June 24, 2020

Malgorzata Jaremko, Ph.D.
SVP, Clinical Diagnostics & Research
CLIA-Laboratory Director
Phosphorus Diagnostics
400 Plaza Drive, 4th Floor
Secaucus, NJ 07094

Re: EUA200359/A001
Trade/Device Name: Phosphorus COVID-19 RT-qPCR Test
Dated: June 12, 2020
Received: June 12, 2020

Dear Dr. Jaremko:

This is to notify you that your request to update the Instructions for Use (IFU) of the Phosphorus COVID-19 RT-qPCR Test to revise the intended use to include upper respiratory specimens (including oropharyngeal (throat) swabs, nasopharyngeal swabs, anterior nasal and mid-turbinate swabs, nasopharyngeal washes/aspirates) and bronchoalveolar lavage (BAL) specimens, is granted. Upon review, we concur that the data and information submitted in EUA200359/A001 supports the requested updates for use with the Phosphorus COVID-19 RT-qPCR Test 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 Phosphorus COVID-19 RT-qPCR Test issued on June 4, 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