

# CLIENT SERVICES MANUAL

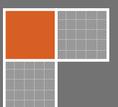
## PUBLIC HEALTH LABORATORY

### COUNTY OF SANTA CLARA

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## 1 General Information

### Role

Public health laboratories serve a key role in our health system. While clinical laboratories cater to the health of the individual, public health laboratories address the health needs of the community as a whole. As a result, public health laboratories focus on disease prevention and control, epidemiological investigations, and environmental health risks. Public health microbiologists specialize in infectious diseases, serving as a valuable resource for local laboratories and physicians in the identification of certain microbes. In addition, public health laboratories are critical in detecting and responding to health emergencies, including, novel strains of disease, natural disasters, chemical spills, food-borne outbreaks, and bioterrorism. Santa Clara County Public Health Laboratory (SCCPHL) works in collaboration with the California State Public Health Department (CPHD), Centers for Disease Control and Prevention (CDC) and other federal agencies including the Environmental Protection Agency, the Food and Drug Administration, the Federal Bureau of Investigation and the Department of Homeland Security.

### Mission Statement

#### County of Santa Clara

The mission of the County of Santa Clara is to plan for the needs of a dynamic community, provide quality services, and promote a healthy, safe and prosperous community for all.

#### Santa Clara County Public Health Department

The mission of Santa Clara County Public Health Department is to prevent disease and injury and create environments that promote and protect the community's health.

#### Santa Clara County Public Health Laboratory

The laboratory provides (1) dependable and high quality laboratory testing services on a timely basis as needed to support the programs and activities of the health department, (2) reference laboratory services for local clinical and environmental laboratories, (3) consultation to local physicians and laboratories, and (4) refresh training for local laboratory personnel as well as training to introduce new test methodologies.

## Abbreviations

ABBREVIATION	FULL NAME
AAS	Atomic Absorption Spectrometry
BA	Blood Agar
BHI	Brain Heart Infusion Agar
BMAT	<i>Brucella</i> Microagglutination Test
C&S	Culture & Sensitivity
CDC	Center for Disease Control
CDPH	California Department of Public Health
CF	Competent Fixation Test
CHOC	Chocolate Agar
CLIA	Clinical Laboratory Improvement Ammendments
CMV	Cytomegalovirus
CNS	Culture and Sensitivity
CSF	Cerebrospinal Fluid
DCDC	CDPH Division of Communicabl Disease Control Branch
DFA	Direct Fluorescent Antibody
DOB	Date of Birth
DOS	Date of Service
DOT	Department of Transportation
EIA	Enzyme Immunoassay
ELAP	Environmental Laboratory Accreditation Program
ELISA	Enzyme-linked Immunosorbent Assay
EM	Electron Microscopy
FA	Fluorescent Antibody
FRA	Fluorescent Rabies Antibody Test
GN	Gram Negative
HI	Hemagglutination Inhibition
HPLC	High-Performance Liquid Chromatography
HSV	Herpes Simplex Virus
IATA	International Air Transport Association
ID	Immunodiffusion Test
IFA	Indirect Fluorescent Antibody
IgG	Immunoglobulin G (antibody)
IgM	Immunoglobulin M (antibody)
IHA	Indirect Hemagglutination
IHC	Immunohistochemistry

ABBREVIATION	FULL NAME
INH	Isoniazide
LA	Latex Agglutination Test
LJ	Löwenstein-Jensen Medium
MAC	MacConckey's Agar
MDL	CDPH Microbial Disease Laboratory Branch
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
MTA	Microtiter Agglutination Test
MTB	<i>Mycobacterium tuberculosis</i>
MTM	Modified Thayer Martin
NA	Nutrient Agar
NAAT	Nucleic Acid Amplification Test
NGHA	Non-diagnostic General Health Assessment
NP	Nasopharyngeal
NPI	National Provider Identifier
PCR	Polymerase Chain Reaction
PFGE	Pulse-field Gel Electrophoresis
PHL	Public Health Laboratory
PRNT	Plaque reduction neutralisation test
PVA	Polyvinyl Alcohol
RFFIT	Rapid Fluorescent Focus Inhibition Test
RIF	Rifampin
RIPA	Radioimmunoprecipitation Assay
RPR	Rapid Plasma Reagin Card Test
RT-PCR	Reverse Transcriptase PCR
SabDex	Sabouraud Dextrose Agar
SCCPHL	Santa Clara County Public Health Laboratory
Serum Neut	Serum Neutralizing Antibody
SPS	Sodium Polyanethole Sulfonate
SST	Serum Separator Tube
STEC	Shiga toxin-producing <i>Escherichia coli</i>
TA	Tube Agglutination Test
TPPA	Treponema pallidum Particle Agglutination
TSA	Trypticase Soy Agar
VRDL	CDPH Viral and Rickettsial Disease Laboratory Branch
VTM	Viral transport media
VZV	Varicella Zoster Virus

## Laboratory Certifications

CLIA ..... 05D0643967  
California Laboratory ..... 1281  
NPI ..... 1528165883  
ELAP ..... 1905  
Federal Tax ID ..... 94-6000-533  
EPA ID ..... CAD085310480

Please visit the SCCPHL website to download current certificates.

## Client Services

### **Hours of Operation:**

Monday through Friday 8:00 a.m. – 5:00p.m.

We are closed all county holidays including:

New Year's Day (January 1<sup>st</sup>)

Martin Luther King, Jr. Day (Third Monday in January)

Presidents' Day (Third Monday in February)

Cesar Chavez Day (March 31<sup>st</sup>)

Memorial Day (Last Monday in May)

Independence Day (July 4<sup>th</sup>)

Labor Day (First Monday in September)

Columbus Day (Second Monday in October)

Veteran's Day (November 11<sup>th</sup>)

Thanksgiving Weekend (Fourth Thursday and Friday in November)

Christmas Day (December 25<sup>th</sup>)

## Supplies

We currently offer the majority of specimen collection supplies to Santa Clara County facilities. For new customers, please call the laboratory at 408.885.4272 to inquire about our current policies. For routine orders, please fax the laboratory the following supply request sheet to 408.885.4275. This form is also available on the SCCPHL website.



# LABORATORY SUPPLY REQUEST FORM

*Please Fax Supply Request Form To: (408) 885-4275*

Please complete <u>all</u> client information fields prior to faxing supply request.			
<b>Client Name:</b>			
<b>Client Address:</b>			
<b>Client Phone #:</b>		<b>Client Fax #:</b>	
<b>Contact Person:</b>			
<b>Date:</b>			
<b>GENERAL SUPPLIES</b>		<b>BLOOD COLLECTION</b>	
<b>Description</b>	<b>Quantity</b>	<b>Description</b>	<b>Quantity</b>
Chlamydia/GC Urine Collection Cups		EDTA Mini Capillaries (50 per bag)	
Specimen Bags			
<b>FORMS</b>		<b>BACTERIOLOGY</b>	
<b>Description</b>	<b>Quantity</b>	<b>Description</b>	<b>Quantity</b>
PM 160 (Blood Lead) Forms		Enterics Containers (Salm/Shig)	
Rabies Submittal Forms		<b>PARASITOLOGY</b>	
Specimen Submittal Forms		<b>Description</b>	<b>Quantity</b>
Tick Submittal Forms		O & P (2 vial) Kits	
Water Submittal Forms		Pinworm Paddles	
CI (Culture for Identification) Forms		<b>ENVIRONMENTAL</b>	
Bacteriology		<b>Description</b>	<b>Quantity</b>
Mycology		Tick Kits	
Malaria		Water Bottles	
<b>VIROLOGY &amp; MOLECULAR TEST COLLECTION</b>		<b>MYCOBACTERIOLOGY</b>	
<b>Description</b>	<b>Quantity</b>	<b>Description</b>	<b>Quantity</b>
Darcon Swabs w/Sterile Tube		QuantiFERON®-TB Gold IT Tubes	
HIV Orasures		<b>OTHER</b>	
NP Swabs		<b>Description</b>	<b>Quantity</b>
NP Swabs w/Sterile Tube			
Viral Transport VTM M4			
<b>NOTES:</b>			

**FOR USE BY LABORATORY PERSONNEL ONLY:**

**ORDER FILLED BY:** \_\_\_\_\_

**DATE ORDER FILLED:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_



## ***Test Reporting***

All test results are returned directly to the submitting agency by first class mail, courier service, secure web portal, or auto fax. Patients may request test results with appropriate proof of identity.

## **Testing Policies**

### ***Cancellations and Additions***

- Tests may be canceled without charge prior to testing.
- Cancellations may be made after an assay has been set-up, but will be subject to the minimum testing charge for that test.
- Cancellations cannot be made after an assay is completed and will be subject to all testing charges.
- Additional testing of a specimen can be requested at anytime if sufficient specimen volume permits.
- SCCPHL requires that all requests for changes and/or modifications to the testing of a specimen be made only by the submitting agency.
- All verbal requests for a change or modification in testing must be followed by written documentation within 1 working day.

### ***STAT Requests***

The SCCPHL is not a STAT laboratory and does not routinely offer STAT testing. However, should you have a special need or request, contact our office and speak to one of our technical staff for more information.

### ***Repeat Testing***

Request for repeat testing of a specimen, may be subject to additional testing charges. Contact our office and speak to one of our technical staff to determine if specimen is still available for testing.

### ***Specimen Returns and Forwards***

- Transportation charges for specimens requested to be returned to submitting agencies will be charged to the requesting agency.
- All requests must be made by the submitting agency.
- Allow 2-3 business days for specimen returns.
- Requests from submitting agencies to forward a specimen to a specific reference laboratory for additional testing is the sole financial responsibility of the requesting agency. Costs will include both transportation and testing charges.

## ***Referral Testing***

Periodically, the SCCPHL will forward specimens to our reference laboratory(s) for consultation. This service is provided at no additional charge to our clients.

## ***Test Changes***

The SCCPHL continuously strives for enhanced quality testing and service to our clients. In an effort to meet this goal, testing methodologies and prices are subject to change. Clients will be notified in writing, 30 days prior to such changes.

## **Mandated Reporting**

### ***For Laboratories***

California Code of Regulations, Title 17, Section 2505 requires laboratories to report test results suggestive of certain diseases of public health importance to the local health department. Please see the following pages for more specific information, including a list of Title 17 diseases.

In addition to reporting diseases, some conditions require a culture or specimen be forwarded to the local public health laboratory. The guideline for required specimen send outs can be found on the following pages, after the Code of Regulations for Title 17, Section 2505.

### ***For Physicians***

California Code of Regulations, Title 17, Section 2500 requires health care providers to report any case or suspected of certain diseases and conditions to the local health officer for the jurisdiction where the patient resides. The Code of Regulations for Title 17, Section 2500 can be found on the following pages, after the guideline for required specimen send outs.

**Title 17, California Code of Regulations (CCR), Section 2505**  
**REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES**  
 (January 2014)

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:

SUBSECTION (E)(1) LIST	SUBSECTION (E)(2) LIST
<p><b>Anthrax, animal</b> (<i>B. anthracis</i>)  <b>Anthrax, human</b> (<i>B. anthracis</i>)  <b>Botulism</b>  <b>Brucellosis, human</b> (all <i>Brucella</i> spp.)  <i>Burkholderia pseudomallei</i> and <i>B. mallei</i>                      (detection or isolation from a clinical specimen)  <b>Influenza, novel strains (human)</b>  <b>Plague, animal</b>  <b>Plague, human</b>  <b>Smallpox</b> (Variola)  <b>Tularemia, human</b> (<i>F. tularensis</i>)  <b>Viral hemorrhagic Fever agents, animal</b> (VHF),                      (e.g., <b>Crimean-Congo, Ebola, Lassa</b> and Marburg viruses)  <b>Viral Hemorrhagic Fever agents, human</b> (VHF),                      (e.g., <b>Crimean-Congo, Ebola, Lassa</b> and Marburg viruses)</p>	<p><b>Acid-fast bacillus (AFB)</b>  <b>Anaplasmosis/Ehrlichiosis</b>  <b><i>Bordetella pertussis</i> acute infection, by culture molecular identification</b>  <b><i>Borrelia burgdorferi</i> infection</b>  <b>Brucellosis, animal</b> (<i>Brucella</i> spp. except <i>Brucella canis</i>)  <b>Campylobacteriosis</b> (<i>Campylobacter</i> spp.)                      (detection or isolation from a clinical specimen)  <b>Chancroid</b> (<i>Haemophilus ducreyi</i>)  <b><i>Chlamydia trachomatis</i> infections, including lymphogranuloma venereum</b>  <b>Coccidioidomycosis</b>  <b>Cryptosporidiosis</b>  <b>Cyclosporiasis</b> (<i>Cyclospora cayetanensis</i>)  <b>Dengue</b> (dengue virus)  <b>Diphtheria</b>  <b>Encephalitis, arboviral</b>  <b><i>Escherichia coli</i>: shiga toxin producing (STEC) including E. coli O157</b>  <b>Giardiasis</b> (<i>Giardia lamblia, intestinalis, or duodenalis</i>)  <b>Gonorrhea</b>  <b><i>Haemophilus influenzae</i></b> (report an incident of less than 15 years of age, from sterile site)  <b>Hantavirus Infections</b>  <b>Hepatitis A, acute infection</b>  <b>Hepatitis B, acute or chronic infection (specify gender)</b>  <b>Hepatitis C, acute or chronic infection</b>  <b>Hepatitis D (Delta), acute or chronic infection</b>  <b>Hepatitis E, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)</b>  <b>Legionellosis</b> (<i>Legionella</i> spp.) (antigen or culture)</p>

SUBSECTION (E)(1) LIST	SUBSECTION (E)(2) LIST
	<p> <b>Leprosy (Hansen Disease) (<i>Mycobacterium leprae</i>)</b>  <b>Leptospirosis (<i>Leptospira</i> spp.)</b>  <b>Listeriosis (<i>Listeria</i>)</b>  <b>Malaria</b>  <b>Measles (Rubeola), acute infection</b>  <b>Mumps (mumps virus), acute infection</b>  <b><i>Mycobacterium tuberculosis</i></b>  <b><i>Neisseria meningitidis</i> (sterile site isolate)</b>  <b>Plague (<i>Yersinia pestis</i>), human or animal</b>  <b>Poliovirus</b>  <b>Psittacosis (<i>Chlamydophila psittaci</i>)</b>  <b>Q Fever (<i>Coxiella burnetii</i>)</b>  <b>Rabies, animal or human</b>  <b>Relapsing Fever (<i>Borrelia</i> spp.) (identification of <i>Borrelia</i> spp. spirochetes on peripheral blood smear)</b>  <b><i>Rickettsia</i>, any species, acute infection (detection from a clinical specimen or positive serology)</b>  <b>Rocky Mountain Spotted Fever (<i>Rickettsia rickettsii</i>)</b>  <b>Rubella, acute infection</b>  <b>Salmonellosis (<i>Salmonella</i> spp.)</b>  <b>Shiga toxin (detected in feces)</b>  <b>Shigellosis (<i>Shigella</i> spp.)</b>  <b>Syphilis</b>  <b>Trichinosis (<i>Trichinella</i>)</b>  <b>Tuberculosis</b>  <b>Tularemia, animal (<i>F. tularensis</i>)</b>  <b>Typhoid</b>  <b><i>Vibrio</i> species infections</b>  <b>West Nile virus infection</b>  <b>Yellow Fever (yellow fever virus)</b>  <b>Yersiniosis (<i>Yersinia</i> spp., non-pestis) (isolation from a clinical specimen)</b> </p>

Revision 01/24/2014

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 always protected.**

**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.

For diseases and agents listed in Subsection (e)(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 electronic reporting system within one working day of identification. Reporting to the state electronic reporting system substitutes reporting by electronic facsimile transmission and electronic mail. 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).”

For diseases and agents listed in Subsection (e)(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 local health officer by courier, mail, electronic facsimile or electronic mail. 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. Reporting to the state electronic reporting system substitutes, reporting by courier, mail, electronic facsimile transmission or electronic mail. 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).”

## **ADDITIONAL REPORTING REQUIREMENTS**

### **ANTHRAX, BOTULISM, BRUCELLOSIS, GLANDERS, INFLUENZA, NOVEL STRAINS, 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 Influenza, novel strains, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory) of the Department of Public Health for instruction.

### **TUBERCULOSIS (Section 2505 Subsections (f) and (g))**

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 (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 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.

## **Additional Cultures and Specimens to be Submitted to Public Health (Section 2505 Subsection (I) List)**

Effective January 1, 2014, the California Code of Regulations, Title 17, Section 2505 subsection (I) lists the following cultures or specimens to be submitted as soon as available to the local or state public health laboratory:

*Listeria monocytogenes* isolates

Measles immunoglobulin M (IgM)-positive sera

*Neisseria meningitides* isolates from sterile sites

Shiga toxin-positive fecal broths

Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157 isolates



## 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](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.

### Anaplasmosis/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 anaplasma 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<sub>1</sub>, L<sub>2</sub>, or L<sub>3</sub>, 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 cayentanensis*)**

- 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  $\geq 4$ -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  $\geq 4$ -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  $\geq 2$
- 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  $\geq 1:128$  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.

## CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

### Division of Communicable Disease Control

#### **Conditions for Which Clinical Laboratories Shall Submit a Culture or a Specimen to the Local Public Health Laboratory.**

January 2014

Assembly Bill 186, chaptered on October 7, 2011 amended the Health and Safety Code Section 120130 (b) to require the California Department of Public Health to "establish a list of communicable diseases and conditions for which clinical laboratories shall submit a culture or a specimen to the local public health laboratory." This list has been added to California Code of Regulations, Title 17 Section 2505(1) effective January 1, 2014.

(1) A culture 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. The following information shall be submitted with the culture or specimen: the name, address, and the date of birth of the person from whom the specimen or culture was obtained, the patient identification number, the specimen or culture accession number or other unique identifier, the date the specimen or culture 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 that isolated the culture or specimen. The cultures or specimens pursuant to this requirement are:

- *Listeria monocytogenes* isolates
- Measles immunoglobulin M (IgM)-positive sera
- *Neisseria meningitidis* isolates from sterile sites
- Shiga toxin-positive fecal broths
- Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157 isolates,

Requirements for submission to local public health laboratories have already been in place for the following:

- *Salmonella* isolates (as per Title 17 Section 261.2 (a))
- *Mycobacterium tuberculosis* isolates (as per Section 2505 (f))
- Malaria smears (as per Section 2505 (h))

Center for Infectious Diseases - Division of Communicable Disease Control  
Infectious Diseases Branch - Disease Investigations Section



**REPORTABLE CONDITIONS: NOTIFICATION BY PHYSICIANS**

**§ 2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.**

- **§ 2500(b)** It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or condition listed below, to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.
- **§ 2500(c)** The administrator of each health facility, clinic, or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.
- **§ 2500(a)(14)** "Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

**URGENCY REPORTING REQUIREMENTS [17 CCR §2500(h)(i)]**

- ⓪ ! = Report immediately by telephone (designated by a ♦ in regulations).
- † = Report immediately by telephone when two or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a ● in regulations).
- FAX ⓪ ☒ = Report by electronic transmission (including FAX), telephone, or mail within one working day of identification (designated by a + in regulations).
- = All other diseases/conditions should be reported by electronic transmission (including FAX), telephone, or mail within seven calendar days of identification.

**REPORTABLE COMMUNICABLE DISEASES §2500(j)(1)**

- Acquired Immune Deficiency Syndrome (AIDS)  
(HIV infection only: see "Human Immunodeficiency Virus")
- FAX ⓪ ☒ Amebiasis
- Anaplasmosis/Ehrlichiosis
- ⓪ ! Anthrax, human or animal
- FAX ⓪ ☒ Babesiosis
- ⓪ ! Botulism (Infant, Foodborne, Wound, Other)
- Brucellosis, animal (except infections due to *Brucella canis*)
- ⓪ ! Brucellosis, human
- FAX ⓪ ☒ Campylobacteriosis
- Chancroid
- FAX ⓪ ☒ Chickenpox (Varicella) (only hospitalizations and deaths)
- Chlamydia trachomatis* infections, including lymphogranuloma venereum (LGV)
- ⓪ ! Cholera
- ⓪ ! Ciguatera Fish Poisoning
- Coccidioidomycosis
- Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)
- FAX ⓪ ☒ Cryptosporidiosis
- Cyclosporiasis
- Cysticercosis or taeniasis
- ⓪ ! Dengue
- ⓪ ! Diphtheria
- ⓪ ! Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
- FAX ⓪ ☒ Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
- ⓪ ! *Escherichia coli*: shiga toxin producing (STEC) including *E. coli* O157
- † FAX ⓪ ☒ Foodborne Disease
- Giardiasis
- Gonococcal Infections
- FAX ⓪ ☒ *Haemophilus influenzae*, invasive disease (report an incident of less than 15 years of age)
- ⓪ ! Hantavirus Infections
- ⓪ ! Hemolytic Uremic Syndrome
- FAX ⓪ ☒ Hepatitis A, acute infection
- Hepatitis B (specify acute case or chronic)
- Hepatitis C (specify acute case or chronic)
- Hepatitis D (Delta) (specify acute case or chronic)
- Hepatitis E, acute infection
- Influenza, deaths in laboratory-confirmed cases for age 0-64 years
- ⓪ ! Influenza, novel strains (human)
- Legionellosis
- Leprosy (Hansen Disease)
- Leptospirosis
- FAX ⓪ ☒ Listeriosis
- Lyme Disease
- FAX ⓪ ☒ Malaria
- ⓪ ! Measles (Rubeola)
- FAX ⓪ ☒ Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
- ⓪ ! Meningococcal Infections
- Mumps
- ⓪ ! Paralytic Shellfish Poisoning
- Pelvic Inflammatory Disease (PID)
- FAX ⓪ ☒ Pertussis (Whooping Cough)
- ⓪ ! Plague, human or animal
- FAX ⓪ ☒ Poliovirus Infection
- FAX ⓪ ☒ Psittacosis

- FAX ⓪ ☒ Q Fever
- ⓪ ! Rabies, human or animal
- FAX ⓪ ☒ Relapsing Fever
- Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus and Typhus-like Illnesses
- Rocky Mountain Spotted Fever
- Rubella (German Measles)
- Rubella Syndrome, Congenital
- FAX ⓪ ☒ Salmonellosis (Other than Typhoid Fever)
- ⓪ ! Scombroid Fish Poisoning
- ⓪ ! Severe Acute Respiratory Syndrome (SARS)
- ⓪ ! Shiga toxin (detected in feces)
- FAX ⓪ ☒ Shigellosis
- ⓪ ! Smallpox (Variola)
- FAX ⓪ ☒ *Staphylococcus aureus* infection (only a case resulting in death or admission to an intensive care unit of a person who has not been hospitalized or had surgery, dialysis, or residency in a long-term care facility in the past year, and did not have an indwelling catheter or percutaneous medical device at the time of culture)
- FAX ⓪ ☒ Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)
- FAX ⓪ ☒ Syphilis
- Tetanus
- Toxic Shock Syndrome
- FAX ⓪ ☒ Trichinosis
- FAX ⓪ ☒ Tuberculosis
- Tularemia, animal
- ⓪ ! Tularemia, human
- FAX ⓪ ☒ Typhoid Fever, Cases and Carriers
- FAX ⓪ ☒ *Vibrio* Infections
- ⓪ ! Viral Hemorrhagic Fevers, human or animal (e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses)
- FAX ⓪ ☒ West Nile virus (WNV) Infection
- ⓪ ! Yellow Fever
- FAX ⓪ ☒ Yersiniosis
- ⓪ ! OCCURRENCE of ANY UNUSUAL DISEASE
- ⓪ ! OUTBREAKS of ANY DISEASE (Including diseases not listed in § 2500). Specify if institutional and/or open community.

**HIV REPORTING BY HEALTH CARE PROVIDERS § 2641.5-2643.20**

Human Immunodeficiency Virus (HIV) infection is reportable by traceable mail or person-to-person transfer within seven calendar days by completion of the HIV/AIDS Case Report form (CDPH 8641A) available from the local health department. For completing HIV-specific reporting requirements, see Title 17, CCR, § 2641.5-2643.20 and <http://www.cdph.ca.gov/programs/aids/Pages/OAHIVReporting.aspx>

**REPORTABLE NONCOMMUNICABLE DISEASES AND CONDITIONS §2800-2812 and §2593(b)**

Disorders Characterized by Lapses of Consciousness (§2800-2812)  
Pesticide-related illness or injury (known or suspected cases)\*\*  
Cancer, including benign and borderline brain tumors (except (1) basal and squamous skin cancer unless occurring on genitalia, and (2) carcinoma in-situ and CIN III of the Cervix) (§2593)\*\*\*

**LOCALLY REPORTABLE DISEASES (if Applicable):**

\* This form is designed for health care providers to report those diseases mandated by Title 17, California Code of Regulations (CCR). Failure to report is a misdemeanor (Health & Safety Code §120295) and is a citable offense under the Medical Board of California Citation and Fine Program (Title 16, CCR, §1364.10 and 1364.11).  
\*\* Failure to report is a citable offense and subject to civil penalty (\$250) (Health and Safety Code §105200).  
\*\*\* The Confidential Physician Cancer Reporting Form may also be used. See Physician Reporting Requirements for Cancer Reporting in CA at: [www.ccrca.org](http://www.ccrca.org).  
CDPH 110a (revised 10/03/2011)



## Privacy Practices

The Public Health Laboratory adheres to the Health Insurance Portability and Accountability Act (H.I.P.A.A.). Please review the following notice of privacy practices:

**NOTICE OF PRIVACY PRACTICES**  
**Santa Clara Valley Health & Hospital System**  
**San Jose, CA 95128**

*January 30, 2014*

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED, SHARED AND DISCLOSED, AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

If you have any questions about this Notice, please contact:

Santa Clara Valley Health & Hospital System  
ATTN: Ethics and Compliance Officer  
Ethics and Compliance Office  
2325 Enborg Lane, Suite 290 San Jose, CA 95128

## WHO WILL FOLLOW THIS NOTICE

The Santa Clara Valley Health and Hospital System (SCVHHS) is a comprehensive safety-net health care system owned and operated by the County of Santa Clara ("County"). The SCVHHS is comprised of multiple County Departments, including Santa Clara Valley Medical Center and Clinics, the Mental Health Department, the Department of Alcohol and Drug Services, the Public Health Department, Custody Health Services, and Valley Health Plan (collectively "SCVHHS Departments") all of which are "Covered Entities" under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"). The SCVHHS Departments share patient health information with each other for the purposes of providing integrated care and coordinating mutual referrals and services for patients of SCVHHS Departments, for administrative oversight, billing and compliance related activities, for analysis and evaluation of services provided by SCVHHS Departments, and for entering data into and maintaining an integrated SCVHHS electronic health record. If you receive care from any of the SCVHHS Departments, your medical, mental health, drug and alcohol treatment and other information may be shared among the SCVHHS Departments.

In addition, our network of providers includes Community Clinics that have agreements with SCVHHS to provide referrals and other health related services to SCVHHS patients and County residents. We may share information with these Community Clinics regarding your care.

**This Notice describes our hospital's practices and that of:**

- **Any health care professional authorized to enter information into your medical chart.**
- **All departments and units of Santa Clara Valley Medical Center and Clinics, the Mental Health Department, the Department of Alcohol and Drug Services, the Public Health Department, Custody Health Services, and Valley Health Plan.**
- **Any member of a volunteer group we allow to help you while you are being seen at the Ambulatory and Community Health Services clinics and Santa Clara Valley Medical Center.**
- **All SCVHHS workforce members.**

**All of these individuals, entities, sites and locations follow the terms of this Notice. In addition, these individuals, entities, sites and locations may share medical information with each other for purposes described in this Notice.**

## **OUR PLEDGE REGARDING MEDICAL INFORMATION**

All of the SCVHHS Departments know that medical, mental health and drug and alcohol treatment information about you and your health is private and confidential. We are committed to protecting medical information about you. We create a record of the care and services you receive at the Hospital, Clinics and SCVHHS locations. We need this record to provide you with quality care and to comply with certain legal requirements. This Notice will tell you about the ways in which we may access, use and share your protected health information ("PHI"). It also describes your rights and certain actions we must take when using or sharing your PHI with other people or organizations. We are required by law to:

- **Make sure that PHI linked to you is kept private and confidential (with some exceptions as listed below);**
- **Give you this Notice about our responsibilities and privacy practices about your PHI; and**
- **Follow the terms of the Notice that is currently in effect.**

Any use and disclosure other than explained in this Notice can only be made with your written authorization. You may revoke your authorization at any time. However, if your PHI has already been used or shared prior to receiving a revoked authorization, we cannot prevent that disclosure.

## **SPECIAL CATEGORIES OF INFORMATION**

In some circumstances, your health information may be subject to restrictions that may limit or preclude some accesses, uses or disclosures described in this Notice. There are special restrictions on the access, use or disclosure of certain categories of information. For example, tests for HIV or treatment, for mental health conditions, or alcohol and drug abuse or emancipated minors constitute special categories of information. Government health benefit programs, such as Medi-Cal, may also limit the disclosure of beneficiary information for purposes unrelated to the program.

## **What is “Protected Health Information”**

Protected health information or “PHI” (also referred to as “individually identifiable health information”): Any individually identifiable information, in electronic or physical form, regarding a patient’s medical history, mental or physical condition or treatment that includes or contains any element of personal identifying information sufficient to allow identification of the individual such as the patient’s name, address, e-mail address, telephone number, Social Security number, or other information that, alone or in combination with other publicly available information, reveals the individual’s identity.

## **HOW WE MAY USE AND SHARE PROTECTED HEALTH INFORMATION**

The following sections describe different ways that we access, use, and share (disclose) your PHI. To respect your privacy, we will limit the amount of information that we access, use or disclose to that which is “minimum necessary” to accomplish the purpose of the access, use or disclosure. The law limits how we can access, use and disclose some PHI related to treatment of drug and alcohol abuse, HIV infection, certain types of care provided to minors, and mental illness. Not every access, use or disclosure in a category will be listed in this Notice. However, all of the ways we are permitted to access, use and disclose information will fall within one of the following categories.

### **Disclosure at Your Request**

If you request your PHI, we may disclose information to you with limited exceptions. Some types of disclosures require a written authorization.

### **For Treatment**

We may access, use and disclose your PHI to provide you with treatment or services. For example, we may disclose medical information about you to bill and receive payment for the treatment and services you receive. We may disclose medical information to doctors, nurses, technicians, health care students, medical students, or other caregivers involved in your healthcare. We may share your medical record with your doctor. We may share your PHI with a lab outside

of SCVHHS that performs tests requested by your doctor. We may also share your PHI with nursing homes or other community healthcare agencies to arrange for on-going treatment after you leave the hospital. Different departments of SCVHHS may share medical information in order to coordinate services you need, such as pharmacy, lab work and x-rays. For mental health, we may share your information with professional persons who have medical or psychological responsibility for your care. For drug and alcohol treatment purposes, we may share your information to assist in your care with providers who are part of SCVHHS network, who are part of your drug and alcohol program or the Drug and Alcohol Department System of Care, or to medical personnel in a medical emergency.

## **For Payment**

We may access, use and disclose medical information about you, so that the treatment and services you receive may be billed and payment may be collected from you, an insurance company or a third party. For example, we may need to give your health plan information about surgery you received at the hospital so your health plan will pay us or reimburse you for the surgery. We may also tell your health plan about a treatment you are going to receive to obtain prior approval or to determine whether your plan will cover the treatment. We may also provide basic information about you and your health plan, insurance company or other source of payment to practitioners outside SCVHHS who are involved in your care, to assist them in obtaining payment for services they provide to you.

## **For Health Care Operations**

We may access, use and share PHI for health care operations. These uses and disclosures are necessary to improve the quality of care, training and educational programs within SCVHHS, or medical staff activities. We may access, use and share your PHI to comply with laws and regulations, for contractual obligations, payer eligibility, claims submission, business planning, marketing, and to operate SCVHHS. For example, we may access, use and disclose PHI to review our treatments and services, and to evaluate our staff performance in caring for you. We may combine PHI we have with that from other health care systems or business associates to compare how we are doing, and to see where we can improve the care and services we offer.

## **Business Associates and Qualified Service Organizations**

There are some services provided in our organization through contracts with business associates and for drug and alcohol program, Qualified Service Organizations. Business Associates and Qualified Service Organizations provide services on behalf of SCVHHS Departments that involve the use or disclosure of patient information. Examples include physician services, certain laboratory tests, billing, analysis, and a copy service we use when making copies of your health record. When these services are contracted, we may disclose your health information to our business associates and qualified service organizations, so that they can perform the job we have asked them to do. To protect your health information, however, business associates and qualified

service organizations are required by federal law to appropriately safeguard your information. In addition, the SCVHHS Departments are business associates and qualified service organizations of each other for purposes of providing integrated care and coordinating mutual referrals and services for patients of SCVHHS Departments, for administrative oversight, billing and compliance related activities, for analysis and evaluation of services provided by SCVHHS Departments, and for entering data into and maintaining an integrated SCVHHS electronic health record.

## **Appointment Reminders**

We will access, use and share PHI to schedule an appointment, or to remind you that you have an appointment for treatment.

