



LABORATORY SERVICES AND CLINICAL SPECIMEN COLLECTION MANUAL

COUNTY OF SAN DIEGO
HEALTH AND HUMAN SERVICES AGENCY
PUBLIC HEALTH SERVICES
PUBLIC HEALTH LABORATORY

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HOURS OF OPERATION:
8 AM - 5 PM, MONDAY - FRIDAY
HOURS OF SPECIMEN DROP OFF:
8 AM – 4:30 PM, MONDAY - FRIDAY

Accreditations:
CLIA: 05D0060808
State License Number: 1238
Federal Tax ID Number: 956000934
MediCare Number: 05L0009312
Medi-Cal Provider Number: LAB60808F
National Provider Number: 1144357948

PREFACE

The San Diego County Public Health Laboratory (SDPHL) mission is to provide quality laboratory services to protect community health and prevent the spread of disease. SDPHL provides reference and diagnostic laboratory services in Bacteriology, Mycobacteriology, Water Bacteriology, Food Bacteriology, Parasitology, Virology, and Serology. SDPHL is also involved in the investigation of disease outbreaks, including possible bioterrorism activities.

Our goal is to reduce morbidity and mortality by providing accurate, precise, and timely results that support Public Health programs, the Health and Human Services Agency, other LiveWell agencies and the medical and laboratory community of the County of San Diego.

Specimen collection is a critical initial step in laboratory diagnosis. Meaningful laboratory results require careful attention to the specimen source, the method of collection, the storage and transport, and timely delivery of the collected specimens. In addition, a completed test requisition with tentative diagnosis and relevant history is essential for optimal and efficient laboratory workup of the collected specimens.

This specimen collection manual is designed as a guide for physicians, nurses and other allied health personnel in charge of ordering, selecting and collecting specimens from patients. Should you need additional information, please feel free to contact us at 619-692-8500, option 1 or at phslaboratory.hhsa@sdcounty.ca.gov. The Public Health Laboratory is committed to providing excellent services to the healthcare and laboratory community.

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I. GENERAL INFORMATION

How to Use This Manual

Consult the Table of Contents to locate information on available tests performed at SDPHL. Each test will provide a detailed description of the test, test method, the types of specimens required, the storage and transportation conditions, the clinical significance of the test, and the turn around time for the test.

Directory of Administrative and Supervisory Staff

Name	Position	Sections
Brett Austin, MA	Laboratory Director	
Syreeta Steele, PhD	Assistant Laboratory Director	
Denise Porter	Administrative Secretary II	
Anna Liza Manlutac	Supervising Public Health Microbiologist	Virology, Serology, BT
Paul Temprendola	Supervising Public Health Microbiologist	Bacteriology, Mycobacteriology, Parasitology
Menka Asudani	Supervising Public Health Microbiologist	Specimen Receiving, LIMS
Thi Thi Van	Administrative Analyst III	Contracts, Purchasing & Finance

How to Obtain Specimen Collection Materials and Forms:

Available specimen mailers and forms may be requested by phone, fax, or email. Supplies can be picked up from specimen receiving one day after the request is submitted. Supplies can also be mailed upon request.

Additional lab supplies are available to the Public Health Services (PHS) clinics and County healthcare facilities. Supplies can be requested by completing a Laboratory Supplies Form indicating the quantity of each item needed, then faxing the request to (619) 692-8558. The most updated supply order form can be found at the SDPHL home page: https://www.sandiegocounty.gov/hhsa/programs/phs/phs_laboratory/

II. GENERAL GUIDELINES

A. Specimen Collection

1. Adhere to standard precautions when handling blood and body fluid specimens.
2. Obtain specimens prior to administering antimicrobial therapy.
3. Use sterile equipment and aseptic techniques for collecting specimens.
4. Obtain an appropriate specimen representative of the diseased site and avoid contamination of the specimen with microbial flora.
5. Collect specimen during the acute phase of the disease.

6. Collect an adequate quantity of specimen to permit complete testing.
7. Collect specimens in appropriate sturdy, leak-proof, screw-cap specimen containers, screw-cap transport tubes or appropriate blood collection tubes.
8. Take care not to contaminate outside surfaces of the specimen containers with the specimen.
9. Screw-cap specimen containers are to be sealed tightly to avoid leakage.

B. Test Requisition Forms

The most updated test requisition form can be found at SDPHL home page:

https://www.sandiegocounty.gov/hhsa/programs/phs/phs_laboratory/

All specimens must be accompanied by a completed test requisition form. Submit one test requisition form per specimen source. All mandatory (*) fields should be completed for the sample to be accepted by SDPHL. Additional patient information is appreciated, especially with viral and parasitology (including malaria) specimens. Travel history and symptoms are helpful in many instances.

Test requisition form comprises 3 sections:

1. Patient and Submitter Information
 - a. Patient name, patient address, identification number, date of birth, gender, pregnancy status, and ethnicity (if available)
 - b. Name and phone number of the ordering physician
 - c. Diagnosis code (ICD-10) related to the requested test
 - d. The submitter's facility name and address
 - e. Facility fax and phone number
 - f. Name and phone number of the person responsible for receiving the test result (if not the ordering provider)
 - i. Pertinent history (if available)
 - ii. In the case of zoonoses and unusual pathogens, include history of travel, exposure, risk factors or occupation of patient.
 - iii. In the case of foodborne illnesses, include symptoms, incubation period and type of food implicated.
 - iv. Any other relevant information that could affect the outcome of the test.
2. Specimen Information
 - a. Source of specimen
 - b. Date of specimen collection
3. Requested Test

C. Specimen Labeling

1. The submitter is responsible for correct labeling of submitted specimens. All specimens **must** be clearly identified with:
 - a. Patient name (last name and complete first name) and a unique patient identifier (UPI), when available. Examples of a unique patient identifier: the HIV antibody confidential form number, the detention center booking number or hospital medical record number. De-identified or confidential testing can be submitted with just a UPI, patient date of birth, date of specimen collection.
 - b. For viral load requests, the date of specimen collection and time of collection

- is required.
- c. Specimen source or body site, as appropriate.
2. All specimens must be accompanied by a completed test requisition form.

D. Specimen Packaging and Shipping

1. Package specimens according to federal regulations for [USPS](#), [IATA](#) and [DOT](#). Consult with your agency's biosafety coordinator or SDPHL for guidance. Please refer to Appendix 1 for examples.
2. Clinical samples are divided into three categories – Infectious Substance Category A, Biological Substance Category B, and Exempt. The definitions for these three categories can be found in the IATA Dangerous Goods Regulations (IATA 1.0) and the Code of Federal Regulations (49 CFR 100-200). A brief description is as follows:
 - a. Biological Substance – Category A (UN 2814)
Category A substance (pathogen or agent) is one that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans (UN2814) or animals (UN2900). Packaging rules for Category A substances are more stringent.
 - b. Biological Substance – Category B (UN 3373)
The majority of specimens will qualify as Category B, which are classified as substances which do not meet the criteria for inclusion in Category A. Category B is generally applicable for all clinical samples that are being shipped by common carrier for diagnostic purposes.
Typical examples include:
 - Clinical or patient specimens (blood, body fluids, excreta, secreta, swabs, blood, tissue)
 - Typical laboratory cultures of routinely encountered non-Category A microorganisms
 - c. Exempt - Samples known not to contain any agent capable of infecting humans or animals.
3. Transport specimens promptly to the laboratory at the appropriate temperature for the test being requested.
4. Use of County mail is not acceptable, since delivery often requires several days and the specimens may deteriorate before arrival.
5. The SDPHL supplies limited courier service for certain specimens. Please call 616-692-8500 for guidance.
6. Submit specimens to the SDPHL, during normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday. SDPHL is closed after-hours, weekends, and County-observed holidays. If a specimen needs to be delivered after hours, contact SDPHL **in advance** to make special arrangements.

Note: Specimens arriving in a box/container by a courier may be rejected if it is not properly labeled and addressed to SDPHL on the outside of the box/container.

E. Unacceptable Specimens

A list of criteria below for specimens that are lacking the proper identification or quality and can be rejected upon receipt:

1. Specimens lacking proper identification
 - a. It must be labelled with at least 2 of the following patient identifiers
 - i. First Name and Last Name
 - ii. Date of Birth
 - iii. Unique identifier
2. Specimens labeled with information that does not match information on the test request form
3. Specimen containers that are broken, leaking, or have evidence of contamination on outer surfaces or on the request form.
4. Specimens exceeding temperature or transport requirements for the specimen.
5. Specimens and requisition which are incompatible (i.e. urine specimen with requisition checked off for sputum).
6. Specimens received with no test requisition form. (The PHL will attempt contact the submitter to retrieve the missing test requisition.).
7. Hemolyzed or clotted blood specimens.

