ARTICLE 13
LABORATORIES

§13.01 Definitions.

When used in this article:

(a) *"Laboratory*" or "*clinical laboratory*" means a facility, including a blood bank, regulated pursuant to Title 5 of Article 5 of the Public Health Law holding a permit issued by the New York State Department of Health, and operating in the City or testing a specimen taken from a City resident.

(b) "*Research laboratory*" means a laboratory used primarily for research, development, storage, examination or testing of one or more biological agents by or under the direct supervision of a technically qualified individual, but does not include: (i) clinical laboratories and blood banks holding permits issued pursuant to Title 5 of Article 5 of the Public Health Law; (ii) laboratories where recombinant DNA experiments are conducted pursuant to Article 32-A of the Public Health Law; (iii) tissue or organ banks holding permits issued pursuant to Article 43-B of the Public Health Law; and (iv) laboratory facilities operated by New York State or federal governments.

(c) "*Biological agent*" means an infectious microorganism or hazardous biological material, such as a bacterium, virus, fungus, parasite, or biological toxin that is associated with human disease.

(d) *"High-containment research laboratory*" means any research laboratory that operates at biosafety level 3 or biosafety level 4, as defined by the Centers for Disease Control and Prevention and National Institutes for Health in Biosafety in Microbiological and Biomedical Laboratories, or successor document available at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf.

(e) *"High-risk agent*" means Middle East respiratory coronavirus (MERS-CoV), all Mycobacterium tuberculosis strains and any other biological agent that the Commissioner, upon notice, determines would be a severe risk to public health if released into the environment and could result in severe morbidity or high mortality.

(f) *"Select agent"* means a biological agent or toxin listed in 42 CFR §§ 73.3 or 73.4 or 9 CFR § 121.4, or any successor provisions, which requires laboratories that possess, use or transfer such agent to register with the Federal Select Agent Program, as described in 42 CFR Part 73, 9 CFR 121 and 7 CFR Part 331.

(g) *"Exposure*" means the ingestion, inhalation, inoculation, or contamination of skin or mucous membranes with a biological agent.

§13.03 Report of Findings, Supplemental Testing and Submission of Isolates.

(a) The director of a clinical laboratory conducting an examination of a specimen submitted for analysis shall, except as noted below with respect to blood banks, report to the Department, within 24 hours of obtaining results, all positive or reactive laboratory findings which indicate the presumptive or confirmed presence of any disease or condition required to be reported by subdivision (a) of §11.03 of this Code, and also any laboratory findings which are otherwise required to be reported pursuant to this section or this Article; provided that findings indicating the presumptive or confirmed presence of diseases or conditions required to be reported pursuant to paragraph (1) of subdivision (b) of §11.03, as well as outbreaks or suspected outbreaks, unusual manifestations of disease or conditions and unusual diseases required to be reported pursuant to subdivision (c) of §11.03, shall also be reported to the Department immediately by telephone. A clinical laboratory which refers a specimen to another laboratory for examination shall provide to the testing laboratory all of the information the testing laboratory will need to fully comply with the reporting requirements set forth in this Article or this Code; provided, however, that if a blood bank refers a specimen to a laboratory for testing without donor identifying information, then the referring blood bank, and not the testing laboratory, shall comply with the reporting requirements of this Article or this Code. Reports shall contain all of the information and data elements required by the reporting forms or electronic reporting format approved by the Department, including but not limited to:

(1) The full name, date of birth and address of the person from whom the specimen was taken; the race, ethnicity and gender of such person, if known; the pregnancy status of such person, if the pregnancy status is known or probable, (e.g., if a pre-natal panel was ordered) and if it is clinically relevant to the positive laboratory result, for example, a positive hepatitis B surface antigen or a positive syphilis test result; the specimen source; and the date the specimen was collected; patient email and mobile phone number, if known; provider email, fax number, mobile phone number and National Provider Identification (NPI) number if known; and facility National Provider Identification (NPI) number.

(2) The medical record number if known, identification number or code assigned to the person, if any, and other personal identifiers as may be required by the Department.

(3) The name, address and telephone number of the physician or other authorized health care practitioner who submitted the specimen, the health care facility, if any, that submitted the specimen, and the clinical laboratory that referred the specimen, if any.

(4) The name and address of the clinical laboratory which performed the test.

(5) The date the test or tests results were first available.

(6) The name(s) of test or tests performed.

(7) The positive or reactive results (including quantitative results related to positive or reactive serologic tests for reportable diseases or conditions specified by the Department if quantitative testing was performed).

