PROPOSED REGULATION TEXT Title 17. California Code of Regulations Division 1, Chapter 4, Subchapter 1, Article 1

Amend Section 2500 to read as follows:

§ 2500. Reporting to the Local Health Authority.

- (a) Through (a)(4) no change to text
- (6) through (9) no change to text

- (10) 'Drug susceptibility testing' means the process where at least one isolate from a culture of a patient's specimen is subjected to antimicrobial testing to determine if growth is inhibited by drugs commonly used to treat such infections, or another type of test using an isolate or specimen that identifies genetic or other features of a microorganism associated with antimicrobial resistance.
- (11) no change to text
- (12) 'Epidemiologically linked case' means a case in which the patient has/hasis likely to have had contact with one or more persons who have/had the disease, and transmission of the agent by the usual modes of transmission is plausible.
- (13) 'Foodborne disease' means illness suspected by a health care provider to have resulted from consuming a contaminated food, non-water beverage, or other ingestible item such as a dietary supplement or herbal remedy.
- (14) 'Foodborne disease outbreak' means an incident in which two or more persons experience a similar illness after ingestion of a common contaminated food, and epidemiologic analysis implicates the food as the source of the illness. There are two exceptions: even one case of botulism or chemical poisoning constitutes an outbreak if laboratory studies identify the causative agent in the foodnon-water beverage, or other ingestible item such as a dietary supplement or herbal remedy.

(15) through (18) no change to text

- (19) 'Laboratory findings' means (A) the results of a laboratory examination of any specimen derived from the human body which yields microscopical, cultural, immunological, serological, microscopic, culture, immunologic, serologic, molecular, pathologic, or other evidence suggestive of a disease or condition made reportable by these regulations; or (B) the results of a laboratory examination of any specimen derived from an animal which yields evidence of rabies or plaguea disease or condition in animals made reportable by these regulations.
- (20) through (21) no change to text
- (22) 'Outbreak' means the occurrence of cases of a disease (illness) above the expected or baseline level, usually over a given period of time, in a geographic area or facility, or in a specific population group. The number of cases indicating the presence of an outbreak will vary according to the disease agent, size and type of population exposed, previous exposure to the agent, and the time and place of occurrence. Thus, the designation of an outbreak is relative to the usual frequency of the disease in the same facility or community, among the specified population, over a comparable period of time. A single case of a communicable disease long absent from a population or the first invasion by a disease not previously recognized requires may constitute an outbreak and require immediate reporting and epidemiologic investigation.

- (23) no change to text
- (24) 'Sexually Transmitted Diseases' means Chancroid, Lymphogranuloma Vvenereum, Granuloma Inguinale, Syphilis, Gonorrhea, and Chlamydia, and Nongonococcal Urethritis.
- (25) 'Suspected case' means (A) a person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence, to probably have a particular disease or condition listed in subsection (j); or (B) a person who is considered a probable case, or an epidemiologically-linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplementsor CSTE; or (C) an animal which has been determined by a veterinarian to exhibit clinical signs or which has laboratory findings suggestive of rabiesa disease or plaguecondition in animals made reportable by these regulations.
- (26) no change to text
- (27) 'Waterborne disease outbreak' means an incident in which two or more epidemiologically-linked persons experienced a similar illness after consumption or use of exposure to the same water intended for drinking or after water contact such as by immersion, source and epidemiologic investigation by public health authorities implicates the same-water as the likely source of the waterborne-illness. There is one exception: a

single case of waterborne This includes any outbreak of an infectious disease, chemical poisoning constitutes an outbreak if laboratory studies indicate that the source water is contaminated by the chemical, or toxin-mediated illness where water is indicated as the source by an epidemiological investigation.

- (b) through (c) no change to text
- (d) Each report made pursuant to subsection (b) shall include all of the following information if known:
- (1) name of the disease or condition being reported; the date of onset; the date of diagnosis; the name, address, telephone number, occupation, race/ethnic group, Social Security number, sexgender, pregnancy status, age, and date of birth for the case or suspected case; the date of death if death has occurred; and the name, address and telephone number of the person making the report.
- (2) If the disease reported pursuant to subsection (b) is hepatitis, a sexually transmitted disease syphilis, or tuberculosis, then the report shall include the following applicable information, if known: (A) for hepatitis, information as to the type of hepatitis, type-specific laboratory findings, and sources of exposure, (B) sexually transmitted disease information as to the specific causative agent for syphilis, syphilis-specific laboratory findings, and any complications of gonorrhea or chlamydia infections, or (C) for tuberculosis, information on the diagnostic status of the case or suspected case,

bacteriologic, radiologic and tuberculin skin test findings, information regarding the risk of transmission of the disease to other persons, and a list of the anti-tuberculosis medications administered to the patient.

