

HOLOGIC®

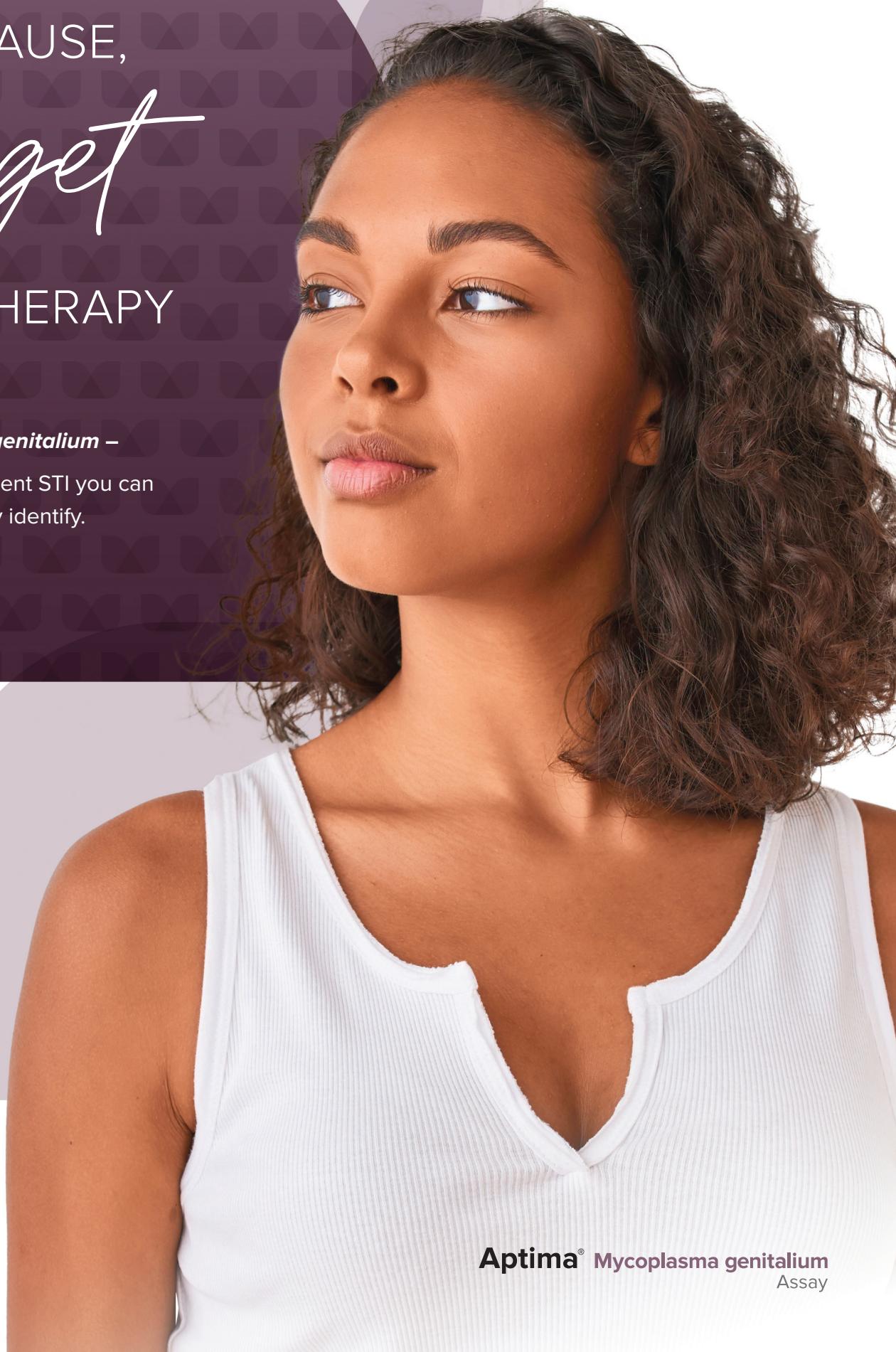
KNOW
THE CAUSE,

Target

THE THERAPY

***Mycoplasma genitalium* –**

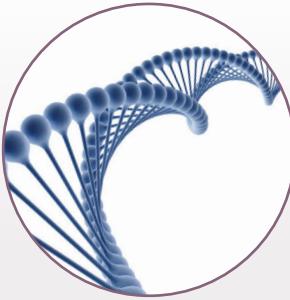
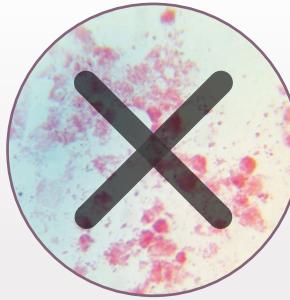
A highly prevalent STI you can
now accurately identify.



