



July 23, 2020

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

Re: EUA200458/A001, EUA200458/A002, EUA200458/A004 and EUA200458/S001
Device Name: RightSign COVID-19 IgG/IgM Rapid Test Cassette
Dated: June 08, 2020 (A001 and A002), July 1, 2020 (A004), and July 9, 2020 (S001)
Received: June 12, 2020 (A001 and A002), July 1, 2020 (A004), and July 9, 2020 (S001)

Dear Mr. Super Liu:

This is to notify you that your request to update the Instruction of Use (IFU) of the RightSign COVID-19 IgG/IgM Rapid Test Cassette to include use of external positive and negative controls, is granted. Upon review, we concur that the data and information submitted in EUA200458/A004 supports the requested updates for adding the external positive and negative controls for use with the RightSign COVID-19 IgG/IgM Rapid Test Cassette. In addition, your request to add additional authorized distributors who will distribute the RightSign COVID-19 IgG/IgM Rapid Test Cassette under the brand names outlined in the table below is granted.

Hangzhou Biotest Biotech Co., Ltd. RightSign COVID-19 IgG/IgM Rapid Test Cassette (EUA200458)		
Submission No.	Authorized Distributor Name	Brand Name Distributed Under
EUA200458/A001	Premier Biotech Inc.	Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette
EUA200458/A002	CLIAwaived Inc.	CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette

We also concur with the addition of two authorized distributors, Lumavi Corp. and Polarian Partners, LLC, who will distribute the test under the brand name RightSign COVID-19 IgG/IgM Rapid Test Cassette and the minor updates to current authorized distributor contact information. By submitting this amendment 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,

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