

## Denka Obtains Regulatory Approval of a Measurement Reagent of sdLDL-C, a novel Risk Marker for Coronary Heart Disease

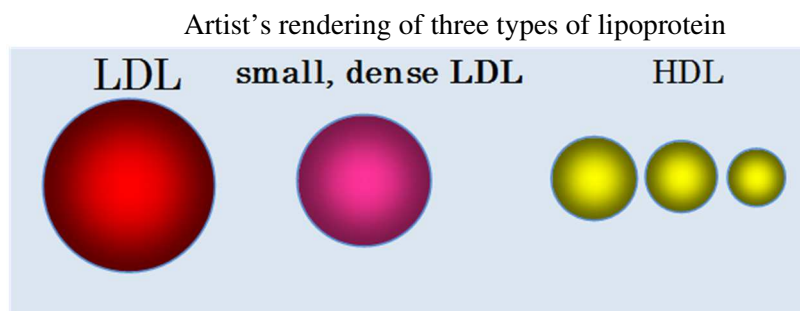
Denka Co., Ltd. (head office: Chuo-ku, Tokyo; President and CEO: Toshio Imai) is the first in Japan to obtain regulatory approval of the sLDL-EX Seiken, a reagent for in vitro diagnostic use to measure “small, dense LDL cholesterol” (“sdLDL-C”) as a risk marker for coronary heart disease (\*1). Once the release date is decided, medical personnel will be informed through our website, etc.

"sdLDL-C" is a marker for accurately assessing the risk of developing coronary heart diseases such as myocardial infarction and angina pectoris through a simple blood test. Cholesterol is a type of lipid in human blood. Excess cholesterol in the blood vessels is accumulated in the liver by particles called HDL. LDL is well known as bad lipoprotein to cause coronary heart diseases and comprised of a group of heterogeneous lipoprotein particles. Among these, small dense LDL is recently focused as ugly lipoprotein as a hidden culprit for heart disease. Historically, a special device had been required to measure sdLDL-C, which takes hours to days. For this reason, we developed the world's first technology in 2007 to measure sdLDL-C easily, quickly, and inexpensively by using conventional automated analyzers that are used in other blood tests. By sLDL-EX Seiken, measurement of sdLDL-C can complete in about 10 minutes.

Overseas, we acquired the CE mark in Europe in 2009, and in China, our strategic partner started sales with the approval of the BFDA (Beijing Food and Drug Administration). In August 2017, we obtained 510(k) clearance from the U.S. FDA (U.S. Food and Drug Administration), and in July of the following year, we began selling this product in the United States.

By obtaining sales approval in Japan, we will contribute to the prevention of heart disease, which is the second most common cause of death in Japan (\*2), and the suppression of medical expenses. Moreover, we will continue to contribute to the health maintenance and disease prevention of people around the world by obtaining sales approval for and disseminating this product in different countries.

Denka will aim to be an irreplaceable company for society, by creating a better world through all the work it can perform better than anybody, using the SDGs as a compass.



Up to now, many studies have indicated that knowing the sd LDL-C level has the following clinical significance:

- (1) The concentration of sd LDL-C is closely related to the risk of developing CHD.
- (2) Even when LDL cholesterol levels are low, high sd LDL-C levels expose patients to a 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 atherosclerosis.

(\*1) Factor that suggests the risk of development of diseases in future

(\*2) Ministry of Health, Labour and Welfare, "2020 Overview of Demographic Statistics (Confirmed Figures)"

\*Source:

- 二宮利治、東岡真由、坂田智子 (2020) 「血清small dense LDL コレステロール値と虚血性心疾患発症の関係：久山町研究」 臨床と研究・97巻3号

[For reference: Previous press release related to this test kit (Denka's website)]

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- July 31, 2018, "The Denka Group Begins U.S. Sales of In-Vitro Diagnostic Reagent for Heart Disease Risk Marker SD LDL-C" [https://www.denka.co.jp/eng/storage/news/pdf/204/20180731\\_sd%20LDL-C\\_en.pdf](https://www.denka.co.jp/eng/storage/news/pdf/204/20180731_sd%20LDL-C_en.pdf)
- August 23, 2017, "Denka Group Receives U.S. FDA 510k Clearance" [https://www.denka.co.jp/eng/storage/news/pdf/176/20170825\\_sdldl\\_clearlance\\_eng.pdf](https://www.denka.co.jp/eng/storage/news/pdf/176/20170825_sdldl_clearlance_eng.pdf)
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#### Product Overview

|                              |                       |
|------------------------------|-----------------------|
| Generic name                 | sdLDL-Cholesterol kit |
| Product name                 | sLDL-EX Seiken        |
| Manufacturing license number | 30300EZX00081000      |
| Target market                | Japan                 |
| Manufacturer and distributor | Denka Company Limited |

## **About Denka**

Denka is a chemical manufacturer headquartered in Chuo-ku, Tokyo. The company specializes in developing business activities on a global scale across a wide range of fields, from inorganic and organic chemicals, to electronic materials and pharmaceuticals. Founded in 1915, Denka has steadily continued to develop and manufacture products that contribute to the development of society by fully utilizing its unique concepts and technological capabilities. Upholding its corporate slogan, “Possibility of chemistry” the company and its president, Toshio Imai, are committed to contributing to the sound development of the society while sincerely tackling the challenges that the society is now confronting.

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