October 3, 2024

Sarah Herzog
Senior Associate, Regulatory Affairs
Luminex Molecular Diagnostics, Inc.
439 University Ave.
Toronto, ON, Canada M5G1Y8

Re: EUA210031/S004
Trade/Device Name: NxTAG Respiratory Pathogen Panel + SARS-CoV-2
Dated: August 30, 2024
Received: August 30, 2024

Dear Sarah Herzog:

This is to notify you that your request to update the authorized labeling of the NxTAG Respiratory Pathogen Panel + SARS-CoV-2 to an additional limitation around any Human Metapneumovirus positive result, especially when detected in a co-infection, is granted. Upon review, we concur that the information submitted in EUA210031/S004 supports the requested updates for use with the NxTAG Respiratory Pathogen Panel + SARS-CoV-2. 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.

Sincerely yours,

_____

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