- (e) through (i) no change to text
- (j) Health care providers shall submit reports for the following diseases or conditions.

+	Amebiasis
	Anaplasmosis
•	Anthrax, human or animal
+	Babesiosis
•	Botulism (Infant, Foodborne, Wound, Other)
•	Brucellosis, human
	Brucellosis, animal (except infections due to Brucella canis)
+	Campylobacteriosis

	Chancroid
+	Chickenpox (Varicella) (outbreaks, hospitalizations and deaths)
	Chlamydia trachomatis infections, including lymphogranuloma venereum (LGV)
*	Cholera
*	Ciguatera Fish Poisoning
+	Chikungunya virus infection
	Coccidioidomycosis
	Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)
+	Cryptosporidiosis
	Cyclosporiasis
	Cysticercosis or taeniasis

<u>+</u>	Dengue virus infection
•	Diphtheria
•	Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
	Erlichiosis
+	Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
<u>♦±</u>	Escherichia coli: shiga toxin producing (STEC) including E. coli O157
♦	Flavivirus infection of undetermined species
+•	Foodborne Disease
	Giardiasis
	Gonococcal Infections
+	Haemophilus influenzae, invasive disease, all serotypes (report an incident of less than five years of age)
+	Hantavirus Infections

•	Hemolytic Uremic Syndrome
+	Hepatitis A, acute infection
	Hepatitis B (specify acute case or, chronic, or perinatal)
	Hepatitis C (specify acute-case or, chronic, or perinatal)
	Hepatitis D (Delta) (specify acute case or chronic)
	Hepatitis E, acute infection
	Human Immunodeficiency Virus (HIV) infection, stage 3 (AIDS)
+	Human Immunodeficiency Virus (HIV), acute infection, (see (k) for additional reporting requirements)
	Human Immunodeficiency Virus (HIV) infection, any stage
	Human Immunodeficiency Virus (HIV) infection, progression to stage 3 (AIDS)
	Influenza, associated deaths in laboratory-confirmed cases for ages 0-64 less than 18 years of age

•	Influenza , due to novel strains (human)
	Legionellosis
	Leprosy (Hansen Disease)
	Leptospirosis
+	Listeriosis
	Lyme Disease
+	Malaria
•	Measles (Rubeola)
+	Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
•	Meningococcal Infections
<u> </u>	Middle East Respiratory Syndrome (MERS)
	Mumps

•	Novel virus infection with pandemic potential
•	Paralytic Shellfish Poisoning
<u>+</u>	Paratyphoid Fever
+	Pertussis (Whooping Cough)
•	Plague, human or animal
+	Poliovirus Infection
+	Psittacosis
+	Q Fever
•	Rabies, human or animal
+	Relapsing Fever
	Respiratory syncytial virus (only report a_associated deaths in a patient laboratory-confirmed cases less than five years of age)

	Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus
	and Typhus-like Illnesses
	Rocky Mountain Spotted Fever
	Rubella (German Measles)
	Rubella Syndrome, Congenital
+	Salmonellosis (Other than Typhoid Fever)
•	Scombroid Fish Poisoning
•	Shiga toxin (detected in feces)
+	Shigellosis
•	Smallpox (Variola)
#	Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)
+	Syphilis (all stages, including congenital)

	Tetanus
+	Trichinosis
+	Tuberculosis
♦	Tularemia, human
	Tularemia, animal
+	Typhoid Fever, Cases and Carriers
+	Vibrio Infections
•	Viral Hemorrhagic Fevers, human or animal (e.g., Crimean- Congo, Ebola, Lassa and Marburg viruses)
+	West Nile virus infection
<u> </u>	Yellow Fever
+	Yersiniosis
<u> </u>	Zika virus infection

*	OCCURRENCE of ANY UNUSUAL DISEASE
•	OUTBREAKS of ANY DISEASE (Including diseases not listed in Section
	2500). Specify if institutional and/or open community.

- (\spadesuit) = to be reported immediately by telephone.
- (+) = to be reported by mailing a report, telephoning, or electronically transmitting a report within one (1) working day of identification of the case or suspected case.
 (No diamond or cross symbol) = to be reported within seven (7) calendar days by mail, telephone, or electronic report from the time of identification.
- (•) = when two (2) or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness, they should be reported immediately by telephone.

