

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

- Denka aims for the official adoption by medical systems in African countries -

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter “Denka”) is pleased to announce that on April 10, 2020 Denka applied for the approval of the domestic manufacture and sales of rapid diagnostic test kits for the Ebola virus (hereinafter the “Kits”) which Denka has jointly developed with Professor Ayato Takada at the Hokkaido University Research Center for Zoonosis Control.

The Kits enable rapid diagnosis of Ebola Virus Disease (EVD), obtaining results in about 10 minutes. The Kits have no need of any special instrument or apparatus, allowing their use in regions where medical facilities are not fully deployed. Denka has donated trial products to the Democratic Republic of the Congo (DRC) several times since 2017 through the Japan International Cooperation Agency (JICA). Prior to this application, Denka conducted clinical trials using the Kits at the National Institute of Biomedical Research in DRC, and it has been confirmed that the Kits have excellent utility.

It is believed that the continued maintenance and improvement of medical systems is required to control the Ebola virus. Denka believes that approval under the internationally recognized Pharmaceutical Affairs Act in Japan will lead to the official adoption of the Kits by the medical systems of African countries. In addition, after approval, Denka aims to obtain WHO approval under their Emergency Use Assessment and Listing (EUAL) program.

Denka regards the healthcare business as one of its key areas in Denka Value-Up management plan. Denka will continue to contribute to improvements in the quality of life of people by working to resolve medical issues throughout the world through the prevention and early diagnosis of infectious diseases.

[Reference: Links related to this announcement]

- 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

• JICA' press release dated May 30, 2017

“Contribution of Japanese Technology to Countermeasures against Ebola Virus Diseases in the Democratic Republic of the Congo” *Japanese

https://www.jica.go.jp/press/2017/20170530_01.html

• 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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