

**New York State Department of Health and
New York City Department of Health and Mental Hygiene**

2016 Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases

Laboratory reporting of suspected or confirmed positive findings or markers of communicable diseases is mandated under the New York State (NYS) Public Health Law 2102 and, for New York City (NYC), additional communicable diseases and poisonings are required pursuant to the NYC Health Code Articles 11 and 13.

In an effort to assist permitted clinical laboratories and blood banks in meeting their obligations to report communicable diseases, the NYS Department of Health (NYSDOH) and the NYC Department of Health and Mental Hygiene (NYCDOHMH) have prepared the guidance presented below. If you require further information on the reporting of diseases:

- **For NYS (Outside NYC):** Please contact the NYSDOH Bureau of Communicable Disease Control at 518-473-4439. For additional details on the submission of isolates or specimens to the NYSDOH Wadsworth Center, contact the Microbiology Laboratories or Biodefense Laboratory at 518-474-4177. Outside routine business hours, contact the NYSDOH Duty Officer at 866-881-2809.
- **For NYC:** Please contact the NYCDOHMH Provider Access Line at 866-NYC-DOH1 (866-692-3641). For additional details on the submission of isolates or specimens, please contact the NYC Public Health Laboratory's Virology Section at 212-447-2864, or the Microbiology Section (including the BioThreat Response Laboratory) at 212-447-6783. For further information on reporting, providers may also consult the NYCDOHMH website at: <http://www.nyc.gov/html/doh/html/hcp/hcp-reporting.shtml>. For further information on reporting poisonings, providers may also contact the NYC Poison Control Center at 1-800-222-1222 or 212-POISONS (212-764-7667).

A. Are laboratories and blood banks required to report communicable diseases?

Yes, NYS Public Health Law 2102 and NYC Health Code Articles 11 and 13 require laboratories and blood banks to report positive and, in select cases, negative, findings or markers of the specific communicable diseases indicated below to public health authorities. Specimen source and result must be indicated. Specimens obtained from cord blood must have cord blood listed as the specimen source.

B. To whom should reports of positive findings or markers of disease be submitted?

Under NYS Public Health Law Section 576-c and the NYC Health Code Section 13.03 all reports for residents of NYS should be made via the Electronic Clinical Laboratory Reporting System (ECLRS), which will direct the reports to the appropriate state and/or local jurisdiction (see section D).

C. What information should be provided to public health authorities?

Patient/donor name; date of birth; sex; address; telephone number; accession number; type and source of specimen; date collected; date of specimen receipt by the testing laboratory; type of test performed; test results; date of final report; requesting facility and requesting provider's name, address, and telephone number.

NYCDOHMH requires some additional data elements. For complete information on NYC requirements, consult Article 13 of the NYC Health Code at: <http://www.nyc.gov/html/doh/downloads/pdf/about/healthcode/health-code-article13.pdf>.

NYCDOHMH requirements that differ from those of NYSDOH include:

- (1) The following information for the patient if available: race/ethnicity, email address, cell phone number, medical record number, date specimen received at the laboratory, and known or probable pregnancy status (for female patients with reportable hepatitis B or syphilis lab results)①
- (2) The following information for the requesting provider and facility, if available and applicable: email address, fax number, mobile phone number, and National Provider Identification (NPI).
- (3) Antibiotic susceptibility testing results are reportable for bacterial diseases listed under subdivision (a) of §11.03 of the NYC Health Code (<http://www.nyc.gov/html/doh/downloads/pdf/about/healthcode/health-code-article11.pdf>). This includes reporting results of conventional broth and agar-based methods, automated methods of antibiotic susceptibility testing, and nucleic acid sequence-based methods to detect determinants of antibiotic resistance.
- (4) Any syphilis treponemal or non-treponemal results are reportable, whether qualitative or quantitative, if positive or reactive. In addition, any negative or non-reactive results, or any quantitative results, on syphilis tests associated with the aforementioned positive or reactive results must also be reported.
- (5) In compliance with Health Code Article 11 and 13 requirements the Health Department is requesting that laboratories performing carboxyhemoglobin (COHb) testing for suspected and confirmed carbon monoxide poisoning report results of such testing of New York City residents.

- (6) Negative and indeterminate hepatitis B virus surface antigen and surface antibody test results are reportable for children ages 0 days to 5 years.

D. When and how should reports be submitted?

All required reports should be submitted within 24 hours of the time and date on which test results are first available.

However, positive results for those diseases indicated by 📌 on the list must also be reported to the local health authorities immediately by phone so that control measures can be implemented promptly.

For NYS residents, under Public Health Law Section 576-c, whenever a clinical laboratory or blood bank is required to report evidence of a disease or health condition to the State Health Commissioner or a local health officer, the laboratory must send such reports electronically to the NYSDOH via ECLRS. ECLRS replaces former reporting methods (mail and fax) for reportable diseases diagnosed by laboratory tests. ECLRS sends reports to the appropriate local jurisdiction as required under NYS Public Health Law, thereby meeting the laboratory's responsibility for reporting directly to local jurisdictions. ECLRS provides a secure system for reporting communicable diseases, heavy metals and other poisonings, cancer, congenital malformation testing, and HIV/AIDS.

