

Clinical Laboratory Reporting and Specimen Submission Guidelines

San Diego County Public Health Laboratory - Epidemiology and Immunization Services

Note: This document describes the laboratory reporting requirements contained in the California Code of Regulations Title 17, including Section 2505, as well as local requirements for submitting specimens and laboratory test results suggestive of specified diseases of public health importance to the local health department. This document is available for download from the San Diego Public Health Laboratory website, under *Disease Reporting Requirements for Laboratorians*.

NOTIFICATION BY LABORATORY

Section 2505 (a): To assist the 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 specified diseases) yields microscopical, cultural, immunological, serological, 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. Laboratory findings for these diseases are those that satisfy the most recent [communicable disease surveillance case definitions](#) established by the Centers for Disease Control and Prevention (unless otherwise specified in this Section). **All laboratory notifications are acquired in confidence. The confidentiality of patient information is protected.**

CHANGES TO SECTION 2505 (Effective June 2016)

Section 2505 specifies that laboratories must report all laboratory testing results suggestive of diseases of public health importance to the local health department within the specified timeframe. A subsection of 2505 specifies isolates or specimens that must be submitted to the public health laboratory. A new subsection, described below, requires laboratories to attempt to obtain a bacterial culture isolate in certain cases.

- The following diseases have been **added** to subsection (e)(2); laboratory results suggestive of these diseases must now be reported to the local health department within one working day.
 - Babesiosis
 - Chikungunya Virus Infection
 - Flavivirus infection of undetermined species
 - *Entamoeba histolytica* (not *E. dispar*)
 - Zika Virus Infection

- The subsection related to isolate and specimen submission has been re-organized as follows:
 - (m)(1) lists the specimens to be submitted as soon as available to the local or state public health laboratory. The following specimen has been **added**:
 - Zika virus immunoglobulin M (IgM) positive sera
 - (m)(2) lists the isolates to be submitted as soon as available to the local or state PHL. The following isolates have been **added**:
 - Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only).
 - *Shigella* isolates.
 - **(m)(3) is a new subsection. It states that laboratories must attempt to obtain a bacterial culture isolate whenever there is a laboratory test result indicative of infection with any of the pathogens listed in subsection (m)(2).** These pathogens are:
 - Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only).
 - *Listeria monocytogenes* isolates.
 - *Mycobacterium tuberculosis* isolates from sterile sites.
 - *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.

HOW TO REPORT

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 about CalREDIE ELR can be found here:

[https://www.cdph.ca.gov/data/informatics/tech/](https://www.cdph.ca.gov/data/informatics/tech/Pages/CalREDIEE_LR.aspx)

[Pages/CalREDIEE_LR.aspx](https://www.cdph.ca.gov/data/informatics/tech/Pages/CalREDIEE_LR.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.

When submitting reports in writing include following information:

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

Send laboratory reports to Epidemiology via fax 858-715-6458 or electronic laboratory reporting.

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.

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. Whenever the specimen, or an isolate there from, is transferred between laboratories, a test requisition with the 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.

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.

List (e)(1) Diseases – Notification within 1 hour		
Disease/Microorganism	Submit to Public Health Lab	Report to Public Health Svcs
Anthrax, animal (<i>B. anthracis</i>)	n/a	<u>Within 1 hour:</u> Call to Epidemiology 619-692-8499 After Hours 858-565-5255 <u>Within 1 day:</u> Fax to Epidemiology 858-715-6458 See ADDITIONAL REPORTING REQUIREMENTS
Anthrax, human (<i>B. anthracis</i>)	suspect isolate	
Botulism	serum	
Brucellosis, human (all <i>Brucella spp.</i>)	suspect isolate	
<i>Burkholderia pseudomallei</i> and <i>B. mallei</i> (detection or isolation from a clinical specimen)	suspect isolate	
Influenza, novel strains (human)	respiratory specimen in VTM	
Plague, animal	n/a	
Plague, human	suspect isolate	
Smallpox (Variola)	scab, scab fluid, dry/wet swab of lesion	
Tularemia, human (<i>F. tularensis</i>)	suspect isolate	
Viral hemorrhagic fever agents, animal (VHF),	n/a	

(e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses)		
Viral hemorrhagic fever agents, human (VHF), (e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses)	serum	

Whenever a laboratory **receives a specimen** for the laboratory diagnosis of a suspected human case of one of these **List (e)(1) diseases**, such laboratory shall **communicate immediately by telephone** with the Microbial Diseases Laboratory 510-412-3700 (or, for Influenza, novel strains, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory 510-307-8585) of the California Department of Public Health for instruction. The laboratory should also immediately contact the San Diego County Public Health Laboratory 619-692-8500. In addition San Diego County Epidemiology branch should be contacted at 619-692-8449.

