



Department of Health and Mental Hygiene

Board of Health

Notice of Adoption of Amendment to Articles 11 and 13 of the New York City Health Code

In compliance with §1043(b) of the New York City Charter (the “Charter”) and pursuant to the authority granted to the Board of Health (the “Board”) by §558 of said Charter, a notice of intention to amend Articles 11 and 13 of the New York City Health Code (the “Health Code”) was published in the City Record on September 20, 2016 and a public hearing was held on October 25, 2016. There was no testimony presented at the hearing but four written comments were received. Several changes were made, some of which were in response to the comments received, as discussed below. At its meeting on December 6, 2016 the Board adopted the following resolution.

Statement of Basis and Purpose

The Department’s Division of Disease Control conducts disease surveillance and control activities for most of the diseases listed in Article 11 (Reportable Diseases and Conditions) of the Health Code. The Division of Disease Control also enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates the manner in which laboratory tests must be performed and the reporting of test results. In addition, the Department is required to comply with various provisions of Part 2 of the New York State Sanitary Code, found in Title 10 of the New York Codes, Rules and Regulations, with respect to control of communicable diseases.

To conduct more effective, timely, and complete disease surveillance and control, the Board is amending Health Code Articles 11 and 13 as follows:

Hepatitis D and E and Other Suspected Infectious Viral Hepatitides Reporting

Hepatitis D and E and “other suspected infectious viral hepatitides” are being removed from Health Code §11.03(a)’s list of reportable diseases and §13.03(b)(3)’s requirements regarding reportable laboratory findings. The New York State Sanitary Code does not require reporting of either hepatitis D or E, nor do a majority of United States jurisdictions.

Hepatitis D and E and “other suspected infectious viral hepatitides” were added to the list of reportable diseases in 2005, largely due to outbreaks of hepatitis D and E observed abroad. After 10 years of surveillance, the Department has determined that these viruses no longer need to be monitored. Hepatitis D is uncommon in the United States. It is an “incomplete virus” in that it can replicate in the presence of hepatitis B virus; thus, hepatitis D is usually detected in connection with hepatitis B infection or outbreak and need not be separately reported. Since hepatitis D cannot be transmitted in the absence of the hepatitis B virus, hepatitis B immunization and treatment are the best approaches to reduce hepatitis D incidence. There were only 21 reports of hepatitis D in New York City from 2013 to 2015.

Hepatitis E outbreaks have not occurred in New York City. Most hepatitis E cases are linked to foreign travel and most persons infected with the virus recover completely. There is no specific vaccine or antiviral therapy for acute hepatitis E. In addition, hepatitis E cases are often misreported, for reasons including the high false-positive rate of hepatitis E tests. Of 86 hepatitis E cases reported 2006-2009, 67 percent were determined not to be actual cases and 89 percent of confirmed cases had a history of foreign

travel. For these reasons, and to redirect Department resources to address more urgent public health threats, the Department stopped routine investigation of hepatitis E cases in 2010.

Any novel strains of viral hepatitis are reportable as part of providers' obligation to report unusual manifestations of disease and any newly apparent or emerging disease under Health Code §11.03(c)(1). Thus, it is unnecessary and redundant to have a separate reporting requirement for these hepatitis strains.

Zika Reporting

Pursuant to Health Code §11.03(a), all confirmed cases and carriers of an acute arboviral infection must be reported to the Department within 24 hours. Although Zika virus is currently reportable as an acute arboviral infection, the Board is amending Health Code §11.03(a) to expressly include Zika virus in the list of named acute arboviruses for clarity. For reportable conditions, the Department can monitor New Yorkers to ascertain where the infection was acquired, helping the Department implement prevention strategies. The Department can also investigate to promptly recognize novel forms of transmission, including by local mosquitos.

Tuberculosis Reporting for Children Less Than Five Years of Age

Children less than five years of age infected with tuberculosis (TB) are at increased risk for progressing to active disease and developing life-threatening forms of the disease, such as disseminated TB and TB meningitis. For this reason, the Health Code requires providers to report a positive reaction to the purified protein derivative Mantoux test or other recognized TB diagnostic test for this age group.

The Board is amending Health Code §11.03(a) and §11.21, regarding tuberculosis reporting, to further augment the reporting requirements for children less than five years of age to require providers to submit qualitative and quantitative test results and radiology reports where there is a positive test for TB infection, and report initiation of treatment for TB infection. This information will enable the Department to help ensure that providers have ruled out active TB disease and that they initiate appropriate treatment in patients. Further, requiring routine submission of radiology reports will save the Department time and resources currently spent to obtain such reports.