For NYC residents, electronic reporting of reportable diseases diagnosed by laboratories is mandated by the NYC Health Code, Section 13.03. Laboratories shall also report to the NYCDOHMH via ECLRS.

Questions regarding ECLRS may be directed to the NYSDOH at 866-325-7743 or to the NYCDOHMH at nyceclrs@health.nyc.gov

E. Which laboratory-diagnosed diseases and conditions are ONLY reportable for residents of New York City (Bronx, Brooklyn, Manhattan, Queens, and Staten Island)? How should these diseases and conditions be reported by laboratories?

The following diseases are reportable only for NYC residents and should be reported via ECLRS:

- Granuloma inguinale (*Calymmatobacterium* [*Klebsiella*] *granulomatis* infection)
- Hepatitis D and E
- Leprosy (*Mycobacterium leprae* infection)
- Leptospirosis, including Weil's disease
- Lymphocytic choriomeningitis virus (LCMV) infection
- Methicillin-resistant *Staphylococcus aureus* (MRSA) infection (any site)
- Norovirus (NV) (formerly the Norwalk agent) infection
- Respiratory syncytial virus (RSV) infection
- Rickettsialpox (*Rickettsia akari* infection)

The following conditions are reportable only for NYC residents and should be reported via ECLRS:

- Carbon monoxide poisoning (carboxyhemoglobin levels):
Report via ECLRS the results of Carboxyhemoglobin (COHb) tests performed to evaluate suspected and confirmed cases of carbon monoxide poisoning, regardless of test result via ECLRS. In addition, when COHb levels are ≥10%, labs must also report results directly by telephone to the NYC Poison Control Center at 212-764-7667 immediately.
- Hemoglobin A1C is reported directly to NYC DOHMH in a separate file from ECLRS for all labs reporting via file to ECLRS. Please contact nyceclrs@health.nyc.gov to make arrangements to report Hemoglobin A1C.
- Toxic Alcohol Poisoning (methanol and ethylene glycol):
Report via ECLRS all test results of any methanol or ethylene glycol tests.

F. Are providers required to report communicable diseases and poisonings too?

Yes, in addition to the reporting required by laboratories, physicians are required to report suspect or confirmed cases of communicable diseases and poisonings to the local health department of the patient's/donor's residence. The clinical information contained in their reports such as symptoms, risk exposure history, treatment, occupation, illness in family members, hospitalization, and other epidemiological factors supplements the data provided by diagnostic laboratories. Providers do not need to report all the diseases laboratories are required to report. For more information about diseases mandated by NYC as reportable by providers, physicians can refer to <http://www.nyc.gov/html/doh/html/hcp/hcp-reporting.shtml>

G. Do isolates or specimens have to be submitted for confirmation?

Yes, under NYS Public Health Law Section 576-c(4) and Article 11 of the NYC Health Code, laboratories are required to submit isolates or specimens as determined by the NYS or NYC Commissioner of Health. The last two columns of the table indicate which isolates or specimens must be submitted to the Wadsworth Center or NYC Public Health Laboratory. Preliminary laboratory results indicating the potential presence of a reportable condition should be reported immediately in ECLRS without awaiting confirmation results.

When culture-independent (molecular) methods are used to diagnose/screen for bacterial infections, reflex to culture is required for public health purposes. Isolates should be submitted to the NYS and NYC Public Health Laboratories.

H. Is additional testing available?

Yes, the Wadsworth Center in Albany and the NYC Public Health Laboratory are available to assist clinical laboratories in the identification or further characterization of isolates or specimens indicating the presence of a reportable disease or condition, and also to confirm the presence of serologic markers of such diseases and conditions. To arrange such testing, the laboratories should be contacted at the telephone numbers listed in the introductory section of this document.

I. Is reporting required for donor testing?

Yes, blood banks and tissue banks must report positive results for any reportable condition via ECLRS (see section D) to the local health department of the donor's residence, except for positive HIV test results which are reportable directly to the NYSDOH. Blood banks and tissue banks do not need to report negative hepatitis B virus, hepatitis C virus, and HIV nucleic acid test results.

J. Are HIV-related tests reportable?

Yes, the following tests are reportable:

- (1) All reactive/repeatedly reactive initial HIV immunoassay results AND all results (e.g. positive, negative, indeterminate) from all supplemental HIV immunoassays (HIV-1/2 antibody differentiation assay, HIV-1 Western blot, HIV-2 Western blot or HIV-1 Immunofluorescent assay);
- (2) All HIV nucleic acid (RNA or DNA) detection tests (qualitative and quantitative), including tests on individual specimens for confirmation of nucleic acid-based testing (NAT²) screening results;
- (3) All CD4 lymphocyte counts and percentages, unless known to be ordered for a condition other than HIV;
- (4) HIV subtype and antiviral resistance. This reporting requirement should be met with the electronic submission of the protease, reverse transcriptase and integrase nucleotide sequence determined through genotypic resistance testing; and,
- (5) Positive HIV detection tests (culture, P24 antigen).

