November 5, 2021

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

Re: EUA201292/S004
Trade/Device Name: Orawell IgM/IgG Rapid Test
Dated: September 27, 2021
Received: September 27, 2021

Dear Xiulan Zhang:

This is to notify you that your request to extend the stability of the Orawell IgM/IgG Rapid Test to 16 months when stored at 2–30°C is granted. Upon review, we concur that the data and information submitted in EUA201292/S004 support the requested updates. FDA requested updates to the Instructions for Use for the Orawell IgM/IgG Rapid Test and the distributed brand INDICAID IgM/IgG Rapid Test to include a limitation related to performance of the test in vaccinated individuals. FDA has also requested updates to the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021. FDA also updated the CDC and FDA webpage section of the Orawell IgM/IgG Rapid Test and the distributed brand INDICAID IgM/IgG Rapid Test Healthcare Provider Fact Sheets to reflect recent authorizations. By submitting this information 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,

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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