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KANEKA CORPORATION

Kaneka develops technology for testing refractory respiratory infections through joint research with the National Institute of Infectious Diseases (NIID)

Kaneka Corporation (Headquarters: Minato-ku, Tokyo; President: Minoru Tanaka) has developed technology to easily test for *Mycobacterium abscessus* complex (MABC), a bacterium that causes *M. abscessus* pulmonary disease, which is a refractory respiratory infection that has increased rapidly in recent years. Development was conducted through joint research with Yoshihiko Hoshino, division chief of the Leprosy Research Center of the National Institute of Infectious Diseases (Shinjuku-ku, Tokyo; Director: Takaji Wakita), along with others at the Center.

Through infecting the lungs, MABC leads to *M. abscessus* pulmonary disease, a refractory respiratory infection. MABC is divided into three subspecies<sup>\*1</sup> and is known for having different treatment strategies and prognoses depending on the subspecies and for there being a strain that is resistant against macrolide antibiotics, a curative treatment. Due to this, Western medical guidelines<sup>\*2</sup> recommend for when treating *M. abscessus* pulmonary disease to identify the subspecies and run tests on its susceptibility to macrolide. However, tests up until now have suffered from cost and speed issues, with expensive analysis devices being required to identify the subspecies and a cultivation period of around two weeks being needed for testing macrolide susceptibility.

By combining genome analysis technology from the National Institute of Infectious Diseases and Kaneka's DNA chromatography technology<sup>\*3</sup>, the subspecies of MABC and the strain's macrolide tolerance will now be able to be determined simultaneously within around an hour. The results of this research were published in the international scientific journal EBioMedicine on January 11, 2021. (Press release from the National Institute of Infectious Diseases: <https://www.niid.go.jp/niid/ja/basic-science/bacteriology/10140-bac-2021-001.html>)

Kaneka is aiming to begin selling a testing kit that uses this technology in April 2021. It is estimated that the number of patients with *M. abscessus* pulmonary disease in Japan is in the thousands, and over 10,000 tests are expected to be used annually in the country. Additionally, patients have been increasing in East Asia and Western countries. There are up to 100,000 tests expected to be used worldwide annually, and up to a billion yen in sales is being aimed for by 2023 by helping to solve unmet medical needs around the globe.

Kaneka has launched the "Infection Research Team" for promoting research and development of measures against infection such as COVID-19. Kaneka is providing a wide range of solutions,

including the contract manufacturing of a DNA vaccine, the supplying of drug substance for “Avigan”, the development of antiviral drugs, and the providing of PCR testing kits. In the near future, Kaneka will make use of its technology that makes gene detection easier and faster, one of the company’s strengths, to provide solutions necessary for a variety of infectious disease countermeasures, including pathogen testing and evaluation kits.

\*1. The three subspecies of *M. abscessus* subsp. *abscessus*, *M. abscessus* subsp. *bolletii*, and *M. abscessus* subsp. *massiliense*.

\*2. Guidelines for treating NTM lung disease jointly announced by the American Thoracic Society, the European Respiratory Society, the European Society of Clinical Microbiology and Infectious Diseases, and the Infectious Diseases Society of America.

\*3. A test strip for visually detecting distinctive genes that originate from bacteria and viruses.