

Denka

March 23, 2021 Denka Company Limited Hokkaido University

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

- Aiming to obtain WHO emergency use approval in 2022 to prevent the spread of infection in Africa -

Denka Company Limited (Head Office: Chuo-ku, Tokyo; President and CEO: Manabu Yamamoto) obtained, on March 18, marketing approval in Japan by the Pharmaceuticals and Medical Devices Agency (PMDA) for the Ebola virus antigen rapid diagnostic kit (hereinafter "this kit") developed in collaboration with Professor Ayato Takada (Research Center for Zoonosis Control) at Hokkaido University. The product name will be "QuickNaviTM-Ebola," and we will study the possibility of utilizing this kit from the viewpoint of domestic quarantine with the cooperation of related government agencies, public institutions, and research institutes.

This kit determines diagnostic results in approximately 10 minutes and requires no special equipment or devices, so it can be used effectively in areas without adequate medical facilities. Therefore, to further contribute to measures to prevent the spread of Ebola virus disease in Africa, where outbreaks of the disease have been confirmed, we will explore the possibility of a formal supply of this kit by providing information to medical institutions in African countries and aim to obtain approval for emergency use from WHO in 2022.

Under the "Denka Value-Up" 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.

< Recent outbreaks of Ebola virus disease in Africa >

In February 2021, there were 11 cases (including 4 deaths) in the Democratic Republic of the Congo and 18 cases (including 9 deaths) in the Republic of Guinea, and the spread is being controlled through measures such as testing and vaccination of contact persons. Genetic analysis of the virus has revealed that the Democratic Republic of the Congo has the same strain as the epidemic up to last year, and the Republic of Guinea has the same strain as the epidemic of 2016 in that country. These are considered to be relapse cases caused by asymptomatic pathogen carriers, and both countries have not declared an end to the disease at this time.

[Reference: Previous press releases related to this topic]

< Website of our company >

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" <u>https://www.denka.co.jp/eng/storage/news/pdf/200/20180528_ebola_en.pdf</u>

• 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

End of Press Release

[For Inquiries about This press Release from Media] Corporate Communications Dept. Tel: +81-3-5290-5511