January 26, 2021

Hyun-Ho Lee
Manager, Regulatory Affairs
GeneMatrix Inc.
8F, #B, Korea Bio Park, 700 Daewangpangyo-ro
Bundang-gu, Seongnam-si, Gyeonggi-do, KOR 13488

Re: EUA200803/S001
Trade/Device Name: NeoPlex COVID-19 Detection Kit
Dated: September 2, 2020
Received: September 2, 2020

Dear Hyun-Ho Lee:

This is to notify you that your request to update the Instructions for Use (IFU) of the NeoPlex COVID-19 Detection Kit to; (1) include data from a post-authorization clinical study, (2) update Inclusivity Study data, and (3) make minor updates, is granted. Upon review, we concur that the data and information submitted in EUA200803/S001 supports the requested updates for use with the NeoPlex COVID-19 Detection Kit. 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 NeoPlex COVID-19 Detection Kit issued on May 14, 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