

Peer Review and Public Comment Plan for “Recommendations for the detection and characterization of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in the United States”

Report Title: “Recommendations for the detection and characterization of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in the United States”

Subject of Planned Report: This document summarizes the evidence informing best practices for the detection and characterization of infections caused by *C. trachomatis* and *N. gonorrhoeae* testing in the United States.

Purpose of Planned Report: The Centers for Disease Control and Prevention (CDC) provides evidence-based recommendations for the management and prevention of infectious diseases, including laboratory testing for screening and diagnostic purposes. Evidence on the available methods for the laboratory detection of *C. trachomatis* and *N. gonorrhoeae* was last reviewed in 2014. New evidence on the performance of point-of-care tests for the detection of *C. trachomatis* and *N. gonorrhoeae*, molecular methods for the detection of *N. gonorrhoeae* resistance markers, and matrix assisted laser desorption ionization-time of flight mass spectrometry for the identification of *N. gonorrhoeae* from culture have yet to be evaluated. The purpose of this report is to describe the performance characteristics, utility, and availability of laboratory and point-of-care methods for the detection of *C. trachomatis* and *N. gonorrhoeae*. The target audience for these recommendations includes any professional that makes decisions and establishes standard operating procedures for collecting, processing, and testing specimens. These recommendations may also benefit clinicians who must choose among multiple tests and use those results along with medical history, clinical findings and epidemiologic data to inform the clinical diagnosis of chlamydia and gonorrhea.

Type of Dissemination: Influential Scientific Information (ISI)

Timing of Review (including deferrals): May-June 2026

Type of Review (panel, individual or alternative procedure): Individual

Opportunities for the Public to Comment (how and when): A notice inviting the public to comment will be posted in the Federal Register with a link to the draft recommendations. The public comment period will last 45 days. Comments and responses will be posted in the Federal Register. The draft recommendations will be made available to key interest holders such as the Association of Public Health Laboratories, American Society for Microbiology, Centers for Medicare and Medicaid Services, and Food and Drug Administration for comment. All materials will be available for review.

Peer Reviewers Provided with Public Comments before the Review: No

Anticipated Number of Reviewers: 4

Primary Disciplines or Expertise: Clinical laboratory diagnostics, clinical care of patients infected with sexually transmitted infections, regulatory assessment of tests marketed for clinical diagnostics in the United States. Laboratory technology and practices for sexually transmitted infections.

Reviewers Selected by (agency or designated outside organization): Centers for Disease Control and Prevention.

Recommended by Scientific/Professional Society or General Public: No

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: We request your review of the body of literature used to develop “Recommendations for the detection and characterization of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in the United States.” As you review the Background, Methods, and Evidence sections, we would appreciate your thoughts as to whether any key studies have been left out or, in your expert opinion, misinterpreted, as well as comments on the appropriateness of the conclusions. Above all, we are interested in your thoughts about the determinations regarding the quality of the evidence and the strength of the recommendations that were drawn. The questions below will serve as a template to collect and organize your responses. Once completed, please send them to Dr. Amanda Smith, Division of STD Prevention (DSTDP) at RQQ8@CDC.gov. After comments are received, they will be posted without attribution along with our responses on a DSTDP webpage at a later date.

Template of specific questions:

1. Are there omissions of information or key studies that are critical for the intended audience of clinical laboratory scientists and clinicians? If so, what should be included?
2. Have we included inappropriate information? If so, what should be removed?
3. Are the recommendations appropriately drawn from the evidence presented? Please explain.
4. Does the strength of recommendation align with the quality of the available evidence and the implementation considerations?
5. Is this document clear and comprehensible for clinical laboratory directors, clinicians, and other laboratory personnel? If not, which sections should be revised?
6. Are the recommendations practical and achievable for clinical, commercial, and public health laboratories?
7. Are there other comments you might have?

Selected Peer Reviewers

Name	Academic and Professional Credentials	Current Affiliations	Areas of Interest
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Scott Shone	<p>PhD, Molecular Microbiology and Immunology. Johns Hopkins Bloomberg School of Public Health, Baltimore, MD</p> <p>Board Certification: High Complexity Clinical Laboratory Director, American Board of Bioanalysis.</p>	<p>Laboratory Director, North Carolina State Laboratory of Public Health</p> <p>President, Association of Public Health Laboratories</p>	Public Health Laboratory Director
William Geisler	<p>MD, University of Tennessee, Memphis, TN</p> <p>MPH, Epidemiology, University of Washington, Seattle, WA.</p>	University of Alabama at Birmingham (UAB)	Research Director and clinical consultant for the UAB Diagnostic Mycoplasma laboratory with expertise in adult infectious disease, including sexually transmitted infections.
Randal Fowler	<p>PhD, Medical Microbiology and Immunology, Creighton University, Omaha, NE</p> <p>Board Certification: American Board of Medical Microbiology</p>	Clinical Laboratory Director, Tennessee Department of Health	<p>Clinical Laboratory Director</p> <p>Special interest in HIV, viral hepatitis and sexually transmitted infections.</p>
Katherine Hsu	<p>MPH, Boston University School of Public Health, Boston, MA.</p> <p>MD, Brown University School of Medicine, Providence, RI</p>	<p>Board-certified Attending Physician in Pediatric Infectious Disease at Boston Medical Center</p> <p>Professor of Pediatrics and Adolescent Medicine at Boston University</p>	<p>Medical Director for the Division of STD Prevention & HIV/AIDS Surveillance, Massachusetts Department of Public Health</p> <p>Director of Ratelle STD/HIV Prevention Training Center</p>