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

REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES

(January 2018)

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results, including molecular and pathologic results, suggestive of the following diseases of public health importance to the local health department:

Subsection (e)(1) List

- Anthrax, animal (B. anthracis)
- Anthrax, human (B. anthracis)
- Botulism
- Brucellosis, human (all Brucella spp.) Burkholderia pseudomallei and B. mallei (detection or isolation from a clinical specimen)
- Influenza, novel strains (human)
- Plague, animal
- Plague, human
- 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 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 infections, including lymphogranuloma venereum
- Coccidioidomycosis
- Cryptosporidiosis
- Cyclosporiasis (Cyclospora cayetanensis)
- Dengue virus infection
- Diphtheria
- Ehrlichiosis
- Encephalitis, arboviral
- Entamoebe histolytica (Not E. dispar)
- Escherichia coli: shiga toxin producing (STEC) including E. coli O157
- Flavivirus infection of undetermined species
- Giardiasis (Giardia lamblia, intestinalis, or duodenalis)
- Gonorrhea
- Haemophilus influenzae, all types (detection or isolation from a sterile site in a person less than five years of age)

- Hantavirus Infections
- 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
- Legionellosis (Legionella spp.) (antigen or culture)
- Leprosy (Hansen Disease) (Mycobacterium leprae)
- Leptospirosis (Leptospira spp.)
- Listeriosis (Listeria)
- Malaria
- Measles (Rubeola), acute infection
- Mumps (mumps virus), acute infection
- Mycobacterium tuberculosis
- Neisseria meningitidis (sterile site isolate)
- Plague (Yersinia pestis), human or animal
- Poliovirus
- 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
- Tularemia, animal (F. tularensis)
- Typhoid
- Vibrio species infections
- 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 notifications are acquired in confidence. The confidentiality of patient information is always protected.**

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 health care provider who first submitted the specimen is located 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 that 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 health care provider is located 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 can report results via electronic laboratory reporting (ELR) to the California Reportable Disease Information Exchange (CalREDIE). Laboratories unable to submit reports electronically must report on paper to the local health department. Additional information 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.

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 Microbial Diseases Laboratory (or, for Influenza, novel strains, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory) of the Department of Public Health for instruction.

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

Any laboratory that isolates *Mycobacterium tuberculosis* or identifies *Mycobacterium tuberculosis* 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 health care provider's office is located as soon as available from the primary isolate on which a diagnosis of tuberculosis was established.

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* 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 submitting physician’s office is located 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* 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 health care provider is located. 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:
- HIV-1/2 antigen or antibody reactive sera or plasma submitted as part of a diagnostic HIV test algorithm, as defined in section 2641.57 (see (n) for additional reporting requirements)
- Malaria positive blood film slides (see (h) for additional reporting requirements)
- Measles immunoglobulin M (IgM)-positive sera
- Shiga toxin-positive fecal broths
- Zika virus immunoglobulin M (IgM)-positive sera

(m)(2) Isolates:

- Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only)
- *Listeriamonocytogenes* isolates
- *Mycobacterium tuberculosis* isolates (see (f) for additional reporting requirements)
- *Neisseria meningitides* 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 Reporting Instructions for (m)(2) Isolates (Section 2505 Subsection (m)(3)):
If there is a laboratory test result indicating infection with any one of the pathogens listed in (m)(2), including identification of Shiga toxin in a clinical specimen, then the laboratory must attempt to obtain a bacterial culture isolate for submission to the public health laboratory in accordance with (m)(2). The 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 Reporting Instructions for HIV-1/2 Specimens (Section 2500 Subsection (n)):
A laboratory that receives a specimen that is reactive for HIV-1/2 antigen or antibody shall communicate with the Department's Viral and Rickettsial Disease Laboratory for instructions on the specimen submission process. A laboratory shall also submit the Clinical Laboratory Improvement Amendments number.