U.S. FOOD & DRUG ADMINISTRATION

September 4, 2020

Frank S. Ong, M.D., CPI
Chief Scientific and Medical Officer
Everlywell, Inc.
823 Congress Avenue
Austin, TX 78701

Re: EUA200283/S001
Trade/Device Name: Everlywell COVID-19 Test Home Collection Kit
Dated: July 30, 2020
Received: July 31, 2020

Dear Dr. Ong:

This is to notify you that your request to update the EUA Summary of the Everlywell COVID-19 Test Home Collection Kit to: (1) include additional distributers, (2) modify the inclusion and exclusion criteria for the use of the device, and (3) add language describing COVID-19 and disease risk factors to the on-line test purchasing website, is granted. Upon review, we concur that the information submitted in EUA200283/S001 supports the requested updates for use with the Everlywell COVID-19 Test Home Collection 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 Everlywell COVID-19 Test Home Collection Kit issued on May 15, 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