**Aptima® *Mycoplasma genitalium*
Assay**

Mycoplasma genitalium is a Highly Prevalent STI

Detection of *Mycoplasma genitalium* (M. gen) Requires
Nucleic Acid Amplification Testing



Clinical Presentation

can be similar to other sexually transmitted infections (STIs).²

Microscopy

cannot be seen because M. gen has no cell wall.¹

Culture

is not clinically feasible as it may take up to six months.¹

Nucleic Acid Amplification Test (NAAT)

is the recommended method of detection.^{1,3}

Trichomoniasis, Chlamydia, Gonorrhea and M. gen are Associated with Similar Clinical Presentation⁴⁻¹³

	Similar Symptoms					
	Trichomoniasis	Bacterial Vaginosis	Yeast Infection	Chlamydia	Gonorrhea	<i>Mycoplasma genitalium</i>
Abnormal Discharge	✓	✓	✓	✓	✓	✓
Vaginal Odor	✓	✓				
Vaginal Irritation	✓	✓	✓	✓	✓	✓
Pain During Urination/Sex	✓	✓	✓	✓	✓	✓

and the Test You Choose Matters¹

Testing is Recommended for Women with Recurrent Cervicitis and Should Be Considered in Women with PID¹



- ▶ Prevalence of **18.3%**¹⁴
- ▶ Detected in **10% - 30%** of women with clinical cervicitis^{1,15}
- ▶ Identified in up to **22%** of pelvic inflammatory disease (PID) cases^{1,15}
- ▶ Untreated PID can lead to adverse pregnancy outcomes^{1,15}

When patients do experience symptoms, they are similar to those associated with other urogenital tract bacterial infections.^{1,18}