## **Treatment Alternatives**

We will access, use and share PHI to tell you about possible treatment options that may interest you.

## **Fundraising Activities**

We may use certain information (name, address, telephone number, e-mail information, age, date of birth, gender, health insurance status, dates of service, department of service information, treating physician information or outcome information) to contact you for the purpose of raising money for the hospital and you will have the right to opt out of receiving such communications with each solicitation. For the same purpose, we may provide your name to the VMC Foundation. The money raised will be used to expand and improve the services and programs we provide the community. You are free to opt out of fundraising solicitation, and your decision will have no impact on your treatment or payment for services.

Opt-Out methods:

1. Phone VMC Foundation at 408-885-2485;
2. Email: [vmcfoundation@hhs.sccgov.org](mailto:vmcfoundation@hhs.sccgov.org)
3. Direct mail solicitation includes a reply form with “do not solicit” box and mail to return address.

## **Facilities Directories**

Our hospital and other facilities access and use PHI to maintain directories of people staying in our facilities, including name, location, general condition (e.g., critical, stable), and religious affiliation. This directory of information, except for your religious affiliation, may also be released to people who ask for you by name. You can make a specific written request to prevent your PHI from being disclosed in this manner. Your religious affiliation may be given to a member of the clergy, such as a priest or rabbi, even if they do not ask for you by name. This information is released so your family, friends and clergy can visit you in the hospital and generally know

how you are doing. If you are a patient receiving mental health services in our inpatient or outpatient mental health facilities, or enrolled in a drug and alcohol treatment program, we will not release your name or any information disclosing whether you are a patient unless you have specifically authorized us to do so.

## **Individuals involved in your care or payment for your care**

We may share your PHI with a family member, friend, personal representative, or anyone else you want to be involved in your care. We may share your PHI with anyone who helps pay for your care. Unless you tell us not to do so in writing, we may also tell your family or friends about your condition and that you are in SCVMC. In addition, we may share your PHI with an organization involved in disaster relief so that your family can learn about your condition, status and location. For mental health and drug and alcohol treatment records, we are only permitted to share your PHI with your treating physician and individuals that you designate. We cannot share your mental health and drug and alcohol treatment records to your family, friend or personal representative without an authorization, with the exception of a parent or guardian (with limited exceptions) or a Conservator.

## **Research**

We may access, use and share your PHI for research purposes. All research projects are evaluated under a special review and approval process. We review a research project's access and use of PHI, and try to balance research needs with patients' need for privacy. Alternatively, we may share your PHI with scientists preparing to conduct a research project to help them find patients with specific medical needs. In these cases, your PHI will not leave our facility. Often, our researchers contact patients about their interest in participating in certain research studies. Before you can be enrolled in a study, you must be given information about the study, be allowed to ask questions, and agree to participate by signing an informed consent form. We may perform other studies using your PHI without requiring your consent. These studies will not affect your treatment or welfare, and your PHI will continue to be protected. For example, a study may involve a chart review to compare the outcomes of patients who received different types of treatments.

## **Public Health Epidemiology – Population Study**

We may access use and share you PHI for the purpose of studying trends in health conditions, health status and to better understand health disparities. In this case your PHI is aggregated with other individuals and the names are removed for the purpose of representing the data. We may examine issues such as income, age, gender and ethnicity as underlying factors affecting the health of populations. Population trend data may be shared with internal SCVJHHS Department and with external partners, academic institutions and may become part of larger reports on the Health Status of populations residing in Santa Clara County. At no time will the names of individuals or other personal identifying information be used, without the express consent of those individuals

## **As Required By Law**

We will access, use and share your PHI when required to do so by federal, state or local law.

## **To Avert a Serious Threat to Health or Safety**

Unless prohibited by law, we may access, use and share your PHI when necessary to prevent or lessen a serious threat to your health and safety, or to that of others. We will only share your PHI with a responsible person who is able to help prevent the threat.

## **Marketing and Sale of PHI**

We may not use or disclose your PHI for marketing purposes without your written authorization. We may not sell your PHI without your written authorization.

## **Psychotherapy Notes**

We may not use or disclose psychotherapy notes without your written authorization unless otherwise permitted or required by law.

## **SPECIAL SITUATIONS**

### **Organ and Tissue Donation**

In some circumstances we may share your PHI with organizations that handle organ procurement or organ, eye or tissue transplantation or with an organ donation bank, as necessary to help with organ or tissue donation and transplantation.

### **Military Service and Veterans**

If you are a current or retired member of the Armed Forces, we will share your PHI if it is required by military command authorities. We may also release PHI about foreign military personnel to the appropriate military authorities as authorized or required by law.

### **Workers' Compensation**

With some exceptions for mental health and drug and alcohol treatment information, we may share your PHI as permitted by law for workers' compensation or similar programs when necessary to provide you with treatment, services or benefits for work-related injuries or illness.

### **Public Health Risks**

We may access, use and share your PHI for public health purposes. In general, these activities include, but are not limited to the following:

- to prevent or control disease (such as cancer or tuberculosis), injury or disability;
- to report births and deaths;
- to report the abuse or neglect of children, elders and dependent adults;
- to report reactions to medications, or problems with healthcare products;
- to notify patients of recalls, repairs, or replacement of products they may be using;
- to notify a person who may have been exposed to a disease or may be at risk for getting or spreading a disease or condition;
- to notify the appropriate government authority if we believe a patient has been the victim of abuse, neglect or domestic violence. We will share your PHI only if you agree or when it is required or authorized by law.
- to notify emergency response employees regarding possible exposure to HIV/AIDS, to the extent necessary to comply with state and federal laws.

## **Health Oversight Activities**

We may access, use and share your PHI with a healthcare oversight agency as authorized or required by law. These oversight activities include, for example: audits, investigations, inspections, and accreditation and licensure surveys. These activities are necessary for the government to monitor the health care system, government programs, and compliance with civil rights laws.

## **Lawsuits and Disputes**

If you are involved in a lawsuit or dispute, we may disclose medical information about you in response to a court or administrative order. We may also disclose medical information about you in response to a subpoena, discovery request or other lawful process by someone else involved in the dispute, but only if efforts have been made to tell you about the request (which may include written notice to you) or to obtain an order protecting the information requested. We will only disclose mental health and drug and alcohol treatment records in response to a subpoena when we receive a court order or authorization from the patient.

## **Law Enforcement**

We may access, use and disclose PHI if asked to do so by a law enforcement official:

- in compliance with a court order, subpoena, warrant, summons, grand jury subpoena or similar process;
- to identify or locate a suspect, fugitive, material witness, or missing person;
- about a victim or a crime, if, under certain limited circumstances, we are unable to obtain the permission directly from the victim of a crime;

- about a death we believe may be the result of criminal conduct;
- about criminal conduct in any of our facilities; and
- in emergency circumstances to report: a crime; the location of the crime or victims; or the identity, description or location of the person who committed the crime.

Mental Health and Department of Alcohol and Drug Services records require additional legal protections and cannot be released without a court order or an authorization by the patient or the patient's representative, except in certain limited circumstances as allowed by law.

## **Coroners, Medical Examiners and Funeral Directors**

We may access, use and share PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death. We may also release your PHI to funeral directors when necessary for them to carry out their duties. We will only disclose mental health and drug and alcohol treatment records to the Coroner or medical examiner with a court order or an authorization from the patient's next of kin.

## **National Security and Intelligence Activities**

We may access, use and share your PHI to federal officials for intelligence, counterintelligence, and other national security activities as authorized or required by law.

We may use and share your PHI to authorized federal officials so they can protect the President, the President's family, other designated persons or foreign heads of state, or conduct special investigations.

## **Inmates**

If you are an inmate of a correctional institution or under the custody of law enforcement officials, we may access, use and share your PHI with the correctional institution or law enforcement officials. Disclosure is necessary:

1. to provide the healthcare services you need;
2. to protect your health and safety or the health and safety of others; or
3. for the safety and security of the correctional institution.

## **MULTIDISCIPLINARY PERSONNEL TEAMS**

We may disclose PHI to a multidisciplinary personnel team relevant to the prevention, identification, management or treatment of an abused child and the child's parents, or elder abuse and neglect.

## **MANDATORY REPORTING**

We will disclose PHI as required by law to make a mandatory report for abuse or neglect, or any other reporting obligations.

## **YOUR RIGHTS REGARDING YOUR PROTECTED HEALTH INFORMATION**

You have the following rights regarding your PHI that we maintain in our facilities.

### **Right to Notice of Breach or Unauthorized Access**

You have the right to be notified if there is an unauthorized access to your PHI or a breach of unsecured PHI involving your information. We are required to notify you and provide you with information on how to protect your personal information.

### **Right to Inspect and Copy**

Except for certain information related to treatment of mental illness, or information gathered in a civil, criminal or administrative action or proceeding, or some PHI subject to the Clinical Laboratory Improvements Amendments of 1988, you have the right to ask to inspect and copy your PHI. To inspect and copy your PHI, you must send a specific, detailed request in writing to the Release of Information Unit whose address is provided at the end of this Notice.

If you request a copy of the information, we may charge a fee for the costs of copying, mailing or other supplies associated with your request.

If we deny a request to inspect and copy, you may ask for a review of why we denied the request. Reviews will not be accepted if

1. you are not entitled to the records according to the paragraph above;
2. you are an inmate and the copies would jeopardize your health safety, security, custody, or rehabilitation or that of others;
3. if the PHI is obtained as part of a research study and your right to access your PHI is suspended during the research;
4. if the PHI is controlled by the Privacy Act and access is not permitted by law; or
5. if the PHI was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the PHI would reveal who that person is.

The SCVHHS Departments will choose a different licensed provider to review the reason for denial. The person who reviews your denial will not be the person who denied your initial request.

## Right to Amend

If you feel that the medical information we have about you is incorrect and incomplete, you may ask us to amend the PHI in your record. You have the right to request an amendment for as long as we keep your PHI. A request for amendment must be made in writing and must provide a reason that supports the request.

Your request for an amendment can be denied if it is not in writing or does not include a reason to support your request. We may deny your request if you ask us to change information that:

- was not created by us;
- is not part of the information kept by or for us;
- is not part of the information which you are permitted by law to inspect and copy; or
- is accurate and complete.

If we deny your request for amendment, you have the right to submit a written addendum, not to exceed 250 words, with respect to any item or statement in your record you believe is incomplete or incorrect.

## Right to an Accounting of Disclosures

You have the right to request an “accounting of disclosures”. This is a list of the disclosures we made of PHI about you other than our own for treatment, payment and health care operations (as those functions are described above), and with other exceptions pursuant to the law.

Your request must state a time period, which cannot be more than six years, and cannot include dates before April 14, 2003. Your request should describe the type of list you would like (for example, on paper or electronically). The first list you request within a 12-month period will be free. For additional lists, we may charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

## Right to Request Restrictions

You have the right to request a restriction or limitation on the medical information we use or disclose about you for treatment, payment or health care operations. You also have the right to request a limit on the medical information we disclose about you to someone who is involved in your care or the payment of your care, like a family member or friend. For example, you could ask that we not access, use or share information about a surgery that you had done at SCVMC, or about a treatment you received at one of our other facilities. **We are not required to agree to your request.** If we do agree, we will comply with your request, unless the information is needed to provide emergency treatment to you.

You have the right to request a restriction or limitation on certain PHI provided to your health plan if you have paid out of pocket in full for the care you received from our facility.

To request restrictions you must tell us

1. what information you want to limit;
2. whether you want to limit our use, disclosure or both; and
3. to whom you want the limits to apply, for example, disclosures to your spouse.

## **Right to Request Confidential Communications**

You have the right to ask that we communicate with you about your PHI in a certain way or at a certain location. For example, you can ask that we contact you only at work or by U.S. mail. To request confidential communications, you must write to the Release of Information Unit at the address indicated in this Notice. We will not ask you the reason for your request, and we will try to accommodate all *reasonable* requests. You must tell us how or where you want to be contacted.

## **Right to a Paper Copy of This Notice**

You have the right to a paper copy of this Notice. Even if you have agreed to receive this Notice electronically, you are still entitled to a paper copy of this Notice if you ask us at the address provided at the end of this Notice. You may obtain an electronic copy of this Notice at our website: [www.sccgov.org](http://www.sccgov.org), then select “Health and Human Care” and find “HIPAA Notice of Privacy Practices.”

## **CHANGES TO THIS NOTICE**

We reserve the right to change this Notice. We reserve the right to make the revised or changed Notice effective for the PHI we already have about you, as well as any other information we receive in the future. We will post a copy of the current Notice in our facilities. The effective date of the Notice will be displayed on the first page. The current notice will be available at [www.scvmed.org](http://www.scvmed.org).

## **COMPLAINTS**

We welcome the opportunity to respond to your questions and concerns and to resolve any complaints you may have about the access, use or disclosure of your PHI. If you believe your privacy rights have been violated, you may file a complaint with us, or with the Secretary of the Department of Health and Human Services. To file a complaint with us, you must contact:

Santa Clara Valley Health & Hospital System  
Attn: Ethics and Compliance Officer  
2325 Enborg Lane, Suite 290  
San Jose, CA 95128  
(408) 885-3794

***You will not be penalized for filing a complaint.***

## **OTHER USES OF PROTECTED HEALTH INFORMATION**

Other uses and disclosures of PHI not covered by this Notice, or by the laws that apply to us, will be made only with your written permission. If you allow us to access, use or share your PHI, you may cancel that permission, in writing, at any time. If you cancel your permission, we will stop any further access, use or disclosure of your PHI for the purposes covered by your written permission. You understand that we are unable to take back any disclosures we have already made with your permission and that we are required by law to keep records of the services or treatment we provided to you.

## **CONTACT INFORMATION FOR RIGHTS INVOLVING PHI**

Please contact the Release of Information Unit for

1. Requests to inspect or copies of medical record;
2. Requests to amend your medical record;
3. Request for an accounting of disclosures;
4. Requests to restrict the release of information.

Santa Clara Valley Medical Center  
ATT: Release of Information Unit Medical Record Services  
751 South Bascom Avenue  
San Jose, CA 95128

### **Right to Review**

Please contact the Privacy Office of the SCVHHS Department where you receive your services at the following addresses for

1. Request for a review of a denial of your request for your PHI;
2. Requests for a paper copy of this Notice;
3. Requests for confidential communications.

Santa Clara Valley Medical Center  
ATT: Privacy Coordinator Medical Record Services  
751 S. Bascom Avenue  
San Jose, CA 95128

Privacy Officer, Drug and Alcohol Department  
976 Lenzen Avenue  
San Jose, CA 95126

Privacy Officer, Department of Mental Health  
Mental Health Department Administration  
828 S. Bascom Avenue, Suite 200  
San Jose, CA 95128

Privacy Officer, Custody Health Services  
Custody Bureau Administration  
180 W. Hedding St.  
San Jose, Ca. 95110

Privacy Officer, Public Health Department  
976 Lenzen Avenue  
San Jose, CA 95126

## 2 Specimen Submission

### General Submission Instructions

#### Specimen Collection

- Collect specimens in containers appropriate for the test requested.
- Use media or collection containers with current expiration dates.
- Hold specimens under correct conditions before transport.
- Observe time restrictions on collection and transport to the laboratory.

#### Specimen Identification

- Label specimen container with patient's first and last name. For anonymous HIV testing only, use the identification number. The name or anonymous number on the specimen must be exactly as written on the test requisition form. Specimens without the patient's full name or anonymous HIV number will not be processed.
- Label specimen container with the date of collection

#### Test Requisition Form – select the appropriate form

- Required Information – specimens will not be processed without the following information:
  - ◆ **Patient's name** – type or print the patient's first and last name. For anonymous HIV testing only, use the identification number. The name on the request form must be exactly as written on the specimen.
  - ◆ **Patient's date of birth**
  - ◆ **Patient's sex**
  - ◆ **Patient's address**
  - ◆ **Client information** – the name, address and phone number of the submitting client.
  - ◆ **Physician information** – type or print the name, address and phone number of the attending physician if different from the client (submitter).
  - ◆ **Date specimen was collected**
  - ◆ **Specimen source** – check the appropriate box for specimen source. If the appropriate source is not available, write the source on the line next to “other”.
  - ◆ **Test requested** – check the appropriate box or write on the line next to “other”.
  - ◆ Submit one specimen for each test requested. The following exceptions can be made:
    - Stool for enteric bacteriology
    - Blood for multiple serologic tests
- Additional Information – this information will appear on the report of test results.
  - ◆ If requested by the Public Health Department, write or type on the bottom of lab request: “Requested by Public Health Disease Control/epidemiology”

## Transport (Hand Delivery)

- Check that both specimen and test requisition form are labeled with identical spelling of the patient's first and last name or anonymous HIV Antibody Test number.
- Ensure the test(s) requested are appropriate and correlate with the specimen collected.
- Retain a copy of the requisition form for your records.
- Ensure the integrity of specimens before transport. Screw caps down tightly. Check for punctures or leakage.
- Place completed Specimen Test Requisition in the outer pocket of the laboratory specimen bag.
- Place the labeled specimen in the zip lock section of the laboratory specimen bag.
- Zip the bag.
- Place bag with specimen in container with appropriate coolant.

Changes to information on the test request form must be requested in writing. FAX to 408-885-4275.

**Specimen quality assurance criteria** – To help assure quality testing and to meet federal and state regulations, the laboratory has strict requirements for specimen identification.

- The following specimens do not meet quality assurance standards and will not be tested.
  - ◆ Specimen or request form lacking patient name or anonymous HIV number.
  - ◆ Specimen with compromised quality (e.g., collected in improper or expired container, received leaking or broken, or past acceptable transport time).
  - ◆ Test request without client number or client name and address.
- The following specimens do not meet quality assurance standards. The client will receive a telephone call requesting correction.
  - ◆ Test request without specimen source, date taken, or test request will not be tested until the information is received.
  - ◆ Missing information must be provided by Fax (408-885-4275) by 4:30 p.m. the next working day following notification
- The following specimens do not meet quality assurance standards and will not be tested until corrected by a physician or nurse practitioner.
  - ◆ Specimen whose patient name does not match name on the test request EXACTLY (i.e., identical spelling of all names)
  - ◆ Client will be notified of mismatched identification by telephone.
  - ◆ Corrections must be made by 4:30 p.m. the next working day following notification.

For information specific to type of specimen, please see the appropriate collection guide in this manual.

To determine what type of specimen is acceptable for specific tests, please see the testing services section of this manual.

### Select Agents/Bioterrorism Guide

The California Department of Public Health provides the following guide for submission of select agents.



## Division of Communicable Disease Control

**Guidance for Laboratories on Reporting Select Agent Test Requests and 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](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)**



## Test Requisition Forms

The SCCPHL has several specimen submittal forms customized for specific tests. Please see the following pages for the most commonly used requisition forms:

- General Submissions
- Tick
- Water
- Bacterial Culture for Identification
- Mycology Culture for Identification

These forms are also available at the SCCPHL website.

Some tests require additional forms as noted in the testing services section of this manual. Please contact the SCCPHL for more information.



**Public Health Laboratory**

**County of Santa Clara**

2220 Moorpark Ave., 2nd Fl., San Jose, CA 95128

(408) 885-4272 FAX (408) 885-4275

Patricia A. Dadone, Laboratory Director

CLIA NO.: 05D0643967 / NPI NO: 1528165883

LABORATORY USE ONLY	
LAB NUMBER	DATE/TIME

**INFORMATION BELOW MUST BE PROVIDED BEFORE REQUISITION WILL BE PROCESSED**

Patient Name (Last) (First) (M)		Sex M F	Date of Birth (DOB)	Social Security No. (SSN) - -
Address Street		City		State Zip
Patient Telephone Number	Patient ID Number	Medical Record Number	Submitting Laboratory's Specimen ID Number	
Date Specimen Taken	Date of Onset	Next CHDP Visit	Patient History/Travel History	
Reason For Testing <input type="checkbox"/> Contact <input type="checkbox"/> Clearance <input type="checkbox"/> Screen <input type="checkbox"/> Immunity Status <input type="checkbox"/> Other _____				
Type of Specimen <input type="checkbox"/> Blood <input type="checkbox"/> CSF <input type="checkbox"/> Urine <input type="checkbox"/> Cervix <input type="checkbox"/> Rectal <input type="checkbox"/> Urethral <input type="checkbox"/> Throat <input type="checkbox"/> Naso-Pharyngeal <input type="checkbox"/> Feces <input type="checkbox"/> Serum <input type="checkbox"/> Wound <input type="checkbox"/> Sputum <input type="checkbox"/> Gastric <input type="checkbox"/> Skin <input type="checkbox"/> Plasma (Heparin) <input type="checkbox"/> Other _____				

**ORDERING PHYSICIAN INFORMATION**

Name (physician's name)	UPIN #	ICD-9 code (diagnosis code required)
-------------------------	--------	--------------------------------------

**COMPLETE INFORMATION & A COPY OF INSURANCE CARD MUST BE ATTACHED OR SUBMITTER WILL BE BILLED**

Responsible Party		Relationship (circle one) Self / Spouse / Child / Other		Name	
Address Street		City	Zip	Address	
Responsible Person:		Telephone		City State Zip	
Bill to / Insurance Number: <input type="checkbox"/> Submitter <input type="checkbox"/> Medi-Cal <input type="checkbox"/> Blue Cross - Medi-Cal <input type="checkbox"/> Medicare <input type="checkbox"/> CHDP <input type="checkbox"/> VHP <input type="checkbox"/> CCAH <input type="checkbox"/> Other				Telephone FAX    Contact _____	

**Check Test Being Ordered and Source**

**BACTERIOLOGY:**

- Gonorrhea Smear
  - Cervix
  - Pharyngeal
  - Rectal
  - Urethra
- Gonorrhea Culture
  - Pharyngeal
  - Rectal
- Urine Culture
- B. pertussis DFA
- B. pertussis culture
- MRSA
- Streptococcus (Strep A)
- Enteric culture (primary stool)
  - Salmonella / Shigella / E. coli O157 (circle one)
- Shiga-Toxin Immunoassay

**SEROLOGY:**

- RPR (red or tiger top)
  - previous positive
- TPPA
- Darkfield microscopy
  - Ext. genitalia
  - Int. genitalia
  - Oral

**MYCOBACTERIOLOGY / TB:**

- Quantiferon-TB Gold In-Tube Assay
- NAAT - GenXpert
- Culture
- Sensitivities (1st line drugs)
- Molecular Beacon
- Pyrosequencing

**VIROLOGY:**

- Respiratory Panel Culture
- Respiratory Panel - direct smear
- Chlamydia - direct smear
  - Cervix
  - Eye
  - Rectal
  - Throat
  - Urethra
- Herpes 1/2 DFA

**VIRAL SEROLOGY (red or tiger top):**

- HBsAg
- HBcore Total
- HCV
- HIV (serum)
- HIV (oral fluid)
- Measles IgG
- Measles IgM
- Herpes 1/2 IgG
- West Nile Virus

**PARASITOLOGY:**

- Ova and Parasites
- Pinworm
- Cryptosporidia
- Helminth identification
- Arthropod identification
- Blood film
- Malaria speciation
- B. burgdorferi (tick ID & test)

**CHEMISTRY/ TOXICOLOGY:**

- Blood Lead - capillary screen
- Blood Lead - venous confirmation

**MOLECULAR TESTING:**

- Gonorrhea - molecular method
  - Cervix
  - Urethra
  - Urine
  - Pharyngeal
  - Rectal
- Chlamydia - molecular method
  - Cervix
  - Urethra
  - Urine
  - Pharyngeal
  - Rectal

**MYCOLOGY**

- Fungal culture
- Yeast culture

**SPECIAL TEST REQUEST(S)**





# SUBMITTAL SLIP FOR TICK ID AND IFA

Santa Clara County Public Health Laboratory  
2220 Moorpark Ave, 2nd Floor, San Jose, CA 95128  
(P) 408.885.4272 | (F) 408.885.4275  
CLIA No: 05D0643967  
Patricia Dadone, Laboratory Director

LABORATORY USE ONLY	
AMOUNT ENCLOSED:	_____
CHECK#/CASH:	_____

## SUBMITTER INFORMATION

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
\_\_\_\_\_

PHONE#: \_\_\_\_\_

## PATIENT INFORMATION

NAME: \_\_\_\_\_

DOB: \_\_\_\_\_ SEX: \_\_\_\_\_

BITE LOCATION ON BODY: \_\_\_\_\_  
\_\_\_\_\_

APPROXIMATE TIME OF ATTACHMENT (hrs): \_\_\_\_\_

DATE TICK ATTACHED: \_\_\_\_\_

DATE TICK REMOVED: \_\_\_\_\_

GEOGRAPHIC LOCATION TICK WAS PICKED UP: \_\_\_\_\_  
(COUNTY, CITY, PARK NAME, ETC.) \_\_\_\_\_

LABORATORY USE ONLY		
TICK SPECIES:	_____	STAGE: _____
IFA RESULTS:	_____	

# Tick Collection Procedure for Lyme Disease Examination

Testing for the causative agent, *Borrelia Burgdorferi*

## Tick Removal

- If a tick is found, remove it immediately. Prompt removal can prevent Lyme disease.
- Use a pair of tweezers to grasp the tick's mouth-parts. If you do not have tweezers use your fingers, but protect them with a tissue. Do not squash the tick; spirochetes released in fluids may penetrate skin.
- Slowly and steadily pull the tick straight out; do not twist. Remove mouth-parts left in skin (tick mouth-parts have harpoon like barbs that do not screw into skin).
- DO NOT apply alcohol, fingernail polish, heat (lit match), or petroleum jelly to the tick. Applying heat may cause the tick to regurgitate or secrete saliva, sending disease agents into the bite.
- Clean wound with soap and water. Apply a mild antiseptic if available.
- Save the tick for identification and testing for the Lyme disease spirochete.
- Consult with your physician about questions and treatment if bitten.

## Submitting Ticks to Santa Clara County Public Health Laboratory for Testing

(Only ticks that are vectors for Lyme disease will be tested for the Lyme organism.)

- Place whole tick, preferably alive, in a small plastic bag and send as soon as possible to the Santa Clara County Public Health Laboratory.
- Keep the tick moist in the small plastic bag with a piece of cotton ball damp with water.

## Submittal Slip

Fill out *Submittal Slip for Tick ID and IFA* (under "Test Requisition Forms" in this manual)

Be sure to complete:

- Name, Sex, and Date of Birth of victim bitten by tick.
- Where on the body the tick was found.
- Date person was bitten or found the tick on skin.
- The geographic location of the tick (where you were when the tick bit you).
- Address and phone number of the clinic, clinician, or person submitting tick.

## Fee

Please call the laboratory at 408.885.4272 for current pricing. Only cash, check and money order are accepted. Make check / money order payable to: **Santa Clara County Public Health Laboratory**

## Mail tick and payment to:

Santa Clara County Public Health Laboratory, 2220 Moorpark Avenue, 2<sup>nd</sup> Floor, San Jose, CA 95128

# WATER SUBMITTAL FORM

SANTA CLARA CO. PUBLIC HEALTH LABORATORY  
2220 MOORPARK AVENUE, RM. 204L, SAN JOSE, CA 95128  
SAN JOSE, CA 95128  
(408) 885-4272, FAX (408) 885-4275  
PATRICIA A. DADONE, DIRECTOR  
ELAP NUMBER: 1905

LABORATORY USE ONLY

## LOCATION OF COLLECTION

Site Address \_\_\_\_\_  
City \_\_\_\_\_  
State \_\_\_\_\_ Zip \_\_\_\_\_  
Sample point \_\_\_\_\_

## SUBMITTER (party to be billed)

Name \_\_\_\_\_  
Address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Collected by \_\_\_\_\_ Phone # \_\_\_\_\_

## SPECIMEN INFORMATION

Date \_\_\_\_\_ Time Collected \_\_\_\_\_ AM / PM Cl<sub>2</sub> \_\_\_\_\_ pH \_\_\_\_\_  
Observations / Comments \_\_\_\_\_

## CHECK APPROPRIATE BOX FOR SOURCE

- Well     Drink     Stream     Surface     Ice (2 bottles per sample)  
 Spring     Pool     Bottled     Spa     Other \_\_\_\_\_

## CHECK APPROPRIATE BOX FOR TEST

- Coliform Presence/Absence (drinking water)     MPN (raw water)     Other \_\_\_\_\_

## COPY OF RESULTS TO :

- Santa Clara County     State     Other \_\_\_\_\_

**SAMPLES TESTED 8:00am - 5:00pm Monday - Thursday**  
**NO TESTING on Fridays or County Observed Holidays**  
**INSTRUCTIONS FOR SAMPLE COLLECTION ON REVERSE SIDE**

#### Drinking Water Sampling Procedure for Coliform Bacteriological Examination

Water samples are tested 8:00am – 5:00pm, Monday through Friday. No testing the day before county holidays.

1. Select a suitable sample tap that does not have the potential of contaminating the water. **DO NOT USE:** water subject to any household treatment device, lavatory sinks, showers or tubs, swiveling faucets with aerators, plastic or rubber hoses, faucets less than 18” above ground, faucets surrounded by plants, hose bibs with leaking valve stems or excessive splattering, or rarely used faucets. Samples must represent the water being tested.
2. The tap should be opened fully to allow water to run for 1-2 minutes. The sampling bottles have a plastic seal around the cap and bottle to ensure sterility. The powder in the bottle will neutralize any chlorine present in the water sample. **DO NOT OPEN** the sterilized sample bottle until you are ready to collect the water sample. Remove cap without contaminating the inner surface of the cap or neck of the bottle. Reduce the flow to permit filling the bottle without splashing. Hold the bottle by the base and fill to the 100ml line without rinsing.
3. Write on the sample bottle label: date and time collected, sample site, and collector’s initials. Complete all information on the submittal form. Wrap the form around the sample bottle and secure with a rubber band.
4. Deliver the sample to the laboratory within 24 hours. If delay is anticipated in transport, the sample must be refrigerated or in a cooler until delivered to the laboratory. **Sample must be tested within 24 hours of collection.**

The Santa Clara County Public Health Laboratory is certified for the bacteriological testing of water by the California Department of Public Health Environmental Laboratory Accreditation Program (ELAP).

<b>Public Health Laboratory, County of Santa Clara</b> 2220 Moorpark Avenue, Rm. 2 <sup>nd</sup> Flr., San Jose, CA 95128 Phone: (408) 885-4272 Fax: (408) 885-4275 CLIA No.: 05D0643967 <b>Patricia A. Dadone, Director</b>	<i>Public Health Label Area</i> <i>Place Label Here</i>
--	--

<b>Patient's Name (Last, First)</b>	<b>DOB</b>	<b>BACTERIAL CULTURE FOR IDENTIFICATION</b> (Include Actinomyces-Like Cultures; Exclude Mycobacteria Cultures)
Address	<b>Sex</b>	<b>DESCRIPTION OF SPECIMEN</b>
Physician's Name		<b>Date Collected</b> Check Source: <input type="checkbox"/> Human <input type="checkbox"/> Animal, species: _____ <input type="checkbox"/> Other, specify: _____

Clinical Condition or Suspected Disease	<b>Date of Onset</b>	<b>Origin of Specimen:</b> <input type="checkbox"/> Blood <input type="checkbox"/> Serum <input type="checkbox"/> Sputum <input type="checkbox"/> CSF <input type="checkbox"/> Throat <input type="checkbox"/> Urine <input type="checkbox"/> Feces <input type="checkbox"/> Skin
<input type="checkbox"/> Case <input type="checkbox"/> Epidemic <input type="checkbox"/> Sporadic <input type="checkbox"/> Contact <input type="checkbox"/> Carrier		Tissue, Type: _____ Pus, Source: _____ Exudate, Source: _____ Wound, Location: _____ Other, Specify: _____

<i>Return Report To:</i>  Name, Address, Zip	<b>SUBMITTER'S IDENTIFICATION OF ORGANISM</b>
--	---

Antimicrobial Agents: <input type="checkbox"/> None	Date Begun	Date Completed	
Types	Dosage		

**IMPORTANT:**  
Enter Your Laboratory Findings on REVERSE Side

**Brief But Complete Case History, Therapy, Outcome (Type or Print)**

**PUBLIC HEALTH LABORATORY RESULTS**

		Result	Date	Init			Result	Date	Init			Result	Date	Init			Result	Date	Init			
Morphology																						
Gram Stain					TSI:	Slant				Growth:					Base Used	Glucose						
Catalase				Butt							MacConkey Agar						Levulose					
Oxidase				H <sub>2</sub> S							SS Agar						Xylose					
Motility					Aesculin Hydrolysis					Cetrimide Agar				Lactose								
Loeffler's Agar	Pigmentation				Falkow Lysine					25° C				Maltose								
	Proteolysis				Malonate					35° C				Sucrose								
Pseudomonas Agar	F				Phenylpyruvic Acid					42° C				Raffinose								
	P				Sodium Acetate					Nutri. Br. 0% NaCl				Adonitol								
Gelatin Hydrolysis					Moeller's Lysine Decarboxylase					Nutri Br. 3% NaCl				Dulcitol								
Litmus Milk					Moeller's Arginine Dihydrolase					Nutri Br. 6.5% NaCl				Glycerol								
Citrate (Simmons)					Moeller's Ornithine Decarboxylase					Anaerobically				Inositol								
Indol					ONPG									Mannitol								
Urea Hydrolysis					OF Medium	Open								Sorbitol								
Nitrates					+ Glucose	Closed								Salicin								

<b>MR/VP</b>		<b>Organism Identified As:</b>				
<b>Key</b> A = acid K = alkaline S = strong Gr. = growth NGr. = no growth G = gas * = vial for gas detection + = positive - = negative () = # of days Blank = not done	<b>Other Tests or Comments:</b>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; padding: 5px;"><b>Initials</b></td> <td style="width:50%; padding: 5px;"><b>Date Reported</b></td> </tr> <tr> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> </table>	<b>Initials</b>	<b>Date Reported</b>		
<b>Initials</b>	<b>Date Reported</b>					

**SUBMITTER'S LABORATORY FINDINGS:**

Cultures made from original *clinical sample* were:  Pure  Mixed

If mixed, list other organisms present: \_\_\_\_\_

Indicate colony count where applicable (e.g., Urine): \_\_\_\_\_

Number of times submitted organism: (a) isolated from patient: \_\_\_\_\_

(b) transferred in the laboratory: \_\_\_\_\_

Medium(s) on which primary growth was obtained: \_\_\_\_\_

Were stained smears or other preparations made *directly* from clinical material?  Yes  No

If yes, was this organism seen?  Yes  No

Medium on which organism is being submitted: \_\_\_\_\_

Date inoculated: \_\_\_\_\_

Conditions of incubation prior to mailing: Temp. \_\_\_\_\_; Atmosphere \_\_\_\_\_; Length \_\_\_\_\_.

