August 23, 2023

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

Re: Revocation of EUA200415

Dear Beth Kraemer:

This letter is in response to the request from dba SpectronRx, received via email on March 24, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Hymon SARS-CoV-2 Test Kit issued on May 22, 2020, and amended on August 11, 2020. dba SpectronRx indicated that they are discontinuing the distribution of the Hymon SARS-CoV-2 Test Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Hymon SARS-CoV-2 Test Kit reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because dba SpectronRx has requested that FDA terminate the EUA for the Hymon SARS-CoV-2 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200415 for the Hymon SARS-CoV-2 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Hymon SARS-CoV-2 Test Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration