



November 30, 2020

Andrew Brooks, PhD
Chief Executive Officer
Infinity BiologiX LLC
604 Allison Road
Piscataway, NJ 08854

Re: EUA200090/S004
Trade/Device Name: Infinity BiologiX TaqPath SARS-CoV-2 Assay
Dated: November 18, 2020
Received: November 18, 2020

Dear Dr. Brooks:

This is to notify you that your request to add an authorized distributor, AZOVA Health, to distribute the IBX Saliva Collection Kit under the brand name, AZOVA At-Home COVID-19 Test 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/S004 supports the requested update for use with the Infinity BiologiX TaqPath SARS-CoV-2 Assay. FDA has also provided edits to the IBX Saliva Collection Kit instructions, for accuracy. 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