Indicate in chart below the results of your laboratory examinations of the pure cultures being submitted using symbols given in the Key:

(KEY)		
A = Acid	Gr. = Growth	* = Vial for Gas Detection
K = Alkaline	NGr. = No Growth	( ) = # of Days
S = Strong	+ = Positive	BLANK = Not Done
G = Gas	- = Negative	

*Fill in as completely as possible*

Morphology				Hemolysis		Base Used	
Gram Stain		TSI: <u>Slant</u> <u>Butt</u> <u>H<sub>2</sub>S</u>		Growth: <u>MacConkey Agar</u> <u>SS Agar</u> <u>Cetrimide Agar</u>		<u>Glucose</u>	
Catalase						<u>Levulose</u>	
Oxidase						<u>Xylose</u>	
Motility		<u>Aesculin Hydrolysis</u>				<u>Lactose</u>	
Loeffler's	<u>Pigmentation</u>	<u>Falkow Lysine</u>		<u>25° C</u>		<u>Maltose</u>	
	<u>Proteolysis</u>	<u>Malonate</u>		<u>35° C</u>		<u>Sucrose</u>	
<u>Pseudomonas</u>	<u>F</u>	<u>Phenylpyruvic Acid</u>		<u>42° C</u>		<u>Raffinose</u>	
<u>Agar</u>	<u>P</u>	<u>Sodium Acetate</u>		<u>Nutri. Br. 0% NaCl</u>		<u>Adonitol</u>	
<u>Gelatin Hydrolysis</u>		<u>Moeller's Lysine Decarboxylase</u>		<u>Nutri Br. 3% NaCl</u>		<u>Dulcitol</u>	
<u>Litmus Milk</u>		<u>Moeller's Arginine Dihydrolyase</u>		<u>Anaerobically</u>		<u>Glycerol</u>	
<u>Citrate (Simmons)</u>		<u>Moeller's Ornithine Decarboxylase</u>				<u>Inositol</u>	
<u>Indol</u>		<u>ONPG</u>				<u>Mannitol</u>	
<u>Urea Hydrolysis</u>		<u>KCN</u>				<u>Sorbitol</u>	
<u>Nitrates</u>		<u>Mucate</u>				<u>Salicin</u>	
<u>V-P</u>		<u>OF Medium</u>	<u>Open</u>				
		<u>+ Glucose</u>	<u>Closed</u>				

Agglutination Reactions	Other tests or Comments:
-------------------------	--------------------------



# Santa Clara County Public Health Laboratory

Patricia Dadone, Director | CLIA No: 05D0643967

## Submitter's Laboratory Findings

Cultures made from original specimen were:  Pure  Mixed

If mixed, list other organisms present:

How many colonies of this organism on primary isolation?  1-10  10-25  25-50  Over 50

How frequently has this organism been recovered?  Once only  2-5 times  Over 5 times

Was the submitted organism seen in stained smears made directly from clinical material?  Yes  No

Medium on which organism is being submitted:

Date inoculated: \_\_\_\_\_

Conditions of incubation prior to mailing: \_\_\_\_\_ Temperature: \_\_\_\_\_

Atmosphere: \_\_\_\_\_

Indicate the results of your laboratory examinations of the pure culture being submitted:

Medium	Growth Rate		Pigment		Colony morphology on Sabourduraud Medium Age: ____			Microscopic Characteristics		
	25-30°	37°	Surface	Reverse				Medium: _____	Age: _____	
SC										
SCC										
BBHI					Ferm.		Assim.			
CM						Dextrose		Other tests or comments:		
PDA						Galactose				
CMD						Lactose				
						Maltose				
EMB						Sucrose				
CMT						Trehalose				
Urease						Raffinose				
VB Agar						Melibiose				
Hair Penetration						Cellobiose				
Thiamine						Inositol				
						Xylose				
Loeffler						Dulcitol				
Gelatin						KNO3				
SC = Sabouraud dextrose agar + chloramphenicol					CM = Cornmeal agar					Date
SCC = Sabouraud dextrose agar + chloramphenicol + cycloheximide					CMD = Cornmeal dextrose agar					Date
BBHI = Brain heart fusion agar + blood					CMT = Cornmeal tween agar					
PDA = Potato dextrose agar					V8 = Vegetable juice agar					

## Collection & Transport Guides

Before collecting specimens for the SCCPHL, carefully read the general submission instructions on page 41. In addition to the following collection guides, specimen requirements are included in the testing services section.

### ***For Select Tests***

On the following pages, please find collection guides for these tests:

- Blood Lead
- *Mycobacterium tuberculosis* by QFT IT
- Scabies
- Tick (Lyme Disease)
- Variolla (Smallpox)
- Water (Coliform)

### ***By Specialty***

On the following pages, please find collection guides for these specialties:

- Bacteriology
- Mycology
- Serology
- Virology



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# Finger-stick Method for Blood Lead Specimens

## Collection and Transport Instructions

### **Principle / Purpose:**

Atomic Absorption Spectrometry (AAS) is used to quantitatively measure lead levels in fresh whole blood which has been collected in the specially provided EDTA microtainer.

### **Agents:**

Lead can be found in a number of environmental sources, including, paint, soil and dust. Exposure to lead can cause irreversible damage, especially in children.

### **Materials:**

- Lancet
- Cotton balls or gauze pads
- EDTA-microcontainer (“microtainer”) for blood collection
- Alcohol prep pads
- Band-Aid
- D-Wipe towels (this item is not required but is highly recommended)
- Label for the “microtainer” with the minimum information of the patient’s name, date of birth (DOB), and collection date.
- Paper towels (lead free, do NOT use brown towels)

### **Procedure / Collection:**

1. Assemble supplies listed above.
2. Wash hands as directed in the presentation materials and put on gloves.
3. Remove cap from microtainer.
4. Wash the child’s hand with warm soapy water.
5. Dry child’s hand with a clean, lint-free white paper towel (Do not use brown towels)
6. Finger must not contact any surface or other fingers once washed.
7. Wipe child’s hand with a D-Wipe and then wrap the D-Wipe around the finger that will be punctured. Do not “milk” finger.
8. Clean the child’s finger with an alcohol prep pad.

9. Dry finger with cotton or gauze.
10. Puncture finger with lancet device as instructed in training.
11. Wipe away first drop of blood with a cotton ball or gauze.
12. Hold the microtainer at a 45-degree angle with the scoop end at the base of the finger, but not touching the finger.  
**Tip:** Keep finger below the patient's heart so the blood will flow more quickly and smoothly.
13. Collect blood by touching tip of collection container to beaded drop of blood avoiding contact between skin and container.  
**Tip:** While it is fine to gently massage the finger, take care not to push so hard as to dilute the blood with tissue fluids.
14. Collect no less than four drops (>50µl) of blood.
15. Cap and rotate microtainer to mix blood with anticoagulant.
16. Label the tube with the patient's name, DOB and collection date.

**Storage:**

Specimens should be stored in the refrigerator (4°C) and are stable for 30 days.

**Packing / Transport:**

If a professional judgment has been made that there is minimal likelihood that the blood contains a pathogen, specimens may be shipped according to the guidelines for Exempt Patient Specimens as outlined by IATA.

## Quick Guide QuantiferON<sup>®</sup>-TB Gold Blood Collection

### Option 1: Incubate at Collection Site

Please see reverse for instructions if incubating tubes at Laboratory.

For comprehensive instructions for use, please refer to the Package Insert, available in up to 25 different languages, on [www.cellestis.com](http://www.cellestis.com).



<p>①</p> <p><b>BLOOD COLLECTION</b></p>		<p>Collect 1mL blood by venipuncture into each QFT blood collection tube. <b>Tubes should be at 17–25°C at the time of blood filling.</b> <i>Tubes fill slowly—hold tube on needle for 2–3 seconds after flow ceases. If blood level is not close to the black mark on the side of the tube label, obtain another sample.</i></p> <p><b>Technical Tip</b> Butterfly needles—prime tubing with a “purge” tube (not supplied) before filling QFT tubes.</p>
<p>②</p> <p><b>BLOOD COLLECTION</b></p>		<p>Immediately after filling, shake tubes ten (10) times just firmly enough to ensure that the inner surface of the tube is coated in blood (to solubilize antigens on tube walls). <b>Over-energetic shaking may cause gel disruption and could lead to aberrant results.</b> <i>Label tubes appropriately.</i></p>
<p>③</p> <p><b>SHIPPING / INCUBATION</b></p>		<p><b>Incubate at Collection site</b> Blood must be incubated as soon as possible (and within 16 hours of collection). Incubate tubes <b>upright</b> at 37°C for 16–24 hours. <i>Humidity/CO<sub>2</sub> not required. Portable incubators are available from Cellestis.</i></p> <p>If tubes are not incubated at 37°C soon after collection, re-mix tubes by inverting ten (10) times immediately prior to incubation.</p>
<p>④</p> <p><b>SHIPPING / INCUBATION</b></p>		<p>Ship incubated tubes to testing laboratory (within 3 days, if not centrifuged) <i>Maintain tubes at 4 – 27°C .</i></p> <p><b>Technical Tip</b> Label tubes as “Incubated”.</p>

For more information on QFT in your area, please visit [www.cellestis.com](http://www.cellestis.com).  
World Headquarters | Cellestis Limited | Email: [info@cellestis.com](mailto:info@cellestis.com) | Tel: +61 3 8527 3500

⚠ WARNING: Standard blood handling precautions apply.

## Quick Guide QuantiferON<sup>®</sup>-TB Gold Blood Collection

### Option 2: Incubate at Laboratory

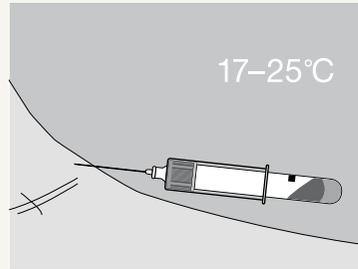
Please see reverse for instructions if incubating tubes at collection site.

For comprehensive instructions for use, please refer to the Package Insert, available in up to 25 different languages, on [www.cellestis.com](http://www.cellestis.com).



①

#### BLOOD COLLECTION



Collect 1mL blood by venipuncture into each QFT blood collection tube.

**Tubes should be at 17–25°C at the time of blood filling.**

*Tubes fill slowly—hold tube on needle for 2–3 seconds after flow ceases. If blood level is not close to the black mark on the side of the tube label, obtain another sample.*

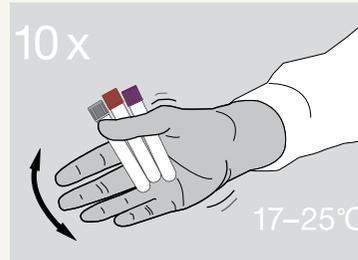
#### Technical Tip

Butterfly needles—prime tubing with a “purge” tube (not supplied) before filling QFT tubes.



②

#### BLOOD COLLECTION



Immediately after filling, shake tubes ten (10) times just firmly enough to ensure that the inner surface of the tube is coated in blood (to solubilize antigens on tube walls).

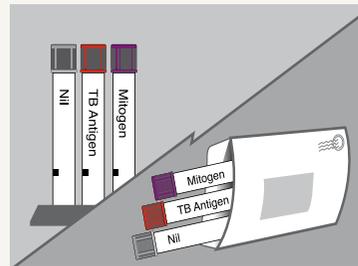
**Over-energetic shaking may cause gel disruption and could lead to aberrant results.**

*Label tubes appropriately.*



③

#### SHIPPING / INCUBATION



#### Incubate at Laboratory

Ship tubes to laboratory at 17–27°C.

Blood must be incubated at 37°C as soon as possible (and within 16 hours of collection).

**Re-mix tubes by inverting 10 times immediately prior to incubation.**

#### Technical Tip

Label tubes as “Not Incubated”.

For more information on QFT in your area, please visit [www.cellestis.com](http://www.cellestis.com).

World Headquarters | Cellestis Limited | Email: [info@cellestis.com](mailto:info@cellestis.com) | Tel: +61 3 8527 3500

⚠ WARNING: Standard blood handling precautions apply.

# Scabies Testing

## Collection and Transport Instructions

### Principle / Purpose:

Scabies is an infectious disease of the skin caused by a mite whose penetration is visible as papules or vesicles, or as tiny linear burrows containing mites and their eggs. Itching is intense, especially at night, but complications are limited to lesions secondarily infected from scratching. To diagnose scabies, a mite must be recovered from its burrow and identified microscopically. Obtain the specimen (mite) by scraping a lesion, which has not been scratched.

### Agents:

*Sarcoptes scabiei*, a mite.

### Materials:

- Scalpel or needle
- Plastic bag

### Procedure / Collection:

1. With a scalpel or a needle remove or aspirate mite from burrow.
2. Place skin/mite in a small plastic bag.
3. Label the plastic bag with patient information and collection date.
4. Fill out a submittal form with all pertinent patient information and submitter identification.

### Storage:

Deliver to the Public Health Lab at room temperature as soon as possible to prevent desiccation.

### Packing / Transport:

Send or deliver to Santa Clara County Public Health Laboratory, 2220 Moorpark Ave., 2<sup>nd</sup> floor, San Jose, CA 95128



# Tick Collection Procedure for Lyme Disease Examination

Testing for the causative agent, *Borrelia Burgdorferi*

## Tick Removal

- If a tick is found, remove it immediately. Prompt removal can prevent Lyme disease.
- Use a pair of tweezers to grasp the tick's mouth-parts. If you do not have tweezers use your fingers, but protect them with a tissue. Do not squash the tick; spirochetes released in fluids may penetrate skin.
- Slowly and steadily pull the tick straight out; do not twist. Remove mouth-parts left in skin (tick mouth-parts have harpoon like barbs that do not screw into skin).
- DO NOT apply alcohol, fingernail polish, heat (lit match), or petroleum jelly to the tick. Applying heat may cause the tick to regurgitate or secrete saliva, sending disease agents into the bite.
- Clean wound with soap and water. Apply a mild antiseptic if available.
- Save the tick for identification and testing for the Lyme disease spirochete.
- Consult with your physician about questions and treatment if bitten.

## Submitting Ticks to Santa Clara County Public Health Laboratory for Testing

(Only ticks that are vectors for Lyme disease will be tested for the Lyme organism.)

- Place whole tick, preferably alive, in a small plastic bag and send as soon as possible to the Santa Clara County Public Health Laboratory.
- Keep the tick moist in the small plastic bag with a piece of cotton ball damp with water.

## Submittal Slip

Fill out *Submittal Slip for Tick ID and IFA* (under "Test Requisition Forms" in this manual)

Be sure to complete:

- Name, Sex, and Date of Birth of victim bitten by tick.
- Where on the body the tick was found.
- Date person was bitten or found the tick on skin.
- The geographic location of the tick (where you were when the tick bit you).
- Address and phone number of the clinic, clinician, or person submitting tick.

## Fee

Please call the laboratory at 408.885.4272 for current pricing. Only cash, check and money order are accepted. Make check / money order payable to: **Santa Clara County Public Health Laboratory**

## Mail tick and payment to:

Santa Clara County Public Health Laboratory, 2220 Moorpark Avenue, 2<sup>nd</sup> Floor, San Jose, CA 95128



# Variola (Smallpox) Testing

## Collection and Transport Instructions

### **Principle / Purpose:**

To safely collect adequate cellular material from suspected VZV, Vaccinia, or Variola lesions that will be processed and tested by one or more of the following labs: Santa Clara County Public Health Lab (SCCPHL), California Department of Public Health Viral and Rickettsial Diseases Laboratory (VRDL) and The Center for Disease Control and Prevention (CDC). Depending on the patient history and clinical picture, the specimens collected could be tested for HSV, VZV, Vaccinia and Variola at the appropriate laboratory.

**If Vaccinia vaccine adverse reactions or possible smallpox virus is suspected, the primary physician must contact the Health Officer On-Call at Santa Clara County Disease Prevention and Control for consultation, and Case History forms must be filled out. Disease Prevention and Control can be reached by calling:**

**Daytime Phone: 408-885-4214 | After Hours Phone: 408-299-2501**

Using safety precautions, epithelial cells are collected from a suspected vesicle, pustule or scab. The lesion is unroofed and the top is saved in a collection device for testing. Blood and fluid are wiped away from the unroofed lesion. Four slide preparations with three cell spots are collected from the base of lesions. The base of the lesions is also sampled with Dacron® swabs using the step-by-step instructions provided to be used for PCR and or culture. A blood specimen is also collected for serology testing. The specimens are sent to SCCPHL for testing in-house or referral. Recommended specimens to collect are:

- Blood specimen (5-10 ml clotted blood in plastic red or tiger top tube)
- 6-10 top of vesicles or scabs (transport in 2 plastic screw cap tubes) for possible PCR
- 4 vesicular fluid smears (3 spots per slide) for possible VZV and HSV DFA
- 2 Dacron® swabs in viral transport media (VTM) for possible virus isolation attempts
- 2 Dacron® vesicular swabs placed in plastic screw cap transport tubes (no VTM) for possible PCR

### **Agents:**

Variola virus, vaccinia virus, varicella zoster virus and herpes simplex virus.

**Materials:**

- Gloves
- 5 Santa Clara County Public Health Lab Transport Bags
- Sterile needles or sterile scalpels
- Sterile gauze
- 1 Febrile Rash History and Specimen Submittal Form
- 4 Sterile Dacron® swabs (required for testing)
- 2 Viral Transport Media (VTM) tubes
- 2 Sterile plastic tubes (1 ml tubes) for transporting dry swabs
- 5 Small plastic screw cap tubes (2ml screw cap tubes) for transporting vesicle caps or scabs
- 4 Clean microscope slide for collecting vesicular fluid
- 2 Plastic blood tubes
- 1 Plastic microscope slide holder
- Parafilm for sealing tubes and slide holders

**Procedure / Collection:**

Personal protective equipment must be worn before collecting any samples. All samples must be labeled with patient's first and last name, type of specimen and date collected. All appropriate paperwork and case history forms must accompany specimens. For Laboratory questions call 408-885-4272.

1. Collect 10 ml of blood in a plastic Serum Separator Tube (i.e. SST, "gold top" or "tiger top") or plastic vacutainer (i.e. "red top") for serology testing.
2. Collect 6-10 vesicle caps or scabs for PCR testing.
  - a. Use a sterile scalpel or needle, or the plastic end of a swab, to lift off the vesicle cap or scab.
  - b. Place 2 vesicle caps or scabs into a sterile screw capped plastic tube.
  - c. Label tube with patient's name, specimen type (vesicle or scab), and date collected.
  - d. Do not add any fluid or VTM to the vesicle caps or scabs.
  - e. Paraffin the tube caps for transport
3. Collect 4 slides of the base of the lesion for PCR, EM or FA.
  - a. Wipe away any pus or vesicular fluid before collecting cells with sterile gauze.
  - b. Scrape the base of the vesicle or pustule with the blunt edge of a scalpel or applicator stick, or plastic end of a swab.

- c. Prepare touch preps of the scraped area (vesicular fluid) by applying a clean microscope slide to the area.
  - d. Make 3 spots per slide so that there are three distinct areas on the slide.
  - e. Make a total of 4 slides per patient using four different lesions, if possible.
  - f. Label the slide with patient's name, type of specimen, and collection date.
  - g. Allow the slides to dry for approximately 10 minutes.
  - h. Place the labeled slides into a slide holder
  - i. Paraffin the lid of the slide holder.
4. Collect 2 Dacron® swabs in VTM for possible virus culture.
  - a. Collect basal cells at the vesicle(s) base with a Dacron® swab.
  - b. Collect two swabs per patient from several vesicles.
  - c. Place each swab into separate VTM.
  - d. Label the tube with the patient's name, type of specimen, and date collected.
  - e. Paraffin tubes for transport.
5. Collect 2 Dacron® swabs in sterile plastic tube (no VTM) for possible PCR.
  - a. Collect basal cells at the vesicle(s) base with a Dacron® swab.
  - b. Collect two swabs per patient from several lesions.
  - c. Place each swab into separate plastic screw cap tubes without adding any media.
  - d. Label the tubes with patients name, specimen type, and date of collection
  - e. Paraffin tubes for transport.
  - f. Place each labeled specimen type into a separate Santa Clara County transport bag.
6. Fill out a Febrile Rash History and Specimen Submittal Form.
  - a. Include patient name, date of birth, sex, doctor requesting the test, date collected, date of onset of symptoms, VZV and/or Vaccinia vaccine history, and specimens submitted.
  - b. Other history forms may need to accompany the specimens depending on the clinical history and patient exposure (Vaccinia Adverse Reaction Case History form).
  - c. Place the History Form on the outside of a specimen transport bag.

**Storage:**

If specimen transport is delayed, the slides, VTM, and blood specimens must be kept at 4°C. The vesicle caps or scabs and Dacron® swabs without transport media should be stored at room temperature.

**Packing / Transport:**

Specimens should be sent to Santa Clara County Public Health Laboratory immediately for testing. All specimens must be transported in accordance with IATA and DOT regulations.

**References:**

1. CDC VZV DFA Training Session Manual. November 18, 2002.
2. CDC Guide D, Specimen Collection Guidelines
3. Chemicon International, Light Diagnostics VZV Direct Immunofluorescence Assay Procedure Manual. June 2001.

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## Drinking Water Sampling Procedure for Coliform Bacteriological Examination

Water samples are tested 8:00am – 5:00pm, Monday through Friday.  
No testing is done on the day before county holidays.

1. Select a suitable sample tap that does not have the potential of contaminating the water. **DO NOT USE:** water subject to any household treatment device, lavatory sinks, showers or tubs, swiveling faucets with aerators, plastic or rubber hoses, faucets less than 18” above ground, faucets surrounded by plants, hose bibs with leaking valve stems or excessive splattering, or rarely used faucets. Samples must represent the water being tested.
2. The tap should be opened fully to allow water to run for 1-2 minutes. The sampling bottles have a plastic seal around the cap and bottle to ensure sterility. The powder in the bottle will neutralize any chlorine present in the water sample. **DO NOT OPEN** the sterilized sample bottle until you are ready to collect the water sample. Remove cap without contaminating the inner surface of the cap or neck of the bottle. Reduce the flow to permit filling the bottle without splashing. Hold the bottle by the base and fill to the 100ml line without rinsing.
3. Write on the sample bottle label: date and time collected, sample site, and collector’s initials. Complete all information on the submittal form. Wrap the form around the sample bottle and secure with a rubber band.
4. Deliver the sample to the laboratory within 24 hours. If delay is anticipated in transport, the sample must be refrigerated or in a cooler until delivered to the laboratory. **Sample must be tested within 24 hours of collection.**

The Santa Clara County Public Health Laboratory is certified for the bacteriological testing of water by the California Department of Public Health Environmental Laboratory Accreditation Program (ELAP).



## Collection Guide – Bacteriology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Abscess	Clean abscess surface with sterile saline or 70% alcohol. Collect fluid and/or abscess material in a sterile, screw cap tube or vial. If there is an insufficient amount (<1 ml), swab abscess and place in tube containing Modified Amies Clear media.	<ul style="list-style-type: none"> <li>• Room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>
Anaerobic (Deep Wounds / Body Fluids)	Collect under anaerobic conditions. Use swab and transport tube designed for anaerobic specimens. Please call laboratory for specific instruction and more information at 408.885.4272.	<ul style="list-style-type: none"> <li>• 48 hours at room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>
Blood, Whole & Serum	Aseptically collect 8 – 10ml of whole blood in SST (i.e. Tiger Top or Gold Top) or vacutainer with no additives (i.e., Red Top).	<ul style="list-style-type: none"> <li>• Refrigerate specimens at 2 – 8°C for up to 7 days. If longer storage is needed, pipette serum only and freeze at –20°C.</li> <li>• Transport at room temperature (15 – 30°C)</li> </ul>
CSF	Collect as much spinal fluid as possible (2 – 5ml for children and adults, or 1 ml for infants) in a sterile, screw cap tube or vial. Refrigerate as soon as possible.	<ul style="list-style-type: none"> <li>• 24 hours at room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>
Drainage (Ear / Eye)	Swab drainage and place in sterile, leak proof, screw cap tube or vial with Modified Amies Clear media.	<ul style="list-style-type: none"> <li>• 5 days at room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>
Extragenital Site Swab (Ear / Eye)	Swab infected area and place in sterile, leak proof, screw cap tube or vial with Modified Amies Clear media.	<ul style="list-style-type: none"> <li>• Room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>
Genital / Urinary Discharge	Swab infected area and place in sterile, leak proof, screw cap tube or vial with Modified Amies Clear media.	<ul style="list-style-type: none"> <li>• Room temperature (15 – 30°C)</li> <li>• DO NOT REFRIGERATE OR FREEZE</li> </ul>

## Collection Guide – Bacteriology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Genital Swab	<p><b>FEMALE:</b> Prior to collecting the specimen, clean mucus from the cervix using a sterile swab then discard this swab. Using another sterile swab or Cytobrush, obtain cells from the cervical os by gently rotate the swab for 10 to 30 seconds to ensure adequate sampling. Be sure to swab any lesions that may be visible. Avoid touching the vaginal mucosa when withdrawing the swab. Remove swab or brush and place in vial with appropriate media (for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> PCR assays use VTM, for <i>Neisseria gonorrhoeae</i> culture use MTM, and for all other tests use Modified Amies Clear media).</p> <p><b>MALE:</b> The patient should not urinate for at least one hour prior to collection. Insert a sterile swab 2 – 4cm into the urethra and gently rotate the swab for 2–3 seconds. Withdraw the swab carefully, and place in a sterile, leak proof, screw cap tube or vial with with appropriate media (for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> PCR assays use VTM, for <i>Neisseria gonorrhoeae</i> culture use MTM, and for all other tests use Modified Amies Clear media).</p> <p><b>For PCR assays, DO NOT use swabs with calcium alginate or wooden shaft. For <i>Chlamydia trachomatis</i> direct detection (PCR assay), use a rayon- or Dacron®-tipped swab and place in sterile, leak proof, screw cap tube or vial with VTM. For <i>Neisseria gonorrhoeae</i> direct detection (PCR assay), use a rayon- or Dacron®-tipped swab and place in sterile, leak proof, screw cap tube with MTM.</b></p>	<ul style="list-style-type: none"> <li>• 24 hours at room temperature (15 – 30°C) NOT acceptable for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> direct detection</li> <li>• 24 hours refrigerated (2 – 8°C) and up to 72 hours for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> direct detection, transport on cold pack.</li> <li>• DO NOT FREEZE</li> </ul>
Joint Fluid	Collect 3 - 5ml aseptically into sterile tube.	<ul style="list-style-type: none"> <li>• Refrigerate specimens at 2 – 8°C</li> </ul>
Nasal Swabs	<p>Nasal swab specimens should be collected as soon as possible, no later than 5 days after onset of the disease. Use 1 or 2 swab(s), to swab each nostril. Allow the swab to remain in place for a few seconds to absorb secretions. Place swab in a sterile, screw cap vial (if preparing a slide, see Slide listing below for details).</p> <p><b>For PCR assays, DO NOT use swabs with calcium alginate or wooden shaft. For MRSA direct detection (PCR assay), use a rayon- or Dacron®-tipped swab.</b></p>	<ul style="list-style-type: none"> <li>• 24 hours at room temperature (15 – 30°C) or refrigerated (2 – 8°C) and transport to lab as soon as possible</li> </ul>

# Collection Guide – Bacteriology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Nasopharyngeal Swab	<p>Insert a calcium alginate swab into one or both nostrils to the nasopharyngeal area and press against the nasal wall. Allow the swab to remain for a moment to absorb secretion, rotate the swab two to three times and withdraw slowly. Insert the swab into a sterile 15ml collection tube and bend wire to fit in the tube and screw cap back on (no saline, water, or other media need to be added).</p> <p><b>For PCR assays, DO NOT use swabs with calcium alginate or wooden shaft. For <i>Chlamydia trachomatis</i>, <i>Bordetella pertussis</i>, <i>Mycoplasma pneumonia</i>, and <i>Neisseria gonorrhoeae</i> direct detection (PCR assay), use a rayon- or Dacron®-tipped swab and place in sterile, leak proof, screw cap tube or vial with VTM.</b></p>	<ul style="list-style-type: none"> <li>ROOM TEMPERATURE IS UNACCEPTABLE except for <i>Bordetella pertussis</i> and <i>Mycoplasma pneumonia</i>, up to 24 hours.</li> <li>48 hours refrigerated (2 – 8°C) (24 hours for <i>Bordetella pertussis</i> and <i>Mycoplasma pneumonia</i>)</li> <li>DO NOT FREEZE</li> </ul>
Rectal Swab	<p><b>For PCR assays, DO NOT use swabs with calcium alginate or wooden shaft.</b></p> <p><b>For <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> direct detection (PCR assay), use a rayon- or Dacron®-tipped swab and place in sterile, leak proof, screw cap tube or vial with VTM.</b></p> <p><b>For <i>Neisseria gonorrhoeae</i> culture, Insert a dry cotton swab 1cm past the anal sphincter and hold for about 10 seconds. Remove the swab and immediately inoculate Jembec® plate by rolling the swab across the agar surface.</b></p> <p><b>For all other tests, use CNS media.</b></p>	<p><b>For <i>Chlamydia Trachomatis</i>,</b></p> <ul style="list-style-type: none"> <li>72 hours refrigerated (2 – 8°C), transport on cold pack</li> </ul> <p><b>For <i>Neisseria gonorrhoeae</i>,</b></p> <ul style="list-style-type: none"> <li>Hold at 2 – 8°C for up to 7 days.</li> <li>Freeze at –70°C for longer storage.</li> </ul>
Sputum	<p>Collect 5 – 10ml of fresh sputum in a sterile screw cap cup. In the early morning, patient should remove any dental devices, rinse mouth and cough deeply (may be induced by aqueous aerosol).</p>	<ul style="list-style-type: none"> <li>ROOM TEMPERATURE IS UNACCEPTABLE</li> <li>24 hours refrigerated (2 – 8°C), transport on cold pack</li> <li>DO NOT FREEZE</li> </ul>
Sterile body fluids	<p>Pleural, synovial and peritoneal fluids should be collected aseptically. Place in a sterile, leak proof, screw cap container.</p>	<ul style="list-style-type: none"> <li>Room temperature (15 – 30°C).</li> </ul>

## Collection Guide – Bacteriology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Stool	Pass the stool into a clean, dry container before transferring to a sterile screw cap cup with Cary Blair media (Para Pak C&S containers are available through the laboratory, call 408.885.4272). Using the collection spoon built into the lid of the tube, place 2 – 5g of stool from areas that appear bloody, slimy or watery into the tubes until the contents rise to the red line. If the stool is formed (hard) please try to sample small amounts from each end and the middle. Mix the contents of the tube with the spoon, then twist the cap tightly closed and shake the tube until the contents are well mixed. Keep the stool specimen cool, do not incubate.	<ul style="list-style-type: none"> <li>• 5 days at room temperature (15 – 30°C)</li> <li>• 5 days refrigerated (2 – 8°C)</li> <li>• DO NOT FREEZE</li> </ul>
Throat swab	Take swab from the tonsillar area and/or posterior pharynx, avoiding the tongue and uvula.  <b>For PCR assays, DO NOT use swabs with calcium alginate or wooden shaft. For <i>Chlamydia trachomatis</i>, MRSA, <i>Mycoplasma pneumonia</i>, <i>Neisseria gonorrhoeae</i>, and <i>Streptococcus pneumonia</i> direct detection (PCR assay), use a rayon- or Dacron®-tipped swab and place in sterile, leak proof, screw cap tube or vial with VTM.</b>	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C (24 hours for <i>Mycoplasma pneumonia</i> and <i>Streptococcus pneumonia</i>).</li> </ul>
Tissue	Collect tissue aseptically from center and edge of lesion. Place specimen between moist gauze squares, add a small amount of sterile water or 0.85% NaCl to keep tissue from drying out. Place in a sterile, leak proof, screw cap container.	<ul style="list-style-type: none"> <li>• Room temperature (15 – 30°C).</li> </ul>
Urine	Collect 5 – 20ml of clean-catch midstream urine in sterile, leak proof, screw cap cup.  <b>For PCR assays (<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>), Patient should not urinate 1 hour prior to collection. Collect the first 15 – 20ml of random voided urine (beginning of stream) in a plastic, preservative-free, sterile urine collection cup. Specimens that are bloody (&gt;0.5%) or grossly mucoid (&gt;10%) are UNACCEPTABLE. Refrigerate immediately.</b>	<ul style="list-style-type: none"> <li>• <b><i>Salmonella typhi</i> specimens must be received within 4 hours of collection</b></li> <li>• 6 hours at room temperature (15 – 30°C).</li> <li>• 24 hours refrigerated (2 – 8°C), transport on cold pack (7 days for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> PCR assays)</li> <li>• 30 days frozen (–20°C)</li> </ul>

## Collection Guide – Bacteriology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Vesicular fluids & Wounds	Collect vesicular fluids from the bases of lesions before crusting and healing have begun or gently remove any crusts, and discard. For aspirates, use a 26 – 27 gauge needle attached to a tuberculin syringe or a capillary pipette to aspirate clear vesicular fluid. Cleanse the surface of the lesion with physiological saline and blot dry. Abrade superficially until slight bleeding occurs. Wipe away the first few drops of blood. For tests that require direct specimens, moisten a sterile cotton swab with sterile phosphate buffered saline (pH 7.2). Sample the cleansed ulcer base with the moistened swab. Place the swab into a sterile screw capped test tube containing 0.5ml saline solution and send immediately to the laboratory. For slides, apply gentle pressure at lesion base, touching clear exudate in ulcer base with a glass slide. Place coverslip and transport immediately to lab.	<ul style="list-style-type: none"> <li>• 24 hours refrigerated (2 – 8°C), transport on cold pack.</li> </ul>

### GENERAL CONSIDERATIONS

1. Collect specimens within 3 – 7 days after the onset of illness for isolation and prior to antimicrobial therapy.
2. Collect postmortem specimens, using aseptic techniques, as soon as possible after death. Refrigerate specimens after collection and transport to lab as soon as possible.
3. Swabs with calcium alginate or wooden shafts are not acceptable for PCR assays or *Chlamydia trachomatis* testing.
4. Swab and urine specimens that are bloody (>0.5%) or grossly mucoid (>10%) may inhibit PCR assays and are therefore, UNACCEPTABLE.



