



February 12, 2021

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

Re: EUA202927/S001  
Trade/Device Name: GENETWORx Covid-19 Nasal Swab Test  
Dated: December 30, 2020  
Received: December 30, 2020

Dear Dr. Jacobs-Helber:

This is to notify you that your request to update the EUA Summary of the GENETWORx Covid-19 Nasal Swab Test to add an online ordering system through your web portal, is granted. Upon review, we concur that the information submitted in EUA202927/S001 supports the requested updates for use with the GENETWORx Covid-19 Nasal Swab Test. In addition, FDA updated the Fact Sheet for Healthcare Providers and EUA Summary to reflect more recent policy and 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 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