(k) no change to text

Note: Authority cited: Sections 120130, 131050, 131051, 131052, 131080 and 131200, Health and Safety Code. Reference: Sections 1603.1, 100325, 103925, 113150, 113155, 120125, 120130, 120140, 120175, 120245, 120250, 131050, 131051 and 131080, Health and Safety Code; Sections 551, 554 and 555, Business and Professions Code; Section 1798.3, Civil Code; 42 C.F.R. Sections 2.11 and 2.12; Cal. Const., art. 1, Section 1; and Section 1040, Evidence Code.

Amend Section 2505 to read as follows:

§ 2505. Notification by Laboratories.

(a) To assist the local health officer, the laboratory director, or the laboratory director's designee, of a clinical laboratory, an approved public health laboratory or a veterinary laboratory in which a laboratory examination of any specimen derived from the human body (or from an animal, in the case of rabies or plaque testing disease or condition in animals made reportable by these regulations) yields microscopical, cultural, immunological, serological, microscopic, culture, immunologic, serologic, molecular, pathologic, or other evidence suggestive of those diseases listed in subsections (e)(1) and (e)(2) below, shall report such findings to the health officer of the local health jurisdiction where the health care provider who first submitted the specimen is located, except for acute HIV infection reporting which shall be reported to the local health jurisdiction in which the patient resides by telephone (see (j) for specific acute HIV infection reporting requirements). If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located. The reporting specified above shall include any initial findings as well as any subsequent findings as a result of additional laboratory examination. In addition, the laboratory director or the laboratory director's designee shall also report negative laboratory test results or other laboratory findings when requested by the Department or a local health officer.

- (1) For those diseases listed in subsection (e)(1), the report of such findings shall be made within one hour after 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 health officer of the jurisdiction in which the health care provider is located where the patient resides within one hour from the time the laboratory notifies the referring laboratory that submitted the specimen. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located.
- (2) For those diseases listed in subsection (e)(2), the report of such findings shall be made within one working day 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 health officer of the jurisdiction in which the health care provider is located where the patient resides within one working day from the time the laboratory notifies the referring laboratory that submitted the specimen, except for acute HIV infection reporting which shall be reported to the local health jurisdiction in which the patient resides by telephone (see (j) for specific acute HIV infection reporting requirements). If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located.

- (b) To permit local health officer follow-up of laboratory findings, all specimens submitted for laboratory tests or examinations related to a disease or condition listed in subsections 2505(e)(1) or 2502(e)(2) shall be accompanied by a test requisition which includes the name, gender, pregnancy status, address and age or date-of-birth of the person from whom the specimen was obtained and the name, address and telephone number of the health care provider or other authorized person who submitted the specimen. Whenever the specimen, or an isolate therefrom, 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.
- (c) Each notification to the local health officer shall include the date the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the specimen site, the diagnosis code, the laboratory findings for the test performed, the date that any positivethe laboratory findings were identified, the name, gender, address, telephone number (if known), pregnancy status, and age or 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. Laboratories shall report the elements specified above in a format specified by the Department.

- (d) The notification shall be submitted as specified in subsections (e)(1) and (e)(2) of this Section to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located patient resides. When the specimen is from an out-of-state submitter, the state epidemiologist of the submitter shall be provided the same positive findings per subsections (e)(1) and (e)(2) of this Section. If the laboratory that finds evidence for any of those diseases listed in subsections (e)(1) and (e)(2) is an out-of-state laboratory, the California clinical laboratory that receives a report of such findings from the out-of-state laboratory shall notify the local health officer in the same way as if the finding had been made by the California laboratory.
- (e) Laboratory reports to the local health officer shall include the information as specified in (c) of this Section and laboratories shall submit the reports within the following timeframes:
- (1) The diseases or agents specified shall be reported within one hour after the health care provider or other person authorized to receive the report has been notified.

