



Department of Health

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Governor

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Executive Deputy Commissioner

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Dear Colleague:

In January 2014, the New York State (NYS) Hepatitis C Testing Law went into effect requiring the offering of an HCV screening test to all persons born between 1945 and 1965 receiving care as an inpatient of a hospital or in primary care. The law further requires providers to ensure follow-up health care, including an HCV RNA test, for those with a reactive HCV screening test. The objective of the law is to increase the number of people who know their HCV status and get linked to care.

The purpose of this letter is to provide information on HCV reflex testing as a method for ensuring timely HCV diagnosis and linkage to care.

Recommended HCV testing algorithm

In order to appropriately identify anyone with active HCV infection, two laboratory tests must be conducted. **The first is a test that screens for HCV antibodies. If this initial HCV antibody test is reactive, it should be immediately followed with an HCV RNA test. If HCV RNA is detected in serum or plasma, active HCV infection is confirmed. See attached HCV testing algorithm.**

Despite longstanding clinical guidelines emphasizing the need for confirmatory HCV RNA testing following an initial reactive HCV antibody test, recent surveys have indicated that 50% of those with a positive HCV antibody have not completed HCV RNA testing.^{1,2} Reasons cited for this diagnostic omission are: patients do not return to have the second specimen drawn, providers fail to order the follow-up HCV RNA test explicitly, and the lack of or perceived lack of reimbursement for the second test. Antibody testing is an important first step, but antibody detection is not sufficient to identify someone with an active HCV infection. To ensure the complete and timely diagnosis of HCV, HCV reflex testing is recommended to ensure that the HCV RNA test is performed following all reactive HCV antibody screening tests.³

Reflex testing

Reflex testing simply means a laboratory will automatically perform a second test, or refer the specimen for the second test, when the result of the first test meets specific criteria. In the case of hepatitis C reflex testing, the laboratory will automatically perform an HCV RNA test on a specimen only if the HCV antibody test is reactive. If the subsequent HCV RNA test is negative, HCV infection is effectively ruled out for most patients. If the reflex HCV RNA test is positive, a diagnosis of active HCV infection is confirmed, and the individual should be referred directly for HCV care and treatment. Reflex testing allows active HCV infection to be confirmed or excluded with a single test order, obviates the need for the patient to return for follow-up testing, expedites identification of persons with current HCV infection and provides the data necessary to link those who are infected to care, including preventive services, medical management, and evaluation for antiviral treatment.

Laboratories may offer an HCV antibody test with reflex to an HCV RNA test. However, in order to do so, the laboratory must perform an HCV RNA test that was approved by the Food and

Drug Administration (FDA) or by the New York State Department of Health's (NYSDOH) Clinical Laboratory Evaluation Program for the purpose of diagnosing HCV infection. Several of the currently available quantitative HCV RNA tests (i.e., viral load tests) were approved by the FDA for the management of patients undergoing antiviral therapy and not for the purpose of diagnosing HCV infection. Therefore, in order to reflex to a quantitative HCV RNA test in the diagnostic algorithm, the laboratory must perform an appropriate validation study and obtain approval under the regulatory authority of the NYSDOH. Currently available qualitative HCV RNA tests have been FDA-approved for diagnosing HCV infection, and no additional laboratory validation is required for use of these tests in the HCV diagnostic algorithm.

There are practical steps providers can take to implement and streamline reflex testing, such as talking with your laboratory director about whether reflex testing is feasible 'in-house' or must be out-sourced, initiating changes to your EMR template ensuring HCV reflex testing is the only option when ordering an HCV screening test, and training staff on the importance of HCV testing and appropriate specimen handling. Finally, if your laboratory does not provide reflex testing following a reactive HCV antibody test, an HCV RNA test should be ordered as soon as possible to resolve the patient's HCV infection status. In light of recent advances in HCV treatments, timely diagnosis and linkage care are essential in order for persons infected with HCV to be cured of their disease and to reduce the overall burden of HCV in NYS.

Resources

Guidance for laboratories on test validation and approval from the NYS Department of Health Wadsworth Center can be found at:

http://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/reflex_testing.htm

HCV reflex testing is covered by NYS Medicaid. Information regarding Medicaid reimbursement for HCV reflex testing can be found at:

http://www.health.ny.gov/health_care/medicaid/program/update/2015/august15_mu.pdf

Additional information on HCV prevention, screening, care and treatment can be found at:

www.health.ny.gov/hepatitis.

