January 4, 2023

Bojana Ilic
Manager, Regulatory Affairs
Luminex Molecular Diagnostics, Inc.
439 University Ave.
Toronto, ON, Canada M5G1Y8

Re: EUA210031/S003
Trade/Device Name: NxTAG Respiratory Pathogen Panel + SARS-CoV-2
Dated: May 31, 2022
Received: May 31, 2022

Dear Bojana Ilic:

This is to notify you that your request to update the authorized labeling of the NxTAG Respiratory Pathogen Panel + SARS-CoV-2 to; (1) add a claim of 6 months storage for collected specimens stored at ≤-70°C, and (2) updates to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, is granted. Upon review, we concur that the data and information submitted in EUA210031/S003 supports the requested updates for use with the NxTAG Respiratory Pathogen Panel + SARS-CoV-2 and addresses Condition of Authorization (1) in the Viral Mutation Revision Letter issued on September 23, 2021. FDA have updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with more recent authorizations. 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 NxTAG Respiratory Pathogen Panel + SARS-CoV-2 issued on March 3, 2021, and the Viral Mutation Revision Letter issued on September 23, 2021.

Sincerely yours,

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