July 31, 2018
Denka Company Limited
Denka Seiken Co., Ltd.

The Denka Group Begins U.S. Sales of In-Vitro Diagnostic Reagent for Heart Disease Risk Marker SD LDL-C

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter "Denka") hereby announces that Denka Seiken Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Mitsukuni Ayabe; hereinafter "Denka Seiken"), a core Denka Group operating company, began sales of an in-vitro diagnostic reagent that measures the level of small, dense LDL cholesterol (hereinafter "sd LDL-C"[1]) in blood in the United States from July 30, 2018.

Since the 510k clearance[2] for the s LDL-EX "SEIKEN" test, dated on August 18, 2017, Denka Seiken undertook the process of gaining CLIA categorization for other instrument platforms by validating our performance data on different instruments. In July, 2018, the process was completed and the s LDL-EX "SEIKEN" test system has been CLIA categorized as moderately complex for use on different instrument platforms, which encourages us to launch in the U.S. market.

The measurement of sd LDL-C serves as an accurate risk indicator for cardiovascular disease. At the same time, despite sd LDL-C being one of a number of the lipoprotein subclasses[3] that comprise LDL cholesterol, a special method had to be devised to measure it. With the aim of popularizing diagnosis based on sd LDL-C measurement, Denka Seiken applied its highly sophisticated diagnostic reagent technologies to develop the reagent so that it could be employed in commonly used automated clinical chemistry analyzers.

Currently, heart disease is the No. 1 cause of death in the United States. Accordingly, we are convinced that the creation of a simple, quick and low-cost diagnostic solution for assessing heart disease risk will promote the maintenance of good health, help prevent disease and reduce medical expenses for people in the United States.

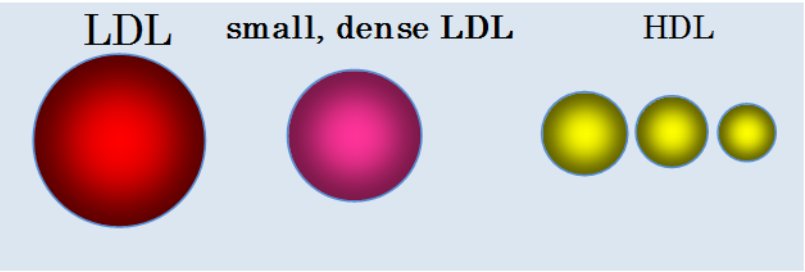
The Denka Group is working hard to expand its health-care related businesses in line with the priority measure of "accelerating the growth of specialty businesses," which is part of the "business portfolio shift" growth strategy outlined in the new management plan Denka Value-Up.

Today, an estimated 2,000 million lipid panel examinations take place every year in countries around the world. At the same time, a growing number of people are suffering from lifestyle-related diseases, including those attributable to abnormal lipid metabolism, reflecting such factors as changes in diet. Denka Seiken will now ramp up marketing of this and other reagents for measuring lipoprotein subclasses in the United States in addition to China, where the company had already been carrying out full-scale marketing activities. Simultaneously, Denka Seiken will engage in initiatives to raise public awareness regarding heart disease and to help increase the number of institutions that provide relevant examination. We will thus popularize the sd LDL-C measurement as part of multi-faceted efforts aimed at contributing to people's well-being.

The impact of the reagent on profits for the fiscal year ending March 31, 2019, has been taken into account in the business performance forecasts already released.

1. A lipoprotein with a comparatively small particle size and high density relative to ordinary LDL. The new diagnostic reagent is used to measure the density of sd LDL in the overall cholesterol count.

Artist's rendering of three types of lipoprotein



Currently, our studies indicate that knowing the sd LDL-C level has the following clinical significance:

(1) The density of sd LDL-C is closely related to the risk of developing CHD.
(2) Even when LDL cholesterol levels are low, a high sd LDL-C density exposes patients to greater risk of developing CHD.
(3) A number of studies indicate a relationship between sd LDL-C levels and metabolic syndrome, the accumulation of visceral fat and high blood pressure as well as the aggravation of diabetes and arterial sclerosis.

2. Approval from the U.S. FDA for the sale of medical equipment and in-vitro diagnostic reagents.
3. Detailed classifications of lipoproteins based on density, particle size and proportion of components.

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