Hepatitis C virus (HCV) is recognized as the cause of most cases of post-transfusion hepatitis and is a significant cause of liver disease-related morbidity and mortality worldwide. In the United States, HCV infection is quite common, with an estimated 3.5 to 4 million chronic HCV carriers.1

COMPREHENSIVE TESTING FOR HCV

We recommend an algorithmic approach to testing that takes the guesswork out of test ordering and focuses on proper test utilization, saving your institution time and money. These HCV-focused algorithms were developed collaboratively by physicians and laboratorians to assist with diagnosis, treatment, and monitoring of chronic hepatitis C.

Mayo Clinic Laboratories offer specialized testing to screen and diagnose patients with HCV. In addition, tests are available to monitor an individual’s HCV status prior to and during antiviral treatment.

DETECTION, CONFIRMATION, AND QUANTIFICATION

The U.S. Preventative Services Task Force recommends one-time screening for HCV infection for adults born between 1945 and 1965 and for those determined to be at high risk for infection.

We offer two comprehensive tests for the detection and confirmation of both acute and chronic HCV infection, depending on whether a patient presents with symptoms and/or signs (Mayo ID: HCVDX) or is asymptomatic (Mayo ID: HCSRN). Both tests use the same serologic testing method, but an additional CPT code is added to HCSRN to comply with Medicare billing requirements.

If the HCV antibody test is reactive, then testing will automatically reflex to HCV RNA by RT-PCR (Mayo ID: HCVQN) to confirm the diagnosis of chronic hepatitis C and is performed at an additional charge. This confirmatory test can be used to establish a baseline HCV viral load (quantification) before initiating antiviral therapy and during therapy to measure response to therapy.

BY THE NUMBERS

- 9 HCV-specific tests
- 2 Algorithmic guides
- 130,000+ Tests performed annually

FEATURED TESTS

- Hepatitis C Antibody with Reflex to HCV RNA by PCR, Serum (Mayo ID: HCVDX)
- Hepatitis C Antibody Screen with Reflex to HCV RNA by PCR, Serum (Mayo ID: HCSRN)
- Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR (RT-PCR), Serum (Mayo ID: HCVQN)
GENOTYPING

Unique nucleotide sequences of 5’ noncoding (5’ NC), core, and NSSB regions of the HCV genome allow classification of the virus into 6 major genotypes or clades (1 to 6). In the United States, the most commonly encountered HCV genotypes/subtypes are 1a and 1b, followed by genotypes 2 and 3. Worldwide geographic distribution, disease outcome, and response to antiviral therapy differ among these genotypes. Therefore, reliable methods for genotype determination are important for proper selection of antiviral therapy and optimal patient management, including the use of direct-acting antiviral (DAA) drugs.

GENOTYPIC ANTIVIRAL DRUG-RESISTANCE TESTING

COST-SAVING, PERSONALIZED TREATMENT FOR HCV INFECTION

DAA drug-combination therapy is now a standard of care for patients with chronic HCV infection, but existing pre-treatment antiviral drug resistance and treatment-induced mutations may compromise efficacy of such drug therapy.

Our comprehensive testing is useful for:

- Guiding selection of DAA drug combinations for the most effective antiviral therapy
- Determining if a change in antiviral drug combinations is needed

This test detects and identifies codon substitutions in the HCV NS3, NS5A, and NS5B genomic sequences that confer resistance to current FDA-approved DAA drugs used for treating HCV.

FDA RECOMMENDED PRE-TREATMENT TESTING

Certain FDA-approved DAA drugs for treating chronic HCV due to genotypes 1a, 1b, and 3 (regardless of subtypes) require pre-treatment testing for resistance-associated substitutions in the relevant HCV genomic sequences to best guide selection of optimal DAA combination therapy.

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### DAA TARGET

<table>
<thead>
<tr>
<th>DAA TARGET</th>
<th>HCV GENOTYPE</th>
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<tbody>
<tr>
<td></td>
<td>1a</td>
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<tr>
<td>HCV NS3</td>
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<tr>
<td></td>
<td>Glecaprevir (Mavyret)</td>
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<tr>
<td>HCV NS5A</td>
<td>Daclatasvir (Daklinza) Elbasvir (Zapater) Ledipasvir (Harvoni) Pibrentasvir (Mavyret) Velpatasvir (Epclusa, Vosevi)</td>
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<tr>
<td>HCV NS5B</td>
<td>Sofosbuvir (Sovaldi)</td>
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FEATURED TEST

- Hepatitis C Virus Genotype, Serum (Mayo ID: HCVG)
- Hepatitis C Virus Genotypic Antiviral Drug Resistance, Serum (Mayo ID: HCVDR)
ADDITIONAL HCV TESTING

To help clinicians manage patients who have a positive HCV antibody screen result or are suspected of having acute or chronic HCV infection, MCL offers an HCV quantification test that automatically reflexes to the HCV genotype test when HCV viral load is ≥500 IU/mL. This test simplifies the ordering process and assists with:

- Detection of acute HCV infection before the appearance of HCV antibodies in serum (i.e., <2 months from exposure).
- Detection and confirmation of chronic HCV infection and determining HCV genotype (1 to 6) to guide antiviral therapy in patients with chronic hepatitis C.
- Quantification of HCV RNA in serum of patients with chronic HCV infection (HCV antibody-positive) before initiating antiviral therapy
- Determining cure and detection of relapse of HCV infection after completion of antiviral therapy

FEATURED TEST

- Hepatitis C Virus RNA Quantification with Reflex to HCV Genotype, Serum (Mayo ID: HCVQG)

REFERENCES