



April 1, 2020

Brian Ciccariello, RAC
Head of Regulatory & Medical Affairs - Americas
PerkinElmer, Inc.
940 Winter Street,
Waltham, MA 02451 US

Re: EUA200055/A001
Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit
Dated: March 30, 2020
Received: March 30, 2020

Dear Mr. Ciccariello:

This is to notify you that your request to update the Instructions for Use (IFU) of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit to; (1) add an additional nucleic acid extraction method which utilizes the chemagic Viral DNA/RNA 300 Kit H96 on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor changes and edits to the IFU labeling, has been granted. Upon review, we concur that the data submitted in EUA200055/A001 supports the additional extraction method and instrument for use with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit. We also concur with the related changes to the Instructions for Use for the PerkinElmer New Coronavirus Nucleic Acid Detection Kit that reflect the requested updates. By submitting this amendment 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 PerkinElmer New Coronavirus Nucleic Acid Detection Kit issued on March 24, 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