



November 18, 2024

James B Chang, D.V.M., Ph.D.
President
Nano-Ditech Corporation
259 Prospect Plains Road, Building K.
Cranbury, NJ 08512

Re: EUA240009/S002
Trade/Device Name: Nano-Check Influenza+COVID-19 Dual Test
Dated: November 6, 2024
Received: November 6, 2024

Dear Dr. Chang:

This is to notify you that your request is granted to; (1) update the Nano-Check Influenza+COVID-19 Dual Test to extend the shelf-life expiration date to 11 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, and (2) update the Instructions for Use Nano-Check Influenza+COVID-19 Dual Test to fix a typographical error with respect to storage temperature. Upon review, we concur that the data and information submitted in EUA240009/S002 supports the requested update for the Nano-Check Influenza+COVID-19 Dual 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 Influenza+COVID-19 Dual Test issued on July 8, 2024.

Sincerely yours,

Joseph Briggs, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health