

ORDER OF THE HEALTH OFFICER OF THE CITY OF BERKELEY DIRECTING ALL LABORATORIES CONDUCTING COVID-19 DIAGNOSTIC TESTS TO REPORT COVID-19 TEST INFORMATION – INCLUDING POSITIVE, NEGATIVE, AND INCONCLUSIVE TEST RESULTS – TO LOCAL AND STATE PUBLIC HEALTH AUTHORITIES.

DATE OF ORDER: March 24, 2020

Please read this Order carefully. Violation of or failure to comply with this Order is a misdemeanor punishable by fine, imprisonment, or both. (California Health and Safety Code § 120295, et seq.; California Penal Code §§ 69, 148(a)(1);

Summary: The virus that causes Coronavirus 2019 Disease ("COVID-19") is easily transmitted, especially in group settings, and it is essential that the spread of the virus be monitored and slowed to protect the ability of public and private health care providers to handle the influx of new patients and safeguard public health and safety. Because of the risk of the rapid spread of the virus, and the need to protect all members of the community and the Bay Area region, especially our members most vulnerable to the virus and health care providers, this Order requires that all Laboratories conducting COVID-19 Diagnostic Tests comply with mandated Reporting Requirements as defined below. Reporting Requirements include, but are not limited to, promptly reporting <u>all</u> individual positive, negative, and inconclusive test results electronically to the California Department of Public Health ("CDPH") and, in limited cases where electronic reporting is not possible, to Berkeley Public Health.

This order begins at 12:01 a.m. on March 25, 2020 and will continue to be in effect until it is rescinded, superseded, or amended in writing by the Health Officer.

UNDER THE AUTHORITY OF CALIFORNIA HEALTH AND SAFETY CODE SECTIONS 101040, 101085, AND 120175, THE HEALTH OFFICER OF THE CITY BERKELEY ("HEALTH OFFICER") ORDERS:

1. The intent of this Order is to ensure that any Laboratory conducting Diagnostic Tests adheres to Reporting Requirements established by the Health Officer as those initially capitalized terms are defined in Section 4 and to ensure that complete Diagnostic Test data are promptly shared with the individuals from whom the tested samples were taken, their health care providers, if any, and with public health officials, using the California Reportable Disease Information Exchange ("CalREDIE") system.

- 2. Every Laboratory that generates any test result that was generated from a resident of the City of Berkeley ("City") or was collected or processed in the City from a Diagnostic Test must fully and timely comply with all Reporting Requirements.
- 3. Within one hour of receiving Diagnostic test results, Laboratories must report those results to: (1) the tested individual's health care provider who ordered the test, if any, and other authorized recipients; and (2) public health officials via the CalREDIE system in accordance with all Reporting Requirements.

4. Definitions.

For purposes this Order, the following terms will have the meaning given below.

- a. "Reporting Requirements" means:
 - i. Reporting all <u>positive</u>, <u>negative</u>, <u>and inconclusive</u> Diagnostic Test results in accordance with this Order;
 - ii. Adhering to any and all CDPH reporting and notification requirements for Laboratories conducting Diagnostic Tests, including, without limitation: notification requirements of Chapter 17 of the California Code of Regulations section 2505; the March 9, 2020 CDPH Letter to Laboratory Directors and Managers, attached to this Order as Exhibit A; and the March 9, 2020 CDPH Reportable Conditions: Notification by Laboratories document attached to this Order as Exhibit B, except:
 - 1. Where a Laboratory promptly submits Diagnostic Test results via electronic laboratory reporting to CalREDIE, no further reporting is required. Where a Laboratory is unable to report electronically, it must temporarily report to the City's Communicable Disease Prevention and Control Program via confidential facsimile or telephone; Phone: (510) 981-5292 /Fax: (510) 981-5345.
 - iii. Reporting 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;
 - iv. If provided to the Laboratory, the Laboratory shall report in all test requisitions the name, gender, address including ZIP Code, telephone number, pregnancy status, and date of birth, of the individual who is the subject of the Diagnostic Test; and
 - v. All Laboratories are requested, but at this time not required, to report to the Health Officer and CDPH whether a specimen was collected from an inpatient or outpatient individual.
- b. "Diagnostic Test" means nucleic acid amplification testing or serologic testing to determine the presence of SARS-CoV-2 (the virus that causes COVID-19) or novel

coronavirus infection.

- c. "Laboratory" means any facility meeting the requirements to perform testing classified as high complexity under the Clinical Laboratory Improvement Amendments of section 353 of the Public Health Service Act.
- 5. This Order is issued based on evidence of increasing occurrence of COVID-19 within the City and throughout the Bay Area, scientific evidence and best practices regarding the most effective approaches to slow the transmission of communicable diseases generally and COVID-19 specifically, and evidence that the age, condition, and health of a significant portion of the population of the City places it at risk for serious health complications, including death, from COVID-19. Due to the outbreak of the COVID-19 virus in the general public, which is now a pandemic according to the World Health Organization, there is a public health emergency throughout the City. The scientific evidence shows that at this stage of the emergency, it is essential to slow virus transmission as much as possible to protect the most vulnerable and to prevent the health care system from being overwhelmed. Accurate and precise diagnostic testing is an essential tool for combatting the spread of COVID-19. By sharing high quality test result data at scale, state and local health authorities can better track COVID-19, predict its spread, and better focus public resources to end this global pandemic.
- 6. This Order also is issued in light of the existence of 11 cases of COVID-19 in the City, as well as at least 1,700 confirmed cases and at least 27 deaths in California, as of 10:00 a.m. on Monday, March 23, 2020, including a significant and increasing number of suspected cases of community transmission and likely further significant increases in transmission.
- 7. This Order is issued in accordance with, and incorporates by reference, the March 12, 2020 Executive Order (Executive Order N-25-20) issued by Governor Gavin Newsom, the March 4, 2020 Proclamation of a State of Emergency issued by Governor Gavin Newsom, the March 3, 2020 Proclamation by the Director of Emergency Services, Declaring the Existence of a Local Emergency, the March 10 Resolution of the City Council Ratifying the Proclamation, and guidance issued by the California Department of Public Health, as each of them have been and may be supplemented.
- 8. Pursuant to Government Code sections 26602 and 41601 and Health and Safety Code section 101029, the Health Officer requests that the Chief of Police ensure compliance with and enforce this Order. The violation of any provision of this Order, including any law or regulation cited in this Order, constitutes an imminent threat and creates an immediate menace to public health and may lead to enforcement measures or referral to the relevant enforcement authorities.
- 9. This Order shall become effective at 12:01 a.m. on March 25, 2020 and will continue to be in effect until it is rescinded, superseded, or amended in writing by the Health Officer.
- 10. The City must promptly provide copies of this Order as follows: (1) by posting on the City's website (www.cityofberkeley.info); (2) by posting at 2134 Martin Luther King Jr. Way, Berkeley, CA 94704,; and (3) by providing to any member of the public requesting a copy. In addition, the owner, manager, or operator of any Laboratory that is likely to be impacted by this Order is strongly encouraged to post a copy of this Order onsite and to

provide a copy to any member of the public asking for a copy.

11. If any provision of this Order or its application to any person or circumstance is held to be invalid, then the reminder of the Order, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect. To this end, the provisions of this Order are severable.

Dated: March 24, 2020

IT IS SO ORDERED:

Lisa B. Hernandez, MD, MPH

Health Officer of the City of Berkeley