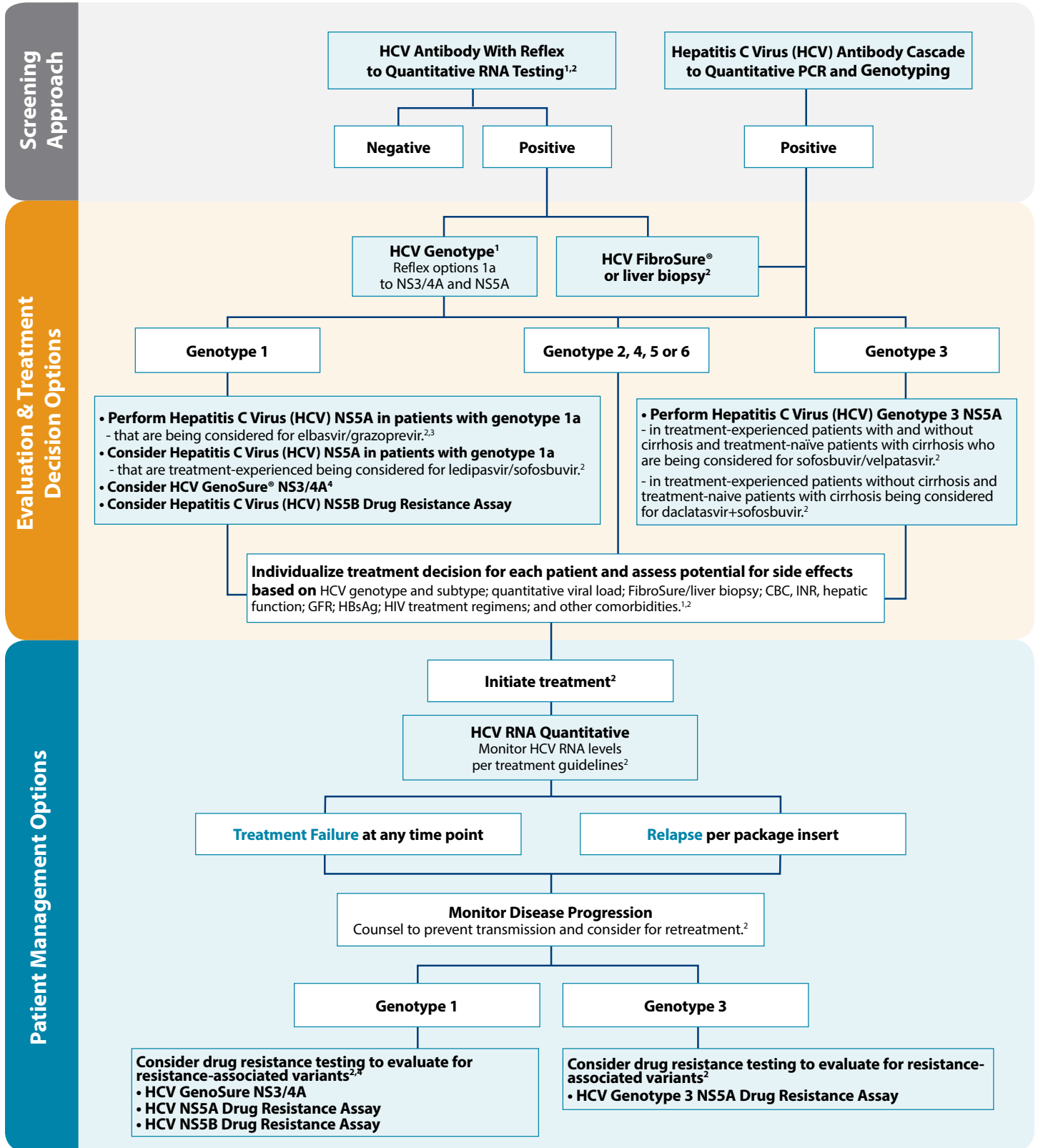


LabCorp offers the leading HCV menu for complete care decisions

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



LabCorp offers the leading HCV menu for complete care decisions

LabCorp offers a comprehensive menu of HCV tests to aid in screening, diagnosis, prognosis, and monitoring of patients with hepatitis C virus (HCV).

Our portfolio of HCV tests includes the following tests that are represented in the diagram on the previous page. For complete test options, visit our online Test Menu at www.LabCorp.com/testmenu.

