Peer Review and Public Comment Plan for "Recommendations for the Use of Specimens Collected At-Home or in Other Nonclinical Settings for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Testing"

Report Title: Recommendations for the Use of Specimens Collected At-Home or in Other Nonclinical Settings for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Testing.

Subject of Planned Report: This document summarizes the evidence informing best practices for specimen self-collection at home and in other nonclinical settings for *C. trachomatis* and *N. gonorrhoeae* screening and diagnostic testing.

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. Nucleic acid amplification tests (NAATs) are currently recommended for screening and for the detection of *C. trachomatis* and *N. gonorrhoeae* due to their high sensitivity and specificity and ease of specimen collection. Food and Drug Administration (FDA) cleared specimen types are both self- and clinician-collected genital specimens and clinician-collected extragenital specimens in clinical settings, i.e., under the supervision of a healthcare provider who guides specimen collection. One company recently received marketing-authorization from the FDA for the collection of specimens at home and in other nonclinical settings to be used for the detection of *C. trachomatis* and *N. gonorrhoeae*. A comprehensive review is needed to understand the benefits and potential risks of non–clinic-based specimen collection and transport methods and how this new approach will further reduce transmission of these highly prevalent infections. The target audience for these recommendations includes laboratory directors and laboratory staff that establish standard operating procedures for collecting and processing specimens. These recommendations should inform clinicians on how to use nonclinical settings for the collection of specimens for *C. trachomatis* and *N. gonorrhoeae* testing.

Type of Dissemination: Influential Scientific Information (ISI)

Timing of Review (including deferrals): September 2024-December 2024

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

Opportunities for the Public to Comment (how and when): Simultaneous to peer review, 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 30 days. All materials will be available for review. The draft recommendations will be made available to key stakeholders such as the Association of Public Health Laboratories, American Society for Microbiology who can provide feedback through the public comment mechanism.

Draft recommendations will also be sent to key federal stakeholders Centers for Medicare & Medicaid Services, and FDA for comment outside of the public comment portal (i.e., direct email).

Peer Reviewers Provided with Public Comments before the Review: No

Anticipated Number of Reviewers: 4

Primary Disciplines or Expertise: Laboratory technology and practices for sexually transmitted infections and specimen self-collection or testing in nonclinical settings.

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

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: We request your review of the body of literature used to develop "Specimen self-collection at home and in other nonclinical settings for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing." 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 the Division of STD Prevention (DSTDP). After DSTDP reviews your comments, they will be posted without attribution along with our responses on the DSTDP webpage at a later date. Peer reviewer names will be listed.

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. Do the recommendations take into consideration key populations based on the available evidence?
5. Is this document clear and comprehensible? If not, which sections should be revised?
6. Are the recommendations practical and achievable?
7. Are there other comments you might have?

Selected Peer Reviewers

Name	**Academic and Professional Credentials**	**Current Affiliations**	**Areas of Interest**
Yukari Manabe	MD, Columbia University College of Physicians and Surgeons, New York City, NY Board Certification: Internal Medicine and Infectious Diseases	Johns Hopkins University	Associate Director of Global Health Research and Innovation Rapid, point-of-care diagnostics for HIV, TB and STIs in resource-limited settings
Barbara Van Der Pol	PhD in Philosophy, Indiana University, Bloomington, IN MPH in Biological and Biomedical Sciences, Indiana State University, Terre Haute, IN	University of Alabama – Birmingham	Professor of Medicine and Public Health Director of UAB diagnostics laboratory
Megan Crumpler	PhD in Microbiology and Immunology, Virginia Commonwealth University, Richmond, VA Board Certified in Bioanalysis	Orange County Public Health Laboratory	Laboratory Director of Orange County Public Health Laboratory

Sarah Buss	PhD in Biochemistry, University of Virginia, Charlottesville, VA	Association of Public Health Laboratories	Program Director for HIV, Hepatitis, STD, and TB at APHL