 Laboratories shall make the initial reports to the local health officer by telephone and follow the initial report within one working day by a report in writing submitted by electronic facsimile transmission or electronic mail to the local health officer. Within one year of the establishment of the state electronic reporting system, all List (e)(1) diseases, in addition to being reported by telephone within one hour, shall be reported electronically to the state or local electronic reporting system within one working day of identification. Reporting that is linked to the state electronic reporting system. If

reporting substitutes to the state or local electronic system is not possible, reporting by electronic facsimile transmission and electronic mail may temporarily substitute for reporting to the state or local electronic reporting system. Laboratories shall also report by other means (e.g., electronic facsimile) if requested by a local health officer or the Department. Laboratory findings for these diseases are those that satisfy the most recent communicable disease surveillance case definitions established by the CDC (unless otherwise specified in this Section). The diseases or agents reported pursuant to this requirement are:

Anthrax, human (*B. anthracis*) (see section 2551 for additional reporting instructions)

Anthrax, animal (*B. anthracis*)

Botulism (see section 2552 for additional reporting instructions)

Brucellosis, human (all *Brucella spp.*) (see section 2553 for special reporting instructions)

Burkholderia pseudomallei and B. mallei (detection or isolation from a clinical specimen)
Influenza, novel strains (human) (see (i) for additional reporting requirements)

Plague, animal

Smallpox (Variola) (see section 2614 for additional reporting instructions)

Plague, human (see section 2596 for additional reporting instructions)

Tularemia, human (*F. tularensis*) (see section 2626 for additional reporting instructions)

Viral Hemorrhagic Fever agents, human (VHF), e.g., Crimean-Congo, Ebola, Lassa,

and Marburg viruses (see section 2638 for additional reporting instructions)

Viral Hemorrhagic Fever agents, animal (VHF), e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses

(2) The diseases or agents specified shall be reported within one working day after the health care provider or other person authorized to receive the report has been notified. Laboratories shall transmit these reports to the state electronic reporting system or local health officer by courier, mail, electronic facsimile or electronic mailreporting system that istinked to the state electronic reporting system, except for acute HIV infection reporting which shall be reported by telephone (see (j) for specific acute HIV infection reporting requirements). Within one year of the establishment of the state electronic reporting system, all List (e)(2) diseases shall be reported electronically to the state electronic reporting system within one working day of identification. Acute HIV infection shall be reported both by telephone and to the state electronic reporting system within one working day of identification. If Reporting to the state or local electronic reporting system substitutes for is not possible, reporting by courier, mail, electronic facsimile transmission or electronic mail may temporarily substitute for reporting to the state or local electronic reporting system. Laboratories shall also report by other means (e.g., electronic <u>facsimile</u>) if requested by a health officer or the <u>Department</u>. Laboratory findings for these diseases are those that satisfy the most recent communicable disease surveillance case definitions established by the CDC (unless otherwise specified in this Section). The diseases or agents reported pursuant to this requirement are:

Acid fast bacillus (AFB) (see (g) for additional reporting requirements)

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 a clinical specimen)

Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing)

Chancroid (Haemophilus ducreyi)

Chikungunya virus infection

Chlamydia trachomatis infections, including lymphogranuloma venereum (LGV)

Coccidioidomycosis

Cryptosporidiosis

Cyclosporiasis (Cyclospora cayetanensis)

Dengue virus infection

Diphtheria

Ehrlichiosis

Encephalitis, arboviral

Entamoeba histolytica (not E. dispar)

Escherichia coli: shiga toxin producing (STEC) including E. coli O157(see (m) for additional reporting requirements)

Flavivirus infection of undetermined species

Giardiasis (Giardia lamblia, intestinalis, or duodenalis)

Gonorrhea

Haemophilus influenzae, all types (detection of or isolation from a sterile site in a person less than 5 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 (see (j) for additional reporting requirements)

Influenza

Legionellosis (*Legionella spp.*) (antigen or culture)

Leprosy (Hansen Disease) (*Mycobacterium leprae*)

Leptospirosis (Leptospira spp.)

Listeriosis (*Listeria*) (see (*I*m) for additional reporting requirements)

Malaria (see (h) for additional reporting requirements)

Measles (Rubeola), acute infection (see (/) for additional reporting requirements)

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Mumps (mumps virus), acute infection

Mycobacterium tuberculosis (see (f) for additional reporting requirements)

Neisseria meningitidis (sterile site isolate or eye specimen) (see (Im) for additional reporting requirements)

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 (*Rickettsia rickettsii*)

Rubella, acute infection

Salmonellosis (*Salmonella* spp.) (see Section 2612 (a) for additional reporting requirements)

Shiga toxin (detected in feces) (see (<u>fm</u>) for additional reporting requirements)

Shigellosis (*Shigella* spp.) (see (m) for additional reporting requirements)

Syphilis

Trichinosis (*Trichinella*)

Tuberculosis, including *Mycobacterium tuberculosis* complex (see (f) for additional reporting requirements)

Latent Tuberculosis Infection identified by a positive laboratory test (see (o) for additional reporting requirements)

