



## Quest Launches New Hepatitis C Virus Test Capabilities for Recently FDA-approved Antiviral Therapies

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MADISON, N.J., April 14, 2016 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it has expanded its chronic hepatitis C virus (HCV) test services to include new capabilities to help physicians identify or predict resistance to several HCV therapies, including the recently FDA-approved Zepatier™, from Merck, and Daklinza™, from Bristol-Myers Squibb.



The new services enhance the ability of physicians to determine the type, dose or duration of treatment with direct acting antiviral agents (DAAs) therapies that inhibit the NS5A protein, which influences hepatitis C viral replication. The FDA has approved several DAA therapies that act by inhibiting NS5A, most recently Zepatier (elbasvir and grazoprevir) for the treatment of HCV in adults with genotypes 1 or 4 infections, in January 2016, and Daklinza™ (daclatasvir), in combination with sofosbuvir with or without ribavirin, for the treatment of patients with genotypes 1 or 3, in July 2015. The FDA approved an expanded indication for daclatasvir to include HCV patients with HIV-1 coinfection, advanced cirrhosis, or post-liver transplant recurrence of HCV in February 2016.

The hepatitis C virus is genetically diverse and can mutate, including during drug therapy, with genotypes 1 and 3 comprising most cases of HCV. Prescribing information for both Zepatier and Daklinza recommends laboratory testing to determine the presence of certain drug-resistance NS5A polymorphisms (genetic mutations) in patients with genotype 1a, a subtype of genotype 1. Guidelines updated in February 2016 from the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) recommend HCV genotype and subtype and quantitative HCV RNA (viral load) testing for all HCV patients prior to the initiation of antiviral therapies.

"These new Quest services underscore the value of diagnostics to advance precision medicine," said Rick L. Pesano, M.D., Ph.D., vice president, research and development, Quest Diagnostics. "Our new offerings can help improve health care quality and cost savings using specialty pharmaceuticals for an infectious disease, HCV, that is highly prevalent yet curable when treated appropriately. With insight into HCV NS5A status, the physician can better determine if the patient will not benefit from, or develops resistance to, an NS5A inhibitor, so an alternative treatment can be prescribed more quickly."

In recent years, Quest Diagnostics has introduced molecular testing to identify all six HCV genotypes as well as NS3, NS5A (for Genotype 1) and NS5B resistance testing. The new capabilities include:

- **NS5A Genotype 3 Testing to Aid Patient Selection for daclatasvir:** Virologic response to daclatasvir is substantially poorer in patients with genotype 3 HCV harboring the Y93H mutation. The new Quest test service detects this and other NS5A gene mutations in patients with genotype 3 HCV, helping the physician predict response with daclatasvir therapy.
- **Therapy-based Results Reporting to Improve Management of Patients on Zepatier and other DAAs:** Quest now provides results reporting of NS5A status specific to Zepatier, including for NS5A-associated drug-resistant polymorphisms in HCV genotype 1a described in prescribing rules for the drug. These reports will provide insight regarding the likelihood of successful therapy with elbasvir/grazoprevir.
- **NS5A Reflex Testing Aligned with Guidelines to Simplify Testing:** Physicians now have the option to order test services that will automatically perform, for an additional fee, NS5A drug resistance testing in patients whose genotyping test identifies the presence of HCV genotype 1a. Physicians can also now order a test service that will automatically reflex to genotype if a patient's viral load is greater than 300 IU/mL. If genotype 1a is identified, an additional reflex will occur to determine NS5A status. Reflex tests can reduce time delays in treatment and other gaps in care because the patient does not need to visit the physician multiple times to provide blood specimens. Physicians may continue to order these test services individually if preferred.

"Resistance-associated polymorphisms in the NS5A gene have been detected at baseline or following treatment of HCV infection with NS5A inhibitors, including daclatasvir, ledipasvir, ombitasvir and elbasvir," said Dr. John A.D. Leake, MD, medical director, infectious disease, Quest Diagnostics. "Newly emerging evidence suggests that a substantial number of patients may be affected by these polymorphisms. For instance, in clinical trials of elbasvir, 12 percent of U.S. study participants infected with genotype 1a had resistance-associated NS5A polymorphisms at baseline. Testing to determine genotype, subgenotype and drug-resistant NS5A polymorphisms is an essential part of treatment with selected new

DAA regimens."

As many as 3.9 million Americans are chronically infected with HCV. The hepatitis C virus is genetically diverse and highly subject to mutation, including during drug therapy. While six HCV genotypes exist, the majority of chronic HCV infections in the U.S. are caused by hepatitis C genotype 1. Patients with genotype 1a, which comprises approximately two-thirds of genotype 1 infections, are more likely to develop viral drug resistance than those with genotype 1b. Another 10-12 percent of infections are caused by genotype 3.

Quest Diagnostics is a leader in hepatitis diagnostic information testing with services that include genotyping, viral load and antiviral resistance testing to aid diagnosis, treatment and monitoring. The company also collaborates with the CDC to identify trends in screening, diagnosis and treatment for viral hepatitis (hepatitis A, B, C and E) in the United States based on the national Quest Diagnostics Health Trends™ database of de-identified clinical hepatitis test data.

#### **About Quest Diagnostics**

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 44,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. [www.QuestDiagnostics.com](http://www.QuestDiagnostics.com).

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#### **Contacts:**

Wendy Bost, Quest Diagnostics (Media): 973-520-2800

Dan Haemmerle, Quest Diagnostics (Investors): 973-520-2900

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