CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

CDPH California Department of PublicHealth

Division of Communicable Disease Control

Guidance for Laboratories on Reportable Diseases and Laboratory Results January 2014

The California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results suggestive of specified diseases of public health importance to the local health department (http://www.cdph.ca.gov/HealthInfo/Documents/TITLE_17_SECTION_2505.pdf). Section 2505, however, lists only the specified diseases and not which laboratory testing results to report. To guide laboratories with the reporting requirement, the California Department of Public Health (CDPH) Division of Communicable Disease Control has compiled the following list of laboratory testing results for specified diseases in Section 2505 list (e)(2) that should be reported to local health departments. This listing is based mainly on the U. S. Center for Disease Control and Prevention (CDC) and Council of State and Territorial Epidemiologists (CSTE) surveillance case definitions. Detailed case definitions can be found on the CDC website: **http://wwwn.cdc.gov/nndss/script/casedefDefault.aspx**

In addition, AB 186 chaptered in 2011 requires CDPH to establish a list of diseases and conditions for which clinical laboratories shall submit a culture or a specimen to the local public health laboratory. This list in Title 17 Section 2505 (l) was added to the regulations in January, 2014 and is available at http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx. Specimen submission requirements are included in the list below.

Separate Instructions are provided for the Select Agents, Section 2505, List (e)(1): anthrax, botulism, brucellosis, *Burkholderia* infections, influenza novel strains, plague, smallpox, tularemia, and viral hemorrhagic fever agents on the Reportable Diseases website: http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx

Title 17 - List (e)(2) Bacteria, Fungi, Parasites, Viruses – Reportable Findings

Positive lab results for List (e)(2) agents or diseases are reportable to the local Public Health Officer or designee per Title 17 Section 2505 within 1 day of submission of results to the health care provider.

Acid-fast bacillus

- Report any detection to the local health department

Per Title 17 §2505 (g) 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.

Anaplasmiosis/Ehrlichiosis

A. ***Ehrlichia chaffeensis* (formerly Human Monocytic Ehrlichiosis [HME])**

- Serological evidence of elevated IgG or IgM antibody reactive with *E. chaffeensis* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or assays in other formats
- Identification of morulae in the cytoplasm of monocytes or macrophages by microscopic examination
- Detection of *E. chaffeensis* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay
- Demonstration of ehrlichial antigen in a biopsy or autopsy sample by immunohistochemical methods
- Isolation of *E. chaffeensis* from a clinical specimen in cell culture

B. ***Ehrlichia ewingii***

- *E. ewingii* DNA detected in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay

C. **Anaplasma phagocytophilum**

- Serological evidence of elevated IgG or IgM antibody reactive with *A. phagocytophilum* antigen by indirect immunofluorescence assay (IFA), enzyme-linked immunosorbent Assay (ELISA), dot-ELISA, or assays in other formats
- Identification of morulae in the cytoplasm of neutrophils or eosinophils by microscopic examination
- Detection of *A. phagocytophilum* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay
- Demonstration of anaplasmal antigen in a biopsy/autopsy sample by immunohistochemical methods
- Isolation of *A. phagocytophilum* from a clinical specimen in cell culture

Bordetella pertussis (Pertussis) (Whooping Cough)

- Isolation of *Bordetella pertussis*
- Positive PCR for *Bordetella pertussis*

Borrelia burgdorferi (Lyme Disease)

- *B. burgdorferi* cultured from skin biopsy
- *Positive IgM or IgG Western immunoblot for B. burgdorferi* using established criteria [1-4]
- CSF antibody positive for *B. burgdorferi* by Enzyme Immunoassay (EIA) Immunofluorescence Assay (IFA), when the titer is higher than it was in serum

Borrelia References

1. Centers for Disease Control and Prevention. Recommendations for test performance and interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease. MMWR MMWR Morb Mortal Wkly Rep 1995; 44:590–1.

2. Dressler F, Whalen JA, Reinhardt BN, Steere AC. Western blotting in the serodiagnosis of Lyme disease. J Infect Dis 1993; 167:392–400.
3. Engstrom SM, Shoop E, Johnson RC. Immunoblot interpretation criteria for serodiagnosis of early Lyme disease. J Clin Microbiol 1995; 33:419–27.
4. Centers for Disease Control and Prevention. Notice to readers: caution regarding testing for Lyme disease. MMWR Morb Mortal Wkly Rep 2005; 54:125–6.