In addition, §13.03(b)(1) of the Health Code, regarding laboratory reporting of tuberculosis, is being amended to require laboratories to report positive results for TB infection obtained from a blood-based test (e.g., interferon-gamma release assays) or other laboratory test when performed on children less than five years of age. Currently, only providers submit positive TB test results for this age group. Requiring reporting by both laboratories and providers will help ensure the Department is made aware of all children less than five years of age with a positive test for TB infection.

Immunization Reporting

Health Code §11.07(a)(3) is being amended to allow for adult patients' non-written consent for immunization reporting (currently, consent must be in writing). State Public Health Law § 2168 was amended in 2013, with the support of the Department, to similarly allow non-written consent for reporting to the State-run registry, and subparagraph 2168(3)(b)(i) allows non-written consent for reporting to the City registry. Written consent is a barrier to immunization reporting and eliminating this requirement will help increase provider reporting.

Isolation of Suspected and Confirmed Varicella Cases

The Board is amending Health Code §11.17(a), regarding control and isolation of certain diseases, to require isolation of patients with suspected or confirmed varicella in hospitals and other

clinical facilities, as is required for other communicable diseases that pose a significant threat to public health. Since varicella can be spread by air, isolation is important to reduce the risk of transmission in healthcare facilities. As a recent example, in June 2016, a one-year-old baby developed varicella infection after being exposed to patients with varicella at a medical facility. The proposed language has been modified to clarify that varicella includes both primary varicella (chickenpox) and disseminated zoster, and that patients with either disease must be isolated.

Syphilis Testing and Reporting

The Board is amending Health Code §13.03(b)(2) to require laboratories to report indeterminate syphilis test results and, where a result is indeterminate, perform a second test on the same specimen and report the result of that test. If the result of the second test is also indeterminate, the laboratory would not be required to perform additional testing. While many laboratories already report indeterminate test results, it is not explicitly required in the Health Code. The amendment provides for more complete reporting. Based on a comment received, the proposal has been modified to clarify that “indeterminate” results do not include instances in which two separate tests have conclusive but discordant results.

In 2015, there were 1,968 indeterminate syphilis test results reported to the Department. The standard approach to resolving an indeterminate test is for a laboratory to retest the same specimen with the same or an alternate diagnostic test or for a healthcare provider to collect another specimen from the patient and test that specimen. To help ensure prompt initiation of treatment of individuals with syphilis, the Department classifies indeterminate test results as positive. This results in the initiation of case investigation and field activities, which include Department staff contacting providers, laboratories, patients, and sex partners of patients.

Requiring laboratories to routinely perform a second syphilis test at the time an indeterminate result is obtained will enable prompt treatment initiation and reduce the risk of disease progression and transmission if the test is positive. The Department will also be able to focus its resources on those New Yorkers with confirmed infections or exposure to infected persons.

Other minor language changes that have no bearing on provider reporting obligations are being made to simplify and clarify §13.03(b)(2).

Enteric Disease Testing and Isolate Submission

The Board is amending Health Code §13.03(b) to require laboratories to perform culture testing on all specimens that are found to be positive by a culture-independent diagnostic test (CIDT) for certain enteric bacterial pathogens (*Campylobacter*, *Listeria monocytogenes*, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia*). Culture testing involves a laboratory using a specimen to grow the pathogen; a sample of the pathogen grown by culture is termed an “isolate.” The amendment also requires laboratories to submit all resulting isolates to the Department. For Shiga toxin-producing *Escherichia coli* (STEC), laboratories will be required to submit Shiga toxin-positive broth (if available) and stool or an isolate. In response to comments received, the proposed requirements have been modified to reflect that where no isolate is produced, only the negative result need be reported, and that the broth need be submitted only if available. The proposed requirements have also been modified to include a timeframe for initiating or ordering the culture testing.

Laboratories are increasingly using CIDTs and not performing culture testing. At least two New York City laboratories can no longer perform bacterial culture on stool specimens, and several New York City laboratories have limited capabilities. The Department and other public health agencies in the United States rely on testing isolates of enteric pathogens to detect and manage outbreaks. Isolates of enteric pathogens undergo testing at the Department laboratory by methods such as pulsed-field gel

electrophoresis, colloquially known as ‘DNA fingerprinting.’ The Department combines the results of ‘DNA fingerprinting’ with patient interviews and environmental investigation to confirm and remediate sources of food contamination. CIDTs do not yield isolates for such testing.

