

ResistancePlus®
MG FlexiBle



ResistancePlus® MG FlexiBle

M. genitalium + macrolide resistance

ResistancePlus® MG FlexiBle offers simultaneous detection and identification of *Mycoplasma genitalium* and azithromycin (macrolide) resistance in ~ 2 hours to support appropriate treatment decisions at the earliest opportunity for improved patient management.

ResistancePlus® MG Flexible

ResistancePlus® MG Flexible brings **accuracy and simplicity** to your lab in combination with GeneXpert® Systems* for a complete solution. Detect both *M. genitalium* and macrolide resistance markers in a single test and help overcome the challenges of treating *M. genitalium* due to high levels of azithromycin resistance.⁴



The Challenges:

- ▶ *M. genitalium* is a recognised Sexually Transmitted Infection (STI), treated syndromically, with clinical presentation similar to that of *Chlamydia trachomatis*.¹
- ▶ Prevalence of *M. genitalium* infections in the general population ranges from 1-3%, with an increased incidence in men with non-gonococcal urethritis (NGU) (10-20%).²
- ▶ *M. genitalium* infections contribute to 10–35% of non-chlamydial non-gonococcal urethritis in men and in women, it is also associated with cervicitis and pelvic inflammatory disease (PID).³
- ▶ *M. genitalium* treatment is challenging due to high levels of macrolide resistance.⁴

The Need:

- ▶ Macrolide resistance testing is **recommended by international and local guidelines** on management of *M. genitalium* infections.^{2,3,5-7}
- ▶ Macrolide resistance testing can guide appropriate treatment choice enabling Resistance Guided Therapy.⁵
- ▶ Resistance Guided Therapy is clinically demonstrated to **improve patient cure rate** and overall patient management.⁸
- ▶ Fast detection of macrolide resistance can reduce time to cure, preventing ongoing transmission.⁸

The Solution:

- ▶ **ResistancePlus® MG Flexible** detects both *M. genitalium* and macrolide resistance in ~ 2 hours.
- ▶ **ResistancePlus® MG Flexible** offers a fast and simple solution in combination with GeneXpert® Systems. Easily implemented into your existing workflow or setting, with minimal preparation time ~ 10 mins.
- ▶ High performance test validated on **wide range of specimen types** and collection devices, including urine and swabs (vaginal, cervical, rectal).^{**}

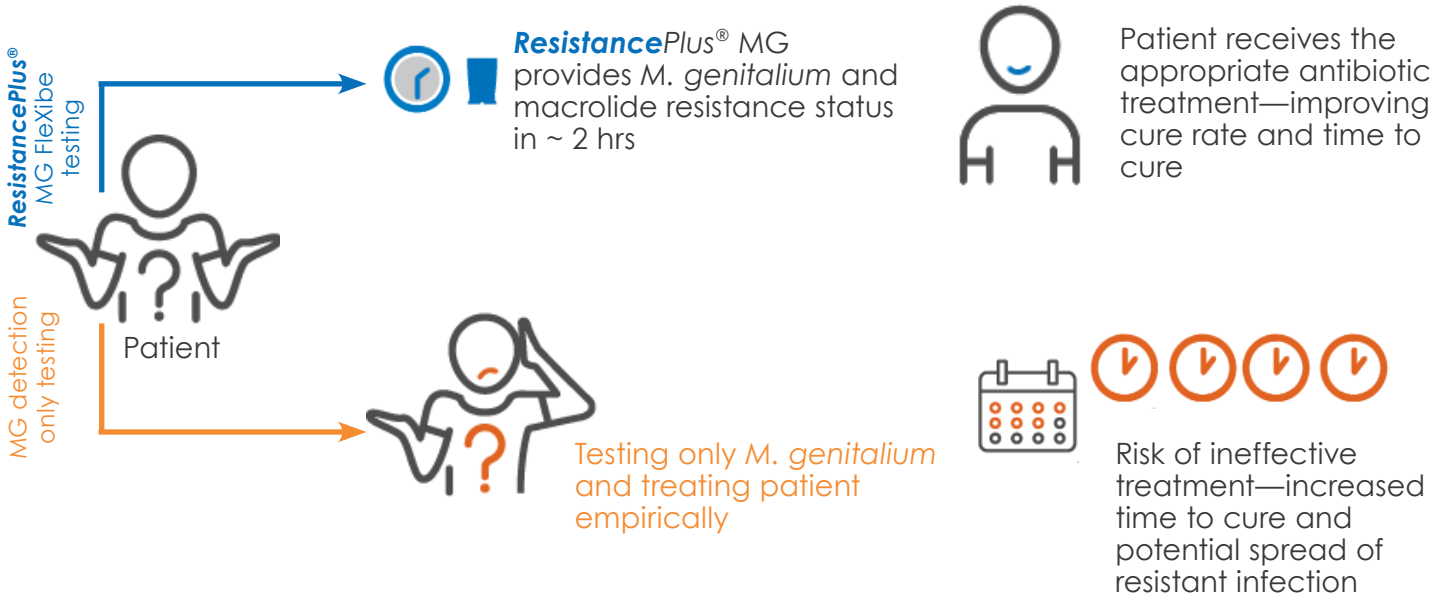
* CE-IVD. In Vitro Diagnostic Medical Device.