## Collection Guide – Mycology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Abscess	Clean abscess surface with sterile saline or 70% alcohol. Fluid or abscess material is preferred over swab. Collect fluid/abscess material in clean tube and swab in Modified Amies Clear media (transport swabs with Modified Amies Clear media available at lab).	• Refrigerated at 2 – 8°C.
Hair	Collect at least 10 hairs (at base of shaft) between two glass slides, in clean tube or container, in a paper envelope, or directly inoculated onto SabDex media.	• Room temperature (15 – 30°C).
Mucocutaneous membranes (mouth, vaginal, urethral)	Collect swab of infected area and transport in Modified Amies Clear media (transport swabs with Modified Amies Clear media available at lab)	• Refrigerated at 2 – 8°C.
Nails	Clean nail with 70% alcohol then scrape outer surface of the nail and discard. Scrape deeper portion of the nail (infected area) and save in sterile container, a paper envelope, or directly inoculated onto SabDex media. Collect the whole nail or nail clippings and include with scraping.	• Room temperature (15 – 30°C).
Respiratory	Collect 7 – 10 ml of aerosol, early morning sputum, tracheal aspirates, lung biopsy, or bronchoscopy specimens in sterile container.	• Refrigerated at 2 – 8°C.
Skin	Clean skin with 70% alcohol. Scrape the lesion at the active margin but do not draw blood. Place scrapings between 2 glass slides, in clean container or directly inoculate onto SabDex media.	• Room temperature (15 – 30°C).
Sterile Fluids (CSF, bone marrow, pleural, pericardial, joint, peritoneal)	Collect as much spinal fluid as possible (2 – 3 ml) in a sterile, screw cap tube or vial (1 ml for infants). Do not dilute the specimen and refrigerate as soon as possible.	• Refrigerated at 2 – 8°C

## Collection Guide – Mycology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Tissue / Biopsy	Collect tissue aseptically from center and edge of lesion. Place specimen between moist gauze squares, add a small amount of sterile water or 0.85% NaCl to keep tissue from drying out, and send immediately to the laboratory in a sterile container. Submit in sterile container with small amount of sterile saline (do not allow tissue to dry out).	• Refrigerated at 2 – 8°C
Urine	Collect 25 – 30 ml of catheterized or early morning midstream clean-catch urine in a sterile container.	• Refrigerated at 2 – 8°C for up to 12 – 14 hours.

### GENERAL CONSIDERATIONS

1. In general, specimens for isolation should be held at 4°C (but not frozen) just prior to inoculation and should be transported to the laboratory as soon as possible, no later than 72 hours. Specimens that cannot be transported to the lab within 72 hours should be frozen at –70°C and transported on dry ice.
2. Collect specimens within 3 – 7 days after the onset of illness for isolation.
3. Collect postmortem specimens, using aseptic techniques, as soon as possible after death. Refrigerate specimens after collection and transport to lab as soon as possible.
4. Avoid the use of anaerobic transport media.
5. Do not use swabs with wooden shafts.

## Collection Guide – Serology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
CSF	<p>CSF specimens should be collected as soon as possible, no later than 3 days after onset of the disease. Collect 1 – 3 ml (1 ml for infants) of CSF into a sterile, screw cap tube or vial. Specimens contaminated with blood are UNACCEPTABLE. Do not dilute the specimen and refrigerate as soon as possible.</p>	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at –70°C or below and transported on dry ice.</li> </ul>
Oral fluid	<p><b>BY TRAINED PERSONNEL ONLY (contact the laboratory for more information at 408.885.4272).</b></p> <p>Patient should not eat, drink (including water) or smoke within 5 minutes of collecting the specimen. Instruct patient to place pad between lower cheek and gum and rub back and forth until moist, pad should remain in place for 3 minutes (not longer than 5 minutes). Hold vial in an upright position, open, and have the patient place the pad in the vial. Break the pad handle by snapping it against the side of the vial. Replace cap, making sure the cap snaps tight. Oral fluid specimens are approved for patients 13 years of age or older.</p>	<ul style="list-style-type: none"> <li>• Transport to laboratory at room temperature (15 – 30°C) within 21 days of collection.</li> </ul>
Plasma	<p><u>Fresh:</u> Aseptically collect whole blood in plastic vacutainer with EDTA anticoagulant (i.e. Purple Top). Draw at least 2.5 times amount needed. Mix well by gently inverting the tube 5 - 6 times. Do not freeze whole blood.</p> <p><u>Frozen:</u> If transportation to the lab is delayed more than 6 hours, centrifuge the specimen at 800-1,600 x g for 20 minutes, transfer plasma to a sterile polypropylene tube and freeze at –20°C. Ship the frozen plasma to the lab on dry ice.</p>	<ul style="list-style-type: none"> <li>• Hold at 2 – 8°C prior to transportation to the lab. Transport to the laboratory within 6 hours of collection.</li> <li>• Plasma may be frozen at –20°C and shipped to the lab on dry ice.</li> </ul>

## Collection Guide – Serology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Serum & Whole Blood	Aseptically collect 8 – 10 ml of whole blood in SST (i.e. Tiger or Gold Top) or vacutainer with no additives (i.e. Red Top).	<ul style="list-style-type: none"> <li>• Refrigerate specimens at 2 – 8°C for up to 72 hours. If longer storage is needed, pipette serum into separate tube and freeze at –20°C.</li> <li>• Transport on cold pack</li> </ul>
Serum, Acute-phase	Acute-phase specimens should be collected as soon as possible, no later than 5 – 7 days after onset of the disease. Aseptically collect 8 – 10 ml of whole blood in SST (i.e. Tiger or Gold Top) or a plastic vacutainer with no additives (Red Top). If transportation to the lab is delayed more than 48 hours, centrifuge. Gold Tops contain 5 ml of whole blood and may be used for small draws. Label lab slip and specimen as acute.	<ul style="list-style-type: none"> <li>• Refrigerate specimens at 2 – 8°C for up to 72 hours. If longer storage is needed, pipette serum and freeze at –20°C.</li> <li>• Transport on cold pack</li> </ul>
Serum, Convalescent-phase	Convalescent-phase specimens should be collected 10 – 14 days after acute-phase specimens (14 – 21 days after onset). Aseptically collect 8 – 10 ml of whole blood in SST (i.e. Tiger or Gold Top) or a plastic vacutainer with no additives (Red Top). If transportation to the lab is delayed more than 48 hours, centrifuge. Gold Tops contain 5 ml of whole blood and may be used for small draws. Label lab slip and specimen as convalescent.	<ul style="list-style-type: none"> <li>• Refrigerate specimens at 2 – 8°C for up to 72 hours. If longer storage is needed, pipette serum and freeze at –20°C.</li> <li>• Transport on cold pack</li> </ul>

### GENERAL CONSIDERATIONS

1. Whole blood should never be frozen, as this will cause the specimen to hemolyze rendering it unacceptable for testing.
2. Allow blood to clot at least 30 minutes at room temperature 15 – 30°C before centrifuging to prevent hemolysis.
3. Blood may be stored refrigerated after clotting prior to being transported to the lab.
4. Some tests may require an acute and convalescent specimen and are so noted in the testing services section of this document.
5. Specimens with bacterial contamination, hemolysis or lipemia are UNACCEPTABLE.

## Collection Guide – Virology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Bronchial Wash/Aspirates	Bronchial specimens should be collected as soon as possible, no later than 5 days after onset of the disease (no later than 3 days after onset of suspected influenza cases). Bronchial and bronchoalveolar washes and aspirates are usually collected from hospitalized patients using specialized (invasive) procedures.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>
Buccal Swab	To collect a buccal specimen, massage the parotid gland area (between cheek and teeth inside mouth just below the ear) on each side of the face for about 30 seconds prior to collection of the secretions. Use a plain Dacron® swab and rub the inside of each cheek with the same swab for 10 seconds. Sweep the swab between the upper and lower molar areas on each side of the mouth. Place swab in sterile tube with 2-3 ml viral transport medium or sterile isotonic solution. DO NOT place in Amies or Stuart transport media since these contain viral inhibitory substances. DO NOT use swabs with wooden shafts as they inactivate virus infectivity. For PCR assays, DO NOT use calcium alginate swabs.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 24 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 24 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>
CSF	CSF specimens should be collected as soon as possible, no later than 3 days after onset of the disease. Collect 1 – 3 ml (1 ml for infants) of CSF into a sterile, screw cap tube or vial. Specimens contaminated with blood are UNACCEPTABLE. Do not dilute the specimen and refrigerate as soon as possible.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>

## Collection Guide – Virology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Nasal Swabs	Nasal swab specimens should be collected as soon as possible, no later than 5 days after onset of the disease (no later than 3 days after onset of suspected influenza cases). Use 1 or 2 Dacron® or rayon swab(s), to swab each nostril. Allow the swab to remain in place for a few seconds to absorb secretions. Place swab in a sterile, screw cap vial with 2 – 3 ml of VTM (if preparing a slide, see "Slide Preparation" below for details). DO NOT use swabs with wooden shafts as they inactivate virus infectivity. For PCR assays, DO NOT use calcium alginate swabs.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>
Nasal Washings	While the patient's head is tilted back slightly, instill several ml of sterile saline into each nostril; bring the head forward and allow the saline to drain into a small sterile container held beneath the nose. A small catheter with suction may be used with infants. Pour the contents into a sterile, screw cap vial.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>
Nasopharyngeal Swab	Nasopharyngeal swab specimens should be collected as soon as possible, no later than 5 days after onset of the disease (no later than 3 days after onset of suspected influenza cases). Immobilize the patients head. Using 1 or 2 wire or straight shaft Dacron® swab(s) with a dry tip, insert into one or both nostrils to the nasopharyngeal area and press against the nasal wall. Allow the swab to remain for a moment to absorb secretion, rotate the swab two to three times and withdraw. Place swab in a sterile, screw cap vial with 2 – 3 ml of VTM (if preparing a slide, see Slide listing below for details). Send the specimen to the lab as soon as possible. DO NOT use swabs with wooden shafts as they inactivate virus infectivity. For PCR assays, DO NOT use calcium alginate swabs.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours (48 hours for influenza specimens), at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at – 70°C or below and transported on dry ice.</li> </ul>

# Collection Guide – Virology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Oral Fluid (Mucosal Secretions)	<p><b>BY TRAINED PERSONNEL ONLY.</b> Contact the lab at 408.885.4272 for more information. Patient should not eat, drink liquid (including water) or smoke within 5 minutes of collecting the specimen. Instruct patient to place pad between lower cheek and gum and rub back and forth until moist, pad should remain in place for 2 minutes (not longer than 5 minutes). Hold vial in an upright position, open, and have the patient place the pad in the vial. Break the pad handle by snapping it against the side of the vial. Replace cap, making sure the cap snaps tight. Oral fluid specimens are approved for patients 13 years of age or older.</p>	<ul style="list-style-type: none"> <li>• Transport to lab at room temperature within 28 days.</li> </ul>
Slide Preparation	<p>Firmly roll one side of swab over top half of well, then roll other side over bottom half. Cover entire well evenly and stay within well perimeter. Well will appear opaque when there is adequate cell coverage. Allow specimen to completely air dry. Lay slide flat. Flood with 0.5 ml acetone fixative and let entire quantity evaporate. To speed evaporation, tip slide after 5 minutes to drain excess fixative. Place the direct specimen slide in a slide storage box.</p>	<ul style="list-style-type: none"> <li>• Store at 2 – 8°C for up to 24 hours.</li> <li>• For longer storage, freeze at –20°C for up to 72 hours</li> </ul>
Stool	<p>Stool specimens should be collected as soon as possible, no later than 7 days after onset of the disease. Collect a 2 – 5 g of stool (formed or liquid) and place in a sterile leakproof container. No transport medium is required.</p> <p><b>FOR NOROVIRUS RT-PCR:</b> Specimen must be refrigerated immediately.</p>	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at –70°C or below and transported on dry ice.</li> </ul>
Throat & Oral Swab	<p>Throat and oral swab specimens should be collected as soon as possible, no later than 5 days after onset of the disease (no later than 3 days after onset of suspected influenza cases). Use tongue blade to depress tongue to prevent contamination of swab with saliva. Using 1 or 2 Dacron® or rayon swab(s), dry or moistened with VTM, vigorously rub the tonsils and posterior nasopharynx and place in sterile, screw cap vial with 2 – 3 ml of VTM (if preparing a slide, see Slide listing below for details). DO NOT use swabs with wooden shafts as they inactivate virus infectivity. For PCR assays and Herpes Simplex Virus testing, DO NOT use calcium alginate swabs.</p>	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours (48 hours for influenza specimens), at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at –70°C or below and transported on dry ice.</li> </ul>

# Collection Guide – Virology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
Urine (Viral Isolation)	Clean-catch urine specimens, while not the specimen of choice, are acceptable for isolation of most viruses. Collect 10 – 40 ml in a sterile, leakproof container.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at –70°C or below and transported on dry ice.</li> </ul>
Urine (CMV)	Urine is the specimen of choice for the isolation of Cytomegalovirus (CMV). 10 – 40 ml of clean-catch urine, collected in sterile, leakproof container are recommended.	<ul style="list-style-type: none"> <li>• Transport to lab within 4 hours of collection at 2 – 8°C on WET ICE (place ice in double ziploc bag).</li> <li>• Specimens that cannot be transported within 4 hours should be mixed with an equal portion of 70% sorbital, frozen at –70°C or below and transported on dry ice.</li> </ul>
Vesicular Fluid/Swab, Scab & Eschar	Collect specimens of vesicular fluids from the bases of lesions before crusting and healing have begun. For swabs, obtain both fluid and cells from open lesions and place swab into a screw cap vial with 2 – 3 ml of VTM (if preparing a slide, see Slide listing above for details). DO NOT use swabs with wooden shafts as they inactivate virus infectivity. For PCR assays and Herpes Simplex Virus testing, DO NOT use calcium alginate swabs. For aspirates of vesicular fluids, use a 26 – 27 gauge needle attached to a tuberculin syringe or a capillary pipette to aspirate clear vesicular fluid.	<ul style="list-style-type: none"> <li>• Transport to lab as soon as possible, no later than 72 hours, at 2 – 8°C on a cold pack.</li> <li>• Specimens that cannot be transported within 72 hours should be frozen at –70°C or below and transported on dry ice.</li> </ul>

## GENERAL CONSIDERATIONS

1. In general, specimens for viral isolation should be held at 4°C (but not frozen) just prior to inoculation and should be transported to the laboratory as soon as possible, no later than 72 hours. Specimens that cannot be transported to the lab within 72 hours should be frozen at –70°C and transported on dry ice.
2. Collect specimens within 3 – 7 days after the onset of illness for viral isolation.

## Collection Guide – Virology

SPECIMEN	COLLECTION INSTRUCTIONS	TRANSPORT/HOLDING CONDITIONS
	3. Do not use swabs with wooden shafts as they inactivate virus infectivity.	
	4. Calcium alginate swabs are not acceptable for PCR assays or Herpes Simplex Virus and Chlamydia testing.	
	5. LQ Stuart (green or red top), Amies (with or without charcoal), A.C.T.I. and charcoal-impregnated swabs contain antiviral substances that render the specimen UNACCEPTABLE.	
	6. When using swabs, be careful not to collect blood on the swab which may inhibit viral activity.	
	7. Collect postmortem specimens, using aseptic techniques, as soon as possible after death. Refrigerate specimens after collection and transport to lab as soon as possible.	
	8. Please contact the laboratory at 408.885.4272 to obtain supplies.	



## Packaging and Shipping

The following guideline is meant as an overview and should not be used as a primary source of information regarding packaging and shipping infectious agents.

To ensure proper packaging and shipping, responsible parties should have current training as rules and regulations are subject to change. The shipper, not the carrier, is responsible for the proper packaging and labeling of specimens.

Several governing bodies provide different sets of regulations and individual carriers may have even more stringent policies. Check with your carrier for additional requirements and assume packages will be shipped by air unless specified otherwise.

IATA Dangerous Goods Regulations (IATA 1.0) and the Code of Federal Regulations (49CFR 171.8) defines three categories for specimens:

- Biological Substance, Category A
- Biological Substance, Category B
- Exempt Patient Specimens

### **Biological Substance, Category A (UN 2814)**

Category A Biological Substances are capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals. Category A substances have more strict packaging rules which include:

- Packager must be currently certified as an Infectious Substance Shipper
- A Shipper's Dangerous Goods Declaration must accompany the package
- A 24/7 contact phone number must be provided in case the package leaks during transportation

### **Biological Substance, Category B (UN 3373)**

Category B Biological Substance includes any clinical specimen that does not meet the definition of Category A Biological Substance. In general, Category B is applicable for all clinical samples that are being shipped for diagnostic purposes including virus isolates being shipped for further characterization (such as influenza virus for strain typing). However, high concentrations of infectious agents, such as cultures, may be capable of causing life-threatening disease, and would thus be considered a Category A Biological Substance.

### **Patient Exempt Specimens**

A direct patient specimen is considered exempt when a professional judgment has determined that it has a minimal likelihood of containing a pathogen.

Further information on the shipment of Biological Substances is available at the following websites:

DOT website:

[http://www.phmsa.dot.gov/pv\\_obj\\_cache/pv\\_obj\\_id\\_54AC1BCBF0DFBE298024C4C700569893C2582700/filename/Transporting\\_Infectious\\_Substances\\_brochure.pdf](http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_54AC1BCBF0DFBE298024C4C700569893C2582700/filename/Transporting_Infectious_Substances_brochure.pdf)

IATA website:

<http://www.iata.org/whatwedo/cargo/dgr/Pages/download.aspx>

The following pages provide additional information:

- IATA guidelines for classification of infectious substances
- Packaging guidelines for Category B Biological Substances
- Flowchart for classification of infectious substance
- Labels used for shipping infectious substances
- Diagrams of appropriately labeled packages
- Detailed diagram of Category A package
- Shipper's Declaration of Dangerous Goods

# IATA Classification

52nd EDITION, 1 JANUARY 2011

## 3.6.2 Division 6.2 - Infectious Substances

STATE VARIATIONS: AUG-03, CAG-10/11, VUG-02

OPERATOR VARIATIONS: AF-02, BZ-07, CO-07, CS-07, FX-09, JJ-06, LA-07, OO-01, OU-16, SN-03, SQ-10, UU-05

### 3.6.2.1 Definitions

For the purposes of these Regulations:

**3.6.2.1.1 Infectious substances** are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

*Note: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assigned to UN 3172.*

**3.6.2.1.2 Biological products** are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

**3.6.2.1.3 Cultures** are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined below in 3.6.2.1.4.

**3.6.2.1.4 Patient specimens** are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

**3.6.2.1.5 Medical or clinical wastes** are wastes derived from the medical treatment of animals or humans or from bio-research.

## 3.6.2.2 Classification of Infectious Substances

**3.6.2.2.1** Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 or UN 3373, as appropriate.

**3.6.2.2.2** Infectious substances are divided into the following categories:

**3.6.2.2.2.1 Category A:** An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D.

**Note:** *An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.*

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

**Notes:**

1. *The proper shipping name for UN 2814 is Infectious substance, affecting humans. The proper shipping name for UN 2900 is Infectious substance, affecting animals only.*
2. *The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.*
3. *In the following table, the micro-organisms written in italics are bacteria, mycoplasma, rickettsia or fungi.*

**TABLE 3.6.D**  
**INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES**  
**INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (3.6.2.2.2.1)**

UN NUMBER AND PROPER SHIPPING NAME	MICRO-ORGANISM
UN 2814 Infectious substance affecting humans	<i>Bacillus anthracis (cultures only)</i> <i>Brucella abortus (cultures only)</i> <i>Brucella melitensis (cultures only)</i> <i>Brucella suis (cultures only)</i> <i>Burkholderia mallei – Pseudomonas mallei – Glanders (cultures only)</i> <i>Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)</i> <i>Chlamydia psittaci – avian strains (cultures only)</i> <i>Clostridium botulinum (cultures only)</i> <i>Coccidioides immitis (cultures only)</i> <i>Coxiella burnetii (cultures only)</i> <i>Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only)</i> <i>Eastern equine encephalitis virus (cultures only)</i> <i>Escherichia coli, verotoxigenic (cultures only)</i> <i>Ebola virus</i> <i>Flexal virus</i> <i>Francisella tularensis (cultures only)</i> <i>Guanarito virus</i> <i>Hantaan virus</i> <i>Hantavirus causing hemorrhagic fever with renal syndrome</i> <i>Hendra virus</i> <i>Hepatitis B virus (cultures only)</i> <i>Herpes B virus (cultures only)</i> <i>Human immunodeficiency virus (cultures only)</i> <i>Highly pathogenic avian influenza virus (cultures only)</i> <i>Japanese Encephalitis virus (cultures only)</i> <i>Junin virus</i> <i>Kyasanur Forest disease virus</i> <i>Lassa virus</i> <i>Machupo virus</i> <i>Marburg virus</i> <i>Monkeypox virus</i> <i>Mycobacterium tuberculosis (cultures only)</i> <i>Nipah virus</i> <i>Omsk hemorrhagic fever virus</i> <i>Poliovirus (cultures only)</i> <i>Rabies virus (cultures only)</i> <i>Rickettsia prowazekii (cultures only)</i> <i>Rickettsia rickettsii (cultures only)</i>

UN NUMBER AND PROPER SHIPPING NAME	MICRO-ORGANISM
	Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus Shigella dysenteriae type 1 (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) Yersinia pestis (cultures only)
UN 2900 Infectious substances affecting animals	African swine fever virus (cultures only) Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) Mycoplasma mycoides – Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

**3.6.2.2.2 Category B:** An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.

**Note:**

*The proper shipping name of UN 3373 is Biological substance Category B.*

### 3.6.2.2.3 Exceptions

**3.6.2.2.3.1** Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

**3.6.2.2.3.2** Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

**3.6.2.2.3.3** Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

**3.6.2.2.3.4** Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection are not subject to these Regulations, unless they meet the criteria for inclusion in another class

**3.6.2.2.3.5** Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.

**3.6.2.2.3.6** Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen,” as appropriate. The packaging must meet the following conditions:

(a) The packaging must consist of three components:

1. a leak-proof primary receptacle(s);
2. a leak-proof secondary packaging; and
3. an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

**Note:** *In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of auto-immune disease, etc.).*

### 3.6.2.3 Biological Products

**3.6.2.3.1** For the purposes of these Regulations, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations;

(b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

**Note:**

*Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these bio-logical products to be in compliance with local requirements for infectious substances or may impose other restrictions. 3.6.2.4 Genetically Modified Micro-organisms and Organisms 3.2.6.2.4.1 Genetically modified micro-organisms not meeting the definition of an infectious substance must be classified according to Subsection 3.9.*

### **3.6.2.5 Medical or Clinical Wastes**

**3.6.2.5.1** Medical or clinical wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900, as appropriate. Medical or clinical wastes containing infectious substances in Category B, must be assigned to UN 3291. For the assignment, international, regional or national waste catalogues may be taken into account.

**3.6.2.5.2** Medical or clinical wastes which are rea-sonably believed to have a low probability of containing infectious substances must be assigned to UN 3291.

**Note:** *The proper shipping name for UN 3291 is **Biomedical waste, n.o.s., Clinical waste, unspecified, n.o.s.** or **Medical waste, n.o.s.** or **Regulated medical waste, n.o.s.***

**3.6.2.5.3** Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

### **3.6.2.6 Infected Animals**

**3.6.2.6.1** A live animal that has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be trans-ported under terms and conditions approved by the appropriate national authority.

**3.6.2.6.2** Unless an infectious substance cannot be consigned by any other means, live animals must not be used to consign such a substance.

**3.6.2.6.3** Animal material affected by pathogens of category A or which would be assigned to category A in cultures only, must be assigned to UN 2814 or UN 2900 as appropriate.

### **3.6.2.7 Patient Specimens**

Patient specimens must be assigned to UN 2814, UN 2900 or UN 3373 as appropriate except if they comply with 3.6.2.2.3.

## **3.7 Class 7- Radioactive Material**

STATE VARIATIONS: RUG-01, USG-10

**3.7.1** Definition Radioactive material means any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in 10.3.2.

The following radioactive materials are not included in Class 7 for the purposes of these Regulations:

- (a) Radioactive material implanted or incorporated into a person or live animal for diagnosis or treatment;
- (b) Radioactive material in consumer products which have received regulatory approval, following their sale to the end user;



# IATA Packaging

52nd EDITION, 1 JANUARY 2011

## PACKING INSTRUCTION 650

STATE VARIATIONS: BHG-02, CAG-05, DQG-03, FRG-05, GBG-05, VCG-04

OPERATOR VARIATIONS: AF-02, AM-06/10, AR-02, AS-08, BR-14, BZ-07, CI-01, CO-07, CS-07, FX-09, IJ-06/10, JJ-06, JK-03, KC-08, KE-06, LA-07, LH-05, MN-03, MS-06, MX-06/11, OO-01, OU-12/16, PX-08, SQ-10, SV-12, TN-05, TY-03, UA-14, UU-05

This instruction applies to UN 3373 on passenger and cargo aircraft and Cargo Aircraft Only.

### General Requirements

The packagings must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

The packaging must consist of three components:

- (a) a primary receptacle(s);
- (b) a secondary packaging; and
- (c) a rigid outer packaging.

Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

#### (a) For liquid substances:

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 130°F).

**Note:**

The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:

- ◆ flexible receptacles and flexible packagings;
- ◆ receptacles and packagings filled and closed under a absolute atmospheric pressure lower than 95 kPa.
- ◆ The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

**(b) For solid substances:**

- The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
- The secondary packaging must be siftproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm (4 in × 4 in).

The completed package must be capable of successfully passing the drop test described in 6.5.1.1 except that the height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side

having a length of at least 50 mm (2 in), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high. The proper shipping name “Biological Substance, Category B” in letters at least 6 mm high must be marked on the outer packaging adjacent to the diamond-shaped mark.



Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- the overpack must be marked with the word “Overpack”; and
- the package markings must be reproduced on the outside of the overpack.

A Shipper's Declaration for Dangerous Goods is not required.

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions in 5.0.6.7.

### Specific Requirements

*Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:*

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If dry ice is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.

- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these Regulations except for the following:

- (a) the name and address of the shipper and of the consignee must be provided on each package;**
- (b) the name and telephone number of a person responsible must be provided on the air waybill or on the package;**
- (c) the classification must be in accordance to 3.6.2;**
- (d) the incident reporting requirements in 9.6.1 must be met; and**
- (e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.**

**Note:**

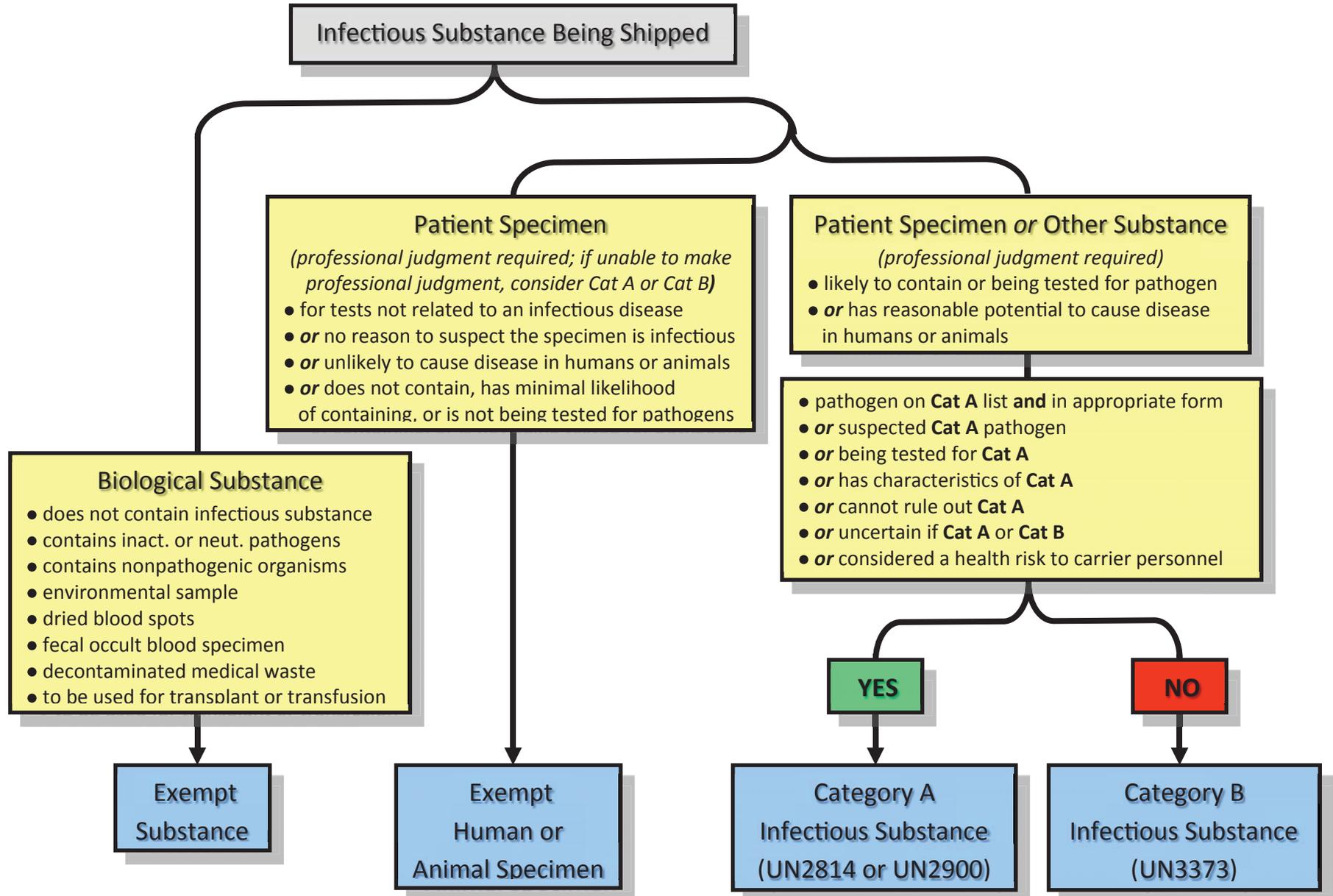
*When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.*

Passengers and crew members are prohibited from transporting infectious substances as or in carry-on baggage, checked baggage or on their person.

If an Air Waybill is used, the "Nature and Quantity of Goods" box must show "UN 3373", the text "BIOLOGICAL SUBSTANCE, CATEGORY B" and the number of packages.