Notes:

- Samples will be considered unsatisfactory after a week if SDPHL does not receive all mandatory info for the test requisition.
- Cultures should not be submitted in Petri dishes (except for gonorrhea cultures submitted by the STD clinic at the Rosecrans location).

F. Receiving Test Results from the Public Health Laboratory

Any release by the laboratory of results or protected personal health information must comply with regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). By submitting samples for testing to the Public Health Laboratory the submitter is agreeing to accept and follow the Public Health Laboratory's reporting policies and HIPAA requirements.

Results will be sent to the responsible individual such as the ordering physician name or alternate contact name with phone and/or fax number listed on the test requisition. Results may also be sent to a pre-approved secure email.

G. Send-out and Referral Specimens

Referral testing through the California Department of Public Health (CDPH) or the Centers for Disease Control and Prevention (CDC) is available for certain bacterial, fungal, mycotic or viral diseases. Tests performed at CDPH and CDC may need pre-approval by the Epidemiology Program and either CDPH or CDC.

Tests that CDPH Microbial Diseases Laboratory performs can be found at <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/MDLServicesAndTestCatalog.aspx>

Tests that CDPH Viral and Rickettsial Diseases Laboratory performs can be found at

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/VRDL_Guidelines_for_Laboratory_Services.pdf

Test that the CDC performs can be found at
<https://www.cdc.gov/laboratory/specimen-submission/list.html>

For more information about send-outs please contact SDPHL.

I. Suspected Chemical or Biological Terrorism samples

Call SDPHL for instructions for the following organisms:

- *Bacillus anthracis*
- *Francisella tularensis*
- *Brucella sp.*
- *Yersinia pestis*
- *Burkholderia pseudomallei*
- *Burkholderia mallei*
- Ricin toxin

J. Water and Food samples

SDPHL has the ability to test water samples such as drinking water and recreational water for the presence of total coliforms, fecal coliforms, *E.coli*, and *Enterococci sp.*. Additionally, testing can be performed on food products that may be suspected of causing a foodborne outbreak. For collection of samples, please call the San Diego County Department of Environmental Health for guidance and instructions at 800-253-9933. To submit samples, please call SDPHL for more information.

San Diego County Public Health Laboratory

Suspected Agents of Bioterrorism from Sentinel Laboratories

CPT Code(s): N/A

Sentinel laboratories should consult with the San Diego County Public Health Laboratory (SDPHL) prior to, or concurrent with, testing if a bioterrorism (BT) agent is suspected. Immediately notify the SDPHL and the Epidemiology Program at (619)-692-8499 if a BT agent cannot be ruled out. Send isolate(s) to SDPHL immediately for rule-out or confirmatory testing. BT agents include: *Bacillus anthracis*, *Francisella tularensis*, *Brucella sp.*, *Yersinia pestis*, *Burkholderia pseudomallei*, *Burkholderia mallei*

Description of Test:

Qualitative detection of BT agents

Test Method:

Nucleic Acid Amplification Test following the Laboratory Response Network for bioterrorism protocols and culture identification using conventional biochemical methods.

Specimens:

Pure culture isolates in tubes of solid growth medium.

Storage and Transport Conditions:

Transport specimens at ambient temperature. Although the isolate is still presumptive, submitter is encouraged to follow Category A Shipping and Packaging instructions.

Clinical Significance/Interpretation:

Negative for all agents tested by PCR and TRF.
Positive-(organism) by real-time PCR and culture.

Days Test is Performed and Turn Around Time for Results:

Performed same day of receipt, otherwise determined on a case by case basis.

San Diego County Public Health Laboratory

Suspected Agents of Chemical Terrorism

CPT Code(s): N/A

Please notify San Diego County Public Health Laboratory (SDPHL) prior to submission of specimens. Decision will be made depending on the chemical emergency situation and the chemical involved.

Description of Test:

Test will be performed at the California Department of Public Health (CDPH) Drinking Water and Radiation Laboratory Branch and/or at Centers for Disease Control and Prevention (CDC).

Test Method:

State will decide the method depending on the presumptive agent being tested.

Acceptable specimens:

- Urine specimens from potentially exposed adults and children.
 - Collect at least 40-60 ml of urine. For each lot number of urine cups, please include two (2) empty, unopened urine cups as blanks for measuring background contamination. Note method of collection on the specimen cup (clean catch or catheterization). Freeze urine specimen as soon as possible (-70°C in a locked freezer).
- Blood specimens from **ADULTS ONLY** unless there is a specific instruction from CDC to collect blood from pediatric patients.
 - Collect a minimum 12 ml of blood; use three 4-ml or larger vacuum-fill only (unopened), non-gel, **purple-top (EDTA) tubes**. Alternatively, collect four tubes if using 3-ml tubes, plus one 3-ml or larger, vacuum-fill only, **non-gel, green or gray-top tube**.
 - For each lot number of tubes, include two (2) empty, unopened purple-top tubes and two (2) empty, unopened green or gray-top tubes as blanks for measuring background contamination.
 - Store blood tubes at 1°C-10°C.
 - Each specimen must be labeled with at least the following information: specimen identification number, collector's initials, and time and date of collection. Please do not include the patient's name.

Storage Transport Conditions:

Transport urine specimens in dry ice. Transport blood specimens on cool packs. Include Chain of Custody form with the submittal form. Follow Category B Packaging and Shipping instructions.

Clinical Significance/Interpretation:

Result language will be provided by CDPH or the CDC

Days Test is Performed and Turn Around Time for Results:

To be determined by CDPH or the CDC

Note: During a chemical threat or chemical exposure incident, you may be asked by public health or other authorities to collect specimens from persons exposed. Proper handling of these specimens will ensure that laboratory test results are meaningful, and if the exposure is caused by an intentional act, that the results can be used as evidence in court if needed.

San Diego County Public Health Laboratory

***Chlamydia trachomatis* and *Neisseria gonorrhoeae* NAAT**

CPT Code(s) 87491, 87591

Description of Test:

Automated qualitative nucleic acid amplification for the identification of *Chlamydia trachomatis* and *Neisseria gonorrhoea*

Test Method:

Nucleic Acid Amplification Test

Acceptable Specimens:

- Urine
 - Patients should not have urinated for at least 1 hour prior to specimen collection. Female patients should not cleanse the labial area prior to providing the specimen.
 - Urine must be submitted using the Aptima® [Urine Specimen Collection Kit](#). Follow instructions found in collection kit for detailed procedure. Brief instructions are as follows:
 - Instruct patient to provide **first-catch** urine sample (approximately 20-30 ml of the initial urine stream) into urine collection cup free of preservatives.
 - Transfer 2 ml of urine into Aptima® Urine transport tube within 24 hours of collection using disposable pipette provided. Ensure fluid level is between black fill lines on urine specimen transport tube label.
 - Urine specimens not transferred to the Aptima®® Urine Transport tube MUST be refrigerated and received by the Public Health Laboratory within 24 hours of collection.
- Endocervical swab
 - Swabs must be submitted using the Aptima® [Unisex Swab Specimen Collection Kit](#). Follow instructions found in collection kit for detailed procedure. Brief instructions are as follows:
 - Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical and surrounding mucosa. Discard this swab.
 - Insert collection swab (blue shaft swab with green printing) into endocervical canal and rotate swab clockwise for 10 to 30 seconds to ensure adequate sampling. Withdraw the swab carefully, avoiding any contact with vaginal mucosa.
 - Immediately place the swab into the transport tube.
 - After collection, swab must be transported and stored in the Aptima® Unisex Swab Specimen Collection Kit transport tube.

- Urethral swab
 - **Patient should not have urinated for at least 1 hour prior to specimen collection.**
 - Swabs must be submitted using the Aptima® [Unisex Swab Specimen Collection Kit](#). Follow instructions found in collection kit for detailed procedure. Brief instructions are as follows:
 - Insert the blue shaft swab into the urethra 2-4 cm and rotate clockwise for 2-3 seconds to ensure adequate sampling
 - Immediately place the swab in the Aptima® Unisex swab transport tube.
- Vaginal swab
 - Swabs must be submitted using the Aptima® [Multitest Swab Specimen Collection Kit](#). Follow instructions found in collection kit. Brief instructions are as follows:
 - Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
 - Immediately place the swab into the transport tube, without spilling the contents of the tube.
- Rectal swab
 - For patient-collected rectal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.
 - Swabs must be submitted using the Aptima® [Multitest Swab Specimen Collection Kit](#). Follow instructions found in collection kit. Brief instructions are as follows:
 - Holding the swab shaft below the score line, carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin and gently rotate the swab for 5 to 10 seconds. Withdraw the swab without touching the skin.
 - Immediately place the swab into the transport tube, without spilling the contents of the tube.

