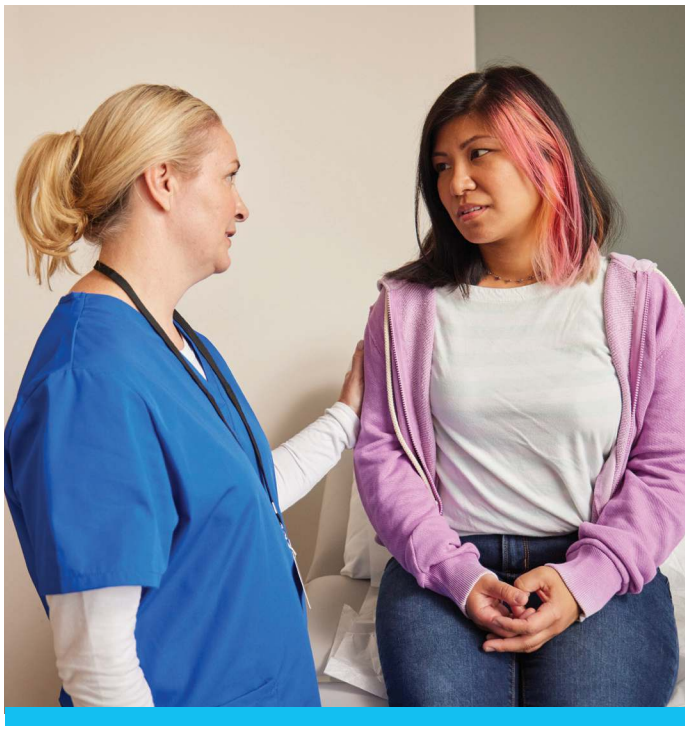
# *ResistancePlus*® MG FleXible*

*Improve patient management.*
*Test for macrolide resistance.*



## The Facts

- *Mycoplasma genitalium (M. genitalium)* presents clinically with symptoms similar to *Chlamydia trachomatis*.[1]
- Globally, macrolide resistance mediating mutations have been observed in 20–80% of cases.[2-5,17]
- Anorectal infection is common with a high percentage harbouring macrolide resistance putting men who have sex with men (MSM) at a higher risk.[6-7]
- Individuals who are HIV positive or diagnosed with bacterial vaginosis (BV) have higher incidence of macrolide resistant *M. genitalium*.[8-9]
- Evidence suggests *M. genitalium* is an important factor in spontaneous abortion and preterm birth.[10]
- International and local guidelines advise treating *M. genitalium* infections according to their macrolide resistance status.[11-14,18] [Termed, Resistance Guided Therapy (RGT)]

Macrolide resistance in Germany **53%** | Spain **35%** France **42%** | UK **74%** Denmark **57%** [2-5,15,17,19]

**75.6%** of *M. genitalium* anorectal infections harbouring macrolide resistance[6,7]

**40%** cure rate of *M. genitalium* without RGT[16]

**95%** cure rate of *M. genitalium* with RGT[16]

## *ResistancePlus*® MG FleXible

### Resistance Guided Therapy (RGT) for improved patient outcomes

***ResistancePlus***® MG FleXible offers simultaneous detection and identification of Mycoplasma genitalium and azithromycin (macrolide) resistance from symptomatic and asymptomatic patients with the following specimen types: male and female urine, and vaginal, cervical, rectal, and urethral swabs.

It enables treatment of patients via RGT, recommended by International and European treatment guidelines.[11-14,18] RGT has been clinically proven to improve cure rates in populations with high macrolide resistance.[16]


**Turnaround Time**

*M. genitalium* + resistance status obtained **in around 2 hours**

**Clinical Performance**

*M. genitalium* detection
Sensitivity **100%** | Specificity **96.3%**

Resistance markers
Sensitivity **92.9%** | Specificity **100%**

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| Your Needs | Our Answers |
|---|---|
| **Identify**<br>Determine a patient's *M. genitalium* and macrolide (azithromycin) resistance status | Syndromic management of *M. genitalium* is challenging. It has demonstrated high levels of resistance to macrolides (azithromycin).[10]<br>Treating solely based on *M. genitalium* status may result in treatment failure, leading to the ongoing transmission in the population.[10]<br>***Resistance**Plus*® MG FleXible enables you to simultaneously identify a patient's *M. genitalium* and macrolide resistance status, reducing both treatment failure and patient's time to cure.[16] |
| **Decide**<br>Easy access to macrolide resistance data | Having both *M. genitalium* and macrolide resistance data available within 2 hours, enables personalized treatment based on your patient's macrolide resistance status, and eliminates the need to send samples away for additional testing.<br>Macrolide resistance testing is recommended by international and local guidelines.[11-14,18] |
| **Prescribe**<br>Administer macrolide antibiotics only to susceptible patients | Benefits of macrolide resistance testing with ***Resistance**Plus*® MG FleXible:<br>• **Improve antimicrobial stewardship.** Prevent over-treatment and prescribe macrolides when most appropriate, preserving quinolines and last line antibiotics for the most pertinent cases.<br>• **Meet International, European, and local guidelines** which recommend knowing the resistance status of positive M. genitalium samples prior to treatment.[11-14,18]<br>• **Easily implement Resistance Guided Therapy (RGT).** RGT has been demonstrated to clinically improve patient cure rate and overall patient management.[16] |

