

Quanterix Expands Laboratory Developed Test Menu with Launch of Neurofilament Light Chain Test

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New CLIA blood test expands access to important “brain health” biomarker to advance research and clinical care

BILLERICA, Mass.--(BUSINESS WIRE)--Jan. 9, 2023-- Quanterix Corporation (NASDAQ: QTRX), a company fueling scientific discovery and breakthrough diagnostics through ultrasensitive biomarker detection, today announced the validation of a Laboratory Developed Test (LDT) to quantitatively measure neurofilament light chain (NfL) in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage.

NfL is a well-studied biomarker for neuro-axonal injury with wide applicability to different neurological disorders. Any disorder or injuring force resulting in neuronal damage can lead to the release of NfL into the interstitial fluid and cerebrospinal fluid (CSF). A fraction of these proteins diffuses into the blood, where concentrations are typically 50- to 100-fold lower than in CSF and difficult to measure with conventional immunoassay technologies. Measurement of this protein in serum and plasma was first enabled with the release of the research use only (RUO) Simoa NfL kit several years ago.

Simoa NfL is the most widely published NfL test with hundreds of research papers demonstrating its validity for assessing neuronal damage, and it has become widely adopted in therapeutic clinical trial designs. Published research using the Simoa NfL test has shown correlations between increased serum NfL levels and neuronal injury across a range of disorders, including amyotrophic lateral sclerosis (ALS), Huntington's disease, HIV infection, Parkinsonian disorders, traumatic brain injury (TBI), concussion, small vessel disease, Alzheimer's disease, and multiple sclerosis (MS). Additionally, recent studies characterizing changes of blood NfL levels in normal aging populations have provided necessary reference range values to aid the interpretation of measurements from individuals being evaluated in clinical care settings. Simoa NfL measurements have supported approval of therapeutics, such as Novartis' Kesimpta (ofatumumab) for MS, and have been used in a number of therapeutic trials related to Alzheimer's disease, including Eisai's lecanemab Phase 3 Clarity AD study, [highlighted](#) at the recent Clinical Trials for Alzheimer's Disease (CTAD) conference.

Last year, the FDA [granted](#) Breakthrough Device designation for Quanterix's NfL test as a prognostic aid in assessing the risk of disease activity in patients diagnosed with relapsing-remitting MS (RRMS). The FDA's Breakthrough Device designation is granted to products that have the potential to offer more effective diagnosis or treatment of life-threatening diseases with an unmet medical need. The program is designed to enable accelerated development, assessment, and review processes, with the intention to provide patients with more timely access to breakthrough technologies or devices.

“Assessment and monitoring of brain health is incredibly difficult and typically performed in limited fashion by surgery or imaging. We see NfL as not only an important marker for neurodegenerative disease but also a critical measure of brain-related side effects during chemotherapy, CAR T-cell therapy, and stroke,” said Masoud Toloue, CEO at Quanterix. “Today is another translational step on our mission. We expect the launch of our CLIA validated NfL blood test to power future therapeutic trials and advance clinical care.”

The Simoa NfL LDT will be offered through Quanterix's Accelerator Laboratory, a CLIA-licensed and ISO 15189 accredited laboratory fully equipped to support both clinical diagnostic testing and translational research. To learn more about Quanterix's Simoa® Accelerator Laboratory, visit: <https://www.quanterix.com/products-and-services/pharma-services/>.

For more information about Quanterix's work in neurology, visit: <https://www.quanterix.com/therapeutic-areas/neurology/>.

About Quanterix

From discovery to diagnostics, Quanterix's ultrasensitive biomarker detection is fueling breakthroughs only made possible through its unparalleled sensitivity and flexibility. The Company's Simoa® technology has delivered the gold standard for earlier biomarker detection in blood, serum or plasma, with the ability to quantify proteins that are far lower than the Limit of Quantification (LoQ) of conventional analog methods. Its industry-leading precision instruments, digital immunoassay technology and CLIA-certified Accelerator laboratory have supported research that advances disease understanding and management in neurology, oncology, immunology, cardiology and infectious disease. Quanterix has been a trusted partner of the scientific community for nearly two decades, powering research published in more than 2,000 peer-reviewed journals. Find additional information about the Billerica, Massachusetts-based company at <https://www.quanterix.com> or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release are based on Quanterix's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix's filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” sections contained therein. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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