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided these substances meet the requirements of 2.6. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.



**Figure 1.** Algorithm for classifying infectious substances





**Infectious Substance,  
Affecting Humans  
UN 2814 4 mL**

**Figure 2.** Labels which indicate an infectious substance (Class 6), proper shipping name, UN number, and quantity of substance

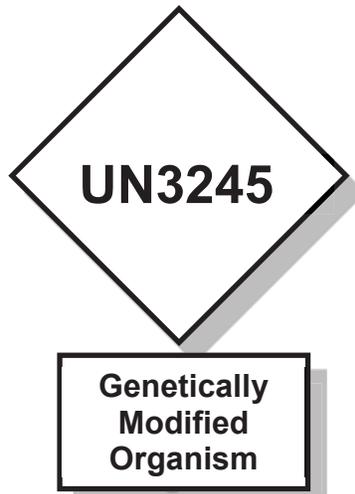


**Biological  
Substance,  
Category B**

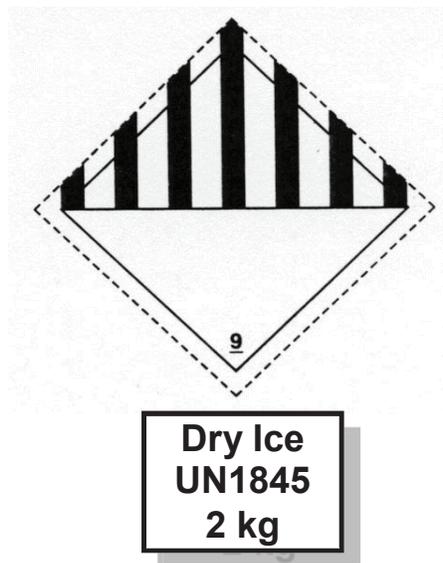
**Figure 3.** Labels which indicate a Biological Substance, Category B, appropriate UN number, and proper shipping name

**Exempt  
Human  
Specimen**

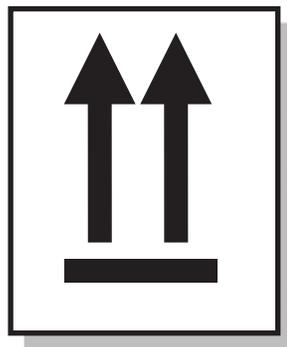
**Figure 4.** Label which indicates an Exempt Human Specimen



**Figure 5.** Labels which indicates GMO



**Figure 6.** Labels which indicate a miscellaneous (Class 9) dangerous good (2 kg of dry ice)



**Figure 7.** Label which indicates correct orientation of package during shipping

**Danger!**  
**DO NOT Load into**  
**Passenger Aircraft**

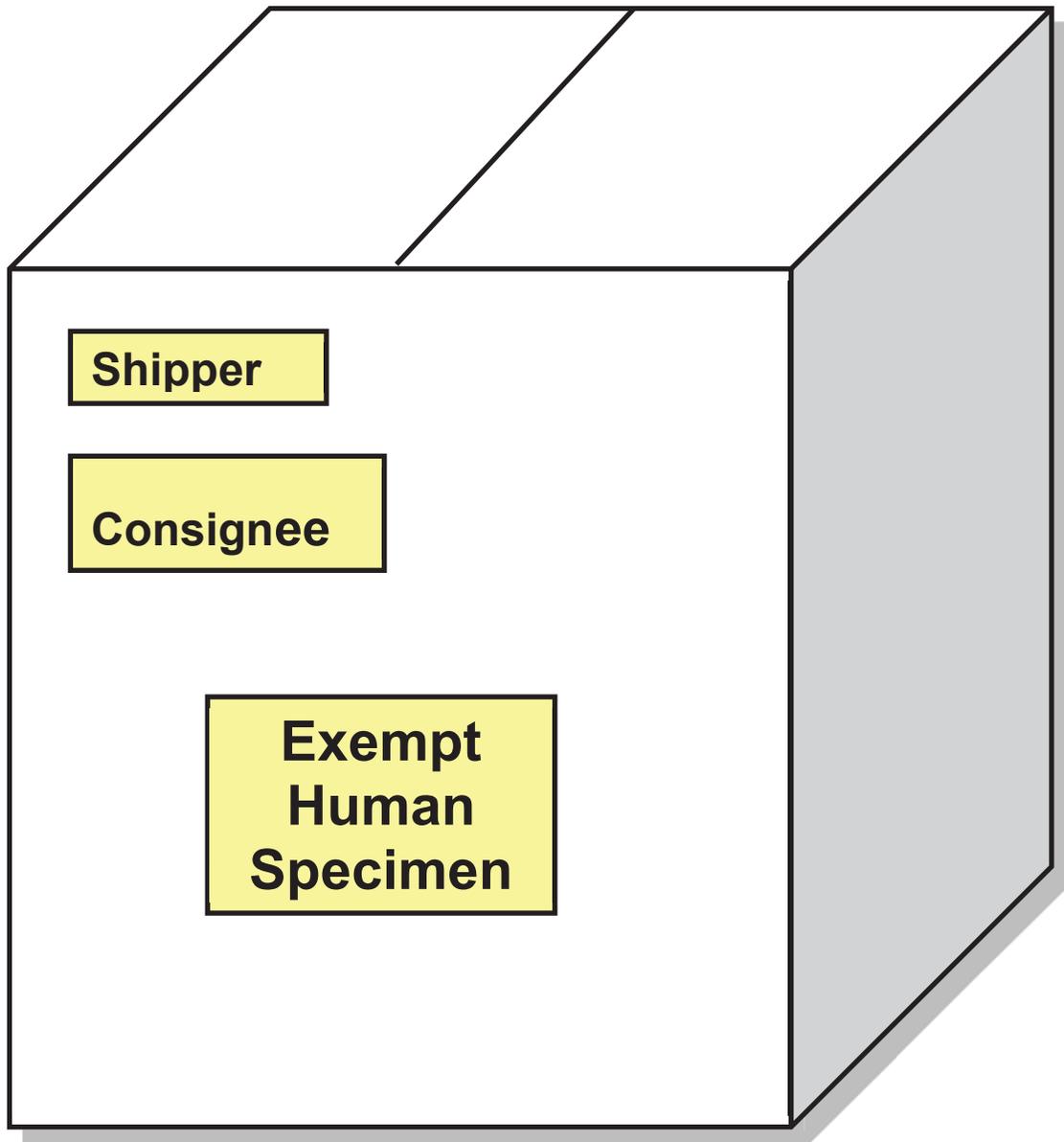
**Figure 8.** Label which indicates substance must be transported only in cargo (*not passenger*) aircraft

**OVERPACK**

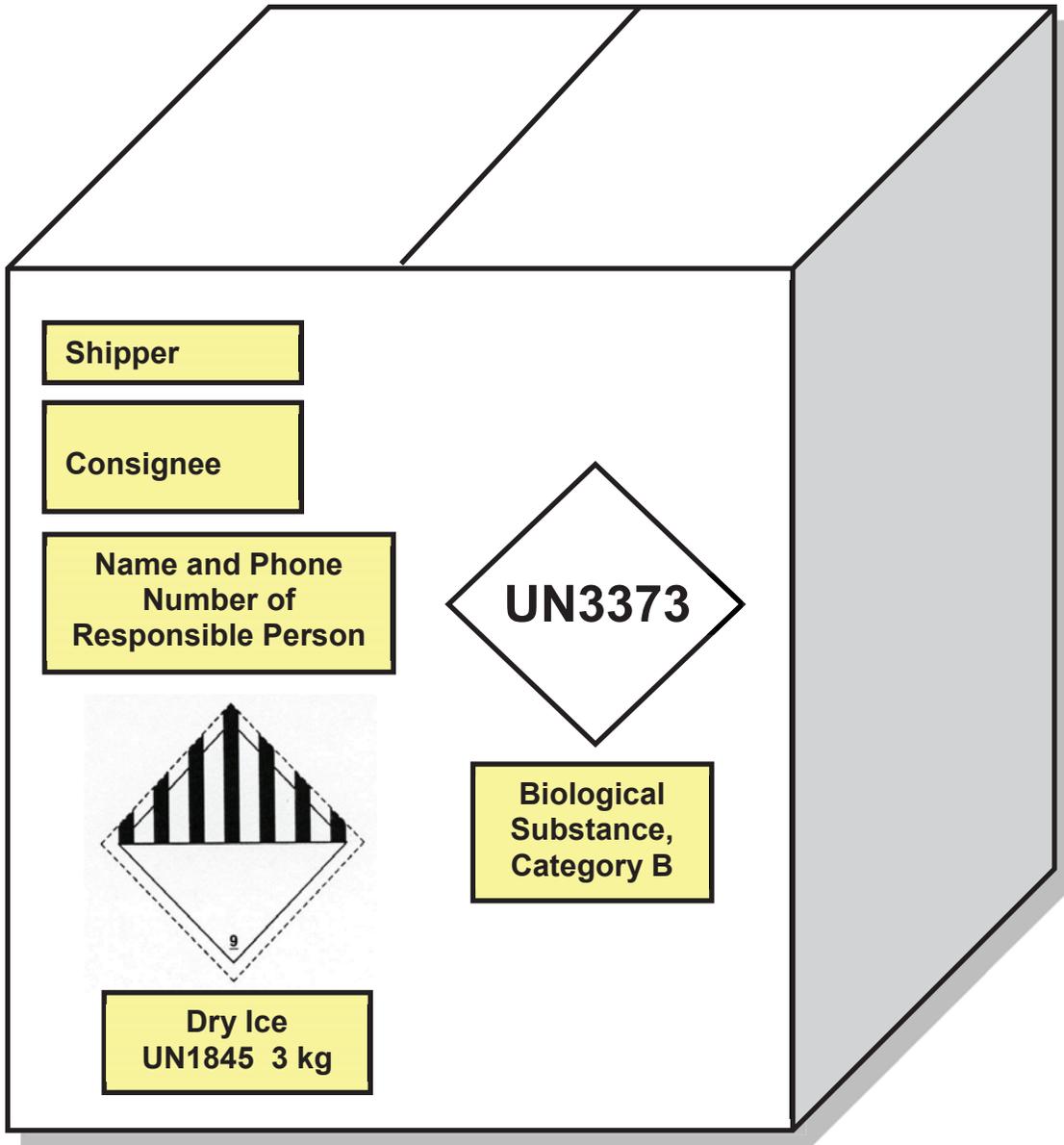
**Figure 9.** Label which indicates an overpack is used and inner packages comply with regulations

**U**  
**N**      **4G/CLAS 6.2/2004**  
**CAN/8-2 AIRPACK**

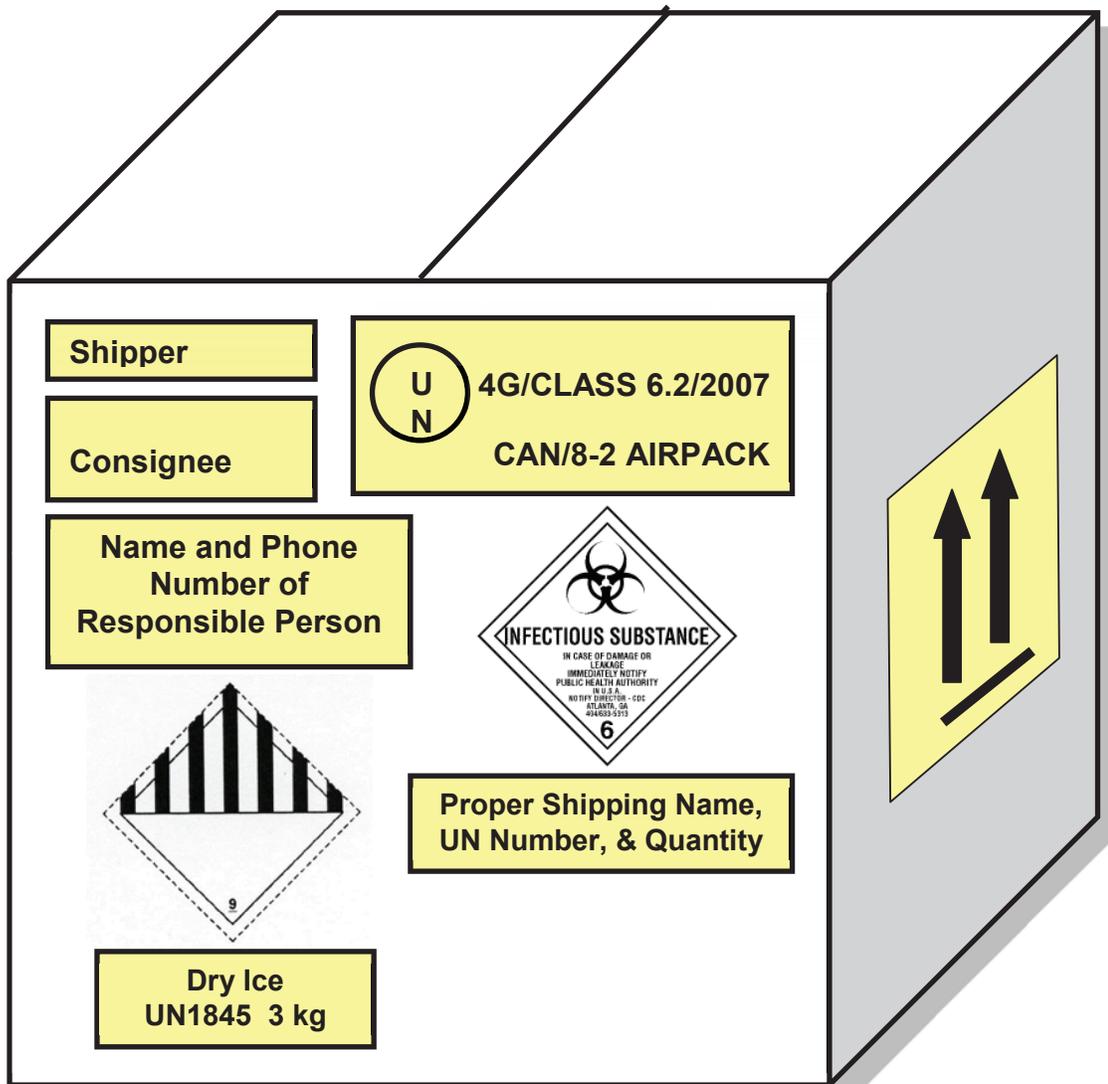
**Figure 10.** Label which indicates outer container has met UN-specified manufacturing standards



**Figure 11.** Example of an appropriately labeled outer package. The primary container inside the package contains an Exempt Human Specimen and is packed according to IATA instructions.

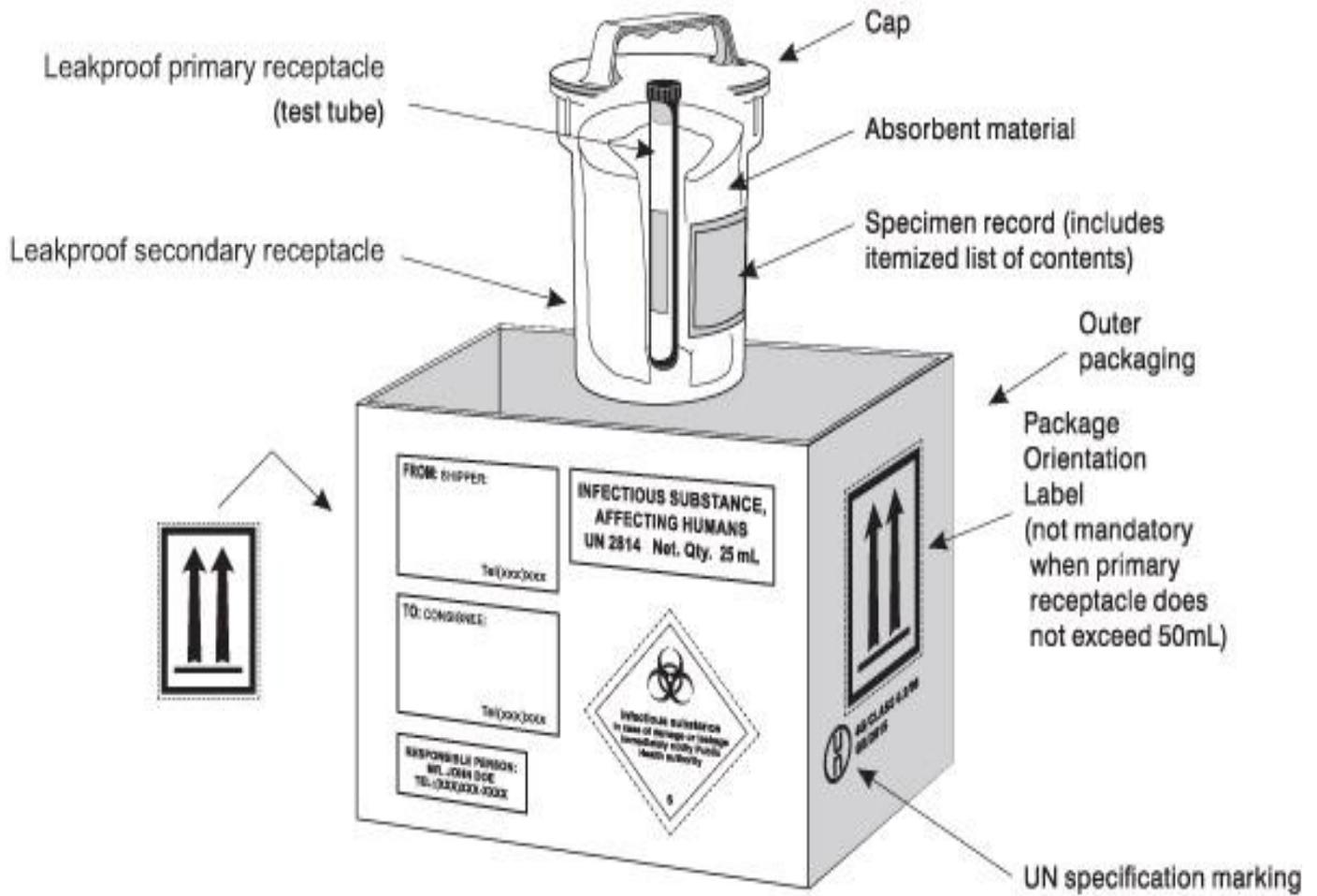


**Figure 12.** Example of a completely labeled outer package. The primary container inside the package contains a Biological Substance, Category B substance and is packed according to PI 650.



**Figure 13.** Example of a completely labeled outer package. The primary container inside the package contains a Category A infectious substance and is packed according to PI 620.

**Category A Shipping Guidelines and Diagram**



1. The smallest external dimension of the outer packaging must not be less than 100mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95kPa.



**SHIPPER'S DECLARATION FOR DANGEROUS GOODS**

Shipper		Air Waybill No.			
		Page      of      Pages			
		Shipper's Reference Number <i>(optional)</i>			
Consignee		<i>For optional use for Company logo name and address</i>			
<i>Two completed and signed copies of this Declaration must be handed to the operator.</i>		<b>WARNING</b>			
<b>TRANSPORT DETAILS</b>		Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.			
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>				Airport of Departure:	
<table border="1"> <tr> <td>PASSENGER AND CARGO AIRCRAFT</td> <td>CARGO AIRCRAFT ONLY</td> </tr> </table>				PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY				
Airport of Destination:		Shipment type: <i>(delete non-applicable)</i> <table border="1"> <tr> <td>NON-RADIOACTIVE</td> <td>RADIOACTIVE</td> </tr> </table>		NON-RADIOACTIVE	RADIOACTIVE
NON-RADIOACTIVE	RADIOACTIVE				
<p><b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>  <i>UN Number or Identification Number, proper shipping name, Class or Division (subsidiary risk), packing group (if required), and all other required information.</i></p>					
<p>-----</p> <p>Additional Handling Information</p>					
<p>I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.</p>		<p>Name/Title of Signatory</p> <p>Place and Date</p> <p>Signature <i>(see warning above)</i></p>			



## 3 Testing Services

### Alternative Names for Testing Services

ALTERNATIVE NAME	LISTED AS
Avian Flu	Influenza A/H5
Botulism	<i>Clostridium botulinum</i>
Chickenpox	Varicella zoster virus
Cholera	<i>Vibrio cholera</i>
Cowpox	Orf
Encephalitis	St. Louis/Western Equine Encephalitis
Enterobius	Pinworm
Gonorrhoeae	<i>Nessieria gonorrhoeae</i>
HGA or HE	<i>Anaplasma phagocytophilia</i>
HME	<i>Ehrlichia chaffeensis</i>
Lyme Disease	Tick (Veterinary Testing Service)
Milker's Nodules	Orf
Mononucleosis	Epstein-Barr Virus
Norwalk Virus	Norovirus
Pertussis	<i>Bordetella pertussis</i>
Plague	<i>Yersinia pestis</i>
Q Fever	<i>Coxiella burnetii</i>
Sin Nombre Virus	Hantavirus Pulmonary Syndrome
Smallpox	Variola virus
Treponemal pallidum	Syphilis
Typhoid	Salmonella
Whooping Cough	<i>Bordetella pertussis</i>
Winter Vomiting Disease	Norovirus



## Bacteriology

# Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Adult Botulism	See <i>Clostridium botulinum</i> .				
<i>Aeromonas</i> , Culture for Identification	2305	Confirmation or identification of <i>Aeromonas</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BHI, NA, TSA or CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture
<i>Aeromonas</i> , Primary Culture	5025	Screening procedure for isolation and identification of <i>Aeromonas</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Stool, 2 – 5g  <b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&amp;S)  <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 5 days                      Refrigerated (2 – 8°C): Acceptable up to 5 days</p>	Negative	Culture
Anthrax	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
<i>Bacillus anthracis</i> (Anthrax)	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
Bacterial Culture for Identification, Aerobic	2305	Aerobic bacterial culture identification by aerobic biochemical testing techniques.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Bacterial Culture for Identification, Anaerobic	5630	Anaerobic bacterial culture identification by anaerobic biochemical testing techniques.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> Anaerobic media (e.g. chopped meat, anaerobic plate)</p> <p><b>COLLECTION:</b> See Anaerobic specimen in Bacteriology Collection Guide. Please call laboratory for specific instructions and more information at 408.885.4272</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours</p>	Negative	Culture
Bacterial Culture from Primary Specimen, Aerobic	2295	Identification of all aerobic organisms found using conventional aerobic culture techniques.	<p><b>SPECIMEN:</b> Urine, sputum, swab (eye, ear drainage, genital, wounds, abscesses) tissue or sterile body fluids.</p> <p><b>CONTAINER:</b> Urine – sterile, leakproof, screw cap cup Swab – transport system with Modified Amies Clear media Sputum, tissue and sterile body fluid – Sterile screw cap container</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 24 hours (genital swabs) Refrigerated (2 – 8°C): 24 hours (swabs, sputum and urine)</p>	Negative	Culture
Bacterial Culture from Primary Specimen, Anaerobic	2215	Identification of all anaerobic organisms found using conventional anaerobic culture techniques.	<p><b>SPECIMEN:</b> Deep wounds, abscesses, tissue or Body fluids</p> <p><b>CONTAINER:</b> Swab, tissue or fluid in anaerobic tube.</p> <p><b>COLLECTION:</b> See Anaerobic specimen in Bacteriology Collection Guide. Please call laboratory for specific instructions and more information at 408.885.4272</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 24 hours</p>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Bordetella pertussis</i> , Direct Detection	2110	Direct detection of <i>Bordetella pertussis</i> by Real-time PCR Assay.	<p><b>SPECIMEN:</b> Nasopharyngeal Dacron® swab</p> <p><b>CONTAINER:</b> Empty, sterile, leakproof, screw cap tube or vial DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Preferred, within 24 hours Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Not Detected	Real-time PCR Assay
<i>Bordetella pertussis</i> , Primary Culture	5080	Screening procedure for isolation and identification of <i>Bordetella pertussis</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> 2 nasopharyngeal calcium alginate swabs or culture</p> <p><b>CONTAINER:</b> Regan-Lowe bottles or tubes</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Preferred, within 24 hours Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Negative	Culture FA
<i>Borrelia</i> spp., Primary Culture	2505	Identification and confirmation of <i>Borrelia</i> species.	<p><b>SPECIMEN:</b> Blood, skin biopsy (Erythema Migrans Rash) and others upon consultation (i.e. cultures, blood smears for confirmation, spinal fluid, synovial fluid)</p> <p><b>CONTAINER:</b> For a skin biopsy, contact laboratory prior to collection and/or shipment for specific requirements. Blood may be collected in heparin, citrate or EDTA. All specimen should be collected and shipped prior to antibiotic treatment if possible.</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 6 hours Refrigerated (2 – 8°C): Acceptable, transport with cold pack Frozen (–20°C): Acceptable, transport with dry ice</p>	Negative	Culture Microscopy
Botulism	See <i>Clostridium botulinum</i> .				
<i>Brucella</i> spp.	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				

# Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Burkholderia mallei</i> and <i>pseudomallei</i>	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
<i>Campylobacter</i> spp., Primary Culture	5065	Screening procedure for isolation and identification of <i>Campylobacter</i> species by conventional biochemical testing techniques.	<p><b>SPECIMEN:</b> Stool, 2 – 5g</p> <p><b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&amp;S)</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable up to 5 days</p> <p>Refrigerated (2 – 8°C): Acceptable up to 5 days</p> <p>Note: Buffered Glycerol Saline is an unacceptable transport medium</p>	Negative	Culture
Carbapenemase Gene	See <i>Enterobacteriaceae</i> , Carbapenemase Gene.				
<i>Chlamydia Trachomatis</i> , Direct Detection	2005	Direct detection of <i>Chlamydia trachomatis</i> by PCR Assay.	<p><b>SPECIMEN:</b> Vaginal, rectal or throat Dacron® swab; or urine</p> <p><b>CONTAINER:</b></p> <p>For swab, use transport tube with VTM. DO NOT use calcium alginate swabs.</p> <p>For urine, use sterile, leakproof, screw cap container</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours (up to 7 days for urine only), transport on cold pack</p>	Not Detected	PCR Assay
<i>Chlamydia Trachomatis</i> , Direct Smear	2035	Identification of <i>Chlamydia trachomatis</i> using direct fluorescent antibody Test.	<p><b>SPECIMEN:</b> Genital, rectal, eye or nasopharyngeal swab (NO COTTON SWABS) smeared on slide</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable</p> <p>Refrigerated (2 – 8°C): Acceptable</p> <p>Frozen (–20°C): Acceptable</p>	Negative	DFA

# Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Cholera		See <i>Vibrio cholerae</i> .			
<i>Clostridium botulinum</i> Toxin (Food)		See the Environmental Testing Services section of this manual.			
<i>Clostridium botulinum</i> Toxin (Infant)		Please call the California Department of Public Health Duty Officer at 510.231.7600.			
<i>Clostridium botulinum</i> Toxin, Wound (NOT Infant)	2505	<i>Clostridium botulinum</i> culture and wound cases in patients over 1 year old.	<p><b>SPECIMEN:</b> Pre-antitoxin serum from 30ml of blood, 50ml of enema and 25g of stool and effluent or gastric or tissue</p> <p><b>CONTAINER:</b> Sterile, leakproof, screw cap container</p> <p><b>COLLECTION:</b> Please call laboratory for specific instructions and more information at 408.885.4272</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 24 hours, transport with cold pack</p> <p><b>NOTE:</b> Patient's physician must have discussed the case and received approval from the local health department and the state's Communicable Disease Control Duty Officer of the day prior to submission of specimen. Additional forms are required</p>		
<i>Corynebacterium diphtheriae</i> , Confirmation, Toxigenicity Testing and Strain Typing	2505	<i>Corynebacterium diphtheriae</i> confirmation, toxigenicity and typing by conventional biochemical techniques, and culture.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Preferred Refrigerated (2 – 8°C): Acceptable</p>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Corynebacterium diphtheriae</i> , Primary Culture	2305	<i>Corynebacterium diphtheriae</i> identification by conventional biochemical techniques and culture.	<b>SPECIMEN:</b> Nose, throat or wound swab. Swab should be polyester, rayon or nylon. <b>CONTAINER:</b> Transport tube with Amies or Stuart media <b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable, transport on ice pack	Negative	Culture
<i>Coxiella burnetii</i> (Q fever)	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
Diphtheria	See <i>Corynebacterium diphtheriae</i> .				
<i>Ehrlichia chaffeensis</i> , Antibody	2515	Screening procedure for <i>Ehrlichia chaffeensis</i> IgG and IgM by indirect fluorescent antibody test.	<b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml) <b>CONTAINER:</b> Serum Separator Tube (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) <b>COLLECTION:</b> See Serology Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 6 hours Refrigerated (2 – 8°C): Acceptable up to 72 hours Frozen (–20°C): Serum only	Negative	IFA
Enteric Culture	5025	Screening for: <i>Salmonella</i> <i>Shigella</i> <i>Campylobacter</i> <i>E. coli</i> O157:H7 <i>Vibrio</i> <i>Yersinia enterocolitica</i> <i>Aeromonas</i> <i>Pleisiomonas</i> Shiga toxin	<b>SPECIMEN:</b> Stool, 2 – 5g (rectal swab for shigella specimens only) <b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&S) <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 5 days Refrigerated (2 – 8°C): Acceptable up to 5 days	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Enteric Culture for Identification and Subtyping	Varies	Screening for: <i>Salmonella</i> <i>Shigella</i> <i>Campylobacter</i> <i>E. coli</i> O157:H7 <i>Vibrio</i> <i>Yersinia enterocolitica</i> <i>Aeromonas</i> <i>Pleisiomonas</i> Shiga toxin	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture
<i>Enterobacteriaceae</i> , Carbapenemase Gene Detection	2505	Identification of carbapenemase gene ( <i>kpc</i> , <i>ndm</i> ) by PCR assay.	<b>SPECIMEN:</b> Pure isolate resistant to third generation cephalosporins and intermediate or resistant to imipenem, doripenem, or meropenem. <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Preferred Refrigerated (2 – 8°C): Acceptable	Not Detected	PCR Assay
<i>Escherichia coli</i>	See listings under " <i>Escherichia coli</i> " and "Shiga toxin".				
<i>Escherichia coli</i> O157:H7, Culture for Identification	5035 5030 5120	Screening procedure for identification of <i>Escherichia coli</i> O157:H7 and Shiga toxin gene associated with <i>Escherichia coli</i> O157:H7 ( <i>stx1</i> ).	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture LA Real-time PCR Assay

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Escherichia coli</i> O157:H7, Primary Culture	5040 5030 5120	Screening procedure for isolation and identification of <i>Escherichia coli</i> O157:H7 by conventional biochemical and serological testing techniques. Identification of Shiga toxin gene associated with <i>Escherichia coli</i> O157:H7 ( <i>stx 1</i> ) by PCR Assay.	<b>SPECIMEN:</b> Stool, 2 – 5g <b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&S) <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 5 days Refrigerated (2 – 8°C): Acceptable up to 5 days	Negative	Culture LA Real-time PCR Assay
<i>Escherichia coli</i> Toxicity	2505	Toxin Assay screening for <i>Escherichia coli</i> toxins: Hemorrhagic Enterotoxigenic Enteroinvasive Enteropathogenic Enteroaggregative Cytolethal distending toxin Cytotoxic necrotizing factor	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 48 hours Refrigerated (2 – 8°C): 48 hours	Negative	Culture
<i>Francisella tularensis</i>	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
Gonorrhea	See <i>Neisseria gonorrhoeae</i> .				

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Haemophilus ducreyi</i> , Primary Culture	2295	Screening procedure for the isolation and identification of <i>Haemophilus ducreyi</i> , the pathogen associated with genital "soft chancre" lesions.	<b>SPECIMEN:</b> Vesicular fluid from genital lesion <b>CONTAINER:</b> Swab in sterile screw-capped tube with 0.5ml saline solution. <b>COLLECTION:</b> See Bacteriology Collection Guide <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 30 minutes Refrigerated (2 – 8°C): Acceptable	Negative	Culture
<i>Haemophilus influenzae</i> , Culture for Identification	2305	Screening procedure for isolation, identification and typing of <i>Haemophilus influenzae</i> by conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 7 days	Negative	Culture
<i>Haemophilus influenzae</i> , Serotyping	2505	Serotyping of <i>Haemophilus influenzae</i> by slide agglutination or PCR assay.	<b>SPECIMEN:</b> Pure culture from serum or CSF <b>CONTAINER:</b> CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 7 days	N/A	Slide Agglutination PCR Assay
Infant Botulism	Please call the California Department of Public Health Duty Officer at 510.231.7600.				
<i>Klebsiella</i> and <i>Serratia</i> , Culture for Identification	2505	Identification and molecular subtyping of <i>Klebsiella</i> and <i>Serratia</i> .	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Legionella</i> , Culture for Identification <b>(Call SCCPHL at 408.885.4272 before submitting specimens)</b>	2505	Screening procedure for the identification and confirmation of <i>Legionella</i> by conventional biochemical testing techniques and/or PCR assay.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	Negative	Culture PCR Assay
<i>Listeria monocytogenes</i> , Culture for Identification	2305	Identification of <i>Listeria monocytogenes</i> by conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	Negative	Culture
<i>Listeria monocytogenes</i> , Subtyping		Subtyping of <i>Listeria monocytogenes</i> .	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	N/A	PFGE
Lyme Disease	See Tick in Veterinary section.				
Methicillin-resistant <i>Staphylococcus aureus</i>	See MRSA.				

