

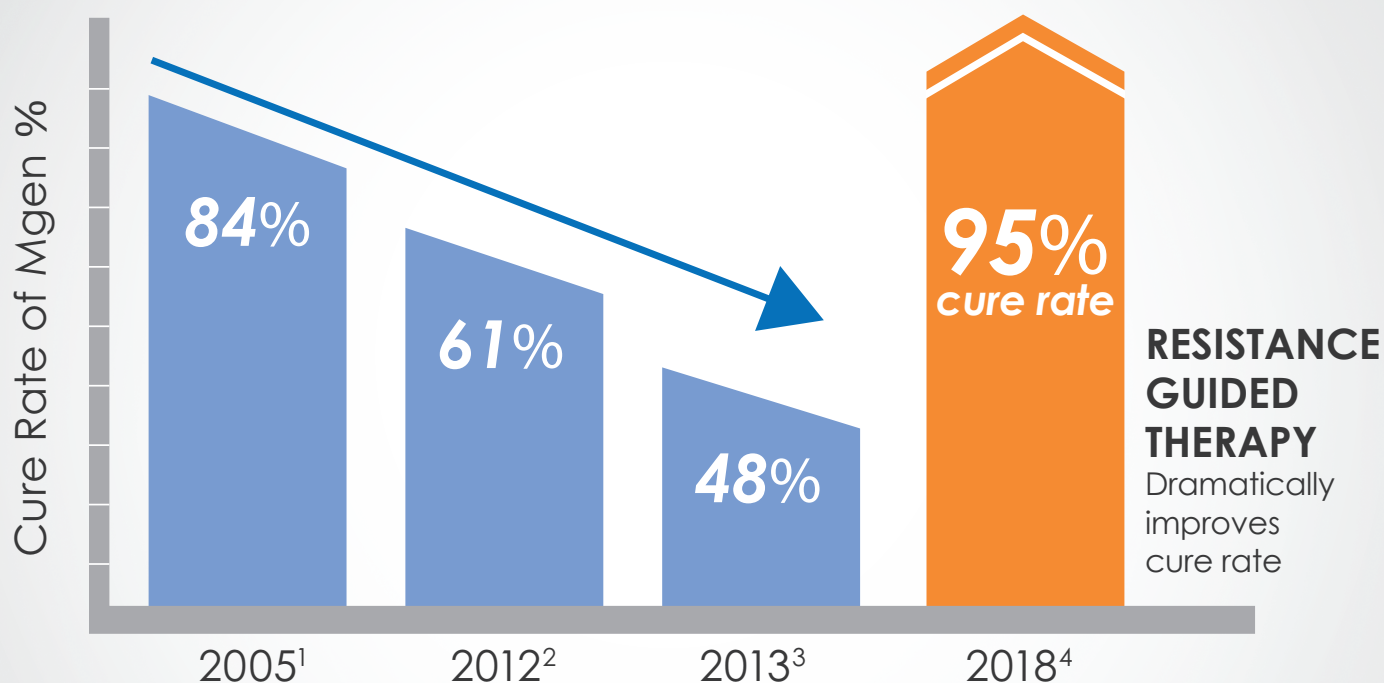
ResistancePlus[®] MG

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 Rate⁴

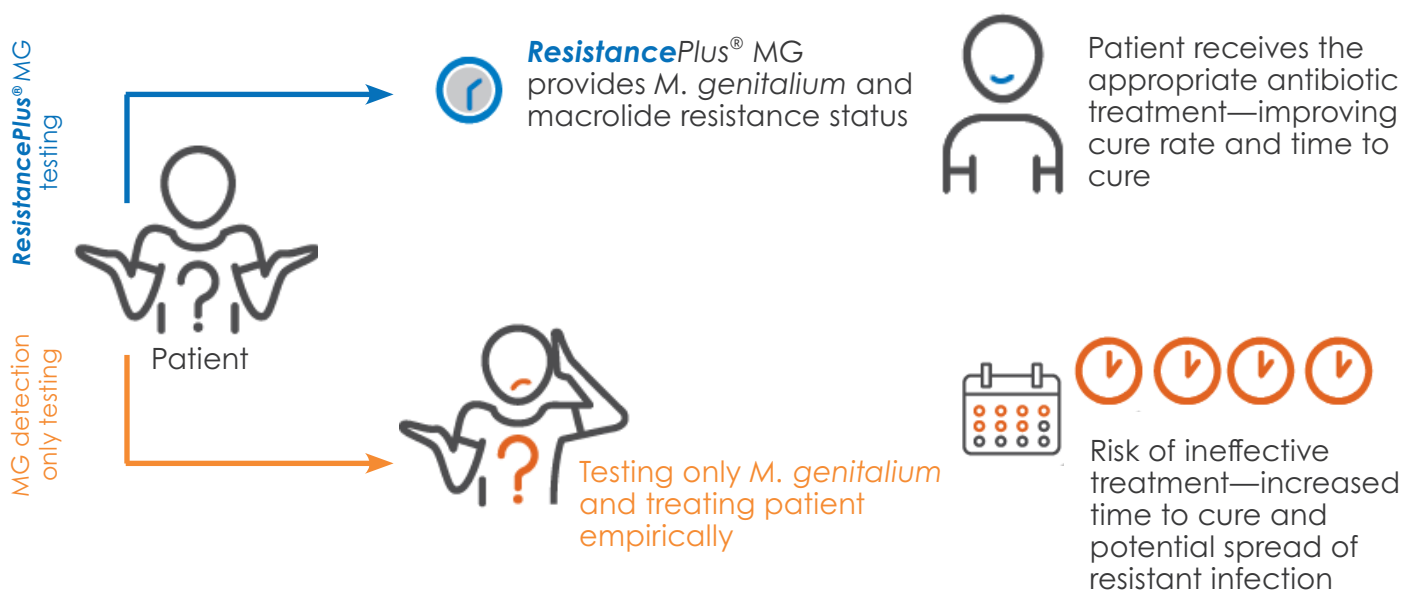
- ▶ Resistance Guided Therapy is clinically demonstrated to improve patient cure rate and overall patient management.⁴
- ▶ Detection of macrolide resistance can reduce time to cure, preventing ongoing transmission.⁴
- ▶ Macrolide resistance testing is **recommended by International, British, French, US, and Australian guidelines** on Mgen infection.⁵⁻¹⁰

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)⁴
- ▶ Prevalence of Mgen infections in the general population ranges from 1-3%, with an increased incidence in men with NGU (15-25%)^{8,11}
- ▶ Mgen is more prevalent than gonorrhoea and presents clinically similar symptoms to chlamydia – leading to potential mistreatment and increased resistance^{12,13}
- ▶ Increasing rates of antibiotic resistance coupled with lower prevalence in general population mean current guidelines do not recommend screening for Mgen in asymptomatic populations^{5,7,8,9}

Resistance & *Mycoplasma genitalium*

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



*"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."*¹⁴

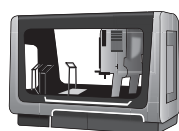
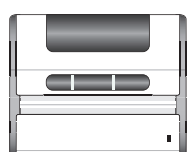
ResistancePlus® MG

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, reduce time to resistance data
- ▶ Pack sizes to suit your laboratory throughput, minimising reagent wastage

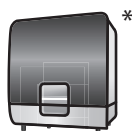
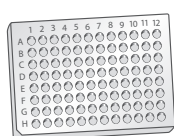
Easy set up, Simple Analysis, Fast Results†

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



**90
min**

Sample extraction
(Automated)