Brucellosis, animal cases (*Brucella spp. except Brucella canis*)

- Culture and identification of *Brucella* spp. from clinical specimens
- *Brucella* total antibody titer of greater than or equal to 160 by standard tube agglutination test (SAT) or *Brucella* microagglutination test (BMAT) in one or more serum specimens obtained after onset of symptoms
- Detection of *Brucella* DNA in a clinical specimen by PCR assay

Campylobacteriosis (Campylobacter species)

- Detection of *Campylobacter spp*. in a clinical specimen using non-culture based laboratory methods
- Isolation of *Campylobacter spp*. in a clinical specimen

Chancroid (*Haemophilus ducreyi*)

- Isolation of *H. ducreyi* from a clinical specimen
- Detection of *H. ducreyi* nucleic acid in a clinical specimen

***Chlamydia trachomatis* infections, including lymphogranuloma venereum**

- Isolation of *C. trachomatis* by culture
- Detection of *C. trachomatis* antigen or nucleic acid in a clinical specimen

A. Lymphogranuloma venereum

- Isolation of *C. trachomatis*, serovar L_1, L_2, or L_3, from a clinical specimen
- Demonstration by immunofluorescence of inclusion bodies in leukocytes of an inguinal lymph node (bubo) aspirate
- Positive microimmunofluorescence serologic test for a lymphogranuloma venereum strain of *C. trachomatis*

Coccidioidomycosis

- Cultural, histopathologic, or molecular evidence of presence of *Coccidioides* species.
- Detection of coccidioidal immunoglobulin M (IgM) by immunodiffusion, enzyme immunoassay (EIA), latex agglutination, or tube precipitin in serum, cerebrospinal fluid, or other body fluids
- Detection of coccidioidal immunoglobulin G (IgG) by immunodiffusion, EIA, or complement fixation in serum, cerebrospinal fluid, or other body fluids

Cryptosporidiosis (*Cryptosporidium spp.*)

- Evidence of *Cryptosporidium* organisms or DNA in stool, intestinal fluid, tissue samples, biopsy specimens, or other biological sample by certain laboratory methods with a high positive predictive value (PPV), e.g.,
  - Direct fluorescent antibody [DFA] test
  - Polymerase chain reaction [PCR]
  - Enzyme immunoassay [EIA]
  - Light microscopy of stained specimen

- Detection of *Cryptosporidium* antigen by a screening test method, such as immunochromatographic card/rapid card test; or a laboratory test of unknown method

Cyclosporiasis (*Cyclospora cayetanensis*)

- Detection of *Cyclospora* organisms or DNA in stool, intestinal fluid/aspirate, or intestinal biopsy specimens

Dengue Fever (Dengue Hemorrhagic Fever) (Dengue Shock Syndrome)

- Isolation of dengue virus from or demonstration of specific arboviral antigen or genomic sequences in tissue, blood, cerebrospinal fluid (CSF) or other body fluid by polymerase chain reaction (PCR) test, immunofluorescence or immunohistochemistry
- Demonstration of a ≥4-fold rise in reciprocal Immunoglobulin G (IgG) antibody titer or Hemagglutination inhibition titer to dengue virus antigens in paired acute and convalescent serum samples
- Demonstration of a ≥4-fold rise in PRNT (plaque reduction neutralization test) end point titer (as expressed by the reciprocal of the last serum dilution showing a 90% reduction in plaque counts compared to the virus infected control) between dengue viruses and other flaviviruses tested in a convalescent serum sample
- Virus-specific immunoglobulin M (IgM) antibodies demonstrated in CSF
- Dengue-specific IgM antibodies present in serum with a P/N ratio ≥2
- Positive dengue- specific IgM antibody test, on a single acute- or convalescent-phase serum specimen to one or more dengue virus antigens.

