



PerkinElmer, Inc.
940 Winter Street
Waltham, MA 02451 USA
www.perkinelmer.com

May 18, 2021

Elsa Eleco
Section Chief, On-Site Licensing Inspections
California Department of Public Health - Laboratory Field Services
320 W. 4th Street, Suite 890
Los Angeles, CA 90013

Dear Elsa,

The FDA has granted Emergency Use Authorization for the PerkinElmer® New Coronavirus Nucleic Acid Detection Kit. The kit's instructions for use (version 7; pg 28 #7, 8, and 9) was reviewed and authorized by FDA to include the testing of asymptomatic patients.

As part of the EUA agreement, PerkinElmer is conducting a post authorization clinical evaluation with asymptomatic individuals. When the study is complete, the kit's instructions for use will be updated with the consultations and concurrence of FDA.

Sincerely,

Brian Ciccariello
Head of Regulatory & Medical Affairs
PerkinElmer | For the Better
brian.ciccariello@perkinelmer.com
Phone: +1 781.663.6025
Mobile: +1 508-962-3743
940 Winter Street, Waltham, MA 02451 USA
www.perkinelmer.com