GENERAL DIRECTORATE OF PUBLICH HEALTH-
DEPARTMENT OF MICROBIOLOGY REFERENCE
LABORATORIES AND BIOLOGICAL PRODUCTS
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REPUBLIC OF TURKEY
MINISTRY OF HEALTH
General Directorate of Public Health

Number : 80962070-953.02.07.03
Subject : Türkinnova-Foaming Test
Evaluation Final Report

TO THE PRESIDENCY OF TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TİTCK)

Kits released to the market for the diagnosis of COVID-19 infection by the manufacturer in line with the definition of medical devices made under the "Regulation on In Vitro Medical Devices" published in the Official Journal dated 09.01.2007 and numbered 26398 are considered as an in-vitro medical diagnosis device and the abovementioned products must meet the requirements of the relevant regulation.

The registrations to UST (Product Tracking System) and import of these diagnosis kits are up to the prior authorization of TİTCK to protect the public health and prevent the spread of COVID-19 Pandemic due to the possibility of them hosting a higher margin of error than the specified confidence interval based on the technical difficulties such as that the kits used in the diagnosis of COVID-19 are newly developed and are not tested with a sufficient number of clinical samples ("The Communique on Import of Medical Diagnostic Kits" published in the Official Journal dated 02.14.2020 and numbered 31087). In this context, the authority to determine whether COVID-19 diagnosis kits are effective in the diagnosis of the disease has been given to the General Directorate of Public Health with the article dated 03.04.2020 and numbered 48535386-511-E.85079 by TİTCK. While the registration procedures of Covid-19

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diagnosis kits to the UTS are continued by TİTCK, comparative compliance tests showing that the products meet the regulatory requirements in terms of basic reliability and performance parameters were made by us, and the results were requested to be reported to TİTCK to register to the UTS.

Provided by Türkinnova company to be used in the diagnosis of COVID-19,

Foaming test kit; Trials have been conducted with the clinic samplings of COVID-19 suspicious patients. It was concluded that the Foaming test kit is suitable for use as a screening test to evaluate the clinical course in the diagnosis of COVID-19 as a result of the evaluation.

Kindly submitted for your information and necessary action.

e-signed.
Assoc. Dr. Fatih KARA
General Director

Appendix: 1- Letter of Application
2- Analysis Fee Receipt

Note: This document is only for the registration to TİTCK UTS and cannot be used for any other purposes.

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