August 23, 2022

Weike Mo, Ph.D., FAACC
GenaBio Diagnostics, Inc.
303 Wyman Street, Suite 300
Waltham, MA 02451

Re: EUA220205/S001
Trade/Device Name: Genabio COVID-19 Rapid Self-Test
Dated: July 26, 2022
Received: July 26, 2022

Dear Dr. Mo:

This is to notify you that your request to update the Genabio COVID-19 Rapid Self-Test's Instructions for Use (IFU), Quick Reference Instructions (QRI)) and package labelling to: **(1)** correct typographical errors and make minor edits, and **(2)** update the manufacturing site information, is granted. Upon review, we concur that the data and information provided in EUA220205/S001 supports the requested updates to the authorized labelling for Genabio COVID-19 Rapid Self-Test. By submitting this supplement for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Genabio COVID-19 Rapid Self-Test issued on July 08, 2022.

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