Note: This test is validated by SDPHL but not FDA approved.

- Throat swab
 - NOTE: For patient-collected throat swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit. Brief instructions are as follows:
 - Swabs must be submitted using the Aptima® [Multitest Swab Specimen Collection Kit](#). Follow instructions found in collection kit.
 - Holding the swab shaft below the score line, carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
 - Immediately place the swab into the transport tube, without spilling the contents of the tube.

Note: This test is validated by SDPHL but not FDA approved.

Storage and Transport Conditions:

Specimens must be transported to the laboratory in the provided swab specimen transport medium and tube at 2°C to 30°C until tested.

Urine specimens in primary containers must be transported to the laboratory at 2°C to 30°C and must be transferred into the Aptima® urine specimen transport tube within 24 hours of collection.

Swab specimens must be tested with the Aptima® assay for CT/GC within 60 days of collection, and processed urine specimens within 30 days of collection.

If longer storage is needed, freeze at -20°C to -70°C for up to 12 months after collection.

Clinical Significance/Interpretation of Laboratory Findings:

Negative- Negative by Nucleic Acid Amplification, *C. trachomatis* RNA and/or *N. gonorrhoeae* RNA not detected

Positive- *C. trachomatis* RNA and/or *N. gonorrhoeae* RNA detected

Equivocal- Indeterminate (specimen should be repeated)

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily, TAT=7 business days

San Diego County Public Health Laboratory

Cryptosporidium and Giardia DFA

CPT Code(s):87209, 87177

Description of Test:

Identification of *Cryptosporidium sp.* or *Giardia sp.* infection.

Test Method:

Microscopic examination utilizing a direct fluorescent antibody assay

Acceptable Specimens:

Stool samples preserved in Total-Fix™ Stool Collection System. (5) grams of specimen in each vial.

Storage and Transport Conditions:

Transport preserved specimens at room temperature.

Clinical Significance/Interpretation:

Negative for the presence of *Cryptosporidium sp.* or *Giardia sp.*

Positive for the presence of *Cryptosporidium sp.* or *Giardia sp.*

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=5 business days

San Diego County Public Health Laboratory

Enteric Pathogens Isolation

CPT Code(s): 87045, 87147

NOTE: This test can only be requested by the County of San Diego Epidemiology Program for patients who need clearance in sensitive occupations.

Description of Test:

Isolation and identification of enteric pathogens such as *Salmonella* sp., *Shigella* sp., *Campylobacter* sp., *E. coli* O157 and other shiga toxin-producing *E. coli*, *Vibrio* sp., and *Yersinia* sp.

Test Method:

Isolation by culture and identification using conventional biochemical, serological, or matrix-assisted laser desorption/ionization time of resolution (MALDI-TOF) techniques.

Acceptable Specimens:

- Feces submitted in Meridian Para-Pak C&S stool transport medium. The specimen is collected in a clean, dry container, transferred to the transport medium and mixed well. A vial of Meridian Para-Pak C&S transport medium filled $\frac{1}{2}$ to $\frac{3}{4}$ full. Do not exceed the fill volume line.
- Unpreserved or fresh stool must be cultured within **2 hours** of collection.

Storage and Transport Conditions:

Keep samples placed in Para-Pak C&S at room temperature. Unpreserved or fresh stool specimens must be kept cold and received by the lab within 2 hours of collection. Specimens in transport medium must be received by SDPHL within 3 days (72 hours) of collection.

Clinical Significance/Interpretation:

Negative – Negative for (organism).

Positive – (organism) isolated.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=2-5 business days, except *Campylobacter* sp. which is up to 14 days

Note: Positive samples and/or isolates may be sent for further testing to the CA State Microbial Diseases Laboratory, 850 Marina Bay Parkway, Richmond, CA 94804.

Specimens sent to the CA State Microbial Diseases Laboratory for additional testing can take several weeks to receive final results.

San Diego County Public Health Laboratory

Enteric Pathogens Confirmation

CPT Code(s): NA

NOTE: Per Title 17, California Code of Regulations, Section 2505, enteric organisms (*Salmonella* sp. isolates, *Shigella* sp. isolates, and Shiga-toxin producing *E. coli* (STEC) including O157 and non-O157 isolates) are required to be sent to a SDPHL. In Subsection (m)(3), if a laboratory test results indicates infection with the aforementioned pathogens, then the testing laboratory shall take steps necessary to obtain an isolate.

Test Method:

Culture and identification using conventional biochemical, serological, or matrix-assisted laser desorption/ionization time of resolution (MALDI-TOF) techniques.

Acceptable Specimens:

- Isolates on a nutrient agar slant (i.e. tryptic soy agar or brain heart infusion agar)
- Shiga toxin positive GN broth for STEC's

Storage and Transport Conditions:

Slants can be held at 4-25°C for up to 7 days. STEC broths should be refrigerated at 2-8°C and tested within three days.

Clinical Significance/Interpretation:

Negative – Negative for (organism).

Positive – (organism) isolated.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=5 business days

Note: Positive samples and/or isolates may be sent for further testing to the CA State Microbial Diseases Laboratory, 850 Marina Bay Parkway, Richmond, CA 94804.

Specimens sent to the CA State Microbial Diseases Laboratory for additional testing can take several weeks to receive final results.

San Diego County Public Health Laboratory

Hepatitis B Core Antibody Total Reflex Panel

CPT Code(s): 86704, 87340, 87341, 86706

Description of Test:

This is a chemiluminescent microparticle immunoassay (CIA) for the detection of antibody to hepatitis B virus (anti-HCV) in human serum and plasma.

Test Method:

Immunoassay

Acceptable Specimens:

- Serum collected in either red-top or serum separator tubes, with no anticoagulants.
 - Allow blood to clot at room temperature and separate serum from cells within 6 hours of collection.
 - Minimum volume of 1 ml of serum
- Performance has not been established using cadaver specimens or other body fluids other than human serum or plasma.
- Serum specimens should be free of fibrin, red blood cells, or other particulate matters.
 - Such specimens if collected, must be transferred to a centrifuge tube and centrifuged at least 10,000 RCF (Relative Centrifugal Force) for 10 minutes.
- Any specimen received with the following conditions will be rejected.
 - Heat-inactivated
 - Pooled samples
 - Grossly hemolyzed
 - Obvious microbial contamination

Storage and Transport Conditions:

- Specimens may be shipped ambient, at 2-8°C (wet ice or cold packs), or -20°C or colder (dry ice). Prior to shipment, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
- Serum specimens should be stored for no longer than 3 days at room temperature or 7 days at 2 to 8°C following specimen collection.
- If a storage period ≥ 7 days is anticipated, the specimen should be removed from the clot, red blood cells, or separator gel, and stored frozen at $\leq -20^\circ\text{C}$.

Clinical Significance/Interpretation:

- Hepatitis B Core Antibody Total
 - Reactive- Anti-HBc antibodies were detected in the sample which suggests either an on-going or previous HBV infection.
 - Nonreactive- Anti-HBc antibodies were not detected in the sample.
 - Gray Zone- Gray Zone

- Indeterminate- Indeterminate
- Anti-Hepatitis B surface Ag Quantitative
 - Reactive- Individual is considered immune to HBV infection
 - Nonreactive- Individual is considered not immune to HBV infection
 - Gray Zone- Gray Zone
 - Inconclusive- The immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information
- Hepatitis B Surface Ag Qualitative
 - Reactive- HBsAg Confirmatory assay to follow
 - Nonreactive- The specimen is considered negative for HBsAg
- Hepatitis B Surface Ag Qualitative Confirmatory
 - Reactive- Confirmed Positive: the presence of HBsAg was confirmed via neutralization
 - Nonreactive- The presence of HBsAg cannot be confirmed via neutralization

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed 3 times a week, TAT=7 business days

San Diego County Public Health Laboratory

Hepatitis C Antibody Reflex Panel

CPT Code(s): 87522

Description of Test:

This is a chemiluminescent microparticle immunoassay (CIA) for the detection of antibody to hepatitis C virus (anti-HCV) in human serum and plasma.

