September 22, 2020

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

Re: EUA200079/S003
Trade/Device Name: ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit
Dated: September 4, 2020
Received: September 4, 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 add a multiplex testing format (multiplex kit, ScienCell, catalog #RX7048), is granted. Upon review, we concur that the data and information submitted in EUA200079/S003 supports the requested updates for use with the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit. FDA also requested a minor update to the intended use to reflect more recent reporting recommendations and have updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. 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 ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit issued 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