



Federal Guidelines Recommend New HIV Testing Method

March 27, 2013

U.S. Department of Health and Human Services issues medical guidelines recommending genotypic testing to aid HIV therapy selection

MADISON, N.J., March 27, 2013 /PRNewswire/ -- A new test based on gene sequencing may be used to assess a patient's suitability for treatment with CCR5 antagonists, a class of HIV antiretroviral therapies, under new medical guidelines issued by the U.S. Department of Health and Human Services (DHHS).

The new genotypic test performs comparably to the standard culture-based phenotypic tropism technique for predicting response to CCR5 antagonists, but at about half the cost and with faster results, according to Quest Diagnostics (NYSE: DGX), the leading provider of diagnostic information services. Quest Diagnostics is believed to offer the only genotypic HIV tropism test service in the United States to demonstrate comparable performance to the standard phenotypic method, previously the only method available nationally to help physicians predict response to CCR5 antagonists.

"CCR5 antagonists can be an important component of an effective and well-tolerated drug combination in some HIV-infected patients. Tropism testing is a requirement for using this drug class, and fast test results facilitate timely treatment decisions," said Jonathan M. Schapiro, MD, director of HIV/AIDS at the National Hemophilia Center, Tel Hashomer, Israel. "The inclusion of genotypic tropism testing by the DHHS HIV Guidelines is a very welcome development. Faster, cost-effective diagnostics are greatly needed to improve HIV management."

Testing for HIV tropism is necessary to predict response to CCR5 antagonist therapy. This therapy can help slow HIV disease progression in patients with a certain type of tropism, but offer no known clinical benefit in patients with other forms of tropism. Tropism refers to a type of cellular mechanism by which the HIV virus infects human cells.

The revised DHHS guidelines, titled *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, recommend "that a genotypic tropism assay be used as an alternative to a phenotypic tropism assay before initiation of a CCR5 antagonist-containing regimen." While prior HHS guidelines only recommended phenotypic assays, medical guidelines in Europe have supported genotypic HIV tropism tests since 2011.

The DHHS guidelines are available at: <http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0/>

"Genotyping is an example of how diagnostic innovation can expand clinical options for physicians while driving down costs for payers and patients," said Rick L. Pesano, M.D., Ph.D., medical director, infectious diseases, Quest Diagnostics. "We expect this method will provide the basis for developing additional diagnostic innovations that are clinically valuable and more cost effective than traditional techniques."

Quest Diagnostics has offered its clinical genotypic tropism test as a laboratory-developed test, named the Quest Diagnostics HIV-1 Tropism with Reflex to Ultradeep sequencing (UDS), since the spring of 2012. The company's advanced genetics laboratory in San Juan Capistrano, California, developed, validated and performs the test for clinicians in the United States. Quest Diagnostics can provide test results in as few as 10 business days, compared to average turnaround times of two to three weeks for phenotypic tests, and at roughly half the list price for the standard phenotypic test.

In late 2012, the peer-reviewed, open-access journal PLOS ONE published a study that found the Quest Diagnostics deep-sequencing genotypic method predicted response to HIV antiretroviral therapy as well as the industry's standard phenotypic test.

Quest Diagnostics has one of the most comprehensive HIV testing services menu in the diagnostic industry, with services that range from HIV screening, viral load, therapeutic monitoring, co-infection and resistance testing. In late 2012, the company launched the HIV proviral DNA tropism lab-developed test, which uses DNA extraction and sequencing followed by bioinformatic analysis to help enable genotypic tropism testing for patients with low or undetectable HIV-1 viral RNA (<1000 copies/mL).

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic information services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic information services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at QuestDiagnostics.com. Follow us at [Facebook.com/QuestDiagnostics](https://www.facebook.com/QuestDiagnostics) and [Twitter.com/QuestDX](https://twitter.com/QuestDX). Additional information for healthcare professionals, including access to ASCLS P.A.C.E.-certified webinars, is available at QuestDiagnostics.com/Education.

Quest, Quest Diagnostics, any associated logos, and all associated Quest Diagnostics registered or unregistered trademarks are the property of Quest Diagnostics. All third-party marks are the property of their respective owners.

Quest Diagnostics Contacts:

Dan Haemmerle (Investors): 973-520-2900

Wendy Bost (Media): 973-520-2800

SOURCE Quest Diagnostics