Diphtheria (*Corynebacterium diphtheriae*)

- Isolation of *Corynebacterium diphtheriae* from the nose or throat
- Histopathologic diagnosis of diphtheria

Encephalitis, arboviral See CDC comments regarding test interpretation

- Isolation of virus from, or demonstration of specific viral antigen or nucleic acid in, tissue, blood, CSF, or other body fluid
- Four-fold or greater change in virus-specific quantitative antibody titers in paired sera
- Virus-specific IgM antibodies in serum with confirmatory virus-specific neutralizing antibodies in the same or a later specimen
- Virus-specific IgM antibodies in CSF and a negative result for other IgM antibodies in CSF for arboviruses endemic to the region where exposure occurred
- Virus-specific IgM antibodies in CSF or serum

Escherichia coli:* shiga toxin producing (STEC) including *E. coli O157

- Isolation of Shiga toxin-producing *Escherichia coli* from a clinical specimen

Submit isolates of *E. coli* O157 and non O157 shiga toxin-producing *E. coli* to the local public health laboratory for additional testing.

Giardiasis (*Giardia lamblia, intestinalis, or duodenalis*)

- Detection of *Giardia* organisms, antigen, or DNA in stool, intestinal fluid, tissue samples, biopsy specimens or other biological sample

Gonorrhea

- Isolation of typical gram-negative oxidase-positive diplococci (presumptive *Neisseria gonorrhoeae*) from a clinical specimen

- Detection *of N. gonorrhoeae* antigen or nucleic acid in a clinical specimen
- Demonstration of gram-negative intracellular diplococci in a smear obtained from the urethra, cervix, rectum or oropharynx
- Quantitative results from *N. gonorrhoeae* antimicrobial susceptibility testing (e.g. minimum inhibitory concentration by agar dilution or Etest)

Haemophilus influenzae (report an incident in a patient of less than 15 years of age from sterile site)

- Detection *of Haemophilus influenzae* type b antigen in cerebrospinal fluid (CSF)
- Isolation of *Haemophilus influenzae* from a normally sterile body site (e.g., blood or CSF, or, less commonly, joint, pleural, or pericardial fluid)

Comment: Positive antigen test results from urine or serum samples are unreliable for diagnosis of *H. influenzae* disease.

Hantavirus Infections

- Detection of hantavirus-specific IgM or IgG
- Detection of hantavirus-specific ribonucleic acid sequence by polymerase chain reaction in clinical specimens
- Detection of hantavirus antigen by immunohistochemistry

Hepatitis A, acute infection

- Detection of Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV)

Hepatitis B, acute or chronic infection (specify gender)

A. Acute

- HBsAg positive, AND Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

B. Chronic

- Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR
- HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Hepatitis C, acute or chronic infection

- Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/hepatitis/HCV/LabTesting.htm)
- Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing)

Hepatitis D (Delta), acute or chronic infection

- Detection of viral antigen, antibody or nucleic acid

Hepatitis E, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)

- Detection of viral antigen, antibody or nucleic acid

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

- Detection of specific *Legionella* antigen or staining of the organism in respiratory secretions, lung tissue, or pleural fluid by direct fluorescent antibody (DFA) staining, immunohistochemistry (IHC), or other similar method, using validated reagents
- Detection of *Legionella* species by a validated nucleic acid assay
- Isolation of any *Legionella* organism from respiratory secretions, lung tissue, pleural fluid, or other normally sterile fluid
- Detection of *Legionella pneumophila* antigen in urine using validated reagents
- Fourfold or greater rise in antibody titer in paired sera to *Legionella pneumophila* serogroup 1 or other serogroups (e.g., *L. micdadei*, *L. pneumophila* serogroup 6) using validated reagents

Leprosy (Hansen Disease) (*Mycobacterium leprae*)

- Demonstration of acid-fast bacilli in skin or dermal nerve, obtained from the full-thickness skin biopsy of a lepromatous lesion

Leptospirosis (*Leptospira spp.*)

- Isolation of *Leptospira* from a clinical specimen
- Fourfold or greater increase in *Leptospira* agglutination titer between acute- and convalescent-phase serum specimens obtained greater than or equal to 2 weeks apart and studied at the same laboratory
- Demonstration of *Leptospira* in a clinical specimen by immunofluorescence

Listeriosis (Listeria)

- Isolation of *L. monocytogenes* from a normally sterile site (e.g., blood or cerebrospinal fluid [CSF] or, less commonly, joint, pleural, or pericardial fluid)
- In the setting of miscarriage or stillbirth, isolation of *L. monocytogenes* from placental or fetal tissue

Submit *Listeria monocytogenes* isolates to the local public health laboratory for additional testing.

