March 26, 2020

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

Re: EUA200026/A001
Trade/Device Name: Simplexa COVID-19 Direct assay
Dated: March 24, 2020
Received: March 26, 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 the use of the following transport media; Remel M5, Remel M6, Copan ESwab (Liquid Amies), Puritan UniTranz-RT, and saline (0.9% sodium chloride in water), is granted. Upon review, we concur that the data submitted in EUA200026/A001 supports the use of the additional identified transport media with the Simplexa COVID-19 Direct assay. We also concur with the related updates to the Instructions for Use for the Simplexa COVID-19 Direct assay that reflect the requested update. 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
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health