



December 06, 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/S002
Trade/Device Name: Clear Dx SARS-CoV-2 WGS v3.0 Test
Dated: October 31, 2023
Received: October 31, 2023

Dear Dr. Eisenberg:

This is to notify you that your request to update the Clear Dx SARS-CoV-2 WGS v3.0 Test to provide software validation documentation to fulfill Condition of Authorization "M." from the August 1, 2023 Letter of Authorization, is granted. Upon review, we concur that the information submitted in EUA230011/S002 supports the requested updates for the Clear Dx SARS-CoV-2 WGS v3.0 Test and fulfills Condition of Authorization "M." from the August 1, 2023 Letter of Authorization. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. 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
Center for Devices and Radiological Health