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

Updated April 6, 2020

Dear Laboratory Directors and Managers,

The California Department of Public Health (CDPH) expects that many CLIA-certified laboratories qualified to perform high complexity testing are eligible to test for SARS-CoV-2, the virus that causes COVID-19, or novel coronavirus infection, and is providing the following information to address laboratory concerns.

Emergency Use Authorization and COVID-19 Tests

- 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, and followed it with a new guidance on March 16, 2020. 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.
- Please note: The State of California is not authorizing California laboratories to develop and perform tests for COVID-19 at this time and currently has not established a process for authorizing such tests. Laboratories seeking authorization for their own tests for COVID-19 should refer to the FDA Guidance linked above and submit an EUA submission to the FDA as directed in that guidance.
- 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.

Disease Reporting

- 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 all positive, negative, and inconclusive 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

Laboratory and Personnel Requirements

- 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.
- If a California laboratory sends biological specimens originating in California for SARS-CoV-2 testing to a laboratory outside the state that does not hold California licensure, the California laboratory can apply for approval to add the out-of-state laboratory as a temporary testing site to test for SARS-CoV-2 for the duration of the emergency.
    - For more information on this process or to request an application, please contact LFS at LFSCOVID@cdph.ca.gov. LFS will process the application within 10 days of receipt of a complete application, which should be sent to the same email address.
    - Both the California and the out-of-state laboratory must have a CLIA certificate of compliance.

- On March 12, 2020, Governor Newsom issued Executive Order N-25-20, which suspends the certification and licensure requirements of California Code of Regulations, Title17, section 1079 and Business and Professions Code section 1206.5 for the duration of the COVID-19 emergency. This order allows all persons who meet the requirements for personnel performing high-complexity testing specified in Title 42, Code of Federal Regulations, Section 493.1489 to test for SARS-CoV-2, the virus that causes COVID-19, in any certified public health laboratory or licensed clinical laboratory for the duration of the emergency.
    - The laboratory director is responsible for the competency assessment and documentation of all personnel testing for SARS-CoV-2.
    - This order applies to high-complexity testing personnel. It does not alter the qualifications required of a laboratory director, clinical consultant, technical consultant, technical supervisor, and general supervisor or the supervision requirements in current California law.
    - The laboratory director must provide the list of testing personnel along with documentation of competency upon request by LFS.

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

Robert J. Thomas

Robert J. Thomas
Branch Chief

EXHIBIT B

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

March 31, 2020

To: Directors of laboratories conducting testing for SARS-CoV-2

Thank you very much for your efforts to test for SARS-CoV-2 and report results to public health agencies. Increasing testing statewide and monitoring test results will provide critical data needed to guide the response to the COVID-19 pandemic.

As the situation with COVID-19 evolves, the data needs are also changing. The purpose of this letter is to inform you that the California Department of Public Health no longer requires laboratories to immediately notify the local health officer via telephone of a positive SARS-CoV-2/COVID-19) result.

In keeping with Title 17, California Code of Regulations, section 2505, **Laboratories must continue to report both positive and negative SARS-CoV-2/COVID-19 results at least daily through electronic laboratory reporting (ELR).** Questions about reporting via ELR can be directed to calrediehelp@cdph.ca.gov .

We very much appreciate the critical role that laboratories play in the effort to protect public health.

Thank you,

James Watt, MD, MPH
Interim State Epidemiologist
Acting Deputy Director for Center for Infectious Diseases

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EXHIBIT C

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

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.