

October 8, 2020

KANEKA CORPORATION

Kaneka releases a coronavirus PCR test kit that uses their original sample processing technology

On October 7, Kaneka Corporation (Headquarters: Minato-ku, Tokyo; President: Minoru Tanaka) began selling an RT-qPCR test kit that allows detection of the novel coronavirus within an hour (product name: KANEKA Direct RT-qPCR Kit “SARS-CoV-2”; referred to below as “the product”) to medical institutions and testing facilities.

The product has a suggested retail price of 110,000 yen excluding tax (enough for 100 tests), and it will be sold by affiliate Kaneka Medix Corporation (Headquarters: Osaka City, Osaka Prefecture; President: Shozo Ishizaka).

The product uses an original sample processing technology that was developed through harnessing technologies that include molecular testing-related products that Kaneka has worked on previously. Pre-treatment is completed by heat treatment only, as there is no need to purify RNA\*1 from the virus using samples taken from saliva or the top of the throat. Accordingly, the pretreatment that with conventional methods took around one hour is reduced to around 5 minutes, allowing the overall time needed for the PCR test to be greatly reduced from the previous 2 to 3 hours to within an hour.

Evaluation of the product is being conducted in cooperation with AVSS Co., Ltd. (Headquarters: Nagasaki City, Nagasaki Prefecture; CEO: Nobuyuki Kobayashi) in conformance with the standards of the National Institute of Infectious Diseases.

The product is mentioned in the Ministry of Health, Labor and Welfare’s “Validation of 2019-nCoV molecular testing method in which evaluation results were obtained using clinical specimens”\*\*2, and is applicable for regulatory examinations and Japan’s National Health Insurance. The plan in the future is to aim for approval as a medicine for *In vitro* Diagnostics in accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

Kaneka has launched the “Infection Research Team” for progressing research and development into infection control measures beginning with measures for the novel coronavirus, and, along with the product announced here, is taking a wide range of measures to help solve the coronavirus crisis, including the intermediate manufacturing of a DNA vaccine, the supplying of raw materials for “Avigan”, and the supplying of PCR reagents in Belgium. Kaneka will continue to utilize its own technologies to provide the solutions necessary for infection control measures.

\*1: Refers to the genes characteristic of the new coronavirus. Through PCR testing, RNA viruses are amplified to detect infection.

\*2: Testing methods that have had their accuracy and versatility verified by the Ministry of Health, Labor and Welfare and the National Institute of Infectious Diseases are, in the interest of disseminating testing methods, applicable for National Health Insurance as well as able to be used in regulatory examinations, even in the absence of manufacturing and selling approval from the PMDA (The Pharmaceuticals and Medical Devices Agency).

< General description of AVSS Co., Ltd.>

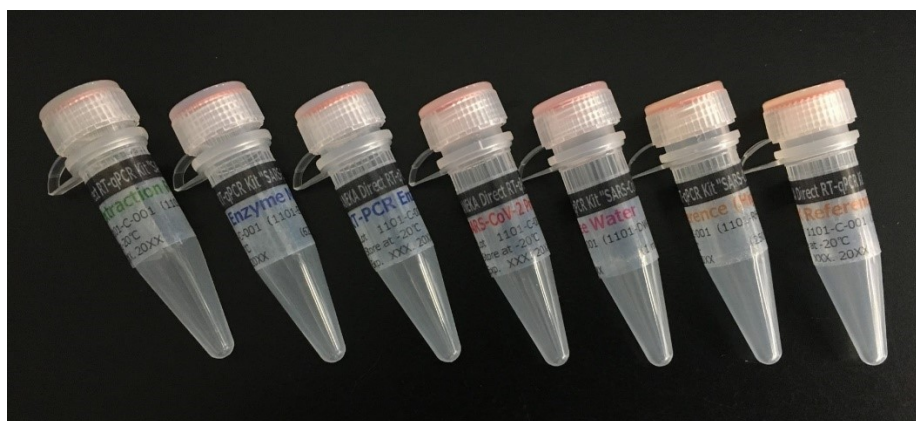
Headquarters: Nagasaki City, Nagasaki Prefecture

Representative: Nobuyuki Kobayashi

Description of business: Consigned evaluation work and development of antiviral medication

Foundation: 2006

Notes: A bio-venture company formed by Nagasaki University's Department of Infectious Molecular Pharmacy



KANEKA Direct RT-qPCR Kit "SARS-CoV-2"