



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 occur 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 on April 3, 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