

Denka to Step Up Collaboration with the Taiwan-Based PlexBio, Co-Developing an Infectious Disease Diagnostic Testing System

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter “Denka” or the “Company”) hereby announces that it has signed a basic agreement with PlexBio Co., Ltd. (hereinafter “PB”¹), its strategic partner headquartered in Taiwan, with the aim of co-developing an infectious disease diagnostic testing system comprising a set of new equipment and reagents.

Taking on one of the major issues infectious disease experts are now confronting, this co-development project is aimed at shortening the time it takes to detect pathogenic microorganisms and identify drug-resistant bacteria genes. If successful, the project is expected to open the door for the creation of a number of innovative medical products that are more effective in ameliorating the symptoms of such infectious diseases as sepsis² and reduce the mortality rates of such diseases. Moreover, the project is looking to contribute to drug-resistant bacteria countermeasures³ by facilitating the more prudent use of antibacterial drugs.

Currently, patients suspected to have been infected with diseases attributable to microorganisms, including sepsis, are supposed to undergo bacteriological examination procedures in which specimens—blood, urine, sputum or feces—are cultured to detect the presence of pathogenic microorganisms and identify the type of such microorganisms. These procedures also entail drug susceptibility testing aimed at assessing whether the detected microorganisms can be subdued by antibacterial drugs. Although the results of these procedures are accurate and useful, each diagnosis usually takes two or more days. Because of this, genome-based methods⁴ aimed at identifying pathogenic microorganisms and drug-resistant bacteria genes, are attracting growing interest as they can obtain testing results in a shorter period of time.

Against this backdrop, in September 2016 the Denka Group obtained a license to utilize IntelliPlex™, a multiplex-assay technology⁵ developed by PB, to promote research into these methods. While the Group found IntelliPlex™ to be an excellent candidate for a genome-based diagnostic platform, it came to the conclusion that the development of a diagnostic testing system specialized in sepsis and other infectious diseases is imperative. Thus, the Group has decided to step up its collaboration with PB and launched the aforementioned co-development project.

Outline of the Basic Agreement with PB

The Denka Group and PB will develop, respectively, diagnostic reagents and measurement equipment, with the objective of realizing an easy-to-use diagnostic testing system capable of identifying pathogenic microorganisms and drug-resistant bacteria genes within a period of 24 hours, a significant improvement compared with the time needed to obtain testing results using conventional methods.

In line with “Denka Value-Up,” a new management plan spanning the five-year period from fiscal 2018 to 2022, Denka is promoting a shift in its business portfolio as part of its growth strategies. Specifically, the Company has positioned accelerating the growth of its specialty businesses as a priority initiative, to this end promoting the selection and concentration of its management resources. Under this initiative, Denka is endeavoring to expand its healthcare-related operations, including the provision of illness prevention and early diagnosis solutions, while looking to create new businesses in such fields as cancer

remedies and gene alteration analysis. Looking ahead, the Denka Group will meet the needs of frontline medical practitioners through the pursuit of this co-development project, thereby contributing to solutions for health issues people around the world now face.

- Targeted release date: Fiscal 2022
- Sales target for resulting products (reagents and equipment for identifying pathologic microorganisms and drug-resistant bacteria genes):
¥2 billion to ¥3 billion (several years after the release)

For inquiries:

Denka Company Limited
 CSR & Corporate Communications Dept.
 TEL: +81-3-5290-5511 E-mail: csr-koho@denka.co.jp

For inquiries from medical service providers:

Denka Company Limited
 Business Promoting Dept., Life Innovation Div.
 TEL: +81-3-5290-5568

1. Overview of Plex Bio

(1) Company name	PlexBio Co., Ltd.
(2) Main business	Development, manufacture and sale of medical equipment and biotechnology services
(3) Establishment	December 17, 2009
(4) Headquarters	Taiwan
(5) Representative	Dr. Dean Tsao
(6) Capital	Approximately ¥1,920 million
(7) Employees	Approximately 70

2. Sepsis

Sepsis is a condition arising from organ failures caused by infection. When the body is invaded by bacteria, viruses or molds, its immune response works to combat these foreign agents. Sometimes, however, the immune system goes into overdrive, triggering failures in such organs as heart, lung and kidney. This is called sepsis. To appropriately treat the condition, medical practitioners must determine the causative agent, which may be a bacteria, virus or fungus (e.g., molds and yeasts).

