FOR IMMEDIATE RELEASE
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Eisai Co., Ltd.
Sanko Junyaku Co., Ltd.
Sekisui Medical Co., Ltd.

Sanko Junyaku Launches Diagnostic Reagent Kit For Automated Clinical Chemistry Analyser To Determine KL-6, Detecting Marker of Interstitial Pneumonia

Sanko Junyaku Co., Ltd. (Headquarters: Tokyo, President: Keisuke Watanabe, "Sanko Junyaku"), a subsidiary of diagnostics business of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO, Haruo Naito, "Eisai"), will launch NANOPIA® KL-6 Eisai ("the product"), new test kit for automated clinical chemistry analyser to determine KL-6, detecting marker of interstitial pneumonia. The product will be manufactured by Sekisui Medical Co., Ltd. (Headquarters: Tokyo, President and CEO: Mutsumi Fukuda, "Sekisui Medical") and available on the Japanese market from July 1st this year.

Sanko Junyaku, Eisai, and Sekisui Medical jointly developed NANOPIA® KL-6 Eisai. Sekisui Medical received manufacturing and marketing approval for the product from the Ministry of Health, Labour and Welfare in Japan. It is listed under coverage of national health insurance effective today. The product will be marketed by Sanko Junyaku with marketing support by Eisai and Sekisui Medical.

KL-6 is a serum marker highly specific for interstitial pneumonia. Sanko Junyaku currently markets EITEST® KL-6 (sandwich enzyme immunoassay method) and PICOLUMI® KL-6 (electrochemiluminescence immunoassay method), reagents to determine KL-6, and also LUMIPULSE® KL-6 Eisai and LUMIPULSE Presto® KL-6 Eisai for fully automated chemiluminescent enzyme immunology system.

NANOPIA® KL-6 Eisai, the new diagnostic reagent kit that was developed with the techniques of Sekisui Medical and are based on latex immunoturbidimetric assay, for automated clinical chemistry analyser, which is being widely used in a medical setting, especially in hospitals, will further enhance the convenience of diagnostic aid for interstitial pneumonia.

Idiopathic interstitial pneumonia and drug-induced pneumonia are the most common types of interstitial pneumonia. Recent increase in number of patients with drug-induced pneumonia has raised social concern about and awareness of the importance of the disease. Sanko Junyaku, Eisai, and Sekisui Medical are committed to contribute to increasing the benefits of potential patients with interstitial pneumonia, making the product available in Japan.

[Please refer to the following notes for product and glossary]

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<Notes to Editors>

■ Product Information

Product Name	NANOPIA® KL-6 Eisai	
Assay System	Automated Clinical Chemistry Analyser	
Reagents	KL-6 buffer solution	KL-6 latex test solution
Package	24mL x 2	8mL x 2
List Price	136,000 JPY	204,000 JPY
Intended Use	Determination of sialylated carbohydrate antigen (KL-6) level in serum or plasma	
Manufactured by	Sekisui Medical Co., Ltd.	
Marketed by	Sanko Junyaku Co., Ltd.	
Marketing supported by	Eisai Co., Ltd.	

Solution and Calibrator （sold separately）

Product Name	KL-6 Calibrator
Package	0.5 mL x 4 concentrations
List Price	20,000 JPY
Manufactured by	Sekisui Medical Co., Ltd.
Marketed by	Sanko Junyaku Co., Ltd.
Marketing supported by	Eisai Co., Ltd.

■ Glossary

1. Automated Clinical Chemistry Analyser

A device mainly for colorimetric analysis of marker in serum or plasma using enzyme reaction or colour reaction. The process from sampling to output of assay result is automated. Although discrete method is widely used currently, electrolyte test by electrode method and immunological test by latex immunoturbidimetric assay can also be done using this analyser.

2. Latex Immunoturbidimetric Assay

Latex particles that have sensitised antibody and antigen in specimen cause antigen-antibody reaction to agglutinate latex particles. This assay determines the agglutination as a change of absorbance. Reagent for latex immunoturbidimetry is widely used as the agglutination of latex particles can be determined quantitatively with an easy operation of the automated clinical chemistry analyser.

3. 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.

4. KL-6 (Sialylated Carbohydrate Antigen)

KL-6 is expressed on the surface of type II alveolar epithelial cells which consist of the walls of the alveolus (interstitium). In interstitial pneumonia, type II alveolar epithelial cells are excessively formed and the KL-6 level increases. Determination of serum KL-6 level is effective for the diagnosis of interstitial pneumonia since intracellular KL-6 exudes into blood.