



March 11, 2021

Christian Bixby
Senior Director, Analytical and Clinical Services
Infinity BiologiX LLC
604 Allison Road
Piscataway, NJ 08854

Re: EUA200090/S005
Trade/Device Name: Infinity BiologiX TaqPath SARS-CoV-2 Assay
Dated: February 8, 2021
Received: February 10, 2021

Dear Mr. Bixby:

This is to notify you that your request to add an authorized distributor, Wellness 4 Humanity, to distribute the IBX Saliva Collection Kit under the brand name, Wellness 4 Humanity SDNA-1000 Saliva Collection Kit for use with the Infinity BiologiX TaqPath SARS-CoV-2 Assay, is granted. Upon review, we concur that the information submitted in EUA200090/S005 supports the requested update for use with the Infinity BiologiX TaqPath SARS-CoV-2 Assay. 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 re-issued letter authorizing the emergency use of the Infinity BiologiX TaqPath SARS-CoV-2 Assay issued on November 13, 2020.

Sincerely yours,

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