May 14, 2021

Sarah Jacobs-Helber, PhD, HCLD(ABB)
Chief Laboratory Officer
RCA Laboratory Services LLC dba GENETWORx
4060 Innslake Drive
Glen Allen, VA 23060

Re: EUA202927/R02
Trade/Device Name: GENETWORx Covid-19 Nasal Swab Test
Dated: February 19, 2021
Received: March 1, 2021

Dear Jacobs-Helber:

This is to notify you that your request to update the EUA Summary of the GENETWORx Covid-19 Nasal Swab Test to include data from a sample adequacy clinical study to fulfil a Condition of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA202927/R02 supports the requested updates for use with the GENETWORx Covid-19 Nasal Swab Test. In addition, FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect 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 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