

County of Santa Clara Public Health Department



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DATE: March 21, 2019

TO: Honorable Members of the Board of Supervisors
Jeffrey V. Smith, M.D., J.D., County Executive

FROM: René G. Santiago, Deputy County Executive/Director, CSCHS

Sara H. Cody, MD, Health Officer and Public Health Director

SUBJECT: Report related to HIV Testing at The Health Trust

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Following the Office of LGBTQ Affairs’ program update at the December 18, 2018 Health and Hospital Committee, Supervisor Yeager requested that the Public Health Department provide an off-agenda report on options for HIV and sexually transmitted disease (STD) testing at The Health Trust (THT) through collaboration with the Department. This report provides the requested information.

BACKGROUND

As of 2017, 3,361 people were currently living with HIV in the County of Santa Clara, and 156 people were newly diagnosed in the same year. The State estimates that 9% of people living with HIV are unaware of their diagnosis, and without this awareness, they’re unable to access the treatment they need to remain healthy and prevent transmission of the disease. In addition, the county and State have seen rising rates of bacterial STDs including syphilis, gonorrhea, and chlamydia in nearly all ages, genders, and races/ethnicities, disproportionately impacting people of color and LGBTQ communities.

The US Centers for Disease Control and Prevention currently recommend testing for HIV for all individuals ages 13-65 at least once, and more frequently if at increased risk. Testing for STDs is recommended for nearly all sexually active individuals based on age, sex at birth, and other risk factors. However, not all county residents have access to routine recommended testing through primary care or other health care facilities. Expansion of testing services to underserved populations is a vital tool for the reduction of new infections and the health and safety of county residents.

The majority of clinical laboratory tests require specimen collection by persons with specific clinical licenses and must be performed in a laboratory setting licensed by the Centers for Medicare & Medicaid Services through the Clinical Laboratory Improvement Amendments (CLIA). However, California Health and Safety Code §§ 120885-120917 authorizes the creation of “Alternate Test Sites” specifically to provide confidential testing for HIV and Hepatitis C virus (HCV) under a unique CLIA Waiver specific to this purpose. In addition, this regulation allows individuals who are not otherwise

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licensed to collect clinical specimens to be trained to lawfully collect specimens for and perform HIV and HCV testing if they complete a training program provided by the California Department of Public Health Office of AIDS.

In addition, the California Department of Public Health, Laboratory Field Services (LFS) branch has recently specified that certain programs may be allowed to provide CLIA-waived testing for syphilis under oversight by a Public Health Laboratory with additional training requirements in place for any staff collecting specimens who are not otherwise licensed to do so. Testing for other sexually transmitted diseases may be performed in an appropriately licensed laboratory, such as the County's Public Health Laboratory, and specimens for such tests may be collected by the patients themselves by providing urine specimens or swabs of other potentially infected body sites for which validated tests are available (e.g. self-collected throat swabs may be tested for gonorrhea in laboratories that have validated this specimen type.)

The above laws and regulations allow non-clinical entities to provide a subset of clinical tests that may include HIV, HCV, syphilis, self-collected gonorrhea, self-collected chlamydia, and other non-diagnostic general health assessment (NGHA) test such as for diabetes or high cholesterol (Sections 1244, 1244.1, 1244.3, and 1233.4 in Chapter 195 of the California B&P Code regulate NGHA programs).

To qualify as an Alternate Test Site and begin offering HIV and HCV testing in accordance with the above regulations, a non-clinical entity would need to perform at minimum the following:

- Successful completion of staff training to become certified HIV/HCV test counselors by attending the State Office of AIDS Basic Counseling Services Training.
- Completion of training and certification in phlebotomy for a subset of staff in order to obtain confirmatory test specimens that require venipuncture for collection.
- Maintenance of staff certifications and competencies to provide safe and correct testing techniques.
- Successful application for CLIA waived certificates (for both HIV/HCV testing and NGHA testing) with the State Laboratory Field Services branch.
- Development and review of internal policies and procedures to respond to blood borne pathogen exposures, disposal of medical waste, and transportation of medical waste.

ACTIONS TO DATE

In late December 2018 and early January 2019, members of the STD/HIV Prevention & Control Program and Public Health Laboratory verified the above items necessary for creation of a new Alternate Test Site operated by THT. On January 11, 2019, the STD/HIV Program reached out to the CEO and AIDS Services Director at THT to outline the requirements above, meet with THT leadership, and offer technical assistance wherever needed.

After conferring internally, THT replied on February 7, 2019 to confirm their interest in pursuing becoming an Alternate Test Site for HIV and reported that additional details would be forthcoming. On February 14, 2019, they provided further detail regarding their planning and timeline for a future Client Services Center that would host HIV and STD screening services as detailed below.

The STD/HIV Program replied to reiterate subsequent logistic steps and schedule a forthcoming meeting to proceed.

NEXT STEPS

In late summer/early fall 2019, THT plans to open a new Client Service Center (CSC), where they will provide services to all clients and potential clients in a harm reduction, whole person care setting. Because many of their clients, living with HIV or not, are at elevated risk for other chronic conditions, their goal is to provide not only HIV, Hepatitis C, and STD screenings, but general health screenings for diabetes, hypertension, and possibly additional diseases. Due to the success of their recent grant application to enhance HIV and STD screening in County jails, THT may be able to leverage this experience and funding opportunity to recruit phlebotomy and/or nursing staff to support health screenings at the new CSC.

Representatives of THT, STD/HIV Program, and Public Health Laboratory will meet on March 28, 2019 to review preliminary training, licensure, and procedural requirements for creation of the new Alternate Test Site. After this meeting, the STD/HIV Program Public Health Nurse Manager I who serves as the Alternate Test Site coordinator will work with the THT AIDS Services Director to schedule required training for THT staff through State Office of AIDS and to receive required policies and procedures necessary for CLIA licensure. The STD/HIV Controller will coordinate with the Public Health Laboratory to pursue the CLIA Waivers necessary for HIV and HCV testing as well as the Waiver needed for other NGHHA testing.

Please contact Dr. Sarah Lewis Rudman for additional information or if you have questions.

cc: Miguel Marquez, Chief Operating Officer
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