All HIV-related laboratory reporting, including that for NYC residents, should be made directly to the NYSDOH, submitted electronically via ECLRS.

Clinical laboratories are required to report results using patient identifying, demographic and locating information, as well as requesting provider information. For a complete list of this information and instructions on how to report required data elements, please call 518-474-4284.

Physicians and others authorized to order diagnostic tests or make medical diagnoses should report HIV diagnoses and AIDS diagnoses within 14 days on NYSDOH Form 4189. For questions regarding laboratory or physician HIV reporting or to obtain Form 4189, please call 518-474-4284.

K. How do laboratories submit specimens related to Select Agents?

When a Select Agent cannot be ruled out, all work on the specimen must be stopped immediately. The specimen and all derivatives (culture plates, tubes, Gram stains, and specimen aliquots) must be secured within an incubator or refrigerator in a leak proof container (i.e., biosafety carrier). Note that clinical laboratories should not attempt to isolate viruses that are Select Agents.

For NYS patients, contact the NYS Wadsworth Center Biodefense Laboratory 518-474-4177 for detailed guidance on how to proceed with specimen packaging and shipment for further testing.

For NYC patients, immediately contact the NYCDOHMH Provider Access Line at 1-866-692-3641 for guidance on next steps, including packaging and shipping of the isolate for further testing at the NYC Public Health Laboratory.

If a specimen is confirmed as a Select Agent, additional guidance will be provided regarding specimen disposition and destruction, evaluation of laboratory exposures, and CDC reporting requirements. A current list of Select Agents and toxins can be accessed at <http://www.selectagents.gov>.

- L. If multiple laboratories perform testing on a specimen, which testing laboratories should report results?**
If multiple laboratories perform testing on a specimen, then each laboratory is required to report only their own test result(s), with two NYC exceptions (see below). If a specimen is sent to another laboratory for testing, the originating send-out laboratory must include all required information (see Section C above) on the requisition to ensure each testing laboratory's reporting will be complete.

NYC Exceptions:

- 1) The New York City Health Code provides that if a blood bank refers a specimen to a laboratory for testing without donor identifying information, the referring blood bank and not the testing laboratory is responsible for reporting results.
- 2) For syphilis testing, the New York City Health Code provides that if a laboratory performs syphilis testing on a specimen and then refers the specimen to a second laboratory for further syphilis testing, and the specimen is positive by any syphilis test at either laboratory, the referring laboratory is required to report all positive and negative test results for the specimen, whether those tests were performed by the referring or the second laboratory. This does not change the requirement for individual laboratories to report any positive or reactive syphilis test results along with any associated negative or non-reactive test results for syphilis obtained by an individual laboratory.

2016 Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases and Conditions

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
<i>Anaplasma phagocytophilum</i>	Anaplasmosis	Positive by any method	No	No
 Arboviruses: California serogroup virus (LaCrosse, Jamestown Canyon, etc.), Eastern, Venezuelan or Western equine encephalitis virus, Japanese encephalitis virus, St. Louis encephalitis virus, Powassan virus, Deer Tick virus, Yellow Fever virus	Arboviral infection (acute), viral encephalitis/meningitis	For all residents, report positive culture or Nucleic Acid Test (NAT ②). For NYS residents outside of NYC, report positive IgM or IgG antibodies against any of the arboviruses. For NYC residents, report positive IgM antibodies only.	Yes – Submit acute and convalescent sera, NAT positive specimens, and/or IgM positive CSF specimens	Yes – Submit directly to the Wadsworth Center③ (Arboviral select agents for confirmation include EEE and VEE)
➤ Chikungunya virus	Chikungunya	Positive serologic evidence of IgM antibodies, culture or NAT	Yes – Submit acute and convalescent sera. Submit NAT positive specimens	Yes – Submit directly to the Wadsworth Center
➤ Dengue virus	Dengue fever, Dengue hemorrhagic fever	Positive serologic evidence of IgM antibodies, culture or NAT	Yes – Submit acute and convalescent sera. Submit NAT positive specimens	Yes – Submit directly to the Wadsworth Center
➤  Rift Valley Fever virus	Hemorrhagic fever, encephalitis, ocular disease	Positive serologic evidence of IgM or IgG antibodies, culture, antigen test or NAT	Yes – Submit acute and convalescent sera	Yes – Submit directly to the Wadsworth Center③
➤  West Nile (WN) virus	WN viral neuroinvasive disease, WN fever	For all residents, report positive NAT, immunohistochemical staining or viral culture. For NYS residents outside of NYC, report positive IgM or IgG for WN virus. For NYC residents, report positive WN IgM only.	Yes – Submit acute and convalescent sera, NAT positive specimens, and/or IgM positive CSF specimens	Yes – Submit directly to the Wadsworth Center
 Arenaviruses (Lassa, Junin)	Viral hemorrhagic fever	Positive by any method	Yes	Yes – Submit directly to the Wadsworth Center③
<i>Babesia</i> species	Babesiosis	Positive blood smear, NAT, immunoblot, or <i>Babesia</i> -specific antibody titer ≥ 256 with an indirect fluorescent antibody (IFA) test for IgG or total antibody	Yes - Positive blood smear or NAT only	Yes – Positive blood smear or NAT only. Submit directly to the Wadsworth Center