## Statements in favour of RGT for treatment of *Mycoplasma genitalium*

**International Union against Sexually Transmitted Infections (IUSTI)**
European guideline on *Mycoplasma genitalium* infections 2021.[11]

**British Association for Sexual Health and HIV (BASHH)**
Guideline for the diagnosis and management of *Mycoplasma genitalium* in people aged 16 years and older.[12]

**French Haute Autorité de Santé (HAS) evaluation report 2022**
Sexually transmitted infections: significant increase in *Mycoplasma* resistance to antibiotics (macrolides).[13]

**Health Service Executive (HSE) Sexual Health and Crisis Pregnancy Programme**
Guidance on *Mycoplasma genitalium* testing and management in Ireland.[14]


1 Manhart LE and Kay N. Mycoplasma genitalium: Is It a Sexually Transmitted Pathogen? Curr. Infect. Dis. Reps. 2010; 12(4):306-313. Available at: https://pubmed.ncbi.nlm.nih.gov/21308546/
2 Jensen et al. Management of Mycoplasma genitalium infections – can we hit a moving target? BMC Infect. Dis. 2015; 15 :343
3 Fernández-Huerta et al. Prevalence of Mycoplasma genitalium and macrolide resistance among asymptomatic people visiting a point of care service for rapid STI screening. 2020 Jun;96(4):300-305. doi: 10.1136/sextrans-2019-054124. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31451540
4 Deborde et al. High prevalence of Mycoplasma genitalium infection and macrolide resistance in patients enrolled in HIV pre-exposure prophylaxis program. 2019 Aug;49(5):347-349. doi: 10.1016/j.medmal.2019.03.007. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30914213
5 Dumke et al. Prevalence of macrolide- and fluoroquinolone-resistant Mycoplasma genitalium strains in clinical specimens from men who have sex with men of two sexually transmitted infection practices in Berlin, Germany. 019 Sep;18:118-121. doi: 10.1016/j.jgar.2019.06.015. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31252154
6 Alarcón et al. Acceptability and effectiveness of using mobile applications to promote HIV and other STI testing among men who have sex with men in Barcelona, Spain. 2018 Sep;94(6):443-448. doi: 10.1136/sextrans-2017-053348. Available at: https://pubmed.ncbi.nlm.nih.gov/29626174/
7 Soni et al. The prevalence of urethral and rectal Mycoplasma genitalium and its associations in men who have sex with men attending a genitourinary medicine clinic. 2010 Feb;86(1):21-4. doi: 10.1136/sti.2009.038190. Available at: https://pubmed.ncbi.nlm.nih.gov/19843536/
8 Nye et al. Prevalence of Mycoplasma genitalium infection in women with bacterial vaginosis. 2020 Mar 26;20(1):62. doi: 10.1186/s12905-020-00926-6. Available at: https://pubmed.ncbi.nlm.nih.gov/32216785/
9 Ducours et al. Incidence of sexually transmitted infections during pre-exposure prophylaxis for HIV: a worrying outcome at 2 years! 2019 Nov;95(7):552. doi: 10.1136/sextrans-2019-054070. Available at: https://pubmed.ncbi.nlm.nih.gov/31628265/
10 Manhart et al. Efficacy of Antimicrobial Therapy for Mycoplasma genitalium Infections. 2015 Dec 15;61 Suppl 8:S802-17. doi: 10.1093/cid/civ785. Available at: https://pubmed.ncbi.nlm.nih.gov/26602619/
11 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.
12 2018 BASHH UK national guideline for the management of infection with Mycoplasma genitalium. Available at: https://www.bashhguidelines.org/media/1198/mg-2018.pdf
13 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
14 Health Service Executive (HSE) Sexual Health and Crisis Pregnancy Programme. Guidance on Mycoplasma genitalium testing and management in Ireland. Available at: https://www.sexualwellbeing.ie/for-professionals/research/research-reports/irish-guidance-on-m-gen-testing-and-management-january-2020.pdf
15 Dumke et al. Emergence of Mycoplasma genitalium strains showing mutations associated with macrolide and fluoroquinolone resistance in the region Dresden, Germany. 2016 Oct;86(2):221-3. doi: 10.1016/j.diagmicrobio.2016.07.005. Available at: https://pubmed.ncbi.nlm.nih.gov/27448452/
16 Read et al. Outcomes of Resistance-guided Sequential Treatment of Mycoplasma genitalium Infections: A Prospective Evaluation. 2019 Feb 1;68(4):554-560. doi: 10.1093/cid/ciy477. Available at: https://pubmed.ncbi.nlm.nih.gov/29873691/
17 Machelek et al. Lancet Infect Dis. 2020 Nov;20(11):1302-1314
18 Centers for Diesease Control and Prevention STI Treatment Guidelines, 2021 Mycoplasma genitalium. Available online at: https://www.cdc.gov/std/treatment-guidelines/mycoplasmagenitalium.htm
19 Pereyre et al. Sex Transm Infect. 2023 Jun;99(4):254-260.


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