



Department of Health and Mental Hygiene

Board of Health

Notice of Adoption of Amendment to Article 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 Article 13 of the New York City Health Code (the “Health Code”) was published in the City Record on June 22, 2017 and a public hearing was held on July 27, 2017. Three witnesses testified at the hearing and seven written comments were received. No changes were made to the original proposal. At its meeting on September 12, 2017, the Board adopted the following resolution.

Statement of Basis and Purpose

Pursuant to New York Public Health Law Section 580(3), the City has the authority to regulate clinical laboratories. The Department’s Division of Disease Control enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates how laboratory tests must be performed and the reporting of test results.

To conduct more effective, timely, and complete surveillance and control of hepatitis C, the Board is amending Health Code Article 13 as follows:

Hepatitis C Testing and Reporting

The Board is amending Health Code §13.03(b)(3) to require laboratories to routinely perform a confirmatory RNA hepatitis C virus (HCV) test if an antibody test is positive for hepatitis C virus. The confirmatory test must be performed on the same specimen or a second specimen collected at the same time as the initial specimen. This requirement completes diagnostic testing and helps ensure that patients infected with HCV are aware of their status, referred to appropriate medical care and treatment, and cured, thus reducing the risk of further transmission.

Most patients are first screened for HCV via an antibody test, which shows whether the patient has ever been infected with HCV. When a patient tests positive, a confirmatory RNA test is required to establish whether the individual is currently infected with the virus. If the provider does not order the confirmatory test at the same time as the antibody test, the patient must return for an additional blood draw for the RNA test. This multi-step testing process results in treatment delays and in patients not receiving needed care.

In 2016, only 48% of patients newly diagnosed and testing antibody positive who were reported to the Department had a confirmatory RNA test performed on the same specimen; and a review of 2015 data shows that 22% of New York City patients newly reported as HCV antibody positive never received confirmatory RNA testing at all. A 2016 Department survey found that 33% of 21 acute care NYC hospitals do not automatically order confirmatory RNA testing for patients with a positive antibody test.

Routine performance of a confirmatory RNA test follows Centers for Disease Control and Prevention guidelines, and will ensure that patients are accurately diagnosed, promptly treated for HCV, and receive critical related care, such as regular liver cancer screening. (Centers for Disease Control and Prevention. Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR*. 2013; 62(18):362)

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 the heading and paragraph (3) of 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 be printed together with explanatory note to read as follows:

§13.03 Report of findings, supplemental testing, and submission of isolates.

(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 hepatitises.

[(A)] (B) With regard to hepatitis B, all hepatitis B surface antigen and hepatitis B surface antibody test results, including positive, negative, and indeterminate, 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.

[(B)] (C) With regard to hepatitis C[, all]:

(i) All hepatitis C nucleic acid amplification test results, including both positive and negative 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 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.

Note: Section 13.03 was revised by the Board of Health on September 12, 2017, to provide for confirmatory testing following positive antibody testing for hepatitis C.