Test Method:

Immunoassay

Acceptable Specimens:

- Serum collected in either red-top or serum separator tubes, with no anticoagulants.
 - Allow blood to clot at room temperature and separate serum from cells within 6 hours of collection.
 - Minimum volume of 1 ml of serum
- Performance has not been established using cadaver specimens or other body fluids other than human serum or plasma.
- Serum specimens should be free of fibrin, red blood cells, or other particulate matters.
 - Such specimens if collected, must be transferred to a centrifuge tube and centrifuged at least 10,000 RCF (Relative Centrifugal Force) for 10 minutes.
- Any specimen received with the following conditions will be rejected.
 - Heat-inactivated
 - Pooled samples
 - Grossly hemolyzed
 - Obvious microbial contamination

Storage and Transport Conditions:

- Specimens may be shipped ambient, at 2-8°C (wet ice or cold packs), or -20°C or colder (dry ice). Prior to shipment, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
- Serum specimens should be stored for no longer than 3 days at room temperature or 7 days at 2 to 8°C following specimen collection.
- If a storage period ≥ 7 days is anticipated, the specimen should be removed from the clot, red blood cells, or separator gel, and stored frozen at $\leq -20^\circ\text{C}$.

Clinical Significance/Interpretation:

Non-reactive- Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV.

Reactive- Presumptive evidence of antibodies to HCV.

Equivocal- Antibodies to HCV may or may not be present; another specimen should be obtained from the individual for further testing.

Gray Zone- Antibodies to HCV may or may not be present; another specimen should be obtained from the individual for further testing.

Days Test is Performed and Turn Around Time (TAT) for Results:
Performed 3 times a week, TAT=7 business days

San Diego County Public Health Laboratory

Hepatitis A PCR

CPT Code(s): 87801

NOTE: This test can only be requested by the County of San Diego County Epidemiology Program

Description of Test:

For acute screening of Hepatitis A infection by detection of nucleic acid.

Test Method:

Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

Serum specimens from serum separator tubes (SST), 2 SSTs are required. Collect appropriate specimens using accepted collection methods in blood collection tubes.

Storage and Transport Conditions:

- Specimens must be transported at 4-25 °C.
- Blood collection tubes must be separated using a centrifuge at 2500 rpm for 10 minutes. Aliquot serum into 2 mL sarstedt tubes and stored at -80°C until it is tested.

Clinical Significance/Interpretation:

Negative-No Hepatitis A nucleic acid detected.

Positive- Hepatitis A nucleic acid detected.

Inconclusive- No nucleic acid obtainable from specimen. Resubmit new specimen if possible.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed on Tuesdays, TAT=7 business days or as needed

Note: Hepatitis A genotyping will be performed if Hepatitis A RNA is detected.

San Diego County Public Health Laboratory

HIV-1 Quantitative Viral Load

CPT Code(s):87536

Description of Test:

Quantitation of HIV-1 RNA copies.

Test Method:

Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

Plasma collected in K₂ EDTA Plasma Preparation Tubes (PPT) with gel barrier with a minimum volume of 2.5 mL.

Storage and Transport Conditions:

Keep specimen cool (2 to 8°C) and transport on cool packs.

- Freshly drawn specimens (whole blood) prior to centrifugation may be held at 15-30°C for up to 6 hours, or at 2-8°C for up to 24 hours.
- After centrifugation and separation from cells with the gel barrier, the plasma specimen may be stored at
 - 15-30°C for up to 24 hours
 - 2-8°C for up to 5 days.
 - -20°C for up to 60 days
 - <- 70°C for >60 days

Clinical Significance/Interpretation:

Results are reported as the number of copies of HIV RNA per milliliter of blood

NOTE: limit of detection is 40 – 10M copies per ml of blood

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed once a week, TAT=14 business days

San Diego County Public Health Laboratory

HIV-1/2 Antibody & HIV-1 p24 Antigen Combo Assay

CPT Code(s): 87389

Description of Test:

The chemiluminescence immunoassay (CIA) is a qualitative screening assay for HIV-1 antibodies, HIV-2 antibodies and HIV-1 p24 antigen.

Test Method:

Immunoassay

Acceptable Specimens:

- Serum collected in either red-top or serum separator tubes.
 - Minimum volume of 1 ml of serum or, 2 ml of whole blood is required.
- Specimens maybe collected from pediatric patients (as young as 2 years old) and pregnant women.
- Specimens should be free of fibrin, red blood cells and other particulate matter. Any specimen received with the following conditions will be rejected.
 - Heat-inactivated
 - Pooled samples
 - Grossly hemolyzed
 - Obvious microbial contamination

Storage and Transport Conditions:

- Specimens may be transported at room temperature or with cool packs.
- Serum specimens should be stored for no longer than 3 days at room temperature or 7 days at 2 to 8°C following specimen collection.
- If a storage period of greater than 7 days is anticipated, the specimen should be removed from the clot, red blood cells, or separator gel, and stored frozen at $\leq -20^{\circ}\text{C}$.

Clinical Significance/Interpretation:

Non-reactive- HIV-1 p24 Antigen and HIV-1/HIV-2 Antibodies not detected

Reactive- HIV-1 p24 Antigen and/or HIV-1/HIV-2 Antibodies detected

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily, TAT=7 business days

San Diego County Public Health Laboratory

HIV-1/HIV-2 Confirmatory Test

CPT Code(s): 86701

Description of Test:

A qualitative assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2 in whole blood or serum specimens

Test Method:

Immunochromatographic Assay

Acceptable Specimens:

Serum sample collected in serum separator tube or red top tubes.

Storage and Transport Conditions:

- Serum may be stored at 2°C to 8°C for 7 days
- Transport blood and/or serum at 4-25°C.
- Samples should be frozen at $\leq -20^{\circ}\text{C}$ for long term storage

Clinical Significance/Interpretation:

Non-reactive- HIV-1 p24 Antigen and HIV-1/HIV-2 Ab not detected

Reactive- HIV-1 p24 Antigen and/or HIV-1/HIV-2 Ab detected

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily for reactive specimens, TAT=3 business days

San Diego County Public Health Laboratory

HSV 1 & HSV 2 NAAT

CPT Code(s): 87529

Description of Test:

Automated qualitative nucleic acid amplification for the primary diagnosis of HSV-1 and HSV-2

Test Method:

Nucleic Acid Amplification Test

Acceptable Specimens:

Swab specimens from anogenital and oral lesions in Aptima® Multitest Swab Specimen collection tube containing STM (Specimen Transport Medium), or in commercially available Viral/Universal Transport Medium (VTM/UTM)

- If vesicles are present, open vesicle and soak Dacron swab with fluid. **Do not use calcium alginate swabs or swabs with wooden shafts.**
- If crusted lesions are present, unroof lesions, scrape the base of the open vesicles with a sterile scalpel blade or rub the base of vesicles vigorously with swab to obtain a sample of the infected cells.
- Place specimen in sterile screw cap tube containing viral transport medium and break off swab shaft.

NOTE: The Aptima® HSV 1 and 2 assay is not FDA cleared for swab specimens from oral lesions. This assay was validated and its performance characteristics determined by San Diego County Public Health Laboratory.

Transport and Storage Conditions:

- Swab specimens collected using the Aptima® [Multitest Swab Specimen Collection Kit](#)
 - Swab specimens must be transported at 2°C to 30°C. Specimens may be stored at 2°C to 30°C or at -20°C to -70°C until tested.
 - Specimens must be tested within 36 days of collections.
 - Specimens may be frozen and thawed up to 3 times prior to testing.
- Swab specimens collected using a VTM/UTM collection kit
 - Swab specimens collected in VTM must be transported at 2°C to 8°C.
 - Specimens must be stored by the submitter at 2°C to 8°C or at -20°C to -70°C prior to arrival in the laboratory.
 - Specimens must be transferred to an Aptima® Multitest Swab Transport Media tube within 5 days of specimen collection.
 - Transferred specimens may be stored at 2°C to 30°C; specimens stored at this temperature must be tested within 30 days of collection.

- Transferred specimens may also be stored at -20°C to -70°C; specimens stored at this temperature must be tested within 36 days of collection.

Clinical Significance/Interpretation:

Negative- No HSV-1 mRNA detected or - No HSV-2 mRNA detected

Positive- HSV-1 positive; HSV-1 mRNA detected of HSV-2 positive; HSV-2 mRNA detected

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed twice a week, TAT=7 business days

San Diego County Public Health Laboratory

Influenza PCR and Subtyping

CPT Code(s): 87801

Description of Test:

Detection of Influenza A or B RNA followed by the identification of the subtype.

