Quest Diagnostics Streamlines Hepatitis C Virus Lab Testing by Performing Molecular Testing for all Positive Antibody Test Results

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MADISON, N.J., December 3, 2015 – In its commitment to provide diagnostic insights that enhance patient care and outcomes, Quest Diagnostics (NYSE: DGX) will automatically perform molecular testing on all patient specimens whose antibody screening results indicate hepatitis C virus infection, and remove standalone positive antibody screening as a test option. The change to the company’s service menu eliminates the prospect a patient may receive a positive screening result but fail to undergo additional molecular testing, as recommended by medical guidelines, to help confirm a diagnosis of active hepatitis C infection, the cause of chronic hepatitis C.

Conventional laboratory and medical practice for hepatitis C virus infection involves referring a patient for a second office visit and blood draw if the initial antibody screening test produces a positive result. As many as 60% of people who receive a positive antibody screening test for hepatitis C in the United States do not undergo guideline-recommended molecular testing to help identify active infection.

“This change to Quest’s test offerings is medically responsible and appropriate. It closes a gap in current hepatitis C care by reducing the possibility a patient will undergo multiple office visits and blood draws or be inappropriately referred to specialists based on incomplete testing,” said Rick L. Pesano, MD, PhD, vice president, development, science and innovation, Quest Diagnostics. “With this change to our offering, we will help more people receive insights they can use to access effective treatment and ultimately lead healthier lives.”

A hepatitis C screening test identifies viral antibodies while a molecular test identifies viral RNA when the infection is active. In some people, the immune system clears hepatitis C infection on its own, but antibodies may linger in the blood for decades. As a result, a positive antibody screening test can signify resolved or active infection, and as much as 3% of antibody screens produce a false positive. Guidelines from the Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Task Force (USPSTF) recommend molecular testing for all positive antibody screening tests to differentiate resolved and active infection. Specimens that produce negative antibody screening results generally do not undergo molecular testing.

With the change to the Quest menu, any specimen that an antibody screening test indicates is positive will automatically reflex to molecular testing. Pricing for the screen and molecular tests are the same as before; positive screening results will reflex to molecular testing automatically and be charged the additional molecular test fee.

As many as 3.9 million Americans are chronically infected with the hepatitis C virus, making it the most common chronic bloodborne infection in the United States, according to the CDC. Hepatitis C may not manifest symptoms for decades, and most patients are unaware of infection. Early diagnosis, through laboratory blood tests, and treatment can help prevent liver damage, cirrhosis, liver cancer and death. In 2012, the CDC recommended screening for Baby Boomers, individuals born from 1945 through 1965, who are five times more likely than other adults to be infected with hepatitis C. The CDC guidelines also acknowledge recently introduced hepatitis C therapies, called direct acting agents, which have cure rates of more than 90%.

“The need for streamlined hepatitis C virus testing takes on greater urgency given medical guidelines recommending one-time antibody screening for the large Baby Boomer cohort and other populations at heightened risk for chronic hepatitis C. Reliable, prompt diagnosis is essential for these populations to fully benefit from highly efficacious new drug therapies,” added Dr. Pesano.

Quest Diagnostics is a leader in hepatitis diagnostic information testing with services that include genotyping, risk stratifying and 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. The goal of the collaboration is to improve the ability of public health authorities to develop and monitor the effectiveness of CDC medical guidelines designed to reduce disease prevalence and enhance outcomes through earlier diagnosis and treatment of hepatitis.

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 45,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

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