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GAVIN NEWSOM
Governor

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Dear Colleague:

In 2017, nearly 2.3 million cases of chlamydia (CT), gonorrhea (GC), and syphilis were diagnosed in the United States. According to the Centers for Disease Control and Prevention (CDC), this exceeded the 2016 record by over 200,000 cases and marked a fourth year of sharp increases in these sexually transmitted diseases (STDs). To effectively detect and treat disease, it is critical that routine STD screening includes all exposed anatomical sites.ⁱ

For men who have sex with men (MSM), CDC recommends screening for urethral/urinary and rectal GC and CT, and pharyngealⁱⁱ GC (as indicated by exposure) with nucleic acid amplification testing (NAAT). Of note, the rectum and pharynx are the most common sites of GC and CT infections among MSM. These infections are usually asymptomatic and typically occur without a coinciding urethral infection.^{1,2} When urine-only screening is performed, up to 95% of GC and 77% of CT infections remain undetected and untreated, thus highlighting the importance of extragenital testing in MSM.³

The California Department of Public Health (CDPH) recommends the following:ⁱⁱⁱ

- Sexually active people living with HIV – regardless of gender – should receive **at least annual** GC/CTⁱⁱ screening at all exposed sites.⁴
- HIV-negative MSM not using HIV Pre-Exposure Prophylaxis (PrEP) should receive **at least annual** STD screening at all exposed sites.
- MSM using HIV PrEP should receive **quarterly** STD screening at all exposed sites.

In addition to provider-collected specimens, patient self-collected swabs are both accurate and acceptable among patients.^{5,6,7} Having patients collect their own specimens could overcome potential barriers to screening such as time constraints and patient/provider communication and discomfort, which might limit provider collection of specimens from extragenital sites.⁸ Standing orders for routine STD screening may further streamline collection for rectal and pharyngeal specimens. The California Prevention Training Center (CAPTC) can assist in implementing routine rectal and pharyngeal STD screening.

ⁱ Comprehensive screening for STDs should also include serologic tests for syphilis among others as indicated. Please review the California STD Screening Recommendations.

ⁱⁱ Testing for oropharyngeal chlamydia is not routinely recommended because its prevalence is generally low.

ⁱⁱⁱ More frequent screening may be appropriate depending on individual risk and local epidemiology.

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The U.S. Food and Drug Administration (FDA) has recently approved two assays that can accurately detect GC/CT through testing of rectal and pharyngeal specimens: the Aptima Combo 2 Assay (Hologic, San Diego, CA) and the Xpert CT/NG (Cepheid, Sunnyvale, CA).^{iv, v, 9} These NAAT assays are the first GC/CT diagnostic tests cleared for this purpose. Other GC/CT assays, which have not yet been FDA-approved for rectal and pharyngeal specimens, are sometimes used for extragenital STD testing by labs that have validated their use. If your site uses such an assay, please consult the laboratory director for further guidance with regards to securing approval of processing this test for rectal and/or pharyngeal specimens.

Prior to FDA approval, many local public health laboratories and three large commercial companies (LabCorp, Quest Diagnostics, and Center for Disease Detection)^v in California had validated and accepted GC/CT NAAT assays for use on rectal and pharyngeal specimens. Due to prior validation, these laboratories already have specific ordering codes in place for this purpose.

Company-specific ordering codes for two widely used laboratories are listed below:

	Combined GC/CT NAAT Tests		CT test only
	LabCorp	Quest	LabCorp
RECTAL	188672	16506	188706
PHARYNGEAL	188698	70051	188714

Current Procedural Terminology (CPT) billing codes:

CT detection by NAAT: 87491; GC detection by NAAT: 87591.^{vi}

NAAT screening for rectal GC/CT and pharyngeal GC is effective at detecting asymptomatic infections and allows for adequate treatment. Appropriate management, in turn, cures disease, interrupts transmission, and decreases the risk of HIV infection among HIV-negative MSM.^{10, 11, 12, 13} With this in mind, CDPH strongly recommends you include routine rectal and pharyngeal STD screening in your practice.

Thank you for your work to improve the sexual health of your patients.

Sincerely,



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^{iv} Letter updated 7/10/19 to reflect new FDA approval of two tests

^v Company and laboratory names are provided for informational purposes only. California Department of Public Health does not endorse any company or its products.