Testing is Recommended for Men with Recurrent Non-gonococcal Urethritis¹

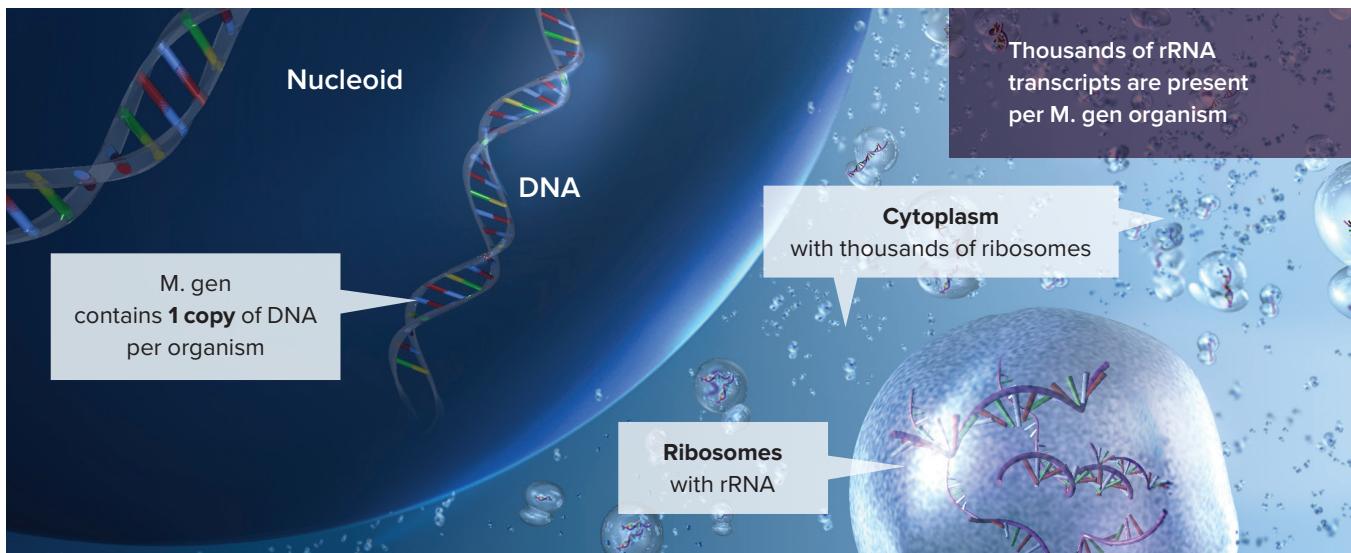


- ▶ Prevalence of **16.5%**¹⁴
- ▶ More likely to exhibit symptoms of *M. gen* infection¹⁵
- ▶ Responsible for **40%** of persistent or recurrent urethritis in men¹



May also increase the risk of HIV acquisition and transmission^{1,16-17}

NAAT is Needed to Detect *M. gen* Because the Infection Contains a Very Low Organism Load³



M. gen can be difficult to detect because the bacterial organism load is low compared to other STIs commonly tested for. This means that a highly sensitive rRNA test is needed for accurate diagnosis.³

Proper Diagnosis is Important to Drive the Right Treatment Decisions

Recommended treatments are organism-specific¹

► **Metronidazole**

500 mg orally 2x/day for 7 days
(Treatment for women)

Trichomoniasis

or

► **Tinidazole**

2g orally single dose
(Treatment for women and/or men)

► **Ceftriaxone**

500 mg* IM in a single dose for
persons weighing <150 kg

Gonorrhea

If chlamydial infection has not been
excluded, treat for chlamydia with
Doxycycline 100 mg orally 2x/day
for 7 days

* For persons weighing ≥150 kg, 1g
Ceftriaxone should be administered.

Chlamydia

► **Doxycycline**

100 mg orally 2x/day for 7 days

M. gen Treatment Considerations¹

Recommended Regimens if M. gen
Resistance Testing Is Available:

► If macrolide sensitive: 100 mg orally 2x/
day for 7 days of **Doxycycline**, followed
by 1g orally initial dose of **Azithromycin**,
followed by 500 mg orally 1x/day of
Azithromycin for an additional 3 days
(2.5g total)

► If macrolide resistant: 100 mg orally 2x/
day for 7 days of **Doxycycline**, followed
by 400 mg orally 1x/daily for 7 days of
Moxifloxacin

Mycoplasma genitalium

Recommended Regimens if M. gen
Resistance Testing Is **NOT** Available:

► 100 mg orally 2x/day for 7 days of
Doxycycline, followed by 400 mg orally
1x/daily for 7 days of **Moxifloxacin**

A DNA-based test has been shown to **miss up to 40% of infections** compared to an rRNA-based test.¹⁹

Sensitivity of Detection in Patients with M. gen Infections¹⁹⁻²¹

UP TO
100%[‡]

vs.

60%^{*}

Aptima® Mycoplasma genitalium assay RNA-based test

DNA-based LDT test

UP TO
100%[‡]

vs.

78%[†]

Aptima® Mycoplasma genitalium assay RNA-based test

DNA test vendor

CDC recommends **NAATs** to detect M. gen.¹



* Sensitivity from Le Roy Study.

† Sensitivity from Unemo Study. Performance in vaginal specimen.

‡ Sensitivity information provided above is specific to patient-collected vaginal swab (PVS) for symptomatic patients. For complete performance characteristics for the Aptima Mycoplasma genitalium assay, please refer to the package insert.

One sample. Multiple results. Maximum Efficiency.

Choose the **FDA-cleared NAAT** for the detection of ribosomal RNA (rRNA) from M. gen.

Aptima® Multitest Swab

Detect up to **7 infections** from one vaginal sample.²¹⁻²⁵

Vaginal swabs are the CDC preferred collection method for M.gen testing.¹²



Vaginal Sample



Penile Meatal Sample*



* Penile meatal sample only FDA-cleared for M. gen.

Alternative Specimen Collection Also Available

Urine

- Female urine (first catch)
- Male urine (first catch)

Unisex Swab

- Endocervical swabs
- Male urethral swabs

Visit **HologicWomensHealth.com** for more information.

Refer to the appropriate assay package insert for available specimen types.

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Aptima® Mycoplasma genitalium
Assay