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

REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES TO PUBLIC HEALTH

March 2024

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*)
- **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)
- ***Candida auris***, colonization or infection
- **Carbapenemase-producing organism,** colonization or infection
- **Chancroid** (*Haemophilus ducreyi*)
- **Chikungunya Virus** infection
- ***Chlamydia trachomatis*** infection, including lymphogranuloma venereum
- **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
- **Monkeypox or orthopox virus** 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)
- **Respiratory syncytial virus**
- ***Rickettsia***, any species, acute infection (detection from a clinical specimen or positive serology)
- **Rocky Mountain Spotted Fever** (*Rickettsia rickettsii*)
- **Rubella**, acute infection
- **Salmonellosis** (*Salmonella spp*.)
- **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)**
- **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, race, ethnicity 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 forinstruction.

### 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 specimens or isolates listed below must be submitted as soon as available to the local or state public health laboratory. The isolate or specimen submission must include the name, address, and date of birth of the person from whom the isolate or specimen was obtained, the patient identification number, the isolate or specimen accession number or other unique identifier, the date the isolate or specimen was obtained from the patient, the name address, and telephone number of the health care provider for whom such examination or test was performed, and the name, address, telephone number and laboratory director's name of the laboratory submitting the isolate or specimen.

(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.

**Instructions for HIV-1/2 Specimens (Section 2505 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.

**Instructions for SARS-CoV-2 Specimens (Section 2505 Subsection (p)):**

Upon written request and submission instructions by the Department or a local health officer, a laboratory that tests any specimen for SARS-CoV-2 shall submit the specimen and any nucleic acid extract to either the local public health laboratory, the State Public Health Laboratory, or their designee. The specimen submission must include the data elements specified under the HOW TO REPORT section on page 3 of this document. In addition, the submission must include the Cycle Threshhold (CT) or Relative Light Units (RLU) value and the federal Clinical Laboratory Improvement Amendments (CLIA) certificate number.

**Instructions for SARS-CoV-2 Sequence Data (Section 2505 Subsection (q)):**

A laboratory that performs genetic sequencing of SARS-CoV-2 shall submit sequence data to the Department in an electronic format specified by the Department. In addition, a laboratory that identifies a SARS-CoV-2 strain designated as a variant of public health importance by the Department shall transmit the report in a format specified by the Department to the state electronic reporting system or local electronic reporting system that this linked to the state electronic reporting system. The sequence data submission and the strain report shall include the information specified under the HOW TO REPORT section on page 3 of this document and if applicable, the federal Clinical Laboratory Improvement Amendments (CLIA) certificate number.

**Instructions for *Candida auris* isolates (Section 2505 Subsection (r)):**

If a Candida auris isolate(s) is identified from a sterile site, and the laboratory has obtained a fungal culture isolate, the isolate(s) must be submitted to a public health laboratory within 10 working days from the date the specimen was collected. The isolate submission must include the data elements specified in subsection (m) and the federal Clinical Laboratory Improvement Amendments (CLIA) certificate number.

Additionally, if requested by the Department or local health officer, the laboratory must attempt to obtain a fungal culture isolate from a specimen site for submission as soon as available to the public laboratory for the local health jurisdiction where the patient resides.