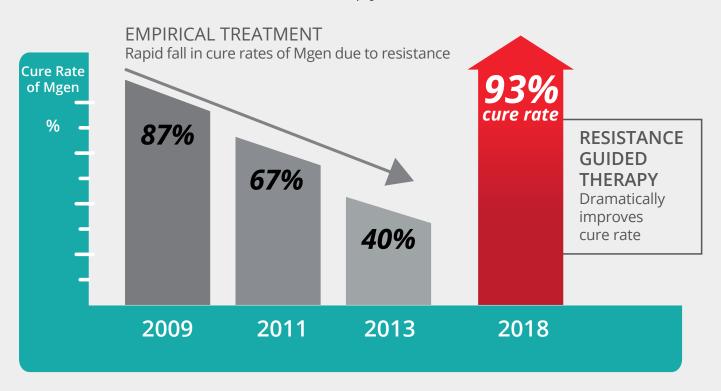
ResistancePlus® MG

M. genitalium (Mgen) + macrolide resistance

Enabling Resistance Guided Therapy

Resistance Guided Therapy Increases Cure Rate¹



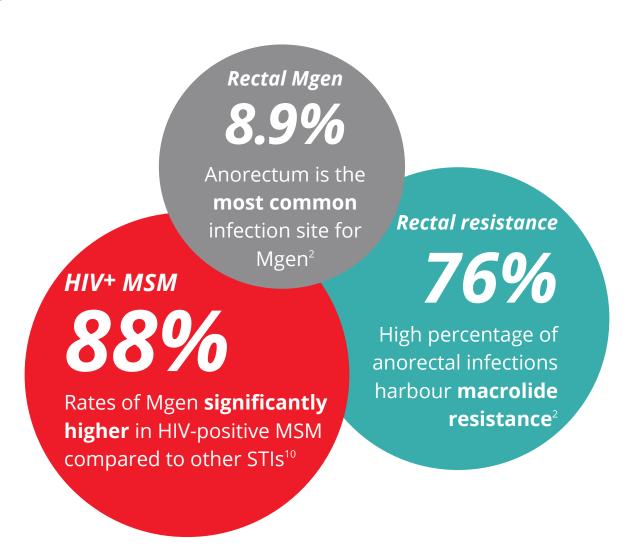
- § Resistance Guided Therapy is clinically demonstrated to improve patient cure rate and overall patient management.¹
- § Detection of macrolide resistance can reduce time to cure, preventing ongoing transmission.²
- § Macrolide resistance testing is **recommended by International**, **British**, **and 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}



"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

Resistance Plus® 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



Day 1

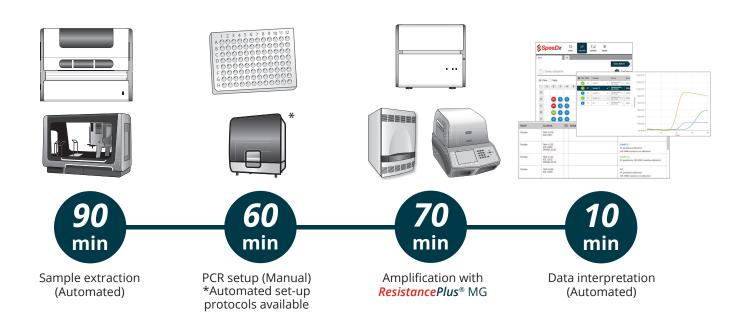
Routine CT/GC screen performed **Day 2-6**

Mgen-requested samples batch-tested for Mgen and macrolide resistance mutations (*ResistancePlus*® MG) **Day 2-6**

Mgen infection and resistance information sent to the clinic

Easy set up, Simple Analysis, Fast Results[†]

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



Test	Resistance Detection Time of Sample to Answer	
Resistance Plus® MG	Yes	3 hours 10 minutes
Competitor D	Yes	7 hours 10 minutes
Competitor F	No	3 hours 30 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 **Plex**PCR® Test

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

Demonstrated clinical performance^{1,11}

	MG Detection	Resistance Markers
Sensitivity	98%	92.5%
Specificity	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#
	LC480 II	100 reactions	20001L-01
		25 reactions	2000125
ResistancePlus® MG*	ABI 7500/ 7500 Fast/Dx	100 reactions	2000201
		25 reactions	2000225
	CFX96 IVD/ CFX96 Touch	100 reactions	2000301
		25 reactions	2000325
Resistance Plus® MG Positive Control	All platforms	10 reactions	95001
PlexPCR® Amplification Control	All platforms	400 reactions	90002

1. Read TRH. et al CID June 5 2018 doi.org/10.1093/cid/ciy477. 2. Couldwell DL. et al. Sex Transm Infect. 2018 Mar 22. pii: sextrans-2017-053480. doi: 10.1136 3. Jensen, M Cusini, M Gomberg. 2016 European guideline on Mycoplasma genitalium infections. 4. Horner PJ et al. 2016 European guideline on the management of non-gonococcal urethritis. 5. Australian STI Management Guidelines – *Mycoplasma genitalium* 2018. 6. Soni 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):5412-5419. 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. Published online 23 Jan 2017 *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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