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
MRSA (Methicillin-resistant <i>Staphylococcus aureus</i> ), Direct Detection		Identification and serogrouping of Methicillin-resistant <i>Staphylococcus aureus</i> by PCR assay.	<p><b>SPECIMEN:</b> Nasal swab</p> <p><b>CONTAINER:</b> Sterile, screw cap container</p> <p><b>COLLECTION:</b> Dacron® swabs are recommended. DO NOT use calcium alginate swabs.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 24 hours                      Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Not Detected	PCR Assay
MRSA (Methicillin-resistant <i>Staphylococcus aureus</i> ), Primary Culture	8009	Isolation, identification and serogrouping of Methicillin-resistant <i>Staphylococcus aureus</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Nasal, wound or vesicular swab, or positive blood culture</p> <p><b>CONTAINER:</b>                      For nasal swabs, sterile screw cap container                      For positive blood culture, use blood culture system (BacT/ALERT®, VersaTREK® and BACTECTM)</p> <p><b>COLLECTION:</b> Dacron® swabs are recommended.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 24 hours                      Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Negative	Culture
<i>Mycoplasma pneumoniae</i> , Antibody	2515	Screening procedure for <i>Mycoplasma pneumoniae</i> IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (-20°C): Serum only</p>	Negative	EIA

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Mycoplasma pneumoniae</i> , Direct Detection	2505	Direct detection of <i>Mycoplasma pneumoniae</i> by Real-time PCR Assay.	<p><b>SPECIMEN:</b> Nasopharyngeal/throat Dacron® or rayon swab or CSF</p> <p><b>CONTAINER:</b> Sterile, screw cap container. DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 24 hours Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Not Detected	Real-time PCR Assay
<i>Neisseria gonorrhoeae</i> , Primary Culture	2020	Screening procedure for the isolation and identification of <i>Neisseria gonorrhoeae</i> .	<p><b>SPECIMEN:</b> Genital, rectal, eye or throat swab or joint fluid</p> <p><b>CONTAINER:</b> Sterile screw cap container with Modified Amies Clear media</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable for eye, rectal swabs; unacceptable for throat swabs Refrigerated (2 – 8°C): 72 hours for throat swabs, 60 days for genital swabs; unacceptable for rectal Frozen (–20°C): Unacceptable (rectal)</p>	Negative	Culture
<i>Neisseria gonorrhoeae</i> , Culture for Identification	2155 2045	<i>Neisseria gonorrhoeae</i> culture identification by conventional biochemical testing techniques.	<p><b>SPECIMEN:</b> Pure culture isolate from genital, rectal, eye or throat swab or joint fluid</p> <p><b>CONTAINER:</b> CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 7 days</p>	N/A	Culture
<i>Neisseria gonorrhoeae</i> , Direct Detection	2531 2010	Direct detection of <i>Neisseria gonorrhoeae</i> by PCR Assay	<p><b>SPECIMEN:</b> Vaginal, rectal or throat swab; or urine</p> <p><b>CONTAINER:</b> Transport tube with VTM</p> <p><b>COLLECTION:</b> See Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack (up to 7 days for urine)</p>	Not Detected	PCR Assay

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Neisseria meningitidis</i> , Serogrouping	2165	Serogrouping of <i>Neisseria meningitidis</i> by Agglutination.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	N/A	Culture Agglutination
<i>Neisseria meningitidis</i> , Antimicrobial Susceptibility	2505	Antimicrobial susceptibility testing of <i>Neisseria meningitidis</i> .	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Susceptible	Disk Diffusion, Agar Dilution or Broth Microdilution, Antimicrobial Gradient Strip Diffusion
<i>Neisseria meningitidis</i> , Culture	2165	Confirmation or identification of <i>Neisseria meningitidis</i> by culture.	<p><b>SPECIMEN:</b> Primary specimen or pure culture  <b>CONTAINER:</b> CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture
<i>Neisseria meningitidis</i> , Direct Detection	2505	Real-time PCR assay of <i>Neisseria meningitidis</i> .	<p><b>SPECIMEN:</b> Serum, 1 ml or CSF, 1 ml  <b>CONTAINER:</b>                      For serum, use a SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)                      For CSF, use a sterile, empty, screw cap vial  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable, transport with cold pack</p>	Not Detected	Real-time PCR Assay

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Neisseria meningitidis</i> , Molecular Subtyping	2505	Molecular subtyping of <i>Neisseria meningitidis</i> .	<b>SPECIMEN:</b> Primary specimen or pure culture <b>CONTAINER:</b> CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	N/A	Unknown
Pertussis	See <i>Bordetella pertussis</i> .				
<i>Pseudomonas aeruginosa</i> , Subtyping	2505	Molecular subtyping of <i>Pseudomonas aeruginosa</i> by pulse-field gel electrophoresis.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	N/A	PFGE
Q Fever	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				
<i>Salmonella</i> spp. (Not <i>typhi</i> ), Primary Culture	5105	Screening procedure for isolation and identification of <i>Salmonella</i> by conventional biochemical and serological testing techniques.	<b>SPECIMEN:</b> Stool, 2 – 5g <b>CONTAINER:</b> Transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&S) <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 5 days Refrigerated (2 – 8°C): Acceptable up to 5 days	Negative	Culture
<i>Salmonella typhi</i> , Primary Culture	5105	Screening procedure for isolation and identification of <i>Salmonella</i> by conventional biochemical and serological testing techniques.	<b>SPECIMEN:</b> Urine <b>CONTAINER:</b> Sterile screw cap container or BD Urine transport Kit <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable <b>within 4 hours</b>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Salmonella</i> , Serotyping, Phage Typing and Molecular Epityping	2505	Serotyping, phage typing and molecular epityping for <i>Salmonella</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube  <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable for up to 48 hours                      Refrigerated (2 – 8°C): Acceptable for up to 48 hours</p>	Negative	Culture
<i>Salmonella</i> , Culture for Identification	5050	<i>Salmonella</i> culture identification and confirmation by conventional biochemical and serological grouping.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture
<i>Serratia</i> spp.	See <i>Klebsiella</i> and <i>Serratia</i> .				
Shiga Toxin, Culture for Identification	5042	Shiga toxin culture identification and confirmation by conventional biochemical and serological testing techniques.	<p><b>SPECIMEN:</b> Stool inoculated GN or MAC broth*  <b>CONTAINER:</b> Leakproof, screw cap tube or vial with GN or MAC broth  <b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable for up to 24 hours                      Refrigerated (2 – 8°C): Acceptable for up to 7 days                      *2 – 5g fresh stool is acceptable within 5 hours or in Cary-Blair media within 24 hours</p>	Negative	Culture STEC PCR Assay

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Shiga Toxin, Immunoassay (Type 1 or 2)	5043	Shiga toxin culture identification and confirmation by immunoassay.	<p><b>SPECIMEN:</b> Stool inoculated GN or MAC broth*</p> <p><b>CONTAINER:</b> Leakproof, screw cap tube or vial with GN or MAC broth</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable for up to 24 hours                      Refrigerated (2 – 8°C): Acceptable for up to 7 days                      Frozen (–20°C): Acceptable up to 21 days                      *2-5g fresh stool is acceptable within 5 hours or in Cary-Blair media within 24 hours</p>	Not Present	Immunoassay
<i>Shigella</i> , Culture for Identification	5110	<i>Shigella</i> culture identification and confirmation by conventional biochemical testing techniques.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture
<i>Shigella</i> , Primary Culture	5125	Screening procedure for isolation and identification of <i>Shigella</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Stool, 2 – 5g or rectal swab</p> <p><b>CONTAINER:</b> Transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&amp;S)</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 5 days                      Refrigerated (2 – 8°C): Acceptable up to 5 days</p>	Negative	Culture
<i>Staphylococcus aureus</i> Enterotoxin	2505	Identification of <i>Staphylococcus aureus</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Staphylococcus aureus</i> , Antimicrobial Susceptibility	2505	Antimicrobial susceptibility testing of <i>Staphylococcus aureus</i> by conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture
<i>Staphylococcus aureus</i> , Identification and Confirmation	8008	Identification of <i>Staphylococcus aureus</i> by conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture
<i>Streptococcus</i> Group A Beta-Hemolytic, M & T Typing	2505	Identification of Group A <i>Streptococcus</i> , a common cause of bacterial pharyngitis by conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture
<i>Streptococcus</i> Group A Beta-Hemolytic, Primary Culture (Throat Screen)	2505	Screening procedure for isolation and identification of Group A <i>Streptococcus</i> , a common cause of bacterial pharyngitis, by conventional biochemical techniques.	<b>SPECIMEN:</b> Throat swab <b>CONTAINER:</b> Sterile screw cap container <b>COLLECTION:</b> Dacron swabs are recommended. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 24 hours Refrigerated (2 – 8°C): Acceptable up to 24 hours	Negative	Culture
<i>Streptococcus Pneumonia</i> , Primary Culture	2305	Identification <i>Streptococcus pneumonia</i> by conventional biochemical techniques and/or PCR assay.	<b>SPECIMEN:</b> Throat, wound, or sterile site swab; or CSF <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 24 hours Refrigerated (2 – 8°C): Acceptable up to 24 hours	Negative	Culture PCR Assay

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Streptococcus pneumoniae</i> , Serotyping and Antimicrobial Susceptibility	2505	Serotyping and antimicrobial susceptibility for <i>Streptococcus pneumoniae</i> by conventional biochemical techniques and/or PCR assay.	<p><b>SPECIMEN:</b> Pure culture from blood or CSF</p> <p><b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture PCR Assay
<i>Streptococcus</i> , Primary Culture	5625	Isolation, identification and serogrouping of <i>Streptococcus</i> by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Throat, wound, or sterile site swab</p> <p><b>CONTAINER:</b> Sterile screw cap container</p> <p><b>COLLECTION:</b> Dacron® swabs are recommended.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 24 hours                      Refrigerated (2 – 8°C): Acceptable up to 24 hours</p>	Negative	Culture
<i>Treponema pallidum</i> (Syphilis), Antibody Confirmation, TPPA	2030	Confirmation of <i>Treponema pallidum</i> by <i>Treponema pallidum</i> Particle Agglutination	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	TPPA
<i>Treponema pallidum</i> (Syphilis), Antibody	2085	Identification of <i>Treponema pallidum</i> by direct fluorescent antibody.	<p><b>SPECIMEN:</b> Vesicular fluid from genital lesion smeared on slide</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>COLLECTION:</b> See vesicular fluids in Bacteriology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable</p>	Negative	DFA

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Treponema pallidum</i> (Syphilis), Screen, Qualitative and Quantitative RPR	2015 2040	Nontreponemal serological screening for identification and evaluation of <i>Treponema pallidum</i> by Rapid Plasma Reagin (RPR) Card Test. Confirmation test performed if positive.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	RPR
Typhoid	See <i>Salmonella typhi</i> .				
<i>Vibrio cholerae</i> , Serotyping, Molecular Subtyping and Toxin Testing	2505	Identification, biotyping, serotyping, toxin testing and molecular subtyping for <i>Vibrio cholerae</i> .	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture PCR Assay
<i>Vibrio</i> spp., Culture for Identification	5070	Screening procedure for the identification of <i>Vibrio</i> spp. by conventional biochemical testing techniques.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture
<i>Vibrio</i> spp., Hemolysin and Molecular Epityping	2505	Identification, hemolysin testing and molecular epityping of <i>Vibrio</i> spp.	<p><b>SPECIMEN:</b> Pure culture  <b>CONTAINER:</b> BA or CHOC agar slant tube  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture

## Testing Services – Bacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Vibrio</i> spp., Primary Culture	5155	Screening procedure for the isolation and identification of <i>Vibrio</i> spp. by conventional biochemical testing techniques and serology.	<p><b>SPECIMEN:</b> Stool, 2 – 5g</p> <p><b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&amp;S)</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 5 days                      Refrigerated (2 – 8°C): Acceptable up to 5 days                      Note: Buffered Glycerol Saline is an unacceptable transport medium</p>	Negative	Culture
Whooping Cough	See <i>Bordetella pertussis</i> .				
<i>Yersinia enterocolitica</i> , Primary Culture	2305	Identification of <i>Yersinia enterocolitica</i> using biochemical techniques.	<p><b>SPECIMEN:</b> Stool, 2 – 5g</p> <p><b>CONTAINER:</b> Stool transport bottles with Cary-Blair or other holding media (e.g. Para Pak C&amp;S)</p> <p><b>COLLECTION:</b> See Bacteriology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 5 days                      Refrigerated (2 – 8°C): Acceptable up to 5 days</p>	Negative	Culture
<i>Yersinia pestis</i>	<b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b>				

## Testing Services – Chemistry

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Blood Lead	3005	Quantitative screening procedure for Pb (lead) utilizing atomic absorption spectrometry	<p><b>SPECIMEN:</b> Blood, ≥50 µl</p> <p><b>CONTAINER:</b> Plastic vacutainer or capillary device with anticoagulant EDTA, lead free</p> <p><b>COLLECTION: BY TRAINED PERSONNEL ONLY (contact the laboratory for more information at 408.885.4272).</b> Ensure all products used, such as soaps and towels, are free of lead or any other heavy metal to reduce the probability of false positives. Avoid using printed or recycled material, which regularly contain lead.</p> <p><b>DO NOT USE BROWN PAPER TOWELS AT ANY POINT.</b></p> <p>D-Wipes® are especially designed to remove lead particles from skin and can be obtained from the laboratory for facilities within Santa Clara County.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable</p> <p>Refrigerated (2 – 8°C): Acceptable up to 30 days</p>	<5.0 µg/dl	AAS



Environmental

Testing Services – Environmental

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Clostridium botulinum</i> Toxin (Food)	2505	<p><i>Clostridium botulinum</i> culture and toxin testing for suspected foodborne cases.</p> <p><b>PLEASE NOTE:</b> Testing performed for possible foodborne illness requires consultation with Environmental Health Division and Communicable Disease Control. Please contact the laboratory for specific instructions and more information at 408.885.4272.</p>	<p><b>SPECIMEN:</b> Food items in original containers, empty containers, food subsampled to a sterile container, or utensils</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw-cap container</p> <p><b>COLLECTION:</b> Please call laboratory for specific instruction and more information at 408.885.4272</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 24 hours, transport with cold pack</p> <p><b>NOTE:</b> Patient's physician must have discussed the case and received approval from the local public health department and environmental health prior to submission of specimen.</p>	N/A	N/A

## Testing Services – Environmental

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Food, Culture	8005	<p>Screening procedure for the isolation and identification of foodborne illnesses utilizing conventional biochemical testing techniques.</p> <p><b>PLEASE NOTE:</b> Testing performed for possible foodborne illness requires consultation with Environmental Health Division and Communicable Disease Control. Please contact the laboratory for specific instructions and more information at 408.885.4272.</p>	<p><b>SPECIMEN:</b> Food, &gt;25g or environmental swabs  <b>CONTAINER:</b> Sterile container, whirl bags or original container  <b>COLLECTION:</b> By Environmental Health Specialist only. Please contact Environmental Health for specific instructions and more information at 408.918.3400.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable for shelf-stable items                      Refrigerated (2 – 8°C): Preferred, transport with cold pack                      Frozen (-20°C): Acceptable only if frozen when collected, transport with dry ice.</p>	Negative	Culture

## Testing Services – Environmental

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Staphylococcus aureus</i> Enterotoxin	2505	<p>Identification of <i>Staphylococcus aureus</i> by conventional biochemical techniques.</p> <p><b>PLEASE NOTE:</b> Testing performed for possible foodborne illness requires consultation with Environmental Health Division and Communicable Disease Control. Please contact the laboratory for specific instructions and more information at 408.885.4272.</p>	<p><b>SPECIMEN:</b> Food samples  <b>CONTAINER:</b> BHI, NA, TSA, BA or CHOC agar slant tube  <b>COLLECTION:</b> Please call laboratory for specific instruction and more information at 408.885.4272  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours                      Frozen (–20°C): Unacceptable</p>	Negative	Culture
Water, Coliform and <i>E. coli</i> , Qualitative	4005	<p>Qualitative assessment of the presence of coliforms and/or <i>E. coli</i> in water using Colilert® reagent.</p>	<p><b>SPECIMEN:</b> Water, 100ml  <b>CONTAINER:</b> Sterile, wide-mouthed, screw cap bottle with dechlorinator. Please obtain from laboratory.  <b>COLLECTION:</b> For specific instructions and more information, please contact the laboratory at 408.885.4272.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable, up to 4 hours                      Refrigerated (2 – 8°C): Preferred, up to 24 hours                      Frozen (–20°C): Acceptable if initially frozen. Please contact the laboratory for special requirements</p>	<p>Absent for coliform</p> <p>Absent for <i>E. coli</i></p>	Culture

## Testing Services – Environmental

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Water, Coliform and <i>E. coli</i> , Quantitative	4018	Quantitative assessment of the most probable number (MPN) of coliform and <i>E.coli</i> present in a water sample.	<p><b>SPECIMEN:</b> Water, 100ml</p> <p><b>CONTAINER:</b> Sterile, wide-mouthed, screw cap bottle with dechlorinator. Please obtain from laboratory.</p> <p><b>COLLECTION:</b> For specific instructions and more information, please contact the laboratory at 408.885.4272.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable, up to 4 hours                      Refrigerated (2 – 8°C): Preferred, up to 24 hours</p>	Absent for coliform  Absent for <i>E. coli</i>	Colorimetric Analysis

## Mycobacteriology

# Testing Services – Mycobacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Leprosy	See <i>Mycobacterium leprae</i> .				
<i>Mycobacterium leprae</i> , Direct Detection	7015	Identification of <i>Mycobacterium leprae</i> utilizing PCR assay.	<p><b>SPECIMEN:</b> Tissue</p> <p><b>CONTAINER:</b> Sterile screw cap container</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>            Room Temperature (15 – 30°C): Acceptable            Refrigerated (2 – 8°C): Acceptable</p>	Not detected	PCR Assay
<i>Mycobacterium tuberculosis</i> , Diagnostic Identification	7052	Identification of <i>Mycobacterium tuberculosis</i> and preliminary exam for rifampicin resistance ( <i>rpo</i> gene) using GeneXpert MTB/RIF test.	<p><b>SPECIMEN:</b> Sputum from first morning collection or processed specimen</p> <p><b>CONTAINER:</b> Sterile container</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>            Refrigerated (2 – 8°C): Acceptable</p>	Not detected	NAAT
<i>Mycobacterium tuberculosis</i> , Drug Susceptibility	7035	Identification of <i>Mycobacterium tuberculosis</i> complex and screening for resistance to INH, RIF, quinolones & injectable drugs by pyrosequencing.	<p><b>SPECIMEN:</b> Sputum sediments (at least 0.5 mL) with positive AFB-smear (1+ or greater); solid media or broth (1 mL)</p> <p><b>CONTAINER:</b> Agar (LJ or 7H10) slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>            Room Temperature (15 – 30°C): Acceptable up to 24 hours for solid media or broth            Refrigerated (2 – 8°C): Acceptable up to 24 hours for sediment, solid media or broth</p>	N/A	Pyro-sequencing

## Testing Services – Mycobacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Mycobacterium tuberculosis</i> , Genotyping for Multi-drug Resistance	2505	Rapid Detection of Isoniazid (INH) and Rifampin (RIF) resistance in <i>Mycobacterium tuberculosis</i> by Molecular Beacons.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> Agar (LJ or 7H10) slant tube. Specify isolate identification.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable</p>	Negative	Molecular Beacon
<i>Mycobacterium tuberculosis</i> , Screening (Exposure Status)	7700	Screening procedure for <i>Mycobacterium tuberculosis</i> by measuring the release of interferon-gamma (IFN-g) and utilizing enzyme immunoassay technique.	<p><b>SPECIMEN:</b> Blood (3ml)</p> <p><b>CONTAINER:</b> 3 Qunatiferon In-tubes Vacutainer with Heparin anticoagulant (Green Top specimens must be well mixed (shaken) to make sure antigens in tubes mix with patients blood.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable within 16 hours of collection, otherwise incubate specimen at 37°C for 12-24 hours and transport within 3 days.                      Refrigerated (2 – 8°C): Acceptable within 3 days IF tubes have been incubated at 37°C for 12-24 hours and centrifuged</p>	Negative	EIA
<i>Mycobacterium tuberculosis</i> , Culture for Identification	2505	Identification of Mycobacteria is based on a combination of tests: PCR assay, HPLC, and biochemical techniques. Susceptibility performed on <i>M. tuberculosis</i> by Radiometric method on first isolate or after 2 months if culture is still positive.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> Agar (LJ or 7H10) slant tube. Specify isolate identification.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture HPLC PCR Assay

## Testing Services – Mycobacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Mycobacterium</i> (non-tuberculous), Culture for Identification	2505	Identification of Mycobacteria is based on a combination of tests: HPLC, biochemical techniques, morphology, and 16S-cpn60 PCR and DNA sequencing.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> Agar (LJ or 7H10) slant tube. Specify isolate identification.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	Negative	Culture HPLC PCR Assay
<i>Mycobacterium</i> , DNA Fingerprinting	2505	Analysis of DNA sequence to distinguish unique characteristics.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> Agar (LJ or 7H10) slant tube. Specify isolate identification.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 48 hours                      Refrigerated (2 – 8°C): Acceptable up to 48 hours</p>	N/A	Sequencing
<i>Mycobacterium</i> , Isolation	2505	Isolation and identification of Mycobacteria by digestion and decontamination, inoculation into broth and solid media, and acid-fast microscopy.	<p><b>SPECIMEN:</b> Sputum, tissue, body fluid, stool, respiratory, CSF etc</p> <p><b>CONTAINER:</b> Varies</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable</p>	Negative	Culture Microscopy

## Testing Services – Mycobacteriology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Mycobacterium</i> , Culture and Sensitivity	2505	Identification of Mycobacteria is based on a combination of tests: PCR assay, HPLC, and biochemical techniques. Tests include Acid Fast smear, culture on solid media and a liquid media. Susceptibility performed on <i>M. tuberculosis</i> by Radiometric method on first isolate or after 2 months if culture is still positive.	<p><b>SPECIMEN:</b> Blood, bone marrow, CSF, gastric lavage fluid, respiratory (aerosols, sputums, bronchial washings, transtracheal aspirates), stool (for HIV patients only), tissue biopsies, and urine.</p> <p><b>CONTAINER:</b> Varies</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable</p>	Negative	Culture HPLC PCR Assay
Quantiferon	See <i>Mycobacterium tuberculosis</i> , Screening.				
Tuberculosis	See <i>Mycobacterium tuberculosis</i> .				

## Mycology

## Testing Services – Mycology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Actinomyces</i> , Culture for Identification	2505	<i>Actinomyces</i> (i.e. actinobacteria) confirmation and identification, serologic grouping and typing, biotyping and molecular typing.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> BHI, NA, TSA or SabDex agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 48 hours Refrigerated (2 – 8°C): Acceptable up to 48 hours	Negative	Culture
<i>Coccidioides</i> , Culture for Identification		Identification and confirmation of <i>Coccidioides</i> spp. utilizing molecular and conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> SabDex agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Incubated (20 – 30°C): Acceptable Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	Negative	Culture Molecular
<i>Histoplasma</i> , Culture for Identification		Identification and confirmation of <i>Histoplasma</i> spp. utilizing molecular and conventional biochemical techniques.	<b>SPECIMEN:</b> Pure culture <b>CONTAINER:</b> SabDex agar slant tube <b>TRANSPORT/HOLDING CONDITIONS:</b> Incubated (20 – 30°C): Acceptable Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	Negative	Culture Molecular
Mycology, Microscope Exam	7060	Identification of fungi or yeast by direct microscopic exam.	<b>SPECIMEN:</b> Tissue, aspirates, respiratory specimens or urine (for suspected cases of histoplasmosis, blastomycosis or coccidioidomycosis ONLY). Any specimen is acceptable for neonates except stool. <b>CONTAINER:</b> Sterile screw cap container. For tissue specimens, include a small amount of saline to keep moist. <b>COLLECTION:</b> See Mycology Collection Guide. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable (tissue) Refrigerated (2 – 8°C): Acceptable (aspirates, respiratory, urine)	Negative	Microscopy

## Testing Services – Mycology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Mycology, Culture for Identification	7055	Isolation and identification of fungi or yeast utilizing conventional biochemical techniques.	<p><b>SPECIMEN:</b> Pure culture</p> <p><b>CONTAINER:</b> SabDex agar slant tube</p> <p>Specify isolate identification.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable</p>	By report	Culture
Mycology, Primary Culture	7045	Isolation and identification of fungi or yeast utilizing conventional biochemical techniques.	<p><b>SPECIMEN:</b> Abscess, bone marrow aspirates, biopsy, bronchial brushings, bronchial washings, CSF, mucocutaneous membranes (mouth, vaginal, urethral, i.e. not digested), hair, nails, respiratory, skin, sterile body fluids and urine.</p> <p><b>CONTAINER:</b> See Mycology Collection Guide.</p> <p><b>COLLECTION:</b> See Mycology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> See Mycology Collection Guide.</p>	Negative	Culture

## Parasitology

# Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Amoeba, Antibody	2515	Identification of amoeba using enzyme immunoassay.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml) or plasma also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>            Refrigerated (2 – 8°C): For serum and whole blood, acceptable up to 72 hours. For plasma, acceptable up to 6 hours            Frozen (–20°C): Acceptable for serum and plasma only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA ELISA Antibody Detection
Arthropod, Identification	5705	Identification of arthropod by microscopic exam. (See also Scabies or Tick under Veterinary Testing Services)	Please call laboratory at 408.885.4272 for submission instructions.	N/A	Microscopy
<i>Babesia</i> spp., Identification	5115	Identification of <i>Babesia</i> spp. utilizing indirect fluorescent antibody technique.	<p><b>SPECIMEN:</b> Stained blood film</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>            Room Temperature (15 – 30°C): Acceptable            Refrigerated (2 – 8°C): Acceptable</p>	Negative	Microscopy

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Balamuthia</i> spp., Anitbody	2520	Screening procedure for <i>Balamuthia</i> spp. IgG by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> Serum Separator Tube (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 7 days                      Frozen (–20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA
<i>Balamuthia</i> spp., Direct Detection	5090	Screening procedure for <i>Balamuthia</i> spp. IgG and IgM by real-time PCR Assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw-cap tube or vial with 2 – 3ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p> <p><b>NOTE:</b> Additional history form required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not detected	Real-time PCR Assay
<i>Balamuthia</i> spp., Isolation	5090	Isolation, identification and typing of <i>Balamuthia</i> spp. by tissue culture and direct smear. If positive, direct fluorescent antibody test confirmation performed.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw-cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Negative	Culture DFA

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Blood Parasites	5090	Identification and confirmation of blood parasites including malarial parasites, hemoflagellates, filarial worms, etc. by microscopy and PCR assay.	<p><b>SPECIMEN:</b> Thick <u>and</u> thin blood film  <b>CONTAINER:</b> Slide holder  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable</p>	Not detected	Microscopy PCR Assay
Chagas Disease, Antibody	2515	Identification of <i>Trypanosoma cruzi</i> using enzyme immunoassay.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml) or plasma also acceptable]  <b>CONTAINER:</b> Plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): For serum and whole blood, acceptable up to 72 hours. For plasma, acceptable up to 6 hours                      Frozen (–20°C): Acceptable for serum and plasma only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA EIA ELISA Antibody Detection
<i>Cryptosporidium</i> spp., Antigen*	5060	Identification of <i>Cryptosporidium</i> utilizing direct fluorescent antibody. (See also Ova and Parasite, Microscopic Exam)  * <i>Cryptosporidium</i> is a significant pathogen in immunocompromised patients.	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)  <b>CONTAINER:</b> Para-Pak® parasitology container with 10% formalin  <b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable                      NEVER INCUBATE.</p>	Negative	DFA

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Cryptosporidium</i> spp., Direct Detection*	5090	Identification of <i>Cryptosporidium</i> spp. by PCR assay.  * <i>Cryptosporidium</i> is a significant pathogen in immunocompromised patients.	<b>SPECIMEN:</b> Liver aspirates, stool <b>CONTAINER:</b> Containers with PVA or Cary-Blair media <b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable Frozen (–20°C): Acceptable	Not detected	PCR Assay
<i>Cryptosporidium</i> spp., Microscopic Exam*	5075	Identification of <i>Cryptosporidium</i> utilizing modified acid fast test on concentrated formalized specimens. (See also Ova and Parasite, Microscopic Exam)  * <i>Cryptosporidium</i> is a significant pathogen in immunocompromised patients.	<b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended) <b>CONTAINER:</b> Stool kit with 10% formalin <b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable NEVER INCUBATE.	Negative	Microscopy
<i>Cyclospora</i> <i>Cayetanensis</i> , Direct Detection*	5090	Identification of <i>Cyclospora cayetanensis</i> by PCR assay.  * <i>Cyclospora</i> spp. is a significant pathogen in immunocompromised patients.	<b>SPECIMEN:</b> Liver aspirates, stool <b>CONTAINER:</b> Containers with PVA or Cary-Blair media <b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable Frozen (–20°C): Acceptable	Not detected	PCR Assay

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Cyclospora spp., Microscopic Exam*	5075	<p>Identification of Cyclospora spp. utilizing modified acid fast test on concentrated formalized specimens. (See also Ova and Parasite, Microscopic Exam)</p> <p>*Cyclospora spp. is a significant pathogen in immunocompromised patients.</p>	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)</p> <p><b>CONTAINER:</b> Stool kit with 10% formalin</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable                      NEVER INCUBATE.</p>	Negative	Microscopy
Cysticercosis, Antibody	2515	<p>Identification of the pork tapeworm, <i>Taenia solium</i>, antibody using immunoblot.</p>	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml), plasma or CSF also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): For serum, whole blood and CSF, acceptable up to 72 hours. For plasma, acceptable up to 6 hours                      Frozen (–20°C): Acceptable for serum, plasma and CSF only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	Immunoblot Western Blot Antibody Detection

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Cysticercosis, Antigen	2515	Identification of the pork tapeworm, <i>Taenia solium</i> , antigen using enzyme immunoassay.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml), plasma or CSF also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): For serum, whole blood and CSF, acceptable up to 72 hours. For plasma, acceptable up to 6 hours Frozen (–20°C): Acceptable for serum, plasma and CSF only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	ELISA Antigen Detection
<i>Echinococcus</i> spp., Antibody	2515	Identification of <i>Echinococcus</i> tapeworm antibody using immunoblot.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml) or plasma also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): For serum and whole blood, acceptable up to 72 hours. For plasma, acceptable up to 6 hours Frozen (–20°C): Acceptable for serum and plasma only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	Immunoblot Western Blot Antibody Detection
<i>Entamoeba histoltica</i> , Direct Detection	5090	Identification of <i>Entamoeba histoltica</i> by PCR assay.	<p><b>SPECIMEN:</b> Liver aspirates, stool</p> <p><b>CONTAINER:</b> Conainers with PVA or Cary-Blair media</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable Frozen (–20°C): Acceptable</p>	Not detected	PCR Assay
<i>Enterobius vermicularis</i>	See Pinworm.				

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Filarioidea spp., Antibody	2515	Identification of Filarioidea tapeworm antibody using enzyme immunoassay.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml) or plasma also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): For serum and whole blood, acceptable up to 72 hours. For plasma, acceptable up to 6 hours Frozen (–20°C): Acceptable for serum and plasma only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA ELISA Antibody Detection
<i>Giardia lamblia</i> , Antigen	5060	Screening procedure for identification of <i>Giardia lamblia</i> utilizing direct fluorescent antibody technique. (See also Ova and Parasite, Microscopic Exam)	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)</p> <p><b>CONTAINER:</b> Para-Pak® parasitology container with 10% formalin</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable NEVER INCUBATE.</p>	Negative	DFA
<i>Giardia lamblia</i> , Direct Detection	5090	Identification of <i>Giardia lamblia</i> by PCR assay.	<p><b>SPECIMEN:</b> Liver aspirates, stool</p> <p><b>CONTAINER:</b> Containers with PVA or Cary-Blair media</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable Frozen (–20°C): Acceptable</p>	Not detected	PCR Assay
Helminth	See Worm, Identification.				