The Centers for Disease Control and Prevention encourages laboratories to culture enteric specimens with a positive CIDT result (*Morbidity and Mortality Weekly Report*. Centers for Disease Control and Prevention. Bacterial Enteric Infections Detected by Culture-Independent Diagnostic Tests — FoodNet, United States, 2012–2014. *MMWR*. 2015;64(09):252-257). The Association of Public Health Laboratories (APHL) recommends that “all public health departments establish legal requirements for the submission of enteric bacterial disease isolates and/or clinical specimens by hospital and clinical laboratories. . . .” APHL’s position is based in part on its finding that “[t]he rapidly increasing availability of CIDTs for foodborne pathogens poses serious challenges for public health and is threatening to derail current laboratory-based surveillance systems” (APHL Position Statement: Establishing Legal Requirements for the Submission of Enteric Disease Isolates and/or Clinical Material to Public Health Laboratories, Approved by Membership February 2015). Requiring laboratories to perform culture testing and submit resulting isolates is consistent with the APHL recommendation.

Statutory Authority

The authority for these proposed amendments is found in Sections 556 and 558 of the New York City Charter (the “Charter”). Sections 558(b) and (c) of the Charter empower the Board (the “Board”) to amend the Health Code and to include all matters to which the Department’s authority extends. Section 1043 grants the Department rule-making authority.

Section 556 of the Charter provides the Department with jurisdiction to protect and promote the health of all persons in the City of New York.

The rule is as follows:

Note: Matter in brackets [] is to be deleted. Matter underlined is new.

“Shall” and “must” denote mandatory requirements and may be used interchangeably unless otherwise specified or unless the context clearly indicates otherwise.

RESOLVED, that subdivision (a) of section 11.03 of Article 11 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

§11.03 Diseases and conditions of public health interest that are reportable.

(a) Cases and carriers affected with any of the following diseases and conditions of public health interest, and persons who at the time of their death were apparently so affected, shall be reported to the Department as specified in this article:

Amebiasis

Anaplasmosis (Human granulocytic anaplasmosis)

Animal bite, or exposure to rabies

Anthrax

Arboviral infections, acute (including but not limited to the following viruses: [Chikungunyavirus,] chikungunya virus, Zika virus, dengue virus, Eastern equine encephalitis virus, Jamestown Canyon virus, Japanese encephalitis virus, La Crosse virus, Powassan virus, Rift Valley fever virus, St. Louis encephalitis virus, Western or Venezuelan equine encephalitis virus, West Nile virus and yellow fever)

Babesiosis

Botulism (including infant, foodborne and wound botulism)

Brucellosis (undulant fever)

Campylobacteriosis

Chancroid

Chlamydia trachomatis infections

Cholera

Creutzfeldt-Jakob Disease

Cryptosporidiosis

Cyclosporiasis

Diphtheria

Drownings, defined as the process of experiencing respiratory impairment from submersion/immersion in liquid whether resulting in death or not

Ehrlichiosis (Human monocytic ehrlichiosis)

Encephalitis

Escherichia coli 0157:H7 infections

Falls from windows in multiple dwellings by children sixteen (16) years of age and under

Food poisoning occurring in a group of two or more individuals, including clusters of diarrhea or other gastrointestinal symptoms; or sore throat which appear to be due to exposure to the same consumption of spoiled, contaminated or poisonous food, or to having eaten at a common restaurant or other setting where such food was served. Also includes one or more suspected cases of neurologic symptoms consistent with foodborne toxin-mediated, including but not limited to botulism, combroid or ciguatera fish poisoning, or neurotoxic or paralytic shellfish poisoning.

Giardiasis

Glanders

Gonococcal infection (gonorrhea)

Granuloma inguinale

Hantavirus disease

Hemolytic uremic syndrome

Hemophilus influenzae (invasive disease)

Hepatitis A; B; and C; D (“Delta Hepatitis”); E; and other suspected infectious viral hepatitises]

Herpes simplex virus, neonatal infections (in infants 60 days or younger)

Hospital associated infections as defined in Title 10 New York Codes, Rules and Regulations (NYCRR) Section 2.2 (New York State Sanitary Code) or its successor law, rule or regulation

Influenza, novel strain with pandemic potential

Influenza, laboratory-confirmed (only required through the Department’s electronic reporting mechanism set forth in §13.03(c) of this Code)

Influenza-related deaths of a child less than 18 years of age

Legionellosis

Leprosy

Leptospirosis

Listeriosis

Lyme disease

Lymphocytic choriomeningitis virus

Lymphogranuloma venereum

Malaria

Measles (rubeola)

