August 11, 2020

Beth Kraemer, RPh
Director of Quality, Regulatory & Technical Compliance
dba SpectronRx
9550 Zionsville Rd. Suite 1
Indianapolis, IN 46268

Re: EUA200415/S001
Trade/Device Name: Hymon SARS-CoV-2 Test Kit
Dated: July 28, 2020
Received: August 7, 2020

Dear Dr. Kraemer:

This is to notify you that your request to update the Instructions for Use (IFU) for the Hymon SARS-CoV-2 Test Kit to add the Applied Biosystems QuantStudio 5 Thermocycler (Q5 software version is C.0) as an additional RT-PCR instrument, is granted. Upon review, we concur that the data and information submitted in EUA200415/S001 supports the requested update for use with the Hymon SARS-CoV-2 Test Kit. In addition, we have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting this EUA revision request 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 Hymon SARS-CoV-2 Test Kit issued on May 22, 2020.

Sincerely yours,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
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