ORDER OF THE HEALTH OFFICER No. C19-10

ORDER OF THE HEALTH OFFICER OF THE CITY AND COUNTY OF SAN FRANCISCO 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); San Francisco Administrative Code section 7.17(b).)

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 **all** 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 the San Francisco Department of 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This order begins at 12:01 a.m. on March 25, 2020 and will continue to be in effect until it is rescinded, superseded, or amended in writing by the Health Officer.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 AND COUNTY OF SAN FRANCISCO ("HEALTH OFFICER") ORDERS:

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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 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 collected from a resident of the City and County of San Francisco ("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. **<u>Definitions.</u>**

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

- **a. "Reporting Requirements" means:**
  - **i. Reporting all <u>positive, negative, 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 San Francisco Department of Public Health via confidential facsimile or telephone as shown at https://www.sfcdcp.org/wp-**

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content/uploads/2018/01/Reportable-Diseases-List-CMR-SFDPH-EFF-10.2019-UPDATED-12.2019.pdf;

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.

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6. **This Order also is issued in light of the existence of 131 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 February 25, 2020 Proclamation by the Mayor Declaring the Existence of a Local Emergency issued by Mayor London Breed, the March 6, 2020 Declaration of Local Health Emergency Regarding Novel Coronavirus 2019 (COVID-19) issued by the Health Officer, 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 Sheriff and the Chief of Police in the City 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 Administrator's website (sfgsa.org) and the Department of Public Health website (sfdph.org); (2) by posting at City Hall, located at 1 Dr. Carlton B. Goodlett Pl., San Francisco, CA 94102; 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**

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continue in full force and effect. To this end, the provisions of this Order are severable.

IT IS SO ORDERED:

Tomás J. Aragón, MD, DrPH,
Health Officer of the
City and County of San Francisco

Dated: March 24, 2020

EXHIBIT A

State of California—Health and Human Services Agency
California Department of Public Health

SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

GAVIN NEWSOM
Governor

Dear Laboratory Directors and Managers,

The California Department of Public Health (CDPH) expects that CLIA-certified laboratories qualified to perform high complexity testing will soon become eligible to test for SARS-CoV-2, the virus that causes COVID-19, or novel coronavirus infection.

- On February 29, 2020, the Food and Drug Administration (FDA) issued an immediately in effect guidance with policy for diagnostic testing specific to the COVID-19 public health emergency, along with a template for Emergency Use Authorization (EUA) submissions. The guidelines and template are available on the FDA website:
  - Guidance for obtaining approval: https://www.fda.gov/media/135659/download.
  - Template for EUA submissions: https://www.fda.gov/media/135658/download.
- On March 9, 2020, the list of reportable diseases in Title 17, California Code of Regulations (17 CCR) section 2500 was amended to include COVID-19 and Novel coronavirus infections, and 17 CCR section 2505 was amended to include SARS-CoV-2 and Coronavirus, novel strains, effective immediately.
  - Any laboratories approved to test for SARS-CoV-2 must report any positive test results for SARS-CoV-2 **within one hour** to the local health officer for the jurisdiction where the patient resides, by telephone and through the Electronic Laboratory Reporting system (ELR).
  - For more information about the ELR, please visit the CDPH website at https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx.
  - Please use the encoding guidelines for ELR messages for SARS-CoV-2. The LOINC codes are pre-release codes, developed for special use. You can find them, and check for future updates, at https://loinc.org/prerelease/.
  - In addition, please use the following SNOMED codes:

• 260373001	Detected	|	• 260415000	Not detected
• 419984006	Inconclusive	|	• 125154007	Specimen unsatisfactory

- Please note that any California laboratory performing testing under the provisions of the EUA must hold a valid California clinical laboratory license pursuant to Business and Professions Code (BPC) section 1265, and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in BPC section 1206.5 (c).
  - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, BPC section 1241 requires the out-of-state laboratory to hold a valid California clinical laboratory license.
- CDPH requests that any laboratory applying for an EUA please copy Laboratory Field Services (LFScovid@cdph.ca.gov) on the email submitting the completed EUA request to the FDA.

