June 4, 2020

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

Re: EUA200026/A003
Trade/Device Name: Simplexa COVID-19 Direct assay
Dated: May 28, 2020
Received: May 28, 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 wash/aspirate (NW) specimen types to the intended use and update the performance section accordingly, is granted. Upon review, we concur that the data submitted in EUA200026/A003 supports the requested updates for use with the Simplexa COVID-19 Direct assay, we have also updated the Healthcare Provider and Patient Fact Sheets. 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