Malaria

- Detection of circulating malaria-specific antigens using rapid diagnostic test (RDT)
- Detection of species specific parasite DNA in a sample of peripheral blood using a Polymerase Chain Reaction test
- Detection of malaria parasites in thick or thin peripheral blood films.

Per Title 17 § 2505(h). Notification by Laboratories:
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. When requested, all blood films shall be returned to the submitter.

Measles (Rubeola), acute infection

- Positive serologic test for measles immunoglobulin M antibody
- Significant rise in measles antibody level by any standard serologic assay
- Isolation of measles virus from a clinical specimen
- Detection of measles-virus specific nucleic acid by polymerase chain reaction

Submit Measles immunoglobulin M (IgM)-positive sera to the local public health laboratory.

Mumps (mumps virus), acute infection

- Isolation of mumps virus from clinical specimen
- Detection of mumps nucleic acid (e.g., standard or real time RT-PCR assays)
- Detection of mumps IgM antibody
- Demonstration of specific mumps antibody response in absence of recent vaccination, either a four-fold increase in IgG titer as measured by quantitative assays, or a seroconversion from negative to positive using a standard serologic assay of paired acute and convalescent serum specimens

Mycobacterium tuberculosis See CDPH Laboratory Reportable Diseases

- Isolation of *M. tuberculosis* from a clinical specimen
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test
- Demonstration of acid-fast bacilli in a clinical specimen

Refer to the website above for additional instructions regarding submission of cultures and antimicrobial testing per Title 17§ **2505**.

***Neisseria meningitidis* (sterile site isolate)**

- Isolation of *Neisseria meningitidis* from a normally sterile body site (e.g., blood or cerebrospinal fluid, or, less commonly, synovial, pleural, or pericardial fluid), or from purpuric lesions
- Detection of *N. meningitidis*-specific nucleic acid in a specimen obtained from a normally sterile body site (e.g.,. blood or CSF), using a validated polymerase chain reaction (PCR) assay
- Detection of *N. meningitidis* antigen in formalin-fixed tissue by immunohistochemistry (IHC); or in CSF by latex agglutination

Submit all *Neisseria meningitidis* isolates from sterile sites to the local public health laboratory.

Poliovirus

- Isolation of poliovirus from stool, oropharynx, urine, CSF or blood
- Detection of poliovirus nucleic acid by polymerase chain reaction
- Detection of poliovirus immunoglobulin M antibody
- Elevated serum poliovirus immunoglobulin G antibody level by any standard serologic assay

Report **test requests** to the local health department.

Psittacosis (*Chlamydophila psittaci*)

- Isolation of *Chlamydophila psittaci* from respiratory specimens (e.g., sputum, pleural fluid, or tissue), or blood

- Elevated IgG antibody against *C. psittaci* by complement fixation (CF) or microimmunofluorescence (MIF)
- *C. psittaci* antibody titer IgM of greater than or equal to 32 in at least one serum specimen obtained after onset of symptoms
- Detection of *C. psittaci* DNA in a respiratory specimen (e.g. sputum, pleural fluid or tissue) via amplification of a specific target by polymerase chain reaction (PCR) assay.

Q Fever (*Coxiella burnetii*)

- Detection of *C. burnetii* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay
- Demonstration of *C. burnetii* in a clinical specimen by immunohistochemical methods (IHC)
- Isolation of *C. burnetii* from a clinical specimen by culture.
- IFA IgG titer of ≥1:128 to phase II antigen
- Elevated phase II IgG or IgM antibody reactive with *C. burnetii* antigen by enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or latex agglutination

Rabies, animal or human

A. Animal

- A positive direct fluorescent antibody test performed on central nervous system tissue
- Isolation of rabies virus in cell culture or in a laboratory animal

B. Human

- Detection of Lyssavirus antigens in a clinical specimen (e.g., the brain or the nerves surrounding hair follicles in the nape of the neck) by direct fluorescent antibody test
- Isolation in cell culture or in a laboratory animal of a Lyssavirus from saliva or central nervous system tissue
- Identification of Lyssavirus-specific antibody by indirect fluorescent antibody (IFA) test or complete rabies virus neutralization at 1:5 dilution in the CSF
- Identification of Lyssavirus specific antibody by indirect fluorescent antibody (IFA) test or complete rabies virus neutralization at 1:5 dilution in the serum of an unvaccinated person
- Detection of Lyssavirus viral RNA using reverse transcriptase-polymerase chain reaction [RT-PCR] in saliva, CSF, or tissue.

