

COUNTY OF SAN LUIS OBISPO PUBLIC HEALTH LABORATORY

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LABORATORY TEST FACT SHEET

TEST: MYCOPLASMA GENITALIUM NAAT ORDER CODE: 2930

TEST DESCRIPTION

Mycoplasma genitalium is a sexually transmitted infection that lives on and in the epithelial cells of the urinary and genital tracts of men and women. The County of San Luis Obispo Public Health Laboratory performs a nucleic acid amplification test (NAAT) for the detection of Mycoplasma genitalium (Mgen) using a real-time polymerase chain reaction assay (cobas® TV/MG assay, Roche Molecular Systems, Inc). This test is intended as an aid in the diagnosis of Mgen infections in individuals suspected of infection. Scientific studies have linked M. genitalium with urethritis and epididymitis in males, and infections such as cervicitis (often asymptomatic), endometritis, and pelvic inflammatory disease (PID) in females. Insufficient research has been conducted to conclusively identify risk factors that might guide control strategies, but reports show the prevalence of M. genitalium infection often exceeds that of Chlamydia trachomatis, Neisseria gonorrhoeae, or Trichomonas vaginalis, the most common STI agents.

Sensitivity and Specificity

- 1. The cobas® TV/MG test has ≥95% sensitivity for detecting:
 - a. Mycoplasma genitalium at concentrations between 0.5–4 copies/mL
- 2. Sensitivity and specificity by sample type are shown in the table below.

| Sample type | Sensitivity | Specificity |
|----------------------------|-------------|-------------|
| Urine (female) | 86.4% | 97.0% |
| Vaginal swab (female) | 96.6% | 97.0% |
| Endocervical swab (female) | 83.1% | 98.4% |
| Urine (male) | 100% | 97.6% |

SPECIMENS ACCEPTED FOR TESTING

- Urine, vaginal swabs (female, self-collected or clinician-collected), endocervical swabs (female)
- cobas® collection kits are required for each specimen type

Storage and Transport temperature: 2-30°C (refrigerated or room temperature)

Holding time: Up to 12 months once transferred into cobas® PCR Media

CPT code: 87798

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