



August 22, 2024

Denka Company Limited

Hokkaido University

Announcement of Obtaining the Approval for the Use of Ebola Virus Antigen Rapid Diagnostic Kit “QuickNavi™-Ebola” in the Democratic Republic of the Congo

- Efforts to prevent the spread of infection in Africa -

Denka Company Limited (Head Office: Chuo-ku, Tokyo; President and CEO: Toshio Imai) jointly developed with Professor Ayato Takada, Director of the International Research Institute for Zoonosis Control at Hokkaido University, the Ebola virus antigen rapid diagnostic kit, “QuickNavi™-Ebola” (hereinafter “this kit”), which obtained marketing approval in Japan by the Pharmaceuticals and Medical Devices Agency (PMDA) on March 18, 2021.

Recently, the National Institute for Research and Biomedical (INRB) of the Democratic Republic of the Congo, in cooperation with the Japan International Cooperation Agency (JICA), had applied to the Ministry of Health of the Democratic Republic of the Congo for permission to use this kit, which was approved for domestic use on June 21, 2024.

A prototype of this kit has been provided to the Democratic Republic of the Congo through JICA with the cooperation of Professor Takada from Denka Co., Ltd. for research use only purposes since before 2018. It was used for initial testing during the emergence of the Ebola outbreak in Equateur Province of the country in May 2018 and contributed to the prevention of the spread of the epidemic. It was also concurrently used with the PCR test and showed excellent performance during the outbreak in North Kivu Province and elsewhere in the country from 2018 to 2020. Based on the experiences and test results, the performance and efficacy of this kit were also confirmed by INRB, and the marketing approval by PMDA had been obtained based on those results.

This kit can demonstrate diagnostic results in approximately 10 minutes, can be stored at room temperature, and requires no special equipment or devices, so it is also expected to be used in remote areas that are far from cities and without adequate medical facilities. Therefore, formal approval for the use of this kit in the Democratic Republic of the Congo will enable the official supply of our products to the country and is expected to lead to the prevention of the spread of infection by enabling rapid diagnosis of future cases of Ebola hemorrhagic fever.

Under the “Mission 2030” management plan, we have positioned the healthcare business as one of our priority areas. We will continue to work on solving global healthcare issues through prevention and early diagnosis of infectious diseases and contribute to the improvement of people’s QOL.

[Reference: Previous press releases related to this topic]

< Website of our company >

- Denka's press release dated March 23, 2021

“Obtained Marketing Approval in Japan for Ebola Virus Antigen Rapid Diagnostic Kit”

https://www.denka.co.jp/eng/storage/news/pdf/508/20210323_denka_quicknavi_ebola_en.pdf

- Denka's press release dated April 13, 2020

• “Application for Approval of Domestic Manufacture and Sales of Rapid Diagnostic Test Kits for Ebola Virus”

https://www.denka.co.jp/eng/storage/news/pdf/279/20200413_denka_ebola_testkit_en.pdf

- Denka's press release dated May 28, 2018

“The Denka Group Donates Ebola Virus Rapid Diagnostic Test Kits to the Democratic Republic of Congo”

https://www.denka.co.jp/eng/storage/news/pdf/200/20180528_ebola_en.pdf

- Denka's press release dated May 30, 2017

“The Denka Group Donates Ebola Virus Rapid Diagnostic Test Kits to the Democratic Republic of the Congo”

https://www.denka.co.jp/eng/storage/news/pdf/172/20170530_ebola_en.pdf

- Denka's press release dated March 31, 2015

“DENKA SEIKEN and Hokkaido University Develop a Rapid Antigen Detection Test Kit for Ebola Virus”

https://www.denka.co.jp/eng/storage/news/pdf/90/20150331_ebolakit_eng.pdf

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Corporate Communications Dept. Tel: +81-3-5290-5511