

Hepatitis C Reflex RNA Confirmatory Testing in New York City

Implementation Guide

Reflex RNA testing for hepatitis C following a positive antibody test is the standard of care in New York City (NYC). This guide provides background and case studies from four NYC hospitals on their implementation process.

Problem Definition

In 2016, 2,684 of 11,847 (23%) newly reported patients with a positive hepatitis C (HCV) antibody test result in NYC **never** had an RNA test to confirm their diagnosis.¹

Reflex RNA testing –automatically performing an RNA confirmatory test on the same specimen as a positive antibody test – streamlines HCV diagnosis and linkage to care. Patients with positive RNA results can immediately receive a referral for medical evaluation and treatment for HCV.

At HepCX hospitals that perform reflex RNA testing, 88% of antibody tests are confirmed, but at hospitals without reflex testing, only 46% of antibody tests are confirmed (*New York City Health Department, 2016*). In 2017, at least 22 NYC hospitals conducted reflex confirmatory testing for HCV (*Figures 1 and 2*).

As of September 2017, the NYC Board of Health **requires laboratories to routinely perform RNA reflex testing on all HCV antibody positive results.**² This resource aims to support NYC hospitals in the important task of implementing reflex testing.

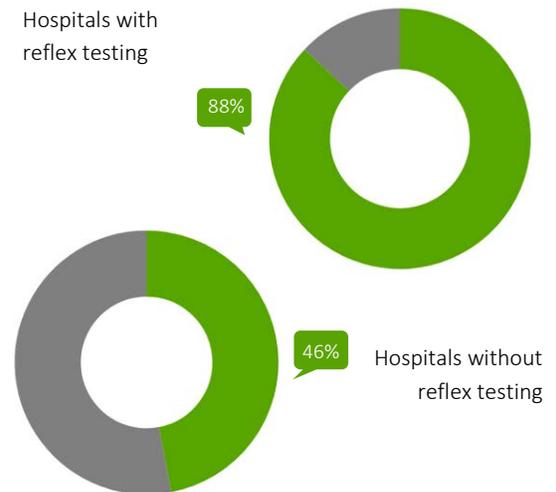
Steps for Implementing HCV Reflex Testing

1. Monitor and track HCV RNA testing rates for HCV antibody positive patients.
2. Understand the current testing methods throughout your facility. *Are HCV antibody and polymerase chain reaction (PCR) tests performed in-house or at an external lab?*
3. Collaborate with relevant staff and departments. Include: Physicians, Nursing, Administration, Laboratory, Billing, Information Technology (IT), representatives from the Electronic Medical Record (EMR) System, and Laboratory Information System (LIS).
4. Develop an implementation plan. Consider the following:
 - EMR ordering: Create a new order, removing standalone HCV antibody testing.
 - Specimen collection: Train staff to draw sufficient blood quantity and select appropriate collection tube.
 - Laboratory work flow: Maximize efficiency, minimize specimen contamination.
 - Billing and reimbursement: Collaborate to prevent hold-ups.
5. Evaluate effectiveness and efficiency of the plan, then modify accordingly.

The Hepatitis C Clinical Exchange Network (HepCX) is a provider-to-provider learning collaborative managed by the New York City Health Department. It focuses on improving hepatitis C screening, linkage to care and treatment capacity. For more information, visit hepCX.nyc.

Figure 1

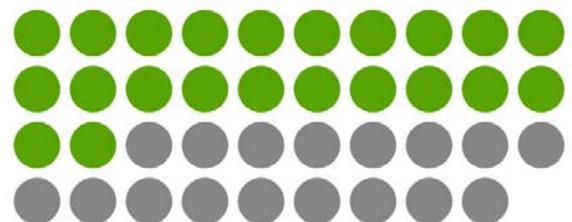
Rates of HCV RNA testing at HepCX hospitals, 2016



All positive HCV antibody test results and HCV RNA positive and negative test results are reported to the Health Department.

Figure 2

Number of HepCX hospitals with reflex testing, 2017



At the time of this report, of the 39 hospitals in the HepCX network, 22 currently conduct reflex testing.

Success Drivers for Implementation: Case Studies

Based on the case studies below, successful implementation of reflex RNA testing relied on collaboration between the Laboratory, Clinical Medicine and IT Departments and required changes to the EMR, LIS or both. At most facilities, the decision to implement reflex testing came from clinical or laboratory leadership.

CASE 1: MONTEFIORE HEALTH SYSTEM

- ◆ Montefiore implemented reflex RNA testing in 2015.
- ◆ The facility changed its EMR and LIS.
- ◆ One specimen tube was collected from each patient.
- ◆ All HCV testing was done in-house.
- ◆ A new electronic laboratory protocol implemented.
- ◆ For more information, visit hepCX.nyc, search “reflex testing” and click on Montefiore.

CASE 2: WYCKOFF HEIGHTS MEDICAL CENTER

- ◆ Wyckoff Heights Medical Center implemented reflex RNA testing in 2015.
- ◆ The facility changes its LIS.
- ◆ Two specimen tubes were collected from each patient.
- ◆ Nurses received electronic reminders to collect the specimen.
- ◆ All HCV testing done in-house.
- ◆ A new laboratory workflow implemented.
- ◆ For more information, visit hepCX.nyc, search “reflex testing” and click on Wyckoff Heights Medical Center.

CASE 3: NORTHWELL HEALTH

- ◆ Northwell Health implemented reflex RNA testing in 2015.
- ◆ The facility changed its LIS.
- ◆ One specimen tube was collected from each patient.
- ◆ For more information, visit hepCX.nyc, search “reflex testing” and click on Northwell Health.

CASE 4: MOUNT SINAI HOSPITAL

- ◆ Mount Sinai Hospital implemented reflex RNA testing in 2016.
- ◆ The hospital changed its LIS.
- ◆ Two specimen tubes were collected from each patient.
- ◆ For more information, visit hepCX.nyc, search “reflex testing” and click on Mount Sinai Hospital.

“Adding Reflex Testing to [our] offerings is medically responsible and appropriate. It closes a gap in current hepatitis C care by reducing the possibility that a patient will undergo multiple office visits and blood draws or will be inappropriately referred to specialists based on incomplete testing.”

Rick L. Pesano, MD, PhD, Vice President of Development, Science and Innovation at Quest Diagnostics.

To read the NYC Health Code Amendment to Article 13, visit hepCX.nyc and search “health code.”

For more information about reflex testing, visit www.hepCX.nyc and search “reflex testing.”

If you have questions about reflex testing, email the HepCX Clinical Advisor, Ann Winters, M.D. at awinters@health.nyc.gov.

Additional Resources:

1. [CDC Hepatitis C Testing Guidance for Clinicians and Laboratories](#)
2. [New York State Department of Health's \(NYSDOH\) HCV Reflex Testing Dear Colleague Letter](#)
3. [New York City Health Department's Reflex Testing Guidance for Health Care Providers](#)
4. [NYSDOH's Validation of Viral Load Assays for Diagnostics](#)
5. [NYSDOH's Medicaid Reimbursement for Reflex Testing](#)

References:

¹ Hepatitis B and C in New York City, 2016 Annual Report, published Fall 2017. New York City Department of Health and Mental Hygiene. www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-b-and-c-annual-report-2016.pdf

² Notice of Adoption of Amendment to Article 13 of the New York City Health Code. New York City Department of Health and Mental Hygiene, Board of Health. 2017. <http://www1.nyc.gov/assets/doh/downloads/pdf/notice/2017/noa-article13.pdf>