July 28, 2022

Marcia Eisenberg, PhD
Senior Vice President & Chief Scientific Officer
Laboratory Corporation of America
531 S. Spring Street
Burlington, NC 27215

Re: EUA210522/S002, EUA210592/S001 and EUA220163/S001
Trade/Device Name: Labcorp SARS-CoV-2 & Influenza A/B Assay (EUA210522/S002)
Labcorp Seasonal Respiratory Virus RT-PCR Test (EUA210592/S001)
Labcorp Seasonal Respiratory Virus RT-PCR DTC Test (EUA220163/S001)
Dated: July 18, 2022
Received: July 18, 2022

Dear Dr. Eisenberg:

This is to notify you that your request to provide for the record the updated "Accessioning of the Labcorp COVID-19 Home Collection Kits" Standard Operating Procedure (SOP), Revision 12.0 dated 06/16/2022, that is common across Labcorp COVID-19 EUA submissions (EUA200011, EUA203057, EUA210522, EUA210592 and EUA220163), is granted. Upon review, we concur that the information submitted in EUA210522/S002, EUA210592/S001 and EUA220163/S001 supports the requested update for use with the Labcorp SARS-CoV-2 & Influenza A/B Assay, the Labcorp Seasonal Respiratory Virus RT-PCR Test, and the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test, respectively. By submitting these EUA revisions for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letters authorizing the emergency use of the Labcorp SARS-CoV-2 & Influenza A/B Assay (EUA210522 – reissued March 22, 2022), the Labcorp Seasonal Respiratory Virus RT-PCR Test (EUA210592 – issued May 17, 2022), and the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test (EUA220163 – issued May 16, 2022).

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