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Isospora</i> spp., Microscopic Exam*	5075	Identification of <i>Isospora</i> utilizing modified acid fast test on concentrated formalized specimens. (See also Ova and Parasite, Microscopic Exam)  * <i>Isospora</i> is a significant pathogen in immunocompromised patients.	<b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended) <b>CONTAINER:</b> Stool kit with 10% formalin <b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable NEVER INCUBATE.	Negative	Microscopy
Malaria, Microscopic Exam	5115	Identification of <i>Plasmodium</i> spp. by microscopic exam of Wright's or Giemsa-stained blood smear.	<b>SPECIMEN:</b> Stained (or unstained) blood films <b>CONTAINER:</b> Blood film in slide holder <b>COLLECTION:</b> Blood drawn between chills with successive draws at 6, 12, and 24 hours is recommended. Blood drawn any time is still acceptable. <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272	Negative	Microscopy
Microfilaria, Identification	5115	Identification of microfilaria by microscopic exam of Wright's or Giemsa-stained blood smear.	<b>SPECIMEN:</b> Stained blood film <b>CONTAINER:</b> Slide holder <b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable	Negative	Microscopy

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Microsporidium, Microscopic Exam*	5085	<p>Identification of Microsporidia utilizing modified trichrome stains on concentrated formalized specimens.</p> <p>*Microsporidium is a significant pathogen in immunocompromised patients.</p>	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)</p> <p><b>CONTAINER:</b> Stool kit with 10% formalin</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable                      NEVER INCUBATE.</p>	Negative	Microscopy
Ova and Parasite, Direct Detection	5090	<p>Identification of ova and parasites utilizing PCR assay.</p>	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)</p> <p><b>CONTAINER:</b> 2 vial stool kits with 10% formalin and modified PVA</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Preferred                      Refrigerated (2 – 8°C): Acceptable                      NEVER INCUBATE.</p>	Not detected	PCR Assay
Ova and Parasite, Microscopic Exam	5015 5010	<p>Screening procedure for identification of ova and parasites utilizing both a concentrated wet preparation and a trichrome stain.</p>	<p><b>SPECIMEN:</b> Stool, 2 – 5g (3 collected every other day is strongly recommended)</p> <p><b>CONTAINER:</b> 2 vial stool kits with 10% formalin and modified PVA</p> <p><b>COLLECTION:</b> Add stool to each vial up to the "fill" line immediately after passage. Then mix specimen thoroughly.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Preferred                      NEVER INCUBATE.</p>	Negative	Microscopy

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Pinworm, Microscopic Exam	5205	Examination of pinworm paddle for presence of pinworm ova by microscopy.	<p><b>SPECIMEN:</b> Potential pinworm eggs obtained from perianal area over 4 – 6 consecutive days</p> <p><b>CONTAINER:</b> Paddle in collection tube.</p> <p><b>COLLECTION:</b> Please contact the laboratory at 408.885.4272 to obtain pinworm paddles. Hold the paddle by the cap and remove it from the tube. Separate the buttocks and press the tacky surface against several areas of the perianal region. Replace the paddle in the tube for transport.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable within 24 hours                      Refrigerated (2 – 8°C): Acceptable</p>	Negative	Microscopy
<i>Schistosoma</i> , Antibody	2515	Isolation and identification of <i>Schistosoma</i> antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Serum, 2.5ml [whole blood (6ml) or plasma also acceptable]</p> <p><b>CONTAINER:</b> Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): For serum and whole blood, acceptable up to 72 hours. For plasma, acceptable up to 6 hours                      Frozen (–20°C): Acceptable for serum and plasma only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA
Tapeworm	See Worm, Identification.				

## Testing Services – Parasitology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Toxocara, Antibody (Visceral or Ocular Larval Migrans)	2520	Isolation and identification of Toxocara antibody utilizing ELISA.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml) or plasma Please call laboratory at 408.885.4272 before submitting plasma specimens</p> <p><b>CONTAINER:</b> Serum – plastic vacutainer Blood – Serum Separator Tube (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) Plasma – Please call laboratory for specific instruction and more information at 408.885.4272</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 16 hours Refrigerated (2 – 8°C): Acceptable up to 7 days Frozen (–20°C): Serum only</p>	Negative	ELISA
Worm, Identification	5095	Identification of helminth (worm) by microscopic exam. (See also pinworm)	<p><b>SPECIMEN:</b> Adult worm or proglottids.</p> <p><b>CONTAINER:</b> Clean jar or cup.</p> <p><b>COLLECTION:</b> Place in tap water or 0.85% saline. Do not use formalin or alcohol as a preservative.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Preferred</p>	Negative	Microscopy



## Testing Services – Select Agents / Bioterrorism

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS
Anthrax	See <i>Bacillus anthracis</i> .		
<i>Bacillus anthracis</i>	2115 2195 2120	Identification of <i>Bacillus anthracis</i> using biochemical and molecular techniques.	<p><b>SPECIMEN:</b> Culture isolate, stool (5g), vesicular fluid or eschar material</p> <p><b>CONTAINER:</b> For culture isolate, use a CHOC agar slant tube For stool, use a transport container with Cary-Blair media For vesicular fluid or eschar material, collect with a dacron swab and place in a sterile, leakproof, screw cap container.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable for culture isolate (24 hour culture preferred) Refrigerated (2 – 8°C): Acceptable, transport on cold pack</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Brucella</i> spp.	2255 2220 2435 2420	Identification of <i>Brucella</i> spp. using biochemical and molecular techniques.	<p><b>SPECIMEN:</b> Serum (2.5ml) each, or culture isolate</p> <p><b>CONTAINER:</b> For serum, sterile, leakproof, screw cap vial For culture isolate, use a CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable for culture isolate (24 hour culture preferred) Refrigerated (2 – 8°C): Acceptable up to 72 hours Frozen (–20°C): Acceptable for serum only</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Brucella</i> spp., Antibody	See <i>Brucella</i> spp. in Serology Testing Services section.		

## Testing Services – Select Agents / Bioterrorism

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS
<i>Burkholderia mallei</i> and <i>pseudomallei</i>	5640 5645 5644	Identification of <i>Burkholderia</i> spp. using biochemical and molecular techniques.	<p><b>SPECIMEN:</b> Culture isolate, urine, abscesses, tissue aspirates, or fluids (throat, nasal, skin or sputum specimens may be submitted for screening exposed individuals if a release of <i>Burkholderia mallei</i> has been confirmed.)</p> <p><b>CONTAINER:</b> For culture isolate, use a CHOC agar slant tube For urine, use a sterile, leakproof, screw cap container For abscesses, tissue aspirates or fluids, use a sterile, leakproof, screw cap container. For small tissue sample, add 1-2 drops of saline to keep the tissue moist.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable for culture isolate (24 hour culture preferred) Refrigerated (2 – 8°C): Acceptable, transport on cold pack</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Coxiella burnetii</i> (Q fever)	2540	Identification of <i>Coxiella burnetii</i> using molecular techniques.	<p><b>SPECIMEN:</b> Serum (2.5ml) each, or whole blood (6ml)</p> <p><b>CONTAINER:</b> For serum, sterile, leakproof, screw cap vial For whole blood, vacutainer with EDTA</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack Frozen (–20°C): Acceptable for serum only</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Coxiella burnetii</i> (Q fever), Antibody	See <i>Coxiella burnetii</i> (Q fever) in Serology Testing Services section.		

## Testing Services – Select Agents / Bioterrorism

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS
<i>Francisella tularensis</i>	2240 2290 5620	Identification of <i>Francisella tularensis</i> using biochemical and molecular techniques.	<p><b>SPECIMEN:</b> Serum (2.5ml) each, or culture isolate</p> <p><b>CONTAINER:</b> For serum, sterile, leakproof, screw cap vial For culture isolate, use a CHOC agar slant tube</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable for culture isolate (24 hour culture preferred) Refrigerated (2 – 8°C): Acceptable up to 72 hours Frozen (–20°C): Acceptable for serum only</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Francisella tularensis</i> , Antibody	See <i>Francisella tularensis</i> in Serology Testing Services section.		
Vaccinia Virus	2250	Identification of vaccinia virus using molecular techniques.	<p><b>SPECIMEN:</b> Vesicular tissue and fluid, scab, Dacron swab</p> <p><b>CONTAINER:</b> For vesicular tissue and fluid, collect on a slide or in a vial For scab, collect on a slide or in a vial For Dacron swabs, place in sterile tube with no transport medium</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable, transport on cold pack</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>

## Testing Services – Select Agents / Bioterrorism

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS
Varicella Zoster Virus (VZV)	2530	Identification of Varicella Zoster Virus (VZV) using molecular techniques.	<p><b>SPECIMEN:</b> Vesicular tissue and fluid, scab, Dacron swab</p> <p><b>CONTAINER:</b>                      For vesicular tissue and fluid, collect on a slide or in a vial                      For scab, collect on a slide or in a vial                      For Dacron swabs, place in sterile tube with no transport medium</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable, transport on cold pack</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Yersinia pestis</i>	5610 5650	Identification of <i>Yersinia pestis</i> using biochemical and molecular techniques.	<p><b>SPECIMEN:</b> Bronchial wash or transtrachael aspirate, nasopharyngeal swab, culture isolate, aspirate of involved tissue (Bubo)</p> <p><b>CONTAINER:</b>                      For bronchial wash or transtrachael aspirate, use a sterile, screw capped container                      For nasopharyngeal swab, use Dacron swabs [for PCR testing place in sterile tube without transport media and for culture place in Cary-Blair transport media]                      For culture isolate, use a CHOC agar slant tube                      For aspirate of involved tissue (Bubo), use a sterile container. For small tissue samples, add 1-2 drops of saline to keep tissue moist.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable for culture isolate (24 hour culture preferred)                      Refrigerated (2 – 8°C): Acceptable</p> <p><b>NOTE:</b> Specimens must be handled using BSL3 practices and sent directly to the Santa Clara County Public Health Laboratory. Specimens must be packaged according to packing &amp; shipping guidelines for infectious substances.</p>
<i>Yersinia pestis</i> , Antibody	See <i>Yersinia pestis</i> in Serology Testing Services section.		

## Serology

# Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Adenovirus, Antibody	2520	Screening procedure for adenovirus IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA
<i>Anaplasma phagocytophilia</i> (HGA or HGE), Antibody	2520	Screening procedure for <i>Anaplasma phagocytophilia</i> IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	IFA
<i>Balamuthia</i> , Antibody	2520	Screening procedure for <i>Balamuthia</i> IgG by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Brucella</i> spp., Antibody	2515	Identification of <i>Brucella</i> spp. using <i>Brucella</i> microagglutination test, a modified version of serum agglutination test.	<p><b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b></p> <p><b>SPECIMEN:</b> Acute and convalescent serum (2.5ml) each  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 12 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Acceptable</p>	Negative	BMAT
Chickenpox	See Varicella Zoster Virus.				
Chikungunya (CHIKV), Antibody	2520	Screening procedure for chikungunya IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	IFA Western Blot

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Coxiella burnetii</i> (Q fever), Antibody	2520	Screening procedure for <i>Coxiella burnetii</i> antibody by indirect fluorescent antibody test.	<p><b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b></p> <p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Not Detected	IFA
Dengue Virus (DENV), Antibody	2520	Confirmation of dengue virus antibodies by enzyme immunoassay test, indirect fluorescent antibody test and/or plaque reduction neutralization.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA IFA PRNT
Dengue Virus (DENV), Screen	2520	Screening procedure for dengue virus antibodies by western blot.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	Western Blot

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Dengue Virus (DENV), Direct Detection	2091	Identification of dengue virus by RT-PCR Assay.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	RT-PCR Assay
Ebola Virus, Antibody	2515	Identification of Ebola virus by enzyme-linked immunosorbent assay (ELISA).	<p><b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b></p> <p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b>                      For serum, use a SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)                      For whole blood, use a purple, yellow or blue top plastic vacutainer.  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack  <b>NOTE:</b> If Ebola is suspected, please call laboratory immediately at 408.885.4272. An additional history form is required.</p>	Not Detected	ELISA
Encephalitis	See St. Louis Encephalitis or Western Equine Encephalitis.				

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Enterovirus, Antibody, Acute Infection	2520	Screening procedure for enterovirus IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> CSF and/or whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial</p> <p>Blood – SST (i.e. Tiger/Gold Top) or Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): 12 hours (serum or blood only)</p> <p>Refrigerated (2 – 8°C): 72 hours (serum, blood, CSF), transport on ice pack</p> <p>Frozen (–70°C): Acceptable (serum, CSF only), transport on dry ice</p>	No antibody detected	EIA
Enterovirus Antibody, Past Infection	2520	Screening procedure for enterovirus IgG by Serum Neutralization.	<p><b>SPECIMEN:</b> Acute and convalescent serum (2.5ml) each</p> <p><b>CONTAINER:</b> Plastic vacutainer</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable up to 12 hours</p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack</p> <p>Frozen (–20°C): Acceptable</p>	No antibody detected	Serum Neut
Epstein–Barr Virus (EBV), Antibody	2520	Screening procedure for Epstein–Barr virus EBNA, VCA IgG or VCA IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable up to 6 hours</p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack</p> <p>Frozen (–20°C): Serum only</p>	Not Detected	IFA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Francisella tularensis</i> , Antibody	2280	Identification of <i>Francisella tularensis</i> antibody by direct fluorescent antibody test.	<p><b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b></p> <p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	DFA
Hantavirus Pulmonary Syndrome (Sin Nombre Virus), Antibody	2520	Identification of Sin Nombre Virus antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA
Hepatitis B, Panel	2050 2105 2055 2150	Screening procedure for Hepatitis B virus total core antibody, surface antibody, surface antigen by enzyme immunoassay test. If positive, secondary neutralization test may be performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Hepatitis C, Total Antibody (Screen)	2065	Screening procedure for Hepatitis C virus total antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA
Human Immunodeficiency Virus-1 (HIV-1), Antibody Confirmation	1020 1025	Secondary testing of HIV antibodies by western blot.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml), or Oral Fluid  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) or Orasure® oral fluid collection tube or vial  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	Western Blot
Human Immunodeficiency Virus-1/2 (HIV-1/2), Antibody	1005 1010	Screening procedure for HIV-1/2 by enzyme immunoassay test (3rd generation). If positive, secondary testing by western blot performed.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml), or oral fluid  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) or Orasure® oral fluid collection tube or vial  <b>COLLECTION:</b> See Serology or Virology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA Western Blot

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Human Immunodeficiency Virus-1/2 (HIV-1/2), Combo Antigen and Antibody	1008 1021	Screening procedure for HIV-1/2 antigen and antibody by enzyme immunoassay test (4th generation). If positive, secondary testing with Multi-Spot HIV-1/2 antibody test performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology or Virology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours (serum)                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Acceptable</p>	Negative	EIA Multi-Spot
Human T Cell Lymphotropic Virus (HTLV) I & II, Antibody	2520	Identification of IgG by enzyme immunoassay test or indirect fluorescent antibody test. If positive confirmation with western blot or radioimmunoprecipitation assay (RIPA) performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA, IFA, Western Blot or RIPA
Lymphocytic choriomeningitis (LCM), Antibody	2520	Identification of Lymphocytic choriomeningitis IgG by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	IFA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Measles Virus, Antibody	2056 2057	Identification of measles IgM and IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA
Milker's Nodules	See Orf virus, Cowpox.				
Mononucleosis	See Epstein–Barr Virus.				
Mumps Virus, Antibody	2520	Identification of mumps virus IgG and IgM by enzyme immunoassay test or indirect fluorescent antibody tests.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA or IFA
<i>Mycoplasma pneumoniae</i> , Antibody	2515	Screening procedure for <i>Mycoplasma pneumoniae</i> IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Orf Virus, Cowpox, Antibody	2520	Identification of parapoxvirus IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Not Detected	IFA
Parapoxvirus	See Orf virus, Cowpox.				
Q Fever	See <i>Coxiella burnetii</i> .				
Rabies (Immune Status), Antibody	2520	<p><b>Only for Public Health Department and Vector Control staff.</b>                      Identification of rabies virus IgG by rapid fluorescent focus inhibition test.</p>	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	≥1:5 for immunity	RFFIT
<i>Rickettsia typhi</i> (typhus), Antibody	2520	Identification of <i>Rickettsia typhi</i> IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Rocky Mountain Spotted Fever (RMSF), Antibody	2520	Identification of Rocky Mountain spotted fever IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA
Rubella, Antibody	2520	Identification of Rubella IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA
Schistosoma, Antibody	2515	Isolation and identification of Schistosoma antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA
Shingles	See Varicella Zoster Virus.				
Sin Nombre Virus	See Hantavirus Pulmonary Syndrome Antibody				

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
St. Louis Encephalitis (SLE), Antibody	2520	Confirmation of St. Louis Encephalitis antibodies by western blot. If virus is suspected, plaque reduction neutralization performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	Western Blot PRNT
Toxocara, Antibody Detection (Visceral or Ocular Larval Migrans)	2520	Isolation and identification of <i>Toxocara</i> antibody utilizing ELISA.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml) or plasma                      Please call laboratory at 408.885.4272 before submitting plasma specimens  <b>CONTAINER:</b> Serum – plastic vacutainer                      Blood – SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)                      Plasma – Please call laboratory for specific instruction and more information at 408.885.4272  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 16 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	ELISA
<i>Treponema pallidum</i> (Syphilis) Antibody Confirmation, TPPA	2030	Confirmation of <i>Treponema pallidum</i> by <i>Treponema pallidum</i> Particle Agglutination	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	TPPA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
<i>Treponema pallidum</i> (Syphilis) Screen, Qualitative and Quantitative, RPR	2015 2040	Nontrepenomal serological screening for identification and evaluation of <i>Treponema pallidum</i> by Rapid Plasma Reagin (RPR) Card Test. Confirmation test performed if positive.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	RPR
Vaccinia (vaccine strain), Antibody	2520	Identification of Vaccinia IgG (found in smallpox vaccine) by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA
Varicella Zoster Virus (VZV), Antibody	2520	Identification of Varicella zoster virus IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA

## Testing Services – Serology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
West Nile Virus, Antibody	2520	Identification of West Nile virus IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA Western Blot PRNT
Western Equine Encephalitis (WEE), Antibody	2520	Identification of Western Equine Encephalitis IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA Western Blot PRNT
<i>Yersinia Pestis</i> , Antibody	5635	Screening procedure for the isolation and identification of <i>Yersinia</i> by conventional biochemical testing techniques.	<p><b>POSSIBLE BIOTERRORISM AGENT. Call the laboratory at 408.885.4272 or 408.885.4200 (after business hours) prior to submitting specimens.</b></p> <p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	DFA

Veterinary

Testing Services – Veterinary

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Rabies Virus	6005	Identification of Rabies virus by direct fluorescent antibody test on specific sections of the animal brain.	<p><b>SPECIMEN:</b> Freshly severed animal head or entire bat or fresh unpreserved animal brain, delivered by approved animal control agencies.</p> <p><b>CONTAINER:</b> Rigid opaque container or double dark plastic bags. Do not use formalin.</p> <p><b>COLLECTION:</b> Sever animal head or remove brain from cranium and place in plastic bag.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 24 hours <b>DO NOT FREEZE.</b></p>	Negative	FRA
Scabies	5100	Identification of Scabies by microscopic exam.	<p><b>SPECIMEN:</b> Skin scrapings on a slide or in a zip lock bag</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>COLLECTION:</b> Use mineral oil to scrape skin, then transfer to glass slide and cover with another glass slide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 3 days Refrigerated (2 – 8°C): Acceptable up to 3 days</p>	Negative	Microscopy
Tick (Lyme Disease)	5020	Speciation of tick and isolation and identification of <i>Borrelia burgdorferi</i> by indirect fluorescent antibody. <i>Borrelia burgdorferi</i> is the primary cause of Lyme Disease in North America.	<p><b>SPECIMEN:</b> Tick</p> <p><b>CONTAINER:</b> Any container. A small plastic bag is sufficient. Include damp material, such as a cotton ball, to keep tick moist.</p> <p><b>COLLECTION:</b> Keep tick moist and body intact</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Holding time varies, tick can be tested if it has body fluid. Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable</p>	Negative	IFA



## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Adenovirus, Antibody	2520	Screening procedure for adenovirus IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA
Adenovirus, Direct Detection	2521	Detection of adenovirus nucleic acid by real time PCR assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3ml of VTM                      DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice  <b>NOTE:</b> Additional history form required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not detected	Real-time PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Adenovirus, Isolation	2430	Isolation, identification and typing of adenovirus by tissue culture and direct smear.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Negative	Culture DFA
<i>Anaplasma phagocytophilia</i> (HGA or HGE), Antibody	2520	Screening procedure for <i>Anaplasma phagocytophilia</i> IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	IFA
Calicivirus (Other than Norovirus), Direct Detection	2160	Identification of gastrointestinal viruses <b>other than norovirus</b> by real-time RT-PCR assay.	<p><b>SPECIMEN:</b> Stool, 2 - 5g</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw-cap cup.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): REQUIRED, transport on cold pack  <b>DO NOT FREEZE.</b></p>	Not detected	Real-time RT-PCR Assay
Chickenpox	See Varicella Zoster Virus.				

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Chikungunya (CHIKV), Antibody	2520	Screening procedure for chikungunya IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	IFA Western Blot
Cytomegalovirus (CMV), Direct Detection	2521	Screening procedure for cytomegalovirus by real-time PCR Assay.	<p><b>SPECIMEN:</b> CSF  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time PCR Assay
Cytomegalovirus (CMV), Isolation	2510	Isolation and identification of cytomegalovirus by cell culture.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates or urine  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3ml of VTM  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 4 hours, transport on wet ice (place ice in double Ziploc bag)                      Frozen (–70°C): Preferred, transport on dry ice</p>	Negative	Culture

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Dengue Virus (DENV), Antibody	2520	Confirmation of dengue virus antibodies by enzyme immunoassay test, indirect fluorescent antibody test and/or plaque reduction neutralization.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA IFA PRNT
Dengue Virus (DENV), Screen	2520	Screening procedure for dengue virus antibodies by western blot.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	Western Blot
Dengue Virus (DENV), Direct Detection	2091	Identification of dengue virus by RT-PCR Assay.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Ebola Virus, Antibody	2515	Identification of Ebola virus by enzyme-linked immunosorbent assay (ELISA).	<p><b>SPECIMEN:</b> Whole blood (4ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> For serum, use a SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) For whole blood, use a purple, yellow or blue top plastic vacutainer. DO NOT OPEN TUBES.</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack Frozen (-20°C): Specimens must be kept frozen and transported on dry ice. Thawing and refreezing reduces sensitivity.</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	ELISA
Ebola Virus, Antigen	2515	Identification of Ebola virus using immunohistochemistry techniques.	<p><b>SPECIMEN:</b> Formalin-fixed or paraffin-embedded tissue (lung, kidney, liver or spleen are preferred)</p> <p><b>CONTAINER:</b> Paraffin blocks are preferred.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable</p> <p><b>NOTE:</b> Autopsy or surgical report is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	IHC

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Ebola Virus, Direct Detection	2515	Identification of Ebola virus by PCR assay.	<p><b>SPECIMEN:</b> Whole blood (4ml) is preferred. Fresh frozen tissue (1 cm<sup>3</sup>, except biopsies) or serum (2.5ml) is also acceptable.</p> <p><b>CONTAINER:</b> For whole blood, use a purple, yellow or blue top plastic vacutainer. For fresh frozen tissue, use a sterile, leakproof, screw cap plastic vial. For serum, use a SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) DO NOT use heparin. DO NOT OPEN TUBES.</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Frozen (-70°C): Specimens must be kept frozen and transported on dry ice. Thawing and refreezing reduces sensitivity.</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	PCR Assay
Encephalitis	See St. Louis Encephalitis or Western Equine Encephalitis.				
Encephalitis, Panel for Neurologic Surveillance	2520	Identification of specified virus by cell culture and viral isolation.	Dependant upon patient symptoms and virus suspected. Please call laboratory for assistance at 408.885.4272 and refer to virology specimen collection guide.	Negative	Culture
Enterovirus, Antibody, Acute Infection	2520	Screening procedure for enterovirus IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> CSF and/or whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial Blood – SST (i.e. Tiger/Gold Top) or Plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): 12 hours (serum or blood only) Refrigerated (2 – 8°C): 72 hours (serum, blood, CSF), transport on ice pack Frozen (-70°C): Acceptable (serum, CSF only), transport on dry ice</p>	No antibody detected	EIA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Enterovirus, Antibody, Past Infection	2520	Screening procedure for enterovirus IgG by Serum Neutralization.	<p><b>SPECIMEN:</b> Acute and convalescent serum (2.5ml) each</p> <p><b>CONTAINER:</b> Plastic vacutainer</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 12 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Acceptable</p>	No antibody detected	Serum Neut
Enterovirus, Direct Detection	2140	Identification of enterovirus by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Stool (2 – 4g) and/or respiratory swab</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–70°C): Acceptable</p>	Not Detected	Real-time RT-PCR Assay
Enterovirus, Isolation	2510	Isolation, identification and typing of enterovirus by tissue culture.	<p><b>SPECIMEN:</b> Stool (2 – 4g) and/or respiratory swab</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–70°C): Acceptable</p>	Negative	Culture
Epstein-Barr Virus (EBV), Antibody	2520	Screening procedure for Epstein-Barr virus EBNA, VCA IgG or VCA IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	No antibody detected	IFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Epstein-Barr Virus (EBV), Direct Detection	2521	Screening procedure for Epstein-Barr virus by real-time PCR Assay.	<p><b>SPECIMEN:</b> CSF</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time PCR Assay
Hantavirus Pulmonary Syndrome (Sin Nombre Virus), Antibody	2520	Identification of Sin Nombre Virus antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA
Hepatitis B, Panel	2050 2105 2055 2150	Screening procedure for Hepatitis B virus total core antibody, surface antibody, surface antigen by enzyme immunoassay test. If positive, secondary neutralization test may be performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (-20°C): Serum only</p>	Negative	EIA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Hepatitis C, Total Antibody (Screen)	2065	Screening procedure for Hepatitis C virus total antibody by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	EIA
Herpes Simplex Virus (HSV), Isolation	2510	Screening procedure for isolation and identification of Herpes Simplex Virus 1/2 by cell culture.	<p><b>SPECIMEN:</b> Vesicular or oral swab  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Preferred up to 72 hours, transport on cold pack                      Frozen (–20°C): Acceptable, transport on dry ice</p>	Negative	Culture
Herpes Simplex Virus 1/2, Direct Detection	2324	Screening procedure for Herpes Simplex Virus 1/2 by real-time PCR Assay.	<p><b>SPECIMEN:</b> Vesicular swab  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial                      DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–70°C): Acceptable</p>	Not detected	Real-time PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Herpes Simplex Virus 1/2, Direct Smear	2205	Screening procedure for Herpes Simplex Virus 1/2 by direct fluorescent antibody test.	<p><b>SPECIMEN:</b> Vesicular swab smeared on slide</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>COLLECTION:</b> See vesicular Fluids and Slide Preparation in Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable                      Refrigerated (2 – 8°C): Acceptable up to 24 hours, transport on cold pack                      Frozen (–20°C): Acceptable</p>	Negative	DFA
Human Herpesvirus 6 (HHV6), Direct Detection	2521	Identification of Human Herpesvirus 6 by real-time PCR Assay.	<p><b>SPECIMEN:</b> CSF</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or tube or vial</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time PCR Assay
Human Immunodeficiency Virus-1 (HIV-1), Antibody Confirmation	1020 1025	Secondary testing of HIV antibodies by western blot.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml), or Oral Fluid</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) or Orasure® oral fluid collection tube or vial</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	Western Blot

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Human Immunodeficiency Virus-1/2 (HIV-1/2), Antibody	1005 1010	Screening procedure for HIV-1/2 by enzyme immunoassay test (3rd generation). If positive, secondary testing by western blot performed.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml), or oral fluid</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top) or Orasure® oral fluid collection tube or vial</p> <p><b>COLLECTION:</b> See Serology or Virology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	EIA Western Blot
Human Immunodeficiency Virus-1/2 (HIV-1/2), Combo Antigen and Antibody	1008 1021	Screening procedure for HIV-1/2 antigen and antibody by enzyme immunoassay test (4th generation). If positive, secondary testing with Multi-Spot HIV-1/2 antibody test performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology or Virology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours (serum)                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Acceptable</p>	Negative	EIA Multi-Spot
Human metapneumovirus (hMPV), Direct Detection	2521	Identification of Human metapneumovirus (hMPV) by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Human T Cell Lymphotropic Virus (HTLV) I & II, Antibody	2520	Identification of IgG by enzyme immunoassay test or indirect fluorescent antibody test. If positive confirmation with western blot or radio-immunoprecipitation assay (RIPA) performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	Negative	EIA, IFA, Western Blot or RIPA
Influenza A or B, Direct Detection	2521	Identification of influenza A or B by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM                      DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 48 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay
Influenza A, Subtyping (Pandemic H1N1, H7H9, etc.)	2521	Subtyping of influenza A for H1, H3, H5 and pandemic influenza A (H1) 2009, (H7) by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM                      DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 48 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Influenza A, Isolation	2230	Isolation, identification and typing of Influenza A by tissue culture. If positive, direct fluorescent antibody test confirmation performed.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 48 hours Frozen (–70°C): Acceptable</p>	Negative	Culture DFA
Influenza B, Isolation	2400	Isolation, identification and typing of Influenza B by tissue culture. If positive, direct fluorescent antibody test confirmation performed.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 48 hours Frozen (–70°C): Acceptable</p>	Negative	Culture DFA
Lymphocytic choriomeningitis (LCM), Antibody	2520	Identification of Lymphocytic choriomeningitis IgG by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 6 hours Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack Frozen (–20°C): Serum only</p>	Negative	IFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Measles Virus, Antibody	2056 2057	Identification of measles IgM and IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–20°C): Serum only</p>	Negative	EIA
Measles Virus, Direct Detection	2059	Identification of measles virus by real-time RT-PCR assay.	<p><b>SPECIMEN:</b> Urine or respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p> <p><b>NOTE:</b> additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not detected	Real-time RT-PCR Assay
Measles, Isolation	2510	Isolation and identification of measles by cell culture.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	Culture

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Direct Detection	2520	Identification of Middle East Respiratory Syndrome by PCR assay.	<p><b>SPECIMEN:</b> To increase the likelihood of detecting infection, please submit specimens from different sites and from different times after symptom onset.</p> <ul style="list-style-type: none"> <li>- Lower respiratory tract specimens typically have the highest yield: bronchoalveolar lavage, tracheal aspirate, pleural fluid and/or sputum, and should be collected whenever possible.</li> <li>- Upper respiratory tract specimens, including nasopharyngeal and oropharyngeal (throat) swabs should be obtained. Nasal washes are not acceptable.</li> <li>- Use Dacron® or rayon swabs with plastic shafts. DO NOT use calcium alginate or wooden shaft swabs.</li> <li>- Serum and stool specimens should also be collected.</li> </ul> <p><b>CONTAINER:</b> See Virology Specimen Collection Guide.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b> See Virology Specimen Collection Guide.  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	PCR Assay
Milker's Nodules	See Orf virus, Cowpox.				
Mononucleosis	See Epstein-Barr Virus.				
Mumps Virus, Antibody	2520	Identification of mumps virus IgG and IgM by enzyme immunoassay test or indirect fluorescent antibody tests.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-70°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	EIA or IFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Mumps Virus, Direct Detection	2051	Identification of mumps virus by real-time PCR assay.	<p><b>SPECIMEN:</b> Buccal swab  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM            DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>            Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack            Frozen (–20°C): Acceptable, transport on dry ice</p>	Not detected	Real-time PCR Assay
Mumps Virus, Isolation	2510	Isolation and identification of mumps virus by cell culture.	<p><b>SPECIMEN:</b> Buccal swab  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>            Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack            Frozen (–20°C): Acceptable, transport on dry ice  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	Culture
Norovirus, Direct Detection (See also Calicivirus)	2145	Identification of norovirus virus by real-time RT-PCR assay.	<p><b>SPECIMEN:</b> Stool, 2 – 4g  <b>CONTAINER:</b> Sterile, leak proof, screw-cap cup.  <b>TRANSPORT/HOLDING CONDITIONS:</b>            Refrigerated (2 – 8°C): REQUIRED, transport on cold pack  <b>DO NOT FREEZE.</b></p>	Not detected	Real-time RT-PCR Assay
Norwalk Virus	See Norovirus.				