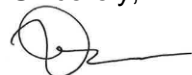
References

¹Centers for Disease Control and Prevention. Vital Signs: Evaluation of hepatitis C virus infection testing and reporting — Eight U.S. Sites, 2005–2011. *MMWR* 2013(18):357-361.

²McGibbon E, Bornschlegel K, Balter S. Half a diagnosis: Gap in confirming infection among hepatitis C antibody-positive patients. *The American Journal of Medicine* (2013) 126, 718-722.

³Centers for Disease Control and Prevention. Testing for HCV infection: an updated of guidance for clinicians and laboratorians. *MMWR* 2013; 62(18):362-365.

Sincerely,



Dan O'Connell
Director
AIDS Institute

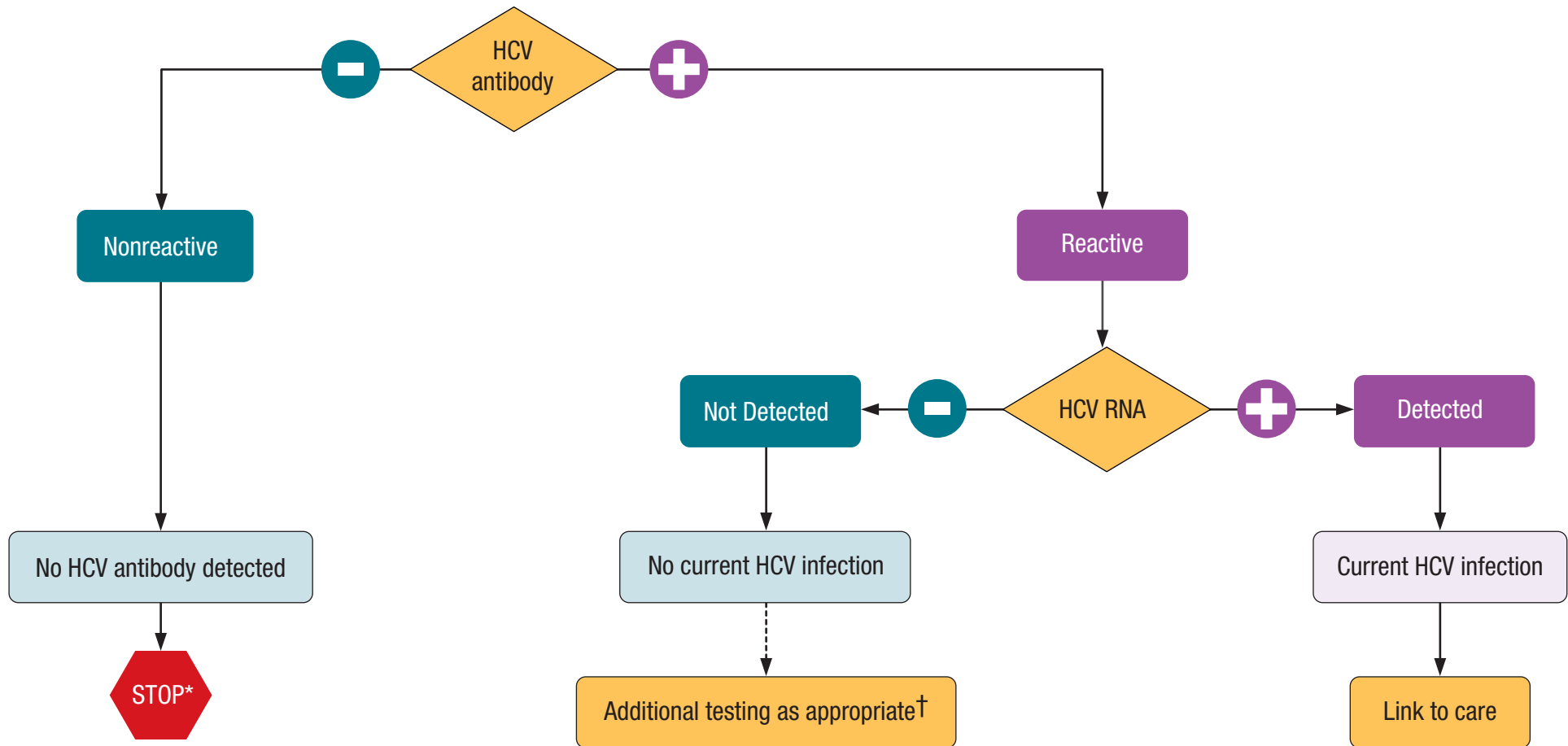


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Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).