



February 1, 2022

Joo Young Choi, Ph.D.
Nano-Ditech Corp.
259 Prospect Plains Road, Building K
Cranbury, NJ 08512

Re: EUA210170/S001
Trade/Device Name: Nano-Check COVID-19 Antigen Test
Dated: December 22, 2021
Received: December 22, 2021

Dear Dr. Choi:

This is to notify you that your request to update the Nano-Check COVID-19 Antigen Test to extend the shelf-life expiration date of the Nano-Check COVID-19 Antigen Test to 11 months, and to extend the shelf-life expiration date of the Positive and Negative Control Swabs to nine months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210170/S001 support the requested update for use with the Nano-Check COVID-19 Antigen Test. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Nano-Check COVID-19 Antigen Test issued on December 6, 2021.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health