Melioidosis

Meningitis, bacterial causes (specify type)

Meningococcal, invasive disease

Monkeypox

Mumps

Norovirus, laboratory-confirmed (only required through the Department’s electronic reporting mechanism set forth in §13.03(c) of this Code)

Pertussis (Whooping cough)

Plague

Poisoning by drugs or other toxic agents, including but not limited to lead poisoning consisting of a blood lead level of 10 micrograms per deciliter or higher (see also §11.09(a) of this Code); carbon monoxide poisoning and/or a carboxyhemoglobin level above 10%; and including confirmed or suspected pesticide poisoning as demonstrated by:

- (1) Clinical symptoms and signs consistent with a diagnosis of pesticide poisoning; or
- (2) Clinical laboratory findings of blood cholinesterase levels below the normal range; or
- (3) Clinical laboratory findings or pesticide levels in human tissue above the normal range.

Poliomyelitis

Psittacosis

Q fever

Rabies

Respiratory syncytial virus, laboratory-confirmed (only required through the Department's electronic reporting mechanism set forth in §13.03(c) of this Code)

Ricin poisoning

Rickettsialpox

Rocky Mountain spotted fever

Rotavirus, laboratory-confirmed (only required through the Department's electronic reporting mechanism set forth in §13.03(c) of this Code)

Rubella (German measles)

Rubella syndrome, congenital

Salmonellosis

Severe or novel coronavirus

Shiga toxin-producing *Escherichia coli* (STEC) (which includes but is not limited to *E. coli* O157:H7)

Shigellosis

Smallpox (variola)

Staphylococcal enterotoxin B poisoning

Staphylococcus aureus, methicillin-resistant, laboratory-confirmed (only required through the Department's electronic reporting mechanism set forth in §13.03(c) of this Code)

Staphylococcus aureus, vancomycin intermediate and resistant (VISA and VRSA)

Streptococcus, Group A (invasive infections)

Streptococcus, Group B (invasive infections)

Streptococcus pneumoniae invasive disease

Syphilis, all stages, including congenital

Tetanus

Toxic shock syndrome

Trachoma

Transmissible spongiform encephalopathy

Trichinosis

Tuberculosis, as demonstrated by:

- (1) Positive culture for *Mycobacterium tuberculosis* complex; or
- (2) Positive DNA probe, polymerase chain reaction (PCR), or other technique for identifying [Mycobacterium tuberculosis] *Mycobacterium tuberculosis* from a clinical or pathology specimen; or
- (3) Positive smear for acid-fast bacillus, with final culture results pending or not available, on either a microbiology or a pathology specimen; or
- (4) Clinically suspected pulmonary or extrapulmonary (meningeal, bone, kidney, etc.) tuberculosis, such that the physician or other health care professional attending the [case] patient has initiated or intends to [initiate isolation] isolate the patient or initiate treatment for tuberculosis, or to continue or resume treatment for previously incompletely treated disease, or, if the patient is not available, that the physician or other health care professional would initiate isolation or treatment if the patient were available; or
- (5) Biopsy, pathology, or autopsy findings in lung, lymph nodes or other tissue specimens, consistent with active tuberculosis disease including, but not limited to presence of acid-fast bacilli, caseating and non-caseating granulomas, caseous matter, tubercles and [fibre-caseous] fibro-caseous lesions; or
- (6) Positive reaction to the purified protein derivative (PPD) Mantoux test, blood-based tests positive for tuberculosis infection, or other recognized diagnostic test positive for tuberculosis infection in a child less than five years of age, regardless of whether such child has had a BCG vaccination.

Tularemia

Typhoid fever

Vaccinia disease, defined as

- (1) Persons with vaccinia infection due to contact transmission; and
- (2) Persons with the following complications from smallpox vaccination: eczema vaccinatum, erythema multiforme major or Stevens-Johnson syndrome, fetal vaccinia, generalized vaccinia, inadvertent inoculation, myocarditis or pericarditis, ocular vaccinia, post-vaccinial encephalitis or encephalomyelitis, progressive vaccinia, pyogenic infection of the vaccination site, and any other serious adverse events (i.e., those resulting in hospitalization, permanent disability, life-threatening illness or death)

Varicella, laboratory-confirmed (only required through the Department's electronic reporting mechanism set forth in §13.03(c) of this Code)

Vibrio species, non-cholera (including *parahaemolyticus* and *vulnificus*)

Viral hemorrhagic fever

Yersiniosis

RESOLVED, that paragraph (3) of subdivision (a) of section 11.07 of Article 11 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

(3) Reports of an immunization administered to any individual age nineteen and above may be submitted to the Department provided that the person administering the immunization or the person in charge of the hospital, clinic or other institution where the immunization is administered, has obtained [written] consent to report such immunization from the person to whom such immunization information relates.