Test Method:

Real-time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

- Upper respiratory tract specimens including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirate, nasal wash, dual nasopharyngeal swab/throat swab
- Lower respiratory tract specimens including bronchioalveolar lavage, bronchial wash, tracheal aspirate, sputum, lung tissue

Collection, Transport and Storage Conditions:

- Swab specimens must be collected using only swabs with a synthetic tip, such as nylon, or Dacron®, and an aluminum or plastic shaft. **Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.**
- Specimens should be stored refrigerated (2-8°C) for up to 72 hours before processing and must be transported in VTM at 2-8°C.
- If unable to transport or process within 72 hours after collection, freeze at ≤ -70°C and transport frozen. Please note it on the requisition form if the sample has been frozen.
- Specimens >5 days old, not frozen will not be tested and will be reported as Unsatisfactory, too old to test

Clinical Significance/Interpretation:

No Influenza A or B nucleic acid detected by PCR.

Influenza A or B (subtype/lineage) nucleic acid detected by PCR.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received for congregate settings (outbreaks), TAT= 1 day

Performed when received for non-outbreaks settings, TAT= 4 days

Performed as needed outside of the Influenza season, TAT=7 days.

San Diego County Public Health Laboratory

Malaria and Blood Parasites Identification

CPT Code(s):87207

Description of Test:

Confirmation of parasite

Test Method:

Microscopic examination of Giemsa-stained blood smears

Acceptable Specimens:

- Thick and thin blood smears positive for malaria or other blood parasites sent for confirmation by clinical laboratories under California Code of Regulations, Title 17, Section 2505. Stained or unstained thick and thin blood smears and any remaining blood in EDTA tubes.
- Whole blood in tubes containing EDTA

Storage and Transport Conditions:

Place glass slides in slide mailer and transport at room temperature. Place EDTA and heparinized whole blood tubes in blood mailer and send to the laboratory immediately at 25°C.

Clinical Significance/Interpretation:

Negative-No malaria or other blood parasites seen

Positive- (organism) seen by microscopic exam

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=1 business day for *Plasmodium sp.* and *Babesia sp.*

San Diego County Public Health Laboratory

Measles PCR

CPT Code(s): 87798

NOTE: All requests for measles testing must be first assessed for the epidemiologic and clinical history. Test must be approved by the Immunization Program staff or medical director at 866-358-2966. Please call for after hours assessments at 858-565-5255.

Description of Test:

This assay is utilized for detection of measles virus nucleic acids in cases associated with rash-related respiratory disease.

Test Method:

Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

- Respiratory swabs
 - Nasopharyngeal swabs
 - Nasal aspirates
 - Oropharyngeal (Throat) swabs
- Urine from a first morning voided specimen collected up to 10 days after rash onset
 - Collect as much as 50-100ml (no minimum amount)
 - Urine specimen must be shipped within 24 hours of collection.
 - DO NOT freeze the urine specimen. The entire specimen must be stored at 4°C and shipped on cold pack

NOTE: Swab specimens must be collected using only swabs with a synthetic tip, such as nylon, or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.

Storage and Transport Conditions:

Swab specimens in Viral Transport Media (VTM) can be stored refrigerated (2-8°C) for up to 72 hours from the time of collection before testing. If unable to transport within 72 hours after collection, freeze at ≤ -70°C and transport frozen and keep frozen at ≤ -70°C until testing. Specimens should be transported on ice packs to the laboratory.

Clinical Significance/Interpretation:

Negative- No measles nucleic acid detected by PCR.

Positive- Measles nucleic acid detected by PCR.

Inconclusive- RNase P not detected which indicated absence of sufficient human cells in sample due to poor collection or loss of specimen integrity. Please collect another specimen for repeat testing.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=1 business day

Note: Testing can be performed the same day if specimen is received in the laboratory by 11:00 am that day.

San Diego County Public Health Laboratory

Measles (Rubeola) IgG CIA Assay

CPT Code(s): 86765

Description of Test:

The chemiluminescence immunoassay (CIA) is a qualitative determination of specific IgG to measles virus.

Test Method:

Immunoassay

Acceptable Specimens:

- Serum collected in either red-top or serum separator tubes.
 - Minimum volume of 1 ml of serum
- Specimens should be free of particulate matter, turbidity, lipemia, or erythrocyte debris. Any specimen received with the following conditions will be rejected.
 - Grossly hemolyzed
 - Obvious microbial contamination

Storage and Transport Conditions:

- Specimens may be transported at room temperature or with cool packs.
- Serum specimens should be stored for no longer than 3 days at room temperature or 7 days at 2 to 8°C following specimen collection.
- If a storage period of greater than 7 days is anticipated, the specimen should be removed from the clot, red blood cells, or separator gel, and stored frozen at $\leq -20^{\circ}\text{C}$.

Clinical Significance/Interpretation:

Negative- Absence of detectable measles virus IgG antibodies

Positive- Presence of detectable measles virus IgG antibodies

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT= 3 business days

San Diego County Public Health Laboratory

Mumps PCR

CPT Code(s): 87798

NOTE: All requests for mumps testing must be first assessed for the epidemiologic and clinical history. Test must be approved by the Immunization Program staff or medical director at 866-358-2966. Please call for after hours assessments at 858-565-5255.

Description of Test:

This assay detects mumps virus in buccal and oropharyngeal specimens

Test Method:

Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

- Buccal (inside of the cheek) swabs
- Oropharyngeal (Throat) swabs

Collect specimen as soon as mumps is suspected. Massage the parotid gland (the space near the upper rear molars between the cheek and teeth) for 30 seconds, then vigorously swab the parotid area with sterile synthetic swab. Place swab into 2-3 ml of liquid viral or universal transport medium (VTM/UTM).

NOTE: Swab specimens must be collected using only swabs with a synthetic tip, such as nylon, or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are not acceptable and cotton swabs with wooden shafts are not recommended.

Storage and Transport Conditions:

Specimens must be transported in UTM at 2-8°C and should be stored refrigerated (2-8°C) for up to 72 hours before processing. If unable to transport or process within 72 hours after collection, freeze at ≤ -70°C and transport frozen and keep frozen at ≤ -70°C until processing.

Clinical Significance/Interpretation:

Negative- No mumps nucleic acid detected by PCR.

Positive- Mumps nucleic acid detected by PCR.

Inconclusive- RNase P not detected which indicated absence of sufficient human cells in sample due to poor collection or loss of specimen integrity. Please collect another specimen for repeat testing.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed twice a week, TAT=2 business days

San Diego County Public Health Laboratory

Coccidian Identification

CPT Code(s):87207

Description of Test:

Confirmation of *Cyclospora* sp., *Isospora* sp., and *Cryptosporidium* sp.

Test Method:

Microscopic examination of acid fast stained stool sediment

Acceptable Specimens:

- Total-Fix™ preserved stool
- Centrifuged duodenal fluid, bile, or pulmonary (induced sputum, bronchial washings, and biopsy specimens)

Storage and Transport Conditions:

Transport at room temperature in Total-Fix™ preservative and send to the laboratory within 5 days of collection.

Clinical Significance/Interpretation:

Negative-No __(organism)__ seen

Positive- __(organism)__ seen by microscopic examination

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=5 business days

San Diego County Public Health Laboratory

Miscellaneous Bacteria Confirmation

CPT Code(s):87070, 87071

Description of Test:

Confirmation of aerobic organisms

Test Method:

Culture and identification using conventional biochemical, serological, or matrix-assisted laser desorption/ionization time of resolution (MALDI-TOF) techniques.

Acceptable Specimens:

Isolates on a nutrient agar slant

Storage and Transport Conditions:

Slants can be held at 4-25°C for up to 14 days except for *Neisseria sp.* and *Haemophilus sp.* which must be 24 hours old upon receipt.

Clinical Significance/Interpretation:

Negative – No growth

Positive – (organism) isolated by culture.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=14 business days

San Diego County Public Health Laboratory

Acid Fast Bacillus (AFB) Smear with Mycobacteria Culture and Susceptibility

CPT Code(s): 87206, 87116, 87188

Description of Test:

AFB smear and identification by culture and NAAT for *Mycobacterium tuberculosis* complex (MTBC). Culture of MTBC is performed using both liquid and solid media. Susceptibility is performed on MTBC by MGIT broth-based method with isoniazid (INH), rifampin, ethambutol, and pyrazinamide (PZA) on first isolate and after 3 months if culture is still positive.

