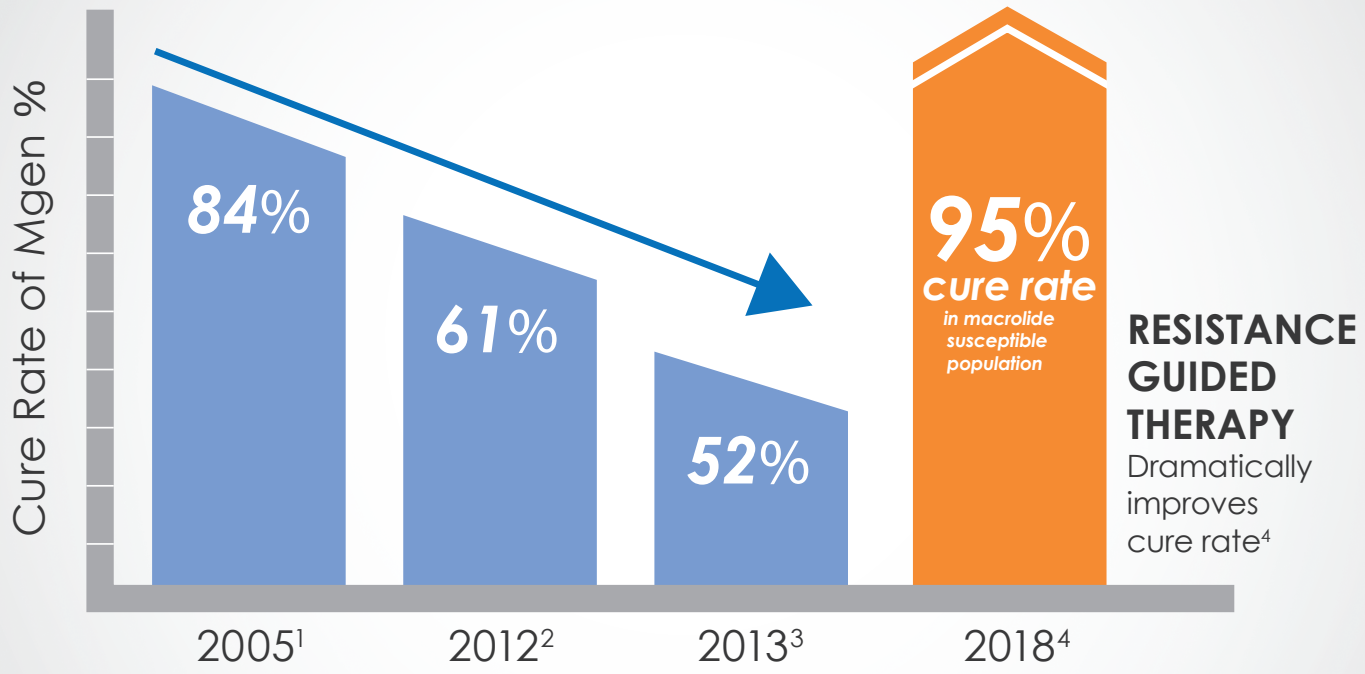
ResistancePlus® MG

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 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.[5]
- Macrolide resistance testing is **recommended by British and European guidelines** on Mgen infection.[6-8]

CE IVD*

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%,[9] with an increased incidence in men with NGU (10-35%).[6]
- Mgen is more prevalent than gonorrhoea[10] and presents clinically similar symptoms to chlamydia – leading to potential mistreatment and increased resistance.[11]
- Mgen is commonly detected in rectal samples,[5,8,12] is often asymptomatic,[5,12] and exhibits high rates of macrolide resistance.[5,12]

7.6x Rates of Mgen **significantly higher** in HIV-positive MSM compared to HIV-negative[12]

Rectal Mgen

8.9% Anorectum is the **most common** infection site for Mgen[5]

Rectal resistance

75.6% High percentage of anorectal infections harbour **macrolide resistance**[5]

"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." [12]

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, 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 0
Sample collected/ received by the lab

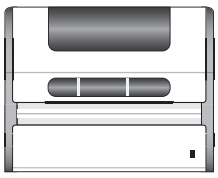
Day 1
Routine CT/GC screen performed

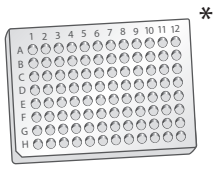
Day 2–6
Mgen-requested samples batch-tested for Mgen and macrolide resistance mutations (*ResistancePlus*® MG)

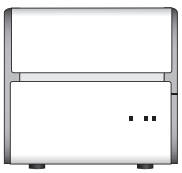
Day 2–6
Mgen infection and resistance information sent to the clinic

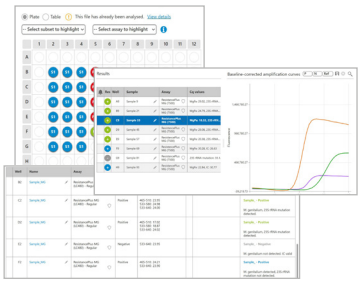
Easy set up, Simple Analysis, Fast Results†

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









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.

***Resistance**Plus*® 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.[13] Powered by proprietary ***Plex**PCR*® technologies demonstrating improved multiplex performance compared with other probe-based tests.[14]

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[3,13]

	MG Detection	Resistance Markers
Sensitivity	96.4%	97.1%
Sensitivity	100%	93.8%

Validated with urine, multiple swabs (anal, rectal, cervical, endocervical, vaginal, urethral, pharyngeal) and extracts (using ***Plex**PCR*® Amplification Control).[13]

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 Positive Control

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

Product	Compatible	Size	Cat#
***Resistance**Plus*® MG*	LightCycler® 480 Instrument II	100 reactions	09257233001
***Resistance**Plus*® MG Positive Control	LightCycler® 480 Instrument II	10 reactions	09256717001
***Plex**PCR*® Amplification Control	LightCycler® 480 Instrument II	400 reactions	09256687001

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. *Clin Infect Dis*. 2019;68(4):554-560 **5.** Couldwell DL et al. *Sex Transm Infect*. 2018;94(6)406-410. **6.** Jensen J et al. *J Eur Acad Dermatol Venereol*. 2016;30:1650-1656 **7.** Horner P J et al. *Int J STD AIDS*. 2016 Oct;27(11):928-37 **8.** Soni S et. al. *Int J STD AIDS*. 2019 Sep;30(10):938-950 **9.** Baumann L et al. *Sex Transm Infect* 2018;94:255-262. **10.** Manhart LE et al. *Am J Public Health*. 2007;97(6):1118-25. **11.** Bradshaw CS et al. *J Infect Dis*. 2017;216 (suppl_2):S412-S419. **12.** Soni S. *Sex Transm Infect*. 2010 Feb;86(1):21-4. **13. ResistancePlus®** MG Instructions for use **14.** Tan LY et al, *PLOS ONE*. 2017; 12(1): e0170087

*Not for sale in USA.

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