CDC Guidelines recommend one-time testing for people born during 1945-1965.
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
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 80% to 99%.6,7,8 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.

LabCorp’s comprehensive HCV menu includes options for screening, diagnosis, staging, prognosis, and monitoring of patients with HCV, including genotyping (subtyping), HCV FibroSure® non invasive liver assessment, quantitative viral load for monitoring, and HCV drug resistance testing, including LabCorp’s NS3/4A, NS5A for HCV genotypes 1 and 3, and NS5B. Furthermore, LabCorp is working with a number of pharmaceutical companies as they move promising new HCV treatments closer to market.

Effective and Promising Treatments for HCV Infection

- 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 80% to 99%.6,7,8 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.

References
6. HARVONI® (ledipasvir and sofosbuvir) tablets, for oral use [package insert]. Foster City, Calif: Gilead Sciences Inc; October 2014.
7. SOVALDI® (sofosbuvir) tablets, for oral use [package insert], Foster City, Calif: Gilead Sciences Inc; December 2013.
11. Vielea PAK (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), co-packaged for oral use [Highlights of Prescribing Information]. North Chicago, IL: AbbVie Inc; 2014.
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**
  - Negative
  - Positive

- **Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping**
  - Positive

- **HCV Genotype**
  - Genotype 1
    - Reflex options 1a to NS3/4A and NS5A
  - Genotype 2, 4, 5 or 6
  - Genotype 3

  - Genotype 1
    - Perform HCV GenoSure® NS3/4A in patients with genotype 1a
    - an alternative, non-simeprevir containing regimen should be used if the Q80K variant is identified
    - Perform Hepatitis C Virus (HCV) NS5A in patients with genotype 1a
    - at baseline with an elbasvir/grazoprevir regimen
    - who were previously treated with an NS5A inhibitor and are being considered for retreatment
    - Consider Hepatitis C Virus (HCV) NS5B Drug Resistance Assay

  - Genotype 2, 4, 5 or 6

  - Genotype 3
    - Consider Hepatitis C Virus (HCV) Genotype 3 NSSA Drug Resistance Assay

**Evaluation & Treatment Decision Options**

- **Initiate treatment**
  - **HCV RNA Quantitative**
    - Monitor HCV RNA levels per treatment guidelines and prescribing information
  - **Treatment Failure at any time point**
  - **Relapse per package insert**
  - **Monitor Disease Progression - Genotypes 1, 2, 3, 4, 5, 6**
    - Counsel to prevent transmission and consider for retreatment

- **Genotype 1**
  - Consider drug resistance testing to evaluate for treatment emergent resistance-associated variants
    - HCV GenoSure NS3/4A
    - HCV NS5A Drug Resistance Assay
    - HCV NS5B Drug Resistance Assay

- **Genotype 3**
  - Consider drug resistance testing to evaluate for treatment emergent resistance-associated variants
    - HCV Genotype 3 NSSA Drug Resistance Assay

**Patient Management Options**

- **Negative**
- **Positive**

- **Screening Approach**

- **Evaluation & Treatment Decision Options**

- **Patient Management Options**