Please contact Laboratory Field Services at LFScovid@cdph.ca.gov if you have questions.

Robert J. Thomas

Robert J. Thomas, Branch Chief

EXHIBIT B

Title 17, California Code of Regulations (CCR), Section 2505

REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES

Effective March 9, 2020

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results, including molecular and pathologic results, suggestive of diseases of public health importance to the local health department. Laboratories must report any initial findings as well as any subsequent findings. In addition, laboratories must report negative test results or findings when requested by the Department or a local health officer. The diseases included are:

Subsection (e)(1) List

- **Anthrax**, animal (B. anthracis)
- **Anthrax**, human (B. anthracis)
- **Botulism**
- **Brucellosis**, human (all Brucella spp.)
- **Burkholderia pseudomallei** (detection or isolation from a clinical specimen)
- **Burkholderia mallei** (detection or isolation from a clinical specimen)
- **Coronavirus,** novel strains
- **Influenza**, novel strains (human)
- **Plague**, animal (Y. pestis)
- **Plague**, human (Y. pestis)
- **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)**
- **Smallpox** (Variola)
- **Tularemia**, human (F. tularensis)
- **Viral hemorrhagic Fever** agents, animal (VHF), (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
- **Viral Hemorrhagic Fever** agents, human (VHF), (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)

Subsection (e)(2) List

- **Acid-fast bacillus** (AFB)
- **Anaplasmosis**
- **Babesiosis**
- **Bordetella pertussis** acute infection, by culture or molecular identification
- **Borrelia burgdorferi** infection
- **Brucellosis**, animal (Brucella spp. except Brucella canis)
- **Campylobacteriosis** (Campylobacter spp.) (detection or isolation from a clinical specimen)
- **Chancroid** (Haemophilus ducreyi)
- **Chikungunya Virus** infection
- **Chlamydia trachomatis** infection, including lymphogranuloma venereum
- **Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing)**
- **Coccidioidomycosis**
- **Cryptosporidiosis**
- **Cyclosporiasis** (Cyclospora cayetanensis)
- **Dengue virus** infection
- **Diphtheria**
- **Ehrlichiosis**
- **Encephalitis**, arboviral
- **Escherichia coli** infection: shiga toxin producing (STEC) including E. coli O157

- **Flavivirus** infection of undetermined species
- **Giardiasis** (Giardia lamblia, intestinalis,or duodenalis)
- **Gonorrhea**
- **Haemophilus influenzae** infection, all types (detection or isolation from a sterile site in a person less than five years of age)
- **Hantavirus** infection
- **Hepatitis A**, acute infection
- **Hepatitis B**, acute or chronic infection (specify gender)
- **Hepatitis C**, acute or chronic infection
- **Hepatitis D** (Delta), acute or chronic infection
- **Hepatitis E**, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)
- **Human Immunodeficiency Virus** (HIV), acute infection
- **Influenza**
- **Legionellosis** (Legionella spp.) (antigen or culture)
- **Leprosy** (Hansen Disease) (Mycobacterium leprae)
- **Leptospirosis** (Leptospira spp.)
- **Listeriosis** (Listeria)
- **Malaria** (Plasmodium spp.)
- **Measles** (Rubeola), acute infection
- **Middle East Respiratory Syndrome Coronavirus (MERS-CoV),** infection
- **Mumps** (mumps virus), acute infection
- **Neisseria meningitidis** (sterile site isolate or eye specimen) infection
- **Poliovirus** infection
- **Psittacosis** (Chlamydophila psittaci)
- **Q Fever** (Coxiella burnetii)
- **Rabies**, animal or human
- **Relapsing Fever** (Borrelia spp.) (identification of Borrelia spp. spirochetes on peripheral blood smear)
- **Rickettsia**, any species, acute infection (detection from a clinical specimen or positive serology)
- **Rocky Mountain Spotted Fever** (Richettsia rickettsii)
- **Rubella**, acute infection
- **Salmonellosis** (Salmonella spp.)
- **Shiga toxin** (detected in feces)
- **Shigellosis** (Shigella spp.)
- **Syphilis**
- **Trichinosis** (Trichinella)
- **Tuberculosis,** including Mycobacterium tuberculosis complex
- **Latent Tuberculosis Infection identified by a positive laboratory test** (includes interferon gamma release assays)
- **Tularemia**, animal (F. tularensis)
- **Typhoid**
- **Vibrio species** infection
- **West Nile virus** infection
- **Yellow Fever** (yellow fever virus)
- **Yersiniosis** (Yersinia spp., non-pestis) (isolation from a clinical specimen)
- **Zika virus** infection