Test Method:

MTB/RIF Assay is automatically performed on the first AFB positive primary sediment from a patient and on *Mycobacterium sp.* isolates. Specimens are inoculated in mycobacterial growth indicator tube (MGIT) liquid-based assay. Decontamination and concentration of AFBs followed by a fluorochrome stain and MTBC/RIF assay may be performed upon request on a smear negative sediment. Susceptibility is reflexively performed on the first positive MTBC cultures from a patient via broth-based method.

Acceptable Specimens:

- Sputum expectorated- minimum volume is 3 mL. Do not pool multiple specimens
- Induced sputum
- Gastric lavage fluid- 10 mL minimum
- Urine- 10 mL minimum
- Stool- 1 gram minimum
- Tissue- submit in 2-3 mL of sterile saline
- Body fluids- 10 mL minimum

Storage and Transport Conditions:

Sputum and other specimens should be stored at 2-8°C and received in the lab within five (5) day of collection. Transport specimens at 2-8°C.

Clinical Significance/Interpretation:

- Smears
 - Negative- no acid-fast organisms isolated.
 - Positive- 1+ (1-9 per 10 fields), 2+(1-9 per field), 3+(10-90 per field), 4+(>90 per 10 field)
- Primary sediments
 - Negative- MTB Not Detected
 - Positive- MTB DETECTED; RIF Resistance DETECTED

- Positive- MTB DETECTED; RIF Resistance INDETERMINATE
- Positive- MTB DETECTED; RIF Resistance NOT DETECTED
- Cultures
 - Negative- MTB Not Detected
 - Positive- MTB DETECTED; RIF Resistance DETECTED
 - Positive- MTB DETECTED; RIF Resistance INDETERMINATE
 - Positive- MTB DETECTED; RIF Resistance NOT DETECTED

Days Test is Performed and Turn Around Time (TAT) for Results:

- Smears- Performed daily, TAT=Same day when received by 9 am Monday-Thursday and by 12 pm on Friday.
- Cultures – Performed daily, TAT=6 -8 weeks or up to 10 weeks by request
- MTB/RIF Assay – Performed as needed, TAT=1 business days

NOTE: If RIF resistance is detected, the isolate is sent to the California Department of Public Health (CDPH) for pyrosequencing (PSQ) confirmation.

San Diego County Public Health Laboratory

Mycobacterium tuberculosis Complex /Rifampin Susceptibility PCR Assay

CPT Code(s): 87556, 87798

Description of Test:

This assay simultaneously detects the presence of the *M. tuberculosis* complex (MTBC) and rifampin resistance associated gene directly from processed sediment from respiratory specimens or culture isolates.

Test Method:

A multiplexed nucleic acid amplification test that detects the presence of MTBC DNA and mutations of the *rpoB* gene that is associated with rifampin resistance.

Acceptable Specimens:

- A minimum 1.0 mL sediment sample from acid fast bacillus (AFB) smear-positive respiratory samples that have been processed using the NaLC-NaOH method of Kent and Kubica.
- Smear negative respiratory samples may be tested; however, this method is less sensitive than other available methods.

Storage and Transport Conditions:

- Processed sediments less than ≤5 days old transported at 2-8°C.
- Isolates and broth cultures can be transported at 25°C.

Clinical Significance/Interpretation:

Negative- MTB Not Detected

Positive- MTB DETECTED; RIF Resistance DETECTED

Positive- MTB DETECTED; RIF Resistance INDETERMINATE

Positive- MTB DETECTED; RIF Resistance NOT DETECTED

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed as needed, TAT=1 business day

NOTE: If RIF resistance is detected, the isolate is sent to the California Department of Public Health (CDPH) for pyrosequencing (PSQ) confirmation.

San Diego County Public Health Laboratory

Mycobacterium – Primary Susceptibility Panel

CPT Code(s): 87188

Description of Test:

Susceptibility performed on Mycobacteria tuberculosis complex (MTBC) by mycobacterium growth indicator tube (MGIT) broth-based method with primary drugs isoniazid (INH), rifampin, ethambutol, and pyrazinamide (PZA). Testing is permitted on a patient once every 3 months.

Test Method:

Broth based susceptibility for Ethambutol, Isoniazid, Rifampin, PZA

Acceptable Specimens:

Pure mycobacterial isolate on Lowenstein Jensen (LJ) or Middlebrook slant. Minimum of 1+ growth on slant required.

Storage and Transport Conditions:

Room temperature – two months

Clinical Significance/Interpretation:

Rifampin (1 µg/mL)- sensitive or resistant
Isoniazid (0.1 µg/mL)- sensitive or resistant
Isoniazid (0.4µg/mL)- sensitive or resistant
PZA (100 µg/mL)- sensitive or resistant
Ethambutol (5 µg/mL)- sensitive or resistant

NOTES:

- Specimens resistant to Isoniazid and Rifampin are sent to the California Department of Public Health (CDPH) at the request of the submitter.
- Specimens requiring second line antimicrobial testing are forwarded to the CDPH at the request of the submitter.
- Specimens requiring linezolid and cycloserine susceptibilities are sent to National Jewish at the request of the submitter.
- Specimens that require MDDR testing are sent to the CDC at the request of the submitter after approval is received from the CDC.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed twice a week, TAT=4 weeks

San Diego County Public Health Laboratory

Neisseria gonorrhoeae STAT Gram Stains and culture

CPT Code(s):87081, 87077

Note: Samples for culture are accepted only from County Health Providers.

Description of Test:

Gram stain for identification of morphologic characteristics of *N. gonorrhoeae* (i.e. presence of intracellular gram negative diplococci) and/or isolation of *N. gonorrhoeae* by conventional culture techniques.

Test Method:

Microscopic examination and identification by convention biochemical and/or matrix-assisted laser desorption/ionization time of resolution (MALDI-TOF).

Acceptable Specimen Sources:

- Cervix
- Throat
- Urethra
- Rectum
- Eye

For smears, expressed pus for gram stain from a swab of the male urethra. For culture, collect the sample using a Dacron swab and immediately inoculate the specimen onto room-temperature Modified Thayer-Martin medium by rolling swab in parallel streaks, or in a "Z" pattern, on surface of the medium plate.

Storage and Transport Conditions:

Smears can be held at 25°C after air-drying

Clinical Significance/Interpretation:

- Gram Stain
 - Negative- No intracellular Gram-negative diplococci seen
 - Positive- Gram-negative, intracellular diplococci seen
 - Doubtful- Extracellular gram negative diplococci seen
 - WBC Quantification- None, Rare 0-1/field, Few 1-4/field, Moderate 5-9/field, Many >10/field
- Culture
 - Negative for *Neisseria gonorrhoeae* by culture
 - Positive- *Neisseria gonorrhoeae* isolated by culture

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily, TAT=30 minutes for gram stain

Performed daily, TAT=5 business days for culture

San Diego County Public Health Laboratory

Norovirus PCR

CPT Code(s): 87798

NOTE: This test can only be requested by the County of San Diego Epidemiology Program. Testing will be performed on a minimum of 2 patient specimens from a single outbreak.

Description of Test:

Detection of Norovirus in stool specimens

Test Method:

Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

Stool sample obtained during the acute phase of illness (within 8-72 hours of diarrhea onset). A minimum of 1 gram (walnut-size sample) unpreserved stool in sterile screw-capped container.) while the stools are still liquid or semi-solid.

- Stool collected in Para-pak C & S medium is acceptable
- Rectal swabs are not satisfactory since the quantity of virus shed may not be adequate.
- Vomitus although has not been validated in our laboratory is an acceptable sample for norovirus testing.
- Single stool samples will not be tested. Positive or negative results will not be meaningful.
- Testing of asymptomatic cases is not encouraged without prior consultation.
- Food, water, or environmental samples are not acceptable.

Storage and Transport Conditions:

- Stool specimens should be kept at 4°C or below after collection to prevent degradation, desiccation, and mold growth.
- Stool specimens are stable at 2-8°C for up to 5 days after collection. If unable to transport to the lab and test within 5 days, specimens may be frozen between -20°C and -70°C.
- Specimens should be transported to the lab in an insulated, waterproof container with 2-8°C.

Clinical Significance/Interpretation:

- Negative- Negative for Norovirus RNA by PCR
- Positive
 - Positive for Norovirus genogroup I RNA by PCR
 - Positive for Norovirus genogroup II RNA by PCR
- Equivocal
 - Equivocal for Norovirus genogroup I RNA by PCR
 - Equivocal for Norovirus genogroup II RNA by PCR

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed as needed, TAT=2 business days

Note: Norovirus genotyping will be performed on Norovirus positive specimens.