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.

List (e)(2) Diseases – Notification within 1 working day		
Disease/Microorganism	Submit to Public Health Lab	Report to Public Health Svcs
**Acid-fast bacillus	n/a	<p>Within 1 day:</p> <p>Fax to Epidemiology 858-715-6458</p> <p><u>Provide the following:</u> Date of specimen Patient ID number Specimen accession number Laboratory findings Date of any positive findings Patient information - Name - Date of birth - Gender - Address - Telephone number</p> <p>Ordering health care provider - Name - Address - Telephone number</p> <p>This information may be submitted via a laboratory report or by completing a Confidential Morbidity Report (please attach the laboratory report to the CMR).</p>
Anaplasmosis	n/a	
Babesiosis	n/a	
<i>Bordetella pertussis</i>	n/a	
<i>Borrelia burgdorferi</i>	n/a	
Brucellosis, animal (<i>Brucella spp. except Brucella canis</i>)	n/a	
Campylobacteriosis (<i>Campylobacter spp.</i>) (detection or isolation from a clinical specimen)	n/a	
Chancroid (<i>Haemophilus ducreyi</i>)	n/a	
Chikungunya Virus Infection	n/a	
Coccidioidomycosis	n/a	
Cryptosporidiosis	n/a	
Cyclosporiasis (<i>Cyclospora cayetenensis</i>)	n/a	
Dengue virus infection	n/a	
Diphtheria	n/a	
Ehrlichiosis	n/a	
Encephalitis, arboviral	n/a	
<i>Entamoeba histolytica</i> (Not <i>E. dispar</i>)	n/a	
<i>Escherichia coli</i> : shiga toxin producing (STEC), including <i>E. coli</i> O157	isolate, broth	
Flavivirus infection of undetermined species	n/a	
Giardiasis (<i>Giardia lamblia, intestinalis, or duodenalis</i>)	n/a	
Gonorrhea		
<i>Haemophilus influenzae, all types</i> (detection or isolation from a sterile site in a person less than five years of age)	n/a	
Hantavirus infections	serum	
Hepatitis A, acute infection	n/a	
Hepatitis B, acute or chronic infection (specify gender)	n/a	
Hepatitis C, acute or chronic infection	n/a	
Hepatitis D (Delta), acute or chronic infection	n/a	
Hepatitis E, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)	n/a	
Human Immunodeficiency Virus (HIV), acute	serum or plasma	

infection		
Legionellosis (<i>Legionella spp.</i>) (antigen or culture)	n/a	
Leprosy (Hansen Disease) (<i>Mycobacterium leprae</i>)	n/a	
Leptospirosis (<i>Leptospira spp.</i>)	n/a	
Listeriosis (<i>Listeria</i>)	isolate	
Malaria	blood film slide, EDTA blood tube	
Measles (Rubeola), acute infection	serum(IgM)	
Mumps (mumps virus), acute infection	serum	
<i>Neisseria meningitidis</i> (sterile site isolate)	isolate	
Poliovirus	n/a	
Psittacosis (<i>Chlamydophila psittaci</i>)	n/a	
Q Fever (<i>Coxiella burnetii</i>)	whole blood and serum	
Rabies, animal or human	n/a	
Relapsing Fever (<i>Borrelia spp.</i>) (identification of <i>Borrelia spp.</i> spirochetes on peripheral blood smear)	n/a	
<i>Rickettsia</i> , any species, acute infection (detection from a clinical specimen or positive serology)	n/a	
Rocky Mountain Spotted Fever (<i>Rickettsia rickettsii</i>)	n/a	
Rubella, acute infection	n/a	
Salmonellosis (<i>Salmonella spp.</i>)	isolate	
Shigellosis (<i>Shigella spp.</i>)	isolate	
Trichinosis (<i>Trichinella</i>)	n/a	
Tuberculosis		
Tularemia, animal (<i>F. tularensis</i>)	n/a	
Typhoid	isolate	
<i>Vibrio species</i> infection	isolate	
West Nile virus infection	CSF, serum	
Yellow Fever (yellow fever virus)	serum	
Yersiniosis (<i>Yersinia spp.</i> , non-pestis) (isolation from a clinical specimen)	isolate	
Zika virus infection	serum	
<i>Chlamydia trachomatis</i> infections, including lymphogranuloma venereum (LGV)	n/a	Within 1 day: Fax to STD Program 619-692-8541
Gonorrhea	Cephalosporin or azithromycin resistant isolates	
Syphilis	n/a	
** <i>Mycobacterium tuberculosis</i> (see additional requirements for drug susceptibility testing and reporting)	isolate	Within 1 day: Fax to TB Program 619-692-5516