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

HCV screening recommendations (AASLD, IDSA, ACG) include: anyone who has ever injected illegal drugs, people with HIV, anyone who received a blood transfusion or organ transplant prior to July 1992, children born to HCV-infected mothers, any health worker experiencing a needle-stick injury, and current sexual partners of HCV-infected people.¹

- In August 2012, the Centers for Disease Control and Prevention (CDC) recommended that all “baby boomers” [people born from 1945-1965] be screened for HCV infection using an FDA-approved antibody test, with an FDA-approved NAT test (also called an HCV RNA PCR test) performed on any specimens with a positive antibody result.¹
- LabCorp offers test 144050—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 the CDC guidance. HCV antibody testing and HCV RNA testing may also be ordered individually.
- Results from the quantitative RNA test can be used to confirm an active hepatitis infection, in addition to providing an accurate measurement of a patient’s viral load.⁵

HCV, Quantitative, Real-time PCR (Nongraphical) 550080

HCV, Quantitative, Real-time PCR (Graphical) 550070

- Quantifies patient’s viral load. Limit of detection is 15 IU/mL for all HCV genotypes, and the quantifiable range of the assay is 15 IU/mL to 100,000,000 IU/mL.
- Can provide a baseline assessment prior to therapy in treatment-naïve patients. Also used to monitor patients on therapy and posttherapy.¹⁻⁴

Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Genotyping 550090

Hepatitis C Virus (HCV), Quantitative, RNA PCR (Graphical) With Reflex to Genotyping 550100

- Quantifies patient’s viral load and allows genotyping of the six major HCV types.

Hepatitis C Virus (HCV) Antibody Cascade to Quantitative PCR and Genotyping 144127

- Antibody cascade with reflex tests for diagnosis and management of HCV.

HCV Genotyping 550475

- Allows genotyping of the six major HCV types and their most common subtypes.
- Genotype is important in determining which therapy and duration is most appropriate for the patient.¹⁻⁴

HCV FibroSure® 550123

- Is a noninvasive blood test of 6 biochemical markers that provides METAVIR fibrosis staging and necroinflammatory grading.
- May be useful in defining the presence or absence of advanced fibrosis.²
- HCV FibroSure has been validated against liver biopsy, and has demonstrated diagnostic value comparable to liver biopsy in assessing fibrosis.⁶

HCV GenoSure® NS3/4A 550540

- Assessment of drug susceptibility by nucleic acid sequencing of a patient’s HCV to NS3/4A inhibitors for patients with documented HCV genotype 1a or 1b.
- Consider screening for the presence of the Q80K polymorphism for patients with compensated cirrhosis infected with HCV genotype 1a prior to initiation of treatment with simeprevir plus sofosbuvir.⁴

Hepatitis C Virus (HCV) NS5A Drug Resistance Assay 550325

- Assessment of drug susceptibility by nucleic acid sequencing of a patient’s HCV to the NS5A inhibitors for patients with documented HCV genotype 1a or 1b.
- Type of test recommended for patients being considered for elbasvir/grazoprevir.^{2,3}
- Consider for treatment-experienced patients being considered for ledipasvir/sofosbuvir.²

Hepatitis C Virus (HCV) Genotype 3 NS5A Drug Resistance Assay 550603

- Assessment of drug susceptibility by nucleic acid sequencing of a patient’s HCV to NS5A inhibitors for patients with documented HCV genotype 3.
- Type of test recommended for treatment-experienced patients with and without cirrhosis and treatment-naïve patients with cirrhosis who are being considered for sofosbuvir/velpatasvir.²
- Type of test recommended for treatment-naïve patients without cirrhosis and treatment-naïve patients with cirrhosis being considered for daclatasvir+sofosbuvir.²

Hepatitis C Virus (HCV) NS5B Drug Resistance Assay 550505

- Assessment of drug susceptibility by nucleic acid sequencing of a patient’s HCV to the NS5B polymerase inhibitors for patients with documented HCV genotype 1a or 1b.

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. 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.
3. Zepatier™ (elbasvir and grazoprevir) tablets, for oral use [package insert]. Initial US Approval: 2016. Whitehouse Station, NJ: Merck and Co Inc; 2016.
4. Olysio® (simeprevir) capsules, for oral use [Highlights of Prescribing Information]. Titusville, NJ: Janssen Therapeutics; 2013. Revised November 2017.
5. Roche Molecular Systems. *COBAS® AmpliPrep/COBAS® TaqMan® HCV Test*, version 2.0. Indianapolis, Ind: Roche Diagnostics; 2016.
6. Poynard T, Morra R, Halfon P, et al. Meta-analyses of FibroTest diagnostic value in chronic liver disease. *BMC Gastro*. 2007 Oct 15;7:40.



www.LabCorp.com