San Diego County Public Health Laboratory

Ova and Parasites Exam

CPT Code(s):87207, 87209, 87177

Description of Test:

Screening for the presence of ova and parasites.

Test Method:

Microscopic examination by wet mount and trichrome staining.

Acceptable Specimens:

Stool samples preserved in Total-Fix™ Stool Collection System. Five (5) grams of specimen in each vial

Storage and Transport Conditions:

Transport preserved specimens at room temperature within 3 days of collection.

Clinical Significance/Interpretation:

Negative –No parasites seen

Positive – (organism) seen by microscopic exam

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed when received, TAT=5 business days

San Diego County Public Health Laboratory

STAT Darkfield Microscopy for *Treponema pallidum*

CPT Code(s):87166

Note: Samples for darkfield testing is accepted only from County Health Providers.

Description of Test:

Examination for morphologic and typical motility characteristics of *Treponema pallidum*

Test Method:

Darkfield Microscopy

Acceptable Specimens:

- Penile lesion
- Rectal lesion
- Genital ulcer
- Any other epidermal surface (except oral)

NOTE: Specimens from oral lesions are not acceptable, due to the presence of spirochetes in the oropharynx that can have similar appearance and motility to *T. pallidum*

To collect, express serum from genital ulcers or lesions on a glass slide with 1 drop of sterile saline and submit to the lab immediately after collection to keep the specimen from drying.

Storage and Transport Conditions:

Specimens are transported at 25°C in plastic square container

Clinical Significance/Interpretation:

Negative – No treponemal organisms or spirochetes found.

Positive – Organisms found that have the characteristic morphology and motility of *T. pallidum*.

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily, TAT=30 minutes

San Diego County Public Health Laboratory

Syphilis Reverse Algorithm

CPT Code(s):86780

Description of Test:

Chemiluminescence immunoassay (CIA) screening for past or present infection with *T. pallidum* (i.e. syphilis) followed by a quantitative non-treponemal test to further characterize infection. In the case of discordant treponemal and non-treponemal test results (i.e. positive treponemal test and negative non-treponemal test), a second treponemal assay is performed.

Test Method:

Immunoassay

Acceptable Specimens:

2 mL of serum collected in a serum separator tube

Storage and Transport Conditions:

- Room Temperature for ≤ 72 hours on or off the clot
- Refrigerated (2-8°C) for ≤ 7 days on or off the clot
- Frozen ($\leq 10^{\circ}\text{C}$) for ≤ 30 days off the clot
- Avoid multiple freeze/thaw cycles

Clinical Significance/Interpretation:

- Syphilis CIA
 - Negative- Nonreactive
 - Positive- Reactive
- Qualitative RPR
 - Negative- Nonreactive
 - Positive- Reactive or Reactive Minimal
- Quantitative RPR
 - Negative- Nonreactive
 - Positive- Reactive (specific titer is reported)
- TP-PA
 - Negative- Nonreactive
 - Positive- Reactive or Reactive Minimal
 - Inconclusive- Inconclusive

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed daily, TAT=7 business days

San Diego County Public Health Laboratory

Trichomonas vaginalis NAAT

CPT Code(s): 87661

Description of Test:

Automated qualitative nucleic acid amplification for the primary diagnosis of *Trichomonas vaginalis*

Test Method:

Nucleic Acid Amplification Test

Acceptable Specimens:

- Vaginal swab
 - Swabs must be submitted using the Aptima® [Multitest Swab Specimen Collection Kit](#). Follow instructions found in collection kit. Brief instructions are as follows:
 - Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
 - Immediately place the swab into the transport tube, without spilling the contents of the tube.

Storage and Transport Conditions:

Specimens must be transported to the laboratory in the provided swab specimen transport medium and tube at 2°C to 30°C until tested. Specimens must be tested within 60 days of collection. If longer storage is needed, freeze at -20°C for up to 24 months after collection.

Interpretation of Laboratory Findings:

Negative- Negative by Nucleic Acid Amplification

Positive- Positive by Nucleic Acid Amplification- *T. vaginalis* RNA detected

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed twice a week, TAT=7 business days

San Diego County Public Health Laboratory

QuantiFERON®-TB Gold Plus Assay

CPT Code(s): 86840

Description of Test:

Interferon gamma release assay that indirectly detects exposure to *M. tuberculosis*.

Test Method:

Enzyme-linked immunosorbent assay

Acceptable Specimens:

One milliliter of blood (Note: blood must be drawn to the black line on the side of the tube label, at least 0.8 to 1.2 ml volume) collected by venipuncture directly into each of the specimen collection tubes.

- a. QuantiFERON Nil tubes (gray cap)
- b. QuantiFERON TB1 tubes (green cap)
- c. QuantiFERON TB2 tubes (yellow cap)
- d. QuantiFERON Mitogen tubes (purple cap)

Storage and Transport Conditions:

- Blood directly drawn into the 4 QFT-Plus Blood Collection Tubes
 - **Prior to incubation:** Specimens can be at room temperature for up to 16 hours before being received by the laboratory.
 - Specimen should be incubated within 16 hours of collection at 37°C ± 1°C for 16-24 hours.
 - **After incubation:** Specimen may be stored at 2 to 27°C for up to 3 days prior to centrifugation.
 - **After centrifugation:** Hold the tubes at 2 – 8°C for up to 28 days before testing.
 - Plasma samples may be stored for up to 28 days at 2 to 8°C in either the original tube or in plasma storage containers.
 - Transport tubes at room temperature (22°C ± 5°C).
- Blood collected into a single lithium-heparin tube:
NOTE: This collection method is not recommended due to the high complexity of the collection and submissions logistics. Prior approval is required by the Serology supervisor.
 - Blood specimens collected in lithium-heparin tubes can be stored up to 12 hours at room temperature (17–25°C) followed by transfer to QFT-Plus Blood Collection Tubes, or
 - Blood specimens in lithium-heparin tubes can be transferred to QFT-Plus Blood Collection Tubes directly after collection.
 - Blood specimens in lithium-heparin tubes may also be stored at 2–8 °C for 16 to

48 hours prior to transfer to the QFT-Plus Blood Collection Tubes.

Clinical Significance/Interpretation:

Negative – *M. tuberculosis* infection NOT likely

Positive – *M. tuberculosis* infection likely

Indeterminate – Likelihood of *M. tuberculosis* infection cannot be determined

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed twice a week, TAT=10 business days

San Diego County Public Health Laboratory

Triplex Real Time RT-PCR Assay

CPT Code(s): 87798

NOTE: All requests for Dengue, Chikungunya, or Zika testing must be first assessed for the epidemiologic and clinical history, and must be approved for testing by the Epidemiology Program staff or medical director at (619)-692-8499.

Description of Test:

The Triplex Real-time RT-PCR (rRT-PCR) Assay amplifies and detects RNA from Zika virus, chikungunya virus, and dengue virus.

Test Method:

Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Acceptable Specimens:

For Zika, chikungunya and dengue testing:

- Serum (collected in a serum separator tube)
 - Tube should be centrifuged prior to sending to our laboratory to avoid hemolysis.
- Whole blood using EDTA as an anticoagulant
- Cerebrospinal fluid (CSF)

For Zika testing only:

- Urine
- Amniotic fluid

Storage and Transport Conditions:

- Serum, urine, CSF and amniotic fluid should be transported on dry ice or using cold packs.
- Whole blood (EDTA) should be transported using cold packs.
- Serum, urine, CSF and amniotic fluid should be stored at $\leq -20^{\circ}\text{C}$ if not tested immediately. After testing, the sample should be placed in a -70°C freezer for long term storage.
- Whole blood (EDTA) should be stored at $2-8^{\circ}\text{C}$. Testing is recommended within one week of collection.