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 (see (m) for additional reporting requirements)

- (f) In addition to notifying the local health officer pursuant to subsection (a), any clinical laboratory or approved public health laboratory that isolates *Mycobacterium tuberculosis* complex or identifies *Mycobacterium tuberculosis* complex by molecular testing from a patient specimen shall:
- (1) Submit a culture as soon as available from the primary isolate on which a diagnosis of tuberculosis was established. Such a culture shall be submitted to the public health laboratory designated in Title 17 California Code of Regulations, Section 1075 for the local jurisdiction where the health care provider's office is locatedpatient resides. The following information shall be submitted with the culture: the name, address, and the date of birth of the person from whom the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the date the specimen was obtained from the patient, and the name, address, and telephone number of the health care provider for whom such examination or test was performed. The public health laboratory shall retain the culture received (one culture from each culture-positive patient) in a viable condition for at least six months.
- (A) If *Mycobacterium tuberculosis* complex is identified by molecular testing but no culture isolate is available, a specimen available to the laboratory shall be submitted to the public health laboratory designated in Title 17 California Code of Regulations

Section 1075 upon request from the local health officer, public health laboratory, or the

<u>Department's Microbial Disease Laboratory.</u>

- (2) no change to text
- (A) Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom *Mycobacterium tuberculosis* complex was isolated; and
- (B) Report the results of drug susceptibility testing including molecular assays for drug resistance, if performed, to the local health officer of the city or countyjurisdiction where the submitting physician's office is located patient resides within one working day from the time the health care provider or other authorized person who submitted the specimen is notified; and
- (C) If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, in additionas soon as available, submit one culture or subculture from each patient from whom multidrug-resistant *Mycobacterium tuberculosis* complex was isolated to the official public health laboratory designated in Title 17 California Code of Regulations Section 1075 for the local health jurisdiction in which the health care provider's office is located patient resides. The local public health laboratory shall forward such cultures to the Department's Microbial Diseases Laboratory. The following information shall be submitted with the culture: the name, address, and the date of birth of the person from whom the specimen was obtained, the patient identification number,

the specimen accession number or other unique specimen identifier, the date the specimen was obtained from the patient, and the name, address, and telephone number of the health care provider for whom such examination or test was performed.

- (g) no change to text
- (h) In addition to notifying the local health officer pursuant to subsection (a), 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 public health laboratory designated in Title 17 California Code of Regulations Section 1075 for the local health jurisdiction where the health care provider is located patient resides. When requested, all blood films shall be returned to the submitter.
- (i) no change to text
- (j) In addition to routine reporting requirements set forth in section 2643.10, for acute HIV infection reporting, laboratories shall report all cases within one 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.

(k) through (l) no change to text

(m) An isolate or a specimen as listed in this subsection shall be submitted as soon as available to the public health laboratory designated in Section 1075 for the local health jurisdiction where the health care provider is located patient resides. The following information shall be submitted with the isolate or specimen: the name, address, and the 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 the laboratory director's name of the laboratory submitting the isolate or specimen.

(1) The specimens pursuant to the requirements in (m) are:

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

Neisseria meningitidis eye specimens

Shiga toxin-positive fecal broths

Zika virus immunoglobulin M (IgM)-positive sera

- (2) no change to text
- (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). This requirement includes identification of Shiga toxin in a clinical specimen, but does not include latent tuberculosis infection identified by a positive laboratory test. 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.
- (n) A<u>Upon written request and submission instruction by the Department, a</u> laboratory which that receives a specimen that is reactive for HIV-1/2 antigen or antibody, as defined within this subsection, shall communicate with the Department's Viral and Rickettsial Disease submit the specimen to either the local public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides, the State Public Health Laboratory for instructions on the, or their designee. The specimen submission process. In addition to shall include the information required identified in subdivision (m), a laboratory shall also submit and the Clinical Laboratory Improvement Amendments number.

- (1) For purposes of this subsection, the specimen shall be defined as the 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
- (o) Results of positive laboratory tests, including positive interferon gamma release assays, should be reported including quantitative components of results, if applicable.

Note: Authority cited: Sections 100275, 120130, 125095, 131050, 131051, 131052, 131080 and 131200, Health and Safety Code. Reference: Sections 100180, 120125, 120130, 120140, 120175, 120575, 121365, 125100 and 131080, Health and Safety Code; Sections 1209, 1246.5 and 1288, Business and Professions Code; Cal. Const., art. 1, Section 1; and Section 1040, Evidence Code.