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Additional Resources *(Please click on a resource to be directed to the webpage)*

- CDPH STD Screening Recommendations
www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CA STD-Screening-Recs.pdf
California Department of Public Health STD screening recommendations, including recommendations for MSM and HIV positive men
- CDC 2015 STD Treatment Guidelines
www.cdc.gov/std/tg2015
The Center for Disease Control and Prevention 2015 STD Treatment Guidelines, including guidelines for testing and treatment of rectal gonorrhea and chlamydia
- National Coalition for STD Directors
www.ncsddc.org/resource/extragenital
Resources for providers and laboratores pertaining to extragenital STD testing
- California Prevention Training Center
<https://californiaptc.com/>
Assistance with developing protocols, validation studies, and teaching material related to self-collected specimens
- STD Clinical Consultation Network
www.stdccn.org
Online consultation for questions about the evaluation and management of STD cases
- National STD Curriculum
www.std.uw.edu
National Network of STD Prevention Training Centers (NNPTC)'s free online STD curriculum and question bank. Offers continuing medical education credits.
- Telephone HIV Consultation hotlines:
HIV/AIDS management: 800-933-3413
PrEP phone consultation: 855-448-7737
PEP phone consultation: 888-448-4911

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- ¹ Klausner, J. D., Bernstein, K. T., Pandori, M., Hall, C., Gibson, S., Ryan, T., ... & Guerry, S. (2009). Clinic-based testing for rectal and pharyngeal *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infections by community-based organizations—five cities, United States, 2007. *Morbidity and Mortality Weekly Report*, *58*(26), 716-719.
- ² Park, J., Marcus, J. L., Pandori, M., Snell, A., Philip, S. S., & Bernstein, K. T. (2012). Sentinel surveillance for pharyngeal chlamydia and gonorrhea among men who have sex with men—San Francisco, 2010. *Sexually transmitted diseases*, *39*(6), 482-484.
- ³ Marcus, J. L., Bernstein, K. T., Kohn, R. P., Liska, S., & Philip, S. S. (2011). Infections missed by urethral-only screening for chlamydia or gonorrhea detection among men who have sex with men. *Sexually transmitted diseases*, *38*(10), 922-924.
- ⁴ Aberg, J. A., Gallant, J. E., Ghanem, K. G., Emmanuel, P., Zingman, B. S., & Horberg, M. A. (2013). Primary care guidelines for the management of persons infected with HIV: 2013 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clinical Infectious Diseases*, *58*(1), e1-e34.
- ⁵ Freeman, A. H., Bernstein, K. T., Kohn, R. P., Philip, S., Rauch, L. M., & Klausner, J. D. (2011). Evaluation of self-collected versus clinician-collected swabs for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* pharyngeal infection among men who have sex with men. *Sexually transmitted diseases*, *38*(11), 1036-1039.
- ⁶ Lunny, C., Taylor, D., Hoang, L., Wong, T., Gilbert, M., Lester, R., ... & Ogilvie, G. (2015). Self-collected versus clinician-collected sampling for Chlamydia and Gonorrhea screening: a systemic review and meta-analysis. *PLoS One*, *10*(7), e0132776.
- ⁷ Barbee, L. A., Tat, S., Dhanireddy, S., & Marrazzo, J. M. (2016). Implementation and Operational Research: Effectiveness and Patient Acceptability of a Sexually Transmitted Infection Self-Testing Program in an HIV Care Setting. *Journal of acquired immune deficiency syndromes (1999)*, *72*(2), e26-31.
- ⁸ Mimiaga, M. J., Goldhammer, H., Belanoff, C., Tetu, A. M., & Mayer, K. H. (2007). Men who have sex with men: perceptions about sexual risk, HIV and sexually transmitted disease testing, and provider communication. *Sexually transmitted diseases*, *34*(2), 113-119.
- ⁹ U.S. Food & Drug Administration (2019). FDA clears first diagnostic tests for extragenital testing for chlamydia and gonorrhea. [Press announcement]. Retrieved July 10, 2019, from <https://www.fda.gov/news-events/pressannouncements/fda-clears-first-diagnostic-tests-extragenital-testing-chlamydia-and-gonorrhea>.
- ¹⁰ Workowski, K. A., & Bolan, G. A. (2015). Sexually transmitted diseases treatment guidelines, 2015. MMWR. Recommendations and reports: Morbidity and mortality weekly report. Recommendations and reports, *64*(RR-03), 1.
- ¹¹ Newman, L. M., Moran, J. S., & Workowski, K. A. (2007). Update on the management of gonorrhea in adults in the United States. *Clinical Infectious Diseases*, *44*(Supplement_3), S84-S101.
- ¹² Bernstein, K. T., Marcus, J. L., Nieri, G., Philip, S. S., & Klausner, J. D. (2010). Rectal gonorrhea and chlamydia reinfection is associated with increased risk of HIV seroconversion. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *53*(4), 537-543.
- ¹³ Pathela, P., Braunstein, S. L., Blank, S., & Schillinger, J. A. (2013). HIV incidence among men with and those without sexually transmitted rectal infections: estimates from matching against an HIV case registry. *Clinical infectious diseases*, *57*(8), 1203-1209.