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
 Bacillus anthracis	Anthrax	Positive by any method	Yes	Yes ^③
<i>Bordetella pertussis</i>	Pertussis	Positive by any method	No	No
<i>Borrelia burgdorferi</i>	Lyme disease	Report a positive or equivocal ELISA/IFA/EIA when: 1) a second step assay (immunoblot/WB) is positive, 2) a second step assay (immunoblot/WB) is equivocal or inconclusive, or 3) a second step assay has not been or will not be performed.	No	No
 Brucella species	Brucellosis	Positive by any method	Yes	Yes ^③
 Burkholderia mallei	Glanders	Positive by any method	Yes	Yes ^③
 Burkholderia pseudomallei	Melioidosis	Positive by any method	Yes	Yes ^③
<i>Calymmatobacterium granulomatis</i> (<i>Klebsiella granulomatis</i>) (NYC only)	Granuloma inguinale	Positive by any method	No	No
<i>Campylobacter</i> species	Campylobacteriosis	Positive by any method	No ^④	No
<i>Chlamydia psittaci</i>	Psittacosis	Positive by any method	No	No
<i>Chlamydia trachomatis</i>	<i>C. trachomatis</i> , including lymphogranuloma venereum	Positive by any method	No	No
 Clostridium botulinum	Botulism	Positive by any method	Yes	Yes ^③
<i>Clostridium tetani</i>	Tetanus	Positive culture	Yes	No
 Corynebacterium diphtheriae	Diphtheria	Positive culture	Yes	Yes
 Coxiella burnettii	Q fever	Positive by any method, including serology when IgG antibody titer is ≥ 64	Yes	No
Creutzfeldt-Jakob agent ^⑤	Creutzfeldt-Jakob disease	Positive by any method	No	No
<i>Cryptosporidium</i> species	Cryptosporidiosis	Positive by any method	Yes – Submit original slide and stool specimen. Stool specimen should be unfixed or be in PCR-compatible fixative.	Yes – Submit directly to the Wadsworth Center
<i>Cyclospora cayetanensis</i>	Cyclosporiasis	Positive by any method	Yes - Submit original slide and stool specimen. Stool specimen should be unfixed or be in PCR-compatible fixative.	Yes – Submit directly to the Wadsworth Center

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
<i>Ehrlichia</i> species	Ehrlichiosis	Positive by any method	No	No
<i>Entamoeba histolytica/dispar</i>	Amebiasis	Positive cyst, trophozoite, or antigen noted by any method	Yes – Submit original slide and stool specimen. Stool specimen should be unfixed or be in PCR-compatible fixative.	No
<i>Escherichia coli</i> , Shiga toxin-producing	Shiga toxin-producing <i>E. coli</i> (STEC) disease	Positive culture or positive shiga toxin in stool	Yes – Submit shiga toxin-positive broth and stool; or isolate	Yes – Submit shiga toxin-positive broth and stool; or isolate
<i>Escherichia coli</i> O157	<i>E. coli</i> O157 disease	Positive by any method	Yes – Submit isolate only ^③	Yes – Submit isolate only ^③
 Filoviruses:	Viral hemorrhagic fever	Positive by any method	Yes	Yes – Submit primary specimens directly to the Wadsworth Center ^③
➤  Marburg				
➤  Ebola	Viral hemorrhagic fever	Positive by any method	Yes	Yes ^③
 <i>Francisella tularensis</i>	Tularemia	Positive by any method	Yes	Yes ^③
<i>Giardia intestinalis</i> (formerly <i>G. lamblia</i>)	Giardiasis	Positive by any method	No	No
<i>Haemophilus ducreyi</i>	Chancroid	Positive by any method	No	No
<i>Haemophilus influenzae</i>	Invasive <i>Haemophilus influenzae</i> disease	Positive culture or NAT from any sterile site; CSF antigen test	Yes – Submit isolate only	Yes – Submit isolate only
 Hantavirus	Hantavirus pulmonary syndrome	Positive IgM or rising IgG titer or positive RNA by NAT or positive immunohistochemistry	Yes	Yes
Hepatitis A virus	Hepatitis A	Positive IgM anti-HAV. Along with positive reportable hepatitis results, include results for all other viral hepatitis markers (positive or negative) and ALT results.	No	No
Hepatitis B virus	Hepatitis B	Positive IgM anti-HBc, HBsAg, HBeAg, or HBV NAT (including genotype). Along with any positive reportable hepatitis results, include all other viral markers (positive or negative) and ALT. ^① NYC only: For children <5 years old, report all results (positive, negative, and indeterminate) for HBsAg and HBsAb.	No	No

