November 17, 2021

Sarah Jacobs-Helber, PhD, HCLD(ABB)
Chief Laboratory Officer
GENETWORx
4060 Innslake Drive
Glen Allen, Virginia 23060

Re: EUA202927/S006
Trade/Device Name: GENETWORx Covid-19 Nasal Swab Test
Dated: October 29, 2021
Received: October 29, 2021

Dear Dr. Jacobs-Helber:

This is to notify you that your request to revise the Emergency Use Authorization for the GENETWORx Covid-19 Nasal Swab Test to: (1) add the Aptima Direct Load Tube Collection Kit as an authorized specimen collection device is granted. Upon review, we concur that the data and information submitted in EUA202927/S006 supports the requested updates for use with the GENETWORx Covid-19 Nasal Swab 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 GENETWORx Covid-19 Nasal Swab Test issued on December 15, 2020.

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