Relapsing Fever (*Borrelia spp.*) (no CDC case definition)

- Identification of *Borrelia spp.* spirochetes on peripheral blood smear

***Rickettsia*, any species, acute infection (no CDC case definition)**

- Detection from a clinical specimen or positive serology

Rocky Mountain Spotted Fever (*Rickettsia rickettsii*)

- Detection of *R. rickettsii* DNA in a clinical specimen via amplification of a specific target by PCR assay
- Demonstration of spotted fever group antigen in a biopsy or autopsy specimen by IHC
- Isolation of *R. rickettsii* from a clinical specimen in cell culture
- Serologic evidence of elevated IgG or IgM antibody reactive with *R. rickettsii* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or latex agglutination

Rubella, acute infection

- Isolation of rubella virus
- Detection of rubella-virus specific nucleic acid by polymerase chain reaction
- Significant rise between acute- and convalescent-phase titers in serum rubella immunoglobulin G antibody level by any standard serologic assay
- Positive serologic test for rubella immunoglobulin M (IgM) antibody

Salmonellosis (Salmonella spp.)

- Isolation of *Salmonella* from a clinical specimen.

  Per Title 17 § 2612 **submit isolate** to the local public health laboratory.

Shiga toxin (detected in feces)

- Detection of shiga toxin in stool specimens by any method

Clinical laboratories are encouraged to carry out simultaneous culture and shiga toxin testing for stools submitted for community-acquired diarrhea.

Shiga toxin positive fecal broths should be submitted to the local public health laboratory for additional testing.

Shigellosis (Shigella spp.)

- Isolation of Shigella from a clinical specimen.

Syphilis

- Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, direct fluorescent antibody (DFA-TP), or equivalent methods
- Detection of *T. pallidum* nucleic acid in a clinical specimen
- Reactive serologic test (nontreponemal: Venereal Disease Research Laboratory [VDRL] or rapid plasma reagin [RPR]; treponemal: fluorescent treponemal antibody absorbed [FTA-ABS] or microhemagglutination assay for antibody to *T. pallidum* [MHA-TP]), enzyme immunoassay (EIA), or chemiluminescence assay (CIA) for antibody to *T. pallidum*)

Trichinosis (Trichinella)

- Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy
- Positive serologic test for *Trichinella*

Tuberculosis See CDPH Laboratory Reportable Diseases

- Isolation of *M. tuberculosis* from a clinical specimen
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test
- Demonstration of acid-fast bacilli in a clinical specimen

Refer to the above website for additional instructions regarding submission of cultures and antimicrobial testing per Title 17§ **2505**.

Tularemia, animal (*F. tularensis*)

- Elevated serum antibody titer(s) to *F. tularensis* antigen
- Detection of *F. tularensis* in a clinical specimen by fluorescent assay
- Isolation of *F. tularensis* in a clinical specimen

Typhoid (*Salmonella typhi*)

- Isolation of *S. typhi* from blood, stool, or other clinical specimen

Per Title 17 § 2612 **submit isolate** to the local public health laboratory for confirmation and additional testing.

***Vibrio* species infections**

- Isolation of *Vibrio spp* from a clinical specimen

West Nile virus infection

- Isolation of virus from, or demonstration of specific viral antigen or nucleic acid in, tissue, blood, CSF, or other body fluid
- Elevated virus-specific IgG quantitative antibody titers in single or paired (if available) sera
- Virus-specific IgM or IgG antibodies in serum with confirmatory virus-specific neutralizing antibodies in the same or a later specimen
- Virus-specific IgM antibodies in CSF and a negative result for other IgM antibodies in CSF for arboviruses endemic to the region where exposure occurred
- Virus-specific IgM antibodies in CSF or serum

Yellow Fever (yellow fever virus)

- Fourfold or greater rise in yellow fever antibody titer in a patient who has no history of recent yellow fever vaccination and cross-reactions to other flaviviruses have been excluded
- Demonstration of yellow fever virus, antigen, or genome in tissue, blood, or other body fluid

Yersiniosis (*Yersinia spp.*, non-pestis)

- Isolation of *Y. enterocolitica* or *Y. pseudotuberculosis* from stool, urine, or a normally sterile site.