



Quest Diagnostics STRATIFY JCV(TM) First FDA Market Authorized Antibody-based Blood Test to Help Stratify PML Risk in Multiple Sclerosis Patients

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Based on exclusive collaboration with Biogen Idec, the test is only available in the U.S. through Quest Diagnostics' Focus Diagnostics lab

MADISON, N.J., Jan. 20, 2012 /PRNewswire via COMTEX/ --Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, today announced that the U.S. Food and Drug Administration (FDA) has granted a *de novo* classification petition to its STRATIFY JCV(TM) Antibody ELISA testing service. STRATIFY JCV is the first blood test to be FDA market authorized for the qualitative detection of antibodies to the polyomavirus JC virus (JCV) for stratifying risk for progressive multifocal leukoencephalopathy (PML), an infrequent but serious brain infection, in patients with multiple sclerosis (MS) receiving TYSABRI® (natalizumab), a highly effective therapy for relapsing forms of MS.

The market authorization follows FDA approval today of a product label change for TYSABRI. The new label identifies JCV antibody status as a PML risk factor; other risk factors include duration of treatment with TYSABRI and prior immunosuppressant therapy use.

STRATIFY JCV was developed under an exclusive collaboration for the United States market with [Biogen Idec](#) (NASDAQ: BIIB), co-manufacturer with Elan Corporation, plc (NYSE: ELN) of natalizumab. The test employs technology licensed from Biogen Idec, and is exclusively offered through Quest Diagnostics' Focus Diagnostics laboratory in the United States. It is based on a test validated and performed by Focus Diagnostics in clinical trials.

"STRATIFY JCV is a great example of the capacity of pharmaceutical and diagnostic companies to collaborate to bring important medical innovations to market," said Kathy P. Ordonez, senior vice president, discovery and development, Quest Diagnostics. "The test has demonstrated its value as a tool that enhances PML risk assessment, and marks a significant step forward in the personalization of clinical management of MS patients who may benefit from natalizumab."

Approximately 50% to 60% of MS patients have been infected with JCV. In the general population, JCV can, in rare instances, reactivate and progress to PML, which may lead to severe neurological disability or death.

MS is an immune disorder that affects the central nervous system, can alternate between remission and relapse, and often progressively worsens over time. As many as 400,000 people have MS in the United States, and about 200 people are diagnosed each week.

About STRATIFY JCV

The STRATIFY JCV Antibody ELISA testing service provided by Focus Diagnostics is intended for the qualitative detection of antibodies to John Cunningham Virus in human serum or plasma. The assay is intended for use in conjunction with other clinical data, in multiple sclerosis and Crohn's disease patients receiving natalizumab therapy, as an aid in risk stratification for progressive multifocal leukoencephalopathy development. The assay is for professional use only and is to be performed only at Focus Diagnostics' Reference Laboratory.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing 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](#) and [Twitter.com/QuestDX](#).

TYSABRI is a trademark of Biogen Idec Inc. and Elan Corporation, plc.

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