U.S. FOOD & DRUG ADMINISTRATION

April 13, 2020

Mari Meyer
Vice President Regulatory and Clinical Affairs, North America
DiaSorin Molecular LLC
11331 Valley View Street,
Cyress, CA 90630 US

Re: EUA200026/A002
Trade/Device Name: Simplexa COVID-19 Direct assay
Dated: April 6, 2020
Received: April 7, 2020

Dear Ms. Meyer:

This is to notify you that your request to update the Instructions for Use (IFU) of the Simplexa COVID-19 Direct assay to add nasal swabs (NS) and bronchoalveolar lavage (BAL) specimen types to the intended use, is granted. Upon review, we concur that the data submitted in EUA200026/A002 supports the use of the Simplexa COVID-19 Direct assay with NS and BAL specimens. We also concur with the related updates to the Instructions for Use for the Simplexa COVID-19 Direct assay that reflect the requested update and have updated the Healthcare Provider Fact Sheet accordiingly. 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 Simplexa COVID-19 Direct assay issued on March 19, 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