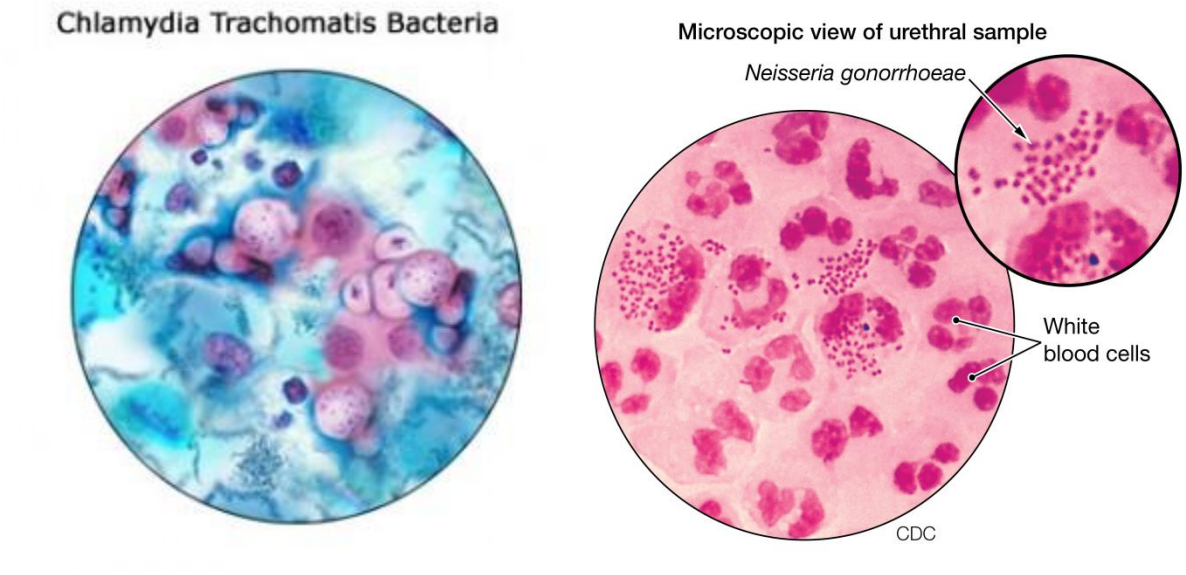
Aptima® *Chlamydia trachomatis* and *Neisseria gonorrhea* assay



Clinical use

- Diagnose *Chlamydia trachomatis* and *Neisseria gonorrhea*

Clinical Background

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) infections are two of the most common sexually transmitted infections worldwide. In the United States alone, an estimated 1,307,893 (426.0 cases per 100,000 population) new cases of CT and 309,341 (100.8 per 100,000 population) new cases of GC infections were reported to the Centers for Disease Control in 2010 [(1)].

Chlamydiae are nonmotile, gram-negative, obligate intracellular bacteria. *N. gonorrhoeae* is the causative agent of gonorrheal disease. *N. gonorrhoeae* are non-motile, gram-negative diplococci.

CDC guidelines for testing:

- Testing for sexually active women under 25 years of age
- Testing for sexually active women aged 25 and older if at increased risk
- All pregnant women should be considered for testing and treatment regardless of pregnancy stage
- Annual screening for HIV positive women
- Retest positive patients in 3 months

Specimen type

- Room temperature or refrigerated Clinician-collected PreservCyt Solution liquid Pap specimen (Thin Prep vial)
- Aptima Unisex Swab Specimen Collection Kit (white tube with foil cap)

Method

- Qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA)

Interpretation

Positive – consistent with active *C. trachomatis* or *N. gonorrhea* infection

Negative – consistent with the absence of *C. trachomatis* or *N. gonorrhea* infection, or
Organism concentration below the assay detection limit, or
Improper specimen collection and handling **(Reference Range)**

References

1. **Centers for Disease Control and Prevention.** 2011. *Sexually Transmitted Disease Surveillance 2010*. Atlanta, GA: U.S. Department of Health and Human Services. November.