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
Hepatitis C virus	Hepatitis C	Anti-HCV screening test positive ^⑥ and all positive and negative NAT results, including genotype. ^⑦ Along with positive reportable hepatitis results, include all other viral hepatitis markers (positive or negative) and ALT.	No	No
Hepatitis D (Delta Agent) (NYC only)	Hepatitis D	Hep D Ag or IgM. Include ALT results.	No	No
Hepatitis E virus (NYC only)	Hepatitis E	Hep E IgM. Include ALT results.	No	No
Herpes simplex virus	Neonatal herpes simplex infection, infants ≤60 days	Positive by any method ^⑧	Yes – Submit primary specimens (and isolate, if available)	Yes – Submit primary specimens (and isolate, if available) directly to the Wadsworth Center
Human immunodeficiency virus	HIV infection, HIV-related illness, and AIDS	HIV-related laboratory test results are reported to the NYSDOH, not the local health department. Clinical laboratories are required to report certain results using patient name and address. See Section J for a listing of reportable results.	Yes ^⑨	Yes ^⑨
Influenza virus	Influenza disease, laboratory confirmed	Positive by any method, excluding serology	No	No
 Suspect novel Influenza virus	Suspect novel Influenza virus	Positive by any method	Yes – Submit swab in viral transport media ^⑩	Yes – Submit swab in viral transport media ^⑩
<i>Legionella</i> species	Legionellosis	Positive culture, NAT, DFA or urine antigen or acute/convalescent serology showing a rising titer to <i>L. pneumophila</i>	Yes – Submit isolate only	Yes – Submit isolate only
<i>Leptospira</i> species (NYC only)	Leptospirosis	Positive by any method	No	Yes
<i>Listeria monocytogenes</i>	Listeriosis	Positive culture from any sterile site	Yes – Submit isolate only ^⑪	Yes – Submit isolate only
Lymphocytic choriomeningitis virus (NYC only)	Lymphocytic choriomeningitis	Positive IgM or NAT	No	Yes – Submit IgM or NAT positive specimens
 Measles virus (Rubeola)	Measles	Positive by viral culture, NAT, single serum with IgM antibody or paired sera with rising IgG antibody	Yes – Submit primary specimen (and isolate, if available), and IgM positive serum only	Yes – Submit primary specimen (and isolate, if available), and IgM positive serum only
 Monkeypox virus	Monkeypox	Positive by any method	Yes	Yes – Submit primary specimens only ^⑬

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
Mumps virus ☎ (Report immediately in NYS only)	Mumps	Positive by viral culture, NAT, single serum with IgM antibody or paired sera with rising IgG antibody	Yes – Submit primary specimen (and isolate, if available), and IgM positive serum only	Yes – Submit primary specimen (and isolate, if available)
<i>Mycobacterium leprae</i> (NYC only)	Leprosy (Hansen's disease)	Acid fast bacilli in skin biopsy, positive NAT or serology for <i>M. leprae</i>	No	No
<i>Mycobacterium tuberculosis</i>, <i>M. bovis</i>, <i>M. bovis</i> BCG, and other members of the <i>M. tuberculosis</i> complex ☎ (Report immediately in NYS only)	Tuberculosis	Positive AFB smear (including any subsequent NAT or culture result for that specimen); NAT or culture positive for <i>M. tuberculosis</i> , <i>M. bovis</i> and other members of the <i>M. tuberculosis</i> complex from any site; Any susceptibility test results from a <i>M. tb</i> complex positive culture; Biopsy, pathology, or autopsy findings consistent with active TB; All subsequent TB test results, including negative or inconclusive results, on samples collected within one year from patients with a prior positive acid fast bacilli (AFB) smear or test for <i>M. tuberculosis</i> complex.	Yes - All initial isolates of <i>M. tuberculosis</i> complex must be submitted to the Wadsworth Center. Save all other isolates for 1 year.	Yes - All initial isolates of <i>M. tuberculosis</i> complex must be submitted to the NYC Public Health Lab. Save all other isolates for 1 year.
<i>Neisseria gonorrhoeae</i>	Gonorrhea	Positive by any method If performed, antibiotic susceptibility test results should be reported, regardless of susceptibility pattern.	Yes – Submit isolate only if decreased susceptibility to cephalosporins or azithromycin is identified ⑫	Yes – Submit isolate only if decreased susceptibility to cephalosporins or azithromycin is identified ⑫
☎ <i>Neisseria meningitidis</i>	Meningococcal disease, invasive	Positive culture from any sterile site, positive CSF antigen test, positive NAT, or Gram stain showing Gram-negative diplococci in CSF or blood	Yes – Submit isolate only	Yes – Submit isolate or specimen
Norovirus (NYC only)	Noroviral gastroenteritis	ELISA, NAT, or other laboratory evidence of disease	No	No
<i>Plasmodium</i> species	Malaria	Positive by any method	Yes – Submit blood smear and whole blood	Yes – Submit blood smear and whole blood directly to the Wadsworth Center
☎ Polio virus	Poliomyelitis	Positive culture or NAT	Yes	Yes

