Nittobo News Release

February 26, 2025

Nittobo

Nittobo Medical Receives Approval from Taiwan Food and Drug Administration (TFDA) to Market Serum IgG4 Reagent for Open System Clinical Analyzers

Nittobo Medical Co., Ltd., a wholly owned subsidiary of Nittobo (President: Masao Fukushima; "NMD"), has received approval from Taiwan Food and Drug Administration (TFDA) to market its serum IgG4 reagent for open system clinical analyzers. The serum IgG4 reagent has been marketed in Japan since 2018 under the brand "N-Assay," and sales in Taiwan will begin under the same brand.

Doctors in Japan and other countries use serum IgG4 values to distinguish autoimmune pancreatitis (AIP), which is an IgG4-related disease (IgG4-RD), from pancreatic cancer. In Japan, IgG4-RD is designated as intractable. Today, it is widely known that IgG4-RD is a multi-organ disease with an autoimmune basis that can affect essentially any organ. Serum IgG4 values are therefore being used in many different medical practices beyond distinguishing AIP from pancreatic cancer. Specifically, other uses of serum IgG4 values include confirming the presence of a disease and determining the effectiveness of steroids and other treatments after diagnosis.

Japan's guidelines on the diagnosis of IgG4-RD (2020 Revised Comprehensive Diagnostic (RCD) Criteria for IgG4-RD) have been generally accepted in Taiwan. There is a growing need there for reagents meeting the guidelines' cut-off value of serum IgG4 concentration of 135 mg/dL. The cut-off value from the using "N-Assay IgG4" meets the cut-off in the guideline.

In fact, Taiwan is experiencing similar trends to those in Japan, with growing numbers of patients with IgG4-RD each year and a need for the testing of serum IgG4 levels in hospitals, not outsourcing in order to make determination of the dose of steroids in the same day. The approval of "N-Assay IgG4", which is available to use in open system analyzers, makes it possible to conduct appropriate testing in hospitals instead of sending samples to outsourcing laboratories. In such an environment of diagnosis and treatment for IgG4-RD, NMD's distributor in Taiwan, Tunyen Enterprise Corporation (head office: Taipei) received approval from TFDA.

NMD and Tunyen Enterprise will collaborate with medical professionals to raise awareness of IgG4-RD in Taiwan as well as the advantages of conducting serum IgG4 value tests in hospitals. Through these enlightenment initiatives, NMD and its partners will strive to support Taiwanese doctors in making accurate diagnoses of IgG4-RD and optimal treatment decisions, similarly to the efforts in Japan.

Product Overview
Product name: N-Assay LA IgG4 Nittobo
Application: Measurement of serum immunoglobulin G4 levels
Markets: Japan, Taiwan
Marketing approval date: April 19, 2018 (Japan)
Marketing approval letter receipt date: February 25, 2025 (Taiwan)
Market release: July 24, 2018 (Japan), February 26, 2025 (Taiwan)

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