(8) The antimicrobial susceptibility testing results for bacterial and fungal diseases listed under subdivision (a) of §11.03 of this Code. This requirement includes traditional broth, agar and newer automated methods of antimicrobial susceptibility testing, as well as molecular-based methods that assay for molecular determinants of antimicrobial resistance.

(b) (1) With regard to tuberculosis, reports shall also include all laboratory findings which indicate presumptive or confirmed presence of tuberculosis, the results of smears found positive for acid fast bacilli (AFB), all results including negatives and species identification on samples which had positive smears, all blood-based or other laboratory test results positive for tuberculosis infection for children less than five years of age, all drug susceptibility testing results and all subsequent test results on samples collected within one year from any patient who had a previous positive AFB smear or a positive *Mycobacterium tuberculosis* complex test result (e.g., culture or NAA). Reports shall specify the laboratory methodology used and shall state if applicable whether the specimen was susceptible or resistant to each anti-tuberculosis drug at each concentration tested.

(2) With regard to syphilis:

(A) All syphilis test results, whether positive, negative or indeterminate shall be reported to the Department. For purposes of this paragraph, syphilis tests include, but are not limited to, treponemal tests, non-treponemal tests and direct detection tests, such as darkfield microscopy, direct fluorescent antibody and polymerase chain reaction tests.

(B) Where the result of a treponemal or non-treponemal syphilis test is indeterminate, the laboratory must perform additional testing as provided herein. For purposes of this subparagraph, an indeterminate test result is one in which the result of a test is weakly reactive, minimally reactive, equivocal, inconclusive, or otherwise indeterminate; an indeterminate result does not include instances where two separate tests have conclusive but discordant results.

i. When a treponemal test result is indeterminate, the laboratory must perform, or refer the specimen to another laboratory for the performance of, a second treponemal test on the same specimen using an alternate treponemal test within 24 hours of obtaining the indeterminate result. Where the result of the second treponemal test is also indeterminate, whether performed by the same laboratory or a different laboratory, no additional treponemal test is required.

ii. When a non-treponemal test result is indeterminate, the laboratory must perform, or refer the specimen to another laboratory for the performance of, a second non-treponemal test on the same specimen using the same or an alternate non-treponemal test within 24 hours of obtaining the indeterminate result. Where the result of the second non-treponemal test is also indeterminate, whether performed by the same laboratory or a different laboratory, no additional non-treponemal test is required.

(3) (A) With regard to hepatitis A, B, or C, reports shall also include the results of alanine aminotransferase testing (ALT) if performed on the same specimen that tests positive for any of the reportable viral hepatitides.

(B) With regard to hepatitis B, all hepatitis B DNA, hepatitis B e antigen and hepatitis B surface antigen test results must be reported, including positive, negative and indeterminate results. In addition, all hepatitis B surface antibody test results, including positive, negative and indeterminate results, for children ages 0 days to 1,825 days (birth up to the fifth birthday) must be reported electronically in accordance with subdivision (c) of this section when patient age is known. Blood bank laboratories and other laboratories that perform hepatitis B DNA, hepatitis B

e antigen or hepatitis B surface antigen tests on donated blood are exempt from reporting negative and indeterminate hepatitis B DNA, hepatitis B e antigen or hepatitis B surface antigen test results for such donated blood.

(C) With regard to hepatitis C:

(i) All hepatitis C nucleic acid amplification and hepatitis C antibody test results, including positive, negative and indeterminate results, must be reported electronically in accordance with subdivision (c) of this section. Blood bank laboratories and other laboratories that perform hepatitis C nucleic acid amplification and hepatitis C antibody tests on donated blood, without a positive hepatitis C antibody test, are exempt from reporting negative hepatitis C nucleic acid amplification test results for such donated blood.

(ii) If an antibody test is positive for hepatitis C virus, the laboratory must perform, or refer the specimen to another laboratory for performance of, a confirmatory RNA test on the same specimen or a second specimen collected at the same time as the initial specimen. The confirmatory RNA test must be initiated, or the specimen forwarded to another laboratory for that purpose, within 72 hours of obtaining the positive antibody test result.

(4) If a culture-independent diagnostic test or other laboratory test demonstrates the possible presence of *Listeria monocytogenes, Salmonella, Shigella, Vibrio, or Yersinia* in a patient specimen, the laboratory must perform, or refer the specimen to another laboratory for performance of, culture on the original specimen to isolate the organism. The culture must be initiated, or the specimen forwarded to another laboratory, within 72 hours of obtaining the positive culture-independent diagnostic test or other laboratory test result. The laboratory that performed the culture-independent diagnostic test or other positive test for one of the listed enteric pathogens must report the results of the subsequent culture test, whether positive or negative and whether performed by it or another laboratory, to the Department within 24 hours of obtaining the result. The laboratory that performed the culture must submit the resulting isolates, if any, to the Department in a manner and form prescribed by the Department. In the case of Shiga toxin-producing *Escherichia coli*, the laboratory must submit (i) an isolate or (ii) a Shiga toxin-positive broth (if available) and stool to the Department in a manner and form prescribed by the Department.