Validated specimens: male and female urine, vaginal swab, cervical swab, rectal swab, urethral swab, from symptomatic and asymptomatic patients. Validated collection kits: Xpert® Vaginal/Endocervical and Xpert® Urine Specimen Collection Kits, Neat urine, Regular FLOQSwab™ in 3 ml of UTM™ media, cobas PCR collection media. For details refer to the **ResistancePlus® MG Flexible Instructions For Use (IF-IV0012)

Impact on Patient Pathway

Improving patient management

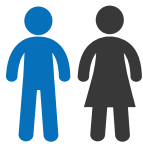
ResistancePlus® MG Flexible provides therapeutic guidance recommendations, enabling clinicians to make informed treatment decisions. Resistance guided therapy is clinically demonstrated to increase overall patient cure rate.⁸



ResistancePlus® MG Flexible

Validated on a wide range of sample types including **rectal**, male and female **urine**, and common collection **swab** kits including Xpert® CT/NG Vaginal/Endocervical Specimen Collection kit and Xpert® CT/NG Urine Specimen Collection Kit.**

Clinical Performance[†]



	MG Detection	Resistance Markers
Sensitivity	100%	92.9%
Specificity	96.3%	100%



Male urine



Female vaginal swab

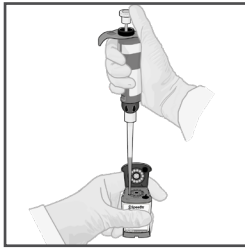
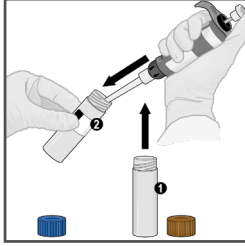
	Expected MG negative	Expected MG positive, wild type	Expected MG positive, mutant
Male urine	33/33	1/1	3/4
Female vaginal swab	22/22	6/6	10/10

[†] All performance results at 95% confidence interval. For details refer to the **ResistancePlus®** MG Flexible Instructions For Use (IF-IV0012)

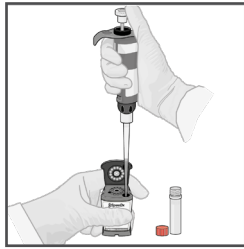
Simple Implementation into Existing Workflow

Easy preparation — Hands-on time < 10 min

1. Prepare reaction mix



2. Transfer samples and Internal Control



3. Insert Cartridge and start test, results in ~2 hours



Product	Size	Cat#
ResistancePlus ® MG Flexible	10 tests	S2A-2000410
ResistancePlus ® MG S2A Positive Control	10 tests	S2A-95004

ResistancePlus[®] MG Flexible

Improve patient management. Test for macrolide resistance.

CE IVD In Vitro Diagnostic Medical Device
Not available in all countries

References:

1. Manhart LE and Kay N. *Mycoplasma genitalium*: Is It a Sexually Transmitted Pathogen? *Curr. Infect. Dis. Reps.* 2010; 12(4):306-313.
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3. Jensen et al. 2016 European guideline on *Mycoplasma genitalium* infections. *J Eur Acad Dermatol Venereol.* 2016 Oct;30(10):1650-1656.
4. Unemo, M et al. Antimicrobial-resistant sexually transmitted infections: gonorrhoea and *Mycoplasma genitalium*. *Nat Rev Urol.* 2017 Mar;14(3):139-152.
5. Horner PJ et al. 2016 European guideline on the management of non-gonococcal urethritis. *Int J STD AIDS.* 2016 Oct;27(11):928-37.
6. Australian STI Management Guidelines – *Mycoplasma genitalium* 2018. <http://www.sfi.guidelines.org.au/sexually-transmissible-infections/mycoplasma-genitalium>
7. Groupe Infectiologie Dermatologique et Infections Sexuellement GRIDIST and Société Française de Dermatologie – Press Release. Available online at: <https://www.sfdermato.org/actualites/communique-commun-gridist-et-sfd.html>
8. Read TRH et al. Outcomes of Resistance-guided Sequential Treatment of *Mycoplasma genitalium* Infections: A Prospective Evaluation. *Clin Infect Dis.* 2019 Feb 1;68(4):554-560.

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