August 13, 2021

Marc Jones
Chief Operating Officer and CFO
binx health, Inc.
77 N. Washington Street
Boston, MA 02114

Re: EUA202509/S006
Trade/Device Name: binx health At-Home Nasal Swab COVID-19 Sample Collection Kit
Dated: May 17, 2021
Received: May 19, 2021

Dear Mr. Jones:

This is to notify you that your request to update the authorized labeling of the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit to; (1) update the binx health Collection Kit patient instructions "*binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for return at a drop-off location Instructions for Use*," (bundle for both individual swab packaging and swab/tube combination packaging) and the "*binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for individual shipping Instructions for Use*," (bundle for both individual swab packaging and swab/tube combination packaging), to further emphasize the need for specimens to be shipped on the day of collection, (2) update the EUA Summary to include the results of an updated specimen stability winter and summer shipping study, and (3) update the specimen accessioning SOP "*Binx Dry Nasal Swab Accessioning Criteria*" to extend the specimen stability to ≤120 hours from being collected, is granted. Upon review, we concur that the data and information submitted in EUA202509/S006 supports the requested updates for use with the binx health At-Home Nasal Swab COVID-19 Sample Collection 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 binx health At-Home Nasal Swab COVID-19 Sample Collection Kit re-issued on May 13, 2021.

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