(c) Reports required pursuant to this article shall be made in a manner and form prescribed by the Department. Notwithstanding any other provision of this Code, clinical laboratories shall report to the Department using electronic or computer media prescribed by the Department in a format specified by the Department, including through the use of the electronic reporting system utilized by the New York State Department of Health. Written paper reports may be submitted for a limited period of time only in the case of extenuating circumstances, temporary equipment failure, or prolonged inability to access the Internet, and only with the specific approval of the Department. In addition, the Department may, on its own initiative, allow written, paper reports to be submitted if electronic reporting is not possible in a particular circumstance, as a result of a deficiency in the Department's or the State Health Department's electronic reporting system. The Department may, in addition, require summary, cumulative or periodic reports on such reporting schedule as it may deem necessary.

§13.05 Testing for tuberculosis.

A clinical laboratory authorized to perform tests for tuberculosis, including the growth of cultures from clinical specimens for the isolation of mycobacteria, shall adhere to the following minimum requirements:

(a) Within 24 hours of observing growth of a culture or subculture of M. tuberculosis complex, a portion of the initial culture or subculture from any specimen from which M. tuberculosis complex has been isolated shall be submitted to the Department for DNA or other molecular analysis.

(1) A laboratory which submits a specimen to the Department for drug susceptibility testing shall be deemed to have complied with subdivision (a) of this section unless otherwise notified by the Department.

(2) The Department's records relating to such DNA analysis shall be confidential in accordance with §11.11 of this Code.

(b) (1) Smears performed to detect acid fast bacilli (AFB) shall be examined within 24 hours after receipt of the specimen in the laboratory, and when concentrated smears for AFB are performed on clinical specimens (e.g., sputum) all positive results shall be reported to the Department. Negative smears shall be reported to the physician or other person authorized to request laboratory tests, or the forwarding laboratory, if any, within 24 hours pursuant to §13.05(b)(7) and must also be reported to the Department if the smear is from a patient who, within the last year, was previously reported with a positive AFB smear. All respiratory specimens which test acid-fast smear positive and are from patients who have not previously been diagnosed with tuberculosis shall have nucleic acid amplification testing performed. If a laboratory examining the specimen does not have the ability to perform nucleic acid amplification testing, it shall submit an appropriate specimen to the Department for testing by the Department or a laboratory designated by the Department.

(2) Conventional cultures of clinical specimens shall be initiated within 24 hours after receipt, shall be examined for growth at least once each week after inoculation and, upon observing adequate suspicious growth, an acid fast smear examination shall be performed. Identification of M. tuberculosis complex shall be completed within four (4) working days after adequate suspicious growth is first observed; and

(3) Cultures of clinical specimens shall be completed within fifteen (15) working days after growth is first indicated. Identification of M. tuberculosis complex shall be completed within four (4) working days after adequate suspicious growth is first observed; and

(4) If direct drug susceptibility testing is performed it shall be initiated within 24 hours or the next scheduled workday after obtaining a smear positive for acid fast bacilli, and, if indirect drug susceptibility testing of pure cultures is performed, it shall be initiated as soon as growth typical of M. tuberculosis is observed; and

(5) If the time periods provided in paragraphs 1 through 4 above cannot be adhered to by the receiving laboratory, then specimens shall be forwarded to another clinical laboratory within 24 hours after receipt of a specimen; and

(6) For other laboratory techniques and methodologies, examination schedules recommended by the manufacturer of each such methodology shall be adhered to; and

(7) The result of any test or examination related to tuberculosis including but not limited to those specified in this section shall be reported to the physician or other person

authorized to request clinical laboratory tests, or the forwarding laboratory, if any, within 24 hours of the test result or finding.

(8) A negative result of any laboratory test or examination related to tuberculosis must also be reported to the Department within 24 hours of the test result being known if the test is conducted on a specimen from a patient with any prior positive laboratory test related to tuberculosis on any sample collected within one year.

§13.07 Reporting of Hemoglobin A1C.

(a) All clinical laboratories, as defined under §13.01 of this Article, that report laboratory test results electronically to the Department and which use a file up-load method, shall electronically report to the Department all laboratory results for Hemoglobin A1C tests, as defined in subdivision (b) of this section, within 24 hours of obtaining such results.