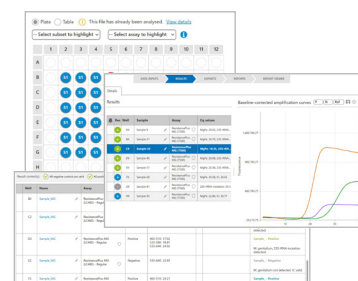
**60
min**

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



**70
min**

Amplification with
ResistancePlus® 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

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.

† 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.¹⁵ Powered by proprietary **PlexPCR®** technologies demonstrating improved multiplex performance compared with other probe-based tests.¹⁶

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^{4,15}

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

Validated with urine, multiple swabs (anal, rectal, cervical, endocervical, vaginal, urethral, penile, penile meatal and pharyngeal swabs) and extracts (using RPMG REFLEX software).¹⁵

Validated sample types: male and female urine, and anal, rectal, cervical, endocervical, vaginal, urethral, penile, penile meatal and pharyngeal swabs, from symptomatic and asymptomatic patients, and pre-extracted samples in a reflex workflow.¹⁵

Validated collection devices: neat urine, dry swab, multiCollect Specimen Collection Kit (Abbott), Aptima® Urine Specimen Collection Kit (Hologic), Aptima® Unisex Swab Specimen Collection Kit (Hologic), DeltaSwab ViCUM® 2 ml + Standard flocked swab (Deltalab), Vacumed® Urine without preservative (FL medical), Regular FLOQSwab™ in 1 ml of UTM™ (Copan), cobas® PCR media (Roche).¹⁵

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
	ABI 7500 / 7500 Fast / Dx	100 reactions	2000201
	CFX96 IVD / CFX96 Touch	100 reactions	2000301
ResistancePlus® MG Positive Control	All platforms	10 reactions	95001

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 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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