



June 5, 2020

Yongjiang Daniel Li, Ph.D.  
Associate Director, Molecular Biology Division  
ScienCell Research Laboratories  
1610 Faraday Avenue  
Carlsbad, CA 92000-0008

Re: EUA200079/A001  
Trade/Device Name: ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit  
Dated: May 7 and May 16, 2020  
Received: May 20, 2020

Dear Dr. Li:

This is to notify you that your request to update the Instructions for Use (IFU) of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit to; (1) add an additional authorized extraction kit, the Viral RNA Isolation kit (ScienCell), for use with the test along with the associated performance data, and (2) and make some minor clarifications and edits, is granted. Upon review, we concur that the data and information submitted in EUA200079/A001 supports the requested updates for use with the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, and we have also updated the Healthcare Provider and Patient Fact Sheets. 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 ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit issued on April 3, 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