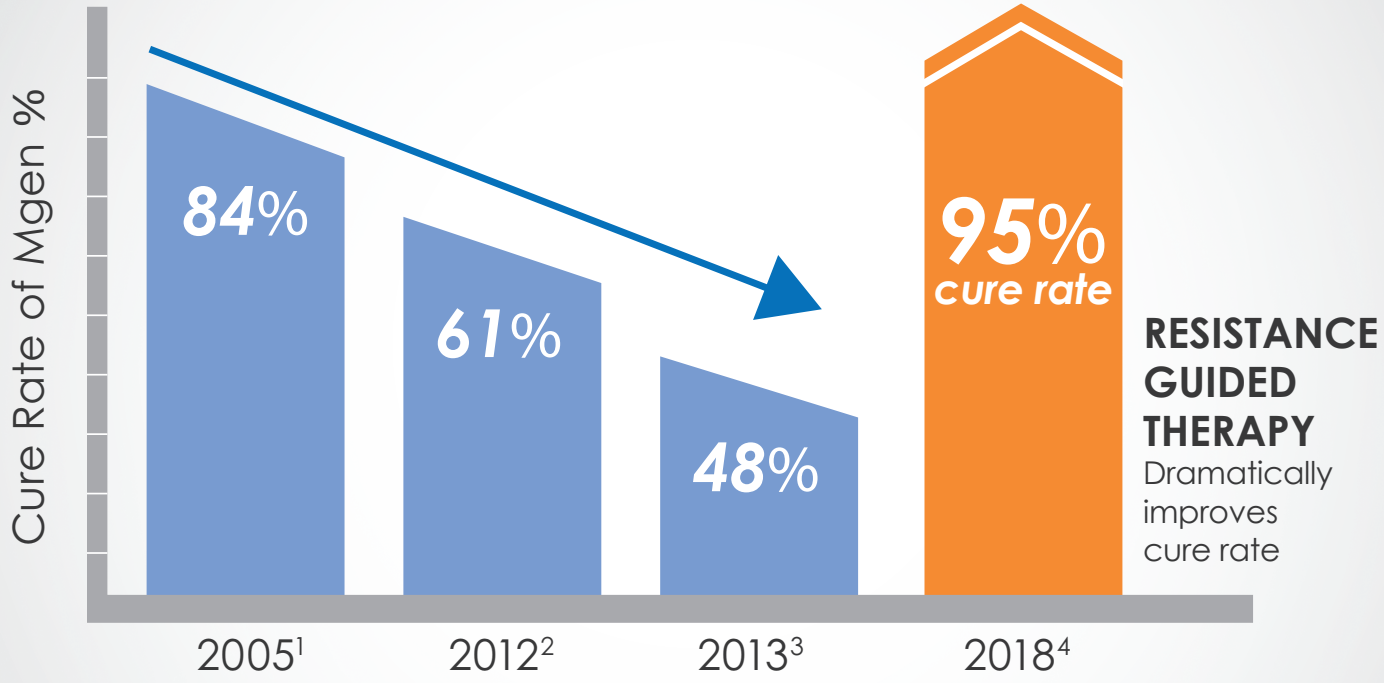
ResistancePlus® MG

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 Rate[4]

- ***Resistance**Plus*® MG is an IVDR Certified product.
- 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]

