CDC Guidelines recommend one-time testing for people born during 1945-1965.
One-time HCV testing for Baby Boomers

In August 2012, the Centers for Disease Control and Prevention issued final guidance recommending that all people born during 1945-1965 be tested for hepatitis C virus (HCV).

- An analysis of 1999-2008 National Health and Nutrition Examination Survey (NHANES) data found that 1 in 30 baby boomers—the generation born during 1945-1965—is infected with hepatitis C.1
- Baby boomers account for approximately 75% of HCV prevalence in the US.1
- Many were infected before there was any awareness of HCV or how it is transmitted. Furthermore, most are asymptomatic and often unaware of their infection until significant complications from chronic HCV arise.1,2

CDC Recommendation
The CDC guidelines recommend an initial screen using an FDA-approved antibody test.1 For any positive antibody result, the CDC recommends using an FDA-approved NAT—also called an HCV RNA test—to identify active HCV infection.1

LabCorp offers test 144050—“Hepatitis C Virus (HCV) Antibody With Reflex to Quantitative Real-time PCR” using FDA-approved antibody and NAT tests to aid in the screening and follow up of those who are indicated for HCV evaluation, including baby boomers under this guidance. Any specimen found to be positive using the antibody test will automatically be tested using a quantitative HCV RNA test that will provide evidence of active HCV infection in addition to providing an accurate measurement of a patient’s viral load.3 HCV testing and HCV RNA testing may also be ordered separately.

Complications of HCV Infection
- Approximately 80% of patients with HCV are asymptomatic.2 In the remaining 20% of patients who do experience symptoms, the symptoms may include poor appetite, nausea, vomiting, and fever.2 These symptoms are not specific to HCV and thus provide no independent indication for HCV testing.2
- Despite delayed onset of symptoms in many patients, HCV persists as a chronic infection in approximately 75% to 85% of patients.4,5
- It is estimated that up to 20% of HCV-infected persons will develop cirrhosis within the first 20 years of infection.4,5
- Patients with HCV have an estimated 17-fold increased risk of developing liver cancer.5

HCV Background
- HCV is the most common bloodborne illness in the US, with an estimated 2.7 million to 3.9 million people living with the disease.4,5
- Hepatitis C is spread through exposure to contaminated blood, often affecting people who are current or former injection drug users, and people who received blood transfusions or organ transplants prior to 1992 when widespread HCV screening of blood supply and organ donors began.1,4
- HCV can also be transferred through sharing of contaminated personal items, such as a razor or toothbrush.1,4

With the availability of new HCV therapies and increased awareness of the need for screening, earlier diagnosis and targeted treatments are expected to reduce HCV progression and the development of HCV-related diseases.
The goal of HCV treatment is to prevent complications such as advanced fibrosis and cirrhosis and to reduce death from HCV-associated liver cancer.

People who achieve a sustained virologic response (SVR) after treatment have been shown to have a greater than 50% reduction in mortality risk and substantially lower rates of liver-related death and decompensated cirrhosis.\(^1\)

Recent advances in therapeutic options and treatment combinations have increased the SVR for hepatitis C. Overall SVR rates for some new options in treatment-naïve patients with genotype 1 have been reported to be as high as 94% to 100%.\(^6-9\) SVR rates for other genotypes vary.

HCV drug resistance testing may help select the optimal treatment option and help guide future treatment decisions.

Note: Treatment and management of patients with HCV is complex. The decision to treat should be individualized for each patient based on a number of factors. Refer to guidelines and prescribing information for important considerations.

Effective and Promising Treatments for HCV Infection

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References

LabCorp offers the leading HCV menu for complete care decisions

Laboratory tests to aid in the screening, evaluation, and management of HCV include

**Screening Approach**

- HCV Antibody With Reflex to Quantitative RNA Testing\(^1,10\)
- Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping

  - Negative
  - Positive

**HCV Genotype**

- Reflex options 1a to NS3/4A and NS5A

**HCV FibroSure\(^10\) or liver biopsy**

- Genotype 1
- Genotype 2, 4, 5 or 6
- Genotype 3

- Perform Hepatitis C Virus (HCV) NS5A in patients with genotype 1a that are being considered for elbasvir/grazoprevir\(^2,10\).
- Consider Hepatitis C Virus (HCV) NS5A in patients with genotype 1a that are treatment-experienced being considered for ledipasvir/sofosbuvir\(^10\).
- Consider HCV GenoSure\(^\text{®}\) NS3/4A\(^11\).
- Consider Hepatitis C Virus (HCV) NS5B Drug Resistance Assay

- Perform Hepatitis C Virus (HCV) Genotype 3 NS5A in treatment-experienced patients with and without cirrhosis and treatment-naïve patients with cirrhosis who are being considered for sofosbuvir/velpatasvir\(^10\).
- in treatment-experienced patients without cirrhosis and treatment-naïve patients with cirrhosis being considered for daclatasvir+sofosbuvir\(^10\).

**Evaluation & Treatment Decision Options**

- Individualize treatment decision for each patient and assess potential for side effects based on HCV genotype and subtype; quantitative viral load; FibroSure/liver biopsy; CBC, INR, hepatic function; GFR; HBsAg; HIV treatment regimens; and other comorbidities\(^1,10\).

- Initiate treatment\(^10\)

  - HCV RNA Quantitative
    - Monitor HCV RNA levels per treatment guidelines\(^10\)

- Treatment Failure at any time point
- Relapse per package insert

  - Monitor Disease Progression
    - Counsel to prevent transmission and consider for retreatment\(^10\)

  - Consider drug resistance testing to evaluate for resistance-associated variants\(^1,5,11\)
    - HCV GenoSure NS3/4A
    - HCV NS5A Drug Resistance Assay
    - HCV NS5B Drug Resistance Assay

**Patient Management Options**

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