REPORTABLE DISEASES:		What to report to the Local Health Department	Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease		NYS Wadsworth Center	NYC Public Health Lab
 Rabies virus	Rabies	Only the Wadsworth Center is approved for human rabies testing	Yes	Yes –Submit directly to the Wadsworth Center
Respiratory syncytial virus (NYC only)	Respiratory syncytial virus	Rapid antigen, NAT, DFA, positive culture	No	No
<i>Rickettsia akari</i> (NYC only)	Rickettsialpox	Positive serology for <i>R. akari</i> or non-specific rickettsiae	No	No
<i>Rickettsia rickettsii</i>	Rocky Mountain Spotted Fever	Positive by any method	No	No
Rotavirus	Rotavirus	Positive rapid antigen, EIA, viral culture, or NAT	No	No
 Rubella virus	Rubella (German measles)	Positive culture, NAT, single serum with IgM antibody, or paired sera with rising IgG antibody	Yes – Submit primary specimen (and isolate, if available), and IgM positive serum only	Yes – Submit primary specimen (and isolate, if available), and IgM positive serum only
<i>Salmonella</i> species	Salmonellosis	Positive by any method	Yes – Submit isolate only ^③	Yes – Submit isolate only ^③
<i>Salmonella</i> Typhi  (Report immediately in NYS only)	Typhoid fever	Positive by any method	Yes – Submit isolate only ^③	Yes – Submit isolate only ^③
<i>Shigella</i> species	Shigellosis	Positive by any method	No ^④	Yes – Submit isolate only ^③
 Severe or suspect novel coronavirus (e.g., SARS or MERS)	Severe or suspect novel coronavirus	Positive by any method (Do not perform culture)	Yes – Submit primary specimens only	Yes – Submit primary specimens only ^③
 <i>Staphylococcus aureus</i>, intermediate or resistant to glycopeptides	Glycopeptide (e.g., teicoplanin, vancomycin) intermediate or resistant <i>S. aureus</i> (GISA/GRSA) infection	Isolate showing reduced susceptibility or resistance to glycopeptides (e.g., vancomycin, teicoplanin)	Yes	Yes
<i>Staphylococcus aureus</i> , methicillin-resistant (MRSA) (NYC only) ^⑭	Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	Isolate showing resistance to oxacillin	No	No
 Staphylococcal enterotoxin B	Staphylococcal enterotoxin B poisoning	Positive for toxin in blood or urine by any method	Yes	Yes – Submit directly to the Wadsworth Center
<i>Streptococcus agalactiae</i> (Group B Strep)	Group B streptococcal disease, invasive	Positive culture from any sterile site	No ^④	No

REPORTABLE DISEASES:			Are specimens/isolates required to be submitted for confirmation?	
Agent	Disease	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i> disease, invasive	Positive culture from any sterile site Penicillin MIC value or oxacillin inhibition zone diameter result must be included, if available	Yes – Submit invasive isolates from patients <5 years of age only For patients ≥5 years of age, submit isolates from EIP counties only ④	Yes – Submit invasive isolates from patients <5 years of age only
<i>Streptococcus pyogenes</i> (Group A Beta Hemolytic Strep)	Group A streptococcal disease, invasive	Positive culture from any sterile site, or any surgically-obtained site, or any site from a patient with necrotizing fasciitis or toxic shock syndrome	No④	No
<i>Treponema pallidum</i> ☎ (Report immediately in NYS only)	Syphilis	Report any treponemal or non-treponemal results, whether qualitative or quantitative, which are positive or reactive by any method. In addition, any negative or non-reactive results, or any quantitative results on syphilis tests associated with the positive or reactive results must also be reported.⑤ For NYC residents, see Section L for additional requirements	No	No
<i>Trichinella</i> species	Trichinosis	Positive biopsy or serology	Yes	No
☎ Vaccinia virus	Vaccinia infection	Positive by any method	Yes – Primary specimens only	Yes – Primary specimens only
Varicella zoster virus	Chickenpox, zoster	Positive IgM, viral culture, DFA or NAT	Yes – Submit primary specimen (and isolate, if available)	No
☎ Variola virus	Smallpox	Positive by any method	Yes – Primary specimens only	Yes – Primary specimens only ③
☎ <i>Vibrio cholerae</i>, O1 or O139	Cholera	Positive by any method	Yes – Submit isolate only ③	Yes – Submit isolate only ③
<i>Vibrio</i> species	Vibriosis	Positive by any method	Yes – Submit isolate only ③	Yes – Submit isolate only ③
<i>Yersinia enterocolitica</i>	Yersiniosis	Positive by any method	Yes – Submit isolate only ③	Yes – Submit isolate only ③
☎ <i>Yersinia pestis</i>	Plague	Positive by any method	Yes	Yes ③

