Title 17, California Code of Regulations (CCR), Section 2505
REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES

(edited date: 08/13/2007)

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

List (e)(1)

Anthrax
Avian influenza
Botulism
Brucellosis
Burkholderia mallei* and *pseudomallei
Plague, animal or human
Smallpox (Variola)
Tularemia
Viral hemorrhagic fever agents (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)

List (e)(2)

Acid-fast bacilli
Bordetella pertussis
Borrelia burgdorferi
Chlamydial infections, including Lymphogranuloma Venereum
Cryptosporidiosis
Cyclospora cayetenensis
Diphtheria
Encephalitis, arboviral
***Escherichia coli* STEC, including O157:H7 infection**
Gonorrhea
Hemophilus influenzae (from sterile site in patient <15 years old)
Hepatitis A, acute infection, by IgM antibody test or positive viral antigen test
Hepatitis B, acute infection, by IgM anti-HBc antibody test
Hepatitis B surface antigen positivity (specify gender of case)
Hepatitis C (see instructions below)
Legionella pneumophila
Listeria monocytogenes
Malaria
Measles (Rubeola), acute infection, by IgM antibody test or positive viral antigen test
Mycobacterium tuberculosis (see instructions below)
Neisseria meningitidis (from sterile site)
Rabies, animal or human
Rubella
Salmonella* species, including *S. typhi (Section 2612 – see below)
Shiga toxin (in feces)
Syphilis
***Vibrio* species infections**
West Nile virus infection

WHEN TO REPORT

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

Laboratory reports must be made in writing and give the following information:

- the date the specimen was obtained,
- the patient identification number,
- the specimen accession number or other unique specimen identifier,
- the laboratory findings for the test performed,
- the date that any positive laboratory findings were identified,
- the name, gender, address, telephone number (if known), and age or date of birth of the patient,
- the name, address, and telephone number of the health care provider who ordered the test.

The notification for **List (e)(1) diseases** shall be reported by telephone within **one (1) hour**, followed by a written report submitted by electronic facsimile transmission or electronic mail within **one (1) working day**, to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. The notification for **List (e)(2) diseases** shall be submitted by courier, mail, electronic facsimile transmission or electronic mail within **one (1) working day** to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. Whenever the specimen, or an isolate there from, is transferred between laboratories, a test requisition with the above patient and submitter information shall accompany the specimen. The laboratory that first receives a specimen shall be
responsible for obtaining the patient and submitter information at the time the specimen is received by that laboratory.

ADDITIONAL REPORTING REQUIREMENTS

ANTHRAX, AVIAN INFLUENZA, BOTULISM, BRUCELLOSIS, GLANDERS, 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 Avian Influenza, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory) of the Department of Public Health for instruction.

TUBERCULOSIS

Any laboratory that isolates *Mycobacterium tuberculosis* 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 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).

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

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.

HEPATITIS C

Any laboratory with a positive hepatitis C virus (HCV) test that meets the CDC laboratory criteria for diagnosis of HCV infection in a California resident shall report the positive test to the local health officer.

The following test results are reportable:

(1) All HCV positive recombinant immunoblot assay (RIBA) tests;

(2) All HCV RNA positive tests [e.g., nucleic acid tests (NAT)];

(3) All HCV genotype reports; and

(4) Anti-HCV reactive by a screening test (e.g., enzyme immunoassay [EIA] or chemiluminescene immunoassay [CIA] with either:

(A) The exact signal-to-cut-off (s/co) ratio or index value; or

(B) A comment that indicates whether or not the screening test s/co ratio or index value is predictive of a true positive as determined for the particular assay as defined by the CDC in the case definition for "laboratory criteria for diagnosis" of Hepatitis C virus infection, past or present. The url for the s/co ratios that meet the CDC case definition is: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm.

If a laboratory chooses to report a reactive anti-HCV screening test (e.g., EIA or CIA test) with a s/co or index value that is lower than required to meet the CDC case definitions AND does not report the exact s/co or index value (i.e., the laboratory report is positive without a specific s/co or index value reported), then the laboratory report must include a comment to indicate the s/co or index value is low and that supplemental testing (e.g. RIBA or NAT) is recommended by the CDC.

SALMONELLA

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.

All laboratory notifications are acquired in confidence. The confidentiality of patient information is always protected.