August 31, 2020

Super Liu
Quality Director
Hangzhou Biotest Biotech Co., Ltd.
No.17, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P.R. China

Re: EUA200458/S004
Device Name (Authorized): RightSign COVID-19 IgG/IgM Rapid Test Cassette
Dated: August 26, 2020
Received: August 28, 2020

Dear Mr. Super Liu:

This is to notify you that your request to update the Package Insert of the RightSign COVID-19 IgG/IgM Rapid Test Cassette to include the RightSign "SARS-COV-2 IgG/IgM External Control Kit" as a material required but not provided, is granted. Upon review, we concur with the additional "Instruction for use of RightSign SARS-COV-2 IgG/IgM External Control Kit" labeling that accompanies the RightSign "SARS-COV-2 IgG/IgM External Control Kit". Accordingly, we also concur with the updated labeling for the authorized distributors who will distribute the RightSign COVID-19 IgG/IgM Rapid Test Cassette and the RightSign SARS-COV-2 IgG/IgM External Control Kit under the brand names outlined below:

- CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette and CoronaCHEK SARS-COV-2 IgG/IgM External Control Kit
- Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette and Premier Biotech SARS-COV-2 IgG/IgM External Control 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 RightSign COVID-19 IgG/IgM Rapid Test Cassette issued on June 4, 2020.

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