

FOR IMMEDIATE RELEASE

September 10, 2015

Eisai Co., Ltd.
EIDIA Co., Ltd.

LAUNCH OF NEW KL-6 DIAGNOSTIC KIT HISCL KL-6, FOR DETECTING MARKER FOR INTERSTITIAL PNEUMONIA WITH HISCL AUTOMATED IMMUNOASSAY SYSTEMS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and its diagnostics subsidiary EIDIA Co., Ltd. (Headquarters: Tokyo, President: Atsushi Saito, "EIDIA") announced today that EIDIA will launch HISCL KL-6, a new diagnostic kit to detect marker for interstitial pneumonia, in Japan on September 16, 2015.

The new product, developed by Sysmex Corporation (Headquarters: Hyogo, Chairman and CEO: Hisashi Ietsugu, "Sysmex") under an agreement between Eisai, is specially designed to measure KL-6, a diagnostic marker for interstitial pneumonia, with the HISCL-Series of automated immunoassay systems manufactured by Sysmex. In line with the agreement, the product will be distributed by EIDIA, and co-promoted by Eisai. Sysmex International Reagents Co., Ltd. (Headquarters: Kobe, Executive Officer: Yukio Hamaguchi), a subsidiary of Sysmex, is responsible for the manufacture of HISCL KL-6.

Interstitial pneumonia is a type of pneumonia that causes inflammation in the walls (interstitium) of pulmonary alveoli. Caused by a number of factors, cases of drug-induced pneumonia, a typical type of interstitial pneumonia, have been increasing recently which raises the significance and public concern around this disease.

KL-6 (sialylated carbohydrate antigen) is a serum marker highly specific to interstitial pneumonia. KL-6 is found on the surface of cells that make up the interstitium, and increases in concentration when interstitial pneumonia occurs. As KL-6 is exuded in the bloodstream, measurement of KL-6 in the blood is used for the diagnosis of interstitial pneumonia. EIDIA currently markets four KL-6 diagnostic kits: PICOLUMI KL-6 for electrochemiluminescence immunoassay, LUMIPULSE KL-6 Eisai and LUMIPULSE Presto KL-6 Eisai for fully automated chemiluminescent enzyme immunology system, and NANOPIA KL-6 for automated clinical chemistry analyzer.

Developed by Sysmex, the HISCL-Series of automated immunoassay systems employs the chemiluminescence enzyme immunoassay (CLEIA) methodology. These systems can measure miniscule quantities of substances found within samples using enzymes for chemiluminescent measurement, and are able to perform measurement in a short amount of time, taking only 17 minutes from sample drawing to presenting an analysis of results. In addition to being used in the diagnosis of hepatitis, infectious disease, cancer, HIV and heart failure, the HISCL-Series is able to be used in a wide range of testing situations with a robust lineup of diagnostic products now available, including hepatic fibrosis marker and atopic dermatitis marker reagents.

With the launch of HISCL KL-6, which is useful for diagnosis of interstitial pneumonia in a wider clinical setting, Eisai and EIDIA aim to contribute to further increasing the benefits for patients.

[Please refer to the following notes for a product outline and a product photograph]

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[Notes to editors]

■ Product Outline

Product name	HISCL KL-6
Indication for use	Determination of sialylated carbohydrate antigen (KL-6) level in serum or plasma
Compatible with	HISCL-5000, HISCL-2000i, HISCL-800
Packaging	Kit for 100 tests
Recommended Price	85,000 Japanese yen
Distributor	EIDIA Co., Ltd.
Marketing Co-promoter	Eisai Co., Ltd.
Manufacturer	Sysmex International Reagents Co., Ltd.

■ Glossary of Terms

1. Interstitial Pneumonia

Human lungs are made up of multiple, small grape-like structures called alveoli, where the exchange of oxygen and carbon dioxide takes place. Inflammation of alveoli causes pneumonia, which can be roughly classified into two groups based on the region where the inflammation occurs: interstitial pneumonia, in which inflammation occurs in the walls of the alveoli (interstitium), and alveolar pneumonia (commonly-termed pneumonia), in which inflammation occurs in the airway between bronchi and alveoli (alveolar space). Differential diagnosis is required since treatment for these two types of pneumonia is different.

■ Product Photograph



(HISCL KL-6 Diagnostic Kit)