TESTING RECOMMENDATIONS FOR HEPATITIS C VIRUS INFECTION

The Center for Disease Control and Prevention (CDC)'s Testing Recommendations for Hepatitis C virus (HCV) infection are summarized below.

HCV TESTING IS RECOMMENDED FOR

- Adults born from 1945 through 1965 ("baby boomers") should be tested at least once in their lifetime and more frequently if they are at ongoing risk
- Persons who inject drugs (currently or in the past)
- Patients who have HIV infection
- Patients with persistently abnormal alanine aminotransferase (ALT) levels
- Patients treated with clotting factor concentrates produced before 1987
- Patients who ever received long-term hemodialysis
- Patients who were recipients of either blood transfusions or organ transplants before July 1992, or who were notified their donor later tested positive for HCV
- Children born to HCV-positive women
- Healthcare, emergency medical, and public safety workers after a recognized exposure to HCV-positive blood through needle sticks, sharps, or mucosal exposures

HCV TESTING MAY ALSO BENEFIT

- Recipients of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm)
- Intranasal cocaine and other non-injecting illegal drug users
- Persons with a history of tattooing or body piercing
- Persons with a history of multiple sex partners or sexually transmitted infections (STI)
- Long-term steady sex partners of HCV-positive persons
- Persons who inject drugs
- Persons who engage high-risk sex and with history of sexually transmitted infections
HCV TESTING – SCREENING

Testing should be initiated with an assay for serum antibody to HCV (anti-HCV). For those with reactive test results, the anti-HCV test should be followed by a confirmatory qualitative or quantitative nucleic acid test for HCV (HCV RNA). This evaluation process is most easily facilitated by a testing algorithm that automatically tests for HCV RNA if the anti-HCV test is positive (reflex testing). This allows definitive testing to be completed with one blood draw.

HCV INITIAL DIAGNOSTIC - LABORATORY & BILLING CODES

<table>
<thead>
<tr>
<th>DIAGNOSTIC NAME</th>
<th>DESCRIPTION</th>
<th>CPT CODE</th>
<th>QUEST LAB CODE</th>
<th>LABCORP CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C (HCV) Antibody with Reflex to HCV, RNA, Qualitative, Real-Time PCR</td>
<td>Reflex testing is the preferred test to be used for HCV screening. If Hepatitis C Antibody is reactive, then Hepatitis C Viral RNA, Qualitative, Real-Time PCR will be performed at an additional charge</td>
<td>86803</td>
<td>n/a</td>
<td>144045</td>
</tr>
<tr>
<td>Hepatitis C (HCV) Antibody with Reflex to HCV, RNA, Quantitative, Real-Time PCR</td>
<td>Reflex testing is the preferred test to be used for HCV screening. If Hepatitis C Antibody is reactive, then Hepatitis C Viral RNA, Quantitative (viral load), Real-Time PCR will be performed at an additional charge</td>
<td>86803</td>
<td>8472</td>
<td>144050</td>
</tr>
</tbody>
</table>

*Note: Quest Lab Codes can vary by region

HCV MANAGEMENT

In individuals with confirmed infection, providers who are inexperienced in HCV treatment or unable to provide the close follow-up needed for optimal outcomes should consider referral to a provider with HCV treatment experience for further management.

For patients who have tested HCV Antibody positive in the past but have not had confirmatory testing, or individuals who have had a qualitative confirmatory PCR test, a quantitative PCR test should be conducted to establish the HCV viral load.

HCV CONFIRMATORY TESTING - DIAGNOSTIC LABORATORY & BILLING CODES

<table>
<thead>
<tr>
<th>DIAGNOSTIC NAME</th>
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<th>QUEST LAB CODE</th>
<th>LABCORP CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C Viral (HCV) RNA, Quantitative, Real-Time PCR (viral load)</td>
<td>Confirmatory test for individuals who have a history of a reactive antibody test</td>
<td>87522</td>
<td>35645</td>
<td>550080</td>
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</tbody>
</table>

*Note: Quest Lab Codes can vary by region

Determination of HCV genotype is the next step in the management of individuals chronically infected with HCV. It is important to determine if patients with genotype 1a have NS5a drug resistance. This can be accomplished using reflexive testing.

HCV GENOTYPE TESTING - DIAGNOSTIC LABORATORY & BILLING CODES

<table>
<thead>
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<th>QUEST LAB CODE</th>
<th>LABCORP CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV Genotype Testing with Reflex to NS5A</td>
<td>Assesses HCV genotype and if GT 1a test will reflex to NS5a drug resistance testing</td>
<td>87902</td>
<td>93871</td>
<td>550615</td>
</tr>
</tbody>
</table>

*Note: Quest Lab Codes can vary by region
A determination must be made of the degree of liver damage, or disease stage; liver biopsy is no longer utilized as the primary method for these determinations.

All patients with chronic HCV infection should be tested for evidence of current or prior Hepatitis B (HBV) infection by measuring Hepatitis B surface antigen (HBsAg) and Hepatitis B core antibody (anti-HBc) before initiating HCV treatment. HBV may be reactivated with treatment of HCV.

The decision to initiate treatment should be determined between patient and an experienced provider. For resources to assist in referral of a patient to an experienced HCV treating provider, see the "Resources" section.

**PATIENT INTERACTION**

Below are examples to assist in discussing the need for testing, and the disclosure of results to patients.

**GENERAL INFORMATION TO PROVIDE TO PATIENTS ABOUT HEPATITIS C:**

Many people with Hepatitis C do not know they are infected. Since many people can live with Hepatitis C for decades without symptoms or feeling sick, testing is critical. Hepatitis C infection can lead to liver damage, cirrhosis, and even liver cancer. New highly effective and usually curative treatments that are easier to tolerate are available for Hepatitis C infection.

