



October 18, 2022

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

Re: EUA220120/S006
Trade/Device Name: Rapid SARS-CoV-2 Antigen Test Card
Dated: July 25, 2022
Received: July 25, 2022

Dear Hairong Zhang:

This is to notify you that your request to offer the Rapid SARS-CoV-2 Antigen Test Card with a set of distributor specific labeling is granted. Upon review, we concur that the information and distributor specific Rapid SARS-CoV-2 Antigen Test Card labeling submitted in EUA220120/S006 is consistent with and supports the requested update. 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 and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health