Health and HIV national guideline for the management of infection with Mycoplasma genitalium (2018) 7. Baumann L et al. Sex Transm Infect 2018;94:255-262. 8. Manhart LE et al. Am J Public Health. 2007;97(6):1118-25. 9. Bradshaw CS et al. J Infect Dis. 2017;216 (suppl_2):S412-S419. 10. Soni S. Sex Transm Infect. 2010 Feb;86(1):21-4. 11. **ResistancePlus**[®] MG Instructions for use 12. Tan LY et al. PLOS ONE. 2017; 12(1): e0170087 *Not for sale in USA. **ResistancePlus**[®] MG kits are developed and manufactured by **SpeedX** Pty Ltd, Sydney. **PlexPCR**[®], **ResistancePlus**[®] & **SpeedX**[®] are registered trademarks of **SpeedX** Pty Ltd. Other copyright and trademarks are the property of the respective owners. **SpeedX** Pty. Ltd. products may be covered by one or more local or foreign patents. Visit www.plexpcr.com/ patents for comprehensive patent information.

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