



## **Quest Diagnostics Introduces ClariSure(TM) Test for Identifying Chromosome Abnormalities Associated With 85 Developmental Disorders in Children**

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First commercial test available nationally

LYNDHURST, N.J., Aug. 30 /PRNewswire-FirstCall/ -- A molecular diagnostic test that detects chromosome abnormalities associated with 85 developmental disorders affecting children now is commercially available from a national diagnostic testing company, affording testing and reimbursement by leading health plans across the U.S. Quest Diagnostics Incorporated (NYSE: DGX), the nation's leading provider of diagnostic testing, information and services, developed its ClariSure(TM) microarray-based comparative genomic hybridization (CGH) test to enable physicians to use results obtained from a single blood test to diagnose patients with mental retardation and dozens of other disorders, including Down, cri du chat, DiGeorge and Williams syndromes.

"Our ClariSure test is an important advance in diagnostic testing resulting from the Human Genome Project(1). This project gave us the map of the human genome and knowledge of DNA required to develop and commercialize our assay," said Charles (Buck) Strom, M.D., Ph.D., medical director of the genetic testing center of Quest Diagnostics Nichols Institute, the esoteric testing laboratory and research and development center of Quest Diagnostics. "Using today's conventional analytical techniques, physicians may inadvertently miss the genetic cause of a patient's developmental disorder. Our ClariSure test is a powerful tool that physicians can use to produce an accurate diagnosis more quickly."

The ClariSure test is a laboratory-developed assay that uses proprietary technologies from Nichols Institute as well as licensed methodologies. Scientists at Nichols Institute have validated the ClariSure test's ability to use a single blood specimen to identify chromosomal abnormalities associated with up to 85 developmental disorders. A positive result may be confirmed using a licensed fluorescence in situ hybridization (FISH) methodology. The company expects to provide test results from its ClariSure assay to physicians within five days of receiving a specimen at a Quest Diagnostics laboratory.

"While CGH microarrays often are used for research purposes, the considerable expertise and development required to commercialize these technologies has limited their use for diagnostic testing," said Joyce Schwartz, M.D., vice president and chief laboratory officer. "Our ClariSure assay bridges the gap between scientific research and real-world testing, affording physicians with a faster technique for diagnosing patients suspected of having a developmental disorder. With better diagnostic insights, parents can provide their child with appropriate schooling and social support, and understand the likelihood that other offspring may have the same disorder."

Quest Diagnostics owns the intellectual property underlying its microarray technology, which is used to analyze information contained within an individual's genetic makeup. CGH microarray technologies compare and contrast a specimen's DNA to the DNA of a healthy individual to identify, at a high resolution, extra or missing genetic material in the specimen. These technologies can detect a substantial proportion of additional abnormalities even in patients who have already had extensive cytogenetic and/or fluorescence in situ hybridization testing.(2) CGH microarray technologies are also more efficient, as multiple FISH tests are required to generate the same amount of information produced from one microarray-based test.

Quest Diagnostics' ClariSure test will be first introduced to physicians at pediatric and children's hospitals, with an emphasis on pediatricians, geneticists and pediatric neurologists.

### **Future ClariSure Test Applications**

Nichols Institute also is developing additional ClariSure tests to identify chromosome abnormalities associated with hematological malignancies, such as Leukemia. The ClariSure test is able to detect abnormalities even if cell division has yet to occur, which may enable it to detect abnormalities that suggest the presence of cancer in a higher percentage of patients than is possible using conventional cytogenetic and FISH techniques. The company expects to begin to provide ClariSure assays for hematological malignancies to hospital physicians, including oncologists and hematologists, by the end of this year.

### **About Mental Retardation**

Mental retardation and developmental delay are characterized by significant limitations in intellectual functioning and impaired conceptual and social development. Causes of mental retardation range from chromosome abnormalities to pre-natal environmental conditions. Array CGH techniques will detect chromosome abnormalities in as many as five percent to 17 percent of individuals with mental retardation.(3) With an accurate diagnosis, children are more likely to receive counseling, education and other support appropriate for their condition.

### **About Quest Diagnostics**

Quest Diagnostics is the 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 national 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 new diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at [www.questdiagnostics.com](http://www.questdiagnostics.com).

This communication contains certain forward-looking statements. These forward-looking statements, which may include, but are not limited to, statements concerning the proposed acquisition, are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements. Certain of these risks and uncertainties may include, but are not limited to the risks and uncertainties described in the Quest Diagnostics Incorporated 2006 Form 10-K and subsequent filings.

(1) The Human Genome Project was the international, collaborative research

program whose goal was the complete mapping and understanding of all the genes of human beings. The full sequence was completed and published in April 2003. Source: National Institutes of Health.

(2) Source: Journal of Pediatrics, 2006;149:98-102.

(3) Source: Shaffer and Bejjani, Cytogenet Genome Res 115:303-309 (2006).

#### SOURCE Quest Diagnostics

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