

Emerging STI testing...

Test 129 **Mycoplasma genitalium** by Real Time PCR with reflex to azithromycin & fluoroquinolone resistance

- Involved in 15% to 30% of non-chlamydial, non-gonococcal urethritis & cervicitis
- Infections are often asymptomatic
- Associated with pelvic inflammatory disease, infertility, preterm labor and endometritis ^{1,2}
- Infection is more widespread than *Neisseria gonorrhoeae*

Antibiotic resistance is on the Rise!

Macrolide resistance (azithromycin), which highly correlates with treatment failure, ranges from **44%** to **90%** in the United States, Canada, Western Europe, and Australia.

The CDC states that ideally, *Mycoplasma genitalium* antibiotic resistance testing should be performed and used to guide therapy.

Percent Positive STI Pathogen qPCR Tests by Age Group

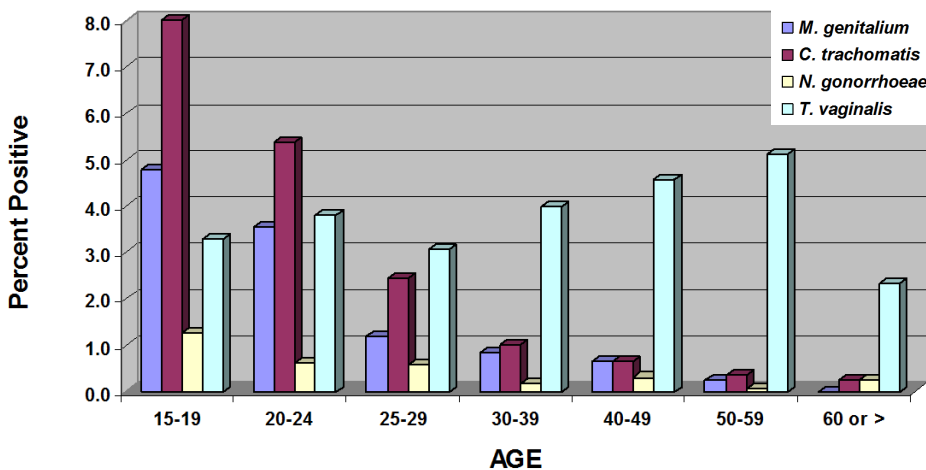


Table 1: Antibiotic resistance rates of *Mycoplasma genitalium* positive specimens. MDL Internal Data.

Antibiotic	% Resistance
Azithromycin (AR)	32
Fluoroquinolone (FR)	7
AR & FR	1
60% Susceptible	

Figure 1: Positivity rate of *Mycoplasma genitalium*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* in patient specimens, differentiated by age group. *Mycoplasma genitalium* n=5,698. *Chlamydia trachomatis* n=33,790. *Neisseria gonorrhoeae* n=33,425. *Trichomonas vaginalis* n=26,741. MDL internal data.

- Available exclusively from MDL
- Resistance testing by genetic marker detection
- Reflex testing at **no additional charge**



For Women:
Cervical Collection
Urine Collection
Endometrial Collection



For Men:
Non-invasive urine collection



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Final

MDL#: 8875032

Test Results

Patient Information: SSN: N/A	DOB: 1/1/1978 (Age:43)	Ordering Physician/Lab:	NPI: 1234567890
DOE, JANE 123 MAIN ROAD MARLTON, NJ 08053		DOE WOMANS GROUP JOHN DOE, MD 555 SMITH STREET ANYTOWN, NJ 55555	
Sex: Female		Tel: (856) 555-5552	
Home: (856) 555-5555		Fax: (856) 555-5553	

Patient ID: _____ Date Received: 7/6/2023 Date Reported: 7/8/2023

Test	Specimen	Date Collected Comment	Results		Reference/Units/Comments
			Normal	Abnormal	
Mycoplasma genitalium by Real-Time PCR (Reflex to Azithromycin and Fluoroquinolone Resistance) 129 Verified 7/8/2023	Swab - 1	7/5/2023 Cerv/End		Positive	A2059G mutation(s) detected. Suggestive of Azithromycin Resistance. parC Fluoroquinolone mutations not detect. Suggestive of Fluoroquinolone susceptibility.

*This test was developed and its performance characteristics determined by the laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Swab-1;129:Mycoplasma genitalium by Real-Time PCR (Reflex to Azithromycin and Fluoroquinolone Resistance)

* The A2058 and A2059 nucleotides represents the E. coli 23S rRNA numbering system used for publishing common macrolide (e.g. Azithromycin) antibiotic resistance mutations and corresponds to the reciprocal A2071 and A2072 nucleotides of Mycoplasma genitalium 23S rRNA gene. The pyrosequencing assay detects the most frequently encountered mutations that confer Mycoplasma genitalium Azithromycin resistance. A2058 and A2059 mutations in the 23S rRNA gene account for the majority of Azithromycin resistant isolates. Additional mutations or acquired genes can result in azithromycin resistance but are considered rare. (Tagg KA et al., 2013. Fluoroquinolone and Macrolide Resistance-Associated Mutations in Mycoplasma genitalium. J. Clin. Microbiol. 51(7): 2245 - 2249).

View: M

Mail:	Yes	USPS
	None	Yes

Fax:	Yes	Manual
	None	No

Medical Director, Jing-Jing Yang, M.D.

MDL#: 8875032 28021
7/8/2023

PATH Final

References

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- McGowin CL, Anderson-Smits C. 2011. *Mycoplasma genitalium*: An Emerging Cause of Sexually Transmitted Disease in Women. 7(5):e1001324.
- Twin J, Jensen JS, Bradshaw CS, et al. 2012. Transmission and selection of macrolide resistant *Mycoplasma genitalium* infections detected by rapid high resolution melt analysis. *PLoS One* 7:e35593.
- Tagg KA, Jeffreys NJ, Couldwell DL, et al. 2013. Fluoroquinolone and Macrolide Resistance-Associated Mutations in *Mycoplasma genitalium*. *J Clin Microbiol* 51(7): 2245-2249.
- Bissessor M, Tabrizi SN, Twin J, et al. 2015. Macrolide Resistance and Azithromycin Failure in a *Mycoplasma genitalium*-Infected Cohort and Response of Azithromycin Failures to Alternative Antibiotic Regimens. *Clin Infect Dis* 2015;60, 1228-36.