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Orf Virus, Cowpox, Antibody	2520	Identification of parapoxvirus IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (–20°C): Serum only</p>	No antibody detected	IFA
Orf Virus, Cowpox, Antigen	2510	Identification of parapoxvirus by direct fluorescent antibody test.	<p><b>SPECIMEN:</b> Vesicular swab or scab</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–20°C): Acceptable, transport on dry ice</p>	No antibody detected	DFA
Parainfluenza 1, 2, 3 or 4, Direct Detection	2521	Identification and typing of Parainfluenza by real-time RT-PCR assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Parainfluenza 1, 2, or 3, Isolation	2405	Isolation, identification and typing of Parainfluenza by tissue culture. If positive, direct fluorescent antibody test confirmation performed.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours Frozen (-70°C): Acceptable</p>	Negative	Culture DFA
Parapoxvirus	See Orf virus, Cowpox.				
Rabies (Immune Status), Antibody	2520	<b>Only for public health and vector control staff.</b> Identification of rabies virus IgG by rapid fluorescent focus inhibition test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable up to 6 hours Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	≥1:5 for immunity	RFFIT
Rabies (Suspected Human Case), Antibody	2520	Identification of rabies virus IgG and IgM by indirect fluorescent antibody test.	Requests for testing suspect human rabies cases are referred to the California Department of Public Health Neurological Surveillance and Testing (NST) program for evaluation. Preferred specimens are determined by clinical status of the patient. Please call laboratory for specific instruction and more information at 408.885.4272	Negative	IFA
Rabies (Suspected Human Case), Antigen	2520	Identification of rabies virus by direct fluorescent antibody test.	Requests for testing suspect human rabies cases are referred to the California Department of Public Health Neurological Surveillance and Testing (NST) program for evaluation. Preferred specimens are determined by clinical status of the patient. Please call laboratory for specific instruction and more information at 408.885.4272	Negative	DFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Respiratory Syncytial Virus (RSV), Direct Detection	2521	Identification of Respiratory Syncytial virus by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay
Respiratory Syncytial Virus (RSV), Isolation	2270	Isolation and identification Respiratory Syncytial Virus by tissue culture and direct smear. If positive, direct fluorescent antibody test confirmation performed.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates or direct smear</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM or slide holder</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (–70°C): Acceptable</p>	Negative	Culture DFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Respiratory Viral Screen	2210	<p>Screening procedure for identification of respiratory viruses:</p> <p>Parainfluenza 1, 2 and 3 Influenza A and B RSV Adenovirus</p> <p>If positive, direct fluorescent antibody test confirmation performed.</p>	<p><b>SPECIMEN:</b> Culture and/or respiratory, i.e. nasopharyngeal, throat or nasal, swabs smeared on 2 slides</p> <p><b>CONTAINER:</b> Slide holder</p> <p><b>COLLECTION:</b> See Nasopharyngeal Swab, Throat Swab and Slide Preparation in Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Room Temperature (15 – 30°C): Acceptable Refrigerated (2 – 8°C): Acceptable up to 24 hours, transport on cold pack Frozen (–70°C): Acceptable</p>	Negative	DFA
Respiratory Viral Screen, Isolation	2180	<p>Screening procedure for isolation and identification by culture of respiratory viruses:</p> <p>Parainfluenza 1, 2 and 3 Influenza A and B RSV Adenovirus</p> <p>If positive, direct fluorescent antibody test confirmation performed.</p>	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates or direct smear</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM or slide holder</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours Frozen (–70°C): Acceptable</p>	Negative	Culture DFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Respiratory Virus, Specific Isolation	2235	<p>Isolation and identification of a specified respiratory virus:</p> <p>Parainfluenza 1, 2 and 3 Influenza A and B RSV Adenovirus</p> <p>If positive, direct fluorescent antibody test confirmation performed.</p>	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates or direct smear</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM or slide holder</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack Frozen (–70°C): Acceptable</p>	Negative	Culture DFA
Rhinovirus, Direct Detection	2521	<p>Identification of Rhinovirus by real-time RT-PCR assay and gel electrophoresis.</p>	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b> Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack Frozen (–70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Rhinovirus, Isolation	2510	Isolation and identification of Rhinovirus by conventional biochemical techniques.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p>	Negative	Culture
<i>Rickettsia typhi</i> (typhus), Antibody	2520	Identification of <i>Rickettsia typhi</i> IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA
Rickettsia, Spotted Fever Group (SFG)	2521	Identification of Rickettsia by real-time PCR assay.	<p><b>SPECIMEN:</b> Vesicular swab and eschar</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not detected	Real-time PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Rocky Mountain Spotted Fever (RMSF), Antibody	2520	Identification of Rocky Mountain spotted fever IgG and IgM by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA
Rubella, Antibody	2520	Identification of Rubella IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only</p>	Negative	EIA
Rubella, Direct Detection	2521	Identification of Rubella by real-time RT-PCR assay.	<p><b>SPECIMEN:</b> Respiratory, i.e. nasopharyngeal swab(s), throat swab(s), nasal swab(s)/wash/aspirates or bronchial wash/aspirates  <b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM                      DO NOT use calcium alginate swabs.  <b>COLLECTION:</b> See Virology Specimen Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p>	Not detected	Real-time RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Rubella, Isolation	2510	Isolation and identification of Rubella by cell culture.	<p><b>SPECIMEN:</b> Throat swab(s) and/or urine</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p>	Negative	Culture
Shingles	See Varicella Zoster Virus.				
Sin Nombre Virus	See Hantavirus Pulmonary Syndrome Antibody				
Smallpox	See Variola Virus.				
St. Louis Encephalitis (SLE), Antibody	2520	Confirmation of St. Louis Encephalitis antibodies by western blot. If virus is suspected, plaque reduction neutralization performed.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	N/A	Western Blot PRNT
Vaccinia (vaccine strain), Antibody	2520	Identification of Vaccinia IgG (found in smallpox vaccine) by indirect fluorescent antibody test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Negative	IFA

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Vaccinia, Direct Detection	2250	Identification of Vaccinia (found in smallpox vaccine) by real-time PCR assay.	<p><b>SPECIMEN:</b> Vesicular swab and/or scab</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack</p>	Not detected	Real-time PCR Assay
Varicella Zoster Virus (VZV), Antibody	2520	Identification of Varicella zoster virus IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Room Temperature (15 – 30°C): Acceptable up to 6 hours</p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack</p> <p>Frozen (–20°C): Serum only</p>	Negative	EIA
Varicella Zoster virus (VZV), Direct Detection	2530	Identification of Varicella zoster virus by real-time PCR Assay.	<p><b>SPECIMEN:</b> CSF or Vesicular swab</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM</p> <p>DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b></p> <p>Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack</p> <p>Frozen (–20°C): Acceptable, transport on dry ice</p>	Not detected	Real-time PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
Varicella Zoster Virus (VZV), Isolation	2260	Identification of Varicella zoster virus by direct smear.	<p><b>SPECIMEN:</b> Vesicular swab or direct smear</p> <p><b>CONTAINER:</b> Sterile, leak proof, screw cap tube or vial with 2 – 3 ml of VTM or slide holder</p> <p><b>COLLECTION:</b> See Virology Specimen Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on cold pack                      Frozen (-70°C): Acceptable, transport on dry ice</p>	Negative	DFA
Viral Isolate for Identification	2510	Identification of specified virus by cell culture and viral isolation.	Dependant upon patient symptoms and virus suspected. Please call laboratory for assistance at 408.885.4272 and refer to virology specimen collection guide.	Negative	Culture
West Nile Virus (WNV), Direct Detection	2521	Identification of West Nile virus by real-time RT-PCR Assay.	<p><b>SPECIMEN:</b> Whole blood (6ml), serum (2.5ml) or CSF. It is recommended to also submit a respiratory swab (in VTM).</p> <p><b>CONTAINER:</b> SST (i.e. Tiger/Gold Top), plastic vacutainer (Red Top) or Sterile, leak proof, screw cap tube or vial                      DO NOT use calcium alginate swabs.</p> <p><b>COLLECTION:</b> See Serology Collection Guide.</p> <p><b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (-20°C): Serum only</p> <p><b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	Not Detected	Real-time RT-PCR Assay

## Testing Services – Virology

TEST NAME	TEST NO.	DESCRIPTION	SPECIMEN REQUIREMENTS	NORMAL VALUE	TEST METHOD
West Nile Virus, Antibody	2520	Identification of West Nile virus IgG and IgM by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours                      Frozen (-20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA Western Blot PRNT
Western Equine Encephalitis (WEE), Antibody	2520	Identification of Western Equine Encephalitis IgG by enzyme immunoassay test.	<p><b>SPECIMEN:</b> Whole blood (6ml) or serum (2.5ml)  <b>CONTAINER:</b> SST (i.e. Tiger/Gold Top) or plastic vacutainer (Red Top)  <b>COLLECTION:</b> See Serology Collection Guide.  <b>TRANSPORT/HOLDING CONDITIONS:</b>                      Room Temperature (15 – 30°C): Acceptable up to 6 hours                      Refrigerated (2 – 8°C): Acceptable up to 72 hours, transport on ice pack                      Frozen (-20°C): Serum only  <b>NOTE:</b> Additional history form is required. Please call laboratory for specific instruction and more information at 408.885.4272</p>	No antibody detected	EIA Western Blot PRNT
Winter Vomiting Disease	See Norovirus.				



## Tests Available at CDC

In addition to the tests described on the preceding pages of this manual, the SCCPHL can forward specimens to the CDC for less commonly requested tests, such as:

- *Acanthamoeba*
- Alkhurma
- *Angiostrongylus cantonensis*
- Arbovirus
- *Arenavirus* (Old World)
- *Bartonella*
- Basidiobolus
- Baylisascariasis
- Blastomyces
- *Chlamydophila pneumoniae*
- *Chlamydophila psittaci*
- Congo-Crimean Hemorrhagic Fever
- *Corynebacterium diphtheriae* / *ulcerans* / *pseudotuberculosis*
- HPV
- Hendra
- Hepatitis A
- Hepatitis D
- Hepatitis E
- Herpesvirus Encephalitis Panel
- Human Herpes Virus 7 (HHV7)
- Human Herpes Virus 8 (HHV8)
- Human Herpes Virus 8 (HHV8)
- Junin
- Kyasanur Forest Disease
- Laguna Negra
- Lassa Fever
- Leishmaniasis
- *Leptospira* species
- Lymphocytic Choriomeningitis (LCM)
- Machupo
- NARMS
- *Naegleria*
- Nipah Virus
- *Nocardia* species
- *Orientia*
- Paracoccidioides
- Paragonimiasis
- Parechovirus
- Picornavirus
- Polio
- Poxvirus - Molluscum Contagiosum
- Poxvirus - Monkeypox
- Poxvirus - Pan-Poxvirus
- Poxvirus - Parapoxvirus
- Poxvirus - Sealpox
- Poxvirus - Tanapox
- Puumala
- Rift Valley Fever (RVF)
- Rotavirus
- SARS
- Seoul Virus
- Sporothrix
- Strongyloidiasis
- Tick Borne Encephalitis (TBE)
- Toxocariasis
- Toxoplasmosis
- Trichinellosis
- *Trichomonas*
- *Trypanosoma cruzi*



## 4 Other Services

### Phlebotomy Services

The SCCPHL provides blood collection services including venipuncture and finger stick draws. Phlebotomists are available to conduct and train proper collection technique for blood lead testing, adhering to the protocol outline in the collection guide section of this manual.

### Courier Services

The Santa Clara County has a designated courier to pick up specimens and expedite delivery of lab testing results. Please contact the laboratory at 408.885.4272 for more information.

### NGHA (Non-diagnostic General Health Assessment)

#### General Information

In July of each year, a new application for Nondiagnostic General Health Assessments (NGHA) (and support documentation) must be submitted to the SCCPHL with the appropriate filing fees. It is required that all fees, a current application and current protocols, licenses, and support documents be on file in our office prior to a program being offered. Programs offered prior to approval of an application and fees being received will be subject to enforcement actions by the Office of the Health Officer.

The Non-Diagnostic General Health Assessment law, section 1244 of the California Business and Professions Code, requires that thirty days prior to the operation of a program of Nondiagnostic General Health Assessment, the entity or person operating that program shall file the necessary documentation with the local health officer (or designee – the Public Health Laboratory Director) in each county in which the program shall operate. In addition, the local health officer (or designee – the Public Health Laboratory Director) shall also be notified of any changes at least 24 hours prior to the program operating at the different locations, dates, or times.

Only original applications will be accepted. If you find it necessary to fax your application in, the original application must be received by our office prior to any event approval being issued. Applications that are incomplete and/or failure to submit all required documents may result in delays in the processing of your application.

Please review the frequently asked questions, fill out the application and collect the supplemental document outlined on the checklist below. Call the laboratory for the current annual registration fee and for more information.

## NGHA Frequently Asked Questions

(taken in part from CAPHLID's "Nondiagnostic General Health Assessment Registration and Enforcement Program Implementation Manual")

### 1. What is the definition of a nondiagnostic general health assessment (NGHA) program?

A NGHA program is a program in which bioanalytical screening is provided to an asymptomatic individual to screen for a non-infectious chronic health condition. Individuals who appear likely to have a marker or risk factor are then referred to licensed sources of care for appropriate follow up. NGHA programs must provide significant public health benefit as determined by accepted public health protocols and practice.

### 2. Which laws govern regulation of NGHA programs in California?

Sections 1244, 1244.1, 1244.3, and 1244.4 in the California Business and Professions Code regulate NGHA programs.

### 3. Which method may be used to collect blood samples during a NGHA program?

If blood must be collected, it shall be obtained by the fingerstick method, not by venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.

### 4. What types of tests are considered nondiagnostic general health assessments?

Non-diagnostic general health assessments include total cholesterol, high-density lipoprotein (HDL), triglycerides, blood glucose, hemoglobin, dipstick urinalysis, fecal occult blood, urine pregnancy, and other tests in which the sample is tested onsite and results are provided on the same day at the same place where the test was administered. Some examples include:

- A cholesterol screening program held at a shopping mall and sponsored by a hospital, in which blood is collected by fingerstick and tested onsite using a portable machine.
- Glucose testing performed at a pharmacy in which blood is collected by fingerstick and tested onsite using a portable analyzer.
- Examination of stool for occult blood at a senior citizens' community center.

### 5. What types of programs are not classified as nondiagnostic general health assessments?

- Collection of blood by venipuncture at a shopping mall which is subsequently tested for glucose (or other components) at a licensed medical laboratory. (Note: this may be illegal in California unless the shopping mall location is approved as a blood drawing station.)
- Body Fat Content

- Blood Pressure Screening

6. I'm performing nondiagnostic general health assessments in your county, but I'm located in a different county. Do I still have to be licensed by your county?

Yes. It doesn't matter if you're located in a different county or state, if you are performing non-diagnostic general health assessments in Santa Clara County you must have an NGHAs license in Santa Clara County.

7. Are testing programs conducted at hospitals exempt from regulations relating to NGHAs programs?

Programs that meet the definition of NGHAs conducted by hospitals are NGHAs except:

- those where testing is performed within the hospital's licensed clinical laboratory
- those exempted by 1241 of the Business and Professions Code.

8. Are testing programs conducted at clinics NGHAs?

Testing programs conducted at licensed community clinics, free clinics, and employee clinics (as defined in subdivision (a) of Section 1204 of the California Health and Safety Code) are not NGHAs programs.

9. What must be done before a NGHAs program can be operated?

Necessary documentation must be filed with the local health officer (or his/her designee – in Santa Clara County the Public Health Laboratory Director) at least 30 days prior to the date the NGHAs will be operated. In most cases, a registration form together with supporting documents must be submitted.

10. Why do fees for operation of NGHAs programs differ among various counties?

Fees are calculated separately by each county or city health department using their own individual methods. Costs of operating programs may be high in some areas depending on the number and complexity of programs being regulated, number of personnel required, and size of geographic area covered.

11. Is a separate permit for transport and disposal of biomedical waste required?

Contact the Santa Clara County Department of Environmental health at 408.918.3400 for specific requirements.

12. Must NGHAs programs comply with CLIA '88?

Yes.

### 13. How do I apply for a nondiagnostic general health assessment license in Santa Clara County?

You can either contact the SCCPHL at 408.885.4272, or submit the following application.

### 14. What items must be submitted for a complete application?

- A completed application.
- Copies of CLIA certificate, clinical laboratory scientist current license, physician's current medical license, and certificates for all staff in instrument training and fingerstick.
- Policies and procedures manual containing biohazard/medical waste disposal plan, quality control and quality assurance plans with supporting QC and QA logs, emergency medical plan, instrument procedure manual for each analyte, and patient education & referral information sheets.
- Any applicable fees.

Please see the following pages for:

***NGHA Application***

***NGHA Checklist***

***NGHA Legal Statute***

Patricia A. Dadone, Director

**NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT APPLICATION (NGHA)**

This registration form must be completed and received by the Santa Clara County Public Health Laboratory *at least 30 days* prior to operation of a program of nondiagnostic general health assessment (NGHA).

Applications that are incomplete and/or failure to submit all required documents may result in delays in the processing of your application.

**PART 1: ADMINISTRATION**

**A. Name of Organization or Operator:** \_\_\_\_\_

Permanent Address: \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

CLIA #: \_\_\_\_\_ Exp.: \_\_\_\_\_

**B. Name of Owner:** \_\_\_\_\_

Address (if different than above): \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

**C. Supervisory Committee Members:**

**Name of Physician:** \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

CA Medical License #: \_\_\_\_\_ Exp.: \_\_\_\_\_

**Name of Clinical Laboratory Scientist:** \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

CA Clinical Laboratory Scientist License #: \_\_\_\_\_ Exp.: \_\_\_\_\_

**D. Record Storage:**

All operators must have a permanent address where records of testing and protocols shall be stored for the purpose of review for at least one year after testing has been completed. The Public Health laboratory must be notified in writing within 30 days of any change in record storage.

**Record Storage Address:** \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

**A. Location where assessment is to be performed (complete a separate Supplemental Form 2A for each additional location):**

Name of Location: \_\_\_\_\_

Permanent Address: \_\_\_\_\_

City

Zip Code

Business Phone: (      )      Fax: (      )

**B. Dates and hours program will be in operation at this location (attach additional sheets if necessary):**

Dates	Hours	Dates	Hours

Note: Any changes in times, dates or location must be reported in writing to the NGHHA program office at least 24 hours prior to the operation of the program.

**C. Nondiagnostic test being conducted at this location:**

( ✓ )	Test	Equipment Name	Manufacturer
<input type="checkbox"/>	Total Cholesterol		
<input type="checkbox"/>	High Density Lipoprotein (HDL)		
<input type="checkbox"/>	Triglycerides		
<input type="checkbox"/>	Blood Glucose		
<input type="checkbox"/>	Hemoglobin		
<input type="checkbox"/>	Dipstick Urinalysis		
<input type="checkbox"/>	Fecal Occult Blood		
<input type="checkbox"/>	Urine Pregnancy		
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

**D. List all employees for this location (attach additional sheets if necessary):**

Name	Title	( ✓ ) Authorized to perform skin puncture	
		Yes	No
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

Note: Submit documentation of authorization to perform skin puncture for each individual checked "Yes" above.

**For Official Use Only:**

Approved /Not Approved: \_\_\_\_\_

Date License Issued: \_\_\_\_\_

License No.: \_\_\_\_\_

Fee Received: \_\_\_\_\_

Date Fee Submitted: \_\_\_\_\_

Check No.: \_\_\_\_\_

**PART 3: COMPLIANCE**

A. This assessment program must be operated per Section 1244 of the California Business and Professions Code. Please answer each of the following questions. To comply with current California law, you must be able to answer yes to all questions and supportive documentation must be submitted with this application.

YES NO

- This program will be a nondiagnostic health assessment program (NGHA), whose purpose will be to refer individuals to licensed sources of care as indicated.
- This program will utilize only those devices, which comply with all of the following:
  - A. Meet applicable state and federal performance standards pursuant to Section 26605 of the Health and Safety Code.
  - B. Are not adulterated as specified in Article 2 (commencing with Section 26610) of Chapter 6 of Division 21 of the Health and Safety Code.
  - C. Are not misbranded as specified in Article 3 (commencing with Section 26630) of Chapter 6 of Division 21 of the Health and Safety Code.
  - D. Are not new devices unless they meet the requirements of Section 26670 of the Health and Safety Code.
- This program maintains a supervisory committee consisting of at a minimum, a California licensed physician and surgeon and a Laboratory Clinical Scientist licensed pursuant to the California Business and Professions Code.
- The supervisory committee for the program has adopted written protocols, which shall be followed in the program. (Include a copy of your written protocols with this application.)
- The protocols contain provisions of written information to individuals to be assessed. (Include a copy of all written information that will be provided to individuals as part of this program.)
- Written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program.
- Written information includes the limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.
- Written information includes information regarding the risk factors or markers targeted by the program.
- Written information includes the need for follow up with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.
- Written protocols contain the proper use of each devices utilized in the program. Protocols must include the operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.
- Written protocols contain the proper procedures to be employed when drawing blood, if blood specimens are to be obtained.
- Written protocols contain procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by biological specimens.
- Written protocols contain proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.
- Written protocols contain procedures for reporting of assessment results to the individual being assessed (please attach a copy of your report form).
- Written protocols contain procedures for referral and follow up to licensed sources of care as indicated.
- The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program during which period, they shall be subject to review by the county health officer or designee.

B. If a skin puncture to obtain a blood specimen is to be performed:

YES NO

[ ] [ ] The individual performing skin punctures shall be authorized to do via (a) their professional scope of practice or (b) meet California phlebotomy regulations as identified in the California Business and Professions Code, Sections 1242.5, 1246, and 1282.2; California Code of Regulations, Title 17, Sections 1029.31–1029.35, 1031.4, 1031.5, and 1034; and Health and Safety Code, Section 120580 and possess a current phlebotomy license issued by the CA Dept. of Public Health, Laboratory Field Services Program. (Documentation must be submitted with this application.)

[ ] [ ] It is understood that “skin puncture” as related to this program means the collection of a blood specimen by the finger stick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimens.

**PART 4: FEES (LICENSE VALID 7/01 – 6/30)**

- Annual fee: \$150
- Additional Site/day: \$25
- Additional Nondiagnostic Tests: \$25

**Make Checks Payable To:** Santa Clara County Public Health Laboratory

**Return Application To:** Santa Clara County Public Health Laboratory  
NGHA Program  
2220 Moorpark Ave, 2<sup>nd</sup> Floor  
San Jose, CA 95128

**PART 5: LICENSE**

The original license for the specific location address must be posted during operation of a nondiagnostic general health assessment program.

**Name of Person Requesting License:** \_\_\_\_\_

Address (if different than above): \_\_\_\_\_

\_\_\_\_\_ City \_\_\_\_\_ Zip Code \_\_\_\_\_  
Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

I certify that the above information is accurate and complete and that I am aware of the laws and regulations that apply to nondiagnostic testing in the State of California and in the County of Santa Clara in which testing is to be performed.

\_\_\_\_\_  
Applicant’s Signature

\_\_\_\_\_  
Date of Application

-----  
**FOR OFFICIAL USE ONLY**

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

License No.: \_\_\_\_\_

Date Issued: \_\_\_\_\_

Expiration Date: \_\_\_\_\_

Fees Received: \_\_\_\_\_

Date Received: \_\_\_\_\_

## RE: NGHA Check-off List

Prior to returning your application and support documentation, make sure all of these items are included (if all items are not included, your application will be returned):

**Application** (check only if all items in subset are completed)

- Application
- Any Applicable "Assessment Program" (Application Part 2) Requests (optional)

**Certificates and Licensure** (check only if all items in subset are completed)

- CLIA Certificate - Current
- Clinical Laboratory Scientist Current License
- Physician's Current Medical License
- Certificates / Licenses for Staff Performing Fingersticks \*
- Instrument Training Certificates on Staff

**Quality Control and Quality Assurance** (check only if all items in subset are completed)

- Quality Control and Quality Assurance Plans
- Blank Quality Control Logs
- Sample Quality Control Logs

**Plans and Manuals** (check only if all items in subset are completed)

- Instrument Procedure Manual for Each Analyte
- Biohazard/Medical Waste Disposal Plan
- Emergency Medical Plan
- Patient Education & Referral Information Sheets

**Miscellaneous and Fees** (check only if all items in subset are completed)

- Registration Fee of \$ \_\_\_\_\_
- Other \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\* As of April 2006 - Due to new regulations, the Santa Clara County Public Health Laboratory can only accept licenses / certificates for persons authorized by their scopes of practice, such as MD, CLB, CLS, PA, RN, LVN, and several others (not MA, CNA ,PCP or nursing/medical students) as proof of individual's ability to perform finger sticks.



## NGHA Legal Statute

### **1202.5. California Business and Professions Code**

(a) For purposes of this chapter "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208.

(b) For purposes of this chapter "HCFA" means the Health Care Financing Administration of the federal Department of Health and Human Services.

### **1204.**

As used in this chapter, "clinical laboratory scientist" means any person other than a licensed clinical laboratory bioanalyst or trainee who is licensed under Sections 1261 and 1262 to engage in clinical laboratory practice under the overall operation and administration of a laboratory director. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a "clinical laboratory scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

### **1206.5.**

(a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Section 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.
6. A person licensed under Chapter 6 (commencing with Section 2700).
7. A person licensed under Chapter 6.5 (commencing with Section 2840).
8. A perfusionist if authorized by and performed in compliance with Section 2590.
9. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
10. A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
11. A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.
12. Other health care personnel providing direct patient care.
13. Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.
6. A person licensed under Chapter 6 (commencing with Section 2700).
7. A perfusionist if authorized by and performed in compliance with Section 2590.
8. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
9. A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
10. Any person if performing blood gas analysis in compliance with Section 1245.

11.
  - a. A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
  - b. Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
12. Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall:
  - a. ensure that the person is performing test methods as required for accurate and reliable tests; and
  - b. have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
13. A pharmacist, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory

director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.
6. A perfusionist if authorized by and performed in compliance with Section 2590.
7. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
8. A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
9. Any person if performing blood gas analysis in compliance with Section 1245.
10. Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall:
  - a. ensure that the person is performing test methods as required for accurate and reliable tests; and
  - b. have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

1. A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
2. A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a

clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

3. A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

#### 1214.

As used in this chapter, "health fair" means a program of health assessment procedures offered to the general public that may include screening, self-ordered, or diagnostic clinical laboratory tests or examinations performed by a clinical laboratory licensed or registered under subdivision (a) of Section 1265 that meets all the requirements of this chapter.

#### 1244.

(a) Nothing in this chapter shall restrict, limit, or prevent a program of nondiagnostic general health assessment provided that:

1. The program meets the requirements of Section 1265 and complies with the requirements of CLIA for waived testing.
2. The purpose of the program is to screen asymptomatic individuals for chronic health disorders and to refer individuals to licensed sources of care as indicated.
3. The program does not test for human immunodeficiency virus or any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.
4. The program utilizes only those devices that comply with all of the following:
  - a. Meet all applicable state and federal performance standards pursuant to Section 111245 of the Health and Safety Code.
  - b. Are not adulterated as specified in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
  - c. Are not misbranded as specified in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
  - d. Are not new devices unless they meet the requirements of Section 111550 of the Health and Safety Code.
  - e. Are approved as waived tests and are used according to the manufacturer's instructions.
5. Blood collection is performed by skin puncture only.
6. Testing of a urine specimen is performed by the dipstick method only.
7. Testing is performed on site and reported directly to the person requesting the test.
8. The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to this code.
9. The supervisory committee for the program adopts written protocols that shall be followed in the program and that shall contain all of the following:

- a. Provision of written information to individuals to be assessed that shall include, but not be limited to, the following:
  - i. The potential risks and benefits of assessment procedures to be performed in the program.
  - ii. The limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.
  - iii. Information regarding the risk factors or markers targeted by the program.
  - iv. The need for followup with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.
- b. Proper use of each device utilized in the program including the operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.
- c. Proper procedures to be employed when collecting blood, if blood specimens are to be obtained.
- d. Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens. These procedures shall comply with all county and city ordinances for medical waste management and blood-borne pathogen control that apply to the location where the program operates.
- e. Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.
- f. Documentation that the testing personnel are following the instructions of the instrument's manufacturer, are trained in the performance of the test, and are competent to perform the testing without supervision.
- g. Reporting of assessment results to the individual being assessed.
- h. Referral and followup to licensed sources of care as indicated. The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program during which period they shall be subject to review by department personnel and the local health officer or his or her designee, including the public health laboratory director.

(b) If skin puncture to obtain a blood specimen is to be performed in a program of nondiagnostic general health assessment, the individual performing the skin puncture shall be authorized to perform skin puncture under this chapter.

(c) A program of nondiagnostic general health assessment that fails to meet the requirements set forth in subdivisions (a) and (b) shall not operate.

(d) For purposes of this section, "skin puncture" means the collection of a blood specimen by the finger prick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.

(e) Nothing in this chapter shall be interpreted as prohibiting a licensed clinical laboratory from operating a program of nondiagnostic general health assessment provided that the clinical laboratory complies with the requirements of this section.

(f) A program for a health fair providing diagnostic or screening tests is not a nondiagnostic general health assessment program if all of the requirements of this chapter are met, and the laboratory performing the testing is licensed or registered under subdivision (a) of Section 1265. For a test that is not authorized for self-ordering pursuant to Section 1246.5 and that is not for a nondiagnostic general health assessment pursuant to this section, the licensed or registered clinical laboratory participating in the health fair shall assure that the test is ordered on-site only by a person licensed under this division who is authorized under his or her scope of practice to order the test or by a person authorized by that licensee. The results of a test performed at a health fair shall be provided to the test subject along with an explanation of the results.

### **1244.1.**

Thirty days prior to operating a program of nondiagnostic general health assessment, the entity or person operating that program shall file the following documentation with the local health officer in each county in which the program shall operate:

(a) The location of the program, the type and kind of nondiagnostic general health assessments being conducted, the dates and times of operation of programs, and evidence that the program shall be operated in compliance with Section 1244.

(b) The local health officer shall be notified in writing of any changes to occur in locations, dates, or times indicated in the documentation required in subdivision (a). The local health officer shall be notified of any changes at least 24 hours prior to the program operating at the different locations, dates, or times.

### **1244.3.**

Responsibility for enforcement of Sections 1244 and 1244.1 shall be with the local health officer or his or her authorized designee, including public health laboratory directors. Nothing in this section shall prevent the department from using any necessary enforcement actions for the protection of the public health and safety.

### **1244.4.**

Any fee for the filing of documentation and related enforcement activities pursuant to Section 1244, 1244.1, and 1244.3 shall be determined by the local enforcement agency and shall not

exceed one hundred dollars (\$100) except that those fees shall be adjusted annually by any annual increase in the California Consumer Price Index as determined pursuant to Section 2212 of the Revenue and Taxation Code. All moneys collected as fees pursuant to this section shall be deposited in the appropriate city, county, or city and county treasury and shall only be expended in carrying out Sections 1244, 1244.1, and 1244.3.

#### **1246.5.**

Notwithstanding any other provision of law, any person may request, and any licensed clinical laboratory or public health laboratory may perform, the laboratory tests specified in this section. A registered clinical laboratory may perform the laboratory tests specified in this section if the test is subject to a certificate of waiver under CLIA and the laboratory has registered with the department under paragraph (2) of subdivision (a) of Section 1265. A program for nondiagnostic general health assessment that includes a laboratory test specified in this section shall comply with the provisions of Section 1244. The results from any test may be provided directly to the person requesting the test if the test is on or for his or her own body. These test results shall be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician and surgeon. The tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section.

#### **Section 1265. California Business and Professions Code**

(a)

1. A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.
2. A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may be required by the department. If the laboratory is performing tests subject to a provider performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

1. Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.
2. Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.
3. Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.
4. Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e)

1. A license or registration shall be valid for one year unless revoked or suspended. A clinical laboratory license or registration shall be automatically revoked 30 days from a major change of laboratory directorship or ownership. The clinical laboratory shall be required to submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice.
2. If a clinical laboratory intends to continue to engage in clinical laboratory practice during the 30 days after a major change in directorship occurs and before the laboratory license or registration is automatically revoked, the laboratory owner may appoint an interim director who meets the requirements of this chapter and CLIA. The interim director shall be appointed within five business days of the major change of the directorship. Written notice shall be provided to the department of the appointment of the laboratory director pursuant to this paragraph within five business days of the appointment.

(f) If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at his or her last known address.

(g) The department shall be notified in writing by the laboratory owners or delegated representatives of the owners and the laboratory directors of any change in ownership, directorship, name, or location, including the addition or deletion of laboratory owners or laboratory directors within 30 days. However, notice of change in ownership shall be the responsibility of both the current and new owners. Laboratory owners and directors to whom the current license or registration is issued shall remain jointly and severally responsible to the department for the operation, maintenance, and conduct of the clinical laboratory and for any violations of this chapter or the regulations adopted thereunder, including any failure to provide the notifications required by this subdivision, until proper notice is received by the department. In addition, failure of the laboratory owners and directors to notify the department within 30 days of any change in laboratory directors, including any additions or deletions, shall result in the automatic revocation of the clinical laboratory's license or registration.

(h) The withdrawal of an application for a license or registration or for a renewal of a license, or registration, issuable under this chapter, shall not, after the application has been filed with the department, deprive the department of its authority to institute or continue a proceeding against the applicant for denial of the license, registration, or renewal upon any ground provided by law or to enter an order denying the license, registration, or renewal upon any such ground, unless the department consents in writing to the withdrawal. (i) The suspension, expiration, or forfeiture by operation of law of a license or registration issued under this chapter, or its suspension, forfeiture, or cancellation by order of the department or by order of a court of law, or its surrender without the written consent of the department, shall not deprive the department of its authority to institute

or continue an action against a license or registration issued under this chapter or against the laboratory owner or laboratory director upon any ground provided by law or to enter an order suspending or revoking the license or registration issued under this chapter.

(i)

1. Whenever a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory ceases operation. For purposes of this subdivision, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.
2.
  - a. Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.
  - b. For purposes of this subdivision, "medical records" means the test requisition or test authorization, or the patient's chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.
  - c. For purposes of this subdivision, "laboratory records" means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.
  - d. Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.
3. The department or any person injured as a result of a laboratory's abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.



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