

HCV SCREENING GUIDELINES

Your single-source HCV Laboratory Solution

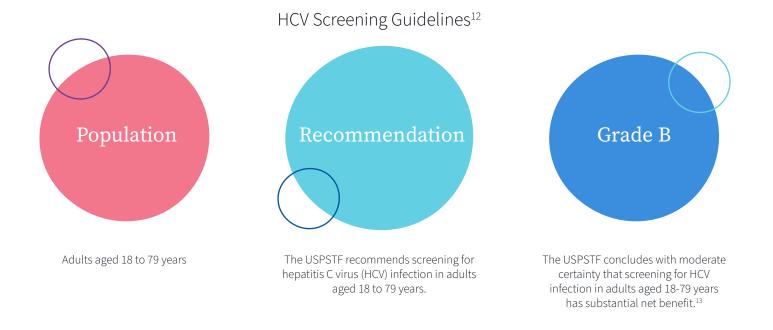
For All Adults Aged 18 to 79 Years



Screen, Diagnose, Monitor

U.S. Preventive Services Task Force Recommended Guidelines for Hepatitis C Screening





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 complications.

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 HCVassociated 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 liverrelated 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 national guidelines and prescribing information for important considerations.

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 nucleic acid test (NAT)—also called an HCV RNA test—to identify active HCV infection.¹

Labcorp offers the following NAT tests:

Hepatitis C Virus (HCV) Antibody With Reflex to Quantitative Real-time PCR (144050) Hepatitis C Virus (HCV) Antibody With Reflex to Qualitative NAA (144045)

These assays support new USPSTF screening recommendations for those individuals aged 18-79 and fulfill CDC guideline recommendations for FDA-approved NAT testing when a positive HCV antibody result occurs. These assays will automatically reflex to NAT testing either quantitatively or qualitatively in the event of a positive HCV antibody screen.

Other standalone assays offered:

HCV RNA quantitative Real-time PCR (graphical 550070 and non-graphical 550080) HCV RNA qualitative NAA (550713)

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.
- Patients with HCV have an estimated 17-fold increased risk of developing liver cancer.⁵

HCV Background

- 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}



Number of people in the U.S. living with HCV^{1,5}

HCV SCREENING GUIDELINES

Labcorp's comprehensive HCV menu includes options for screening, diagnosis, staging, prognosis, and monitoring of patients with HCV including:

Test Name	Test No.
Hepatitis C Virus (HCV) Genotyping, Nonreflex	550475
Hepatitis C Virus (HCV) FibroSURE®	550123
Hepatitis C Virus (HCV) GenoSure® NS3/4A*	550540
Hepatitis C Virus (HCV) NS5A Drug Resistance Assay*	550325
Hepatitis C Virus (HCV) Genotype 3 NS5A Drug Resistance Assay*	550603
Hepatitis C Virus (HCV) NS5B Drug Resistance Assay*	550505
Hepatitis C Virus (HCV) GT1a NS5A Profile	550705

*Viral load reflex test options available.

Furthermore, Labcorp is working with a number of pharmaceutical companies as they move promising new HCV treatments closer to market.

References

1. Centers for Disease Control and Prevention. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. MMWR 2012;61 (No. RR-4):1-32.

- 2. Aman W, Mousa S, Shiha G, Mousa SA. Current status and future directions in the management of chronic hepatitis C. Virology Journal. 2012:9:57.
- 3. Roche Molecular Systems. COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, version
- 2.0. Indianapolis, Ind: Roche Diagnostics; 2016.

4. Centers for Disease Control and Prevention. Hepatitis C FAQs for health professionals. Last reviewed: July 21, 2008. Available at: http://www.cdc.gov/ hepatitis/hcv/hcvfaq.htm. Accessed: June 5, 2012.

- 5. Chen SL, Morgan TR. The natural history of hepatitis C virus (HCV) infection. Int J Med Sci. 2006;3(2):47-52.
- 6. HARVONI® (ledipasvir and sofosbuvir) tablets, for oral use [package insert]. Foster City, Calif: Gilead Sciences Inc; 2014. Revised April 2017.
- 7. EPCLUSA* (sofosbuvir and velpatasvir) tablets, for oral use [package insert]. Foster City, Calif: Gilead Sciences Inc; 2016. Revised August 2017.
- 8. Zepatier™ (elbasvir and grazoprevir) tablets, for oral use [package insert]. Initial US Approval: 2016. Whitehouse Station, NJ: Merck and Co Inc.
- 9. MAVYRET™ (glecaprevir and pibrentasvir) tablets, for oral use [package insert]. Initial U.S. Approval: 2017. North Chicago, IL: AbbVie Inc.
- 10. American Association for the Study of Liver Diseases (AASLD); Infectious Diseases Society of America (IDSA). HCv guidance: recommendations for testing, managing, and treating hepatitis C. Available at http://www.hcvguidelines.org. Updated September 21, 2017. Accessed January 23, 2018.
- 11. Olysio® (simeprevir) capsules, for oral use [Highlights of Prescribing Information]. Titusville, NJ: Janssen Therapeutics; 2013. Revised November 2017.

12. US Preventive Services Task Force. Screening for Hepatitis C Virus Infection in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. JAMA. Published online March 02, 2020. doi:10.1001/jama.2020.1123

13. "U.S. Preventive Services Task Force." U.S. Preventive Services Task Force, 2 Mar. 2020, Assessment of Magnitude of Net Benefit, www.uspreventiveservicestaskforce. org/uspstf/ recommendation/hepatitis-c-screening#fullrecommendationstart.





