



December 21, 2023

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

Re: EUA220120/S012
Trade/Device Name: Rapid SARS-CoV-2 Antigen Test Card
Dated: September 27, 2023
Received: September 27, 2023

Dear Hairong Zhang:

This is to notify you that your request to update the Rapid SARS-CoV-2 Antigen Test Card to extend the shelf-life expiration date to 14 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220120/S012 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,

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