CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

CDPH California Department of PublicHealth

Division of Communicable Disease Control

Guidance for Laboratories on Reporting Select Agent Test Requests and Results
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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 lists of laboratory testing results for specified diseases in Section 2505 list (e)(1) and (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 there are federal requirements for reporting select agents to state and local public health authorities. The information below describes the requirements for the Select Agents in Section 2505 list (e)(1). The guidance for Section 2505 list (e)(2) diseases is also available at http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx

Title 17 - List (e)(1) Select Agent Bacteria – Notifiable Findings

Clinical labs should notify the appropriate Laboratory Response Network (LRN) laboratory when a test request for one of the List (e)(1) Select Agent bacteria is made.

When a *preliminary identification* of a suspected List (e)(1) Select Agent bacterium is made from a clinical specimen at a non-Select Agent registered laboratory, work should cease. The lab should contact their appropriate LRN Reference Lab for guidance on confirmatory testing and submission procedures. Call your local public health lab for guidance if you don't know your LRN catchment area. Also notify the local Public Health Officer or designee.

Positive lab results for* List (e)(1) *bacterial agents*, as listed below by microbe or disease, are reportable by telephone to the local Public Health Officer or designee per Title 17 Section 2505 *within 1 hour of notification of results to the health care provider.

Anthrax, animal or human *(Bacillus anthracis)*

- Evidence of *B. anthracis* DNA (for example, by LRN-validated polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal)

- Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit
- Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry
- Positive result on testing of culture from clinical specimens with the RedLine™ Alert test
- Culture and identification of *B. anthracis* from clinical specimens by the LRN
- Demonstration of *B. anthracis* antigens in tissues by immunohistochemical staining using both *B. anthracis* cell wall and capsule monoclonal antibodies
- Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to protective antigen in paired convalescent sera using CDC quantitative anti-PA IgG ELISA testing

Botulism (includes foodborne, infant, wound, and other) (*Clostridium botulinum*) 2011

A. Infant Botulism (< 1 year old)

Stool specimens for diagnostic testing (serum not needed) from in-patients and out-patients with suspected infant botulism (California residents only) may be submitted to the Infant Botulism Treatment and Prevention Program (IBTPP) laboratory *only* after approval for such submission has been obtained from the IBTPP physician-on-call. Specimens (if any) received without prior authorization will not be tested until such authorization is obtained. Physicians seeking such testing for their patient should contact the IBTPP at (510) 231-7600.

B. Non-Infant Botulism (equal or greater than 1 year old)

Physicians or health providers requesting botulism testing should **immediately** contact their local Public Health Officer or designee to report the suspected botulism case and request testing.

Clinical laboratories that receive specimens for botulism testing should **immediately** inform the physician to contact the local Public Health Officer or designee prior to sending the specimens. Once testing is approved, instructions will be provided to submit specimens for testing to the CDPH Microbial Diseases Laboratory (MDL) or the Los Angeles Public Health Laboratory depending on the patient residence. All specimens to MDL will be routed through the local public health laboratory.

- The local Health Department will investigate to determine type of botulism (food, wound or un-specified). Diagnostic specimens (serum, stool, gastric) and/or food from possible adult botulism may be submitted to the local public health laboratory *only* after approval.
- The local public health laboratory needs to review the MDL acceptance criteria (see MDL182.103107) before shipping. Specimens without the proper volume or conditions will not be tested.
- Email notification from the local public health laboratory, with an attached case history, is required to be sent to MDL prior to shipping.

Specimens (if any) received without prior authorization will not be tested until such authorization is obtained.

Brucellosis, human cases (*Brucella spp.*) 2010

- Isolation of *Brucella* spp. from a clinical specimen
- Detection of *Brucella* antigen or nucleic acid in a clinical specimen
- *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

- Evidence of a fourfold or greater rise in *Brucella* antibody titer between acute- and convalescent-phase serum specimens obtained greater than or equal to 2 weeks apart

Burkholderia mallei or pseudomallei **(no CDC/CSTE case definition)**

- Any detection from a clinical specimen.
- Culture and identification of possible *Burkholderia mallei or pseudomallei* from clinical specimens.
- Evidence of a fourfold or greater rise in *Burkholderia pseudomallei* antibody titer by indirect-hemagglutination-assay (IHA) between acute-and convalescent-phase serum specimens obtained greater than or equal to 2 weeks

Plague, human or animal (*Yersinia pestis*)

- Elevated serum antibody titer(s) to *Yersinia pestis* fraction 1 (F1) antigen
- Detection of F1 antigen in a clinical specimen by fluorescent assay
- Isolation of *Y. pestis* from a clinical specimen

Tularemia, human (*Francisella 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

Title 17 - List (e)(1) Novel Influenza Strains and Select Agent Viruses – Notifiable Findings

Clinical labs should report any test requests for List (e)(1) Select Agent viruses to the local Public Health Officer or designee immediately. If clinically indicated, the local health department may arrange for testing by the CDPH Viral and Rickettsial Disease Laboratory (VRDL).

Positive lab results for **List (e)(1)** ***viruses*****, as listed below by microbe or disease, are reportable to the local Public Health Officer or designee per Title 17** ***within 1 hour of receipt of results by the health care provider.***

Influenza, novel strains (human):

- Any human specimen that is reverse-transcriptase-polymerase chain reaction (RT-PCR) or culture-positive for influenza A and tests negative for currently circulating human subtypes. Depending on the situation, a confirmatory reverse-transcriptase-polymerase chain reaction (RT-PCR) specific for the novel influenza virus of concern may or may not be available.

Specimens from cases with human infection with unsubtypeable influenza A viruses should be forwarded to the local public health laboratory or arrangements made with the California Department of Public Health Viral and Rickettsial Diseases Laboratory (CDPH-VRDL) for confirmation.

Select Agent Viruses:

Smallpox

Viral hemorrhagic fever agents, human or animal (e.g. Crimean-Congo, Ebola, Lassa and Marburg viruses