November 6, 2020

Sophie Vernay
Regulatory Affairs Manager
BioMérieux SA
376, Chemin de L'Orme
Marcy L'Etoile, FR 69280

Re: EUA200445/S001
Trade/Device Name: SARS-COV-2 R-GENE
Dated: July 9, 2020
Received: July 9, 2020

Dear Ms. Vernay:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-COV-2 R-GENE to; (1) include the results of a post authorization clinical evaluation study conducted to fulfill Condition of Authorization S. in the letter authorizing the emergency use of the SARS-COV-2 R-GENE, issued on May 6, 2020, and (2) include the results from testing the FDA Reference Panel that were reviewed and acknowledged under EUA200445/S002, is granted. Upon review, we concur that the data and information submitted in EUA200445/S001 supports the requested updates to the authorized labeling for the SARS-COV-2 R-GENE. FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients 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 SARS-COV-2 R-GENE issued on May 6, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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