



September 12, 2022

Lisa Vershave
Regulatory Affairs Manager
PerkinElmer Inc.
940 Winter Street
Waltham, MA 02451

Re: EUA200055/S014
Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit
Dated: July 22, 2022
Received: July 22, 2022

Dear Ms. Vershave:

This is to notify you that your request to update the Instructions for Use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit to extend the product shelf-life claim from 12-months to 24-months, is granted. Upon review, we concur that the data and information submitted in EUA200055/S014 supports the requested updates for use with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 reissued letter authorizing the emergency use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit issued on July 15, 2021.

Sincerely yours,

Kristian Roth, Ph.D.
Deputy 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