November 10, 2020

Xiulan Zhang
Regulatory Affairs Manager
Jiangsu Well Biotech Co., Ltd.
No.9 Changyang Road
Changzhou, Jiangsu 213149, China

Re: EUA201292/S001
Trade/Device Name: Orawell IgM/IgG Rapid Test
Distributor Device Name: INDICAID COVID-19 IgM/IgG Rapid Test
Authorization Date: September 23, 2020
Supplement Received: October 21, 2020

Dear Ms. Zhang:

This is to notify you that your request to revise the distribution list to include one additional authorized distributor, Phase Scientific International Limited, to market the Jiangsu Well Biotech Co. Ltd.'s Emergency Use Authorized Orawell IgM/IgG Rapid Test (EUA201292) under the device name of INDICAID COVID-19 IgM/IgG Rapid Test is granted. Upon review, we concur that the information submitted in EUA201292/S001 supports the requested updates for use with the Orawell IgM/IgG Rapid Test.

By submitting these revisions 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 Orawell IgM/IgG Rapid Test issued on September 23, 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