(b) The "Hemoglobin A1C" laboratory test represents an index of blood glucose control measuring average blood sugar over the past 90 days, and shall mean the following for the purposes of this section: HgbA1c; HgbA1c by HPLC; HbA1c; Glycohemoglobin A1C; Gycolhaemoglobin; Glycohemoglobin; Glycated Hgb; Glyco-Hb; GHb; Ghb. As defined in this section, "Hemoglobin A1C" shall not mean the following: Hgb; Hemoglobin; Hb; Hb without reference to glycated or glycosylated or A1C; or Glycohemoglobin total.

(c) Reports required by subsection (a) shall contain the information required in §13.03 (a) of this Article and of paragraphs (1) through (6) thereof.

(d) Hemoglobin A1C test results and other identifying information reported to the Department pursuant to this section shall be confidential and shall not be disclosed to any person other than the individual who is the subject of the report or to such person's treating health care providers. If the subject of the report is a minor, information can be disclosed to the subject's parent or legal guardian.

§13.09 Neonatal herpes simplex specimens.

When a clinical laboratory detects herpes simplex virus in a specimen collected from a child 60 days of age or less, the laboratory shall, unless otherwise directed by the Department, send the original specimen and any derived materials to the New York State Department of Health Wadsworth Center laboratories, or another laboratory determined by the Department for further testing as specified by the Department. If testing is conducted, positive and negative test results shall be forwarded to the Department.

§13.11 High-containment research laboratories: registration.

(a) *Registration*. Every person operating a high-containment research laboratory in the City of New York must register such laboratory with the Department. Registrations will expire and must be renewed every three years. An entity or person registering with the Department must provide all the information requested by the Department on the registration form, including but not limited to:

(1) Name, address and other contact information for the officers or persons in control of the operating entity;

(2) Locations and biosafety level rating or ratings for each research laboratory operated by the registering entity;

(3) Name, title and contact information of at least two designated persons who are individuals at the research laboratory designated to submit to the Department the reports required by §13.13 of this Article, provided that one such designated person is the manager or other person in control of the research laboratory biosafety committee; and

(4) A listing of all biological agents stored or used in each high-containment research laboratory at the time of registration. The listing must include the parent strain of the agent and any derivative strains identified by the high-containment research laboratory as having unique virulence or pathogenic potential.

(b) *New facilities*. Any person intending to operate a new high-containment research laboratory must register such laboratory according to this section before such laboratory commences operation.

(c) *Changes in registration information*. The registrant must notify the Department within thirty (30) calendar days of any changes to the information provided on the registration form that pertains to any select agent or high-risk agent.

§13.13 High-containment research laboratories; required reports.

(a) *Loss or theft of a biological agent.* No later than four hours after determining that there has been a theft or loss of a biological agent from a high-containment research laboratory, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of such theft or loss at a telephone number designated by the Department. Any theft or loss must be reported even if the lost or stolen biological agent is subsequently recovered and/or the responsible parties are identified. The following information must be provided:

(1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);

(2) The quantity or an estimate of the quantity of the biological agent that was lost or stolen;

(3) The time or an estimate of the time during which the theft or loss occurred;

(4) The location (building, room) from which the theft or loss occurred.

(b) *Exposure to or unintentional release of biological agents.* Within one hour of determining that a person may have been exposed to a biological agent stored or used in a high-containment research laboratory, or of any unintentional release of a biological agent, or of an illness associated with exposure to a biological agent used or stored in a high-containment research laboratory, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of the actual or potential exposure at a telephone number designated by the Department. The following information must be provided:

(1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);

(2) An estimate of the number of persons potentially exposed to the biological agent in or by the research laboratory and within the entity;

(3) An estimate of the quantity of biological agent that was released;

(4) An estimate of the time and duration of the release of the biological agent;

(5) The environment into which the biological agent was released (e.g., within vs. outside building, into a waste system);

(6) The location (building, room) from which the release of the biological agent occurred;

(7) Identification and contact information for all persons known to be exposed to the biological agent;

(8) Actions taken to respond to the release of the biological agent; and

(9) Hazards posed by the release of the biological agent.

(c) No requirement of this section affects any other obligation under any other law or regulation for a high-containment laboratory to report the loss, theft or release of a biological agent to any other law enforcement or regulatory agency.

(d) All information, records and reports required by this section shall be kept confidential, provided that the Commissioner may disclose to a city, state or federal agency information necessary to respond to an emergency after determining such an emergency exists.