3. Drug-resistant bacteria countermeasures

Drug-resistant bacteria are a type of bacteria capable of withstanding antibacterial drugs, which had once been lethal substances to them. Some of these bacteria are intrinsically equipped with drug-resistant capacities, while others may have obtained such capacities from other bacteria. An excessive dose of antibacterial drugs can also be a contributor to the emergence of such bacteria.

While a growing number of patients are infected with drug-resistant bacteria in regions around the globe, the lineup of mainstay antibacterial drugs has seen few updates in recent years, prompting major public concern regarding the difficulty in subduing a possible outbreak of new types of drug-resistant bacteria. Addressing this concern, the World Health Assembly, held in May 2015, adopted a global action plan to tackle antimicrobial resistance (AMR), requiring member countries, Japan included, to formulate national action plans to counter this phenomena in two years. In response, discussions led by Japan’s Ministry of Health, Labour and Welfare, have been under way in the country to

comprehensively review what must be done by medical industries. Also, with relevant cabinet ministers engaging in deliberation on how to address the international threat of emerging infectious diseases, the Cabinet has put in place a special council in charge of discussing AMR issues and promoting coordination between government agencies. Based on conclusions reached through these discussions, the first of a kind national action plan has been announced on April 5, 2016. Having defined “public awareness and education”; “surveillance and monitoring”; “infection prevention and control”; “proper use of antimicrobial agents”; “research & development and drug development”; and “international cooperation” as six major goals, this plan is largely based on five objectives set forth in the aforementioned global action plan endorsed by the World Health Assembly, but has been tailored to the country’s circumstances with the addition of “international cooperation” to those objectives.

4. Genome-based methods

These methods are uniquely designed to detect targeted genes by exploiting distinctive similarities between certain types of base sequences. Genome-based methods are now expected as promising diagnostic testing methods that would realize highly sensitive measurements.

5. IntelliPlex™ multiplex-assay technology

The π code technology uses a specially processed magnetic micro disc. Semiconductor manufacturing technologies engrave unique patterns on the surface of the magnetic micro disc. Then a probe for antibody and gene measurement is attached to help identify the substances under examination. This advanced technology thereby enables simultaneous multiplex assays.

The IntelliPlex™ system is capable of highly sensitive detection as well as the simultaneous analysis of multiple items thanks to the combination of the π code technology and measurements based on fluorescence spectroscopy. This widely adopted method utilizes fluorescent tagging to analyze substances under examination. The measurement of fluorescence is highly sensitive in detecting the substance of analysis, but the standard technique is incapable of measuring multiple items at the same time. To overcome this difficulty, the IntelliPlex™ system uses image recognition technology to process the unique patterns deposited on the surface of the disc, thereby succeeding in the measurement of multiple items.

Note: IntelliPlex™ is a trademark of PlexBio. For more details of PlexBio, the IntelliPlex™ system and π code technology, please also visit PlexBio’s corporate website. (<http://www.plexbio.com>)

About Denka Company Limited

In 1915, Denka was founded in Tokyo, Japan as a manufacturer of calcium carbide and fertilizers. Over the course of our century-strong history, we have evolved into a corporate group that operates globally and handles a wide variety of operations, ranging from synthetic rubber and other acetylene derivatives to petrochemicals, electronic materials and polymer processing products to pharmaceuticals. With 42 consolidated subsidiaries worldwide, the Company’s consolidated net sales for the fiscal year ended March 31, 2017 totaled ¥362.6 billion. Looking ahead, Denka will continue to take on the challenge of expanding the possibilities of chemistry and, to this end, will relentlessly strive to enhance its manufacturing technologies. For more information, visit <http://www.denka.co.jp/eng/index.html>.

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