NYC ONLY REPORTABLE CONDITIONS			Are specimens required to be submitted for confirmation	
Analyte	Condition	What to report to the Local Health Department	NYS Wadsworth Center	NYC Public Health Lab
Carboxyhemoglobin (COHb) (NYC only) ☎ (Report levels ≥10% immediately)	Carbon Monoxide Poisoning	Results of any Carboxyhemoglobin test performed to evaluate suspected carbon monoxide or confirmed carbon monoxide poisoning. See Section E.	No	No
Hemoglobin A1C (NYC only)	Hemoglobin A1C	All results, including HgbA1c; HgbA1c by HPLC; HbA1c; Glycohemoglobin A1C; Gycolhaemoglobin; Glycohemoglobin; Glycated Hgb; Glyco-Hb; GHb; Ghb. See Section E.	No	No
Toxic Alcohols (methanol and ethylene glycol) (NYC only)	Toxic Alcohol Poisoning	All test results of any methanol or ethylene glycol tests See Section E.	No	No

New York State Department of Health and
New York City Department of Health and Mental Hygiene
**2016 Laboratory Reporting and Specimen Submission Requirements for
Communicable Diseases**

- ◆ **☎ Suspected or confirmed organisms/diseases** must be immediately reported by phone to the local or city health department in which the patient resides. For residents of NYC, call the NYCDOHMH's Provider Access Line at 1-866-692-3641 immediately for guidance on how and where to submit specimens.
- ◆◆ Specimens REQUIRED to be submitted for confirmation are listed in the table. Additional tests on non-required submissions are also available at public health laboratories. For details on required forms and on how to submit isolates or specimens, please contact:
 - **New York State:**
Call the Wadsworth Center's Microbiology Laboratories or Biodefense Laboratory at 518-474-4177. Outside routine business hours, contact the NYSDOH Duty Officer at 866-881-2809.
 - **New York City:**
Laboratory test request forms and general submission guidelines can be accessed at: <http://www.nyc.gov/html/doh/html/hcp/lab-forms.shtml>
For additional information, call: Virology Section at 212-447-2864, or Microbiology Section, including the BioThreat Response Laboratory at 212-447-6783. Outside routine business hours, call the Poison Control Center at 212-764-7667 and ask for the on-call physician or the PHL Duty Officer.

Proper packaging and shipping of infectious substances and diagnostic specimens are defined in the International Air Transport Association (IATA), Department of Transportation (DOT), and United States Postal Service (USPS) regulations. The shipper's responsibility is to properly classify, identify, package, mark, label, and document shipments for transport by air or surface. Consult the following web sites for compliance with packaging and shipping regulations:

<http://www.iata.org>
<http://www.access.gpo.gov>
<http://www.who.org>
<http://www.cdc.gov/od/ohs>

Foot Notes

- ① For NYC residents, include pregnancy status with positive HBsAg reports and positive syphilis reports if patient is indicated as pregnant or pregnancy is probable (e.g., a pre-natal panel is ordered, a pregnancy related diagnostic code is included in the lab requisition, testing is ordered by a hospital Labor and Delivery Unit, etc.). Document known or probably pregnancy in the OBR-13 field (RelevantClinicalInfo) using any of the following terms: "Pregnant", "Prenatal" or "Delivery." Questions regarding ECLRS may be directed to the NYSDOH at 866-325-7743 or to the NYCDOHMH at nyceclrs@health.nyc.gov for more information.
- ② NAT (Nucleic Acid Test) – an assay that detects specific nucleic acids (DNA or RNA) – examples include polymerase chain reaction (PCR), transcription-mediated amplification (TMA), nucleic acid sequence-based amplification (NASBA), and, for hepatitis B and C, genotype tests.
- ③ For NYC residents, if a Select Agent cannot be ruled out from a clinical specimen, please contact the NYCDOHMH Provider Access Line at 1-866-692-3641 for consultation. If warranted, further instruction will be given regarding packaging and shipping of the isolate and/or specimen to the NYC Public Health Laboratory for testing. Refer to <http://www.selectagents.gov/> for more information.
- ④ The Emerging Infections Program (EIP) laboratories should submit isolates from residents of the following counties: Albany, Columbia, Genesee, Greene, Livingston, Monroe, Montgomery, Ontario, Orleans, Rensselaer, Saratoga, Schenectady, Schoharie, Wayne, and Yates. For Group B *Streptococcus*, only isolates from early and late neonatal onset cases (less than 90 days of age) should be submitted to the Wadsworth Center Laboratories.
- ⑤ Creutzfeldt-Jakob disease (and suspicion of) should be reported directly to the NYSDOH Alzheimer Disease and Other Dementias Registry at 518-473-7817 for residents outside NYC. For residents of NYC, report to the NYC DOHMH Provider Access Line at 1-866-692-3641.
- ⑥ Hepatitis C antibody reports should include interpretation of the s/co ratio (high or low positive) and the ratio value in the results section of the laboratory report. Hepatitis C antibody screening test signal-to-cutoff ratio information, listed by assay, can be found on the CDC website: <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm#section1>.

