July 10, 2024

Weike Mo, Ph.D.
Chief Executive Officer
Genabio Diagnostics Inc.
19B Crosby Drive Suite 220
Beford, MA 01730

Re: EUA220205/S008/A001
Trade/Device Name: Genabio COVID-19 Rapid Self-Test Kit
Dated: October 13, 2023
Received: October 13, 2023

Dear Dr. Weike Mo:

This is to notify you that your request to update the Genabio COVID-19 Rapid Self-Test Kit to; (1) provide information on the establishment and maintenance of a quality system that meets the requirements of either the 2016 edition of ISO 13485 or 21 CFR Part 820 to fulfill Condition of Authorization N. of the April 11, 2023, Letter of Authorization, and (2) provide information on lot release procedures to fulfill Conditions of Authorization P. and Q. of the April 11, 2023, Letter, is granted. Upon review, we concur that the data and information submitted in EUA220205/S008/A001 supports the requested updates for the Genabio COVID-19 Rapid Self-Test Kit. FDA has updated the Fact Sheet for Healthcare Professionals to reflect language used in 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 reissued letter authorizing the emergency use of the Genabio COVID-19 Rapid Self-Test Kit issued on April 11, 2023.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health