Reportable laboratory findings for these diseases are those specified in 17 CCR Section 2505 or that satisfy the most recent communicable disease surveillance case definitions published by the Centers for Disease Control and Prevention (https://wwwn.cdc.gov/nndss/conditions/search/). **All laboratory reports to public health agencies are treated as confidential.**

WHEN TO REPORT (ALL DISEASES EXCEPT HIV ACUTE INFECTION)

These laboratory findings are reportable to the local health officer of the health jurisdiction where the patient resides by telephone within one (1) hour (List (e)(1) diseases) or within one (1) working day (List (e)(2) diseases) from the time that the laboratory notifies the health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the local health officer of the jurisdiction in which the patient resides within the time specified above from the time the laboratory notifies the referring laboratory that submitted the specimen. If the laboratory is an out-of-state laboratory, the California laboratory that receives a report of such findings shall notify the local health officer in the same way as if the finding had been made by the California laboratory.

HOW TO REPORT (ALL DISEASES EXCEPT HIV ACUTE INFECTION)

Laboratories must report results via electronic laboratory reporting (ELR) to the California Reportable Disease Information Exchange (CalREDIE). Laboratories unable to submit reports electronically may temporarily report on paper to the local health department; reporting on paper must be approved by the local health department. Additional information, including instructions for format of reports, can be found on the CalREDIE ELR webpage (https://www.cdph.ca.gov/Programs/ CID/DCDC/Pages/CalREDIE-ELR.aspx).

Reporting requirements for diseases and agents listed in Subsection (e)(1):

- Make initial report to the local health officer via telephone **within one hour**, and
- Report result(s) to CalREDIE **within one working day** of identification.

Reporting requirements for diseases and agents listed in Subsection(e)(2):

- Report result(s) to CalREDIE within **one working day** of identification.

All reports to the local health officer must include the following: 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.

HIV ACUTE INFECTION REPORTING REQUIREMENTS

In addition to routine reporting requirements set forth in section 2643.10, for acute HIV infection reporting, laboratories shall report all cases within one business day to the local health officer of the jurisdiction in which the patient resides by telephone. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located. If evidence of acute HIV infection is based on presence of HIV p24 antigen, laboratories shall not wait until HIV-1 RNA is detected before reporting to the local health officer.

ADDITIONAL REPORTING REQUIREMENTS

ANTHRAX, BOTULISM, BRUCELLOSIS, GLANDERS, INFLUENZA (NOVEL STRAINS), MELIOIDOSIS, PLAGUE, SMALLPOX, TULAREMIA, and VIRAL HEMORRHAGIC FEVERS

Whenever a laboratory **receives a specimen** for the laboratory diagnosis of a suspected human case of one of these diseases, such laboratory shall **communicate immediately by telephone** with the Infectious Disease Laboratory Branch of the Department of Public Health for instruction.

TUBERCULOSIS (Section 2505 Subsections (f) and (g))

Any laboratory that isolates Mycobacterium tuberculosis complex or identifies Mycobacterium tuberculosis complex by molecular testing from a patient specimen must submit a culture to the local public health laboratory for the local health jurisdiction in which the patient resides as soon as available from the primary isolate on which a diagnosis of tuberculosis was established. If Mycobacterium tuberculosis complex is identified by molecular testing but no culture isolate is available, a specimen available to the laboratory must be submitted instead.

