U.S. FOOD & DRUG ADMINISTRATION

September 2, 2022

Hairong Zhang
Xiamen Boson Biotech Co., Ltd
90-94 Tianfeng Road,
Jimei North Industrial Park,
Xiamen, Fujian 361021, China

Re: EUA220120/S003
Trade/Device Name: Rapid SARS-CoV-2 Antigen Test Card
Dated: June 15, 2022
Received: June 15, 2022

Dear Hairong Zhang:

This is to notify you that your request to update the Rapid SARS-CoV-2 Antigen Test Card with the results of your shipping stability studies is granted. Upon review, we concur that the data and information submitted in EUA220120/S003 support the requested update for the Rapid SARS-CoV-2 Antigen Test Card. 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 Rapid SARS-CoV-2 Antigen Test Card issued on April 6, 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