n/a = not applicable

**See additional instructions in this document's ADDITIONAL REPORTING REQUIREMENTS

ADDITIONAL REPORTING REQUIREMENTS

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 (and EDTA blood tube, if possible) 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.

TUBERCULOSIS (AND ACID-FAST BACILLUS)

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 the HOW TO SUBMIT SPECIMENS section below must be submitted with the culture. *The San Diego County Public Health Laboratory shall retain the culture received (one culture from each culture-positive patient) in a viable condition for at least six months.*

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 all of 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.
- 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. *The San Diego County Public Health Laboratory shall forward such cultures to the CDPH Microbial Disease Laboratory.*

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.

HOW TO SUBMIT SPECIMENS

The following information should be submitted with the specimen:

- Name, address, and date of birth of the person from whom the specimen was obtained
- Patient identification number
- Specimen accession number or other unique specimen identifier
- Date the specimen was obtained from the patient
- Name, address, and telephone number of the health care provider who ordered the test
- Appropriate form (see Form List below)
 - A legible copy of a laboratory report containing all of the above information is satisfactory if you do not have the correct form.
 - Special forms are required to be submitted for testing of the following diseases:
 - Avian Influenza
 - Botulism
 - Hantavirus
 - Influenza (Seasonal and 2009 Pandemic H1N1)
 - Hepatitis E
 - Malaria
 - Smallpox
 - West Nile virus
 - To obtain forms:
 - Download from the California Health Alert Network (CAHAN) San Diego Public Health Laboratory subfolder.
 - Contact the San Diego County Public Health Laboratory (619) 692-8500.

FORM LIST

- [Confidential Morbidity Report](#)
- Adult C. botulinum Toxin Detection Laboratory Request and Final Report Form
- Avian Influenza A (H5N1) Submittal Form
- Bacterial Culture for Identification Form
- Blood Lead Request Form
- CDC DASH Form 50.34
- Chlamydia/Gonorrhea Examination Form
- Chlamydia/Gonorrhea Examination Form (Juvenile Hall)
- Clinical Laboratory Request Form
- Enteric Culture Form
- Gonorrhea Culture Requisition Form
- Hepatitis Serology Form
- HIV Court Order Form
- HIV-1 Antibody Test Request Form
- Influenza Virus Culture Request Form
- Influenza Virus PCR Requisition Form (Seasonal and 2009 Pandemic H1N1)
- Interfering Substances with Botulism Testing
- Lab Supply Request Form – LAB (P1)
- Medical Examiner Submittal Form
- Molecular Test Request Form
- Mycobacteria (TB) CI Form

- Mycobacteria (TB) Culture Form
- Mycology CI Form
- Parasitology Requisition Form
- Quantiferon In-tube Lab Request Form
- Serologic Examination Form
- Smallpox Sample Submission Form
- Submittal Form for Methicillin Resistant Staphylococcus aureus (MRSA) isolates
- Syphilis Serology Form
- Virus Isolation Request Form
- West Nile Virus Specimen Submittal Form

PACKAGING AND SHIPPING INFORMATION

All specimens submitted to the San Diego County Public Health Laboratory must comply with all applicable U.S. Postal Service, DOT, or IATA requirements (i.e., packaged, labeled, and documented, as per applicable regulations).

Laboratory Telephone Number: (619) 692-8500

Laboratory FAX Number: (619) 692-8558

Mailing Address (w/ Mail Stop): San Diego County Public Health Laboratory
3851 Rosecrans Street, Suite 716
San Diego, CA 92110-3115
MS P572

REFERENCE WEBSITES

1. California Department of Public Health (CDPH) Reportable Diseases and Conditions
<http://www.cdph.ca.gov/HealthInfo/Documents/Title17Section2505List.pdf>
2. County of San Diego Public Health Laboratory
http://sdcounty.ca.gov/hhsa/programs/phs/phs_laboratory/index.html
3. County of San Diego Epidemiology Program
<http://www.sdepi.org/>