

ALAMEDA COUNTY HEALTH CARE SERVICES AGENCY PUBLIC HEALTH DEPARTMENT

Colleen Chawla, Director Kimi Watkins-Tartt, Director

Office of the Health Officer 1000 Broadway, 5th Floor Oakland, CA 94607 Nicholas J. Moss, MD, MPH Interim Health Officer (510) 267-3200 Fax (510) 268-2140

August 4, 2020

Sean Parkin CEO, City Health Urgent Care 13690 E 14th St., Suite 100 San Leandro, CA 94578 Or 1300 Clay St., Suite 165 Oakland, CA 94612

Dear Mr. Parkin:

This letter is to notify you that the Alameda County Public Health Department (ACPHD) has identified problems with the operations at the CityHealth COVID-19 testing site that operated on Wind River Way in the City of Alameda. ACPHD supports reliable, accurate, and safe COVID-19 testing processes that are compliant with all relevant medical, laboratory, and public health regulations, including reporting requirements. To ensure the safety and well-being of the public, COVID-19 testing sites must meet the standards and requirements outlined in the Alameda County ACPHD Guidance and Health Officer Orders.

Observations by County representatives made during multiple visits to the CityHealth testing site on Wind River Way identified violations of the following standards for COVID-19 testing in non-medical settings that pose health risks to the public:

- 1. Inappropriate infection control procedures including use of personal protective equipment (PPE) per Center for Disease Control (CDC) and California Department of Public Health (CDPH) guidance.
 - Staff are stationed closely together and with the testing participants (within 1-3 feet) for hours at a time.
 - Although staff collecting the test specimens are wearing appropriate gowns and face protection, other staff use only face masks and gloves; many staff are wearing sleeveless shirts and open shoes.
 - Testing staff do not change gloves between testing individuals each time, and were instead observed using a shared pump hand sanitizer on the gloves between hundreds of samples.
- 2. Measures to prevent transmission of COVID-19 between participants of the program are not being observed.
 - The facility is not set up in a way that allows testing participants to maintain at least 6 feet of
 distancing from one another while in line to access testing or while they await results. Some tape
 markers are noted in the entry line, but many groups of individuals crowded within those markings
 resulted in a solid crowd of individuals in line within 1-3 feet of one another for extended periods,
 frequently for many hours. No effort was observed to enforce distancing.
 - Testing participants are assigned by site staff into registration lines that place participants within 3
 feet of other testing participants and within immediate proximity to staff with limited PPE during
 registration.

- Testing participants frequently lacked face coverings, in violation of the Face Covering Order. No
 efforts were observed of testing staff providing masks to the testing participants or attempts to gain
 compliance with the Face Covering Order.
- Inadequate trash and biohazardous waste receptacles and management procedures leading to trash and waste blowing over the grounds of the site. On one site visit biohazardous waste was collected in an open bag taped to the end of a table with items observed falling out of the bag.
- 3. Inadequate procedures for appropriate use of tests and to ensure informed consent of participants.
 - SARS-CoV-2 rapid antigen tests are <u>not recommended for non-clinical settings and community</u> testing sites per Association of Public Health Laboratories:

"Due to the lower sensitivity of antigen tests relative to molecular test, SARS-CoV-2 antigen tests should only be considered for use in situations where a positive result would indicate immediate, specific clinical action and should not be used under the following circumstances:

- Screening of asymptomatic individuals.
- Screening of healthcare workers, emergency responders and other essential personnel.
- Population-based surveillance studies.
- Testing underserved or marginalized populations where access to testing is limited.
 - In these scenarios, efforts to improve access to molecular testing should be explored rather than implementing an antigen test antigen tests should not be considered a "better than nothing" alternative as the results for asymptomatic populations could be falsely positive or negative.
 - Alternatives, such as courier services and public service testing resources should be sought, with transfer of specimens to a laboratory for molecular testing."
- The CDPH also warns against the use of antigen tests: "Antigen tests are NOT recommended for screening of asymptomatic individuals or screening of healthcare workers, first responders and other essential personnel." CDPH notes that because of the incidence of false negatives, all negative tests should be treated as presumptive positives.
- The FDA EUAs for COVID-19 antigen tests require distribution of information to all patients being tested regarding the limitations of the approved antigen tests.
- Per ACPHD staff observations, no information is provided to participants about the limitations of the
 antigen testing being provided, the difference between antigen testing and "molecular" testing
 such as with an FDA approved COVID-19 RT-PCR, and required follow up.
- No signs or information are provided to meet different language and literacy needs of testing participants.
- 4. Failure to isolate all patients being tested for COVID-19 including use of Isolation and Quarantine (for contacts) Orders and instructions from ACPHD.
 - No information on Isolation and Quarantine is being provided, even after County staff delivered copies of these materials for distribution.
- 5. Failure to report all positive, inconclusive and negative COVID-19 tests through the state Electronic Laboratory Reporting system (ELR) to CalREDIE or by other secure electronic transfer to ACPHD (or the health jurisdiction of patient residence) as required by law (see 17 CCR §2505) and Alameda County Health Officer Order 20-02.



ALAMEDA COUNTY HEALTH CARE SERVICES AGENCY PUBLIC HEALTH DEPARTMENT

Colleen Chawla, Director Kimi Watkins-Tartt, Director

Office of the Health Officer 1000 Broadway, 5th Floor Oakland, CA 94607 Nicholas J. Moss, MD, MPH Interim Health Officer (510) 267-3200 Fax (510) 268-2140

- Lab reports must include the date the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the specimen site, the diagnosis codes, the laboratory findings for the test performed, and the date that the laboratory findings were identified. In addition, all reports to the local health officer and all test requisitions must include the name, gender, address, telephone number, pregnancy status, and date of birth of the person from whom the specimen was obtained, and the name, address, and telephone number of the health care provider for whom such examination or test was performed (see 17 CCR §2505)
- This testing site is not currently reporting any results.

CityHealth must immediately correct these deficiencies at all testing site it operates within Alameda County. ACPHD staff are available to provide information and guidance regarding appropriate procedures for testing sites. Alameda County will take appropriate action to protect the public health of County residents if necessary. Questions regarding this letter may be directed to the Alameda County Covid-19 Testing Team through Vassilisa Kapila at Vassilisa.Kapila@acgov.org.

Sincerely,

Dr. Nicholas Moss, Interim Health Officer County of Alameda

CC: Colleen Chawla, Agency Director, Health Care Services Agency Scott Dickey, Assistant County Counsel, Office of the County Counsel Eric Levitt, City Manager, City of Alameda Yibin Shen, City Attorney, City of Alameda