



September 13, 2023

Marcia Eisenberg, Ph.D.
Chief Scientific Officer and Senior Vice President
Laboratory Corporation of America (Labcorp)
1912 Alexander Dr.
Research Triangle Park, NC 27709

Re: EUA230011/S001
Trade/Device Name: Clear Dx SARS-CoV-2 WGS v3.0 Test
Dated: August 29, 2023
Received: August 29, 2023

Dear Dr. Eisenberg:

This is to notify you that your request to update the authorized labeling of the Clear Dx SARS-CoV-2 WGS v3.0 Test to; (1) provide the Standard Operating Procedure (SOP) "Variant evaluation for amplicon dropout on Clear Dx WGS SARS-CoV-2 v3.0" as an appendix to the authorized SOP documents, to fulfill Condition of Authorization "K" from the August 1, 2023, Letter of Authorization (LOA), and (2) provide the SOP "Pangolin Update Protocol" as an appendix to the authorized SOP documents, to fulfill Condition of Authorization "L" from the August 1, 2023, LOA, is granted. Upon review, we concur that the data and information submitted in EUA230011/S001 supports the requested updates for use with the Clear Dx SARS-CoV-2 WGS v3.0 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 Clear Dx SARS-CoV-2 WGS v3.0 Test issued on August 1, 2023.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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