- ⑦ For NYS and NYC residents, negative hepatitis C virus RNA results are reportable. Blood banks and tissue banks are exempt from reporting negative hepatitis C virus RNA results (see Section I).
- ⑧ For NYC residents, laboratories detecting herpes simplex virus in any specimen from an infant aged 60 days or younger must submit all such specimens directly to the NYS Wadsworth Center (does not apply to serology). Providers evaluating an infant aged 60 days or younger with suspected herpes simplex virus must collect and submit a swab specimen from vesicular lesion(s) (if present) directly to the NYS Wadsworth Center.
- ⑨ Remnant serum and plasma specimens from HIV-1 positive antibody test specimens ordered by NYS providers or on patients residing in NYS should be submitted for HIV incidence surveillance. Please contact the HIV Incidence Coordinator at 518-474-4284 in the Bureau of HIV/AIDS Epidemiology to arrange for specimen transfer to the CDC STARHS Laboratory. Remnant specimens from tests ordered by NYC providers or on patients residing in NYC may be submitted to the HIV Serosurvey Unit at the NYCDOHMH Public Health Laboratory, 455 First Avenue, New York, NY 10010. Please call 212-442-3388 or 212-447-2923 for further information.
- ⑩ Suspect novel Influenza virus: Any sample testing positive for Influenza A, but failing to test positive for any seasonal circulating human subtypes, should be immediately forwarded. In the event of specimens from patients meeting case criteria for suspected novel influenza, contact the NYS Wadsworth Center or the NYC Public Health Laboratory immediately for guidance.
- ⑪ In addition to reporting positive cultures taken from sterile sites, the EIP laboratories should also submit *Listeria* isolates from non-sterile sites for residents of the following counties: Albany, Allegany, Cattaraugus, Chautauqua, Chemung, Clinton, Columbia, Delaware, Erie, Essex, Franklin, Fulton, Genesee, Greene, Hamilton, Livingston, Monroe, Montgomery, Niagara, Ontario, Orleans, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, Schuyler, Seneca, Steuben, Warren, Washington, Wayne, Wyoming, and Yates.
- ⑫ *Neisseria gonorrhoeae* isolates with any one of the following minimum inhibitory concentrations (MIC) values should be submitted for confirmation: a) ceftriaxone MIC greater than or equal to 0.125 ug/ml, b) cefixime MIC greater than or equal to 0.250 ug/ml, or c) azithromycin MIC greater than or equal to 2 ug/ml
- ⑬ When culture-independent (molecular) methods are used to diagnose/screen for bacterial infections, reflex to culture is required for public health purposes. Isolates should be submitted to the NYS and NYC Public Health Laboratories.
- ⑭ MRSA (for NYC residents only) – Elements required in the reports are the same as those required on paper forms and must also include the results of antibiotic susceptibility testing. Should include both quantitative test results if applicable and interpretation (e.g., susceptible, intermediate, non-susceptible or resistant). Please include the interpretive criteria (CLSI breakpoints) used by your laboratory (see CLSI performance standards for antimicrobial susceptibility testing).
- ⑮ Report all reactive results via ECLRS within 24 hours. Report negative or non-reactive results for any testing associated with positive/reactive results. All reported non-treponemal results must include a titer value using standard notation (e.g., end-point reactivity at a serum dilution of 1:8 is reported as a titer of 8). All reactive non-treponemal screens should be confirmed with a standard treponemal test unless the patient had a known documented prior syphilis infection. Reports of reactive non-treponemal screens must also include either current treponemal test results (positive or negative) or prior confirmation information.
The following reporting guidance is provided:
- 1) All positive results must be reported to ECLRS within 24 hours with the exception of positive treponemal enzyme or chemiluminescence immunoassay (EIA/CIA) results, which must be reported to ECLRS together with the reflex RPR result (reactive or non-reactive) within 24 hours of RPR result availability. Reactive non-treponemal results must include a titer value using standard notation.
 - 2) For NYS residents, labs must also report the following results immediately by telephone to LHD: non-treponemal test titer of ≥ 16 , reactive prenatal or perinatal test results or primary or secondary stage of syphilis.
 - 3) All reactive non-treponemal tests should be confirmed with a standard treponemal test if there is no preceding positive EIA/CIA result. Reports of reactive non-treponemal results must also include the treponemal test result (reactive or non-reactive).
 - 4) For those laboratories that perform an alternate confirmatory treponemal test (i.e., TP-PA) on sera with discordant results from the reverse sequence syphilis screening protocol, i.e., positive EIA/CIA, negative RPR/VDRL, report the results of confirmatory treponemal testing (reactive or non-reactive) together with EIA/CIA and non-treponemal test results.