**EXAMPLE 1: RECOMMEND TESTING BASED ON YEAR OF BIRTH**

A 65 year old woman presents for her annual physical exam. She has never had a Hepatitis C test to her knowledge. Testing is indicated because she is considered a "baby boomer" based on her year of birth, and people in this age range have 5 times the rate of HCV infection than people born in other years.

**PROVIDER:** "Your records show that you have never been tested for Hepatitis C. Did you know that the CDC now recommends that all people in your age range get tested at least once for Hepatitis C?"

**PATIENT:** "Really?"

**PROVIDER:** "Yes, Baby Boomers (people born from 1945–1965) are 5 times more likely to have hepatitis C than other adults. The reasons are complex – transmission of Hepatitis C was highest in the 1960s to 1980s. Experimentation with injection drug use was not uncommon during that time. Universal precautions and infection control procedures that are used to sterilize medical equipment were not adopted until later, and blood donations were not able to be screened for HCV until 1992."

**PATIENT:** "Oh, that is concerning."

**PROVIDER:** "I would like to run a Hepatitis C test today as part of your routine health screening. It is a simple blood test that tells us if you have ever been exposed to the virus and if you are currently infected. Safe and effective medication to cure this virus is now available so we can discuss that if the test comes back positive."

**EXAMPLE 2: RECOMMEND TESTING BASED ON INDICATORS**

A 45 year old man presents with elevated liver enzymes. Testing is indicated because persistently elevated transaminase levels may result from chronic HCV infection.

**PROVIDER:** "Your lab tests show that your liver appears to show signs of inflammation. Do you know if you have ever been tested for Hepatitis C?"

**PATIENT:** "No. I don’t think I have."

**PROVIDER:** "I think it would be good to order some tests to identify the cause of these liver enzyme elevations. One of the tests I would like to order is a Hepatitis C test. Many people with Hepatitis C do not know they are infected because they have no symptoms. Even without symptoms, Hepatitis C infection can still cause liver damage."

**PATIENT:** "Ok, let's do the test."

**PROVIDER:** "If Hepatitis C is the cause of your liver inflammation, there are very good treatments available to cure the infection. We can discuss treatment if the test shows it may be needed."
EXAMPLE 3: RECOMMEND TESTING BASED ON HIV CO-INFECTION

A 27 year old HIV-positive man presents for his routine healthcare visit. He should be tested for HCV because he is at increased risk of infection.

PROVIDER: “Our records show that you have not been tested for Hepatitis C. Did you know that Hepatitis C is the most common co-infection with HIV infection?”

PATIENT: “No. I was not aware of that.”

PROVIDER: “I would like to go ahead and run a test today to assess for Hepatitis C infection. It is a simple blood test that tells us if you are currently infected. Safe and effective medication to cure this virus is now available so we can discuss that if the test comes back positive.”

SAMPLE CONVERSATION: SHARING POSITIVE TEST RESULTS:

A patient’s Hepatitis C test results come back positive.

PROVIDER: “Your test results are back, and they confirm that you have Hepatitis C infection. The good news is that there are new treatment options that offer a cure to over 95% of patients. The treatment can be as simple as one pill once a day for 12 weeks. I would like to do some additional tests to determine if you have any damage in your liver. Would you be comfortable with that? We can also discuss the benefits of additional testing and what you can expect if we determine that you should be treated.”

RESOURCES:

HCV-EXPERIENCED PROVIDERS REFERRAL:

American College of Gastroenterology: Find a Gastroenterologist: http://patients.gi.org/find-a-gastroenterologist/
Find a Liver Expert: http://patients.gi.org/find-a-liver-expert/
The American Academy of HIV Medicine (AAHIVM): Referral Link: https://providers.aahivm.org/referral-link
AAHIVM Institute for Hepatitis C: Referral Link: https://providers.aahivm.org/referral-link

INFORMATION FOR PROVIDERS:

Centers for Disease Control and Prevention (CDC) – Division of Viral Hepatitis: http://www.cdc.gov/hepatitis/hcv/
CDC Division of Viral Hepatitis “Hepatitis C FAQs for Health Professionals”: http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm
World Health Organization (WHO) – Hepatitis C: http://www.who.int/mediacentre/factsheets/fs164/en/
American Association for the Study of Liver Diseases (AASLD): http://www.aasld.org/
American Liver Foundation “For HealthCare Professionals”: http://hepc.liverfoundation.org/for-healthcare-professionals
American Liver Foundation Help Line: 1-800-GO-LIVER (1-800-465-4837)
American Gastroenterological Association http://www.gastro.org/
American College of Gastroenterologists: http://gi.org/
The American Academy of HIV Medicine (AAHIVM): www.aahivm.org
AAHIVM Institute for Hepatitis C: http://www.aahivm.org/hcv
RESOURCES:

INFORMATION FOR PATIENTS:

CDC Division of Viral Hepatitis "Hepatitis C FAQs for the Public": http://www.cdc.gov/hepatitis/hcv/cfaq.htm

The Hepatitis C Association: http://www.hepcassoc.org/index.html

American Liver Foundation: http://hepc.liverfoundation.org/

American Association for the Study of Liver Diseases (AASLD) "For Patients": http://www.aasld.org/patients

American College of Physicians - Information on Hep C: https://www.acponline.org/hepcfacts

American College of Gastroenterologists – Patient Center: http://patients.gi.org/

Help-4-Hep (peer-to-peer helpline counselors for patients) 877-Help-4 Hep (877-435-7443)