March 1, 2021

Malgorzata Jaremko, Ph.D.
Phosphorus Diagnostics LLC
400 Plaza Drive, 4th Floor
Secaucus, NJ 07094

Re: EUA200359/S007
Trade/Device Name: Phosphorus COVID-19 RT-qPCR Test
Dated: February 2, 2021
Received: February 3, 2021

Dear Dr. Jaremko:

This is to notify you that your request to update the authorized labeling "Phosphorus COVID-19 RT-qPCR Test: In-Clinic Ordering Guide," and the "Phosphorus COVID-19 RT-qPCR Test: At-Home Step-by-Step Instructions", is granted. Upon review, we concur that the information submitted in EUA200359/S007 supports the requested updates to the Phosphorus COVID-19 RT-qPCR Test. 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 Phosphorus COVID-19 RT-qPCR Test re-issued on December 15, 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