Clinical Significance/Interpretation:

Negative - No Dengue (or Chikungunya or Zika) RNA detected by rRt-PCR

Positive - Dengue (or Chikungunya or Zika) RNA detected by rRt-PCR

Days Test is Performed and Turn Around Time (TAT) for Results:

Performed as needed, TAT=3 business days

Appendix 1: Packaging and Labeling

Transportation of potentially infectious substances is specifically regulated, to protect those handling and receiving the shipment. Follow federal regulations for transporting hazardous materials. If samples are to be transported to the Public Health Laboratory by a courier service, Category B samples can be put in mailing cylinders and placed inside a sealed cooler or similar carrier and hand-delivered. Cooler should have proper markings, UN3373 label, and a biohazard label. If specimens are to be shipped by air or postal service, follow proper regulations for shipping of Category A or Category B Infectious Substances (depending on agent). The watertight primary collection or sample tube must be wrapped (individually, in the case of multiple tubes) in bubble pack with absorbent material enclosed sufficient to absorb any spilled material, and placed within a secondary watertight package. The secondary package must be placed within a rigid container capable of withstanding standardized crush tests and then be properly labeled. Figures 1 and 2 illustrates some examples.

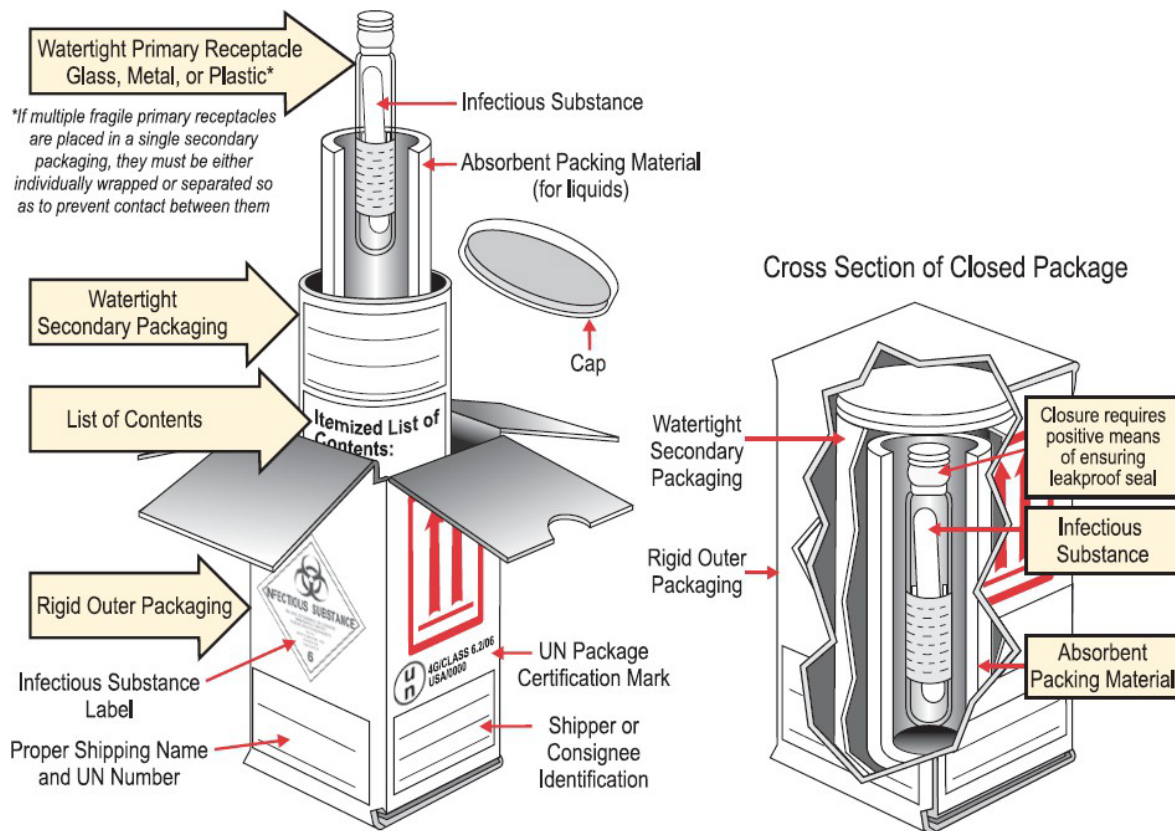


Figure 1. Category A Packing and Labeling from Department of Transportation

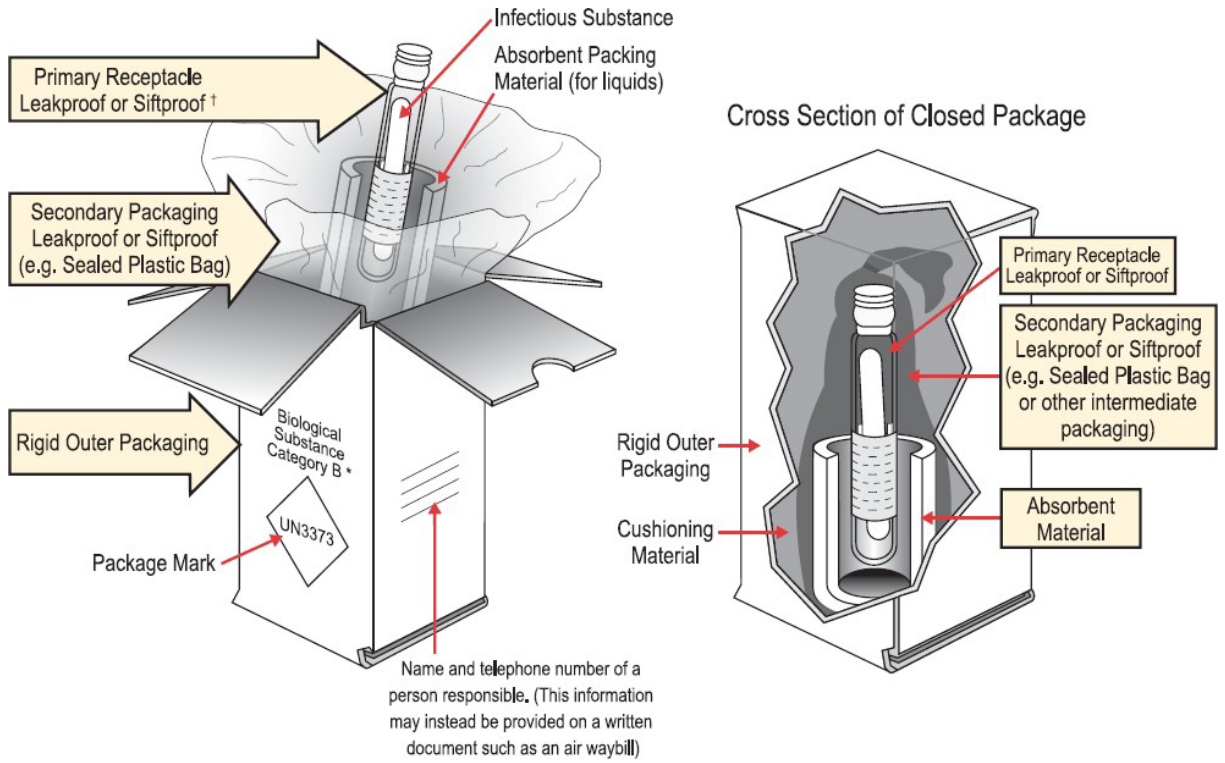


Figure 2. Category B Packing and Labeling from Department of Transportation

References

1. County of San Diego Health and Human Services Agency, <https://www.sandiegocounty.gov/content/sdc/hhsa.html>
2. County of San Diego Public Health Services, <https://www.sandiegocounty.gov/hhsa/programs/phs/>
3. San Diego County Public Health Laboratory, https://www.sandiegocounty.gov/hhsa/programs/phs/phs_laboratory/
4. California Department of Public Health, <https://www.cdph.ca.gov/>
5. Centers for Disease Control and Prevention, <https://www.cdc.gov/>
6. County of San Diego Department of Environmental Health, <https://www.sandiegocounty.gov/deh/>
7. Laboratory Response Network, <https://emergency.cdc.gov/lrn/>
8. US Postal Service, <https://www.usps.com/>
9. International Air Transportation Association, <https://www.iata.org/Pages/default.aspx>
10. US Department of Transportation, <https://www.transportation.gov/>
11. Hologic, <https://www.hologic.com/>

Document Name:		Laboratory Services and Specimen Collection Manual		
Date	Page(s) or Section	Description of Change	Author	Approval
9/12/12	All	Major revision/update. Now 2.0	PHL	
10/12/12	All	Final version update	PHL	
5/25/16	Ova and Parasite Test	Change in stool collection	PHL	
5/19/19	All	Major revision/update. Now 3.0	PHL	BA and SS
11/18/19	All	Minor corrections to language	PHL	SS
	7	Change to language to reflect Title 17 Update		
	20	Added Hepatitis B testing		
	34	Added Measles IgG test		
	36	Added Coccidian Identification test		