Denka

October 22, 2021
Denka Company Limited

COVID-19 Rapid Antigen Test Kits Start of Sales in the U.S. Market from November

~ Our Business Partner Xtrava Health has obtained an EUA from the U.S.FDA ~

< 「SPERA™ COVID19 Ag Test」 >

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Toshio Imai; hereinafter, "Denka") announces that while proceeding with the preparations for the expansion of its COVID-19 antigen testing technology in the U.S., its business partner Xtrava Health(*1) obtained an emergency use authorization (EUA)(*2) from the U.S. Food and Drug Administration (FDA) on October 12 for its *SPERA™ COVID19 Ag Test*. Based on their business partnership, Denka will supply its COVID-19 antigen test kits relabeled as SPERA™ COVID-19 Ag Test as a manufacturer for the U.S.-based Xtrava Health(* 1) per Xtrava Health's U.S. market specifications.

On March 5, 2021, Xtrava Health was awarded a contract by the National Institutes of Health (NIH) under the Rapid Acceleration of Diagnostics (RADx^{SM})(*3) initiative to expedite the launch of *SPERA™ COVID-19 Ag Test*. Clinical studies that were funded and conducted by Xtrava Health with the full cooperation of Denka, confirmed the adequate performance of the SPERA™ COVID-19 Ag Test, and in August 2021 Xtrava Health applied for an EUA from the FDA.

Per FDA guidance, an independent multicenter clinical study confirmed that the *SPERA™ COVID-19 Ag Test detects* the presence or absence of COVID-19 antigen within 15 minutes, and with a test sensitivity(*4) of 92%, and a specificity(*5) of 97%. This study confirmed that the SPERA™ COVID-19 Ag Test has a high detection accuracy. In addition, a NIH-funded study performed by Emory University, Georgia Institute of Technology and Atlanta Children's Clinical Center confirmed that SPERA™ COVID-19 Ag Test reacts with the main COVID-19 variants such as delta, lambda and mu.

As infections with variant strains such as the delta variant are still prevalent throughout the world, COVID-19 testing is expanding in nursing and educational facilities, and into households, among other locations. Consequently, research and development of a test system in preparation for the simultaneous spreading of such variants together with the influenza virus is now being recommended. Denka will continue to cooperate with Xtrava Health and combine the Denka COVID-19 antigen test technology with the Xtrava Health companion digital test platform (*6), which detects the test results with a connected reader that Xtrava Health is developing to enable improved sensitivity, ease of use and result reporting for over the counter (*7) use.
In addition, Denka is also strengthening its partnership with Xtrava Health through the supply of the quick antigen test kit based on *Quick Navi™ -Flu+COVID19 Ag* technology. This product was launched in Japan in August 2021, with which the presence or absence of COVID-19 and influenza viruses can be simultaneously determined within 10 minutes with one device. Meanwhile, Denka is advancing the supply of this COVID-19 antigen test kit to other regions overseas such as Asia according to procedures for application for regulatory approval in each country.

Denka believes that measures to prevent infectious diseases are a part of its social responsibilities and it has strived to prevent the spread of infectious diseases through its work on both preventive and diagnostic measures as the only company producing and selling various types of quick virus antigen test kits and influenza vaccines, including test kits for the COVID-19 coronavirus. Denka will aim to be an irreplaceable company for society, which creates a better world for all through work it can perform better than anybody, using the SDGs as a compass.

(*1) Xtrava Health (headquarters: Santa Clara, California, CEO: Sameh Sarhan)
A manufacturer of medical devices established in 2014 to contribute to global healthcare through cutting-edge technologies, engaging in the development and supply of healthcare devices that allow individuals to monitor their health conditions quickly and easily.

Xtrava Health was selected from a pool of over 700 RADx applicants. The award of this contract followed months of diligence and vetting of Xtrava Health's technology and scale-up plans by clinical, diagnostics industry, and academic experts including independent evaluation and validation of the SPERA™ COVID19 Ag Test's analytical and clinical performance by Emory University. This Xtrava Health project has been funded in part by the NIH Rapid Acceleration RADxSM) initiative with U.S. federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92021C00002).

(*2) FDA Emergency Use Authorization (EUA)
System with which the U.S. Food and Drug Administration (FDA) permits the use of unapproved drugs and the expansion of the indications of approved drugs in an emergency. Based on Article 564 of the Federal Food, Drug, and Cosmetic Act (FDCA), this can be permitted if it is judged that the following conditions are fulfilled: it is a life-threatening disease, a certain degree of effectiveness for the treatment of this disease has been confirmed, and there is no appropriate method for the diagnosis, prevention or treatment of this disease.

(*3) RADx (Rapid Acceleration of Diagnostics Initiative)
A research support initiative launched by the NIH to accelerate innovation for the development and commercialization of technologies for accurate, fast and easy-to-use COVID-19 testing.

(*4) Sensitivity Ratio of people who tested positive to people infected with the disease.
(*5) Specificity Ratio of people who tested negative to people not infected with the disease.

(*6) Xtrava Health's Reader and Companion Digital Testing Platform
Using a reader that is developed by Xtrava Health and an LED light source it can assess the positive/negative test results of the quick antigen test kit that was inserted into the reader with an accuracy and sensitivity that is higher than that when conducted by visual examination. The results can be sent to the cloud or electronic medical records for storage via a smartphone, and it is also possible to obtain an idea of the infection status in each area by synchronizing the data with location information.

(*7)over the counter
A market for drugs that can be purchased over-the-counter without a prescription by a doctor

*”*SPERA™ COVID19 Ag Test”* is a trademark of Xtrava Health.
*This test kit has been incorporated into the consolidated earnings forecast for the fiscal year ending March 31, 2022.

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.

*Reference

- April 28, 2021 ”Denka Supplies COVID-19 Antigen Test Kits to Xtrava Health”
  https://www.denka.co.jp/eng/storage/news/pdf/339/20210428_denka_covid19_xtrava_en.pdf

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