

MBL Launches New ELISA-based Companion Diagnostic Kit for Spinal Muscular Atrophy

NAGOYA, Japan - May 8, 2020 - Medical and Biological Laboratories Co., Ltd. (MBL), a JSR Life Sciences company, announced today that it has launched an *in vitro* diagnostic kit for the genetic disease Spinal Muscular Atrophy (SMA). The MEBCDX AAV9 test kit, which was licensed from Quest Diagnostics, was approved on April 27 by the Ministry of Health, Labour and Welfare (MHLW) as a companion diagnostic (CDx) kit for the SMA gene therapy Zolgensma™ (onasemnogene abeparvovec-xioi) launched by Novartis International AG. The test kit will enable laboratory testing through LSI Medience Corporation starting today.

SMA is a lower motor neuron disorder characterized by progressive muscle weakness and muscle atrophy resulting from degeneration and loss of anterior horn cells in the spinal cord, often taking away the ability to walk, eat, or breathe. It is the number one genetic cause of death for infants [1]. In Japan, it is reported that there were 858 patients as of 2018, and that approximately 30 patients were children between the ages of 0 to 9 years old. SMA is designated as a rare, but intractable, disease [2].

Zolgensma is a gene therapy product that improves prognosis and motor function by increasing survival motor neuron (SMN) protein expression in motor neurons and then replaces the function of the missing or nonworking SMN1 gene, which is the genetic root cause of SMA. The MHLW approved the therapy on March 19, 2020 with indications: spinal muscular atrophy (including those who do not develop clinical findings but are predicted to develop spinal muscular atrophy by genetic testing), but only patients with anti-AAV9 antibodies negative.

The MEBCDX AAV9 test kit was therefore developed as a CDx to be used as an aid in selecting anti-AAV9 antibody negative SMA patients for treatment with Zolgensma. Through mutual agreement, the technology was transferred and a license for commercial manufacturing in Japan was granted to MBL by Quest Diagnostics, who developed this Laboratory Developed Test service for the US market.

Reference

https://www.curesma.org/about-sma/https://www.nanbyou.or.jp/wp-content/uploads/upload_files/koufu20191.pdf

About MBL MBL was founded in 1969 as the first manufacturer of antibodies in Japan. Using technology built on advances in immunology and molecular biology, MBL offers clinical diagnostics and research reagents designed for analysis of proteins and/or genes associated primarily with autoimmune disorders, cancer, gynecological diseases, and infectious diseases. In recent years MBL has also been actively developing biomarker reagents and companion diagnostics, taking advantage of our strength in immunological and gene detection techniques. MBL is a JSR Life Sciences company. More information can be found here: <https://www.mbl.co.jp/>

About Novartis Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>

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 47,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. More information can be found here: <https://www.questdiagnostics.com>

The Global Diagnostics Network (GDN), conceptualized by Quest Diagnostics, is a strategic working group of diagnostic laboratories, each committed to unleashing and sharing local innovation to increase global access to diagnostic science, information, and services - ultimately generating enhanced diagnostic insights to improve the delivery of global healthcare. LSI Medience and Quest Diagnostics are members of the GDN. For more information about the GDN, please visit www.globaldiagnosticsnetwork.com.

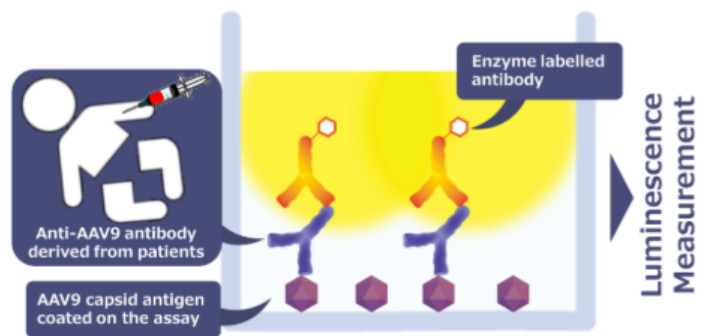
About LSI Medience

Founded in 1975, LSI Medience Corporation is engaged in clinical testing, diagnostics reagents and instruments, and drug development support service as its three core businesses. By utilizing its power of analysis developed in various testing fields in its long history as a core competence and analytical abilities on test results as well, LSI Medience Corporation aims to create new solutions. Contributing to prevention and early detection of diseases and medical care, it also actively supports next-generation healthcare including personalized medicine. LSI Medience is one of the comprehensive leading healthcare service companies in Japan with 89.4 billion yen net sales in FY2017 and approximately 3,500 employees (as of March 31, 2018). For further information, please visit www.medience.co.jp/english/

【Kit appearance】



【ELISA Assay】



【Components】

AAV9 capsid, Conjugated antibody, Substrate, High/Low value positive control, Negative control