CE IVD UK CA

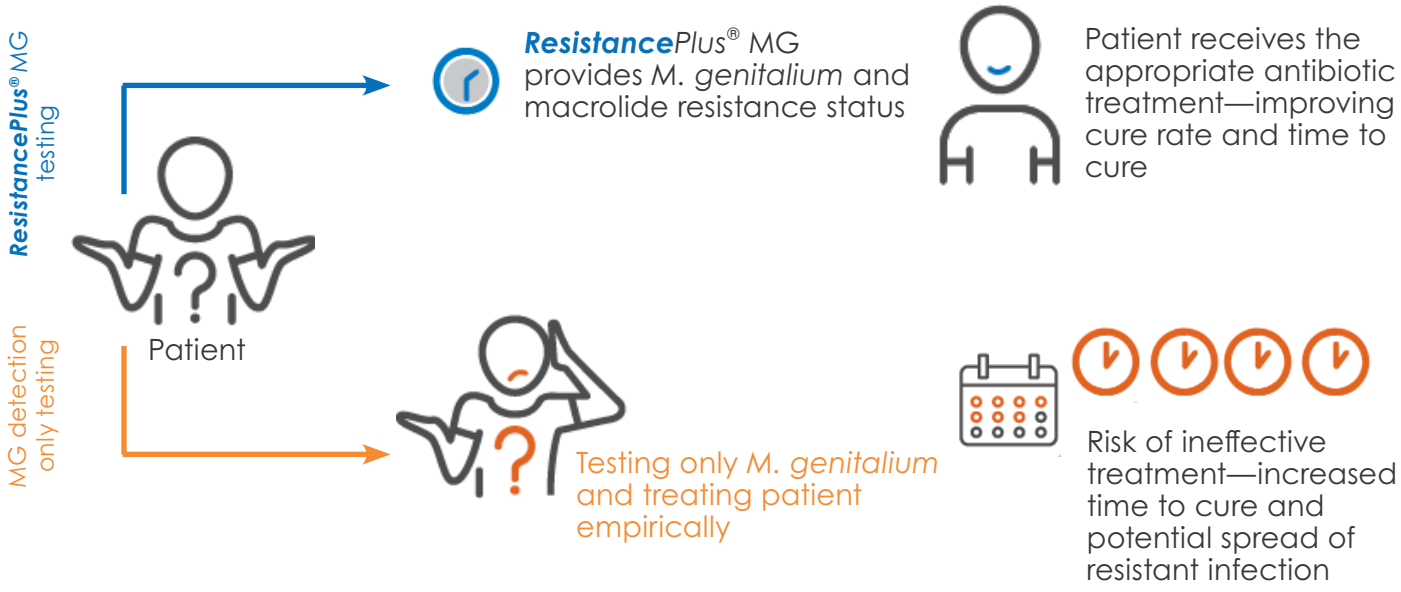
SpeeDx

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*

Resistance*Plus*® 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]

SpeeDx

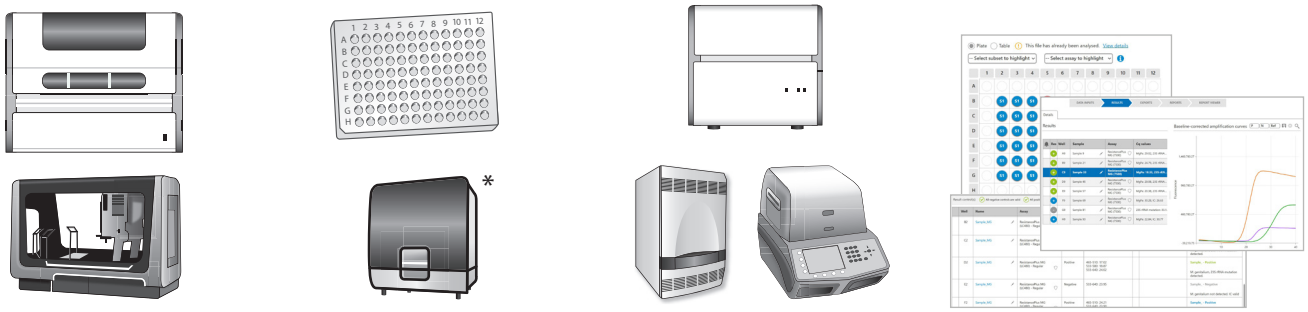
ResistancePlus® MG

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 ***Resistance****Plus*® MG

10 min
Data interpretation (Automated)

SpeeDx Analysis ***Resistance****Plus*® 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.

Resistance*Plus*® MG is a multiplex qPCR test for detection of Mgen and four azithromycin resistance markers, validated for male and female urine and vaginal swabs.[15] Powered by proprietary ***Plex****PCR*® technologies demonstrating improved multiplex performance compared with other probe-based tests.[16]

Single-well ***Plex****PCR*® Test

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

Demonstrated clinical performance[15]

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

Validated with male and female urine and vaginal swabs.[15]

Validated sample types: validated with male and female urine and vaginal swabs, from symptomatic and asymptomatic patients.[15]

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 flocked swab (Deltalab), Vacumed® Urine without preservative (FL medical), Regular FLOQSwab™ in 1 mL of UTM™ (Copan), cobas® PCR media (Roche).[15]

Resistance*Plus*® MG Positive Control

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

Product	Compatible	Size	Cat#
Resistance*Plus*® MG* *	LC480 II	100 reactions	20001L-01
Resistance*Plus*® MG*(675)	CFX96 Dx / Touch	100 reactions	2000301
Resistance*Plus*® MG*(550)	ABI 7500 Fast Dx	100 reactions	2000201
Resistance*Plus*® 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 **10.** Centers for Diesease Control and Prevention STI Treatment Guidelines, 2021 Mycoplasma genitalium. Available online at: https://www.cdc.gov/std/treatment-guidelines/mycoplasmagenitalium.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.** ***Resistance****Plus*® MG Instructions for use **16.** Tan LY *et al*. PLOS ONE. 2017; 12(1): e0170087.

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