The information listed under "HOW TO REPORT" above must be submitted with the culture.

Unless drug susceptibility testing has been performed by the clinical laboratory on a strain obtained from the same patient within the previous three months or the health care provider who submitted the specimen for laboratory examination informs the laboratory that such drug susceptibility testing has been performed by another laboratory on a culture obtained from that patient within the previous three months, the clinical laboratory must do the following:

- Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom Mycobacterium tuberculosis complex was isolated,

- Report the results of drug susceptibility testing, including molecular assays for drug resistance if performed, to the local health officer of the city or county where the patient resides within **one (1) working day** from the time the health care provider or other authorized person who submitted the specimen is notified, and

- If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, in addition, submit one culture or subculture from each patient from whom multidrug- resistant *Mycobacterium tuberculosis* complex was isolated to the local public health laboratory (as described above) as soon as available.

Whenever a clinical laboratory finds that a specimen from a patient with known or suspected tuberculosis tests positive for acid fast bacillus (AFB) staining and the patient has not had a culture which identifies that acid fast organism within the past 30 days, the clinical laboratory shall culture and identify the acid fast bacteria or refer a subculture to another laboratory for those purposes.

MALARIA (Section 2505 Subsection (h))

Any clinical laboratory that makes a finding of malaria parasites in the blood film of a patient shall immediately submit one or more such blood film slides for confirmation to the local public health laboratory for the local health jurisdiction where the patient resides. When requested, all blood films will be returned to the submitter.

SALMONELLA (Section 2612)

California Code of Regulations, Title 17, Section 2612 requires that a culture of the organisms on which a diagnosis of salmonellosis is established must be submitted to the local public health laboratory and then to the State's Microbial Diseases Laboratory for definitive identification.

Additional Specimens or Isolates to be Submitted to Public Health (Section 2505 Subsection (m)(1) and (m)(2) Lists)

The following specimens or isolates must be submitted as soon as available to the local or state public health laboratory:

(m)(1) Specimens:

- Malaria positive blood film slides (see (h) for additional reporting requirements)
- *Neisseria meningitidis* eye specimens
- Shiga toxin-positive fecal broths
- Zika virus immunoglobulin M (IgM)-positive sera

(m)(2) Isolates:

- Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only)
- *Listeria monocytogenes* isolates
- *Mycobacterium tuberculosis* isolates (see (f) for additional reporting requirements)
- *Neisseria meningitidis* isolates from sterile sites
- *Salmonella* isolates (see section 2612 for additional reporting requirements)
- Shiga toxin-producing *Escherichia coli* (STEC) isolates, including O157 and non-O157 strains
- *Shigella* isolates

Additional Instructions for (m)(2) Isolates (Section 2505 Subsection (m)(3)):
If a laboratory test result indicates infection with any one of the pathogens listed in (m)(2), then the testing laboratory must attempt to obtain a bacterial culture isolate for submission to a public health laboratory in accordance with (m)(2). This requirement includes identification of Shiga toxin in a clinical specimen. If latent tuberculosis infection is identified, an attempt to obtain a bacterial culture isolate is not required. The testing laboratory shall take steps necessary to obtain an isolate, including requesting that additional specimens be collected and sending specimens to a laboratory able to carry out bacterial culture as soon as possible.

Additional Instructions for HIV-1/2 Specimens (Section 2500 Subsection (n)):
Upon written request and submission instructions by the Department, a laboratory that receives a specimen reactive for HIV-1/2 antigen or antibody shall submit the specimen to either the local public health laboratory for the jurisdiction in which the patient resides, the State Public Health Laboratory, or their designee. The specimen submission shall include the information identified in subdivision (m) and the Clinical Laboratory Improvement Amendments number.