April 23, 2020

Nahed Mohsen, Ph.D.
Vice President of Regulatory and Clinical Affairs,
NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108 US

Re: EUA200073/A001
Trade/Device Name: NeuMoDx SARS-CoV-2 Assay
Dated: April 13, 2020
Received: April 13, 2020

Dear Dr. Mohsen:

This is to notify you that your request to update the Instructions for Use (IFU) of the NeuMoDx SARS-CoV-2 Assay to; (1) add bronchoalveolar lavage (BAL) specimens to the intended use, (2) modify the intended use to "*Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests*", (3) update the Clinical Performance section with results from recent testing of clinical specimens, and (4) add minor edits for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200073/A001 supports the requested updates for use with the NeuMoDx SARS-CoV-2 Assay and have updated the Healthcare Provider Fact Sheet accordingly. By submitting this amendment 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 NeuMoDx SARS-CoV-2 Assay issued on March 30, 2020.

Sincerely yours,

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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