RESOLVED, that subdivision (a) of section 11.17 of Article 11 the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

§11.17 Control measures; duty to isolate; and isolation, quarantine and examination orders.

(a) It shall be the duty of an attending physician, or a person in charge of a hospital, clinic, nursing home or other medical facility to isolate a case, carrier, suspect case or suspect carrier of diphtheria, rubella (German measles), influenza with pandemic potential, invasive meningococcal disease, measles, monkeypox, mumps, pertussis, poliomyelitis, pneumonic form of plague, severe or novel coronavirus, vancomycin intermediate or resistant *Staphylococcus aureus* (VISA/VRSA), smallpox, tuberculosis (active), vaccinia disease, viral hemorrhagic fever, primary varicella (chickenpox) and disseminated zoster, or any other contagious disease that in the opinion of the Commissioner may pose an imminent and significant threat to the public health, in a manner consistent with recognized infection control principles and isolation procedures in accordance with State Department of Health regulations or guidelines pending further action by the Commissioner or designee.

RESOLVED, that subdivision (a) of section 11.21 of Article 11 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended by adding a new paragraph (5) to read as follows:

(5) Reports for children less than five years of age. When a child less than five years of age has a positive test for tuberculosis infection, the physician who attends the child, or the person in charge of a hospital, dispensary or clinic giving treatment to the child, must submit to the Department reports of all qualitative and quantitative diagnostic tests for tuberculosis infection for such child, including reports of all blood-based tests and purified protein derivative (PPD) Mantoux tests (including induration where a PPD is performed); all radiological examinations (including chest x-rays, computerized tomography scans, and

magnetic resonance imaging scans); and initiation of treatment for latent tuberculosis infection, in a manner prescribed by the Department.

RESOLVED, that the section heading and subdivision (b) of section 13.03 of Article 13 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

§13.03 Report of findings and submission of isolates.

* * *

(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 [M. tuberculosis] *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, in addition to reporting any positive or reactive test results, any treponemal or non-treponemal results, whether qualitative or quantitative, [which are positive or reactive,] shall be reported to the Department [within 24 hours of obtaining any such positive or reactive results. In addition, any], and additional testing must be performed and the results reported, as follows:

(A) Any negative or non-reactive test results, or any quantitative results, on syphilis tests associated with [the aforementioned] positive or reactive results [, and performed by the same laboratory,] shall be separately reported to the Department [by the laboratory performing the associated syphilis tests within 24 hours of obtaining such results].

(B) Where the result of a syphilis test is indeterminate, the laboratory must report the indeterminate test result to the Department. For purposes of this subsection (b)(2), 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 and report the results of that second test to the Department. 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, and report the results of that second test to the Department. 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.

(C) If a laboratory has been referred a specimen to perform only tests associated with a positive [syphilis] result or an indeterminate result obtained at the referring laboratory, and such associated syphilis tests have yielded only negative or non-reactive results, then [, notwithstanding anything to the contrary in subdivision (a) of this section,] only the referring laboratory shall report said negative or non-reactive results to the Department within 24 hours of obtaining the results from the testing laboratory.

(D) If a laboratory obtains negative or non-reactive results or an indeterminate result on a specimen submitted for syphilis testing and refers a specimen for further syphilis testing to another laboratory, and such further syphilis tests yield positive or reactive results, then, [notwithstanding anything to the contrary in subdivision (a) of this section,] in addition to the testing laboratory reporting such positive or reactive results, the referring laboratory shall report both the negative or non-reactive results or indeterminate result obtained by it and also the positive or reactive results of any such further syphilis testing within 24 hours of obtaining the results from the testing laboratory.

(E) If a laboratory has been referred a specimen to perform only tests associated with an indeterminate result obtained at the referring laboratory, and such associated syphilis tests have yielded only indeterminate results, then, in addition to the testing laboratory reporting such indeterminate results, the referring laboratory shall report both the indeterminate result obtained by it and also the indeterminate results of such further syphilis testing within 24 hours of obtaining the results from the testing laboratory.

(3) With regard to hepatitis A, B, or C, [D, E or any other suspected infectious viral hepatitisides,] 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 hepatitisides.

* * *

(4) If a culture-independent diagnostic test or other laboratory test demonstrates the possible presence of *Campylobacter*, *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, 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.